University of Southampton

Faculty of Environment and Life Sciences

School of Health Sciences

Investigating the Implementation of a Complex Intervention to Reduce Central Line-Associated Bloodstream Infections on the Neonatal Intensive Care Unit

by

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Thesis for the degree of Doctor of Philosophy

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Abstract

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Neonatal central line-associated bloodstream infections (CLABSIs) are associated with increased mortality, prolonged hospitalisation, and increased healthcare costs. Over the past decade, global incidences have ranged from zero to 21.8 CLABSIs per 1000 central line days, with inter-centre variations despite adjusting for case mix. Whilst complex interventions such as care bundles may reduce neonatal CLABSIs by 60%, there is heterogeneity in bundled elements and in the magnitude of effect size. It is often unclear if it is the bundle, the implementation process, or a combination of both, that results in CLABSI reductions. In addition, it is now well known that what works in one setting cannot always be directly transferred to another. Therefore, understanding what works, how it works, and in what settings, is important in order to improve the translation of evidence into practice.

This thesis aimed to investigate the implementation of a care bundle aimed at reducing CLABSIs in a UK neonatal intensive care unit (NICU). A sequential, mixed-methods approach was taken, using a focused-case ethnography design that was underpinned by Normalisation Process Theory. A systematic review with meta-analysis was undertaken to identify the evidence for CLABSI care bundles in the NICU and informed data collection. Normalization MeAsure Development (NoMAD) surveys, observations of practice with retrospective interviews and semi-structured interviews were used to investigate implementation. CLABSI rates were prospectively collected, with bundle adherence data collected retrospectively. Quantitative data were analysed using descriptive statistics, with thematic analysis used to inductively analyse qualitative data.

The results of this study found that whilst CLABSI rates reduced by 28% from 2015 to 2018 this was not sustained in 2019, despite apparent increases in bundle adherence. However, this study revealed there was only partial bundle implementation, with minimal changes in NoMAD construct scores between survey two and three. Influences across individual, team and organisational levels moderated bundle adoption, with features of the local context such as social norms and professional cultures sometimes undermining implementation efforts. Ultimately, there were challenges relating to reinforcement and endorsement of the bundle. Recommendations to improve bundle adoption include improving reinforcement, building in accountability and improving knowledge management.

This is the first study to investigate the implementation of a care bundle to reduce CLABSIs on the NICU. Understanding the mechanisms by which an intervention works (or not) in specific contexts is important to optimise the delivery of evidence-based care.

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Research Thesis: Declaration of Authorship

Print name:	Victoria Helen Payne
Title of thesis:	Investigating the Implementation of a Complex Intervention to reduce CLABSIs on the Neonatal Intensive Care Unit

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
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Definitions and Abbreviations

BC	Blood culture
BSI	Bloodstream infection
CAS	Complex adaptive system
CDC	Centre for Disease Control
CVC	Central venous catheter
CLABSI	Central line-associated bloodstream infection
CoNS	Coagulase-negative staphylococci
CPAP	Continuous positive airway pressure
CRP	C-Reactive Protein
EBP	Evidence-Based Practice
EFCNI	European Foundation for Care of Newborn Infants
ELBW	Extremely low birth weight
EPOC	Effective Practice and Organisation of Care
HCAI	Healthcare-associated infections
HHHFNC	Heated and humidified high flow nasal cannula
ICU	Intensive Care Unit
IPC	Infection Prevention and Control
ISID	International Society for Infectious Diseases
LocSSIPs	Local Safety Standards for Invasive Procedures
LOS	Late-onset sepsis
MRC	Medical Research Council
NEC	Necrotising enterocolitis
NHS	National Health Service

NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NNAP	National Neonatal Audit Programme
NoMAD	Normalisation Measure Development
NOS	Newcastle-Ottawa Score
NPT	Normalisation Process Theory
ORI	Observation with Retrospective Interview
PMRT	Perinatal mortality review tool
PICU	Paediatric Intensive Care Unit
PICC	Peripherally inserted central catheter
PIL	Participant information leaflet
QI	Quality Improvement
SQUIRE	Standards for Quality Improvement Reporting Excellence
SSI	Semi-structured Interview
UAC	Umbilical artery catheter
UVC	Umbilical venous catheter
UK	United Kingdom
USA	United States of America
VAP	Ventilator-associated pneumonia
VLBW	Very low birth weight
VON	Vermont-Oxford Network
WCC	White Cell Count

Chapter 1 Introduction

It is estimated that approximately 15 million babies a year are born prematurely, and when including sick term neonates, global estimates suggest that 30 million neonates require inpatient care each year (WHO, 2020). In the United Kingdom (UK), approximately 100,000 neonates are admitted to a Neonatal Intensive Care Unit (NICU) each year, equating to one in seven babies (BLISS, 2020). These sick and preterm neonates frequently require central venous catheters (CVCs) or 'central lines' in order to deliver lifesaving medications and long-term parenteral nutrition. However, these vascular access devices significantly increase the risk of neonates getting a bloodstream infection (BSI) (Zingg et al., 2017). Central line-associated bloodstream infections (CLABSIs), a BSI in the presence of, or associated with, a central line, can result in increased mortality, morbidity and length of stay (Adams-Chapman, 2012, Payne et al., 2004). Whilst data from the EPIcure 2 study[1] suggests the survival rates of extremely low birth weight (ELBW) infants are improving, mortality after the first week of life due to BSIs has increased (Costeloe et al., 2012).

The aim of this research study is to investigate the implementation of a complex intervention (a care bundle) aimed at reducing neonatal central line-associated bloodstream infection rates (CLABSIs).

1.1 Healthcare-Associated Infections

A point-prevalence survey estimated there were 300,000 healthcare-associated infections (HCAIs) in hospitals in England per year, though modelling using combined surveillance and clinical data suggests this is much higher, with an estimate of 653,000 in 2016/17 (Guest et al., 2020). In a European point-prevalence survey of HCAIs in neonates and children, Zingg et al. (2017) found that the prevalence of infections was highest in paediatric and neonatal intensive care units (PICUs and NICUs). In the paediatric population, BSIs were the most common form of HCAI and accounted for almost 60% of HAIs in infants <1 month of age. It also found that the use of invasive vascular devices was significantly associated with HCAIs. This study concluded that infection prevention

[1] EPIcure is a series of observational studies on the mortality and morbidity of extremely prematurely born infants between 22-26 weeks in England. EPIcure 2 compared data between a 1995 and 2006 cohort of extremely preterm infants.

and control (IPC) should focus on the prevention of BSIs in the youngest age groups, particularly in NICUs and PICUs. However, whilst national evidence-based guidelines have been published in an attempt to reduce HCAIs in England, these recommendations are for adults and children >1 year and so cannot be directly applied to neonatal patients (Loveday et al., 2014). The reduction of HCAIs is vital in order to care for patients in a safe environment, one of the core measures of the National Health Service (NHS) Outcomes Framework (DOH, 2014).

1.2 Neonatal Central Line-Associated Bloodstream Infections

CLABSIs are associated with increased mortality, morbidity and prolonged hospitalisation, the latter of which is estimated to result in significantly increased healthcare costs (European Centre For Disease Control, 2018). However, attributing mortality to CLABSIs can be difficult, as it requires the differentiation between deaths 'with' an infection versus deaths 'because' of an infection (The Joint Commission, 2012). In neonates, mortality rates attributable to CLABSIs are even more challenging to determine, with most studies referring to late-onset sepsis, defined as a BSI at greater than 72 hours of age. A recent multi-centre study investigating the use of antibiotic impregnated central lines in neonates found that 1 in 10 neonates had a bloodstream infection, highlighting the seriousness of the problem in the UK (Gilbert et al., 2019). In a retrospective study of 900 very low birth weight (VLBW) infants, Donovan et al. (2013) found that the mortality rate prior to discharge was 30% for neonates with a late-onset BSI compared to 7% in those without. However, there are significant variations in the rates of CLABSIs reported to national agencies in the US, with up to seven-fold variations in reported rates (Folgori et al., 2013).

Whilst the impact of pathogenic bacteria such as *Staphylococcus aureus* and gram-negative rods such as *Escherichia coli* are well known, more recent data suggests that coagulase-negative staphylococcal infections (CoNS), previously considered to be simple skin contaminants, are now considered to be pathogenic in the neonatal population (Laurent and Butin, 2019) . Public Health England (PHE, 2020) have identified CoNS as a major cause of nosocomial infection with antibiotic-resistant strains now emerging (Wirth et al., 2020). In a cohort study of 757 VLBW infants, Davis et al. (2016) found an association between the reduction in CoNS BSIs and reductions in moderate cognitive impairment. However, data collection took place between 2002-2011, a time period that has seen improved survival of extremely low birth weight (ELBW) infants, and there was no concurrent control group.

It has been estimated that paediatric CLABSIs results in an average increased length of stay of 21 days and average attributable costs of $13,727 per CLABSI (Karagiannidou et

al., 2019). Similar data in neonates is limited, and cost analysis studies focus on late-onset sepsis rather than CLABSIs specifically. In the NICU, Johnson et al. (2013) estimated additional costs per late-onset sepsis episode to be approximately $10,055, excluding physician costs, whilst Donovan et al. (2013) estimated that the cost of care was $16,800 greater for each neonate with a bloodstream infection. Payne et al. (2004) estimated an increased length of stay ranging from 4 to 7 days; however, this data is now over 15 years old and may now be longer given the improved survival of ELBW infants.

Finally, CLABSIs require treatment with antibiotics. The over-use of antibiotics and emerging resistance patterns are a global concern, with an estimated 700,000 deaths due to antibiotic resistant organisms each year (DOH, 2019). Reducing the unnecessary use of antibiotics is therefore a global health priority (DOH, 2019).

1.2.1 Aetiology of Neonatal CLABSIs

Central lines are invasive medical devices that are frequently necessary for the administration of lifesaving medications, intravenous maintenance fluids and parenteral nutrition. However, these medical devices are a source of entry for microorganisms, which can enter via two main mechanisms: either through breaching the body's natural defence (the skin) at the point of insertion or via extraluminal entry as a result of colonisation of needleless connectors attached to the central line. Less common aetiologies include the infusion of non-sterile fluid or seeding from another site of infection (Gominet et al., 2017). Risk factors for developing a CLABSI are summarised in Table 1.

Table 1 Neonatal Risk Factors for Developing a CLABSI.

Patient characteristics	**Central line characteristics**
Extremely preterm <28 weeks Extremely low birth weight <1000 grams Longer length of stay Parenteral nutrition Surgical pathologies Abdominal surgery Prolonged courses of antibiotics for early-onset sepsis	Increased dwell times Umbilical lines (increased risk compared to peripherally inserted central catheters) Small lumen catheters Multiple lumen catheters Increased frequency of accessing the line

Translocation of gastrointestinal microorganisms into the bloodstream has been associated with the development of CLABSIs in the preterm infant, putting neonates with gastrointestinal pathologies at increased risk (Dahan et al., 2016). This is important, as this cause of CLABSI may be less susceptible to standard IPC strategies. In a matched

case-control study, Dahan et al. (2016) found that intra-abdominal pathology remained independently associated with an increased risk of CLABSI despite adjusting for confounding factors, prompting some to argue for a change to the mucosal barrier injury surveillance definition for neonates. In fact, unlike in other patient groups, the gut of a preterm baby is thought to be colonised with staphylococci within weeks of birth, and it may be that CoNS infections are partly a result of gut translocation mechanisms (Samarasekara et al., 2012).

More recently, the use of prolonged courses of antibiotics for early-onset sepsis has been associated with increasing incidences of LOS (Cantey and Milstone, 2015). In this observational cohort study of VLBW infants, each additional day of antibiotic therapy within the first 14 days was associated with a 24% increase in the risk of LOS, Necrotising Enterocolitis or death. This remained even when adjusting for illness severity, and it is comparable to findings in previous studies (Kuppala et al., 2011, Ting et al., 2016).

Umbilical venous catheters (UVCs) appear to have a higher risk of developing a CLABSI, and early replacement with a peripherally inserted central catheter (PICC) line is recommended (Sanderson et al., 2017). Some risk factors relevant in adult patients, such as avoiding the femoral site, are not applicable in neonates as these are infrequently used. Several studies have attempted to determine the association between catheter dwell time (the duration of time the line is in situ) and CLABSI risk in order to determine an optimal time for removal or elective replacement. Whilst some studies found that there was an increased risk of a CLABSI after a dwell time of 14 days (Milstone et al., 2013), García et al. (2019) found that a dwell time of more than 21 days was a significant risk factor, though this effect did not remain when included in a multivariate regression model. Greenberg et al. (2015) found no increased risk of developing a CLABSI with increased dwell time, asserting that clinicians should not be routinely replacing PICCs for fear of infection.

The formation of an extracellular matrix or biofilm by bacteria allows them to adhere to central lines, helping them to survive antimicrobial agents and host defences and allowing them to travel to the rest of the body causing widespread infection (Gominet et al., 2017). Biofilms can take as little as 24 hours to establish, though the time delays between bacterial entry into the body and presentation of clinical symptoms can vary, which makes determining the cause of infection challenging.

Microorganisms most commonly associated with neonatal CLABSIs include CoNS, *Staphylococcus aureus* and enteric gram-negative bacteria such as *Enterobacteriaceae* and *Escherichia coli* (Pammi et al., 2020, Gominet et al., 2017). Whilst surveillance studies report prevalence differences in neonates, with some reporting greater gram-

positive cocci isolates compared to gram-negative, the NeoIN network[2] reported that CoNS, *Staphylococcus aureus* and *Escherichia coli* were the main causes of LOS in neonates greater than 72hrs of age in the UK (Cailes et al., 2018). Whilst this study didn't seek to determine rates of CLABSIs, CoNS accounted for 57% of all LOS cases and 83% of cases in infants less than 32 weeks gestation. It also found that these infections were isolated exclusively from the bloodstream. Whilst this study recognised that the definition used may over-report in some cases such as CoNS, it argued that a simple definition is essential to ensure the quality of data collected remains high (Cailes et al., 2018).

1.2.2 Defining CLABSIs

A plethora of definitions of a CLABSI are being used as performance measures and in benchmarking activities worldwide; Appendix 1 outlines three commonly used definitions. Whilst, broadly speaking, a CLABSI is a positive blood culture (BC) in a neonate with a central line, which includes UVCs and PICCs, some definitions require clinical signs of infection, such as pyrexia or apnoea, whilst others require laboratory markers to be included in the definition, such as a rise in C-Reactive Protein (CRP) levels or white cell counts (WCC). Some, such as the National Healthcare Safety Network (NHSN, 2021) definition, require two separate blood cultures to be taken and specify that the infection must not be related to another source, such as a pneumonia. Herein lies one of the challenges in defining a CLABSI: attributing the source of the infection to the central line specifically as opposed to a pneumonia or gut translocation.

The importance of a standardised definition cannot be underestimated. Schulman et al. (2011) found that the 2008 change in the NHSN definition, which required two positive cultures in the case of obtaining a skin contaminant, resulted in a 40% reduction in CLABSI rates without any other intervention. Whilst paired blood cultures have high sensitivity (74%-84%) and specificity (98%–100%), testing central line catheter tips is felt to be a poor diagnostic marker (45%-84% sensitivity; 85% specificity), as it often only detects extraluminal bacteria (Gominet et al., 2017).

Despite the use of an objective definition, interobserver variability in the application of standardised definitions has been reported in the adult literature (Leekha et al., 2013). Uncertainty in attributing central lines as the cause of infection, variations in counting line

[2] NeoIN is a global infection surveillance network of 57 contributing neonatal units, of which 31 are from the UK.

days and logistical challenges in data collection means that this measure of reporting may be subject to measurement bias and local interpretation. An ethnographic study of counting line days in 17 adult ICUs revealed that variations were not the result of gaming strategies — wilful attempts to conceal or deceive — but instead the result of complex, messy definitions, which were subject to local interpretation (Dixon-Woods et al., 2012). It was concluded from this ethnographic study that counting line days was a social practice as opposed to a technical one (Dixon-Woods et al., 2012).

It would appear that what constitutes a CLABSI and how these are reported provide challenges for healthcare professionals. It has been argued that a simpler definition may improve the reliability and consistency of reporting, whilst recognising that this approach may over-estimate the problem through the inclusion of contaminants or false positives (Cailes et al., 2018). However, reducing false positives is arguably equally important and could also be considered a marker for quality of care.

1.2.3 Strategies for CLABSI prevention

Whilst CLABSIs can be treated, it is evident that the impact of these infections is wide-reaching, and preventative strategies are vital to reduce the incidence of and resultant co-morbidities associated with these infections. As part of the DOH plan to tackle antibiotic resistance, improving infection prevention and control (IPC) is high on the national UK agenda (DOH, 2019). Strategies aimed at improving IPC include ensuring good hand hygiene and aseptic techniques, using surveillance systems to monitor and target action and auditing practices to ensure that policies and procedures are effective. The decontamination of medical devices is also a part of this strategy.

Interventions designed to prevent CLABSIs are targeted at two main areas of central line care: minimising the risk of contamination at the point of central line insertion and minimising the risk of bacterial entry via colonised needleless connectors. Minimising the number of needleless connectors and extension sets, including minimising the number of times these connectors are manipulated, is an important aspect of ongoing central line care (Loveday et al., 2014). Interventions addressing other aspects of neonatal care, such as those aimed at improving the nutritional care of neonates, may also have an impact on CLABSI rates. A summary of preventative strategies and the evidence base for these in neonatal practice is outlined in Appendix 2.

1.3 Translating Evidence into Practice

The evidence-based practice (EBP) movement developed in response to several high-profile quality failings in healthcare and in conjunction with the development of clinical

governance aiming to improve clinical effectiveness, safety and patient outcomes (Burns and Grove, 2010). Whilst the EBP movement has undeniably improved neonatal outcomes through the development and translation of interventions such as surfactant, antenatal steroids for preterm birth and therapeutic hypothermia in Hypoxic-Ischaemic Encephalopathy, EBP could also be considered a movement in crisis (Greenhalgh et al., 2014). There are many challenges relating to information overload, with an overwhelming number of guidelines in practice, as well as the volume and frequency with which new research is produced. More recently, the Covid-19 pandemic has highlighted further challenges with the EBP movement (Greenhalgh, 2020). The reliance solely on research-driven policy has been criticised, with Ogilvie et al. (2020) calling for traditional EBP to be combined with what they term the practice-based movement- where policy informs research and the generation of evidence. In addition, modern society has been argued to be entering a post-truth era, epitomised by opinions, emotions, and beliefs prevailing over evidence, the spread of fake news and the distrust of experts (Chinn et al., 2020). Being able to critically evaluate evidence and apply cognitive reasoning is crucial for the future of collective evidence-based decision making in healthcare.

However, whilst the generation of evidence might be happening rapidly, getting evidence from high-quality clinical trials into clinical practice can be slow. It reportedly takes 17 years for research to become integrated into general healthcare practice, with only about half of EBPs becoming part of widespread clinical care (Bauer et al., 2015). Lang et al. (2007) developed the concept of the 'leaky' evidence-based pipeline, demonstrating the challenges in getting high-quality research evidence into clinical practice. Failures in healthcare quality can be linked to three main evidence-to-practice gaps: the misuse, overuse or underuse of medical therapies, which result in healthcare practices that are inefficient, ineffective or unsafe.

More recently, the first annual report from the national Perinatal Mortality Review Tool (PMRT) group published its findings from reviewing 1,500 neonatal deaths (Chepkin, 2019). It found that the most common task-related contributory factor was related to guidelines, policies and procedures not being followed or not being available to follow. Only 10% of the actions taken were considered to be 'strong', meaning that they involved systems-level changes that reduced the reliance on individuals. In fact, the most common actions implemented in response to serious incidences were: sending out a staff reminder (21%), providing staff training (16%) and providing feedback to an individual (15%). Simply reminding staff without any controls was categorised by the PMRT group as a 'weak' action. Interventions to reduce the reliance on individuals, such as a checklist (5%), a decision aid (0.9%) or increasing the number of staff (0.9%), were infrequently used. There are increasing criticisms of guidelines, recognising that they represent less than

perfect knowledge; they may have a poor evidence base, be misleading due to publication bias in the existing literature, may oversimplify and be overwhelming. Rarely do they account for the complexities of clinical practice (Elwyn et al., 2016).

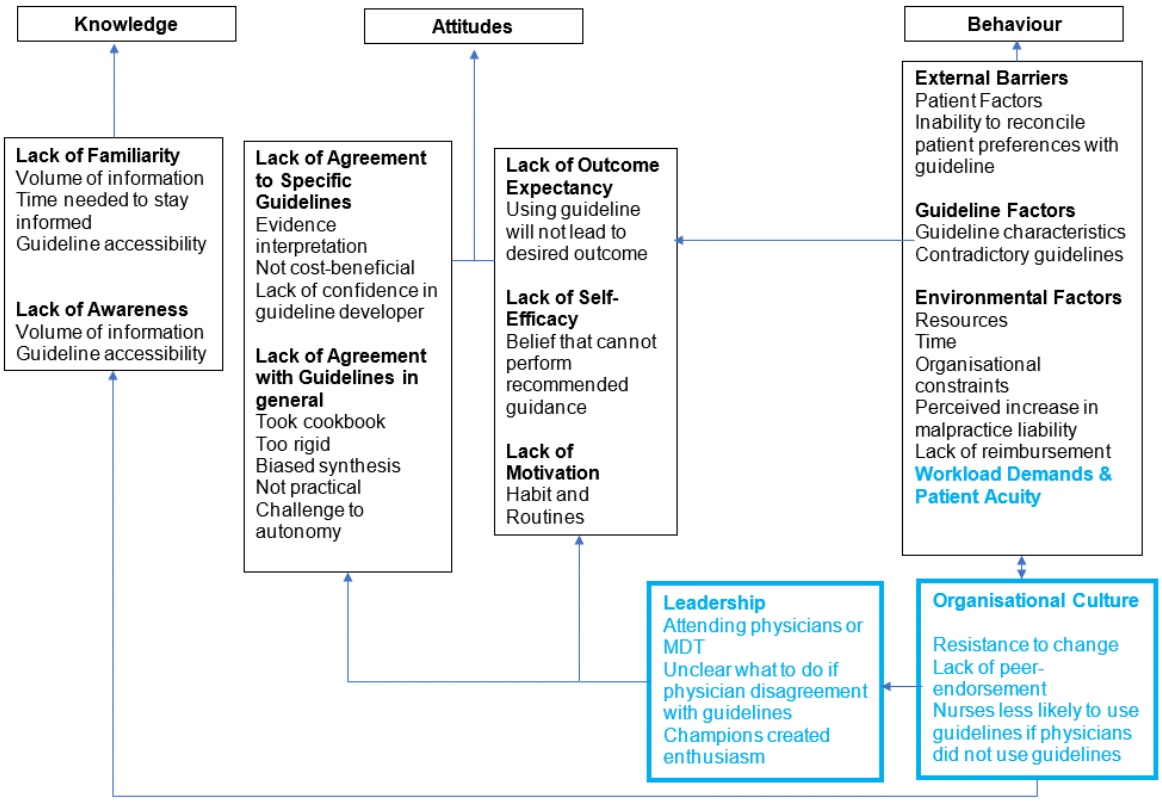
Implementing evidence-based recommendations in clinical practice is notoriously challenging (Grimshaw et al., 2012); simply having an awareness of EBP is insufficient in translating it into practice. Therefore, improving the evidence-based pipeline is important to improve patient safety in healthcare. Strategies such as quality improvement (QI)- a systematic approach to improving quality using specific methods- have been promoted as one way to tackle some of the challenges of translating evidence into practice (The Health Foundation, 2013). QI can include specific interventions designed to improve healthcare procedures and processes, such as the use of a checklist, the development of evidence-based packages of care, or the development of clinical pathways (Dixon-Woods, 2019).

1.3.1 Barriers to Evidence Translation

Several systematic reviews have sought to identify barriers and facilitators of guideline adherence in healthcare professionals. Cabana et al. (1999) performed a systematic review of physician adherence to guidelines and related these to the knowledge, attitudes and behaviours of individuals. Whilst over 20 years old, these findings are still relevant today, with barriers including the lack of familiarity with and lack of awareness of guidelines as well as broader attitudes towards guidelines, such as promoting cookbook medicine and threatening physician autonomy. More recently, Jun et al. (2016) performed an integrative systematic review of 16 studies examining adherence to nursing guidelines, with many similarities to the review by Cabana et al. (1999). However, Jun et al. (2016) also highlighted that there were organisational and leadership influences on guideline adherence. This review found that disagreement regarding guidelines and peer endorsement were strongly influential, and nurses were uncertain of what to do if physicians disagreed about guidelines. Organisational culture was felt to play a major role in adherence, with motivation and consensus facilitating their use. These additional influences have been incorporated into Cabana's model in Figure 1.

Figure 1 Barriers to Guideline Adherence

Adapted from Cabana et al. (1999) and Jun et al. (2016). Blue text highlights additional barriers identified by Jun et al. (2016).



1.3.2 Barriers to IPC Guideline Adherence

Getting evidence into practice has been notoriously difficult within the field of IPC. Yet, with a global drive to reduce HCAIs, there is now increasing research that attempts to understand the factors that influence healthcare professionals' adherence to IPC guidelines. Jenner et al. (1999) highlighted the multiple ways in which the translation of IPC evidence can be impeded; whilst this is now over 20 years old, these barriers are still relevant today. Barriers can occur where there is insufficient research evidence, when evidence is uncertain or contradictory or when healthcare professionals do not believe in the evidence. The use of experiential evidence is powerful but often flawed due to cognitive biases that often incorporate unsupported opinions, while weaknesses in written guidance can lead to ambiguity. Ambiguity can result in individual interpretations of guidelines and resultant variations in practice. In addition, failure to communicate effectively can result in a failure to follow guidance or a complete rejection of it. Quite simply, within the broader context of evidence translation, it is important to "get the evidence straight" and then "get the evidence used" (Lang et al., 2007, p. 356). In addition, human factors, poor staffing levels, physical barriers relating to resource

availability, and impractical rules, are all self-reported reasons why agreed IPC 'rules' may not be followed (Jenner et al., 1999).

Using a systems factor lens, Gurses et al. (2008) highlighted that task ambiguity, expectation ambiguity, responsibility ambiguity, method ambiguity and exception ambiguity were all felt to result in inconsistency in guideline use in two surgical ICUs. It also found that nurses did not see infection rates that were reported as per 1000 central line days as directly relevant to their practice. Shah et al. (2015) undertook a qualitative study of healthcare professionals across three tertiary London hospitals, using semi-structured interviews to understand the barriers to implementing IPC guidelines. Thirty-nine staff were interviewed from a range of healthcare disciplines; the study found that the attribution of responsibilities, prioritisation and risk appraisal and hierarchy of influence were all reported as rationales for behaviour. As this study only used semi-structured interviews, these were self-reported behaviours and may not represent how the work is enacted. It was concluded that whilst behaviours are not independent of policy rules, they are often an amalgamation of local normative practices, individual preferences and professional isolation. In order to improve adherence, reducing ambiguity whilst allowing for pragmatism in situations of uncertainty was recommended.

A more recent study, published after the study in this thesis had commenced, focused specifically on the adherence to infection prevention practices in two adult ICUs; it sampled 82 healthcare workers using observations, videos and qualitative interviews (Gesser-Edelsburg et al., 2018). In particular, this study focused on what it termed 'positive deviants': individuals who found novel approaches to problems. Gesser-Edelsburg et al. (2018) found that these positive deviants found ways of overcoming grey areas in guidelines and suggested that the use of a toolkit incorporating education, simulation training and face-to-face discussions would improve adherence.

However, it is becoming increasingly apparent that education alone is insufficient to change healthcare professionals' behaviour, with there being a complex interaction between the practice being enacted, the actions of individuals, and aspects of the environment (Finch et al., 2012, Soong et al., 2020, Prieto, 2016). The work that people do rather than individual intentions is likely to play an important role in behavioural change, with the implementation of IPC practices being seen increasingly as a problem pertaining to social groups rather than individual practice alone (Dixon-Woods et al., 2011, Saint et al., 2010). If providing education alone is insufficient, then there needs to be an understanding of *how* to improve the translation of evidence.

It is clear that developing strategies to overcome the barriers to evidence adoption and increase both the pace and effectiveness of implementation is a key research priority

(Proctor et al., 2013). One type of intervention that is becoming increasingly popular to tackle the challenges of evidence translation are care bundles (Runnacles et al., 2018). These have been introduced across a variety of healthcare settings to tackle a variety of healthcare problems, including reducing medication errors, improving antibiotic stewardship and reducing a range of HCAIs, including ventilator-associated pneumonias (VAPs) and CLABSIs.

1.4 Complex Interventions

Care bundles, a form of complex intervention that comprises multiple interacting components, are becoming increasingly popular as a way of improving quality in healthcare and are now recommended as a way to tackle a variety of HCAIs, including CLABSIs (Wasserman, 2018). Care bundles have been defined as simple sets of evidence-based practices, implemented collectively, to improve patient outcomes (Wasserman, 2018). It is now generally accepted that they should follow these core principles:

- Be simple, containing 3-5 evidence-based elements.
- Each element must be completed, with an “all or none” approach to measuring compliance.
- Be developed collaboratively, with consensus and strong clinician engagement and endorsement.

The elements should be necessary, specific, and based on the evidence of randomised controlled trials (RCTs), with no controversy about the included elements. These commonly comprise two main components: technical elements and socio-adaptive or professional elements, see Table 2 (adapted from Pronovost et al., 2006).

Table 2 Common Components of CLABSI Bundles

Technical Components	**Professional Components**
Handwashing Full barrier precautions during line insertion Chlorhexidine cleaning of the skin Avoiding the femoral site Removing unnecessary catheters	Unit-based safety culture and daily goal sheet Education on IPC practices Facilitators: central line carts, checklists and the ability to stop the procedure if processes are not adhered to

However, it is not clear which of these professional components are likely to be most effective or how many of them should be used in implementation strategies. The Cochrane Effectiveness of Practice and Organisation of Care (EPOC) group (EPOC,

2015) have developed a taxonomy of professional interventions, summarised and applied to CLABSI bundles in Appendix 3. Mazza et al. (2013) attempted to refine the EPOC taxonomy by applying it to 71 conference abstracts on implementation projects. The majority used only one type of professional intervention (41%), though some used combinations of two (29%), three (7%) and 6 or more (6%) interventions. Commonly used strategies were distributing guidelines (n=17), educating groups (n=15) and individuals (n=6), with few studies utilising reminders (n=6) or feedback (n=1). Ten studies created an implementation team, and only three provided additional human resources.

One frequently included element in central line bundles is that of a checklist; indeed, the International Society for Infectious Diseases (ISID) central line insertion bundle includes the use of checklist with a trained observer (Wasserman, 2018). Checklists — interventions that have become a component of patient safety in the NHS and referred to as Local Safety Standards for Invasive Procedures (LocSSIPs) — have become a popular cognitive aid to address protocol nonadherence and reduce never events (England, 2015). They have been argued to standardise, harmonise and educate as well as reduce human factors that are felt to contribute to serious safety failings in healthcare, such as situational awareness, decision making, teamwork, leadership and coping with stress (England, 2015, Winters et al., 2009). However, there are concerns that bundles and checklists may be seen as ‘magic bullet’ solutions that are implemented freely in practice without understanding the mechanisms of action, and that they risk increasing the likelihood of task omissions and checklist fatigue (Kramer and Drews, 2017, Bosk et al., 2009). To be effective, it has been argued that bundles should change the way in which work is organised and provide a level of accountability (Haraden, 2021).

There have been two large seminal studies investigating the use of a care bundle specifically to reduce CLABSIs. The Michigan Keystone project was a state-wide quality improvement project undertaken in the United States (US) in adult intensive care units (ICUs) (Pronovost et al., 2006). It was designed to reduce CLABSIs and introduced bundled evidence-based interventions alongside a patient safety program. It was considered a major success, reporting zero CLABSI rates post-implementation; low rates have been sustained for 10 years (Pronovost et al., 2016). Attempts to replicate this success in the UK have been less successful. Matching Michigan, a 2-year non-randomised cluster study conducted in adult and paediatric ICUs in the UK, used a combination of technical and non-technical interventions (Bion et al., 2013). Whilst a 48% reduction in paediatric CLABSIs was achieved, the progressive reduction in infection rates did not reach statistical significance. This was attributed to small numbers and large variations in infection rates in paediatric ICUs. Furthermore, there was already a strong secular trend towards reducing BSI rates, and there was a failure to demonstrate with

confidence that improvements were directly attributed to the intervention (Dixon-Woods et al., 2013).

An ex-post theory was developed in an attempt to explain the success of the original US Michigan Keystone project, which included institutional isomorphism, a network community and the identification of CLABSIs as a social problem with a solution (Dixon-Woods et al., 2011). Ultimately, a culture change took place, changing the roles of multidisciplinary team members and promoting collective responsibility. Checklists were argued to be a mechanism of social control, increasing the visibility of the process and reducing social loafing: the concept that people make less effort if working collectively (Dixon-Woods et al., 2011). The US Michigan Keystone project, therefore, addressed a key problem in infection prevention: the diffusion of responsibility. However, these mechanisms were not supported in the UK Matching Michigan study, which found that implementation was not always as intended (Dixon-Woods et al., 2013). Furthermore, the UK study failed to challenge professional norms, which may have contributed to the variations in infection rates, and some participants were unable to understand the value of the programme. The apparent lack of social community in some ICUs meant that many professional norms were not challenged, and the status quo was often reinforced.

A recent systematic review identified 37 randomised and non-randomised studies investigating the effect of care bundles on patient outcomes across a variety of patient populations and health conditions (Lavallée et al., 2017). This heterogenous evidence suggested that whilst care bundles may improve patient outcomes, the evidence from randomised studies was less convincing (Lavallée et al., 2017). An RCT of a multifaceted QI intervention (including a checklist) in adult ICUs found no difference in mortality or secondary outcomes, including CLABSIs (Writing Group for the CHECKLIST-ICU Investigators, 2016). Indeed, there are few negative studies, though recently Hagel et al. (2019) found no difference in infection rates post the intervention of a bundle. Whilst there was a decline specifically in ICU HCAIs, it was unclear if this was attributable to the intervention specifically or part of a general improvement in HCAI management. This is important. It highlights one of the challenges of QI studies, which is not only being able to confidently demonstrate the outperformance of secular trends but also being able to demonstrate a clear impact (or not) of the intervention (the care bundle).

Whilst care bundles in combination with hand hygiene have been shown to reduce CLABSI rates in adult ICUs in the US, they are not always successfully or consistently implemented (Moore et al., 2015, Sax et al., 2013). One of the challenges that care bundles present is that it is often difficult to determine which elements of the intervention worked and in what settings. It is often uncertain whether the intervention, the implementation process or both has contributed to the success (or failure) of the

intervention (Nilsen, 2015). Guidance from the Medical Research Council (MRC) advises that the design of complex interventions should be based on a theoretical understanding of how that intervention causes change; at the time of developing the study in this thesis, few studies had prospectively studied the implementation of care bundles to reduce CLABSIs (Craig and Petticrew, 2013). As Zingg et al. (2011) suggest, the evidence gap now is not what to do but how to do it. However, directly translating adult ICU bundles into NICUs provides additional challenges, as many of the bundled elements are not appropriate or applicable in the neonatal setting (Heron et al., 2013). These are summarised in Appendix 4.

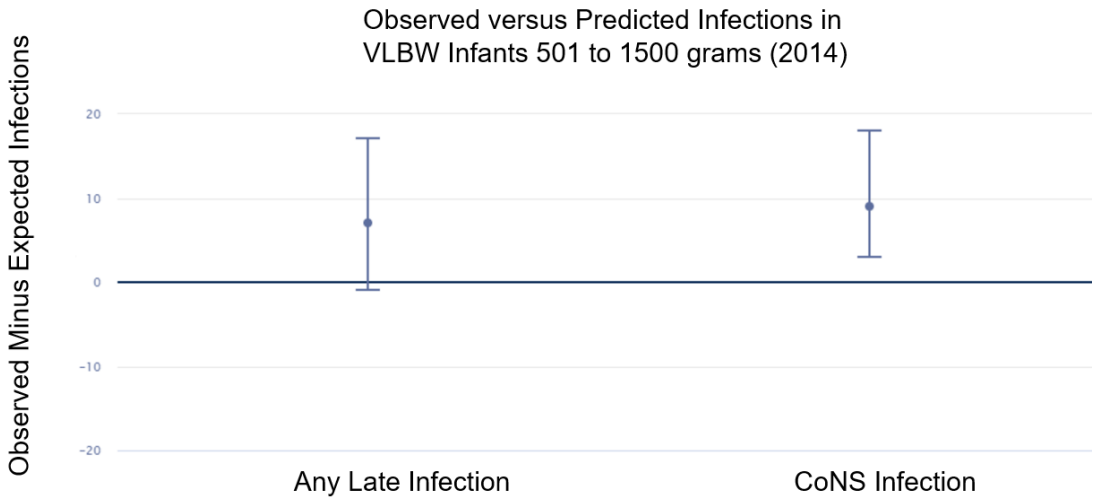
The European Standards for the Care of the Newborn (EFCNI, 2019) have recently stated that all neonatal units should have care bundles for the reduction of CLABSIs. Given the mixed success of translating the Michigan Keystone bundle into UK adult and paediatric ICUs, there is still more to understand about these complex interventions in specific settings. The most efficacious components and factors promoting successful implementation are poorly understood.

1.5 Local CLABSI Rates

The local NICU is a 37-cot tertiary centre with approximately 800 admissions per year. The patient case mix includes preterm and term infants frequently with multiple co-morbidities, including surgical pathologies and complex congenital anomalies referred for specialist input. There are over 160 nursing and medical staff working within multiple teams. Patient turnover can be rapid, though, conversely, some ELBW infants remain inpatients for up to a year.

The Vermont-Oxford Network (VON), an international collaboration of NICUs, does not collect data specifically on CLABSI rates, but it does report on LOS and CoNS infections. In 2014, the VON data reported a LOS rate of 10% in VLBW infants (Horbar et al., 2017). However, local rates were substantially higher with a LOS rate of 22.5%, an outlier compared to similar tertiary NICUs (median 11.8%). This is useful as it provides a comparison to similar centres — for example, to surgical centres where there may be an increased baseline risk for CLABSIs due to abdominal pathologies. Locally, 16.2% of VLBW infants had a CoNS BSI in 2014, higher than the median in comparable centres (4.8%). In addition, the VON provides risk-adjusted data for individual centres including a comparison of actual versus predicted infections. Figure 2 demonstrates the observed versus predicted infections for the local NICU in 2014, with more CoNS infections than would be expected for this type of NICU.

Figure 2 Local VON Data: Observed versus Predicted Infections



Whilst the VON data does not report specifically on CLABSI rates, local CLABSI rates are also high compared to other UK NICUs. In 2015, the average local rate was 9 per 1000 central line days. The National Neonatal Audit Programme (NNAP, 2016) reported a range of 0.9 to 3.8 CLABSIs per 1000 central line days in UK NICUs; whilst the report recognised significant limitations with data reliability due to underreporting and incomplete data, the local NICU appeared to be an outlier (NNAP 2016). A local multi-disciplinary team was therefore formed in 2015 with the aim of addressing local CLABSI rates, and it developed a local multi-faceted bundle aimed at reducing CLABSIs. Appendix 5 provides a summary of local guideline recommendations and Appendix 6 presents the local central line insertion checklist.

Whilst benchmarking standards for neonatal CLABSIs have previously been lacking, the EFCNI (2019) have more recently suggested that CLABSI rates of >5.1 per 1000 central line days should be considered a marker of poor performance.

1.6 Summary

This chapter has briefly introduced key concepts that will underpin this research study relating to improving the safety of neonatal care, the importance of reducing HCAIs and understanding implementation processes. Specifically, it has highlighted the necessity of reducing neonatal CLABSIs and highlighted how care bundles, a type of complex intervention, have gained increasing attention in a variety of healthcare fields but particularly in infection prevention. The use of bundles and checklists to standardise areas of clinical practice and reduce errors resulting from human behaviour to improve patient outcomes have been outlined, as have the risks of assuming that these are quick-fix solutions to complex healthcare problems. It is important that the mechanisms by which these interventions may result in behaviour change and, perhaps more importantly, in

what specific contexts are understood in order to optimise the translation of evidence into practice. The failure of the UK Matching Michigan study to replicate the successes of the Michigan Keystone care bundle in adult and paediatric ICUs demonstrates the importance of understanding the context in which an intervention works (or not).

Finally, this chapter has provided an overview of the drive behind this research study, which is the high local rates of LOS in the local NICU, despite adjusting for case mix, compared to similar NICUs. In addition, more recent benchmarking standards suggest that local CLABSI rates would now be considered indicative of poor performance (EFCNI, 2019). Chapter 2 will explore implementation science, examine the theories and frameworks used to study implementation and present a review of the literature investigating the implementation of care bundles in healthcare settings.

Chapter 2 Implementing care bundles to reduce CLABSIs: a review of the literature.

2.1 Introduction

Care bundles, a form of complex intervention, have been successfully implemented in adult ICUs to reduce CLABSIs (Pronovost et al., 2006). However, attempts to translate this into UK adult and paediatric ICUs was a mixed success, demonstrating the importance of understanding both the context and the implementation (Dixon-Woods et al., 2013). If an intervention fails to demonstrate efficacy when translated into clinical practice it can often be difficult to determine if it was the intervention, the implementation, or a combination of both, that caused the effect seen (Dixon-Woods, 2014).

This chapter will introduce the concept of implementation science, outlining the theories, frameworks and models used to study implementation. It will also put implementation into the context of complexity theory and the importance of understanding the role of context in implementation. Finally, a literature review will be performed to understand in more detail how CLABSI care bundles are implemented.

2.2 Implementation Science

Implementation science is arguably considered to be of unparalleled importance in modern healthcare, constituting the vital and often missing 'how' component of changing behaviour. Implementation has been defined as:

> The use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings.
>
> **Gonzales et al. (2012, p. 2)**

As such, implementation science examines what works, and for who, in what settings. Whilst implementation science is closely connected with quality improvement (QI), they are two distinct entities. Quality improvement is often generated from a specific problem faced in a specific healthcare system, whilst implementation science begins with evidence or knowledge that is underutilised within a healthcare system and addresses quality gaps (Bauer et al., 2015). As a science, it seeks to generate knowledge that can be generalised to other aspects of healthcare (Bauer et al., 2015). Whilst QI studies may improve healthcare practices, the findings can often be difficult to translate to different settings due to a lack of understanding regarding the mechanisms by which change occurred, or the

context in which it occurred (Dixon-Woods, 2019, Dixon-Woods, 2014). Some QI interventions may not be worth the time or cost, some fail to withstand rigorous testing or fail to be upscaled successfully, whilst some may cause harm (Dixon-Woods, 2019). Indeed, following the introduction of an intervention it can be difficult to ascertain if the success (or not) was due to the intervention itself, the implementation, or a combination of both (Dixon-Woods et al., 2011). The Medical Research Council (Craig and Petticrew, 2013) recognises that there is a need to rigorously evaluate improvement programmes in order understand how change is (or isn't) effected and the DOH (2019) recognises that implementation science should be used to improve the uptake of evidence-based practice and guidelines in practice. Indeed, determining if social science studies can run alongside QI work to generate meaningful knowledge on how QI work can be adjusted to different contexts has been identified as a key research priority (Dixon-Woods, 2014).

2.2.1 Implementation Theories, Frameworks and Models

Until recently, few implementation studies were underpinned by a theoretical model (Nilsen, 2015). Indeed, Davies et al (2010) found that only 53 studies of 235 (22.5%) utilised theory in the design or evaluation of an intervention. More recently, O'Cathain et al. (2019) reported that the majority of studies using theory, such as the "diffusion of innovation" or behavioural change theories, have been unable to demonstrate that using theory results in more effective implementation interventions. It has been acknowledged that the current guidance for designing and developing complex interventions is based largely on expert consensus, as there is a research gap around what actions are required to result in a successful intervention (O'Cathain et al., 2019). It is still advised that healthcare professionals have an understanding of, and include, existing implementation theory when designing, developing and evaluating complex interventions.

A plethora of implementation models, theories and frameworks are now available, including a number of determinant frameworks to understand the influences on implementation and process models to guide implementation (Tabak et al., 2012). Due to the complexity of healthcare and the multiple interacting factors that influence implementation, no single framework, model or theory is likely to be able to address all aspects of the implementation process. Whilst recognising the multi-dimensional nature of influences and relationships, determinant frameworks may not be able to account for the interaction between various barriers or enablers to implementation, due to the unpredictable ways in which this can occur (Tabak et al., 2012).

Tabak et al. (2012) reviewed a broad range of theories, models and frameworks to provide a useful way of assessing their appropriateness and utility. A classification system based on dissemination versus implementation, construct flexibility and socio-ecologic

frameworks used within each model, provides a useful overview. Dissemination-only models - those that focus purely on the active spreading of evidence-based interventions to specific audiences-were not appropriate for this research study, due to their lack of focus on implementation. Implementation-based models were categorised by Tabak et al. (2012) as those which focus on the process of integrating evidence-based interventions within a setting. As this research study focuses upon the work that healthcare professionals do in order to adopt new practices and make them part of their routine work, process models focusing on the how-to-implement approach, such as the Provonost 4 E's model, were not appropriate. Indeed, whilst the 4 E's model was the flagship model for reducing CLABSIs in the Michigan Keystone project, it requires significant resource investment and has been recommended for use only in large-scale collaborative interventions. Determinant frameworks- such as the PARHIS framework- can be used to identify barriers and enablers of implementation (Bergström et al., 2020, Nilsen, 2015). Whilst determinant frameworks recognise implementation as multi-dimensional, they cannot address how change occurs or the causal mechanisms at play. Instead, frameworks tend to describe phenomenon by categorising them. Whilst identification of barriers and enablers of implementation is important, being able to explain why changes have occurred, in a particular social context, is likely to generate more generalisable findings. Instead, theories can offer explanations for change mechanisms as well as being able to evaluate what has happened, as opposed to being a tool to bring about change (Nilsen, 2015). Table 3 outlines some of the behavioural change theories considered in this research study.

The theory of planned behaviour (TPB) has previously been used to study healthcare professional behaviour, originally developed as a way of understanding and predicting human behaviour (Kan and Fabrigar, 2017). It is based upon three core influences on intention to perform a behaviour: beliefs about the behaviour, normative beliefs, and control beliefs. The perceived control an individual has over their behaviour is important, for example, if individuals do not believe they have sufficient resources, then they may be less likely to act in a certain way. However, critics recognise that this is based upon an assumption of rationality and whilst it presumes that human beings will carefully consider the implications of their actions, in a complex healthcare setting this may not always be the case. Healthcare professionals are fallible to cognitive biases and heuristics, short cuts in human memory that can result in flawed diagnostic reasoning, which is heightened by human factors such as being tired, interrupted, or making multiple unrelated decisions (Michel, 2019, Kahneman, 2011).

Table 3 Summary of Behavioural Change Theories

Adapted from Conner and Norman (2017), Nilsen (2015), Lamprell et al. (2020).

Theory	**Description**	**Application to this study**
Theory of planned behaviour	Classic psychological behavioural theory linking beliefs, values and attitudes to behaviour.	Focuses on behaviour at an individual level. Commonly used to investigate if attitudes, values and beliefs can predict individual behaviour and is based upon the assumption of human rationality. It has been used in healthcare studies on clinician hand hygiene behaviour (Srigley et al., 2015, Gaube et al., 2021).
Social cognitive theory	Psychological theory that proposes that an individual's acquisition of knowledge can be directly related to observing others.	When people observe a model performing a behaviour, and the consequences of that behaviour, this information is used to guide subsequent behaviours. Social psychology constructs such as the bystander effect and the diffusion of responsibility were theorised to be relevant in the Michigan and Matching Michigan studies (Dixon-Woods et al., 2013, Dixon-Woods et al., 2011).
Nudge theory	Derived from the field of behavioural economics, it focuses upon improving individual choices and decisions by targeting cognitive biases, preferences and social norms.	It builds upon psychological constructs such as cognitive dissonance and the influence of heuristics in decision making. It has been used in healthcare studies on healthcare professional hand hygiene behaviour and on posters to address specific cognitive biases (Kwok et al., 2017, Caris et al., 2018)

Theory	Description	Application to this study
Normalisation process theory	A specific implementation theory designed to understand the work that people do in order to implement and embed new interventions. Draws upon sociological theory.	Can be used to understand both process, integrational and relational problems in implementation and focuses upon how people do the work. It has been used to understand the implementation of health technologies and complex interventions (Huddlestone et al., 2020).
Diffusion of innovations	Social science theory to explain how an idea or innovation gains momentum and becomes adopted by a population or social system.	Whilst this theory takes a broader view of adoption of new practices across populations or groups, it does not take into account the influence of resources or social systems in supporting new behaviours or technologies.

Social cognitive theory- which focuses on the influence of the social environment on an individual's motivation and learning- has been used widely in healthcare, often in relation to understanding health-related behaviours and health promotion (Bandura, 1998, Conner and Norman, 2017). It considers aspects of behaviour related to expectancy- an individual's belief about how likely a specific reinforcement is to occur- and the perceived value of that reinforcement. Indeed, cognitive beliefs about the likelihood of positive consequences following the performance of a specific action or behaviour, is an important influence on motivation (Schunk and DiBenedetto, 2020). Again, whilst this theory recognises the socio-structural determinants influencing behaviour, this theory focuses upon the motivations of individuals as opposed to the work required by groups or teams in order to integrate or enact a new process or technology. Prestwich et al. (2015), in summarising the findings of several reviews, suggests that interventions based upon theories such as TPB and social cognitive theory can result in small to moderate effects on health behaviours, though it is not clear if behavioural change is a result of changes in these behavioural constructs.

Nudge theory has recently gained increasing attention in healthcare, alongside complexity theory and implementation science (Lamprell et al., 2020). It has its foundations in behavioural economics and builds upon constructs such as bounded rationality and cognitive dissonance. These account for individual choices being framed by interests, knowledge and expertise, as well as cognitive biases such as relying on past experiences, stereotypes, preferences and adherence to social norms (Lamprell et al., 2020). 'Nudges'- which can be defined as something that predictably alters people's behaviour without forbidding alternatives-have been proposed as an effective way to change behaviour and improve outcomes with lower cost implications (Perry et al., 2015). They include interventions such as education and persuasion, audit and feedback and incentivisation or coercion. Comparisons can be made here to the EPOC professional interventions (see Appendix 3). Changing the architecture of choice, therefore, may help clinicians make better choices.

However, whilst there is evidence for the effectiveness of individual nudge components from randomised control trials and systematic reviews, the evidence of the actual impact on behaviour is variable. Prompts, reminders, audit and feedback were all found to have a clear impact on behaviours. Other interventions, such as framing gains and losses, framing social comparisons and norms, changing defaults, and incentives, were found to

have variable impact. These individual nudge components rarely occur alone and are often combined to form a multi-component, multi-modal, or complex intervention (Perry et al., 2015). Whilst nudge theory may be useful for healthcare professionals designing interventions, it may be less helpful for explaining the implementation process.

Normalisation Process Theory (NPT) was identified by Tabak et al. (2012) as one of the few theories to consider the individual, organisational, community and system levels of implementation, as opposed to focusing upon individual influences on behaviour. A more detailed discussion of NPT will now follow, and its utility within this research study explored.

2.2.2 Normalisation Process Theory

Normalisation process theory (NPT) is a middle-range theory that recognises implementation as a social process; it is based around four main constructs which are outlined in Table 4 (May, 2013b). It is concerned with three key areas of evidence translation: the process of implementation, the embedding of practices into everyday work, and the integration or sustainability of practices. It proposes that the routine embedding of a new technology or practice is the result of what people do and the enaction of processes, not necessarily solely people's attitudes, beliefs or intentions. It can therefore be used to evaluate the workability of an intervention and how it is integrated into everyday practice (May et al., 2011).

In an NPT-led systematic review on the nursing implementation of clinical guidelines, guidelines were more likely to be successfully implemented when nurses could make them workable in practice and if they minimised disruption to behavioural norms and professional roles (May et al., 2014). Building commitments across professional boundaries, being associated with a community of practice and improving the collective knowledge of users, were also considered important for successful normalisation (May et al., 2014). This fits with the findings of Jun et al. (2016) in which peer-approval and agreement with physicians were important influential factors in guideline adoption.

Table 4 Constructs of Normalisation Process Theory

Construct	Description	Sub constructs
Coherence	The sense making work that actors do in order to operationalise new practices	**Differentiation:** Actors need to understand how new practices are different **Communal specification:** Actors work together to build a shared understanding of the aims, objectives and expected benefits of a set of practices. **Individual specification:** Actors need to do things that will help them understand their specific tasks and responsibilities. **Internalization:** Actors must understand the value, benefits and importance of new practices.
Cognitive participation	The relational work that actors do to build and sustain a community of practice around a new practice	**Initiation:** Are there key actors driving the new practices forward? **Enrolment:** Actors may need to reorganise themselves in order to collectively contribute to new practices **Legitimation:** Actors need to believe it is right for them to be involved in the new practices, and that their contribution is valid **Activation:** Actors need to collectively define the actions needed to sustain new practices.

Construct	Description	Sub constructs
Collection action	The operational work that actors do to enact new practices	**Interactional workability:** The work that actors do with each other, and artefacts, in order to operationalise them in everyday practice. **Relational integration:** The knowledge work actors do to build accountability and confidence in practices and each other. **Skill set workability:** The way in which work is allocated, which underpins the division of labour. **Contextual integration:** Managing a set of practices through the allocation of different resources and protocols, policies and procedures.
Reflexive monitoring	The appraisal work that actors do to assess and understand the ways in which a new set of practices affects them and others	**Systemisation:** Actors seek to determine how effective and useful the new practices are for them and others. **Communal appraisal:** Actors work together formally or informally to evaluate the worth of new practices. **Individual appraisal :** Actors work experientially to appraise the effects of new practices on them and the contexts in which they are set **Reconfiguration:** Appraisal work may lead to attempts by actors to redefine or modify practices.

In a systematic review on behaviour change, underpinned by NPT, Johnson and May (2015) argue that complex interventions work by linking multiple elements together to form social systems. These bundled interventions may work by restructuring and reinforcing both practice and peer group norms, thereby creating a set of rules regarding behaviour and practice. It is hypothesised that this normative restructuring is more likely to lead to behaviour change than ‘soft’ attitudinal components that work through diffusion mechanisms, such as marketing and consensus-building activities. The potential adaptability of the intervention, and the context in which the intervention is introduced, may also play an important role. The replication, regulation and sustainability of new practices within multiple complex teams can result in additional demands on staff with already competing priorities and may hinder the delivery of a complex intervention. This is in addition to the challenges often faced through lack of time, buy-in and resources (Datta and Petticrew, 2013)

A recent systematic review of the use of NPT in implementation research identified 108 studies that have been underpinned by NPT (May et al., 2018). Of these, the majority studied service organisation and delivery, including the investigation of complex interventions. The review concluded that NPT was useful for understanding implementation processes that facilitate an explanation of the work involved in implementation, and that dynamic elements of context can exercise powerful constraints on the action involved in implementation (May et al., 2018). These constraints included not only systems-level processes that structured actions, but also conflict at a micro-level, such as disagreements about participation.

Researchers have used NPT to develop models of implementation, though these have been predominantly linear, starting with coherence and moving through each construct ending with reflexive monitoring. This was felt to be due to the studies focusing on the early stages of implementation rather than the embedding of practices within routine every-day work. The few studies that did study implementation over a longer period of time found it was non-linear, with interactions between all four constructs though one study categorised relational integration as essential (May et al., 2018). Some of the criticisms of NPT as a model included the over-emphasis on agency (rather than how actors experience implementation) and the lack of consideration of temporal factors. May et al. (2018) concluded that NPT was felt to be most effective for studying implementation

when used alongside inductive data analysis, as opposed to deductive framework approaches.

It appears that NPT can be used flexibly to study implementation across a variety of different healthcare settings and interventions, providing explanations for the outcomes in intervention studies.

2.2.3 Understanding Context

Translating successes into different contexts remains one of the key challenges for the transferability of QI programmes (Øvretveit et al., 2011). Context- described by Kaplan et al. (2010) as anything that is not part of the intervention or the implementation process- may include characteristics of the organisational setting, individual roles within that setting and the wider environment. Contextual factors can operate at a micro-level in an individual ward or unit, such as the different groups and teams that interact in order to provide specific aspects of care (Kaplan et al., 2010). The micro-level broadly includes organisational and local cultures, social norms, leadership and local champions, whilst the macro-level incorporates wider socio-political and economic factors that are less easily controlled (Kaplan et al., 2010). Individual clinical practice settings, such as the local NICU, can be viewed as meso-level organisations; they are made up of multiple complex teams, each with their own social processes, cultures, norms and traditional ways of doing things. Barriers to implementation in healthcare not only include issues relating to the intervention, but also individual attitudes, team and organisational structures, and system-wide barriers, all of which are context-specific (de Silva, 2015).

Context is important when considering changes in a social system. It is possible that an intervention is workable and effective, but differences in the potential and capacity of different social systems results in either an intervention that is unworkable or is implemented differently (Dixon-Woods, 2014). It is argued that it is often these contextual factors that matter the most in determining the success or failure of an intervention (Bates, 2014). Indeed, quality improvement work is often hampered by a lack of understanding of the context, which limits the extent to which new knowledge can be generalised and translatable into different healthcare settings (Mannion and Davies, 2018). The MRC guidance (Craig and Petticrew, 2013) recognises that the context in which complex interventions are introduced is important, and that strong evidence may sometimes be ignored or weak evidence quickly integrated, depending on the acceptability or ‘fit’ within that context.

Context is no longer seen as a static stage on which processes or interventions are implemented. Instead, implementation is an interactive, dynamic process (May et al.,

2016). The work of implementation is important in accomplishing order within often chaotic environments and preventing unanticipated consequences. Historical patterns of working and professional relationships are all part of the context in which implementation occurs. In an extended version of NPT, May et al. (2016) proposed that *elasticity*-how relationships and processes develop between those involved in the implementation of a change- is important. Contexts that are rigid and inelastic may require greater effort by those attempting to implement a complex intervention. Similarly, if the complex intervention being introduced has greater *plasticity* (if it is more flexible or adaptable), the relational and normative restructuring that may have to occur may be less (May et al., 2016). Understanding more about what works (or not) in particular clinical settings, and why, is important to improving the quality and safety of healthcare.

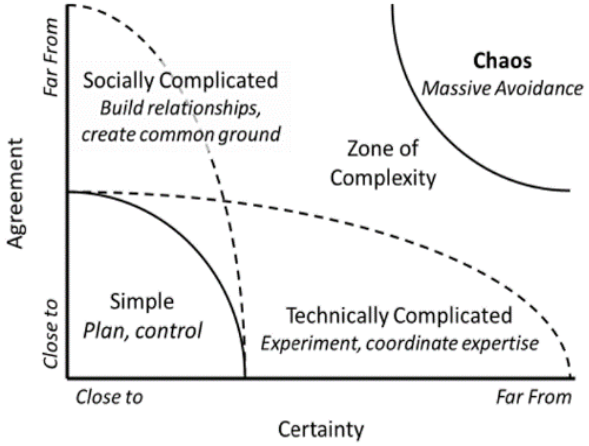
2.2.4 Understanding Complexity

Patton (2011) refers to three main characteristics that define a system: simple, complicated and complex. A simple situation is one where knowledge and experience can guide practice and there is widespread agreement on the best action. There is a clear cause and effect relationship. This is the basis for standardisation so that procedures consistently produce the same outcome. Complicated situations are those where there is less certainty regarding the outcome, and this may be technically complicated, socially complicated, or both. Technically complicated requires extensive knowledge and more than one area of expertise. Socially complicated involves multiple stakeholders, with different perspectives, competing values or conflicting solutions. Complex situations involve high uncertainty and high social conflict. Patton (2011, p. 90) summarises this interaction by saying:

> High uncertainty about how to produce a desired result fuels disagreement, and disagreements intensify and expand the parameters of uncertainty.

These features of complexity can make sustaining change in healthcare notoriously challenging (Braithwaite, 2018). The field of infection prevention is also inherently complex, being both a socially and technically complicated situation and lying firmly within the zone of complexity indicated in Figure 3.

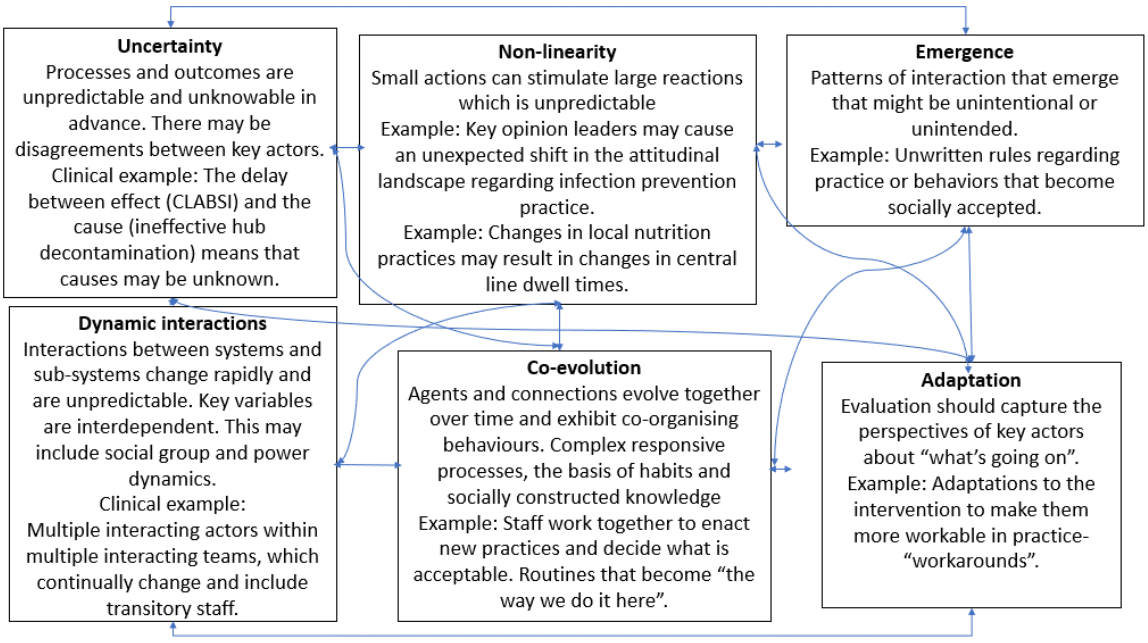
Figure 3 The Zone of Complexity



Adapted from Patton (2011). Reprinted with permission from Guildford Press.

Patton (2011) goes on to describe six concepts relating to complexity, which are applied to the problem of CLABSIs in the local NICU in Figure 4. This highlights several key features of complexity relating to CLABSIs in the NICU; interactions between multiple teams are dynamic, processes are emergent and adaptive, and there may be co-evolution of new practices. The non-linear nature of change may result in unintended consequences.

Figure 4 Complexity Concepts Applied to the Local NICU



Indeed, the very problem of CLABSIs is one of complexity; it has multiple aetiologies, with uncertainties in defining and measuring, and it is also difficult to attribute it to a single cause or behaviour. Indeed, in an ethnographic study on measuring CLABSIs, Dixon-Woods et al. (2012) found that even counting CLABSIs was a technically and socially complex task. Variations in the measurement of CLABSIs was not the result of gaming

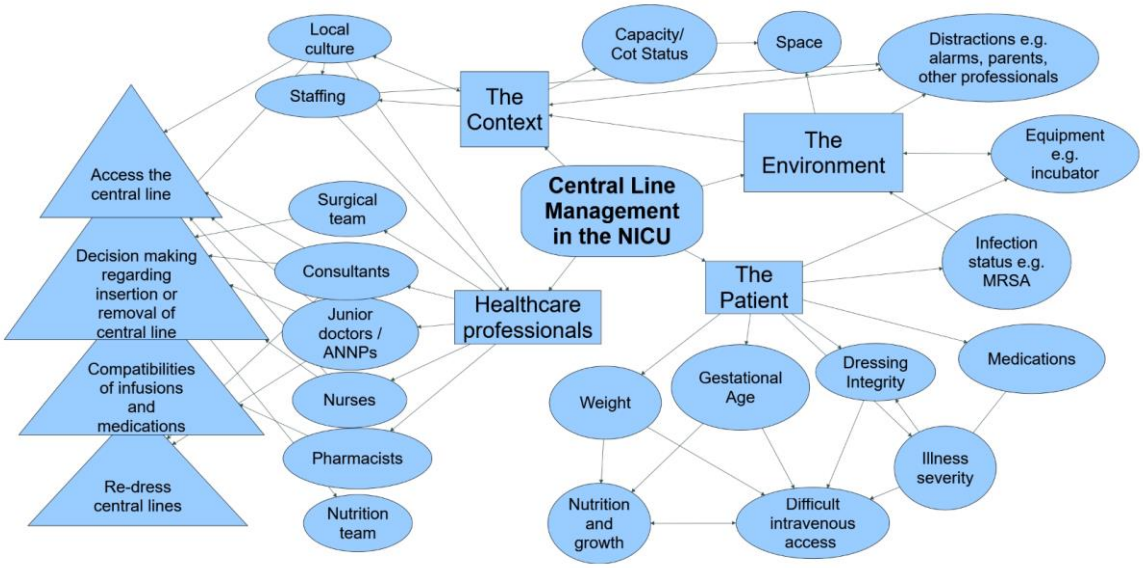
behaviours or devious attempts to subvert the system; it was because measuring these was as much a social practice as a technical one (Dixon-Woods et al., 2012).

Whilst a simple situation may have a clear and predictable cause and effect relationship, infection prevention involves multiple variables and the cause is often unknown until after the effect, if at all. The lack of real-time feedback between the action and the effect, together with the invisibility of micro-organisms, makes this particularly problematic in infection prevention (Jenner et al., 1999). High uncertainty is also evident which may result in intense disagreement between ‘actors’. This has been recognised in the field of infection prevention, whereby healthcare professionals may not only distrust empirical evidence but also disagree on the interpretation of it (Jenner et al., 1999).

Care bundles are a complex intervention, containing multiple active components that are both technical and socio-adaptive. These complex interventions target multiple behaviours, require variable levels of skill by those enacting them and contain variable degrees of interaction between components. As such, Patton (2011) emphasises that a recipe from one or two successful social innovations is unlikely to be successfully replicated in another context (Dixon-Woods et al., 2013). It is therefore important to understand more about how interventions such as care bundles can be translated into different contexts.

Healthcare organisations are now considered to be complex adaptive systems (CAS), systems comprising of individuals who have sense-making capabilities, learn from past experiences, and have informal rules, social hierarchies and self-internalised governance (Braithwaite et al., 2017, Plsek and Greenhalgh, 2001). Whilst CAS have the ability to dynamically evolve this is not necessarily predictable, meaning that systems performance cannot be completely understood by the individual components as the interactions between processes and objects shape the system (Braithwaite, 2018). Interconnections between actors can result in unintended consequences and feedback loops, which will be different for different systems at different points in time, impacting the sustainability of new interventions. The local NICU is a complex micro-system, and both the problem (CLABSIs) and the solution (care bundles) are complex. The concept map in Figure 5, developed from local practice in order to map the key actors involved in, and some of the possible influences on, local NICU central line management, demonstrates the complexity of central line care.

Figure 5 Conceptual Map Demonstrating the Complexity of Central Line Care on the NICU



Legend: MRSA= methicillin resistant *Staphylococcus aureus*

= category of influence on central line management

= involved with central line management

= decision making about, or interactions with, central lines

2.3 Implementing CLABSI care bundles: a review of the literature

Since the Michigan Keystone study, several studies have investigated the use of care bundles to reduce HCAIs in adult ICUs, though these have tended to focus on bundle efficacy (Lavallée et al., 2017). In order to identify the most effective implementation strategies, Borgert et al. (2015) performed a systematic review of 47 studies of central line, ventilator and sepsis care bundles in adult ICUs, using the EPOC taxonomy to categorise professional interventions. Whilst education, reminders, and audit and feedback were the most commonly used strategies, due to widespread heterogeneity conclusions could not be drawn regarding which strategies were most likely to promote the highest levels of adherence. In addition, the number of components ranged from 3 to 7 in the CLABSI bundle, but up to 11 in the sepsis bundle. Borgert et al. (2015) theorised that the more elements, the more difficult the bundle is likely to be to perform and may reduce compliance levels, though there was no data to support this. More recently, Burke et al. (2020) performed an integrative review of 19 studies investigating care bundle adherence to reduce CLABSIs in ICUs, finding that there were gaps in adherence to the

Centre for Disease Control (CDC) checklist and concluded that future research needed to find ways to improve non-adherence. Neither of these reviews investigated the implementation of bundles, reviewing instead the common bundled components and adherence to them. Studies have frequently tended to focus on bundle effectiveness (do they work) rather than implementation (*how* they work).

A literature review was performed in order to ascertain what factors promote or hinder the successful implementation of care bundles to reduce CLABSIs. The literature review question formulated to facilitate the search was framed using SPICE for evaluation questions:

> In healthcare settings, how do healthcare professionals implement care bundles, aimed at reducing CLABSIs?

The goals were to identify what evidence was already available on implementing CLABSI care bundles, gaps in the current evidence-base and research methods used to study implementation. More specifically, it aimed to address the following questions:

1. What factors promote or hinder the implementation of a CLABSI care bundle?
2. How is implementation success (or failure) measured?
3. How is context accounted for in the evidence and what role does it play in implementation?

2.3.1 Search Strategy

Key terms were identified using the SPICE framework (see Table 5). A detailed search strategy, including an audit trail, can be found in Appendix 7. Barriers and facilitators to implementation were categorised using The Health Foundation categories (de Silva, 2015). The search was limited to 2006 onwards, to capture studies published after the Michigan Keystone project.

Table 5 Search Terms

Category	**Key Concept**	**Search Terms**
Setting	All healthcare settings	Not included in search terms
Perspective	All healthcare professionals	
Intervention	CLABSI care bundle	Care bundle* or bundle* or quality improvement or complex intervention AND CLABSI or central line associated bloodstream infection or bloodstream infection
Comparison	Standard practice	Not included in search terms
Evaluation	Implementation	Implement* or evaluat* or barrier* or facilitat*

2.3.2 Results

Seven studies evaluated the implementation of a care bundle to reduce CLABSIs across a variety of healthcare settings, summarised in Table 6. It should be noted that two of these studies were published after data collection had already commenced for the study in this thesis and were identified through re-runs of the search in January and December 2020.

Table 6 Summary of Studies

Author	**Krein et al. (2010)**	**Dixon-Woods et al. (2013)**	**LeMaster et al. (2014)**	**McAlearney and Hefner (2014)**	**Clack et al. (2018)**	**Lee et al. (2016)**	**Woods-Hill et al. (2020)**
Design	Not specified	Ethnographic study	Qualitative grounded theory	Qualitative case study	Qualitative comparative case study	Cross-sectional survey	Cross-sectional survey
Setting	6 Medical and Surgical ICUs, US	19 adult ICUs in England, UK	6 Emergency Departments, US	8 hospitals in the US	Adult ICUs from 6 hospitals, Europe	Medical and surgical ICUs, US	Single-centre PICU
Methods	Interviews Informal observation	Interviews Non-participant observation	Interviews Focus groups	Interviews	Interviews Non-participant observation	Survey	Survey
Sample	86 hospital staff	98 healthcare professionals	49 hospital staff	194 hospital staff	129 hospital staff	507 ICUs	160 nurses
Intervention Characteristics Easy to use Consistent with existing processes Results visible Relevant Clear purpose Evidence base		• Interventions perceived to have poor evidence base • Data collection did not always have a norm-disrupting effect	✓ Timely feedback	✓ Standardisation of process, making it easy to do the right thing ✓ Meaningful use of data, in multiple formats and visible to all staff ✓ Timely access to data			

Author	Krein et al. (2010)	Dixon-Woods et al. (2013)	LeMaster et al. (2014)	McAlearney and Hefner (2014)	Clack et al. (2018)	Lee et al. (2016)	Woods-Hill et al. (2020)
				✓ Valuing new technology • Lack of consistent definition of CLABSI • Lack of agreement on best practice			
Practical issues relating to implementation Financial resources Sufficient staff Involvement of professionals Opinion leaders or champions	• Resources ✓ Champions		• Resources • Time constraints	✓ Support from clinical infection champions ✓ Involving patients in education	✓ Provision of 0.5 WTE nurse ✓ Boundary spanners		• Needing a second person
Characteristics of individuals Knowledge and skills Autonomy Leadership/ Buy-in Role-modelling Workloads	✓ Leadership • Relationships: Difficulties in getting consensus/ buy-in	✓ Leadership-strong, committed and credible • Lack of buy-in	✓ Buy in ✓ Autonomy to adapt bundle • High patient acuity	✓ Cross-disciplinary leaders • Physician resistance		• Workload demands	✓ Goals important to leaders • Workload demands

Author	Krein et al. (2010)	Dixon-Woods et al. (2013)	LeMaster et al. (2014)	McAlearney and Hefner (2014)	Clack et al. (2018)	Lee et al. (2016)	Woods-Hill et al. (2020)
Organisational factors Formal reinforcement and management championing Top-down decision making/ hierarchical structures Staff turnover Teamwork or silo working Negative or positive cultures	✓ Striving to be the best, making a difference, commitment and passion ✓ Evidence-based practice goals • Negative cultures: lack of cohesion and emotional exhaustion • Silo working • Communication hierarchies	• Pre-existing improvement cultures • Consensus and coalition between medical and nursing teams • Top-down, initiative from outside the clinical community ○ Histories of previous IPC interventions could both facilitate and hinder	• Hierarchical culture • Unclear roles	✓ Top-level commitment and leadership ✓ Emphasis on audit and monitoring ✓ Strong physician-nurse alignment and collaboration ✓ Systematic, comprehensive and repetitive education ✓ MDT education • Solely unit-based effort		High-quality staff relationships= no difference	✓ Physician involvement and collaboration • Lack of support from colleagues
Contextual factors Fits into existing regulations Counter-incentives Priorities of commissioning groups	✓ Engaging stakeholders	• Goals and priorities misaligned with those of staff		✓ Aggressive goal setting- striving for zero ✓ Rewards and recognition for success, incentive compensation	✓ Implementation agendas ○ Disruptive events could both negatively or positively impact on implementation	✓ Prioritising quality	

✓ = Facilitator of implementation
• = Barrier to implementation
○ = Could both facilitate or hinder implementation
WTE=Whole time equivalent

2.3.3 What factors promote, or hinder, the implementation of care bundles aimed at reducing CLABSIs?

Professional interventions that were specifically highlighted as facilitating implementation included education, an insertion trolley, audit and feedback, root cause analysis of CLABSIs and the use of a checklist. The barriers and facilitators to implementation identified in these studies will be discussed in turn, using The Health Foundation categories (de Silva, 2015).

Intervention characteristics

Very few studies reported on the ease of use of the intervention, or intervention characteristics. In a single-centre survey of PICU nurses, Woods-Hill et al. (2020) found that the majority of nurses believed the bundle was easy to use and could identify the key components, though the consequences of not using the bundle were less frequently correctly identified. When compared to other bundles, the CLABSI bundle was felt to be the most difficult mostly due to resources and patients' refusal of the bundle, the latter of which was specifically related to chlorhexidine bathing. The need for bundles to have a second person, and the bundle taking longer to perform, were also cited as challenges for those trying to implement the new practices (Woods-Hill et al., 2020). McAlearney and Hefner (2014) reported that valuing new technologies was an important influence, and that new technologies such as impregnated dressings helped to change behaviour. This is in contrast to Krein et al. (2010) who found that technologies were perceived as an easier solution than trying to change healthcare professional behaviour. Not having a clear evidence base, inconsistent definitions of CLABSIs and lack of agreement on best practice all hindered implementation processes (McAlearney and Hefner, 2014, Dixon-Woods et al., 2013). Making it "easy to do the right thing" through standardisation was an important facilitator of bundle adoption (McAlearney and Hefner, 2014, p. p.219).

The use of data formed part of implementation in the majority of studies, though the impact was mixed. LeMaster et al. (2014) found that continuous monitoring of both adherence and CLABSI rates along with timely feedback that addressed non-adherence was the most successful strategy, though it was recognised as being resource intensive. However, whilst McAlearney and Hefner (2014) found that disseminating data in variety of ways was useful to ensure that all staff knew local CLABSI rates, Dixon-Woods et al. (2013) found that feedback on CLABSI rates did not always result in a disruption of normative practices. Compared to the Michigan Keystone project, data collection was shorter (3 to 6 months only) and units determined their own method of collection and reporting. This appeared to impact buy-in for the programme, as some units believed their

rates were already low and so no change was warranted, though the data was not always accurate. Some studies reported frustrations with the definitions used to collect data, and McAlearney and Hefner (2014) emphasised the importance of using meaningful data, though what was considered meaningful was not explored.

Practical issues relating to implementation

Resources-specifically those relating to time and staffing as opposed to financial resources-were frequently cited as a significant barrier to implementation efforts. Champions were identified as important influencers of bundle adoption and able to help overcome some of these resource challenges (Krein et al., 2010, Clack et al., 2018, LeMaster et al., 2014). Clack et al. (2018) found that the provision of a 0.5 whole-time-equivalent nurse to help implementation was key to success. Clack et al. (2018) also found that boundary spanners-staff with roles that traverse traditional professional boundaries- were useful in being able to facilitate change. Involving patients in education regarding central line care and empowering them was felt to support bundle implementation (McAlearney and Hefner, 2014).

Individual characteristics

Individual beliefs and motivations regarding CLABSI bundles were important. Woods-Hill et al. (2020) found that there was high self-reported motivation for reducing CLABSIs among PICU nurses, though motivation was noted to be influenced by physician attitudes. Getting buy-in for the Matching Michigan programme was found to be a significant barrier as there were notable differences in how teams engaged with the programme; this meant that in some cases the status quo went unchallenged (Dixon-Woods et al., 2013). Woods-Hill et al. (2020) found that individuals' knowledge and skills relating to the CLABSI bundle was high, while Dixon-Woods et al. (2013) found that practices were for the most part well implemented. Doing the right thing was an important motivational factor that could be capitalised upon through training (LeMaster et al., 2014). One study found that involving patients in self-education was an important influence, and that this was reliant on the individual professional providing information to enable this to happen (McAlearney and Hefner, 2014).

Leadership was frequently referred to as being a strong influence, including having consensus and collaboration between professions (Krein et al., 2010, McAlearney and Hefner, 2014, Clack et al., 2018, Dixon-Woods et al., 2013). Leaders that crossed disciplines were important as was credibility (McAlearney and Hefner, 2014, Dixon-Woods et al., 2013). Role-modelling, persuasion, and reminding and providing feedback whilst also being able to exercise firmness and sanctions were skills used by local leaders (Dixon-Woods et al., 2013). Leaders who were authoritative and demonstrated

unwavering support were also important for the units that transformed their efforts at CLABSI reduction (Dixon-Woods et al., 2013, McAlearney and Hefner, 2014). Conversely, initiatives or programmes that appeared to be delivered in a top-down manner could be resented (Dixon-Woods et al., 2013). Hierarchies were frequently a negative influence on bundle implementation, with LeMaster et al. (2014) finding that a checklist was found to have flattened hierarchies and promoted nurse empowerment in one ED.

Organisational factors

Whilst the importance of training and education was frequently referred to as important, it was also varied. Multidisciplinary training, repetitive training and re-training were all felt to facilitate implementation, whilst 'train-the-trainer' methods were felt to be useful in resource-limited settings. Some studies found that siloed-working hindered implementation efforts, perhaps explaining why cross-disciplinary leaders were found to be a strong facilitator. Unclear roles and responsibilities hindered adoption of CLABSI bundles in some settings (LeMaster et al., 2014). Indeed, LeMaster et al. (2014, p. p.347) found that "if everyone is responsible, no one is".

Studies consistently reported resources, primarily staffing and time, as key barriers to the implementation of a bundle (Krein et al., 2010, Clack et al., 2018, LeMaster et al., 2014, Woods-Hill et al., 2020). Workload volumes and staffing had an impact on implementation, including on the implementation of a checklist and observer (LeMaster et al., 2014). High acuity levels or competing workloads were identified as barriers. For example, emergency departments with higher patient volumes were reported to face greater obstacles to bundle implementation and required greater flexibility. However, this flexibility often resulted in not having an observer. Rapid staff turnover was felt to hinder implementation due to the need to keep new staff trained (Clack et al., 2018).

2.3.4 How is context accounted for in the evidence and what role does it play in implementation?

It is clear that the influence of local contextual factors overlaps between several of the above categories. Hierarchy, for example, is an important contextual feature, and the influence of physician attitudes on nursing motivation suggests that professional relationships are also important, though studies infrequently referred to team dynamics. Empowering nurses to stop procedures if correct processes were not followed was argued to improve communication between those inserting the line and those observing, though local hierarchies made it hard for some observers to challenge practice (LeMaster et al., 2014). Indeed, the success of the checklist was attributed to its ability to flatten communication hierarchies and improve nurse empowerment (LeMaster et al., 2014).

High-quality staff relationships were positively associated with bundle adherence (Odds Ratio 1.36 95%CI 1.01-1.86), though this was not significant when all work environment variables were included in the modelling. A work environment that prioritised quality and reasonable workloads, remained positively associated with bundle adherence in a multi-variate model. It is unclear what constitutes a reasonable workload, so it is likely that respondents' perceptions of this may be variable.

More frequently, contextual factors were referred to in relation to organisational goals, missions and values. For example, implementation agendas that were misaligned to organisational goals hindered bundle adoption, whereas organisations that prioritised quality or strove for evidence-based practice or were described as having positive cultures or passion, facilitated implementation (Lee et al., 2018, Krein et al., 2010, McAlearney and Hefner, 2014). Negative cultures were characterised by Krein et al. (2010) as lacking cohesion and suffering emotional exhaustion. This did not necessarily equate to centres that struggled with resources constraints, as the hospital with most significant resource constraints was noted to have passion, commitment and a shared mission (Krein et al., 2010). Clack et al. (2018) also found that some sites with poor human and material resources still achieved high levels of implementation success and reduced CLABSI rates.

Culture was less explicitly studied, with Dixon-Woods et al. (2013) reporting the importance of local histories in implementation efforts. Units that had previously tried and failed to reduce infections, or those with already low infection rates, had differences in buy-in for the programme. Organisational cultures were sometimes responsible for ICU staff feeling unable to train colleagues, and this resulted in a lack of feedback on adherence (Clack et al., 2018). In one ED, an underpinning cultural belief that nurses should not be observing physicians was an initial barrier to implementing a two-person technique (LeMaster et al., 2014). McAlearney and Hefner (2014) found that organisational-wide initiatives were more likely to be successful than solely unit-led initiatives, and Dixon-Woods et al. (2013) found that a lack of contact with the wider programme suppressed the restructuring of norms, as units believed their practices were standard. This is likely to be important for smaller, locally led initiatives where clinicians may not perceive there to be a problem and therefore may lack buy-in for the need to change.

Krein et al. (2010) attempted to quantify contexts using negative, positive or mixed categories, as determined by deliberations within the research team. Quantifying context in this way remains a challenge for implementation research.

2.3.5 How is implementation success measured?

Overall, process or outcome measures were not frequently reported. Most studies did not report CLABSI rates, though some studies referred to high-or low-performing units. Clack et al. (2018) were unable to evaluate long-term sustainability, with data collected for only one-year post intervention. Therefore it is difficult to determine with certainty if sites with more successful implementation strategies or improved adherence also had improved CLABSI rates (Krein et al., 2010, McAlearney and Hefner, 2014, LeMaster et al., 2014, Dixon-Woods et al., 2013). Lee et al. (2018) used self-reported bundle adherence rates, finding that 82.4% of ICUs surveyed reported <95% adherence. This was a single one-off measure, and no link was made to CLABSI rates. LeMaster et al. (2014) reported adherence levels as either high or not, for each of the 6 EDs studied, a dichotomous yes or no measure. The three high-volume EDs that faced more implementation challenges were reported to not have high adherence levels, though no CLABSI rates were reported. Adherence rates alone are unable to fully explain how the work is enacted, or the effort required to implement and sustain these new practices.

However, the PROHIBIT study (Clack et al., 2018) did attempt to link implementation success (or failure) with CLABSI rates, revealing the complexities in trying to linearly equate process and outcome measures with implementation. Some sites with less implementation success still improved overall adherence; these centres had low CLABSI rates at the start of the intervention, and they remained low after the intervention. One site, for example, whilst achieving high levels of implementation success, had low hand hygiene compliance, and yet reduced CLABSI rates. Dixon-Woods et al. (2013) also found that adherence with good practice and low infection rates could also be achieved with only partial implementation of the bundles professional components.

This was also the only study that provided a qualitative definition of implementation success, described in Table 7. This study was published after the data collection for the study in this thesis had already commenced, but these definitions might prove useful for future research.

Table 7 Defining Implementation Success

Measure	Description
Acceptability	Satisfaction with the intervention programme, based on design, implementation process and outcome.
Fidelity	The extent to which the intervention was implemented as intended by the study protocol.
Intervention-to-context-fit	The adaptation and re-engineering that takes place to assist implementation and sustainability.

2.3.6 Limitations of the Evidence

There are several limitations to these studies. Only two studies had a theoretical underpinning, Clack et al. (2018) using the diffusion of innovation framework to guide data collection whilst Woods-Hill et al. (2020) used the capability-opportunity-motivation behavioural (COM-B) model to inform survey design.

These studies used a variety of different methods to study implementation, including observations of practice. However, it was not always clear in the three studies using observation exactly what was being observed, even though one study undertook 910 hours of observation (Dixon-Woods et al., 2013). Understanding how the work is enacted, observing the *work as done*, is important in order to understand the *how* of care bundle implementation. Interviews alone are unable to explore how the beliefs or attitudes of individuals align with *actions*. Indeed, the idealised view of work expressed in interviews may not always reflect the *work as done*. The majority of the studies relied upon self-reported measures of adherence or behaviour, and are therefore unable to ascertain how the work is enacted, the work *as done* (LeMaster et al., 2014, Krein et al., 2010). Similarly, as both Woods-Hill et al. (2020) and Lee et al. (2018) performed surveys, they are also reliant on self-reported behaviours and quantitative measures of adherence. Indeed, Lee et al. (2018) only surveyed a single infection prevention clinician for each participating hospital, and it is likely that those implementing the bundle may have responded differently or had different experiences. Whilst surveys have a role in assessing individual motivations and beliefs, self-reported intentions may not always predict behaviour (Eccles et al., 2006). It should also be noted that only 23% of eligible hospitals with medical and surgical ICUs responded to the survey (Lee et al., 2018).

As none of these studies were performed in the NICU, some elements of the bundles implemented may not be applicable, such as chlorhexidine bathing or technologies such as antimicrobial catheters (see Appendix 2). The aspects of central line care being studied also varied, with some only investigating central line insertion (LeMaster et al., 2014, Krein et al., 2010, Lee et al., 2018). The PROHIBIT study (Clack et al., 2018) investigated a hand hygiene and a central line insertion bundle; Woods-Hill et al. (2020) studied a maintenance bundle, though it is not clear what components this included. Dixon-Woods et al. (2013) studied the implementation of both insertion and maintenance bundles. Similarly some studies only studied a single professional group such as nurses (Woods-Hill et al., 2020) or infection prevention leads (Lee et al., 2018). Given the multi-faceted nature of the problem of CLABSIs and that the complex implementation work required often involves multiple teams across different professional groups, focusing on a single profession in isolation may not always be helpful. As some studies have found that

physician's attitudes influence nurses' behaviour, it seems prudent to explore the experiences of both professional groups.

2.3.7 Summary

These studies have highlighted the complexity of studying implementation across a variety of healthcare settings and the importance of understanding the context in which implementation occurs. In some multi-centre studies, there were notable differences across sites despite similar implementation strategies. In addition, there are complexities to studying implementation including defining context and measuring implementation success (or failure). The work required of healthcare professionals to implement and sustain these bundles, as well as the effort to incorporate them into existing workflows and relationships cannot be fully understood solely through quantitative measures of compliance.

Moreover, some studies refer to negative or positive cultures, another concept that is difficult to define. Bates (2014) argues against reifying culture in an attempt to make it less abstract, suggesting that culture is not something an organisation *has* but what an organisation *is*. Indeed, it is hard to know what a 'gold standard' culture should be and quantifying culture is hard; 'more' culture is not necessarily better than 'less', and strong cultures can be resistant to change. One of the challenges for healthcare improvement work is understanding what culture (and context) is, and, perhaps more importantly, how to work *with* it to facilitate successful implementation (Bates, 2014). The following chapter will present the results of a systematic review and meta-analysis of the evidence for the use of care bundles to reduce CLABSIs in the neonatal population, and the professional interventions that may facilitate effective implementation in the NICU.

Chapter 3 Systematic Review and Meta-Analysis

3.1 Introduction

Whilst care bundles have been effective in other healthcare settings (Pronovost et al., 2006, Lavallée et al., 2017), these findings have not always been replicated in randomised controlled trials nor have they always been successful when translated to other healthcare settings (Dixon-Woods and Martin, 2016). Chapter 1 identified that many of these bundled components for adult patients are not directly transferable to the NICU, whilst Chapter 2 identified the NICU as a unique and complex meso-system. Given that a lack of evidence, or an unclear evidence base, has been identified as a barrier to implementation (McAlearney and Hefner, 2014, Dixon-Woods et al., 2013), prior to implementing change in the local NICU a systematic review with meta-analysis was performed to determine if care bundles were effective at reducing CLABSIs in the NICU, and to identify what professional strategies may promote effective implementation. It also informed the study design and data collection methods used in this study.

With research being published at a rapid rate, it is almost impossible for healthcare professionals to keep up to date by searching and appraising the latest evidence (Garg et al., 2008). Whilst systematic reviews can help by summarising the available evidence regarding an intervention, there are limitations-most notably heterogeneity between studies often in regard to the population and the intervention. In some circumstances, RCTs may be unfeasible or unethical, and the evidence available may only be from observational studies. Using data from observational or non-randomised studies in a meta-analysis can result in distortion of the effect size (Stang, 2010), though the Cochrane Collaboration suggests that if a research question cannot be answered by a RCT, using observational studies may be justified with a cautious interpretation of the results (Higgins and Green, 2011). It was anticipated that there would be a paucity of RCT evidence for care bundle efficacy in neonates based on the adult literature, and that the majority of studies would be quasi-experimental.

The review in this chapter has been published (Payne et al., 2018), and the manuscript copy that was accepted for publication is provided in Appendix 8. The search has been updated in 2020 and so this chapter will provide a detailed commentary expanding upon the original manuscript publication. The journal Archives of Disease in Childhood (Fetal and Neonatal Edition) has an Impact Factor of 5.436, and this publication has an Altmetric Score of 41, having been cited in 30 publications to date.

3.2 Research Question

The research questions addressed by the systematic review were:

1. In neonates with a central line, are care bundles, compared to standard practice, effective at reducing CLABSIs?
2. What are the commonly bundled elements?
3. What elements promote effective implementation?

3.3 Updated Systematic Review

The methods have been outlined in detail in the manuscript in Appendix 8, including the search strategy and methods for statistical analysis. The original Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart is available in Appendix 9, and the critical appraisal of QI studies is available in Appendix 10.

In order to ensure the currency of this systematic review, an updated search was performed in August 2020. In total, 10 additional papers were found that met the inclusion criteria and were subsequently added to the meta-analysis. The following sections will provide a commentary on the systematic review, including recent updates, in order to address the research questions.

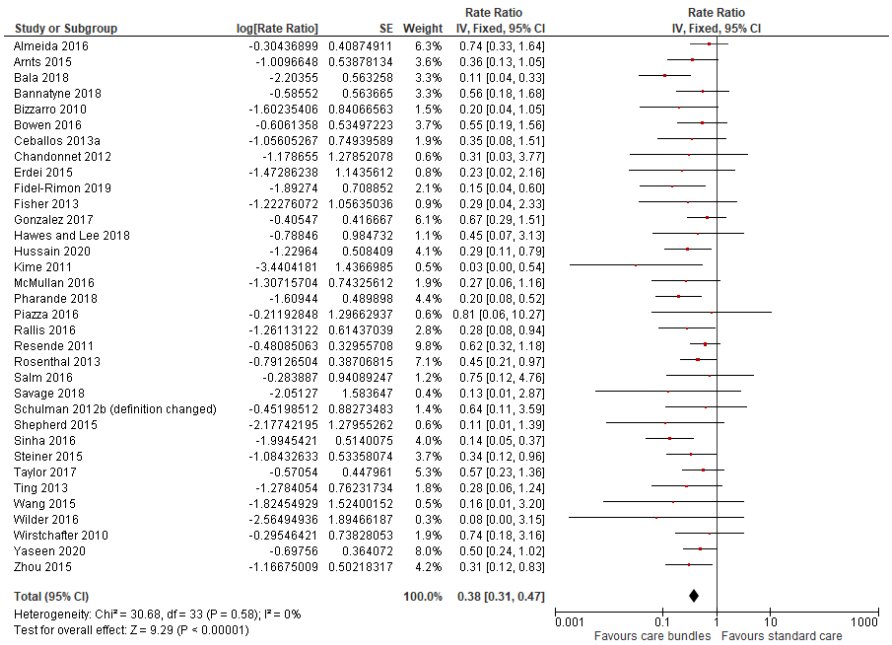
3.3.1 In neonates with a central line, are care bundles, compared to standard practice, effective at reducing CLABSIs?

An updated forest plot for the meta-analysis can be found in Figure 6. The overall rate ratio remained relatively unchanged from previous analysis, with a RR 0.38 (95% CI 0.31-0.47). This equates to a possible 62% reduction in CLABSIs following the introduction of a care bundle, though the pre-post-test study designs of these studies remains a significant limitation. The duration of follow up in terms of CLABSI rates was variable, with 16 studies (47%) having post-intervention epochs of only three to 12 months. This is unlikely to provide robust evidence of sustained changes and may represent natural variation over time.

There continues to be disparities across the studies in the magnitude of effect size, as well as differences in reducing CLABSIs in specific sub-groups. Differences in effect size was most notable in the paper by Schulman et al. (2011), in which a bundle was implemented across 19 NICUs in New York. In this study, one NICU achieved a 96% reduction in CLABSI rates, whilst another NICU reported a 186% increase. This demonstrates that bundles themselves cannot be simply translated from one centre to

another. In a more recent study (Bannatyne et al., 2018), CLABSI rates actually increased in the post-intervention period for babies with birth weights between 751 grams and 1000 grams (from 8.3 per 1000 central line days to 9.0 per 1000 central line days) and rates in the <750gram population remained high, albeit reduced (16.8 per 1000 central line days to 12.0 per 1000 central line days). The study by Taylor et al. (2017) found a 7.3% increase in CLABSI rates in the ELBW population. Whilst studies overall demonstrate impressive reductions, examining rates in specific populations or individual centres reveals a more complex picture of CLABSI reductions.

Figure 6 Meta-Analysis of CLABSI rates



What was not addressed in the original systematic review was the potential risk of detection bias within these studies. This was highlighted in a letter published in response to this review (Degraeuwe, 2018). This letter importantly identified that with many bundled studies including a daily review of central line need, there was likely to be a reduction in risk for developing a CLABSI in the post-intervention periods. This prompted a second review of the data, the results of which were subsequently published (Payne et al., 2020). Of the original 24 studies reviewed, 16 cited a daily review of the need for the central line as part of their bundled components. However, nine of these studies actually reported increases in central line days post-intervention, though differences in follow-up epochs may be relevant here. Incorporating a daily review of the need for a central line was consistently reported in the newer studies published after 2017 (80% of studies); six of these reported reductions in central line (CL) days or utilization rates (Bannatyne et al., 2018, Flidel-Rimon et al., 2019, Balla et al., 2018, Savage et al., 2018, Hussain et al., 2020, García González et al., 2017) while only one study reported an increase post-intervention (Pharande et al., 2014). Most notably, one study reduced its total number of

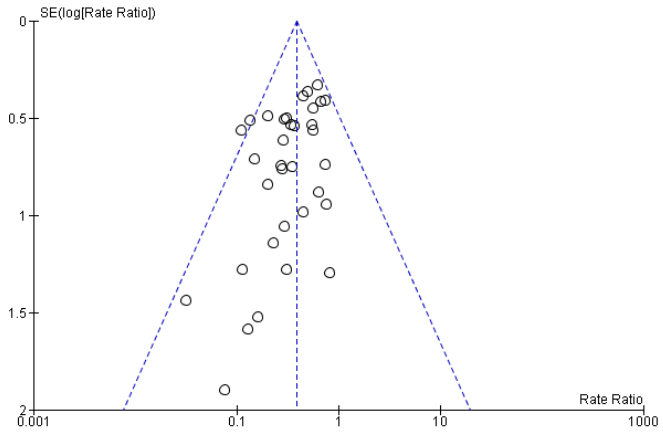
central line days by 52%, clearly reducing the risk of developing a CLABSI (Balla et al., 2018). However, individual dwell times would also be a useful process measure, as the risk of developing a CLABSI may increase with longer dwell times (García et al., 2019, Milstone et al., 2013, Greenberg et al., 2015). Nuances in practices between individual NICUs are likely to be important and yet are often unexplored in the literature. Flidel-Rimon et al. (2019) reported reductions in central line days and dwell times; a primary feature of this study was that pre-intervention, umbilical lines had dwell times of two to three weeks. Reducing this to five to seven days may explain the impressive 84% reduction in CLABSIs observed in the study. Limiting the dwell time of UVCs is already part of local practice and therefore limits the applicability of this study.

It could be argued that a meta-analysis using rate ratios may not be appropriate (Higgins and Green, 2011). Whilst the published data is ratio data, the raw 'count' data of bloodstream infections was not collected. Rate ratios assume that the risk of developing the outcome measure is the same over time; in fact, the risk of developing CLABSI arguably increases with an increasing central line dwell time, so each patient's individual risk of developing a CLABSI within these studies may not be consistent. This was also reflected on by Ista et al. (2016), who recognised that increased catheter use for shorter durations leads to an over-estimate of intervention efficacy. More recently, some studies are reporting outcomes as 'time to infection' and the use of time-to-event data may be more appropriate for future research investigating intervention effectiveness on CLABSI rates (Gilbert et al., 2019).

The limitations outlined in the original publication manuscript remain relevant for this updated review. Individual study authors were not contacted for the original raw data, and only published data was used for the meta-analysis. Whilst it should be trusted that the data published is accurate, it is potentially less reliable than collecting the individual data sets. Such work was outside the scope of this research study.

This updated search still did not find any papers reporting negative results, and the funnel plot in Figure 7 suggests that less precise negative studies are missing from the published literature. There was one conference abstract that found that CLABSI rates increased following the introduction of the Matching Michigan bundle into a tertiary UK NICU, with pre-intervention rates of 4.4 per 1000 CL days and post-intervention rates of 8.9 per 1000 CL days (Marlow et al., 2014). Whilst this study only had a six month pre-and-post epoch, a subsequent conference abstract demonstrated a return of catheter-related BSI rates to 3.42 per 1000 CL days once the bundle was fully implemented (Yee et al., 2016). Full implementation included aseptic non-touch technique (ANTT) education, central line packs and mandatory implementation of a checklist, with root cause analysis for CLABSIs.

Figure 7 Funnel Plot



3.3.2 What are the commonly bundled components?

Appendix 11 provides an overview of the individual bundled elements in each study; the updated search did not find any additional new components. Individual bundled elements varied between studies, though consistent features were a daily review of the need for the central line (71%), use of aseptic-non touch technique (ANTT) for fluid changes and 'scrub the hub' strategies (68%), a dedicated skin preparation protocol (68%) and use of maximal standard barrier precautions (65%). There continued to be discrepancies between studies in terms of the use of skin decontamination agents, such as 2% Chlorhexidine or Povidone Iodine, and in the management of central line dressings. Savage et al. (2018) moved to a policy of removing central lines completely if the line was exposed, rather than re-dressing the line.

Whilst this review did not attempt to analyse the effectiveness of specific bundled elements, this was performed by Ista et al. (2016). Although not a neonatal-specific review, the meta-regression analysis found that having a central line insertion kit and the selection of the insertion vein were the most clinically important components, which was enhanced by the addition of hand hygiene. Minimising central line access in the NICU specifically was the most clinically important item for maintenance bundles (Ista et al., 2016).

There was no consistent 'number' of elements that should be included in a bundle. The number of elements packaged together in each study ranged from four to 13 single elements. Haraden (2021) recommends central line bundles contain three to five elements; however, there is no evidence suggesting a bundle can become ineffective with increasing numbers of components. Whilst checklists are a component of many bundles, some checklists alone had up to 25 elements to complete.

Whilst several studies report bundles to be low-cost interventions, cost-effectiveness analyses have been limited. A conservative estimate of local costs (see Appendix 12) suggested that reducing local positive BSI rates by 50% could save the local NICU £150,000 to £250,000 per year. Fisher et al. (2013) estimated that the reduction in CLABSIs saved 17 lives and saved $1,9152,000 in hospital charges. This is based on a cost differential calculated at $16,800 for neonates with an infection, similar to the calculations performed in Appendix 12 that estimated £10,000 per CLABSI. Whilst these savings reported by Fisher et al. (2013) are phenomenal, it is unclear if calculating bundle costs takes into account the human resources required to ensure new practices are embedded and implemented as intended. This is important, given the findings by Clack et al. (2018); they found that having a 0.5 whole time equivalent nurse to support implementation significantly improved implementation in resource-limited settings.

3.3.3 What components promote effective implementation?

Appendix 11 summarises the main professional components utilised in the bundles in order to facilitate behaviour change. The most common elements were education and training (100%), audit and feedback (65%) and checklists (65%). Whilst only 6 studies referred specifically to having local champions (18%), Ista et al. (2016) found that opinion leaders were most strongly associated with CLABSI reductions, across all healthcare settings. Just as there was variation in the technical elements of the bundles, the same was true for the professional interventions, including frequency of multi-disciplinary team (MDT) meetings, for example. Implementation success was gauged by compliance audits, though these were variable and wide-ranging (<15% to 100%).

The way in which audits, often used as a process measure of implementation success, were carried out was varied. One study reported a random audit of 10% of central lines (Savage et al., 2018). Reported compliance rates with hand hygiene audits and bundled elements was wide. Balla et al. (2018) reported local hand hygiene rates of zero to 50%, much lower than the hospital audits for that NICU which were often greater than 85%, and lower than most rates reported in the literature. This study still demonstrated a significant reduction in CLABSI rates despite low compliance. The utility of audit in providing meaningful insight into the *work as done* has to be questioned, and the lack of meaningful or consistent association between high levels of audit compliance and reductions in CLABSI rates should also be taken into account. Whilst audit can function as a process measure, its utility as a marker of effective implementation is questionable. Measuring implementation, and what constitutes a marker of implementation ‘success’ has been discussed in Chapter 2, but simply measuring healthcare worker compliance may not provide insight into the *work as done*, which may involve significant work arounds by staff

or adaptation of what was intended. Clearly the effectiveness of audit will to some extent depend on how the audit is performed, by whom, as well as if it is covert or overt audits of practice or audits of documentation. The variations in bundle compliance rates make it difficult to ascertain if it is the bundle interventions themselves that result in CLABSI reductions, or something else.

The hospital-wide nature of many of the QI initiatives reviewed suggests an institutional investment is required to reduce CLABSIs. Many of these studies not only included weekly and monthly review meetings, but also performed focus groups with staff and regularly reviewed practices and CLABSI rates. These meetings were varied, but all were reported as MDT meetings, huddles or root cause analysis (RCA) meetings. There was an emphasis on frequent audit and feedback across most studies. One study published after the commencement of data collection for this research study discussed rehumanising CLABSIs through the use of individual patient stories to highlight the immediate impact these infections have such as requiring reintubation or repeated platelet transfusions. Making reported outcome measures more understandable for staff was also highlighted, instead of using a goal of 1.2 per 1000 central line days, they used a 'one or none' campaign (Hawes and Lee, 2018). Again, a more recent study found that the frequency of audit and data collection had to be abandoned due to not achieving the goal of designated quality improvement (QI) nurses (Balla et al., 2018). Whilst bundles may be considered to be cost-effective interventions given the impressive cost-savings associated with reducing CLABSIs (Wilder et al., 2016, Piazza et al., 2016), the actual cost of bundle implementation, including the human resources, has not been formally assessed.

Empowering nurses to stop the procedure if breaches in asepsis were observed appeared to be a consistently reported feature in many of the papers published after 2017, and it was considered the "cornerstone" of improvement (Hawes and Lee, 2018, Pharande et al., 2018, Savage et al., 2018, Hussain et al., 2020). It may be that the improvements seen in these studies are less about the items on the checklist *per se* and more about empowering staff to challenge poor practice. However, not all studies were able to maintain this degree of nurse involvement, and Balla et al. (2018) specifically referred to having to abandon having trained nurses voluntarily collect data, as they did not consider it an important part of their role. They did, however, continue to have senior nurses and doctors observe central line insertions, and stop procedures if any breaches were observed. None of the studies reviewed collected data on how often these procedures were stopped due to concerns regarding breaches in aseptic technique; this may have been a useful measure of implementation 'success'- that is, how many procedures were stopped and whether this declined over time as practice (potentially) improved and new practices became embedded.

Implementation also often occurred over time in these studies, with modifications to existing practices or the addition of new practices -often over the course of years (Savage et al., 2018, Erdei et al., 2015, Shepherd et al., 2015, Hawes and Lee, 2018, Pharande et al., 2018). It is not clear if 'roll-out programmes' or making small, frequent changes over time are likely to be more effective implementation strategies in the NICU. Hawes and Lee (2018) commented that nurses found keeping up with frequent changes to be challenging, resulting in inconsistent performance. Instead, this NICU made educational updates mandatory and required each staff member to demonstrate new practices. Some studies reported changes that have taken place over 10 to 15 years, suggesting that the use of bundles to reduce CLABSIs is not a 'quick fix' solution and requires continual investment to sustain reductions. NICU populations have also undoubtedly changed since some of these studies were undertaken in the early 2000s, with greater extremes of prematurity now surviving from as early as 22 weeks gestation (Backes et al., 2019, Kono et al., 2018).

Chapter 2 argued that context was an important yet often poorly considered factor in terms of implementation. Whilst the studies included in this review often described features of the setting in which implementation took place, such as numbers of beds and total numbers of staff employed, there was little commentary on the impact of context on implementation. Whilst describing the setting is important for establishing generalisability, detail was lacking on local patterns of practice, organisation of work, or cultural influences. One study referred to a culture change that occurred due to regular communication and feedback which was already well established (Pharande et al., 2018). Several studies referred to achieving CLABSI reductions as a result of continued education, reinforcement and feedback, though no studies reported the experiences of staff or were designed to evaluate implementation processes. Bannatyne et al. (2018) referred to positive reinforcement strategies and celebrating successes, though this was not explored further.

3.4 Summary

Following an updated search, the findings remain valid; whilst care bundles have the potential to reduce CLABSIs by up to 62%, it is unclear which combination of elements may be most effective or in which contexts. There is a risk of publication bias.

This review highlights that the implementation processes required to integrate a CLABSI care bundle into NICUs had not been studied, and whilst more recent studies have retrospectively theorised the mechanisms by which these bundles worked, this has not been prospectively studied. The results of this review helped to inform the design of this research study including the choice of data collection methods in order to understand how

the bundle is integrated and enacted by those doing the work. This review, in combination with the studies reviewed in Chapter 2 revealed the importance of understanding *the work as done* rather than solely measuring adherence, which is particularly relevant given the lack of consistent correlation between adherence and CLABSI rates in the studies reviewed. The emphasis on the importance of feedback highlighted in these studies, and the specific role of nurses as observers of central line insertions, were potentially important influences that were subsequently incorporated into the interview prompts in order to explore them further. The limited evidence for sustainability of these bundles, the work that needs to be done by those at the *sharp end* in order to achieve this, and the potential influence that local contextual factors may have, were all important issues to be considered in this study.

Recommendations were also made to the local NICU following this review regarding commonly bundled components and intervention strategies. As such this review informed local bundle development, though the design of the bundle and local implementation strategy was not within the remit of this research study which was instead to explore the process of implementation. The next chapter will discuss the methodology and study design used to underpin this research study

Chapter 4 Study Design

4.1 Introduction

So far, this thesis has highlighted that whilst CLABSI care bundles have been successful in a wider range of clinical settings including NICUs, it is not clear if it is the bundle, the implementation, or both, that has resulted in the effects seen. The seminal work by Dixon-Woods et al. (2013) in conjunction with more recent studies explored in Chapter 2 have highlighted the importance of understanding not only the mechanisms by which these bundles may change healthcare professional behaviour, but also the importance of understanding the context in which bundles are introduced. The issue of context is likely to be significant in the success (or failure) of bundle implementation; it can rarely be simply translated from one setting to another with the same degree of success (Dixon-Woods et al., 2011). As a complex adaptive system, studying how actors interact with each other to implement new practices in healthcare settings is important. This chapter will discuss the underpinning research methodology and provide justification for the study design used evaluate implementation in this research study. It will provide an overview of how the individual components of the study are integrated, though the individual data collection methods used will be explored in detail in Chapter 5. It will start with an overview of the rationale for this study, followed by the research questions to be addressed.

4.2 Study Rationale

Chapter 1 highlighted the importance of reducing neonatal CLABSIs in order to care for patients in a safe environment. It also proposed care bundles as a solution to this problem, recognising that there is now an abundance of quasi-experimental evidence to suggest these are efficacious and cost-effective across a variety of healthcare settings. However, it also highlighted that many of these bundled elements are not applicable to the neonatal population, and national evidence-based guidelines exclude neonates from their recommendations.

Chapter 2 subsequently explored why studying implementation is vital to ongoing quality improvement efforts. The literature review also highlighted the complexities of both the intervention, a care bundle, and the context in which they are implemented, meaning that evidence from single intervention studies or adult settings may not be generalisable to the NICU. It also highlighted the tendency for studies to focus on central line insertion alone, and that there is a lack of investigation into *how* the work of implementation is performed

by healthcare professionals. The importance of understanding *the work as done* is important, as individual attitudes and beliefs do not always translate into behaviour. What works in one setting, and perhaps more importantly *how* it works, cannot be directly translated to other settings, and there has been no prospective study of CLABSI bundle implementation in the NICU. As the EFCNI (2019) recommends that all NICUs have a care bundle to reduce CLABSIs, understanding how they may work is vital to ensuring effective and safe care.

Given the data presented in Chapter 1 highlighting the local NICU as an outlier for both late-onset sepsis, CoNS infections and CLABSI rates, a care bundle was introduced with the aim of improving central line care. Given what little is known about implementation in NICUs, the study in this thesis was designed to prospectively investigate the implementation processes of a CLABSI care bundle in a tertiary NICU, in order to understand more about what works (or not) and why, contributing to the field of implementation science.

4.3 Research Questions

A set of research questions were developed in order to prospectively explore the implementation of a care bundle aimed at reducing CLABSIs in a tertiary NICU. These were:

1. In the NICU, how do healthcare professionals implement a care bundle, aimed at reducing CLABSIs?
    a. How do healthcare professionals make sense of the nature and purpose of the care bundle?
    b. How do clinical teams integrate the care bundle into routine practice?
    c. To what extent does relational and normative restructuring occur?
    d. To what extent is the care bundle adapted by healthcare professionals, and how does the NICU adapt in order to accommodate the care bundle?

In order to address these questions, a sequential mixed-methods study was designed utilising both quantitative and qualitative data collection in order to investigate the phenomenon of implementation on a tertiary NICU.

4.4 Methodological Approach

4.4.1 Ontological and Epistemological Perspectives

Ontology is concerned with the nature of reality and considers how the world works, whereas epistemology is concerned with the study of knowledge. Interpretivism encompasses study designs such as ethnography, grounded theory and phenomenology and is centred upon the premise that all knowledge is socially constructed (constructivism), subjective and influenced by social interactions. Positivism, on the other hand, is concerned with objective truth, takes a deductive theory-testing approach and is objectivist-there is one true reality (Dyson and Brown, 2006, Robson and McCartan, 2016). A comparison of ontological and epistemological perspectives considered in this study is provided in Table 8.

Table 8 Comparison of Ontological and Epistemological Perspectives

Type of Inquiry	**Naturalistic Inquiry**	**Critical Realism**	**Pragmatism**
Ontology	Interpretivism	Interpretivism	Interpretivism and Positivism, Mixed-Methodology
Epistemology	Aims to understand the social world in a cultural context. Meaning does not exist in its own right, but is constructed by human beings	Knowledge is a social and historical product. An explanation of how events occurred in a particular case; events are explained even if unpredictable. Context-Mechanism-Outcome	Knowledge is both constructed and based on the reality of the world that is experienced by those in it.
Analysis	Inductive	Inductive	Abductive
Examples	Ethnography, grounded theory	Process evaluations	Pragmatic RCTs in clinical practice Observational research Case study

It is important to identify the way in which one views the world; however, it is arguably more important to understand which methodological approach is best suited to answer a particular research question. This section begins by discussing two methodological approaches that influenced this study; naturalistic inquiry and critical realism. Following which an exploration of a pragmatic approach will be discussed.

- *Naturalistic Inquiry*

Naturalistic research is an approach to research that aims to understand the social world through the observation, description and interpretation of experiences and actions of specific people and groups, in a cultural context (Guba and Lincoln, 1982). It involves an inductive process whereby the researcher has to make sense of findings after they have been observed, as opposed to deductive models where hypotheses are determined *a priori* and subsequently tested (Gillham, 2000). Unlike traditional experimental scientific approaches, it is less concerned with generalisability to whole populations, but instead focuses upon human behaviour within a specific context; indeed, generalising a group behaviour from one institution, to another, is not appropriate.

Subjectivity is an important part of naturalistic research that is often opposed to that of traditional quantitative research, requiring the naturalistic researcher to be a participant observer. This approach recognises and accepts the influence of the researcher within the field of study but acknowledging it rather than ignoring it. Indeed, all research, including traditional experimental studies such as randomised controlled trials, will be influenced in some way by the presence of a researcher, and even unconscious bias can influence how studies are designed and implemented. It is vital, therefore, that all researchers can reflect upon subjectivity; this will be expanded upon further in Chapter 5.

- *Critical Realism*

Realism asserts that there are underlying causes, structures and processes that create the observations we make of the world, arguing that hypothesising about these can generate explanations for what is observed. It is also concerned with the complexities of the real world, and that within reality there are individual, group, institutional and societal levels (Robson and McCartan, 2016). Furthermore, critical realism argues that there is a reality independent of what is observed; that to understand the social world it is necessary to understand the structures that generate unobservable events. In this way, reality is viewed as a system with causal powers (Morton, 2006). Causal mechanisms theory utilises an approach to data collection that encompasses case study methods in order to collect enough knowledge to form hypotheses regarding the causal links or mechanisms that occur, as opposed to the idealist philosophy, which seeks to describe realities. Mechanisms-the way in which programmes or interventions bring about effects- are a

component of realist thinking. The concept of critical realism moves away from the perspective that a programme either works or does not; it instead views programmes as offering resources that enable participants to make them work (Pawson et al., 2004). This perspective does offer an alternative way to perceive quality improvement work in healthcare and aligns itself with many of the arguments made in Chapter 2 regarding the importance of understanding the way in which these quality improvement programmes work (or not) (Sturgiss and Clark, 2019).

Within social science, critical realism also recognises that culture and society are continuously evolving as they are shaped by the actions of those within them; in turn, culture affects how those within it act. In this way, the rules that govern cultures and societies are not static and are context dependent; they exist within a specific place and time. Mechanisms are often hidden, sensitive to context and produce the outcomes observed (De Souza, 2013). NPT recognises the important interplay between the context and the implementation of an intervention; as such, it fits well within a critical realist approach. With realism acknowledging that interventions are introduced within social systems and that context influences the outcome of an intervention, realist evaluation requires an interpretative approach. Given the limited understanding of the mechanisms by which care bundles may be effective, and in which contexts, this ontological approach to understanding reality appears well suited to the research questions.

- *Pragmatism*

Pragmatism could be argued as being the middle-ground between the two traditional paradigms of positivism and constructionism. It considers that knowledge is both constructed *and* based on the reality of the world that is experienced by those within it. If there is a one single reality, it still has to be experienced by those within in, and therefore both reality and knowledge are shaped by beliefs and habits that are socially constructed. Rather than subscribing strictly to one of two distinct philosophical approaches to research-that is, quantitative or qualitative paradigms- it is arguably more important that researchers are able to use the methods or philosophical principles that are best suited to answer the research questions. It has been suggested that an abductive approach is often used within pragmatic research; rather than being solely deductive or inductive, researchers move between the two (Kaushik et al., 2019). With this in mind, a pragmatic approach, rather than strict adherence to a single philosophy, may be more appropriate, particularly in healthcare settings. For healthcare researchers studying complex systems, pragmatism is an appealing standpoint given that each clinical ward has its own unique culture (its own sets of rules, values and beliefs).

Healthcare research commonly takes place “in the field” (Robson and McCartan, 2016, p. p.31) rather than in controlled environments or under strict experimental conditions; as such it cannot be separated from its context. As outlined in Chapter 2, healthcare systems are now increasingly seen as complex adaptive systems, unpredictable and non-linear in their behaviours, and therefore research should be able to take this into account. More recently, Greenhalgh and Papoutsi (2018) argued the need for a complexity-informed paradigm in healthcare research. Long et al. (2018) identified similarities between complexity theory and pragmatism, arguing it to be a suitable epistemology for studying healthcare. Similarities included:

- Aiming to create ‘useful’ knowledge.
- Favouring the study of whole systems in context.
- Understanding research as a continual learning process.
- Prioritising understanding over theoretical or methodological purity and encouraging the use of multiple methods.

Having explored alternative epistemological and ontological perspectives, pragmatism suits both the philosophical perspective of the research but also provides the most appropriate approach to address the research questions.

4.4.2 Mixed-Methodology

Mixed-methodology is becoming more frequently used in healthcare research and is often used to address complex issues in complex environments, though the justification for this approach is often poorly reported (Östlund et al., 2011, O'Cathain et al., 2007). The integration of both quantitative and qualitative paradigms, the central tenant underpinning mixed-methodology, aligns itself with a pragmatic approach (Creswell and Clark, 2011). Whilst qualitative research has gained increasing attention within healthcare, particularly in the evaluation of complex interventions, it has not always been viewed as scientific or rigorous (Greenhalgh et al., 2016). However, it has become increasingly popular in order to determine not only the acceptability of an intervention but also its social consequences (Datta and Petticrew, 2013). Quantitative data collection, such as is often undertaken as part of local QI programmes, can contribute important knowledge regarding outcome evaluation, such as CLABSI rates, or process measures, such as audit. However, quantitative data alone cannot provide an in-depth understanding of the causes for CLABSI rates or provide explanations for adherence rates, nor can it explain by what mechanisms interventions change practice. Whilst there is an abundance of QI and quasi-experimental studies that examine the impact of complex interventions on CLABSI rates, and other important neonatal health outcomes such as Ventilator Associated Pneumonias

(VAPs) or Necrotising Enterocolitis (NEC), this is only one part of the puzzle. It fails to provide an understanding of how these mechanisms bring about change, which is particularly important given that bundle adherence can be low yet still result in improved patient outcomes (Gokce et al., 2018, Edwards et al., Zachariah et al., 2014).

With this in mind, well-designed and rigorous mixed-methods research should arguably be able to provide added insight into the problem being studied, with the two traditional paradigms being used synergistically. This is emphasised in the simple, yet effective equation below:

1+ 1 = 3 (Cresswell, 2016)

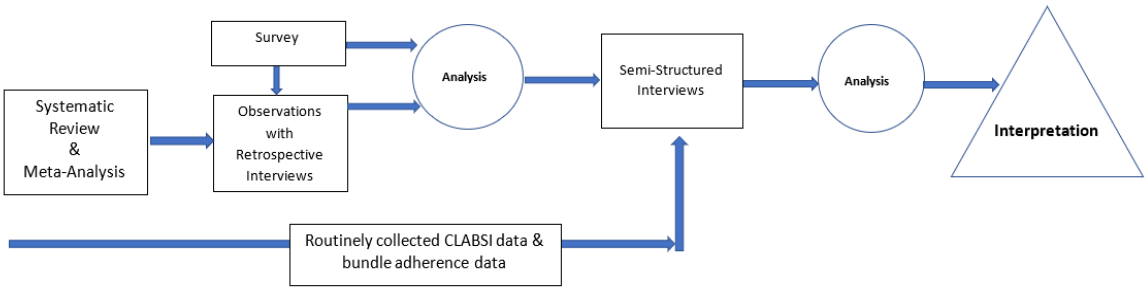
This equation suggests that the two paradigms are not separate, but that through integration they equate to more than the sum of their parts; they bring more value to understanding the phenomenon being investigated than if they were used alone. Creswell (2014) identify several key epistemological assumptions to this paradigm, which are:

- Multiple ways of viewing the world.
- Separate and distinct ways of gathering the quantitative and qualitative data.
- The equality of both paradigms.
- A practical approach to research

This aligns well with a pragmatic approach. It is important to recognise that mixed-methods research does not mean simply using a mixture of different data collection methods. Instead, a mixed-methods study must integrate both paradigms of quantitative and qualitative data, acknowledging the differences in ontological perspectives. In this way, there needs to be an integration of the data sets rather than simply running two separate studies alongside each other.

Whilst convergent designs in mixed methods allow for comparing, contrasting and validating quantitative and qualitative data sets, explanatory designs allow for results to be explained. A sequential design facilitates an iterative data collection process whereby data collected in one stage informs data collection in another. In this study, data from each method was used to inform the next, with semi-structured interviews (SSIs) used to illuminate findings from previous data collection methods. Figure 8 provides a diagrammatic representation of this study.

Figure 8 Sequential, Explanatory, Mixed-Methods Study Design



Data integration occurred in the following ways:

- Systematic review results were used to inform the prospective, mixed-methods study design including data collection methods. The results aided the development of qualitative interview prompts.
- Survey and observations with retrospective interview (ORI) results informed the development of the SSI schedule.
- The SSIs were used to explore the survey and ORI data.
- CLABSI data was prospectively collected for the duration of the study. CLABSI rates were explored in the SSIs and used to provide context for the effectiveness of implementation in the final interpretative phase.
- Bundle adherence (audit data) was planned to be collected prospectively at specific epochs via the clinical team as a process measure as part of implementation.

Designing the study this way allowed for a more in-depth exploration of the *work as done* compared to the *work as imagined* (Hollnagel et al., 2015). Whilst all of the above integrative components are important, the use of SSIs and bundle adherence data were important for understanding if the practices observed were reflective of real life on the NICU, and the use of multiple data collection methods allowed for potential disparities between the ideal and the actual to be explored. Any single data collection method alone may have only provided insight into one of these aspects.

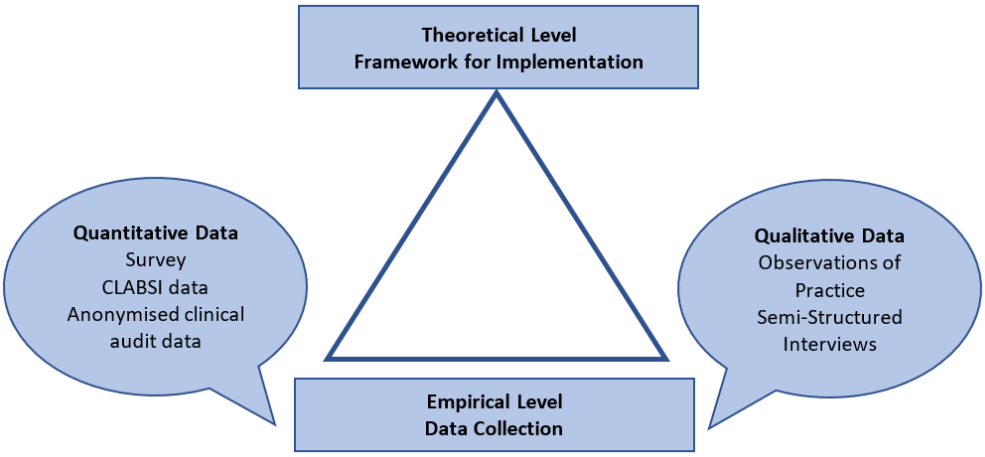
The ability of mixed-methods studies to provide triangulation between data sets is an important feature of this paradigm. There are a variety of different ways in which triangulation can be achieved in mixed-methods research, and these are applied to the study in this thesis in Table 9.

Table 9 Types of Triangulation

Method of Triangulation	**Description**	**Applied in this study**
Methodological Triangulation	Combining quantitative and qualitative approaches	Yes
Data Source Triangulation	Using more than one method of data collection	Yes Anonymised routinely collected clinical data Survey data Observations of practice Semi-structured interviews
Investigator Triangulation	Involves the use of multiple observers.	Yes Whilst a single observer collected the data, data analysis including final themes were reviewed by experienced qualitative and quantitative researchers
Theory Triangulation	Using multiples theories or perspectives	Yes Whilst NPT provided the theoretical underpinning for this study, concepts relating to social psychology were also drawn upon during the interpretation of the results. The use of inductive analysis mitigates the risk of forcing data to fit predetermined theoretical categories
Adapted from Robson and McCartan (2016) and Dyson and Brown (2006)		

Mixed-methods research can provide triangulation between complementary, divergent or convergent results (Östlund et al., 2011). Being able to provide triangulation is considered to be one of the most important ways in which researchers can establish trustworthiness and credibility in ethnographic studies (Rashid et al., 2015). The sequential design enabled data source triangulation to be achieved. Figure 9 represents the concept of triangulation in mixed methods research applied to the research study in this thesis.

Figure 9 Data Triangulation



Adapted from Östlund et al. (2011)

With this in mind, being able to triangulate the results of one data collection method with another, and thus compare and contrast results in order to provide an interpretation of what is happening at a local level, is important to this study design.

4.5 Methodological Approach

This research study was underpinned by a pragmatic methodological approach, and it is important that the research methods undertaken align with both the study methodology and design. Outcome evaluation alone is not always sufficient to address issues of complexity in clinical practice, particularly in situations where there is a need to understand the processes and mechanisms by which things work. Disassembling the practices and processes that occur when new practices are introduced within a system is an important part of understanding implementation (May et al., 2016). Process evaluation, as opposed to outcomes evaluation, can be considered valuable for understanding the mechanisms through which change has (or has not) occurred, being considered the 'black box' of a complex intervention (Minary et al., 2019). Process evaluations can be undertaken using a range of different study designs and data collection methods. The chosen research methods were felt to be the most appropriate to address the research questions; as such they integrate methods from a variety of research disciplines. What follows is a brief overview of ethnographic methods, including focused ethnography, and studies that have utilised this methodology to study both healthcare improvement and infection prevention. It will highlight how it has been utilised in this study in order to generate the data required to address the research questions. Alternative research methodologies that were considered will also be briefly discussed.

4.5.1 Ethnographic Research Methods

Ethnography can be described as the study of the every-day lives of communities of people; in fact, it stems from the Greek word *ethnikos,* which means nation (Knobloch et al., 2017). One of the benefits of ethnographical research within healthcare is that it allows the researcher to go beyond technical issues and consider the context that may be influencing the uptake of evidence-based strategies (Knobloch et al., 2017). However, ethnography can present many challenges for researchers, including the necessary immersion of the researcher within a specific community to establish the trust and rapport required to collect rich data. With this comes the need to understand the responsibilities of the researcher- that is, to interpret the wealth of data gathered and accurately present a mirror image of the cultural context, relationships, and events being observed whilst avoiding distortion by the researchers own interpretation (Leslie et al., 2014). Reflexivity on the benefits and challenges of being a dual clinician- researcher within one's own clinical community will be explored in more detail in Chapter 5 and Chapter 10.

Utilising an ethnographic approach allows for the cross-checking of meaning between data sets, which is important for trying to determine relationships between data (Dyson and Brown, 2006). However, therein lies one of the challenges for the novice researcher; being able to navigate the volume of data available and understanding what data is important. In this respect, the ethnographic researcher can be described as requiring:

> a curious kind of cross-eyed vision, one eye roving ceaselessly around the general context, any part of which may suddenly reveal itself to be relevant, the other eye focusing tightly, even obsessively, on the research topic.
>
> **Hirsch and Gellner (2001, p. 6)**

This was indeed a challenge faced within this study which will be discussed in detail in Chapter 10. With CLABSIs increasingly being framed as a social problem that has a social, or behavioural, solution (Dixon-Woods et al., 2011), ethnography provides a way of understanding and exploring the every-day practices of groups of healthcare workers. As discussed in Chapter 2, many QI innovations often fail to replicate results in different contexts, or have challenges in sustaining improvements over time (Leslie et al., 2014). There is a recognised need to understand the influence context has as well as the extent to which professional, organisational and cultural factors influence evidence translation, the nuances of which are often unaddressed through quantitative data collection alone (Leslie et al., 2014). Ethnography has been used to study information and communication technologies in healthcare (Greenhalgh and Swinglehurst, 2011) and healthcare environments (Higginbottom et al., 2013); it has also been argued to be a useful design

for studying the context of QI programmes (Leslie et al., 2014). In regard to specifically studying patient safety, Dixon-Woods (2003, pp. 326-327) argues that ethnography can:

> Capture the winks, sighs, head shaking, and gossip that may be exceptionally powerful in explaining why mistakes happen, but which more formal methods will miss.

Indeed, ethnography has been frequently used to study healthcare professional infection prevention behaviours and has been argued to lend itself to the understanding of the four major components of complexity: unpredictability, self-organisation, inter-dependencies and sense-making. It can do this alongside exploring how new practices are implemented (Knobloch et al., 2017). The seminal ethnographic study on the implementation of care bundles across 19 intensive care units in the UK (Dixon-Woods et al., 2013), discussed in Chapter 2, provided insight into implementation failure, using observation and interview methods.

A systematic review of 12 ethnographic infection prevention studies found that ethnographic designs were able to provide an understanding of contextual factors (Knobloch et al., 2017). Whilst all studies included in this review undertook observations and interviews, some also used video reflexive ethnography (filming episodes of patient care to facilitate reflexive discussions about improvement) and document analysis (deriving themes from documents such as guidelines, emails or incident reports). Some of these studies were hospital-wide, some in ICUs and EDs, with two studies focusing on patients rather than healthcare professionals. All bar one of the studies were performed in the US, and none focused explicitly on NICUs. Studies found that staff required visual cues and that there was a difference between the ideal and the practical implementation. It was suggested that the focus should not be purely on compliance with guidelines but should instead focus upon situational complexities, which in turn allow staff to evaluate and rethink their actions. This has important implications for the choice of data collection methods outlined in Chapter 5.

Some well-documented challenges of ethnographic research include the amount of time it can take for an ‘outsider’ researcher to be accepted by the clinical teams, especially in settings with frequently changing staff. The time-consuming nature of ethnographic work can also make it expensive, and observing only snap-shots may result in less generalisable results (Dixon-Woods, 2003, Robson and McCartan, 2016).

In addition, undertaking ethnographic studies can be hard for the researcher due to a desire to represent the voices of those being studied, and this can be more challenging when attempting to explain professional practices. Whilst gaining access to and the trust of those being studied can be hard for the ‘outsider’ researcher, there are arguably greater

concerns for the researcher who 'goes native'. Participants may feel betrayed by one of their own when study findings are reported, or participants may feel judged and become defensive (Hiller and Vears, 2016). Participants may have a strong desire to show the best version of themselves, and so the influence of the researcher on behaviour must be taken into account. Detailed field notes and reflective diaries can help ensure transparency in ethnographic studies. Knowing when to intervene can also raise ethical dilemmas for researchers, which can be uncomfortable (Dixon-Woods, 2003). This may be heightened in studies that take place in the researchers own clinical workplace, as in this research study. However, the benefits of data richness as well as the ability to triangulate between sources and delve deep into the often-hidden complexities of clinical practice outweighs the challenges that researchers can face. Reflexivity as a researcher is imperative to ensure rigour, trustworthiness and credibility within ethnographic studies. The challenges in performing ethnographic research and attempts to overcome these will be explored in more detail in Chapter 5.

4.5.2 Focused-Ethnography

A focused ethnography aims to study one specific problem or topic and therefore is a pragmatic approach, allowing data to be collected in a shorter span of time. It still involves immersion into the setting in order to study the participants behaviour; it therefore still requires the construction of multiple diverse realities-those of the researcher and the participants-in keeping with a critical realist approach. A focused ethnography was felt to align with this research study due to the focus on *action* and the work done to try and normalise new practices into everyday routines within complex social systems, as well as aligning with a pragmatic approach. Table 10 applies the features of conventional and focused ethnography to this research study.

It has been argued that focused, or 'rapid-type' ethnographies may be of particular importance in contexts such as healthcare, where interventions take place in time-limited, busy and sensitive settings (Vougioukalou et al., 2019). Vougioukalou et al. (2019) reported the use of a mixed-methods ethnographic study to evaluate a quality improvement project on care pathways in intensive care settings, using observations, questionnaires, and participant reflective diaries. Other studies utilising this focused approach have included studying the culture of specific healthcare teams, such as nurses within a cardiac assessment team or community nurses (Higginbottom et al., 2013).

Table 10 Features of Conventional and Focused Ethnography.

Conventional	**Focused**	**Application to this study**
Long-term field visits	Short-term field visits	Short term Observation of specific events in specific time periods
Experientially intensive	Data/analysis intensity	Data/analysis intensity
Time extensity	Time intensity	Time and data intensity. Large amounts of data in a short time period Observations of practice with retrospective interviews
Writing	Recording	Audio recordings of dual-paired interviews and semi-structured interviews
Solitary data collection and analysis	Data session groups	Data is open to other perspectives. Data reviewed by others Member checking of transcripts and data analysis
Open	Focused	Focused specifically upon central line practices within the NICU
Participant role	Field-observer role	Field-observer role
Insider knowledge	Background knowledge	Insider knowledge of NICU
Notes	Notes and transcripts	Notes and transcripts
Coding	Coding and sequential analysis	Coding and thematic analysis
Adapted from Knoblauch (2005)		

However, there are, of course, opponents to this ‘rapid’ approach to ethnography; some argue that it undermines the ontological principles of the discipline which considers prolonged participant observation as the foundation for good ethnography. This issue was debated in a recent series of editorial letters regarding rapid ethnography in healthcare

(Waring and Jones, 2016, Dixon-Woods and Shojania, 2016, Jowsey, 2016, Sales and Iwashyna, 2016). The benefit of being a clinician-researcher within the context being studied is that there was already an immersion 'in the field'. It is this immersion, alongside engaging with less powerful voices, that is believed by Cupit et al. (2018) to be important in ethnographic studies. Whilst this requires a high degree of reflexivity, already being immersed in the field mitigates one of the criticisms of this rapid ethnographic approach. In a systematic review of 26 rapid ethnography studies in healthcare, Vindrola-Padros and Vindrola-Padros (2018) concluded that whilst focused ethnographies had potential to inform changes in practice, poor method reporting and a lack of reflexivity were significant limitations. The role of clinician-researcher will be reflected upon in depth in Chapter 10.

4.5.3 Case Study Research

As a focused- ethnography is concerned with the study of specific events and specific periods of time, it includes some features of case-study research. A discussion of the underlying principles of case-study research, and how they apply to this research study, is therefore warranted. Gillham (2000) attempts to define what constitutes a 'case', proposing the following:

- A unit of human activity embedded in the real world
- Which can only be understood or studied in context
- Which exists in the here and now
- That merges in with its context so that precise boundaries are difficult to draw

A case can be an individual, but it can also be as large as an institution or even a community, profession or industry. A study that uses the above principles to study a particular phenomenon, with different types of evidence, could be considered to be a case study. Clearly these principles apply to the phenomenon under investigation in this research study, which is studying a human activity in a specific context. Case studies frequently utilise a range of different sources of evidence to attempt to address research questions, and do not start out with *a priori* theories; these can only become known through the process of understanding the context that is being studied. In this study, whilst NPT was used as a lens though which to interpret the results, analysis was inductive and *a priori* theoretical frameworks were not used. This also allowed for any aspects of implementation not addressed by NPT to be identified.

Case study research can include both qualitative and quantitative data collection, as all evidence is of value (Gillham, 2000). The use of different data collection methods is useful for triangulation, which can help determine agreement (or divergence) between

different data sets. This is important when considering studies of human behaviour, as a common and well-known discrepancy is between people's beliefs and their actions; what people know does not always account for what they do (Gillham, 2000). Examining and explaining 'cases' in depth can help to explore these discrepancies further. Indeed, case study methodology has recently been argued to be valuable for studying complex interventions (Paparini et al., 2020).

Crowe et al. (2011) have used case study research to investigate a variety of phenomenon, including evaluating the implementation of electronic patient record systems in healthcare. Whilst they defined NHS Trusts as their case, they recognised that a collective of cases could also be specific groups of doctors or nurses. However, they also recognised that defining the end of the 'case'- defining when implementation ends (if it does at all) to denote the end of the case-may be troublesome.

However, some studies have evaluated implementation using case study methods. The PROHIBIT study (Sax et al., 2013, Clack et al., 2018) is one of the largest case-comparative studies evaluating the implementation of bundles to reduce CLABSIs, taking place in 14 European adult ICUs. Whilst it was published after the data collection for the research study in this thesis had already commenced, it used ethnographic methods of observations and interviews to evaluate the implementation of multiple strategies to reduce CLABSIs. They recognised that without the detailed information on the context of implementation gained through this study design, the interpretation and generalisation of results would have been limited.

Williams et al. (2013) undertook a mixed-methods case study in a single UK hospital to explore the role of intermediaries in infection control practice. It utilised un-structured observations and interviewed nine participants. It found that the presence of intermediaries, also known as champions, opinion leaders or change agents, modified the behaviour of others though increasing surveillance and monitoring. This study was a realist evaluation using a case study design to explore the context, mechanisms and outcomes that resulted in change.

Whilst the research study in this thesis has not used a pure case-study approach, there are many overlaps with this and a focused-ethnographical approach, and a comparison of the two are applied to this study in Table 11. The use of multiple data collection methods and the study of a specific phenomenon (CLABSI care bundle implementation) are in keeping with a case study approach. However, the central difference here is the focus upon culture, which is what distinguishes ethnographic research from other approaches. The study of context alone does not necessarily equate to the rich understanding of culture; and as such, the study in this thesis cannot be said to have used a pure case

study approach. Given the argument made in Chapter 2 for the necessity of understanding context and culture when studying implementation, it is important that this study utilised an ethnographic approach. In order to not discount the features of case study research, this study has taken a focused-case ethnography approach.

Table 11 Comparing Focused Ethnography and Case Study Methods

Focused ethnography	**Case study**	**Application in this study**
Focuses on a specific problem or topic	Focuses on a phenomenon in context Merges with context so that precise boundaries are difficult to draw	Focused specifically on the implementation of a central line care bundle
Focuses on interpreting the processes and products of cultural behaviour	A unit of human activity in a particular context: this may be an individual, a profession, community or institution	Focuses upon a specific single neonatal unit (case) Interested in understanding the influence of context, and culture, on implementation
Focuses on beliefs, kinship patterns and ways of living	Links between events over time	Focused on beliefs, patterns and ways of working Interested in links between culture and implementation, implementation and CLABSI rates (process measures and outcome measures)
Immersion and engagement in fieldwork or participant observation	Multiple methods of data collection	Multiple methods of data collection including observation Immersion in field as part of clinical role
Adapted from Robson and McCartan (2016), Gillham (2000), Thorne (2000)		

Alternative study designs that were considered and discounted will now be briefly explored.

4.5.4 Alternative Study Designs

Several alternative designs were considered in the development of this project. A brief outline follows, with the rationale for why they were discounted.

- *Action Research*

Whilst this approach has a variety of different names-including participatory action research, co-operative enquiry or action learning-broadly it aims to bring about specific change in specific contexts, particularly healthcare environments (Koshy et al., 2011). Whilst a strength of action research may be its ability to empower healthcare professionals through engagement in research, it does require that skills in research methods will need to be developed during the process. A collaborative approach is often taken, with action research being able to generate solutions to practice problems in practice (Koshy et al., 2011). Whilst this is appealing given that this project is firmly situated in clinical practice, the methods within this design are similar to those used in QI work, such as PDSA cycles or research spirals involving periods of reflection, planning, action and observing. As such, it does not evaluate in depth the mechanisms through which change may (or may not) occur, nor can it explore in depth the context in which change is being introduced.

- *Phenomenology*

This approach is focused on the lived experience of those being interviewed in order to gain knowledge by learning through the experiences of others. The key goal of this approach is to describe the meaning of the experience- that is, what was experienced and why (Neubauer et al., 2019). Whilst this can be important in healthcare research- for example, understanding the experiences of fathers on the NICU (Logan and Dormire, 2018)- it does not provide insight into the behaviour or action of participants (what they do), and therefore cannot fully address the research questions central to this project. In order to understand how and why processes are enacted in a particular way, in a particular context, studying the behaviour of individuals is clearly important in combination with understanding their experience of the process. Understanding the experiences of healthcare professionals putting central line practices into action is an important part of the puzzle, but it cannot wholly address how these practices are enacted, and if this is action is consistent with participants attitudes, beliefs and values.

- *Grounded Theory*

Whilst some aspects of sampling and data analysis have been borrowed from a grounded theory approach, such as thematic analysis and the use of data saturation to guide

sampling, this theory focuses solely upon the meanings of the participants and requires the researcher to have no pre-existing theory, hypothesis or expectations of findings (Robson and McCartan, 2016). Whilst an inductive approach to data analysis was used in this project, as opposed to applying the findings to a pre-determined framework or theory, prior knowledge relating to the practices, processes and culture on the NICU being studied could not be unknown and was instead considered a strength of this project. Having the clinician-researcher firmly situated within the 'tribe' being studied was important in order to determine if participants were presenting their experiences in a favourable light or if they were providing realistic accounts of unit practice. That is, the researcher would know, within the confines of this project, if participants were providing an alternative account of central line practices on the NICU. Whilst the clinician-researcher must be able to be reflexive and consider their position within the research they are undertaking, which will be explored later in Chapter 10, having prior knowledge of the key tasks, concepts and context within which the research was taking place was invaluable in understanding healthcare professional behaviour.

4.6 Underpinning Implementation Theory

Whilst a variety of implementation models, theories and frameworks are available to researchers, as explored in Chapter 2, NPT was considered to be the most appropriate theory to underpin this study due to its focus on action and the work that people do to embed new practices. NPT can be used to evaluate implementation processes because it is focused on the *actions* of individuals and groups and the *work that people do* in order to embed new practices, as opposed to other theories or determinant frameworks (May, 2013a). Nudge theory, for example, was felt to be less appropriate for this study which was focused on exploring the extent to which implementation was successful. That being said, nudge theory likely has a lot to offer those studying the design of implementation interventions in healthcare, which was not the focus of this research study (Lamprell et al., 2020).

NPT has been discussed in detail in Chapter 2, but a brief summary of its application to this research is worth noting here. Whilst inductive analysis is a key component of ethnographic approaches, having a theoretical underpinning to explain the mechanisms influencing bundle adoption will enable comprehensive strategies to be developed for future implementation work. By utilising theory in this way, and of course acknowledging the interplay of context in implementation, a conceptual model can be developed to promote generalisable knowledge to other contexts. The MRC (Craig et al., 2008) emphasises that the design of complex interventions, such as bundles, should be based on a theoretical understanding of how they result in change, and yet a recent review

suggests that whilst the use of theories may be frequently cited, they are less frequently applied or tested (McIntyre et al., 2020). There is a need to balance pragmatism with research rigour, in order to improve the study of improvement (Portela et al., 2015). Not understanding *why* care bundles work or which components work in specific settings, means that healthcare providers are left to implement a variety of elements using 'trial and error', which may be resource intensive without any improvement in patient outcomes. By using NPT to interpret the results of this project, broader, more generalisable strategies to promote the sustained adoption of new practices can be recommended. This should help provide results that are more broadly translatable to the implementation of a variety of complex interventions in healthcare, rather than focusing solely on bundles to reduce CLABSIs.

NPT was used to inform and underpin multiple aspects of this research study, including the development of the research questions and data collection methods as well as to provide a conceptual model of implementation at an interpretive level. For clarity, it has not been used to provide a framework for data analysis; it has instead been used as a lens through which to interpret the results after inductive data analysis has taken place. This was in order to mitigate the risk of forcing the data into pre-determined categories or constructs, which would not fit with an inductive approach. The inductive nature of data analysis is outlined in more detail in Chapter 5. Whilst an in-depth discussion of researcher influence will be discussed in Chapter 5, it should be noted that all researchers bring their own ideas, beliefs and unconscious biases within the research process, even in the most rigorously designed randomised control trials. What is important is that these are acknowledged, reflected on and mitigated where possible.

4.7 Summary

As within many areas of healthcare research, a degree of pragmatism is often required in order to balance what would be considered methodologically true to the foundations of specific disciplines, and a pragmatic approach of what can be feasibly achieved. The viewpoint taken within this research is one that aligns research methods with the research question being asked; study designs must ultimately be able to answer the research questions, using the most appropriate data collection methods within given time, setting and resource constraints.

Given the nature of the research study described in this thesis, it requires a design that is able to take account of possible discrepancies between attitudes and behaviours, within a setting that is, itself, complex. A focused-case-ethnography was therefore considered to be appropriate for studying the nuances and complexities of human behaviour, as well as

taking account of the cultural context in which the study took place. The use of NPT, a theoretical framework that aligns well with the ethnographic methods of observing people *in action*, was considered to be an appropriate theory to underpin this research study. This chapter has identified research utilising similar designs to investigate implementation. This provides a sound theoretical rationale for the focused-case ethnography design chosen to evaluate care bundles in the NICU. It also provides precedent for the use of a variety of different data collection methods to answer questions relating to implementation. The following chapter will discuss the methods used in this study in greater detail.

Chapter 5 Methods

5.1 Introduction

Whilst complex interventions such as care bundles have the potential to reduce CLABSIs these are not always successfully or consistently implemented (Sax et al., 2013, Moore et al., 2015, Dixon-Woods et al., 2013). Whilst several studies reviewed in Chapter 2 have evaluated the implementation of these bundles, Chapter 3 showed that the process of implementation has not been prospectively studied in the NICU.

This study has used a focused-case ethnography design to evaluate the processes involved in the implementation of a care bundle to reduce CLABSIs in the NICU. This chapter will present the data collection methods used in this study; it will start with an overview of the setting for data collection, including the locally developed plan for implementation.

5.2 The Study Setting

The setting was a tertiary level NICU in the UK that employs over 160 healthcare professionals. The NICU is also the centre for the network neonatal transport service and is the regional centre for specialist neonatal and paediatric services including surgery, cardiology and neurology. This means there is often high patient turnover, with some patients staying on the NICU for short durations, whilst others such as ELBW infants remaining inpatients for over 100 days. The NICU is divided into smaller nurseries based on care level, so, for example, Nursery 3 (6 cots) and Nursery 4 (8 cots), are intensive care, whilst Nursery 2 (6 cots), is a high dependency nursery and Nursery 1 is the special care nursery.

The NICU comprises multiple nursing and medical teams, including specialist surgical, nutrition, neurology, and research teams; they work across a variety of shift patterns including 8-hour and 12-hour day shifts and night shifts. It is led by a team of 12 (10 WTEs) consultant neonatologists and in any given week, there are three consultant neonatologists responsible for overseeing intensive care, high dependency, special care and postnatal ward services as well as the network transport service, along with an additional on-call consultant each evening. The unit is also led by a matron and 15 Band 7 sisters. In addition, there is a team of five Band 8 advanced neonatal nurse practitioners (ANNPs). These are nurses who have undertaken additional training and work primarily on the medical rota at the level of both senior house officers (SHOs) and speciality registrars (SpRs), alongside junior doctors. There are approximately 20 junior

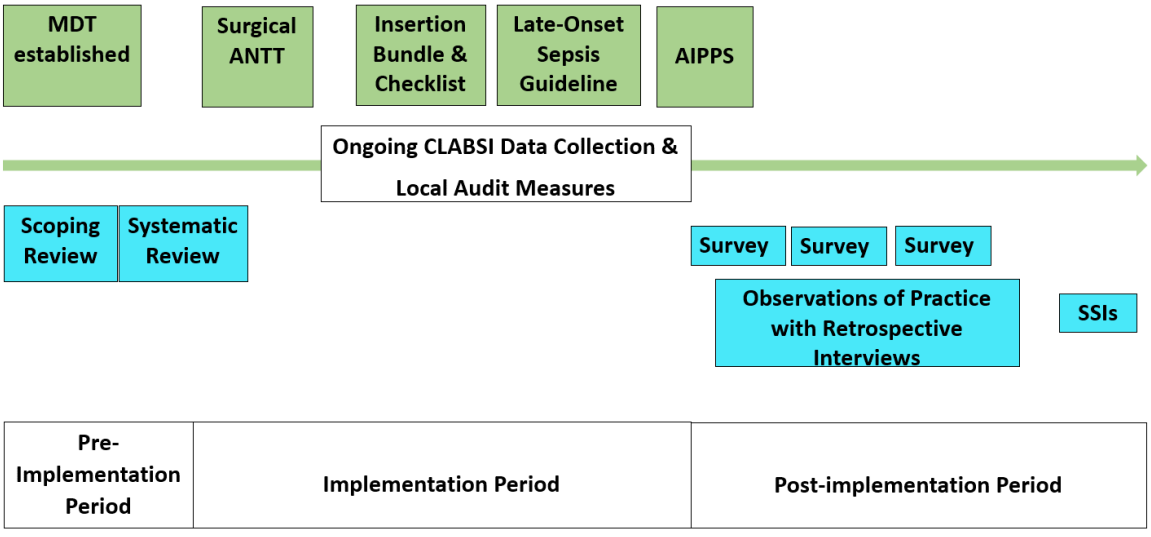
doctors that rotate between different NHS Trusts and clinical areas within the region every six months as part of their paediatric training. There are also doctors who are employed as part of the Medical Training Initiative (MTI) who are employed on the unit for two years or more but are not part of the UK paediatric trainee programme.

It is worth noting that as a clinical academic the researcher works as an ANNP on the NICU being studied in this research study. Reflexivity on the researcher position within the setting being investigated will be explored in more detail in section 5.9 and in Chapter 10.

5.3 Local Bundle Implementation

Local development of the bundled interventions began in 2015 with the formation of a multi-disciplinary team and continued until the final intervention was introduced in March 2018. Recommendations for local bundle development, including the insertion checklist, were able to be made following the systematic review in Chapter 3. The timeline for local implementation of the bundled interventions is provided in Figure 10; it is mapped alongside the data collection that took place as part of this research study.

Figure 10 Data Collection Timeline Mapped Against Local Implementation Processes



Legend: = Local implementation = Research study data collection

MDT= Multi-disciplinary team, ANNT= Aseptic non-touch technique, AIPPs= Alcohol-impregnated port protectors, CLABSI= central line-associated bloodstream infections, SSIs= Semi-structured interviews

Prior to the implementation of the bundle, nurses were required to use standard ANTT for the changing of central line fluids and infusions, in line with local Trust practices. Central lines were generally inserted by a single person, either a medic or ANNP. A timeline for

local implementation on the NICU is outlined in Table 12. It should be noted that one cohort of junior doctors during the study period did not receive their formalised central line insertion simulation training, due to time constraints.

Table 12 Implementation Timeline

- 2015: Formation of a multi-disciplinary team (MDT) to tackle local CLABSI rates and produce consensus guidelines. This consisted of three Consultant Neonatologists, a Band 7 sister responsible for infection prevention, a paediatric Infectious Diseases Consultant, the surgical nurse specialist and the researcher (ANNP). Plans included the development of a bundle, surgical ANTT for central line fluid changes, a checklist with an observer for insertions, and a central line insertion trolley. Infectious diseases meeting to become a bedside ward round.
- 2015-2016 Late-onset sepsis guideline developed by the MDT
- January 2016: Surgical ANTT introduced for central line access. Training provided to all nursing staff using a cascade training approach by the infection prevention sister.
- January 2017: Two-person insertion technique and central line checklist introduced.
- Twice-yearly training with each rotation of junior doctors on ANTT at induction, a central line access simulation study day, video training on central line insertion, and a guideline were produced.
- Audit of checklist use performed 6 months post-introduction.
- October 2017: Late-Onset Sepsis guideline approved.
- February 2018: Alcohol Impregnated Port Protectors (AIPPs) introduced. Visual aids used and training of all nursing staff.
- Daily audit of AIPPs for the first 3 months, then incorporated in the nursing daily checklist on the electronic patient record system.
- Infection rates were disseminated at regular intervals in 2017 to 2019 as part of a NICU infection newsletter, private social media work groups and on NICU display boards. These were also presented as part of regular NICU governance meetings.

5.4 Data Collection Methods

This section will provide an overview of the data collection methods used to study the process of implementation, presented sequentially in the order they were performed. How each method was used to inform the next will be discussed.

5.4.1 Normalisation Measure Development (NoMAD) Survey

The Normalisation Measure Development is a survey that has been previously validated for measuring implementation using the four main constructs of NPT (Finch et al., 2012, Finch et al., 2018, Rapley et al., 2018). It contains 20 statements with Likert scale responses (see Appendix 13). These statements were adapted to suit the intervention (a care bundle); whilst the survey was piloted locally with a selection of nurses to ensure the questions were understandable, validity and reliability testing was not deemed necessary as it was a previously validated survey. No adjustments were deemed to be required following the pilot.

The survey was administered via iSurvey, a web-based survey tool, once every 4 months to all eligible staff over a one-year period during 2018. Invitations were sent to eligible staff via iSurvey and each survey was open for responses for a 4-week period. Given the local shift patterns and taking into account periods of annual leave, this was considered sufficient time to allow all staff to participate. Strategies were employed to improve an initial poor response rate to the first survey:

- Weekly email reminders were sent.
- Information was disseminated via the local audio-visual system in the staff room.
- The researcher's presence on the neonatal unit was increased at handovers to raise awareness of the research.
- An educational display board was set up close to promote the survey.
- Paper versions were also available and distributed at handovers for those who either did not want to complete the web version or found it easier to access a paper version.

The benefit of using a survey was its ability to capture a large number of staff perspectives on implementation and monitor changes in these responses over time. Survey responses were anonymised in order to reduce the risk of participants providing socially desirable responses. The benefits of anonymity in survey research needs to be balanced against the risk of acquiescence bias or the tendency for participants to repeatedly respond in the same way (Hasson et al., 2015). Tracking respondents can help identify this. Whilst this was the original intention unfortunately this feature had not been fully developed within the iSurvey platform, so tracking was not possible.

5.4.2 Observations of Practice with Retrospective Interviews

It has been suggested that observation is key in understanding what is happening in complex systems and that the investigation of implementation should not begin with

simple measurements of compliance but instead start with investigating the complexities of clinical practice (Plsek and Greenhalgh, 2001). In order to understand how new ways of working are implemented, it is important to understand how the bundle is integrated, how it is made 'workable', who performs the work, and how resources are organised. Observations of practice can be valuable when studying clinician behaviour, in order to understand how new practices or processes are enacted, but they also allow clinical staff the opportunity to reflect upon their actions, promoting reflective learning (Bergold and Thomas, 2012). The systematic review in Chapter 3 highlighted that this was missing from the current evidence base.

The observations were not covert; participants consented to be observed and the researcher was not actively involved in the observation, acting as an observer-researcher with full self-revelation to participants (Guest et al., 2013). Whilst this reduces some ethical issues associated with covert observation, the problem of participant reactivity can be challenging, with the potential for participants to alter their behaviour when they know they are being observed (Guest et al., 2013). One of the challenges here is for the researcher-observer to 'fit in' to the setting, so that participants are less likely to adjust their behaviour. Working as an ANNP on the NICU being studied was of benefit, as the researcher was seen as part of both the medical and the nursing teams. In this way, there was an element of the researcher as an insider-observer.

Observations alone cannot help to understand the reasoning and cognitive processes behind clinician behaviour, nor the possible external influences. For this reason, retrospective interviews were built into the unstructured observations, an adaptation of the 'verbal protocol' or 'think aloud' method developed by Newell and Simon's work on information processing theory (Newell and Simon, 1972, Bucknall and Aitken, 2015). This technique allows researchers to elicit information on the underlying thought processes and actions of healthcare professionals, allowing participants to provide explanations for the actions or decisions made. They can link cognitive processing with the concurrent clinical situation, providing insight into the working memory of participants and examining the cues, processes, contexts, goals and strategies that make up behavioural responses. However, given the cognitive demands already required to perform central line insertion and prepare central line fluids, it was too much additional cognitive load to expect participants to talk through the process whilst they were doing it.

Pairs of participants were instead observed either performing a central line insertion or preparing central line fluids. In order to avoid any disruption to clinical care this method was adapted: participants discussed the process retrospectively after the procedure was completed. The retrospective interview was performed either immediately after the procedure, or up to 15 minutes after the procedure had been performed. This was felt to

offer a balance between minimising the risk of memory bias whilst acknowledging that staff may have competing workload demands. Think aloud techniques- talking through the process and explaining what they did and why they did it that way-were used in the retrospective interviews. Some of the challenges to the validity of this method are summarised in Table 13.

Table 13 Challenges in Verbal Protocol Methods

Challenge	**Detail**	**Application in this research**
Limits of working memory	Memory errors can produce false reports. This may be reduced by using prompting or dialogue methods and think aloud techniques.	Dual interviews allowed participants to prompt, corroborate or challenge each other's recall. Performing the interview immediately after the observation helped minimise memory errors.
Disturbance of cognitive processes	This may be reduced by using introspection or retrospection techniques, as well as think aloud methods.	Retrospective techniques were used to avoid potential disruption to clinical care. Interviews were only performed if staff felt able to leave the clinical area.
Interpretation by the subject	The use of a structured technique may not fit with the content of the process, thereby distorting the data. This may be reduced by dialogue techniques and prompting, though it may occur with the latter. Interpretation is not required in think aloud techniques, as the structuring of information is performed in the data analysis.	An unstructured technique was used with prompts. Data analysis was performed after each interview, to inform subsequent sampling and additional interview prompts. For example, after the first two central line insertion observations, how participants learned the skill was felt to be an aspect to prompt if it was not discussed.
Adapted from Van Someren et al. (1994)		

The data was analysed after each observation in order to assist with sampling decisions and to help guide the interview prompts. For example, participants referred to specific aspects of a central line practice, such as how practice might be different with someone less experienced, so attempts were then made to sample specific events or specific pairings of participants. Sampling will be discussed in more detail in section 5.5.2.

As these observations were not an audit but instead assessed how the work is implemented, a structured tool was not used. Instead, an *aide memoir* was developed as a prompt for specific areas of interest, see Appendix 14. This was loosely developed using the sub-constructs of collective action from NPT, working as a prompt to consider how work is negotiated between participants. These observations took place within a natural rather than a simulated setting. Whilst simulated settings provide a degree of control to the circumstances being studied, the purpose of this study is to examine how the bundle is used within the clinical area, therefore data from simulated settings would not have external validity.

A short audio-recorded discussion followed the observation, and a topic guide was developed with prompting questions, see Appendix 15. Whilst a grounded theory approach was not used in this study, features such as constant-comparison analysis were, so the interview prompts were shaped by findings from the previous interviews and the concepts highlighted in the systematic review in Chapter 3. For example, feedback was something that was often reported as a contributory factor in the literature; and following initial interviews, it also appeared important for participants. Similarly, it became clear that central line dressings were a cause of uncertainty for participants in the insertion observations, whereas for the fluid changes, waiting for one minute was frequently raised by participants as an area that may not be performed consistently. It became prudent, therefore, to explore if these beliefs were part of a shared experience, or specific to individuals. These were areas of practice that participants frequently brought up themselves, without the need for prompts, and contributed to the development of the SSI prompts.

In order to reduce the likelihood of recall bias and incomplete recall, interviews were performed as soon as possible after the procedure. The interviews lasted approximately 30 minutes, which was almost double the anticipated duration. The unstructured observational notes were typed into an electronic format and field notes were kept to record participant interactions during interviews, as well as for researcher reflexivity on interview technique, setting and environment.

One unique feature of this study is its use of paired (or dual participant) interviews. To date the use of paired interviews has been infrequently reported (Wilson et al., 2016,

Lohm and Kirpitchenko, 2014). The use of paired interviews can mitigate, to some extent, the potential limitations of memory and participant recall as participants can 'bounce' off each other in discussions. Paired interviews where there is a pre-existing relationship between participants are felt to have several strengths, including reducing the attrition rate, and providing the researcher with additional information regarding dynamics between participants (Wilson et al., 2016). They also have advantages over focus groups, where participants can speak over each other or change the direction of the conversation, and participants may feel more comfortable in pairs (Lohm and Kirpitchenko, 2014). As such, paired interviews often provide more detailed and relevant data regarding the phenomenon being studied (Wilson et al., 2016, Lohm and Kirpitchenko, 2014). However, there are challenges, such as the dominance of one participant in the interview, which can result in the other participant disengaging or being unable to concentrate on interacting. Power dynamics or hierarchies between pairs can mean that participants may not provide genuine accounts, providing instead a single perspective (Wilson et al., 2016). Interviews required crafting by the researcher, with knowledge considered the product of social interaction between the interviewer and participant (Kvale and Brinkman, 2009). Indeed, knowledge of the topic is argued to be required in order to develop the art of follow up questions and responding to the participants responses, rather than mechanically following the 'rules' (Kvale and Brinkman, 2009). An in-depth knowledge of the phenomenon of care bundles was gained from the systematic review in Chapter 3, and being an 'insider' researcher provided an insight into naturally occurring dynamics. Any power dynamics observed in the interviews were likely to reflect those that would occur in clinical practice, and therefore still provided useful insight into how decisions or behaviours were influenced by social relationships.

The paired interview process was piloted to ensure an understanding of the process and the acceptability of the process to clinicians regarding minimising disruption of care as well as to test the interview prompts and the recording equipment. Piloting the process also enabled the refining of the interview prompts and interview technique, such as using open-ended prompts including "can you tell me more about that?". The development of a minimal instruction style was therefore key in allowing participants to share their own experiences without unnecessary influence from the researcher.

Data collection stopped when sample adequacy was achieved. The concept of data saturation in qualitative research is frequently used as a justification for ceasing sampling. It suggests that data collection continues until nothing new is generated, there are fewer surprises, and there are no more emergent patterns in the data (O'Reilly and Parker, 2013). However, O'Reilly and Parker (2013) argue that using this term as a generic marker of research quality is not appropriate; data is never fully saturated as there will

always be new concepts to discover. They instead refer to sampling adequacy, whereby an adequate sample is one that can sufficiently answer the research questions, though this again has its limitations. Researchers need to be certain that a sufficient range of experiences have been sampled, and attempts have been made to sample extreme viewpoints or sources that might be considered disconfirming. Once there was a feeling of familiarity of the topics being discussed, and nothing surprising was being found, one additional ORI was performed as confirmation, and then sampling was stopped.

5.4.3 Semi-Structured Interviews (SSIs)

Interviews can generate rich data reflecting the perspective or experience of the participants, aid the understanding of the context, explain social processes, verify results from other methods of data collection and illuminate survey responses (Adams, 2015, Gillham, 2000). The SSIs were used to explore implementation in greater depth as well as illuminate the survey and ORI results, and explore local CLABSI rate data. SSIs were also used to identify any additional barriers or facilitators that were not identified by the previous methods.

Prior to the SSIs, results from a preliminary data analysis of the NoMAD survey and ORIs were sent to all SSI participants via email. This was important to allow participants time to read and reflect on the results, rather than asking them to comment ‘on the spot’. It was also important ethically that participants and NICU staff were provided with the preliminary results so that they did not find out by ‘word of mouth’, so the preliminary results were also emailed to all NICU staff. This process also allowed for member checking to take place to ensure that data analysis had meaning to staff and had not distorted participants’ experiences. No participants disagreed with the results nor were any concerns raised regarding data analysis.

Whilst interviews should allow the participants the freedom to discuss their experiences in depth, the participants were busy clinicians; this is why SSIs were used with an interview schedule to enable coverage of key areas in a relatively short time period. Open-ended questions designed to investigate implementation were developed, and the interview schedule can be found in Appendix 16. Additional prompts were added that arose from the ORIs and NoMAD survey:

- Survey results suggest that these new practices have not disrupted working relationships. What do you think about that/ how important is that to you?
- Do you feel there are sufficient resources available in order to follow these practices/policies?
- In an ideal world, how would staff learn these skills?

- What feedback do staff receive?
- Findings from the first part of this study suggests that practices are more likely to be implemented when there is a clear rule to follow:
    - Can you tell me about an area of central line practice where there is clear guidance for staff?
    - Can you think of an area of central line practice where there isn't clear guidance for staff?
    - Observations have suggested that there are times when it may be difficult for staff to fully adhere to the central line policies and practices. What do you think about this?

The following were identified as specific areas of interest from the ORIs and were added as prompts if required:

- What is your experience of changing central line fluids when it is busy?
- What does controlled versus uncontrolled fluid changes mean to you?
- Some feel there is a risk with the AIPPs that not everyone may wait for one minute before removing the AIPPs. What do you think about that?
- What is your experience of using the central line checklist?
- Can you tell me about a time when you re-dressed a long line?

The SSIs helped to provide not only triangulation between the quantitative and qualitative data sets, but also further explanation for some responses. For example, it has been argued that new practices are more predisposed to normalisation if working relationships are not disrupted (Finch, 2018). Whilst this may be true for the implementation of new technologies, in the Matching Michigan study, implementation was felt to be less successful because professional norms were unchallenged and the status quo was maintained (Dixon-Woods et al., 2013). Indeed, in some of the studies reviewed in Chapter 2 and Chapter 3, the disruption of normal social hierarchies was believed to be important in bundle success. It was therefore worth discussing to what extent working relationships influenced bundle implementation in order to help understand the responses to question 10 of the NoMAD survey.

5.4.4 CLABSI Rates

CLABSI rates were collected as an outcome measure to provide context for implementation. Anonymised patient data of all positive blood cultures in neonates with a central was routinely collected as part of ongoing benchmarking in the local NICU. The UK National Neonatal Audit Programme (NNAP, 2016) definition of CLABSI was used, which

requires a positive blood culture in a neonate with a central line. Local data is categorised into pathogens and CoNS.

The NNAP has also removed the requirement for three or more of 10 additional clinical signs for CoNS positive blood cultures to be categorised as a CLABSI (NNAP, 2017). Local data has not taken clinical signs into account, the assumption being that clinical signs of sepsis must have been present to prompt clinicians to take a blood culture. This study has therefore used an arguably simpler surveillance definition than others outlined in Chapter 1. The following were used to define a CLABSI:

- All positive blood cultures in neonates with a central line >72 hours of age.
- Duplicate positive cultures within 72 hours of each other were excluded as duplicates of the same *episode* of a CLABSI.

Potential contaminated blood cultures were not excluded from the data and any discrepancies were discussed with a Consultant Neonatologist. Positive blood cultures in neonates with a central line were reported per 1000 central line days. Central line days were counted as all days where a central line (surgical venous line, umbilical venous or arterial catheter, or a peripherally inserted central catheter) was present. Reporting CLABSIs using this denominator is widely used internationally and takes into account changes in acuity level and overall risk of developing an infection.

Central line days were taken from routinely collected data via BadgerNet, a national UK neonatal database (BadgerNet Neonatal, 2020). Data is inputted daily by nursing staff, but the local NICU also employs a data administrator who checks it for completeness. Whilst routinely collected clinical data is subject to error, it is what is submitted nationally and reported in local governance meetings. Therefore, this is the data used to determine care quality and identify the need for practice change. Extreme data values (<250 central line days per month or >550 central line days per month) were double-checked with the local administrator. Anonymised local data on NICU annual admissions (gestational age, birth weight) was also collected from BadgerNet in order to compare baseline demographics.

5.4.5 Bundle Adherence Audits

Audits of practice can provide a record of the *work as done* and as such are a commonly used process measure following the implementation of new practices. Audit measures can also be used as feedback to clinical staff, or for benchmarking. Audit and feedback were frequently used in the bundle studies reviewed in Chapter 2 and Chapter 3, hence the importance of their inclusion as a comparator. However, the evidence of impact of audit on patient outcomes is considered to be weak (Paton et al., 2015). Other challenges related to clinical audits include having sufficient resources such as time and staff to

undertake data collection. A single person undertaking the audit leaves little opportunity for implementing an improvement strategy, or audits may be undertaken by rotating junior doctors with no time to instigate change (Boyle and Keep, 2018).

Whilst prospective audit data was originally planned as part of local governance processes following the introduction of new guidelines, this was not undertaken. Instead, a retrospective spot audit of the NICU-specific bundled interventions was undertaken; the data was collected by a medical student, under the researcher's supervision, and a consultant neonatologist. Anonymised patient data was collected using MetaVision, the electronic patient documentation system (MetaVision ICU, 2017), which included birth weight, gestational age and if the patient was an ex-utero transfer. Central lines inserted in another NICU, before transfer to the local unit, were excluded from the central line insertion audit.

The process measures that were audited were:

- Adherence to the central line insertion checklist including the use of a two-person technique, the use of gestational-age-specific skin decontamination prior to insertion and documentation of reason for removal.
- Adherence to the use of AIPPs.
- Documenting the daily assessment of central line dressings.
- Central line dwell times and number of central lines in situ for greater than 6 weeks.

There are no national recommendations regarding the timing of removal of a central line in neonates, and the evidence is mixed regarding the extent to which dwell times are a risk factor for developing a CLABSI (see Chapter 1). Whilst the local bundle does not specify an absolute cut-off for dwell times, it is recommended that central lines in situ for 6 weeks are risk assessed daily and electively replaced if possible.

In addition to this, prospective Trust audit data was obtained on hand hygiene and surgical ANTT practices on the NICU as it became apparent that the central line access checklist was not being used. These audits were performed by the infection prevention link nurse at quarterly intervals, required as part of local Trust governance activities. This data was collected prospectively by direct observation.

The strategies used to enhance the validity and reliability of the quantitative data collected in this study are outlined in Table 14. A similar table can be found for the qualitative data in Section 5.7.2.

Table 14 Methods to Ensure Validity and Reliability in Quantitative Data

Term	Definition	Applied to this study
Validity	The extent to which a concept is accurately measured	Pre-defined definitions of CLABSI and central lines Discrepancies in CLABSI categorisation discussed with a second investigator. NoMAD survey has previously undergone instrument testing
Reliability	Consistency of measurement	CLABSI data collected by a single researcher to ensure consistent approach. BadgerNet used to collect demographic data and central line days data. Clinical data inputted by clinicians; it may have inaccuracies. However, the NICU data administrator is able to check for data completeness. Data represents that which is submitted nationally. Electronic patient records used to collect bundle adherence data; this is limited by retrospective collection meaning any discrepancies were unable to be investigated. Any missing or extreme data discussed with the NICU data administrator and verified. Cell validation used to highlight data extremes. Missing survey data included in analysis
Adapted from Heale and Twycross (2015).		

5.5 Sampling and Recruitment

Prior to commencing the study and recruiting participants, a variety of presentations were given on local in-house education days for nurses, junior doctors and consultants in order to disseminate information about the research project. Posters and participant information leaflets (PILs) were also displayed in the staff coffee room (see Appendix 17 and Appendix 18). Written information was disseminated to staff both in person and by staff electronic mail following permission from the unit matron.

Recruitment to the qualitative components of the study was performed over a 12-week period prior to commencing data collection. Whilst the central line fluid changes were performed daily by nursing staff, the insertion of central lines was less predictable. In order to ensure that participants had time to read the PILs and to allow sufficient time for informed consent, it was felt that recruiting staff prior to the event would be both ethical

and practical. Staff had the option to consent to being involved in either the ORIs or the SSIs alone, or they could consent to be in both. Staff had the right to withdraw or change their mind at any stage of the project (see Section 5.8). The eligibility criteria for data collection method will now be discussed.

5.5.1 NoMAD Survey

Staff were eligible to participate in the NoMAD survey if they were permanently employed on the NICU at the time of the study and would use the care bundle in their clinical practice. Nursery nurses (Band 4) were included in the survey as whilst they are unable to access central lines, they do provide care for babies in high-dependency areas where infants have central lines, and therefore should be aware of local practices. Rotational members of the medical team, who were not employed on the NICU prior to the implementation of the intervention, were not eligible to participate in the NoMAD survey. This is because staff had to have experienced practice prior to the implementation of the bundle in order to comment on the implementation process. A mailing list of all staff was provided via the unit matron and was used to identify eligible participants. Statistician advice was sought on performing a sample size calculation for the survey, which was felt to not be required.

5.5.2 Observations of Practice with Retrospective Interviews

Qualitative research sample sizes are not commonly predefined prior to data collection, with sampling often driven by data analysis as theories and concepts emerge (Hunt and Lathlean, 2015). Purposive sampling was performed in order to recruit staff across a variety of job roles and experience levels, with recruitment occurring during both night and day shifts. It is important that a range of events were sampled across different times and environments, as well as different combinations of participants experience levels and pairings. Constant-comparison methods were used to inform the sampling of both participants and events.

Staff were eligible to participate in the ORIs if they:

- Accessed central lines and performed central line fluid changes (Band 5 through to Band 8 nurses)
- Performed central line insertions (consultants, ANNPs, MTI doctors, junior doctors)

Staff were excluded if they:

- Were a Band 4 nurse.
- Had previously been observed on two other occasions.

Participants were able to be observed on a maximum of two occasions, providing the pairing of participants were different, in order to capture any potential differences in who performs the work, relationship pairs and variations in performance. Band 4 nursery nurses were excluded as they do not access central lines or attach fluids.

It was anticipated that recruitment to this data collection method would be challenging, due to having to observe staff (Van Someren et al., 1994). The greatest challenge was aligning researcher availability with the availability of a central line insertion by two participants who had consented. As fluid changes are performed daily, this was less difficult to sample but central line insertions were sporadic and less predictable. Attending at handovers, and disseminating laminated researcher contact cards to nurses helped to improve data collection.

5.5.3 Semi-Structured Interviews

The sampling strategy for the qualitative data collection has already been outlined in Section 5.5.2; however, the data from the NoMAD Survey and ORIs was used to inform SSI sampling. Attempts were made to interview those who did not respond to any of the three surveys as well those who had declined to participate in the ORIs as they may have held extreme views. Unfortunately, survey responses were unable to be tracked and so identifying those with potentially extreme viewpoints was not possible. In addition, Consultants and Band 7 nurses were purposively sampled, as neither were sampled in the ORIs, and attempts were made to specifically recruit staff who only worked night shifts. The latter was decided upon because only one ORI observed fluid changes during the night shift, and the ORI results suggested there was a pressure to get fluids changed before night shifts. However, by the time the SSIs took place, there were only two members of staff who worked permanent nights; one did not want to be recruited and the other did not respond. Finally, a selection of participants from the ORIs were purposively sampled in order to explore the confirmability of the NoMAD and ORI results.

5.5.4 Bundle Adherence Audits

The patient records of neonates were eligible for inclusion if:

- They were an inpatient on the NICU on the first day of each quarter, between 1st January 2018 and 1st October 2019.
- They had a central line in situ. A central line included umbilical venous or arterial catheters, surgically inserted venous catheters and PICCs.

- Neonates who had a central line inserted outside of the local NICU were excluded from the central line insertion checklist audit, as they were not subject to the local bundle practices for insertion.
- All neonates with a vascular access device that was not connected to a continuous infusion were included in the AIPP audit, including peripheral venous lines.

5.6 Quantitative Data Analysis

5.6.1 NoMAD Survey

Descriptive statistics and frequency tables were used to analyse the NoMAD survey responses. Normality was assessed using the Shapiro-Wilks test, with a p-value of <0.05 indicating non-normal distribution. Responses on the Likert scale were assigned a numerical value, ranging from -2 (strongly disagree) to +2 (strongly agree), with neither agree nor disagree being assigned a neutral score (0). This allowed for the generation of an overall construct score for each of the constructs of NPT, enabling comparison at a construct level as well at an individual question level. The NoMAD tool has been used in this way previously and contact with the survey developer supported this method of analysis (Finch et al., 2012). However, it should be noted that providing a numerical value to a Likert scale has limited numerical meaning- that is, a construct score of 2 does not mean that particular construct was two times better than a construct with a score of 1. More recently, Finch et al. (2018) have highlighted that it is not possible to extrapolate what such ‘construct’ scores would mean in different settings and therefore generic NoMAD scoring systems cannot by recommended. Indeed, Finch et al. (2018) recognise that the interpretation of results generated by the NoMAD tool should be informed by an understanding of the local context, and the tool should be seen as a “pragmatic” measure of implementation based upon the underlying assumption that the more positive ratings for each item, the higher the potential for interventions to be normalised in practice (Finch et al., 2018, p. 10). However, analysing the results in this way does provide a useful way of assessing the data to highlight patterns or particular areas of the NPT implementation constructs that could be improved. Survey results were graphically depicted using radar plots, with the fuller radar plots indicating more positive scores. Responses were also reviewed according to job role and length of employment on the NICU.

As this study is not attempting to make generalisations to a wider population in relation to sample validity, the need for inferential tests of significance and confidence were felt not to be appropriate following consultation with a statistician.

5.6.2 CLABSI Rates

Descriptive statistics were used for the anonymised patient demographic data, and this was tested for normality to determine the appropriate descriptive statistic to represent the data. As anticipated given that this was a tertiary NICU providing specialist care, the data was not normally distributed, and so the median was used.

Statistical process control (SPC) was used to track trends in CLABSI rates. SPC methods can distinguish between Common Cause Variation and Special Cause Variation, providing more rigour than simple run charts. Common Cause Variation suggests that the process being measured is stable and predictable. It suggests that variation is inherent in the system, and if this is at an unacceptable level, then the system needs to change in order to improve the process. There are several rules to follow when interpreting SPC charts, though these vary slightly between different sources. The following rules (NHS Improvement, 2018) were used to analyse CLABSI rates:

- Rule 1: Any single point outside the control limits.
- Rule 2: A run of 7 points all above, or all below, the centre line (a shift) or a run of 7 points in the same direction consecutively (a trend).
- Rule 3: Unusual patterns or trends in the data points.
- Rule 4: The number of points within the middle third of the region between the control limits differs markedly from two thirds of the total number of points.

If any of these rules are broken, then Special Cause Variation exists. If common cause variation is displayed in the control chart, then there is variation inherent in the system, and the system needs to change in order to improve.

There are several different types of control charts that can be used depending on the type of data being collected. Attribute data, also known as discrete data, is classified into distinct categories, whilst variable data is measured along a continuous scale. Attribute data can be further sub-divided into defectives or defects. Defectives require the count of the event (such as death) and the number of events where the defective did not occur, for example, calculating a percentage of deaths. For defects, however, the opportunity for the event to occur may not be known, so the data may be reported as a rate using the opportunity for a non-defect to occur, such as total ventilator days. This is the case for CLABSI rates, where bloodstream infections are presented as rates per 1000 central line days. CLABSI rates therefore are a type of attribute data with an unequal area of opportunity for the defect to occur- that is, the number of central line days per month varies. For this type of data, a U chart was considered the most appropriate type of SPC chart (NHS Improvement, 2017b).

Per SPC methods (NHS Improvement, 2018) the first 20 data points were used to calculate the mean CLABSI rates, and then the Upper Control Limit (UCL) and the Upper Warning Limits (UWL) were calculated. The UCL represents 3 standard deviations from the mean, and the UWL represents 2 standard deviations from the mean. At any point when a shift or trend was identified, the mean was recalculated based on the data points signalling a shift or trend.

5.6.3 Bundle Adherence data

Descriptive statistics were used to report bundle adherence measures. Data that was not normally distributed was represented using medians and inter-quartile ranges. Nominal data was reported using percentages.

5.7 Qualitative Data Analysis

5.7.1 Observations of Practice

The unstructured observational notes were typed into an electronic format. These notes were not intended to be quantitatively analysed, nor were frequencies ascribed to actions; the purpose was not to quantitatively measure behaviour. Instead, this data was transferred into a table to compare participant beliefs about their behaviour and performance (what they thought they did, the work as imagined), with what was observed (what they actually did, the work as done). Local Trust guidelines were referred to in order to make an overall comment on if the practice being observed was aligned with recommendations, but the focus here was on what made the task challenging, and if the behaviour observed was congruent (or not) with participants beliefs, attitudes or values expressed in the retrospective interviews. Patterns within the data, such as recurring challenges, were also able to be identified by arranging the data in this way. An example of the table used to analyse the observational data is provided in Table 15. The fully completed version of this table is available in Appendix 19.

Table 15 Comparing Observations of Practice Data

Participant code	Process observed	Participant reflexivity	Researcher reflexivity	Positive influences	Negative influences

5.7.2 Interview Data

Thematic analysis was used to analyse the qualitative interview data. Whilst thematic analysis is a widely reported method of analysing qualitative data, is has been argued that

there is a lack of agreement as to how it can be performed, and reported, rigorously (Nowell et al., 2017). It could be considered a core foundational skill for qualitative researchers, and it is a method used to identify, analyse, organise, describe and report themes (Nowell et al., 2017). Whilst it provides a flexible approach, which suits the inductive nature of this research, it was essential, given prior knowledge of NPT and implementation theories, that the data was not forced to fit predetermined concepts or constructs. Directed content analysis, for example, could have been used to analyse the data using NPT constructs, however, given the relative uniqueness of the phenomenon and setting under investigation, it was important to explore the data without any preconceived conscious (or unconscious) biases (Hsieh and Shannon, 2005, Kibiswa, 2019). It has been argued that direct content analysis can result in researchers being more likely to find data that supports pre-existing theories or categories (Hsieh and Shannon, 2005). An inductive analytical approach was therefore used, rather than establishing *a priori* constructs and applying them to the data or using the data to test a pre-established theory (Kibiswa, 2019). This also allowed themes to be developed from the experience of participants, rather than attempting to match their experiences to previously known constructs. Whilst the flexibility afforded by thematic analysis can be criticised as leading to inconsistency in analysis, the methods outlined in the remainder of this section, including a tabular approach for comparing codes and sub-themes across the data, helped provide trustworthiness to the reporting. There are generally considered to be six phases of thematic analysis (Braun and Clarke, 2013) which are:

1. Familiarising yourself with the data
2. Generating initial codes
3. Searching for themes
4. Reviewing themes
5. Defining and naming themes
6. Producing the report

Familiarisation with the data

A transcription service was used to transcribe the qualitative interview data for ORIs and SSIs. When these were returned, the transcript was read and ‘cleaned’ for any incorrect translations (usually of medical terminology) and also inaudible sections of audio. Interview audio was listened to alongside reading the transcript, in order to make any additional memos relating to intonation or turns of phrase. Listening to the audio alongside transcripts allowed for familiarisation with the data; due to time constraints, it was not feasible to transcribe the audio personally. The cleaned transcripts were sent back to all participants to provide an opportunity for further comment or clarification, though no participants had anything to add or anything they wished to be changed.

Transcripts were read to get an overall general impression of the interview and reflect upon interview technique. Then the transcripts were re-read, and initial codes were applied. Transcripts were initially read on paper, with memos and notes made in the margins (just from a personal preference of working on paper), but then formalised coding took place using NVivo v12 (QSR International Pty Ltd) as a way of organising the data. NVivo was used as a data management tool, as the software cannot replace the analytical work done by the researcher. This process was performed for each interview before the next interview was conducted, and previous transcripts were then re-read. Memos were used to document patterns or ask questions of the data, and so were able to inform subsequent interviews. Memos were also used to track concepts or ideas related to language and phrases such as “bosh-that was proper, bang on” or “whip one in”.

Generating initial codes

Codes were initially done freely and liberally, though this approach meant that sometimes similar but different codes were used to categorise the same concept such as balancing risks, navigating risks and competing risks. Preliminary coding identified that there were codes representing actions (what staff did) and explanatory codes that provided explanations for this behaviour.

Searching, Reviewing and Defining Themes

This process involves grouping codes together into those that were describing or explaining similar or related phenomenon. For example, staffing, competing demands, interruptions, distractions and being busy all described similar workload-related concepts and were grouped together as workload demands. At this stage, testing for referential adequacy by returning to raw data was important to ensure that the grouping of codes together made sense, but this was also done once the final themes were established (Nowell et al., 2017). This ensured that the themes had not become too ‘abstract’ or too far removed from the original data and that the meaning had not become distorted during the analysis process. The process of member checking at several stages in the research process was also important in ensuring that there was no distortion of participants experiences. In addition, themes were also reviewed and discussed with experienced qualitative researchers, in order to ensure they made sense and adequately represented the data. Investigator triangulation therefore provided rigour to the analysis. Table 16 outlines the methods used to enhance the overall rigour of the qualitative data.

Table 16 Methods to Enhance Rigour in Qualitative Research

Concept	**Definition**	**Applied in this study**
Credibility	Establishing that the results are believable to participants.	Member checking of individual interviews, after each data analysis phase. Investigator triangulation Data source triangulation
Confirmability	The degree to which the results could be confirmed or corroborated by others.	Disconfirming sources Member checking with individual participants and staff on the NICU Methodological triangulation Data source triangulation Examples of coding and thematic development Example of a coded transcript
Transferability	The extent to which the results can be transferred to other contexts or settings.	Descriptions of setting and context Presentation of findings at several national and international conferences Theory triangulation
Dependability	How consistent and repeatable are the findings.	Use of NVivo software to record audit trail Development of a codebook Investigator triangulation Examples of coding and thematic development
Adapted from Dyson and Brown (2006) and Rashid et al. (2019)		

Whilst coding and organisation was performed on NVivo 12 (QSR International Pty Ltd, 2018), a code book (providing a written description of the groupings of codes) was developed, see Appendix 20. Confirmability requires that researchers can demonstrate that their results are clearly derived from the data. Whilst some argue that this can be determined through the principles of credibility, transferability and dependability it can also be done by providing clear examples of the data analysis process (Nowell et al., 2017). An example of how data were grouped into sub-themes is provided in Appendix 21; how themes were developed is in Appendix 22. It should be noted that the same inductive

approach was taken for the SSIs, and the themes from the ORIs were not used as a framework to analyse the SSI data.

5.7.3 Ethnographic Analysis

However, the approach outlined above- producing categories of data and organising them into simple groups (or themes) - has been criticised as an over-simplification (Thorne, 2000). Indeed, the purpose of ethnographic research is not only to discover what is happening but also to attempt to provide explanations as to why it is happening (Jones and Smith, 2017). It has been argued that there is significantly more cognitive work required in analysing qualitative data than a simple organisation of data into themes. This cognitive work involves comprehending, synthesising, and theorising about relationships and recontextualising this into pre-existing knowledge (Thorne, 2000). This view of qualitative data analysis represents the complex work that is required in order to make links and connections between themes, which is in keeping with an ethnographic analysis approach.

An ethnographic analysis therefore takes an iterative approach, in which cultural ideas are translated or represented into a written form, a process which involves sifting and sorting data sets to interpret themes, searching for inconsistencies and contradictions (Jones and Smith, 2017, Thorne, 2000). In order to do this, initial smaller groups of codes (sub-themes) were put into a table to allow comparison across different behaviours and explanatory influences. Due to the differences between the processes being observed, central line fluid and central line insertion data from the ORIs were analysed separately initially. This not only made the data more manageable, but it also enabled the cross-referencing of preliminary sub-themes and initial groupings, and allowed for the identification of similarities, differences or patterns in the data. An example of this is provided in Appendix 23. This cognitive analytical process best fits with the study design outlined in Chapter 4, though the six stages of thematic analysis outlined above represent the steps taken to develop key themes.

5.8 Research Governance and Ethics

Health Research Authority approval was granted through the Integrated Research Application System (IRAS) for research being performed in the NHS (ID: 208128). The University of Southampton ethics committee also approved the research project (ERGO ID: 25154). Support was obtained from the neonatal charity Bliss (see Appendix 24) and funding was obtained from the Royal College of Nursing Foundation for tuition fees, transcription costs and attendance at a 2-day qualitative data analysis course.

5.8.1 Confidentiality and informed consent

Written consent was obtained from participants for the ORIs and SSIs prior to the start of data collection. This took place after staff had read the information leaflet, and time was given for them to consider participating in the study. Staff email addresses for survey distribution were obtained via the gatekeeper (the NICU matron), and blanket 'all staff' mailing lists were not used. The online survey included a disclaimer that by clicking to continue, consent had been given. This was accompanied by an explanation of the study in an information leaflet, in an email, and on the initial survey page. No one other than the researcher had access to survey responses, and participants were aware of this.

Following the ERGO review, it was felt that two separate consent forms for the ORIs and the SSIs were required, and these were modified. Participants' consent forms were kept in a locked filing cabinet, in a locked research office. A transcription service provided a non-disclosure agreement. Participants were anonymised for data analysis using codes (e.g. NURS0701).

5.8.2 Participant Withdrawal

Participants were able to withdraw from any aspect of the study at any time, with no consequences and no reason required. Staff were reassured that neither their involvement, nor their wish not to participate in the study, would influence how they were viewed or treated by the researcher, the Trust or management. This was of particular importance as the researcher also worked in a senior nursing role on the NICU.

5.8.3 Potential Disruption to Clinical Care

Whilst it has been proposed that observation of practice may interrupt or disrupt care processes and lead to error, in general it is not felt to have an impact on performance (Van Someren et al., 1994, Bucknall and Aitken, 2015). The use of retrospective questioning after the observations ensured that potential disruptions to care were minimised. The researcher attempted to be as unobtrusive as possible, simply observing processes that were already being performed in the clinical area. In addition, the retrospective interviews prompted participants to reflect on the task being observed, arguably outweighing the potential disruption to care. This process promotes experiential thinking, potentially improving practice in the future by enabling meaningful reflection *in action.* A more in-depth discussion on the potential influence of this data collection methods on CLABSI rates can be found in Chapter 10.

Finally, the retrospective questioning and SSIs were only undertaken if participants felt they were able to leave the clinical area. As the researcher also works in this clinical area, there was an acute awareness of the time constraints and competing demands for participants. Support from the NICU matron was gained for members of the education team to be available to cover any absences from the nursery. SSIs were scheduled for a time convenient for the participant; for the most part this was prior to starting a shift, though two SSIs took place during a clinical shift.

5.8.4 Observing Poor or Dangerous Practice

It was anticipated, due to the impetus for performing this study, that sub-optimal practices and practice variation may be observed. The purpose of the care bundle was by its nature designed to improve local practices and reduce CLABSI rates. However, an ethical distinction had to be made between potentially normalised ineffective or poor practice, and dangerous practice that may cause harm and breach infection control policy.

In the event of observing unsafe practice, the observational process would be discontinued, and the practice stopped to avoid immediate harm. Practices that were deemed unsafe or breaching hospital policy that were identified either during observation or discussed in SSIs, would be reported to the NICU matron or responsible consultant neonatologist. This is explored further in Chapter 7.

5.8.5 Addressing Potential Emotional Distress

Whilst it was not anticipated that the topic of this research would cause significant emotional distress, the process of observing participants and then interviewing them afterwards did cause nervousness in some participants, and some initially felt uncomfortable being interviewed. Participants were reassured that this was not a test, and that they could stop at any time. However, in the SSIs, some participants did feel uncomfortable discussing specific examples of practice, or specific colleagues, and recordings were stopped for breaks or when participants asked for discussions ‘off the record’. Whilst the topic itself did not cause obvious emotional distress, being interviewed for up to 60 minutes was uncomfortable for some participants and breaks were offered and recordings were paused.

5.9 Clinician as Researcher

Being a clinician researcher within the local NICU conferred several advantages with regards to having pre-established interviewer-participant trust. As an ‘insider’, the researcher had insight into some of the everyday workings of the NICU and had a pre-

established rapport, not being seen as an outsider. This is important, as it may have meant that participants not only felt able to respond honestly but also expected the researcher to act with integrity.

Many of the concerns regarding studying and observing colleagues have been outlined in section 5.4.2 However, there were some aspects of being a researcher in the same clinical environment that were more challenging; an example is unease at approaching staff during busy shifts due to an awareness of the workload demands placed on colleagues. There was some unease at having to interview senior colleagues such as consultants or Band 7 nurses, due to pre-existing professional relationships. The interviews that may have been more challenging took place later in the data collection period to allow a period of adjustment and familiarisation with the interview process. Further reflections on the clinician-researcher role, and its influence within this research, will be discussed in greater depth in Chapter 10.

5.10 Summary

This chapter has outlined the data collection methods used in this study, providing a justification for each method and its ability to answer the research questions. It has demonstrated how each method informed ongoing data collection in keeping with a mixed-methods approach.

The data collection methods were chosen in order to explore how the work is done, or enacted, through observations and audit, whilst also being able to explore beliefs and attitudes towards the care bundle and its implementation using survey methods and the retrospective interviews. This is important in order to understand the mechanisms underpinning healthcare professional behaviour, in the real world of clinical practice. Being able to explain both the how and the why are in keeping with an ethnographic design which underpins this study. Given that understanding culture underpins ethnographic research, observing how healthcare professionals enact the bundle and how they navigate both professional relationships and the environment, in order to implement the care bundle, is important. Monitoring of both outcome (CLABSI rates) and process (bundle adherence) was important in order to provide the necessary context in which to understand implementation.

The use of observation, retrospective interviews and survey methods also meant that a broad range of participants could be sampled. The survey was distributed to all eligible staff on the NICU, whilst a purposive sample of eligible participants could be observed and interviewed in depth in order to find explanatory mechanisms and identify any contradictory data. It was important that qualitative data analysis was inductive in order to

allow the study findings to be explanatory and derived from the data collected, rather than applying pre-determined ideas or concepts to the data. This is in keeping with an ethnographic approach where the end goal is to determine connections or relationships within the data to generate explanations for what is observed.

Chapter 6, Chapter 7, and Chapter 8 will present the results of the NoMAD survey, ORIs and SSIs, respectively, whilst Chapter 9 will put implementation into the context of the local NICU. This includes an exploration of the local context, CLABSI rates and bundle adherence rates and an analysis of both sets of qualitative data that provided additional insight into NICU culture.

Chapter 6 NoMAD Survey

6.1 Introduction

This chapter will discuss the results of the NoMAD survey, starting by describing the respondent characteristics. The raw data for survey one, two and three is provided in Appendix 25, Appendix 26, and Appendix 27 respectively.

6.2 Survey Respondents

Surveys were distributed once every four months between January 2018 and October 2018. The characteristics of the participants are presented in Table 17 as a percentage of total respondents. The total number of staff eligible to participant in the survey declined over the year due to a combination of maternity leave, no longer being in employment, long-term study leave, and sick leave. Whilst response rates declined over time, over a third of eligible staff completed the final survey.

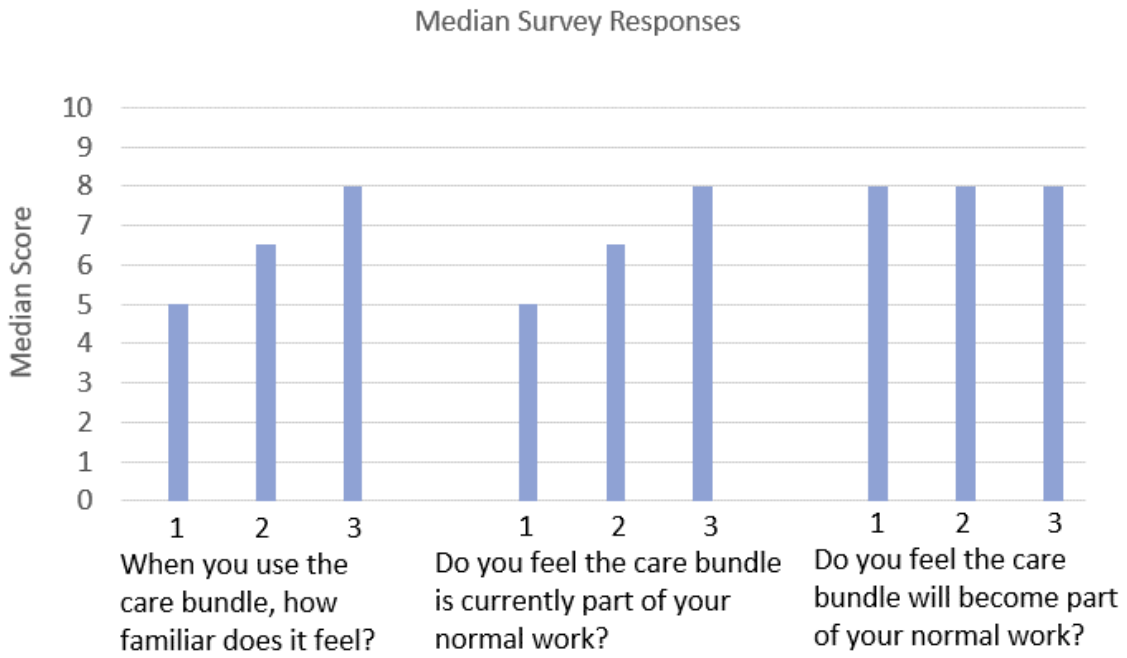
Table 17 Survey Participant Characteristics

Characteristics	**Survey 1 N (%)**	**Survey 2 N (%)**	**Survey 3 N (%)**
Total eligible	127	114	105
Total responses	90	64	45
Response rate (%)	71	56	43
Job role			
Consultant	4 (4)	4 (6)	3 (7)
MTI/Clinical Fellow	4 (4)	0	2 (4)
Nurse Band 8	3 (3)	3 (5)	3 (7)
Nurse Band 7	9 (10)	7 (11)	5 (11)
Nurse Band 6	24 (27)	24 (37)	16 (36)
Nurse Band 5	35 (39)	19 (30)	14 (31)
Nurse Band 4	11 (12)	6 (9)	2 (4)
Missing	N/A	1 (2)	N/A
Length of employment			
< 1 year	12 (13)	0	0
1-2 years	20 (22)	14 (22)	6 (13)
3-5 years	15 (17)	13 (20)	13 (29)
6-10 years	18 (20)	16 (25)	12 (27)
>10 years	25 (28)	21 (33)	14 (31)

6.3 Bundle Integration

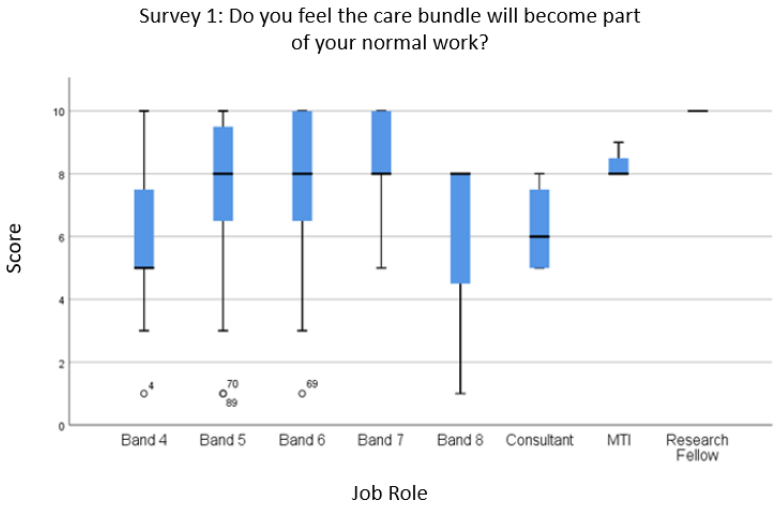
Part one of the survey assessed the extent to which participants felt the bundled practices were integrated into their normal work. Data were tested for normality using Shapiro-Wilks test and p-values were <0.02 meaning that the null hypothesis (the data is normally distributed) was rejected. Therefore, the median was used to best represent the data. As can be seen from Figure 11, median scores regarding the familiarity of the bundle, and the bundle being part of normal work, appeared to improve over time; by survey three the median score was 8. The bundle becoming part of normal work remained consistently at a median score of 8.

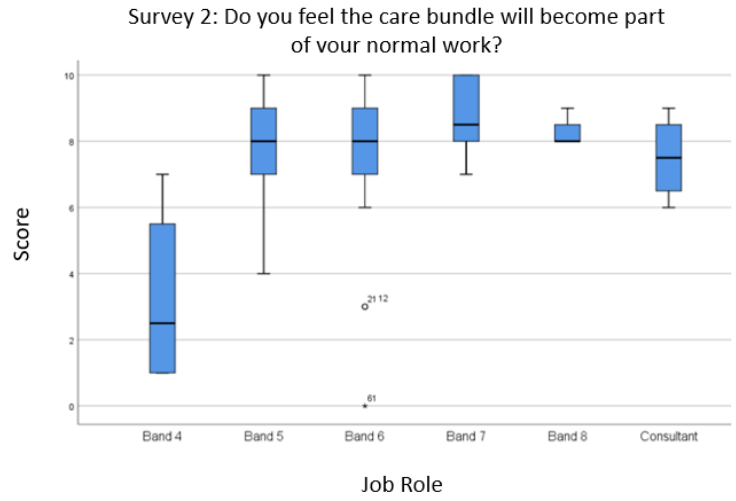
Figure 11 Median Integration Scores in Survey 1, 2 and 3

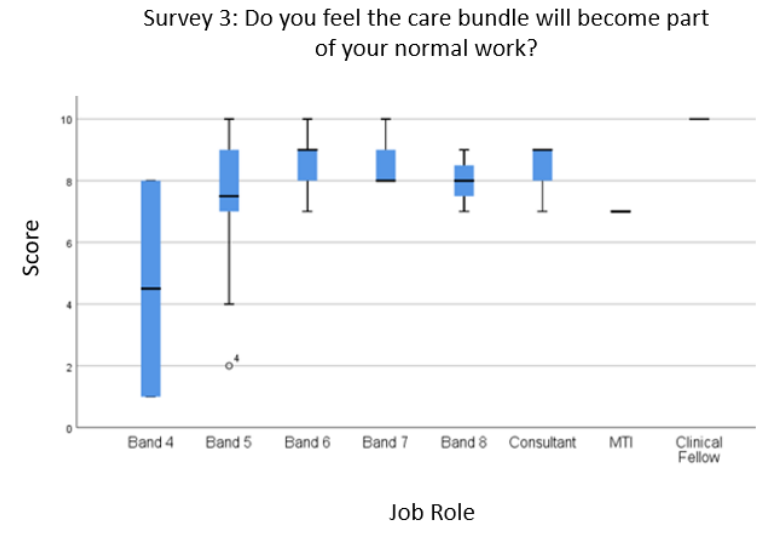


Responses were analysed according to job role and length of employment, with box and whisker plots used to visualise the spread of data between groups. There did not appear to be any differences when the data was analysed according to length of employment. Whilst there appeared to be differences by survey two and three in median scores to the question “do you feel the bundle will become part of your normal work?”, with Band 4 nurses appearing to score lower (see Figure 12), the declining response rate by survey three and the small numbers in some job role groups (Band 4, n=2) makes meaningful interpretation limited.

Figure 12 Box and Whisker Plot for Median Scores by Job Role







Legend: MTI= medical training initiative ◯ = outlier (1 to 3 times the interquartile range)

6.4 Bundle Implementation

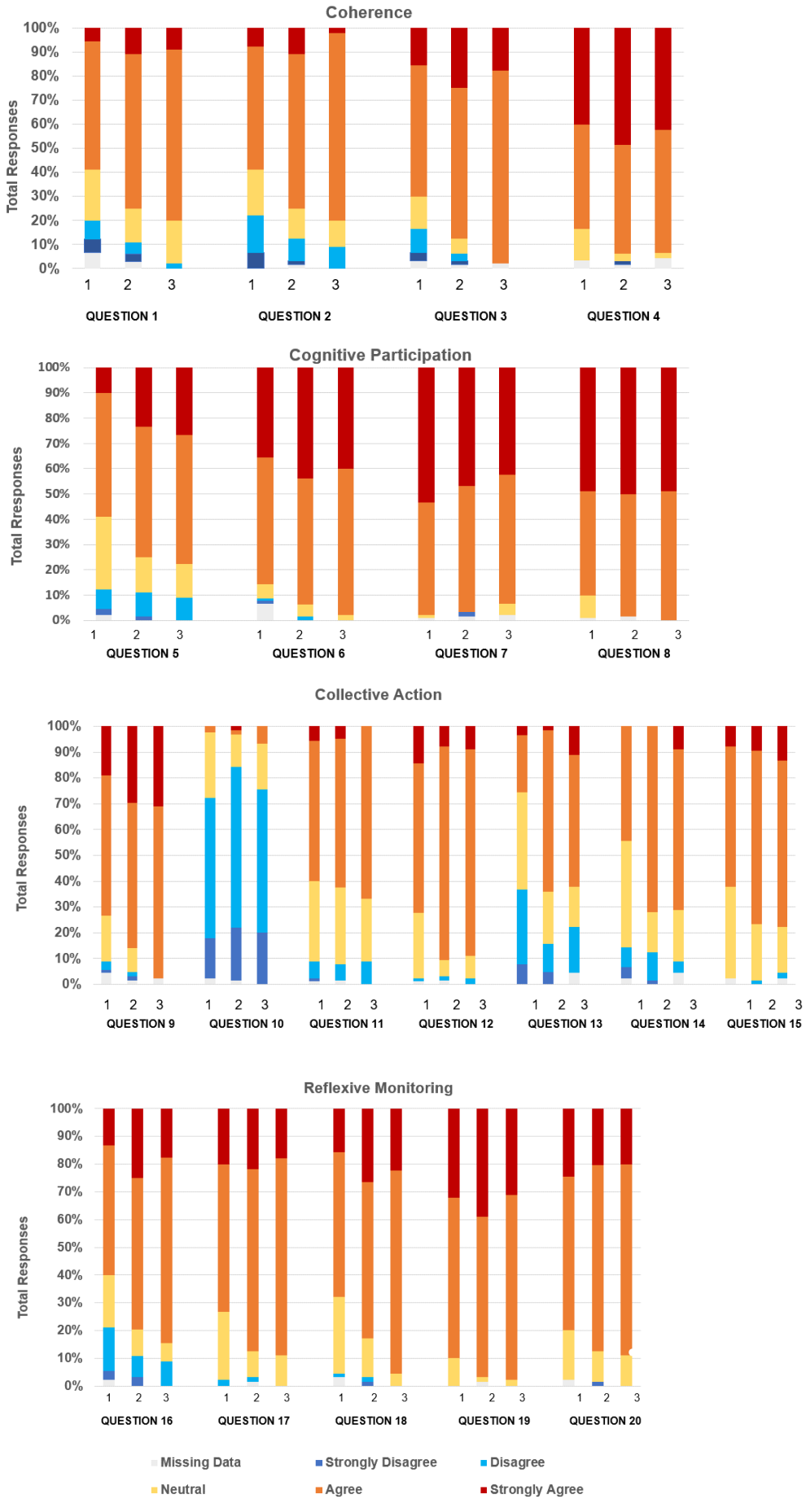
The results from question 1 to 20 of all three surveys are presented in Figure 13 as the percentage of respondents in each Likert scale category and are divided into the four constructs of NPT (Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring). In general, there were high numbers of agree or strongly agree responses for bundle implementation. However, whilst there was an increase in agree and strongly agree responses between survey one and two, there was little change between survey two and three.

For the coherence construct, the percentage of agree and strongly agree responses increased over each survey (questions 1 through 4). The percentage of agree and strongly agree responses increased from 59%, 59%, 70% and 83% (questions 1 through 4 respectively) to 80%, 80%, 98% and 93% by survey three. However, in general there was little additional change between survey two and three, suggesting that the greatest improvement in coherence regarding the care bundle occurred during surveys one and two. For example, in question one there was a 16 percentage points increase in agree or strongly agree responses between survey one and two, but only a 5 percentage points increase between survey two and three. Likewise agree or strongly agree responses to question 4 remained consistently at 93% between surveys two and three, with a slight reduction in responses of strongly agree.

Similar results were found for the construct of Cognitive Participation, where overall agreement improved across the three surveys but with little change in responses between survey two and 3. For example, 59% of respondents to survey one agreed or strongly agreed that there were key individuals promoting the bundle; this increased to 75% in survey two and 78% in survey three. By survey three, 100% of respondents agreed or strongly agreed to continue to support the bundle, and 98% of staff believed the bundle to be part of their role. Respondents were willing to work with colleagues in new ways, with 98% agreeing or strongly agreeing in survey one, reducing to 93% by survey three.

In general responses improved over time for the construct of Collective Action, but again, there were minimal changes between survey two and three. It should be noted that for question 10, regarding the disruption of working relationships, there was a larger proportion of disagree and strongly disagree responses compared to other questions. Whilst this is argued to promote implementation, the interpretation of this will be discussed in more detail in Chapter 10. There was very little change for question 11, with 67% of respondents agreeing that they have confidence in the abilities of others to use the bundled practices by survey three.

Figure 13 NoMAD Results for Survey 1, 2 and 3



Notable differences between surveys one and two were particularly evident for questions 13 and 14, with 25% of staff agreeing or strongly agreeing that there had been sufficient training in survey one compared to 64% in survey two; 44% of staff agreed there were sufficient resources in survey one which increased to 72% agreeing by survey two.

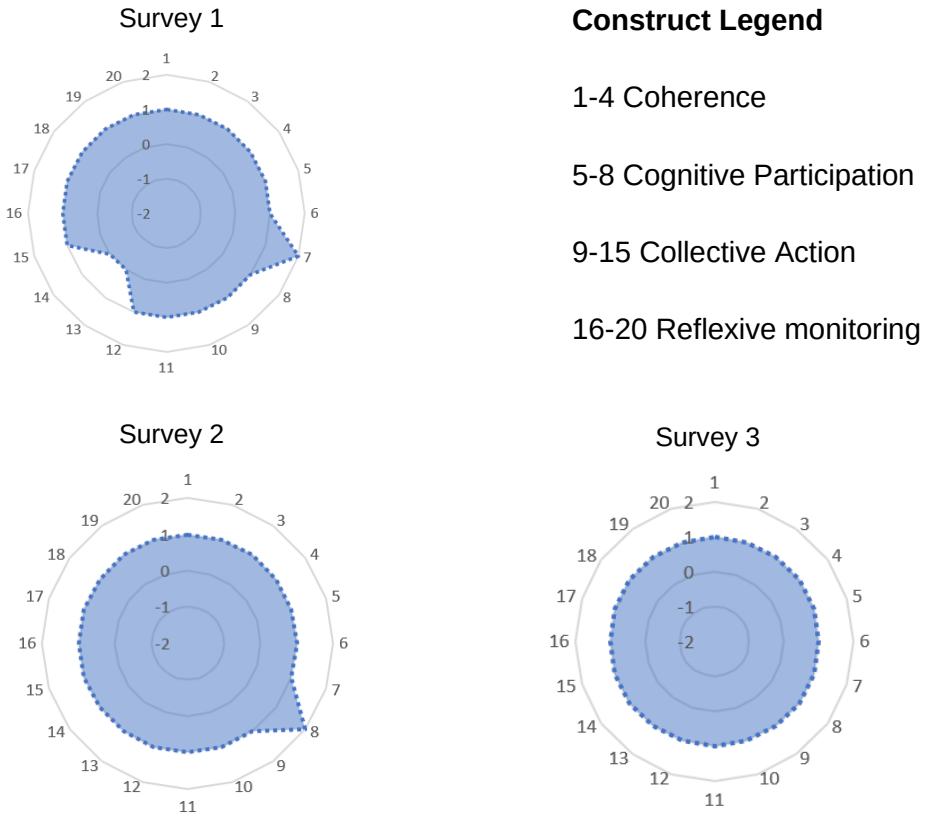
Finally, the construct of Reflexive Monitoring showed improvement in levels of agreement across all questions, but again there was less discernible difference between survey two and three. Staff on the whole appeared to value the effect of the bundle on their work as agree and strongly agree responses increased from 68% in survey one to 95% in survey three; awareness of the bundles impact on infection rates similarly increased from 61% in survey one to 85% by survey three. Respondents felt that feedback could be used to improve the bundle (98% agreed or strongly agreed by survey three) and they could change how they worked with the bundle (89% agreed or strongly agreed by survey three).

6.5 Construct Scores

Data were tested for normality using Shapiro-Wilks test; all p-values were <0.01, meaning that the null hypothesis was rejected. The median was used to best represent the spread of the data. Figure 14 represents median responses using radar plots, with question 10 (the care bundle disrupts working relationships) being reverse scored- that is, strongly disagree was scored as +2 rather than -2. This reflects that not disrupting working relationships is felt to promote normalisation, though this will be discussed futher in Chapter 10.

Overall the radar plots are generally full, with minor changes over time. The fuller the radar plot, the more normalised the practice could be argued to be. Median scores for question 13 (whether there is sufficient training) and 14 (whether there are sufficient resources) improved over time. However, by survey three, median scores for question 7 (being willing to work with others in new ways) and question 8 (continuing to support the bundle) had reduced.

Figure 14 Radar Plots



There were no apparent differences in median scores when data was reviewed by length of employment. Whilst there appeared to be differences in median scores between job roles for some questions, the small numbers in some professional groups particularly by survey three, and lack of statistical testing, makes meaningful interpretation of the data difficult.

6.6 Summary

This chapter has presented the results of the NoMAD survey. This found that whilst construct scores appeared to be positive with some improvement between surveys one and two, there were minimal changes in attitudes towards the bundle and median construct scores between surveys two and three. This was found across all four constructs of NPT.

Whilst the surveys were performed concurrently alongside the observational data collection, the results informed aspects of the observational data collection, providing additional underpinning knowledge regarding the phenomenon being observed- that is, implementation processes. For example, the survey results highlighted aspects of implementation that could be improved, such as having sufficient training and resources,

and also identified that not all respondents were aware of CLABSI rates. Understanding more about these aspects of implementation was therefore important to explore in the qualitative interviews. These results informed the development of the SSI prompts as well as informing the observational data collection and analysis. Links were made between the survey data and what was being observed, such as participants discussing being busy or that colleagues did not always perform procedures in the same way. The following chapter will explore the findings of the observations of practice with retrospective interviews.

Chapter 7 Observations of Practice with Retrospective Interviews

7.1 Introduction

This chapter will present the results of the observations of practice with retrospective interviews (ORIs). An overview of the observations, and how they were informed by the results from Chapter 1 will be provided, followed by the findings from the observations and then the results of the retrospective interviews.

7.2 Observations of Practice

In total 12 observations of practice with retrospective interviews (ORIs) were performed between January 2018 and January 2019. Six of these were observing the nursing process of changing central line infusions and six were observing central line insertions. Twelve pairs of participants were observed, with 22 unique participants interviewed; one Registrar had to leave after the task had been observed due to clinical need and one Registrar participated twice. It should be noted that no Band 7 Sisters were observed performing central line fluid changes, and no consultants were observed inserting central lines. This reflects the broad allocation of workload. This was taken into account when devising the sampling strategy for the SSIs to ensure the experiences of these staff were explored.

A description of the events sampled can be seen in Table 18. Observations took place in two ICU nurseries (ICU3 and ICU4) and one high-dependency nursery (HDU). Nursery 4 (ICU4) appeared to have limited space due to a dividing wall across the middle of the nursery, providing a physical barrier between cots one to four and five to eight. Only one fluid change was observed during a night shift; no emergency fluid changes were observed- that is, for a deteriorating patient. This is likely due to the fact that during these situations staff are primarily focused on the acute patient need, rather than contacting a researcher who was not always present.

Table 18 Description of ORIs

	Participants	Event	Location	Timing	Description
1	Band 7, Band 5	PN	HDU	Afternoon	Term, Open cot, Stable
2	Band 6, Band 6	PN & Infusions	ICU 4	Night	ELBW, CPAP, Incubator Stable
3	Band 5, Band 6	PN & Infusions	ICU 4	Afternoon	ELBW, CPAP, Incubator, Stable
4	Band 6, Band 6	Infusions	ICU 4	Evening	Ex-preterm, Ventilated, Incubator Stable
5	Band 5, Band 6	Infusions	ICU 4	Afternoon	VLBW, Ventilated, post-surgery Sick but stable
6	SPR, MTI	Central line insertion	ICU 4	Afternoon	Term, SVIA, Open Cot, Stable No checklist used
7	SpR, MTI	Central line insertion	ICU 4	Afternoon	ELBW, Ventilated, Incubator Fragile, no checklist used
8	Band 5, Band 5	Infusions	ICU 3	Evening	Term, CPAP, Open Cot, Stable
9	SPR, MTI	Central line insertion	ICU 3	Afternoon	ELBW, CPAP, Incubator, Stable No checklist used
10	SpR, SHO	Central line insertion	ICU 4	Evening	ELBW, Ventilated, Incubator Fragile but stable, no checklist used
11	SpR, MTI	Central line insertion	ICU 3	Evening	ELBW, HHHFNC, Incubator, Stable, no checklist used
12	ANNP, ANNP	Central line insertion	ICU 4	Afternoon	ELBW, Ventilated, Incubator, Stable, no checklist used

PN=Parenteral Nutrition, HDU=High-dependency unit, ICU=Intensive Care Unit, ELBW=Extremely Low Birth Weight <1000g, CPAP= Continuous Positive Airway Pressure, VLBW= Very Low Birth Weight <1500g, SPR=Speciality Registrar, MTI= Medical Training Initiative, HHHFNC= Heated Humidified High Flow Nasal Cannula

Whilst the surveys and ORI data were collected over 12 months in 2018, the results from survey one identified beliefs about training, resources, and feedback as potential weaker aspects of implementation processes; it also found that some staff did not understand how the new practices were different from previous ways of working. It was important that there was an awareness of these findings in the observations, but that the observations remained unstructured, with the researcher keeping an open mind regarding other potentially other important influences. Both the survey results and the findings from the observations helped identify potential prompts for the retrospective interviews, in reality these were rarely needed, as participants naturally discussed similar influences.

After five ORIs of each process, it became clear that participants were discussing the same or similar concepts, challenges, or concerns regarding practice. The observational data was increasingly repetitive, observing the same challenges and raising the same concepts for exploration in interviews. Whilst individual 'codes' may have been new (as it could be argued to be impossible to expect no new ideas to be found), the overall themes and broader concepts, such as role allocation, were repeatedly discussed. At the point at which similar concepts were being found, one further observation was performed and then sampling stopped.

7.2.1 **Results**

The observations of practice revealed key insights into the performance of central line insertion and central line fluid changes. Once observations had been performed, they were typed into an electronic version, an example of which can be found in Appendix 14. Key findings were then compiled into a table, where cross-references could be made with the interviews and patterns identified, see Appendix 23. Reflections on the process were also incorporated to allow comparisons between both participant and researcher observations. It became apparent that these tasks, commonplace in the NICU, were complex and, particularly for central line insertions, cognitively demanding. The following concepts were common themes across the observations, though there were often notable differences between professional groups:

- Routines and habits
- Roles and responsibilities
- Checking together
- Navigating the environment
- Resources

Each one of these will now be briefly explored with examples from the observations.

- **Routines & habits**

The nursing processes appeared to be part of everyday nursing routines compared to line insertions which appeared to involve more uncertainty and appeared to be more stressful for participants. Whilst all participants were anxious about being observed, the central line fluid changes were performed in a repetitive, routine manner; participants seemed familiar with the process and it appeared they had a shared mental model of how to enact it. The process of cleaning the trolley, whilst one participant washed their hands, dried and gelled them, was consistent across all observations. In addition, the way in which the assistant put an apron on the second participant appeared ceremonial. Participants did not need to talk through the process; instead, communication would frequently be about other work-related issues or have a social element.

Central line insertions, in contrast, were less routine and were associated with a greater degree of uncertainty for participants. One participant asked the researcher directly, “am I supposed to get a second person?” (ORI7); another asked if normal hand towels were used to dry hands after performing a surgical hand scrub (ORI11). At the end of a particularly difficult central line insertion, the participants asked, “what would you have done?” (ORI11) in relation to the choice of line used and securing the line. Generally, participants communicated more explicitly with each other, asking questions and problem solving together. Even the aseptic hand washing, gloving and gowning appeared less familiar to those inserting lines in contrast to the repetitive routine nature of the nursing process. An exception was the ANNPs observed in ORI12; they appeared familiar with organising and preparing equipment.

There was one habit that was only apparent from observations that participants did not discuss in the interviews. This was the practice of preparing a syringe of diluted morphine which was then kept for other colleagues to use (ORI 4, 5). In one observation, after preparing the diluted morphine, one participant asked the room, “does anyone else need morphine?” (ORI5). Whilst dilution is necessary due to the small doses of morphine required in the neonatal setting, this may compromise the aseptic process as well as being inappropriate for the storage of controlled drugs. This is an example of a normalised poor practice. In combination with the language used by participants during recruitment (see Appendix 28) and in interviews, such as “uncontrolled” fluid changes, “we know we shouldn’t”, or “sometimes you just have to”, suggested that there were circumstances where it was acceptable to perform practices differently or against what they believed to be best practice. These will be discussed in detail in Chapter 9. Dealing with observing poor practice will be discussed in detail in section 7.2.2.

- **Roles and Responsibilities**

It was apparent that the nursing role not only was well-rehearsed but also had clearly identifiable roles with clear responsibilities. Nurses would pick and choose which role to perform, casually negotiating within the pair which role they would take. This was at odds with an unwritten rule that the nurse connecting the lines- the 'clean nurse'- should be the one who is caring for the patient so that they can identify all the patient lines. The 'clean' nurse and the 'dirty' (assistant) nurse roles were referred to frequently, and once allocated, each nurse appeared to know what their responsibilities were without instruction. There was some variation between pairs as to whose role it was to apply and remove the AIPPs.

The role of the assistant in central line insertions was invariably that of a sterile assistant, except in one observation where the second person comforted the patient underneath the sterile gowns. If there was a difference in experience level between participants, then the more senior one usually assumed the assistant role. If participants perceived each other to be at similar experience levels, there would be a negotiation regarding who wanted to insert the line. Conversations centred around who wanted the opportunity or whose patient it was.

Participants would assign roles throughout the procedure, trying to navigate who would do what as well as providing suggestions or alternative ways of doing things. In some observations two people appeared to be a hinderance, with four hands trying to apply a dressing to the foot of a 680g baby. In other observations, a third person was required to help comfort the patient. The roles were sometimes unclear, and it was not clear who, if anyone, was responsible for monitoring and comforting the patient or monitoring asepsis. Both participants were usually cognitively engaged in what was clearly a complex (and stressful) task.

Nurses did not appear to take a role in the central line insertions, and the insertion checklist was not observed being used.

- **Checking together**

Throughout both processes, participants frequently checked with each other. Nurses reminded each other of what could and could not be touched and appeared to informally monitor each other's practice ("oh no, you don't touch that bit […] that's dirty, I can't touch that now" ORI5). They double-checked with each other which infusions attached to which ports, drug doses and what equipment they needed. Participants were problem solving together *in action*-for example, in making decisions about the need for needlefree extension sets or needleless connectors. Problems were solved through discussion and

talking through the problem with each other, often in relation to determining where to attach the infusions and if there were enough spare ports (“you have two spare ports”,“ok, let’s do two”, “does that work?”, “what shall we do next?” “are you happy that’s 0.4?” ORI2, ORI5).

Central line insertions also required participants to problem solve *in action*, and it appeared that participants learnt together whilst they were performing the task. Pairs frequently sought reassurance from each other regarding what they should do. In one observation a new doctor was also observing the participants; in another, the Registrar felt inexperienced and wanted to insert the line, yet in the next observation she undertook the role of the second person as supervisor. This raised an important point regarding how the skills were learnt and taught, and this was further explored in both the retrospective interview and the semi-structured interviews.

Nurses checked drug prescriptions against the local formulary, which was used for checking dilutions and infusion compatibilities. No visual aids or reminders were referred to if there were uncertainties such as regarding the allocation of roles, handling of parenteral nutrition (PN) or re-using medication vials during the aseptic process, or who applies and removes the AIPPs.

This was also the case for insertions, as participants sought guidance from each other, problem solved together or, in some cases, asked the researcher. The process of inserting a central line appeared to be a cognitively complex task, which demanded high levels of concentration and focus from both participants. In one observation a consultant checked to see how the procedure was going, and other medical colleagues came and offered help in settling the patient, though this was infrequently observed.

- **Navigating the environment**

The environments observed were frequently busy and noisy, with lots of alarms and multiple teams performing different tasks. Nursery 4 saw the greatest shortage of space, particularly when more than one sterile field was in use. Nurses would frequently take the fluids off the sterile trolley and carry them over to the patient incubator or cotside, navigating other equipment that provided physical obstacles. This was similar to doctors performing a surgical handwash and then walking across the room to get to the sterile hand towel, gowns and gloves.

What was striking across all the observations was the volume of traffic in and out of the nurseries and past the sterile fields being used. This included the movement of parents, visitors and staff throughout the clinical area. During one observation, nursing staff were moving a patient in an incubator past the participants inserting the central line and the

sterile field, knocking the lamp being used and the corner of aseptic trolley. In another observation, other sterile procedures were being performed in another part of the nursery, making space around the sterile field a challenge. It was unclear how the different aspects of central line care were co-ordinated between the different teams involved. This may have taken place before the researcher started the observation, though the nurses would check with each other before starting if other tasks needing completing.

- **Resources**

Observations revealed that both nursing and medical staff frequently had to leave the nursery to go and gather additional resources. Gathering and preparing equipment for both procedures took time. Resources, such as surgical hand scrub for line insertions or the correct giving sets, were not always readily available or visible.

There were frequently competing demands on staff performing central line processes. Interruptions included the need to attend to other babies in the nursery who were desaturating, or handling parents arriving or colleagues asking questions. Nurses had to monitor their patients, address monitor alarms and reallocate aspects of their patients' care to other staff, such as observations or feeds. Colleagues would ask participants (across both professions) questions during procedures and provide clinical patient information. For example, during one observation, the assistant in a central line insertion was shown a patient's blood gas.

7.2.2 Dealing with Poor Practice

For the most part participants recalled examples of poor practice in interviews; incidences of poor practice were not frequently observed. However, there were three incidences that are worth noting in this section. One was the use of a pre-diluted syringe of morphine that had been prepared by other staff and kept in an unlocked fridge for other staff to use at a later date. This was escalated to the matron, in confidence, with no participants identified. This is because this was identified as a cultural practice; professional conversations with staff identified that this practice had been occurring for many years. This raised concerns regarding the (un) safe storage and administration of a controlled drug as well as the reusing of medications for a sterile procedure. Another incident observed was the unsafe removal of a central line guidewire, and the third was an inappropriate central line dressing applied after insertion. These occurred in the same observation, where the procedure was being performed by two senior Registrars. This was rectified by the researcher at the time, due to concerns that the technique used may injure the participant or damage the integrity of the line. The central line dressing was escalated by the bedside

nurse to the on-duty consultant, who promptly redressed the central line, as it was not fully secured nor appropriately covered.

7.3 Retrospective Interviews

Following the observations of practice, retrospective interviews were performed with pairs of participants. These were performed either immediately after the observation had been completed or within 15 minutes of it ending. One participant had to go out on an emergency transfer and so was not interviewed, resulting in 23 participants being interviewed. However, one participant was observed twice, so 22 unique participants were interviewed. All interviews took place in a quiet room on the NICU but away from the clinical area, with measures taken to ensure that patient care was not compromised during this time.

Whilst it could be argued that there may be hierarchical or power influences between participants as well as between the participants and the researcher, this was not apparent in the interviews. Even in the pilot, where a Band 5 nurse was interviewed with a senior Band 7, the Band 5 nurse was still able to question suggestions made by the Band 7. In addition, any challenges with power dynamics between participants are likely to reflect the same dynamics that would occur in the nurseries and therefore would be an important finding in itself.

It was important to note the use of language during the interviews and on listening to the recordings in order to capture any turns of phrase or hidden meanings. For example, one participant said “and we left the Curos Cap on for one minute” (ORI3) but when listening to the audio and reading the field notes, it was clear that the intonation suggested that this was a question. These were then added to transcripts as memos to aid data analysis.

7.4 Themes

Eleven themes were developed from the data; these are outlined in Table 19. These were categorised into nine influences at *individual*, *team*, *patient* and *organisational* levels. In addition, two themes spanned these nine main themes. These were considered to be *situational influences*-that is, in any given situation the presence of these factors may influence implementation differently. These will be explored first and then signposted where appropriate.

Table 19 Themes from Observations with Retrospective Interviews

Categories	**Description**	**Themes**	**Situational Influences**	
Individual Influences	Individual attitudes, beliefs and values about the bundled practices	Bundle Endorsement Seeking Reinforcement Reconfiguring Prior Knowledge	Degree of Experience	Degree of Uncertainty
Team and Unit-Level Influences	Issues at the team or unit level that influence how the task is enacted	Division of Labour Surveillance and Monitoring Learning and Supervising		
Patient Factors	Patient factors that influence how the task is enacted	Unavoidable Exceptions		
Organisational Influences	Wider organisational issues that influence how the task is enacted	Resources Environment		

7.5 Situational Influences

7.5.1 Degree of Experience

The amount of experience that participants perceived others to have was frequently referred to as influencing how practices were performed. This perception of a colleague's abilities to perform the task was a thread that spanned several other themes, such as the degree to which participants endorsed the new practices (see section 7.6.1), how the practice was learnt (see section 7.7.3) and how the practice was monitored (see section 7.7.2).

Nursing participants felt that new staff, or those they perceived to be less experienced with accessing central lines, should perform the task with someone experienced to learn the process, otherwise it is "the blind leading the blind" (ORI4, NURS0612); they would frequently advise new staff to take their time. This resonated with the insertion observations, in which even doctors who were supervising less experienced doctors did not appear confident in their own abilities:

> So, that's why I'm always keen to use the opportunity to learn from other people at the same time and see whether they do things in the same way as me as well because, you know, without having had really senior teaching I never know whether what I do is completely right […] Yeah I think I'll be asking my seniors or a Consultant in the first place, you know, how the thing should be done an ideal situation, yeah, because I don't think I'm in the position to teach somebody.
>
> **ORI11, DOC09**

Conversely, one ANNP also felt that as she and her colleague were both experienced in inserting lines, she wasn't sure that anyone else could help them. To some extent, the perception of experience may also influence the degree to which staff ask others for help. This was also the case for a junior doctor who felt that someone more experienced than himself probably wouldn't need help from a second person (ORI10, DOC12). The degree to which participants bought into the role of a second person will be explored in section 7.6.1.

Working with colleagues who were perceived to be less experienced, frequently referred to as new or junior, impacted the way in which practice was monitored. For example, an ANNP recognised that she did not monitor her ANNP colleagues' practice in the same way as if she was working with junior doctor, because her colleague is "quite experienced" (ORI12, NURS0803). One junior doctor recognised that an awareness of the risks of contamination comes with experience:

> I think the more experience you have, the more aware you are of that potential risk happening, and maybe the first few times of doing a procedure you are very tasked focused, but just making sure that you look for any other sort of obstacles that you might have with doors of incubators and the surface and things like that.
>
> **ORI6, DOC06**

This again resonates with ORI11 in which the pair were both cognitively engaged in the task and did not notice that equipment had fallen off the sterile field. In addition, both medical and nursing participants believed that those who are less experienced may not feel able to challenge others.

Working with someone less experienced was also felt to alter the way in which central line processes were performed. One ANNP recognised that if she is working with someone junior, she may change the insertion technique she would choose, whilst nurses recognised that the process took longer if working with someone less experienced. This was believed, by some participants, to add to workload demands. One participant felt that

it was important not to rush the procedure when working with new or junior staff, and that colleagues may avoid performing the task with someone newly qualified:

> I think we could be better sometimes in being prepared – like I said about it not having to be a rush, being prepared for a newly qualified or if they've signed up to do… I have seen on occasion people not keen to do it because they'd rather do it with someone who knows what they're doing.
>
> **ORI4, NURS0612**

The level of perceived experience was also felt to influence the extent to which the work was allocated. For example, the allocation of clean and assistant roles between nurses may depend on the experience or learning needs of those involved; this was similar for central line insertions where the allocation of roles sometimes depended on who wanted the experience. Teaching less experienced colleagues was felt to be more challenging when there were less staff and increased workloads, as colleagues may prefer to do the procedure with a colleague who is experienced.

7.5.2 Degree of Uncertainty

Participants had to frequently balance competing risks and choose between competing rules, resulting in uncertainty. Situations in which this occurred for nurses included balancing the risk of having to 'break the line' (disconnect infusions) in order to administer additional drugs or infusions, versus attaching needleless extension sets that present a risk for infection. Predicting deterioration, or if a patient would need additional infusions in the following 24 hours, influenced the decision to attach a needlefree extension set to the central line versus having to 'break' the line later on:

> I think different people's judgements will go different ways and [pause] I think some people's answer would be oh let's put one on just in case.
>
> **ORI3, NURS0610**

This was an area in which nurses had to use their clinical judgement regarding patient stability, with some participants recognising that personal preference was also an influence. Some nurses had strong opinions ("I'm always like, Octopus!"[3] ORI8, NURS0515). It should be noted that local recommendations (see Appendix 5, page 249-250) advise both minimising needlefree extension sets and avoiding breaking the line. This uncertainty sometimes resulted in tension between teams. For example, some found

[3] Participants commonly refer to needleless extension sets using the manufacturer term 'Octopus'.

it frustrating when nurses on the previous shift had not left a spare port on the central line to allow the attachment of additional infusions.

For the medics, uncertainty was primarily related to central line dressings, though the most effective way to clean the patient's skin was also identified as an area of uncertainty. The management of central line dressings was a gap unaddressed by the bundle. Participants described balancing the risk of a bloodstained dressing or a peeling dressing causing an infection, against the risk of potentially dislodging the line during redressing:

> I guess, there's a risk that you'll then lose the line somehow, or there's a risk that you'll cause more contamination by taking all the dressings down, putting it up and weighing that risk against the risk of having some blood underneath. I'm not sure how, I don't think I have a way in my head of making that calculation but I suppose those are the things that I'm thinking about in that process.
>
> **ORI7, DOC08**

This uncertainty may result in the variations participants recalled experiencing in practice, which may create tension between teams.

7.6 Individual Influences

Three key themes were categorised as influences on implementation at an individual level. These were related to the beliefs, attitudes and knowledge of individuals.

7.6.1 Bundle Endorsement

Participants identified a variety of factors that contributed to the degree of buy-in for the bundle.

Beliefs about bundle utility

In general, participants felt that the new practices were useful and appropriate. The practice of accessing central lines using Surgical ANTT and the adoption of the AIPPs were overwhelmingly supported by nurses who felt that these addressed an aspect of practice that they perceived to have been poorly performed in the past. The previous practice of using standard ANTT was compared to how peripheral cannulas are accessed (ORI 2, 3, 4, 5) and having a different way of accessing a central line was believed to be appropriate. One senior nurse, however, could see the opposing view; that all intravascular lines are entering the bloodstream and therefore should be treated the same:

> I've heard various discussions and various arguments, various ways round. Taking the original argument as to why we went from aseptic to non-touch then poses the argument why do we not use a proper aseptic technique with cannulas? And the original discussion was these are all going into babies' blood system, bloodstream, why is one more important than another? And that's why we stopped treating long lines and central lines differently to cannulas.
>
> **ORI3, NURS0610**

Nurses generally believed that Surgical ANTT was beneficial as it provided a clear, standardised process making it easier to show junior or new staff 'the way we do it here'. In fact, even though one participant questioned why the sterile hand towel was not used, and why hands were gelled after washing them, she still enacted it the same way. Similarly, one participant referred to being "clean in inverted commas", using her hands to represent quotation marks, suggesting that she did not fully buy into this concept yet still enacted (ORI12, NURS0603).

Participants could recall aspects of poor practice using standard ANTT commonly in reference to enacting 'scrubbing the hub' technique. This was felt to be subject to individual variation and nurses liked that the AIPPs addressed that, making their daily work easier:

> I like the Curos caps because you've always got it covered so you know that when you take it off, it's clean, ready to go, you're reducing the risk of somebody being impatient and not cleaning them for long enough or not drying for long enough.
>
> **ORI5, NURS0607**

However, beliefs about the usefulness of a two-person insertion technique were less consistent. Whilst the majority of junior doctors supported this technique, feeling that it was difficult to maintain asepsis when working alone, those more experienced in insertion believed it was possible to perform the task alone and some felt that it may not be appropriate for more experienced colleagues. A Registrar explained how he struggled to see how an assistant could be useful, reflecting after the observation that there were lots of ways the assistant could have helped (ORI7, DOC08). There appeared to be less of a perceived need for the two-person insertion compared to Surgical ANNT and AIPPs.

Participants felt that a second person was useful for a variety of reasons, not just for maintaining asepsis, but also for stabilising the limb, comforting the patient, and increasing the chances of success. Some participants believed that there were specific aspects of the procedure where a second person was useful, but that it was not necessary

for the whole duration, such as for venepuncture and securing the line. One ANNP believed that having multiple attempts was a key factor for infection, and that this could be reduced by having a second person. Whilst this individual was experienced at enacting the task alone, they showed buy-in for the new practices as they believed it would improve patient care and address a perceived problem. Conversely, participants could identify times when they felt it was acceptable to not have a second person, with one ANNP explaining that it could be performed alone on paralysed and sedated babies, or very small preterm babies.

Overall, the new practices appeared to be acceptable across both professions, as participants identified key moments in the processes that had a higher risk of contamination, believing that interventions that reduced these risks were appropriate.

Beliefs about achievability

How achievable an intervention is perceived to be is likely to impact the degree to which new practices are endorsed. Nurses appeared to have fully adopted Surgical ANTT and AIPPs despite the fact that in the beginning they felt it took them longer to do and required significant resource mobilisation. Most felt the process was not difficult, just ‘fiddly’, particularly in an incubator (ORI2). Nurses believed that Surgical ANNT and AIPPs were both useful and achievable, and so an effort was made to embed them into their everyday routines.

Those inserting central lines held varying beliefs regarding achievability, as some participants believed it was not always possible to have a second person due to staffing or workload demands. This will be discussed further in section 7.9.1. Whilst it was sometimes hard to find two people who were free, two ANNPs felt that they “always manage it but sometimes it gets quite late in the day” (ORI12, NURS0801). The requirement to have a second person potentially influenced how other tasks were organised, not only in having to source a second person but also in the fact that it may delay the procedure.

Participants performing central line insertions frequently described what they did as being good enough or that there was no other way, suggesting that sometimes practice is acceptable but not ideal (ORI7, ORI9). One Registrar said that “when it comes to the nitty gritty, its whatever gets the line in to be honest” (ORI9, DOC09). There was an acceptance that sometimes the ‘gold standard’ was not always achievable, and this was referred to for maintaining asepsis through incubator portholes (“I don’t know how you can realistically prevent that” ORI7, DOC08) and whilst changing a central line dressing (“it’s never really sterile” ORI6, DOC02). This was also a similar regarding securing the line with a dressing after insertion; whilst the ‘gold standard’ is that the entry site is visible and

the dressing is clean and dry, participants didn't feel this was always achievable. They recalled circumstances where colleagues in urgent situations might "just put a dressing on and go" (ORI6, DOC06) or where they tried to avoid dressing the line in a certain way but then "you just have to" (ORI9, DOC09).

7.6.2 Seeking Reinforcement

Participants frequently sought reinforcement. There was a strong sense that participants wanted to do the right thing but that there was uncertainty as to what this was. This led to some participants questioning their own competence:

> So, then we got to the part that I would probably a bit…I always feel a little bit unsure about, which is how to clean the limb and at the same time, keep yourself sterile. Because I always find that tricky, sort of, conceptually, to work out how to do that […] I don't know if I'm allowed to ask this, DOC10, did you think there was a different way that could've been done? Have you seen it done in a different way that you think could've been better?
>
> **ORI7, DOC08**

Both professions wanted to make sure they were enacting practices in the right way and all participants were aware of the potential consequences of poor practice- that is, causing contamination or infection. Participants sought to try and gauge if what they were doing was effective; they sought reinforcement that the current practices were effective through NICU infection rates. Two nurses wanted to know the impact of AIPPs on the unit's infection rates before deciding if they were a "good thing" (ORI3, NURS0615); when comparing different practices relating to changing bloodstained dressings, a doctor felt that:

> And you know it is all about what works. If there hasn't been report of infection of that process so why should we want to tamper with that process?
>
> **ORI7, DOC10**

Medical staff in particular could recall times where they thought "oh my god, I'm going to infect this baby" (DOC10) or had "cortical scars that stay with you" (DOC08). One registrar elaborated that no one had ever told her that a line she had put in had ever had infection, though she had had worried about it. Nursing processes were not accompanied by the same degree of negative reinforcement. Whilst nurses were aware of the potential to cause infection through the process, they did not have the same emotional connection to the task, potentially because it was a routine and familiar task. In addition, central line insertions were either successful or not and so there was immediate reinforcement on

performance. The importance of reinforcement was summarised by an experienced Registrar, explaining:

> I have never heard of the long lines that I have done having any sort of secondary infection with whatever precautions I have been– I wouldn't necessarily change practice, unless someone actually came and told me that the line that you put in had this problem or whatever, something went wrong.
>
> **ORI6, DOC02**

This suggests that individuals may not alter their behaviour unless there is specific and individualised feedback on a line that they have inserted.

Participants could recall past experiences, often negative, that influenced implementation. One medic could recall a situation where a baby "nearly suffocated" (ORI 11, DOC05) beneath sterile drapes; he now makes sure he concentrates on the monitor. Past experiences may act as strong moderators of behaviour, for example, one registrar referred to the way in which he primes lines before insertion, which has 'never introduced air before, so I feel that is an ok thing to do' (ORI 7, DOC08). One doctor recalled a delay in reviewing a central line dressing resulting in line dislodgement, which changed her behaviour; another recalled a procedure that took a long time, and she worried about the possibility of infection. In the absence of formalised reinforcement, experiences like this, in conjunction with specific contextual influences (see Chapter 9) may result in speed being seen as a marker for success. Participants frequently praised each other for inserting a line quickly, serving as further positive reinforcement. Nurses did not refer to past experiences in the same way, though some nurses could recall examples of poor practice such as ineffective scrubbing of the hub. One nurse admitted struggling to remember how she used to perform the task, demonstrating one of the problems with past experiences as modifiers of behaviour; ease of recall and recency may mean that these effects can fade suggesting continual reinforcement may be necessary.

Participants were able to identify aspects of practice that they were uncertain about, often areas not specifically addressed by the bundle; this led to staff having to make individual judgements. In addition, some rules such as how to handle TPN bags (are they sterile or not) have changed, resulting in more confusion between nurses. The lack of certainty also resulted in participants questioning their own competence. Some framed their behaviours as a question ("and we left it there…for 30 seconds? One minute? It was a long time anyway" ORI2, NURS0607) and recognised that some practices they had done before may not have been right:

> So for example I didn't used to get this red thing, I didn't know about that today, only I came to know there is something called red stuff to scrub also. So last time […] That's Chlorhexidine, yeah, so the first time we did it was like we just used that soap…
>
> **ORI11, DOC05**

Uncertainties identified by participants included the cleaning and reuse of medication vials, the use of needlefree extension sets, and how to redress central lines. There were also some practices that were explicit in the bundle, such as the appropriate hand scrub, that some participants were unaware of and had learnt incorrect ways to do things from others (see section 7.7.3). In addition, participants commented on seeing colleagues perform processes differently, both within and between professions, making them question their own competence further:

> …because I thought, at the time, thought in my head, "Oh I don't do it that way" or it makes you question, "Oh is that how it's meant to be done?"
>
> **ORI8, NURS0511**

In particular, nurses questioned how they should handle bags of PN, whether they were sterile or clean. One pair referred to the 'rules' regarding this changing which has resulted in confusion and difference in expectations between colleagues (ORI8). Nurses recall seeing medics not accessing central lines in the same way that they do, seemingly undoing their hard work. Having different practices for different professions is likely to contribute to professional tensions and may contribute to some staff not consistently adopting the bundle. The data suggests that length of service on the unit seemed to be related to the need for reinforcement: a registrar who had worked on the unit for more than two years and both ANNPs sought less reinforcement regarding their practice.

7.6.3 Reconfiguring Prior Knowledge

Some participants referred to needing to 'unlearn' how they had previously performed the procedure in order to adopt the bundle. Participants referred to new staff from other clinical areas and healthcare systems who have learnt different ways of performing the task. One doctor referred to having to "unlearn what I have learned there and to learn new things" (ORI9, DOC05). One MTI doctor recognised that:

> So, from my perspective it was a little different because again new unit, new country, new way of working here so, you know, I didn't want to falter […]
>
> **ORI11, DOC07**

Some staff may be more willing to do this than others, and the degree to which this influences bundle adoption will depend on the individual. For example, a Registrar who is used to performing the task alone in other clinical areas commented that he will need to consider how to reconfigure his behaviour to incorporate a second person:

> So that's probably something that I need to reflect on from this really and think about how to use that second person if that's something we're going to do routinely.
>
> **ORI7, DOC08**

This also suggests that this was not currently part of routine practice, despite the observed practices all having two participants. It may be hard to reconfigure prior knowledge if there is limited endorsement for the bundle and no formal reinforcement. For nurses it was felt that it did not take long to adapt to the way of accessing lines in this NICU. The changing of central line fluids is part of the everyday work of nurses. One participant recalled her experience of having to reconfigure her previous ways of enacting the task and that despite not all of the process making sense to her, she still performs the task according to local guidance:

> But, I don't know if this is relevant or not, but I have noticed that you access central lines a lot more freely and a lot … probably more times a day than what I'm used to.[…] Yeah, see the thing is you've all knocked it out of me, I've been from [another Trust] for too long, but I don't remember what we used to do.
>
> **ORI2, NURS0604**

It is worth noting that this participant also recalled questioning "why are you doing morphine for every baby?" when she first started on the NICU, corroborating this as normative way of working in this particular NICU. It should be noted that local guidance highlights the importance of minimising accessing lines, though how this should be implemented in practice is not made explicit (see Appendix 5).

7.7 Team Influences

This section will explore the way in which healthcare professionals worked together, in teams on the NICU to implement, enact and adopt new practices.

7.7.1 Division of Labour

The way in which the work was divided both within and between different professional groups, influenced the way in which bundled practices were implemented. Having clearly

allocated roles and responsibilities appeared to promote the implementation of Surgical ANTT and AIPPs, whereas there appeared to be a lack of clarity on the roles of the second person for central line insertion. For the nurses, having clear roles meant that there appeared to be a shared mental model about how the practice should be enacted, which made monitoring each other's practice easier as they "do not need to watch intently" (ORI3, NURS0610). This supports the observations in which the nursing participants frequently performed the task without the need for instruction.

There was, however, a lack of consensus regarding who was responsible for handling the AIPP, though most participants believed that it was the assistant's role. Dividing the labour into 'clean' and 'dirty' roles helped the nurses understand what was expected of them, delineating what they could and could not touch. The AIPPs appeared to restructure the normal division of labour, making it easier for the 'clean' person to monitor the clock and wait for one minute, instead of having to scrub the hub whilst monitoring the time. This then "frees up" (ORI3, NURS0610) the assistant to change the infusions without also having to monitor the clean person. However, some nurses felt that "we are not really decided on what to do" (ORI8, NURS0511) regarding how that work is allocated. Interestingly the reference to "we" here suggests this is a collective decision made between teams.

For insertions, the division of labour was less clear and the role of the second person was variable. The different endorsement for the two-person insertion technique, outlined in section 7.6.1, meant that different pairs of participants implemented it differently. During the observations, the assistant was always a member of the medical team; although ANNPs recognised that the assistant could be anyone, including student nurses, one registrar felt that nurse involvement was only appropriate if that nurse felt able to challenge doctors. If a nurse was to be involved, this was felt to be in order to provide patient comfort. In one observation a registrar recognised that the lack of comfort measures due to lack of nurse involvement "was a shame for this baby" (ORI11, DOC08). In fact, the provision of non-pharmacological forms of analgesia such as swaddling, containment holding, or sucrose, was not observed, though a third person was used in ORI6 to keep the patient still. Participants explained that when inserting central lines on larger, more active babies, a third person may be required to help calm and settle the patient.

There also appeared to be confusion over the allocation of workload during central line insertions, notably in ORI7 and ORI11. One participant did not understand how his assistant could help, whilst in ORI11, both participants were trying to secure the line on the foot of a 650gram baby, which appeared to make the process harder. The pair subsequently reflected that as the second person, sometimes "you can't see what you

can't see" (DOC09) and that allocating clearer roles at the start of the procedure might have been helpful:

> Yeah, because now we've done this we've worked out that the securing part is harder than the other bit and so actually the securing part needs as much if not more attention and, you know, in resus or anything you stand and you talk through your roles and you talk through what you're going to do, I guess, you know, you can apply that sort of principle here as well, you can decide who's going to have what role […]
>
> **ORI9, DOC09**

There were some aspects of central line management where it was not clear who was responsible, or where the allocation of the work was not felt to be appropriate. For example, the responsibility for monitoring central line dressings appeared to fall between both professions, a clear source of conflict for the ANNPs in ORI12, who felt that it was just as much a nursing responsibility as a medical one:

> And, then from a nursing point of view, is, looking after those long lines and the dressing. Yes, we should have a look at it on our ward rounds but, from my own experience as a nurse, it was my responsibility to look after those longlines and if the dressing is flapping around and doctors are not coming immediately then you just grab someone and say, "You need to come now" and not just tell us in the corridor, "Oh the dressing is a bit loose".
>
> **ORI12, NURS0803**

There appeared to be a division of "their work" and "our work" (ORI5, ORI6), suggesting profession-specific responsibilities for specific tasks rather than a collective approach. One nurse referred to the medics "taking away all our hard work" by not accessing central lines in the same way as the nurses (ORI5, NURS0601). Nurses identified that the medical team, who were responsible for flushing central lines, did not always perform Surgical ANTT in the same way as the nurses which frustrated them, though the only difference that was specifically identified was the wearing of non-sterile gloves (ORI5). Contextual influences are important here, as there was a historical rule that nurses, whose daily work involves using Surgical ANTT, were not allowed to flush them. The influence of context will be discussed in more detail in Chapter 9.

There were shared responsibilities within the nursing team for organising the task as "part of the rooms routine" (ORI2) and that "the needs of the nursery" were taken into account (ORI4, ORI5). Nurses referred to being up to date with their work so that both participants could be free so colleagues didn't have to do their work. A strong culture of teamwork,

which is discussed more in Chapter 9, influenced the organisation of the work, with some nurses commenting on the need to complete fluid changes before the night shift or to help the night team. In some cases, this was a perceived pressure. Organising work between teams could also cause conflict, particularly when there were differences in priorities between different teams. For example, in ORI12, nurses were moving an incubator out of the nursery whilst the medical team were inserting a central line, with the incubator moving past the sterile field:

> **NURS0803:** Yes, or awareness of people that there's a longline going on. Why do they have to move their bed, their baby, just now when we do a longline? Is that absolutely necessary? It's not.
>
> **NURS0801:** Yes, I couldn't believe it when they started moving that baby – that incubator out behind you!

The way in which the labour was divided between and within teams appeared to be a source of not only tension but also in some circumstances, confusion, with no clear responsibilities for some aspects of central line care.

7.7.2 Surveillance and Monitoring

Surveillance and monitoring of the bundle occurred to varying extents within and between professions. Nurses discussed checking together throughout various stages of the task and this two-person process provided informal monitoring. One nurse explained that:

> I've seen it before, just at the very beginning before any of the fluids are made up, someone got their gloves on and they put their hair behind their ears and someone's, "Oh what have you just done?" and started again! (Laughs) So, it's not like it has to be judgmental, it's just, "Oh, do you realise you're -?" "Oh, I did not realise" …
>
> **ORI8, NURS0515**

In the absence of reinforcement, this informal monitoring may provide staff with reassurance regarding how they implement the processes. Less experienced doctors were observed double-checking their choice of vein or insertion technique or asking their assistant to tell them if they were not doing something correctly. Interestingly, not everyone, even those working at senior Registrar level, felt comfortable supervising or teaching the process (see section 7.7.3).

However, some nurses reported not monitoring each other closely. It may be that the process has become so routine that there is some habituation; it has become second nature. Some nurses referred to preparing morphine as easy because:

> We do it so often that it's just automatic, you know what you're doing, you know the prescription, don't have to check the formula for weird and wonderful things because it's never different.
>
> **ORI5, NURS0601**

Similarly, nurses recalled that when Surgical ANTT was first introduced they talked through the process more than they do now, checking with each other about what to do:

> And so it was quite a new thing for us to do it this way, so we, to make sure we were doing it right, we spoke about what we were supposed to do, what we were allowed to touch and what we weren't allowed to touch, and what the role of the clean person and what the role of the assistant was as we were doing it so that we were like, "Is that right?" and someone said, "Yes, that's right," or "No, I think it's like this," and then if we weren't sure someone would go and check how we were supposed to do it because it was quite a new way of doing it."
>
> **ORI2, NURS0603**

Participants also described performing the task more slowly when working with new or junior staff and taking more time to enact it. This suggests that this informal monitoring may not occur in the same way between those perceived to be experienced, and that there is increased vigilance when something (or someone) is new. One nurse recognised that she doesn't "watch that intently what other people are doing" (ORI3, NURS0610) but that if she saw something unexpected then she would discuss it. Whilst there appeared to be a shared mental model as to what the process of Surgical ANTT should look like, which facilitated informal monitoring, it was unclear how detailed this monitoring was regarding the minutiae of the process. Given the uncertainties described in 7.5.2 and 7.6.2, this informal monitoring may not always be effective.

Whilst doctors recognised that the assistant might monitor asepsis, when two ANNPs were asked if they had ever been asked to stop the procedure, the answer was no. It was also clear that policing practices was challenging for many participants. Broadly speaking, new or junior staff were perceived as less able to challenge others but that there was a strong team of Band 7s who were "not afraid to challenge even the Consultants" (ORI5, NURS0601). Some participants could recall instances where they had to challenge other nurses for not scrubbing the hub properly, and Consultants for not wearing gloves during cannulation (ORI5). Some found it uncomfortable: one nurse recalled that "it was very

awkward, for the rest of the shift" after refusing to allow a colleague to attach fluids due to poor cleaning technique (ORI8, NURS0515). A doctor questioned if nurses would feel able to challenge doctors, suggesting that perceived hierarchies may be a barrier to effective monitoring. The influence of context is important here, with hierarchical structures potentially influencing the ability to challenge practice (explored in 0). This, in conjunction with degrees of uncertainty, may mean that staff are not confident challenging colleagues. Despite participants suggesting that one role of the second person during insertion may be to monitor asepsis, this was only observed in one ORI, where the assistant prevented the equipment tray from slipping outside the sterile field. One SHO recognised that if contamination occurs, "only you may know it" (ORI7, DOC10) whilst a registrar recognised that the process can be difficult as the second person because "you can't see often, or someone else's hands are in the way" (ORI9, DOC09). Having an assistant who is unable to observe the whole process, due to their active involvement in the task, may therefore limit effective surveillance. In addition, the lack of checklist use suggests that there is no formal monitoring of central line insertion practice. The absence of a checklist was therefore deemed to be important to specifically explore further in the SSIs and by audit. An ANNP appeared to be seeking greater accountability for monitoring, suggesting that incident forms should be completed if a central line becomes dislodged (ORI12). Participants clearly believed it was important to challenge poor practice and yet this was something that staff did not always feel able to do, highlighting a disconnect between beliefs and behaviour. This was therefore explored further in the SSIs.

7.7.3 Learning from others

Participants across both professions referred to learning central line practices from each other. Experiential learning appeared to be important, with one nurse recognising that there is tacit knowledge- things that are not written down that are "learnt, shared and passed on" (ORI5, NURS0601). One doctor recognised that less experienced colleagues may not have learnt the key moments that are high risk for contamination, such as moving through incubator doors. The description of how staff learnt was reminiscent of the traditional 'see one, do one' approach, in that participants across both professions would advise new staff to watch the procedure first, then assist with one, and then do one. This suggests that the assistant could be less experienced than the person inserting the line and may not have the experiential knowledge to recognise contamination risks nor feel able to challenge a seniors' practice. This is important for monitoring and surveillance of the bundle.

Participants referred to learning the processes from each other in action and yet actively sought reinforcement, suggesting that this may not be enough. This was notable in ORI11

where a junior doctor, who had performed insertions before with another colleague, confessed that he “did not know about this red stuff” (DOC05) for washing his hands, having used normal soap before. This ORI was also his first time performing the procedure in an incubator, having never done this before. The nurses recall having training on Surgical ANTT when it was first introduced and being taught the same way by the same person:

> When it was introduced there was a lot of… there were pictures up that the infection prevention nurse had made for how to do it and I think we were all… we were all taught it actually.
>
> **ORI3, NURS0610**

This did not appear to be the case for the medics with one Registrar recognising that she was taught by someone “not very neonatal” and would prefer to have learnt the procedure from a Consultant or ANNP (ORI11, DOC08). Some participants, across both professions, found teaching others hard. The variations in practice made it harder to teach the procedure, as one nurse explained:

> It’s very hard teaching someone because – well it’s not hard but it makes you flustered and I don’t, I think where people – have adopted like different techniques which you get in nursing anyway, it’s hard for them, a new starter, they get told slightly different things don’t they.
>
> **ORI8, NURS0511**

This also highlights additional challenges for new staff. There were limited references to formal educational resources. One nurse referred to picture aids when Surgical ANTT was first introduced, and one ANNP referred to a central line insertion video. Whilst the doctors referred to learning from each other, two ANNPs discussed whether the doctors are taught how to dress a central line:

> […] because they get taught, don’t they, initially on how to put lines in but I don’t know whether redressing is part of it.
>
> **ORI12, NURS0801**

The ANNPs identified training needs for doctors, including on types of lines, the Seldinger method and how to secure lines. They could each recall examples of central line dressings that were inappropriate or unsafe, which matched the experience in ORI9. Given insider knowledge regarding the availability of training videos, the use of simulation teaching and guidelines on central line insertion and late-onset sepsis prevention, it was important to explore how staff learnt the skills of central line insertion and management in

more detail in the SSIs. How staff learn the skills is going to influence how the task is implemented, increasing the impact of bundle endorsement.

7.8 Theme 3: Patient Factors

This section refers to specific patient factors that influenced the adoption of the bundled components. These were collectively referred to as unavoidable exceptions, as participants adapted their practice to act in the patient's best interests.

7.8.1 Unavoidable Exceptions

Participants identified patient-specific circumstances when bundled practices may not be implemented or may be adapted. Illness severity was one reason why some colleagues may not wait for one minute for the AIPPs; this was in reference to patients with unstable blood pressures who required inotropic support. However, one nurse recognised that "99 times out of 100" these patients are fine (ORI5, NURS0601). Emergencies were also believed to influence how Surgical ANTT was performed, for example, in a deteriorating patient or one needing emergency surgery. During the recruitment process, one participant asked if the ORIs would include observing 'uncontrolled fluid changes' (see field notes, Appendix 28). As no emergency fluid changes were observed, this concept of 'uncontrolled versus controlled' fluid changes was included in the SSIs. Whilst nurses didn't feel an emergency would change the way asepsis was performed, they may be less organised or have more interruptions. Emergency situations also influenced decisions about whether to disconnect lines in order to gain emergency access ('breaking a line'), despite it risking contamination and a subsequent risk of infection:

> It's not ideal to break a line, it depends on what other access you've got. In an emergency I can see the necessity to do it but if there's another choice of other access then I'd prefer to use that, so not ideally, to break a line, unless it's absolutely necessary.
>
> **ORI8, NURS0511**

In addition, neonates who were crying or distressed created anxiety and distraction for both professional groups. This may influence bundle adoption, for example, as colleagues may:

> …in more of an urgent situation with the baby getting distressed, just put a dressing on and go.
>
> **ORI6, SPR6**

These are examples where there is cognitive dissonance between beliefs and behaviours. On the whole, nurses felt that breaking lines may be warranted in an emergency, though some recognised it was not ideal. One nurse explained that she would make up a new set of fluids if the line had to be broken. Similarly, the perceived urgency with which the insertion of a central line is needed may also result in participants having multiple attempts or not having an organised aseptic field (ORI12).

7.9 Theme 4: Organisational Influences

There were broader organisational factors that were believed to influence how new practices were enacted; these were primarily resource related. In addition, the environment was identified as being a challenge for implementation.

7.9.1 Resources

Staffing and Workload Demands

The majority of nurses cited being busy as a reason for performing the task differently, and this was felt to be due to interruptions and distractions. The requirement of two nurses to perform the task meant that sometimes the second person would need to attend to another patient. Whilst nurses didn't feel that this had an impact on aseptic practices, they recognised that interruptions did. For example, sometimes prescriptions would be checked after they had already been prepared and administered, which "you shouldn't, but it does happen" (ORI5, NURS0601). This is another example of 'normalised deviance', where individuals behaviour went against what they knew they should do. Feeling busy was also a potential explanation for poor 'scrubbing the hub' performance:

> …and so particularly with the clean for 30 seconds, dry for 30 seconds and they're standing there anyway everything's a hurry, we're busy, busy, busy, clean, dry, yeah, that's 30 seconds.
>
> **ORI3, NURS0610**

Insufficient staffing and workload demands were also a reason for performing central line insertions with one person. Even with a two-person technique, workload demands were felt to have an impact on how the procedure was enacted. The following summarises the impact that competing demands may have:

> Yes, I think the longline is something you need to find your inner calmness, quiet because you (over speaking)… one hour or even one and a half and there's everything going around but you actually need to plan this out because you need

> to concentrate on what you do, because as soon as you get distracted, you quickly touch something you shouldn't touch and I find that sometimes quite difficult and we are people who are highly energetic, running around having a hundred things in our head.
>
> **ORI12, NURS0803**

The perception of being busy as a shared experience is discussed in more detail in 0. Some nurses felt that Surgical ANTT helped reduce interruptions and distractions:

> I feel like you're less distracted because there's two of you, because you're having to have someone help you and assist you. Whereas, like you said before, you could literally run a TPN through and then be like, "Oh, get someone, come and check this." I feel that people don't come up to you as much or interrupt you when you're doing your fluids in a sterile way.
>
> **ORI4, NURS0612**

The level of experience was an important influence on implementation here, as junior staff may be less equipped to manage the workload demands of other patients as well as assist with a central line insertion. This is particularly evident in the way DOC02 referred to 'just' an SHO:

> I mean I have done a line many a time where I have done it alone, and that is because the other people have been busy or something, the transport person was out and there was an SHO and … just an SHO around, who had also to look at other patients, so in such a scenario obviously it is difficult but then today we did not have much to do, so we agreed to do it together.
>
> **ORI6, DOC02**

For the nursing teams, when workload demands were high participants recognised that some may not want to perform the task with a less experienced colleague as it may take longer.

Accessibility of equipment

Overall, both professions believed that organisation and preparation were important for the procedure to be performed effectively but that the availability of resources within the nurseries, and gathering equipment, took time. Nurses recalled having to "run down the corridor" (ORI8, NURS0515) and a junior doctor recalls working in another NICU that used 'grab bags', reducing the amount of time spent gathering equipment (ORI11). Not having

resources visible and available to participants- for example, the lack of visible chlorhexidine hand scrub (ORI11)- also resulted in not adhering to bundled practices. Finally, whilst cost was infrequently mentioned in relation to task performance, one ANNP did acknowledge it influenced her decision to have another attempt:

> Shall we try again because we've got all this really expensive material already out and -?
>
> **ORI12, NURS0803**

7.9.2 The Environment

The majority of participants would advise colleagues that the preparation of the environment is important for maintaining asepsis, though this was infrequently observed as being part of the process. Ensuring there is sufficient light, that the incubator bed is flat and that patient equipment is not in the way were suggestions for improving the preparation of the task and yet were infrequently observed. One of the most notable findings was the volume of traffic observed in the nurseries and the limited space for the trolleys that participants used to prepare their sterile field. Staff, parents and visitors frequently moved in and out of the rooms around the sterile field. In four out of the five nursing ORIs the sterile field had to be moved within the environment:

> Just preparing better and there isn't really a better place for the trolley, that's the trouble; wherever you go it's just, you're going to get movement past when people want to get to the cupboard.
>
> **ORI8, NURS0511**

Both professions found that the environment could be challenging for implementation, with one ANNP saying she wanted to tell everyone to leave the room, exclaiming that she could "see the trolley being covered in bacteria!" (ORI12, NURS0803). She recalled working in other places where no one was allowed to enter the nursery if a central line was being inserted. Indeed, the environment could be distracting, chaotic and busy, with one doctor advising colleagues to separate themselves from it:

> And the environment that you are in, so maybe trying to use a screen and keep yourself slightly separate from what is going on around the rest of the unit, so just focusing on your task.
>
> **ORI6, SPR06**

Incubators provided a physical obstacle for those inserting lines, as they were unfamiliar to some medics who were new to neonates or had come from different countries. In two ORIs, participants recalled brushing their hands across the incubator portholes, causing contamination of their sterile gloves. Generally, nurses didn't find incubators to be a barrier, though one nurse recognised that it can be more "fiddly" if you are not experienced (ORI3, NURS0615). One participant commented on how the temperature of the environment influenced his behaviour:

> Probably I was being a bit impatient because I was very hot, maybe I should've taken a few deep breaths and just held it on there for 10 minutes and not be talking or doing anything and just calm down, I don't know?
>
> **ORI7 SPR08**

7.10 Researcher Reflexivity

The influence of researcher presence on participant behaviour is worth noting briefly here, though it will be explored in more detail in Chapter 10. Whilst there appeared to be good engagement of staff overall with the project, the researcher was required to frequently reassure both professional groups that this was not an audit nor a test. Whilst participants were often nervous at the start, their focus appeared to be on the task at hand once they started to perform the procedure. Similarly, whilst initially nervous at being interviewed, most participants chatted freely between each other about the observed procedure. On one occasion, after the interview had ended, the pair started discussing other relevant experiences, and so having asked permission, the recording was restarted.

Whilst participant behaviour is of course likely to be altered with an observer, with participants wanting to show the best version of themselves, as an insider with knowledge of NICU practices, participants did not appear to be purposefully adjusting their behaviour. The very fact that poor practice was observed whilst participants were being watched raises important questions about what practice may be like without an observer. Of course, participants were likely to be nervous having a member of their team observe their practice, and this accounts for some practices that were observed, such as accidentally dropping gauze swabs on the floor or unfolding a sterile apron in the wrong direction. These are different to the conscious, deliberate decisions being made about how to prepare morphine infusions or secure a central line. In addition, researcher presence may have been what prompted a consultant to request a second person assist in ORI; it may also have prevented some nurses from getting involved, if they thought the researcher was already observing the procedure.

It is also important to reflect on the adequacy of the ORIs as a data collection method. Interviews, for the most part, were double the anticipated duration, ranging from 20 to 40 minutes, and therefore each ORI provided a rich, detailed dataset. This may explain why the number required was slightly less than anticipated (10-20). However, ORI 4 was shorter than the others, with participants who answered prompts briefly and were hesitant. In fact, these participants asked “did we pass?” at the end of the interview, despite being reassured that this was not a test. This interview, therefore, had limited depth, compared to others. It should be noted that for interviews that were longer than over the anticipated 20 minutes, participants were given the opportunity to stop so as to not have an impact on clinical need.

There are some limitations to the data collected that are worth briefly noting here. It is important to recognise that no ‘uncontrolled’ or emergency fluid changes were observed, so this concept was explored in the SSIs. Similarly, whilst umbilical catheters are a type of central line used on the NICU, the insertion of these catheters was not captured in the ORIs, which focused upon percutaneously inserted central catheters (PICC) lines. Again, this reflects the more urgent nature of umbilical catheter insertion, whereas PICC lines are more frequently a planned procedure.

7.11 Summary

Observations and interviews suggested that not all central line bundle practices were consistently implemented, and some were adapted. Observations found that whilst some aspects of practice appeared almost ritualistic, there was also much underpinning uncertainty across both professions regarding best practice. In the absence of formalised reinforcement, variations and uncertainties led participants to question their own competence, and on the whole, participants were actively seeking reinforcement of their practice. There was mixed endorsement of the central line insertion practices, though there was widespread buy-in from the nurses for accessing lines using Surgical ANTT and AIPPs.

There were professional differences in how central line care was enacted within teams, with the nursing process having more clearly defined roles compared than the central line insertions. The role of the second person in insertion as a teaching role suggests that both staff are cognitively engaged in the task, as opposed to the second person being an external observer. There were challenges in the division of labour between medical and nursing teams, as well as between night and day shifts, and this caused tension and conflict. Challenging poor practice was felt to be hard, and there was a suggestion that colleagues with less experience may not feel able to challenge senior colleagues. Finally,

there were unavoidable exceptions where deviations were felt to be necessary, and organisational factors including a lack of resources and environmental factors influenced bundle adoption.

The ORIs identified potential influences that were felt important to explore in greater detail in the SSIs, in order to obtain corroboratory or contradictory data to ascertain the extent to which these accounts represented the experiences of others. Issues relating to how staff learnt the skills required to access or insert central lines, the availability of resources and working with colleagues (such as how able staff feel to ask for help or to challenge each other), were explored in the SSIs. It should be noted that similar issues were also identified in the NoMAD survey (see Chapter 6). In addition, it was also important to explore practices that participants in the ORIs believed were subject to variation or uncertainty, such as waiting for one minute for the AIPPs or managing central line dressings.

The following section will present the results of the SSIs, providing examples of where experiences corroborated, illuminated, or contradicted the findings of both the survey and ORI data.

Chapter 8 Semi-Structured Interviews

8.1 Introduction

This chapter will present the results of the semi-structured interviews (SSIs) that took place after the survey and observations with retrospective interviews data analysis. Fifteen SSIs were performed between July and August 2019. The SSIs took place in an office away from the NICU, apart from two which took place in an office on the NICU at the request of participants. Interviews lasted approximately 50-70 minutes. Two participants took a break part of the way through (SSI6, SSI7) and one participant asked not to be recorded for a particular part of the interview (SSI6). The participant characteristics can be found in Table 20. A range of professional roles and experiences were sought, including those who had not been sampled as part of the ORIs such as consultants and Band 7 sisters.

Table 20 Characteristics of Participants in SSIs

Job Role	**Number (number participated in ORIs)**
Band 5	2
Band 6	4 (2)
Band 7	3 (1*)
ANNP	2 (1)
Consultant	4 (0)
Total	15 (4)
*One Band 7 interviewed had participated in the ORIs as a Band 6	

As with the ORIs, notes were made following the interview on key features of the interviews, such as the participants body language, tones of phrase, specific turns of phrase or language used. Interactions between the researcher and the participant were noted in order to aid reflexivity.

8.2 Themes

Many themes were consistent with those found in the ORIs, with two additional new themes identified, as outlined in Table 21. Some of the results contradicted, or further

illuminated, the ORI results, and some new sub-themes were found. Where findings corroborated previous results, these are summarised in Appendix 29.

Table 21 Themes from SSIs

Categories	**Description**	**Themes**	**Situational Influences**	
Individual Influences	Individual attitudes, beliefs and values about the bundled practices	Bundle Endorsement ***Understanding Expectations** Seeking Reinforcement Reconfiguring Prior Knowledge ***Adapting the Bundle**	Degree of Experience	Degree of Uncertainty
Team and Unit Level Influences	Influences at a team or unit level on how the task is enacted	Division of Labour Surveillance and Monitoring Learning and Teaching		
Patient Factors	Issues at the team or unit level that influence how the task is enacted	Unavoidable Exceptions		
Organisational Influences	Wider organisational issues that influence how the task is enacted	Resources Environment		
*Additional themes identified from the SSIs				

8.3 Situational Influences

As in Chapter 7 (section 7.5), the degree of experience and the degree of uncertainty were believed to influence implementation across a variety of other themes, corroborating the ORI results. Appendix 29 provides evidence to support this. These influences will be highlighted where relevant across the remaining themes.

8.4 Individual Influences

8.4.1 Bundle Endorsement

The ORI findings were corroborated by the SSIs, as participants discussed how useful the bundle was for practice and how achievable it was felt to be. However, the SSIs also revealed participants beliefs about the utility of guidelines more generally and their beliefs regarding CLABSI measurement.

- *Beliefs about bundle utility*

Participants across both professions believed reducing infections on the NICU was important, contributing to endorsement. One participant believed there was a "cultural desire" to reduce infections (SSI3, DOC01); another believed that "most people can see the benefit" (SSI6, NURS0801). The fact that the bundle was designed to make things better for the patient was felt by one nurse to be a strong endorsement for the new practices:

> You're doing it because it improves patient care and that's why we do the job in the first place, because actually, we do care about these patients and we don't want them to get sick, and the fact that all the things that we do to them can introduce infections. Why not just do this added little extra bit in your day and avoid it?
>
> **SSI5 NURS0601**

Both professions could see additional benefits to reducing infections such as reducing workload, cost and distress to the patient. Nurses felt that reducing infections would reduce the need for antibiotics and therefore workload. It was also felt that these practices were better for all staff, "as a collective and a unit" (SSI6, NURS0801). There was consensus across both professions that on the whole the new bundle appeared to have increased awareness of infection rates on the NICU, which was seen as a benefit.

The new practices were believed by nurses to make their work easier, and this corroborated the ORI results (see Appendix 29). However, the SSIs revealed that nurses also believed that the two-person insertion technique made their work easier. The two-person technique reduced their workload as they were no longer expected to be the assistant-this was perceived to be a medical job. Nursing endorsement appears to be important for bundle adoption, as one Band 7 explains that if something new "doesn't fit with us, there will be push back" (SSI9, NURS0703). One ANNP also recognised that the two-person insertion made her job easier, admitting that she "never thought it was

important, but now it's so much easier" (SSI14, NURS0804). Nurses believed it was impossible to maintain asepsis with one person whilst keeping the baby "comfortable, happy and safe" (SSI11, NURS0610), though using a second person in this way was rarely observed in the ORIs. However, some consultants believed that a two-person technique and checklist were not appropriate for experienced staff. Indeed, one consultant felt that colleagues were not happy with the changes, as "it added to working pressure, and time" with some colleagues not "very happy about it being implemented" (SSI12, DOC04).

Given that the two-person technique was viewed primarily as a supervisory or educational role, rather than for monitoring asepsis, it is unsurprising that experienced staff did not feel the need for a supervisor. Some did not perceive the new practices to be that different to what had been done before:

> I think in some ways, before it was written down, informally, if you went to put a line in, you would want someone to help you, because it makes it, you know, these babies sometimes are a moving target and you can't physically do it if you haven't got someone to help you, so I think that was sort of what we were doing anyway.
>
> **SSI3, DOC01**

This also reduces buy-in and corroborates the ORI findings that there was mixed endorsement (see Appendix 29). However, ANNPs experienced in central line insertion still believed the two-person technique was appropriate. One consultant felt that whilst standardisation was important, a two-person technique was not always appropriate, and that the decision to have a second person should be based on clinical need and individual skill. Similarly, some nurses did not think that a 'rule' about who should be the clean or dirty nurse was appropriate, as the needs may change depending on who is performing the task, particularly when working with less experienced staff. Not surprisingly then, this was less consistently adhered to in the ORIs, where other factors influenced how the work was allocated. Less experienced nurses were believed to adopt this more rigidly.

Participants beliefs in the evidence behind new practices contributed to endorsement, though this was not always referred to specifically as research evidence. For example, one nurse had "faith" that the new practices had been considered and "thought out" by senior staff (SS1, NURS0617), and another nurse, despite evidence that the AIPPs had not improved infection rates, still wanted the NICU to continue using them (SSI7, NURS0618). The use of hats and masks, for example, were felt to lack evidence by a consultant, who felt like "they've fallen by the wayside" (SSI3, DOC01). Some participants compared local practices to those of other NICUs, as a

way endorsing (or not) the practices, though these were sometimes contradictory. For example, whilst one nurse believed that all NICUs had moved to using sterile ANTT for accessing lines, one consultant referred to knowing a NICU that used standard ANTT, though she was unaware of their CLABSI rates.

- *Beliefs about CLABSIs*

There were differences in the extent to which CLABSIs were perceived to be a genuine problem. This was twofold and related to the extent to which the central line itself was perceived to be the problem, alongside the extent to which CoNS infections were a problem:

> Is this genuinely lines or is this poor culture taking method or is the situation where we're interpreting something in a slightly different way. That's where I would say you then know which of these periods obviously are genuinely beneficial or genuinely periods for worry where you can then do the education contemporaneously.
>
> **SSI12, DOC04**

When asked specifically about the spikes in CoNS infections, one ANNP replied:

> I don't know really. It's not a really bad infection! […] But, you know an infection is an infection, so often when you lose the line from it, whether it's a CoNS or a Staph, or E. coli, whatever.
>
> **SSI14, NURS0804**

The extent to which CoNS represents a genuine problem compared to other microorganisms such as *Staphylococcus aureus*, is important. One consultant believed it was important to note the difference between bacteraemia's and "just colonisation" where it was "unlucky" that the baby also had a line in, warning against "beating ourselves up too much" about "bugs which are going to colonise and cause infection" (SSI12, DOC04). If participants do not believe there is a problem, there may be less endorsement for change. Another consultant critiqued the extent to which local rates indicated a problem, as one consultant believed:

> That infection rates go up and down. Deciding there is a problem is difficult. Deciding there's an ongoing problem is difficult.
>
> **SSI3, DOC01**

This was supported further by another consultant, who questioned if peaks in local infections rates could be due to “statistical variation” (SSI13, DOC03), whilst one nurse wondered if “we've just got more patients so it looks worse” (SSI7, NURS0618). This is an important part of gaining endorsement for new practices: if participants do not believe the data, there may be less buy-in for the bundle. Local increases in *Staphylococcus aureus* infections were compared, by one consultant, to previous patterns of infection:

> When I started in 2008, we used to have gram negative and CoNS and we used to have gram negatives, mainly the surgical babies and CoNS mainly in the pre-term cohort. That's more like a unit where, that's what I've seen nationally, in other units who have surgical babies, very similar kind of clinical picture. So that to me says that there's an element of infection that's going to happen despite your best efforts.
>
> **SSI12, DOC04**

There is a belief that eradicating these infections is not possible and comparing local performance to NICUs with “similar” patterns of infection provided confirmation of this. Finally, getting endorsement for new practices is likely to be difficult when the data does not show any improvement in CLABSI rates, as one consultant recognised.

- *Beliefs about guideline utility*

Nurses, including ANNPs, supported the use of guidelines in practice. It was felt that guidelines standardised practice and that this, on the whole, was beneficial. Having something that was written down in a guideline made it easier for nurses to follow and to respond to challenges (NURS0617). One nurse recognised that:

> […] like, if you just hear something word of mouth, “That’s how we’ve to do it now,” I think you think, “Well, says who?” But if there’s a clear black and white, it’s written down, you’ve been emailed the policy or whatever, the policy’s up on the wall, I think it’s much more, like, “Oh right, that’s it.”
>
> **SSI1, NURS0617**

Standardisation was felt to be important in making practices easier to teach, and guidelines were felt to make that easier. Indeed, one participant stopped challenging practice because she saw that it was “clearly in your picture guide of what to do” (SSI1, NURS0617). In this respect, guidelines helped to reduce conflict between colleagues, which may help with surveillance and monitoring of new practices (see 8.5.2). Guidelines were felt to help empower nurses to “know the truth” (SSI11, NURS0610) suggesting professional differences in access to knowledge. This was supported by another Band 7

who felt that the bundle increased nurse's knowledge about insertion practices (SSI4, NURS0707).

Whilst participants could see that guidelines were important for providing staff with information, one Band 7 explained that staff have to have read these in order to know what to do, and it is not realistic for staff to read every guideline before a shift. The central line insertion guideline itself was felt to be too long, and one participant noted that information on infusion compatibilities varied across different sources of information. Generally, it was felt that guidelines are not used that much in practice, triangulating with the ORIs, though they were felt to be useful to help monitor practice (see 8.5.2) and for new or junior staff. This belief was supported by a consultant who believed guidelines and checklists were important for junior staff. One ANNP explained how she "gets torn" with guidelines, believing that whilst high staff turnover means guidelines are necessary for patient safety, she also likes to have room for "nursing creativity" (SSI14, NURS0804).

- *Beliefs about achievability*

The SSI results corroborated the findings from the ORIs regarding how achievable participants felt the new practices were. Nurses believed they always managed to use Surgical ANTT, whilst some participants who inserted central lines believed it was not always possible to follow the bundle (see Appendix 29). In fact, one ANNP highlighted professional differences in adoption of the new practices:

> I don't think the nurses, they're changing the fluids, the way you have to have two people, so they either just leave the fluids not done or adhere to the guideline, I guess. It's not a job that I do very often. From the insertion point of view, yes, I guess it is this second assistant that is not there for the duration, when you make a start and they'll come and join you is another suggestion.
>
> **SSI14, NURS0804**

This is likely to be influenced by the different professional cultures towards standardisation versus autonomy, which is explored further in Chapter 9. In addition, being able to fully adhere to the bundle practices during central line insertion could be challenging:

> Actually, the process of totally cleaning a limb and getting it through a hole and onto a sterile field without any contamination, is quite tricky and I guess that's where my, 'as best you that you can,' comment, comes from...
>
> **SSI14, NURS0804**

Many nurses felt that it would not be achievable nor appropriate to have nurses as the second person for central line insertion due to competing workload demands (see section 8.7.1). Whilst all participants felt that reducing infections was important, some felt that reducing infection rates completely is not achievable and that an element of infection is always going to occur “despite your best efforts” (SSI12, DOC04):

> but clearly there's an expectation in an intensive care unit with lines, given that we're all colonising organisms in our skin, and we are subverting their immune systems by having all these tubes and wires in, that actually a level of infection is to be expected. You want to minimise it as much as possible, but it's unrealistic to think you could eradicate it completely.
>
> **SSI3, DOC01**

Beliefs about the achievability of reducing CLABISs is therefore likely to be an important moderator of bundle adoption.

8.4.2 Understanding Expectations

In order to implement new practices, staff need to understand what is expected of them. Participants’ understanding of what was expected of them varied and they had different perceptions of what the bundle components were. Participants were asked if they could think of an aspect of central line practice that was clear for staff, as well as if there were any aspects that were unclear. Both professions felt that accessing lines using Surgical ANTT and AIPPs was a clear rule. Most participants across both professions recognised that there was clear guidance that lines had to be accessed, inserted and re-dressed with two people, though one nurse did question this:

> I don't know if the medical team know that they are supposed to be using two people and be properly sterile. I guess I'd like to think they don't do it because they don't know they're supposed to, not that they're actively not doing it.
>
> **SSI11, NURS0610**

This same participant referred to needing to know “the truth” (SSI11, NURS0610) regarding medical practices, with several participants feeling that there were different expectations for different professional groups particularly in relation to accessing lines and the hand-washing process. This corroborated the variations discussed in the ORIs; the SSIs highlighted that this resulted in confusion, contributing to professional tensions when nurses tried to monitor practice (see section 8.5.2). One participant explained that the nurses rely on the doctors to know what to do (SSI8, NURS0509), which was in contradiction to another participant who felt that the junior doctors “don’t always know

what to do" and frequently look to the nurses to instruct them even though they may not know what to do either (SSI1, NURS0617). Participants had different expectations of essential and optional practices, which were often contradictory. For example, whilst nurses thought that central line insertions should be a two-person technique, a consultant felt that this was "ideal, but not essential" (SSI15, DOC13). Whilst there was an expectation that when it was busy, not having two people for insertion was acceptable, the expectations for the nursing work of scrubbing the hub were different:

> Yes, maybe you could be excused for not having a second pair of hands, but I don't think you can say, 'I was busy, so I didn't clean the hub for so many seconds', because I think, yes, you're busy, but then you can't compromise on safety just because you're busy, so I don't think that's acceptable.
>
> **SSI15, DOC13**

The two-person insertion technique, therefore, was not perceived to be a safety measure in the same way as the decontamination of needleless connectors. There was an expectation expressed by participants across both professions that strict aseptic practice was an essential part of the bundled practices and yet there was a disconnect between this expectation and participants' experiences. One consultant recognised that she is familiar with the guideline and the checklist, knows what is expected and feels it is important to insert a line "as cleanly as possible" (SS3, DOC01). However, this participant still recognised that some practices, such as using a hat and mask, are not adhered to (SS3, DOC01). Another participant felt it was "accepted" that a second person may "join you halfway through" or not remain for the entire procedure and that colleagues sometimes walk around the unit wearing sterile gloves and gowns (SSI14, NURS0804). Similarly, nurses were aware that they were required to record hourly percutaneous pressure scores (PEP) for central lines, yet several nurses recalled experiences where this was not done. This is an example of normalised deviance; one nurse explained that "we all know we should look at them" but recognised this was not always done "as closely" as it should be (SSI1, NURS0617).

Participants spoke of examples where there had been shifts in expectations regarding central line management, referred to by one consultant as a "mind-set shift" (SSI13, DOC03). These unintended shifts included putting in a percutaneous intravenous central catheter (PICC) rather than umbilical lines in ELBW babies, the acceptable number of attempts, and using a transilluminator "even for easy veins" (SSI12, DOC04). It should be noted that these aspects of central line management were not addressed in written guidance, nor did the bundle provide expectations regarding number of attempts. In

addition, there were unwritten rules, which caused uncertainty regarding what was expected:

> "I don't know if its explicitly stated, but I always assume that you shouldn't detach and then re-attach it… but then sometimes you have to because…"
>
> **SSI1, NURS0617**

Unclear or different expectations seems to cause tension between, and within, professional groups. This may make monitoring practice and providing reinforcement difficult.

8.4.3 Seeking Reinforcement

The SSI data corroborated the ORI findings that participants sought reinforcement regarding their practice, including the impact on local infection rates. However, in the SSIs participants also apportioned responsibility for infections, which is an important consideration for the provision of reinforcement.

Seeking Reinforcement

Participants sought reinforcement regarding central line practices, corroborating the ORI findings (see Appendix 29). It was suggested that whilst there may be increased awareness when new practices are initially implemented, this can fade over time, suggesting a need for further reinforcement:

> It can be difficult, I think. I think with say, for example, when something new comes in there's a drive when it first comes in. Then it seems that bad habits come in or it sometimes slips back to the old way.
>
> **SSI9, NURS0703**

Participants wanted to know what infection rates were, and there were differences in participants beliefs regarding the impact of interventions on infections. For example, one nurse felt that the AIPPs had not made a difference (but still wanted to keep them), some believed they had, and some did not know. Whilst these are reported in local governance meetings, these are not attended by all staff. One participant recognised that reporting results in this way means that the NICU is waiting to find out if there is a problem rather than being proactive (SSI3, DOC01). Interpreting reported infection rates could also be problematic, with one ANNP commenting that it was "difficult to extrapolate that data, for it to mean something" (SSI6, NURS0801). Indeed, when presented with the local infection data, some participants found interpreting it challenging:

> And it can't be when we're busy, because it accounts for that, if it's… Like this is per…yeah, that doesn't make sense. So it's not like it's… Although I suppose busyness could have an impact on it in terms of that time constraint and your…so it's not so simple.
>
> **SSI1, NURS0617**

Participants wanted to find ways to report infection rates using positive reinforcement, and suggested reporting infection-free days or informing staff that a line had "completed its journey" infection-free (SSI3, DOC01). However, some participants felt that there was a danger of providing feedback for "just doing a job you were expected to do" (SSI13, DOC03) and providing feedback on routine tasks was not appropriate (SSI11, NURS0703). Some participants believed that there was a "feedback culture" that was not always appropriate (SSI13, DOC03). Reporting CLABSI rates at monthly teaching sessions, sending regular short emails or displaying information in the staff room were suggested to improve reinforcement.

Another challenge of providing frequent reminders was the potential for habituation, with one nurse recognising that:

> The thing is, you see so many reminders and things, you then, after a while, because we've done this with developmental care, sucrose, you just don't see it anymore.
>
> **SSI7, NURS0618**

Past experiences or adverse events were also felt to influence behaviour, again corroborating with the ORI findings (see Appendix 29). However, the SSIs revealed that in the absence of formal reinforcement, participants constructed their own links between behaviour and consequence:

> That child was subsequently ragingly septic and had the line removed. I don't know if it was the line, but the two don't hang together very nicely.
>
> **SSI11, NURS0610**

Without formalised reinforcement, individual interpretations may be flawed; the line in the quotation above may not have been the cause of infection. Indeed, reassurances were also sought for specific practices; for example, one nurse commented that using a wipe, rather than an AIPP "feels like you are cleaning better" for changing needleless connectors (SSI8, NURS0509). With no formal reinforcement, participants constructed their own beliefs of intervention effectiveness and some participants believed that the AIPPs and Surgical ANTT had improved local infection rates.

Outbreaks of infections, such as methicillin-resistant *Staphylococcus aureus* (MRSA), were felt to act as a reinforcer for practice:

> I think it really hits home when you know that a baby you have been caring for is having a severe infection. So I think really focusing on our rates of infection and constantly reinforcing that […] So I think it's just a reminder to you how you impact your patient's life, so I think knowing about it really helps.
>
> **SSI15, DOC13**

This participant also referred to getting feedback from parents as powerful reinforcement, particularly because parents are "not exactly in the medical field", so if they can detect lapses in asepsis, this "really brings it home" (SSI15, DOC13). The absence of formal reinforcement, in addition to the unclear expectations, resulted in some participants questioning their own competence. This corroborates the ORI findings (see Appendix 29).

Apportioning responsibility

Where individuals apportion responsibility (or blame) for infections is likely to be an important moderator of bundle adoption, as feedback may not be an effective reinforcer if an individual does not feel they are responsible for a problem or outcome. For example, if nurses feel that babies get more infections when the new doctors start, they may not see themselves as part of the problem, or that they have a role in the solution. Participants provided various reasons for the NICU infection rate, which included patients admitted from other NICUs, that the types of patients being cared for were high risk ("were they surgical, were they pre-term babies" SSI13, DOC03), or that other professions coming onto the unit do not wash their hands ("we see it all the time" SSI7, NURS0618). Nurses commonly asked if peaks in infections correlated with new doctors or nurses starting as well as with higher numbers of agency staff. One consultant was "wary" of attributing blame for infections to shortages in nurse staffing (SSI12, DOC04), whilst nurses felt they always got the blame for high infection rates (SSI7, NURS0618). One nurse reflected that feedback may not always be effective, due to this apportioning of responsibility:

> [...] we never think it's us, do we? We always think, oh, well, that's the doctors, that's the surgeons do that. We haven't seen people washing their hands. As nurses, we always feel that we get the blame for when infection rates rise […] It's everyone, isn't it, and we're all responsible for it.
>
> **SSI7, NURS0618**

Interestingly, very few participants referred to their own practice, or behaviour, as being a contributory factor. Only one nurse suggested that 'we' might be the cause. If individuals

see themselves as responsible for the problem, then they will feel that they have responsibility for the solution, as a nurse suggests here:

> For us, I think infection, it could be really dramatic for babies, and sometimes if they're born with an infection that's fine, but if we're giving them so it's probably our fault and we can improve. It's good to know if we're doing something, if we're doing a good job or we're not doing that, or we still have some areas where we can improve.
>
> **SSI8, NURS0509**

Given the high-stakes context of the NICU, it is unsurprising that individuals may not take ownership of the problem; one consultant referred to the “moral distress” that can result from trying to do the right thing and inadvertently causing potential harm to a patient (SSI3, DOC01). Indeed, attributing the responsibility for a CLABSI to a specific individual would be “an awful thing to lay at the door of that person”, but that everyone understanding their “own personal contribution” was important (SSI3, DOC01).

However, there was a reluctance by some to provide enforcement for the bundle components. Enforcement, in this context, held negative connotations. There were aspects of central line insertion that were felt to not be “strictly enforced” (SSI12, DOC04) which was the two-person technique and the use of hat and masks. This consultant was reluctant to provide enforcement in case it “makes people not like their job and leave” (SSI12, DOC04). It should be noted these are both practices that were not fully endorsed by all participants. Anxiety and uncertainty around providing effective reinforcement without attributing blame was a concern for participants, who frequently wanted to find positive mechanisms of reinforcement. It was important that this was not “blamey” or “negative” due to the potential impact on staff morale (SSI11, NURS0610).

It would appear that in this high stakes setting where there are degrees of uncertainty around practice and no formalised reinforcement, participants attribute the cause of infections externally to themselves. This may explain the strong endorsement among nurses for guidelines and standardisation, which may provide an element of reassurance that the work is being done ‘right’.

8.4.4 Reconfiguring prior knowledge

Participants recognised that new staff have to reconfigure what they have previously been taught which can be a significant challenge, corroborating the ORI results (see Appendix 29).

8.4.5 Adapting the bundle

Participants suggested how the bundle could be adapted. Generally, consultants believed that that the bundle was too big and too complex. The checklist was too long with too many components, and both the accompanying guideline and the video training for central line insertion were too long. Participants suggested reconfiguring the insertion checklist to include key preparatory parts of the process relating to communication and organising work between teams. Ensuring laminated paper copies were available was also recommended. Checklists were acknowledged to be an important part of patient safety, serving as documentation of what was done, but there were concerns that these were being used as a "tick and flick" exercise (SSI12, DOC04). Nurses suggested including checking dressings as part of their daily checklist.

Finally, adapting implementation processes may improve bundle adoption, though there was a lack of certainty amongst staff on the best approach in a context that one participant described as frequently changing. Participants recognised that the collection of interventions had been dripped in over time as opposed to a single roll-out programme. Participants were not sure which approach was best, but it was suggested that re-launching the bundle might be useful. This may triangulate with the minimal changes in survey responses highlighted in Chapter 6, suggesting the need for continual reinforcement.

8.5 Team and Unit Influences

The SSIs corroborated the results of the ORIs, in that team influences were important moderators of bundle adoption. However, the SSI data revealed additional insights into each of the sub-themes, which will be discussed.

8.5.1 Division of labour

Whereas the ORI results provided specific detail on the division of labour, the SSIs identified that there were differences in beliefs regarding the allocation of central line work, and responsibilities for different aspects of the bundle. Some nurses believed that the bundle had resulted in joint care of the line, increasing endorsement, whereas others felt that there was no clear responsibility for some aspects such as line removal, number of attempts, and central line dressings. The SSIs corroborated the ORIs in terms of the unclear roles regarding handling the AIPPs, and this unclear responsibility was felt to have an impact on if they were used correctly (see Appendix 29). The day-to-day management of central lines, such as assessing the need for the line, and when it should be removed, was infrequently discussed by participants; whilst one Consultant recognised that "ideally"

it would be a consultant responsibility, ultimately central line management should be part of everyone's role:

> Well, I'd like to think it's a consultant role to think about it all, but I think it should- I think you can't really expect a junior bedside nurse to think about that, but I think there should be the- I think it's everybody's responsibility to think, is this still required and do we still need it, and if we still need it, is it safe and are we managing them well?
>
> **SSI13, DOC03**

If it is unclear which team is responsible, it will make both monitoring and reinforcing practice more difficult. In addition, the degree of experience an individual is perceived to have influences how the work is divided. This corroborates the ORI findings, where roles might be allocated differently depending on an individual's level of experience.

Both professions referred to role-specific knowledge, suggesting that staff in certain job roles would not have the same knowledge about bundle practices or infection rates. For example, Band 5 nurses may not see the broader overview of infections on the NICU, caring for one or two patients per shift, compared with a Band 7 nurse who attends the NICU governance meeting and has oversight of all the patients. Consultants may be aware of the NICU infection rates but do not have knowledge regarding attaching infusions to a central line. One consultant explained he wouldn't want to comment on the nursing practice of Surgical ANTT, as he doesn't do it. There were references to specific nursing knowledge around central line care, such as purging air from lines and attaching specific connectors, of which medics were believed to be unaware of. Role-specific knowledge, and a lack of shared knowledge, is likely to make monitoring each other's practice harder between teams as each team has its own role-specific knowledge. One consultant referred specifically to a siloed approach to central line management, with "nobody thinking holistically" (SSI13, DOC03).

One Band 6 nurse recognised that often the medics look to the nurses to guide them in inserting a line and that they don't know what to suggest as its not "our job" (SSI1, NURS0617). Another nurse referred to central line insertion as "their [doctors'] own business" and what they do is "totally up to them" (SSI7, NURS0509). Participants across both professions felt that multi-disciplinary training could improve the understanding of each other's roles.

The division of labour was not always felt to be appropriate. It was clear to nurses that they had the most experience in accessing central lines and yet they were not allowed to flush them, give contrast or change dressings. This appeared to be a historical, unwritten

rule resulting from serious adverse incidents. This was the responsibility of the medical team, and throughout both the ORIs and SSIs, nurses questioned the way in which medics accessed central lines. A similar example was central line dressings; whilst this was the medical team's responsibility, one consultant recognised that "some of our more experienced nurses would be better placed to do that" (SSI13, DOC03). It appeared that the division of labour was not always aligned with those with the knowledge and skill to perform the task.

The organisation of tasks between different teams was also an important influential factor and corroborates the findings of the ORIs (see Appendix 29). However, the SSIs explained further how this influenced the work, with one Band 7 explaining:

> There's this feeling as well that you're a failure if you hand your patient over on to the night shift and go, 'I haven't done any fluids. Haven't done any infusions.' The response you get sometimes from some night people that are like, 'What?! What have you been doing?!' We do have a huge amount of night nurses that just work nights who do not understand the pace of a day. The difference in the pace between a day and a night is massive. There are times when you don't manage to get it all done. There's this feeling like, 'Let's just try and do something. Look, why don't we just do the morphine's. Let's just get the morphine's done, so that we're not handing everything over to them.' It's that kind of mentality and that sort of feeling.
>
> **SSI9, NURS0703**

This pressure to complete fluids before the night shift appeared to be a shared experience for nurses in this NICU (see Chapter 9), and one nurse referred to this as "nursing guilt" (SSI5, NURS0601). Whilst some participants suggested making this a night shift role, others raise concerns regarding the safety of making up complicated infusions or controlled drugs during night shifts, as well as with fewer staff. The timing of TPN being delivered to the NICU in the evening was also felt to influence how the work was organised. A frequent suggestion was to have a specific nurse whose role was to prepare all the fluids.

The role of key individuals was recognised as important for driving implementation, and deficiencies in accessing resources were felt to be due to key individuals responsible for those tasks no longer working on the NICU. Champions were infrequently mentioned, with one consultant feeling that they had "died off" (SSI13, DOC03). One consultant felt that developing enhanced nursing roles and having ANNPs working with a core consultant team, to provide training, may be useful. Participants felt that developing an infection team

may be helpful in promoting bundle adoption. Leadership was infrequently referred to, though some participants recognised that change required someone to drive it forward.

8.5.2 Surveillance and Monitoring

For the most part, nursing participants referred to informally monitoring each other checking together, corroborating the ORI findings. Participants across both professions believed that behaviour changes when there is someone watching, such as when someone is performing an audit. It was believed that staff may wash or gel hands more when they are being observed formally. Nurses asked for more monitoring of their practices to ensure they were doing it correctly, and one consultant recognised that whilst existing central line practices may be able to reduce infections, he “can’t say” that existing practice is being “done properly” (SSI13,DOC04). The surveillance of central line insertions appeared to be ad-hoc, with one consultant feeling that:

> Sometimes the coordinator's around just to keep an eye […] so the coordinator will walk around just to make sure that it is done properly.
>
> **SSI15, DOC13**

This also suggests that the role of the assistant in central line insertion is not acting formally as a monitor of asepsis, corroborating the ORI findings. One ANNP admitted that when it is busy, corners may be cut if no one is watching (SSI14, NURS0804). This is powerful as it suggests that being observed is likely to be a strong moderator of bundle adoption. One ANNP felt that some doctors “don’t like to be watched” (SSI14, NURS0804), whilst a consultant believed that self-monitoring through an individual’s conscience was more important, as “nobody can actually come behind you and make sure you're waiting for the correct one or two seconds before cleaning the hub” (SSI15, DOC13).

In describing using the AIPPs for the first time, one ANNP explained that she followed it “to the letter” (SSI14, NURS0804) because it was new. This suggests that the first time a new practice is enacted it may be more strictly adhered to than once a process is familiar. Indeed, one nurse recognises that surveillance is not as strict between staff who are familiar with the process:

> If another person already knows what the main things are, no one really cares how you are doing.
>
> **SSI8, NURS0509**

This suggests that this informal monitoring of colleagues practice may not performed as strictly as when the process is new or unfamiliar, and whilst the ORIs suggested that there was a shared mental model between nurses, this may not actually be the case. A Band 7 nurse suggested that observing each other might help provide feedback on practice, providing the reinforcement that was felt to be missing:

> We don't really have very much feedback, and whether we should be observing each other, having an outside observer…
>
> **SSI4, NURS0704**

The AIPPs were monitored daily by the nurse in charge for the first three months during their implementation, and this was felt to explain why they have “done really well” (SSI9, NURS0703). This monitoring was built into daily workloads and infrastructure, it was clear who was responsible for ensuring they were present and who was monitoring them:

> If they weren't, the first few weeks we were a bit like, 'Right, come on. You need to put those on.' But by the third or fourth week, we were a bit like, 'Right, there's no excuse why you've not got [AIPPs] on. I'd like you to put the [AIPPs] on please.' It would be done pretty much as they were handing over. Then we had this thing of, well, just after handover, so someone will go, 'Oh, it wasn't me!' 'Well, you need to be checking this on handover.' [Anonymous] has put a little thing on MetaVision, on our nursing checklist in the morning, and one of them is [AIPPs] are in. We've really embedded that.
>
> **SSI9, NURS0703**

There were clear lines of accountability for ensuring this was implemented. If the division of labour is clear, it may be easier to monitor and subsequently reinforce the bundled practices. For some practices, it was unclear who was responsible for monitoring. For example, one consultant admitted they had never observed a doctor administering contrast, yet this was frequently identified by nursing participants as not performed in the same way. In addition, when asked how colleagues use the insertion checklist, one ANNP said:

> The same as I do, afterwards when you've been hassled by the nurse a few times to record your central line on Metavision so that they can put some fluids on it.
>
> **SSI14, NURS0804**

This suggests that nurses informally act as monitors or enforcers of checklist completion, as they cannot perform their work without the central line being documented on the electronic record.

The SSIs corroborated findings from the ORIs that challenging practice was difficult (see Appendix 29). Changing responses to being challenged was one suggestion to improve this, with a Band 7 recalling a positive experience challenging a consultant about handwashing when the consultant responded with “yes, you are right, thank you” (SSI11, NURS0610). This nurse also felt that doctors respond to her differently now that she wears a sister’s uniform. Another nurse recognised that all staff, including student nurses, should feel able to challenge everyone, with another recognising that “seniority” in terms of length of time on the unit, not just uniform colour, is important (SSI11, NURS0610).

With the two person-technique, neither ANNPS nor consultants could recall a time they were challenged, and one consultant reflected that this was unlikely to be because she was perfect but instead because of a reluctance of staff to challenge practice (SSI3, DOC01). Hierarchies within this context may influence the degree to which staff feel able to challenge both within and between professional teams and groups; this will be explored in Chapter 9. In addition, when some nurses did recall challenging practice, they did not always feel they were listened to, nor was the response always appropriate. Nurses across all job roles admitted they found challenging doctors hard, with one Band 7 feeling that:

> I don't think that- when we challenge doctors it's almost, we're not listened to. It then becomes a more challenging thing, that you feel like you're badgering them. Then in the end, the nurses just give up. Then that's not right.
>
> **SSI9 NURS0703**

Another Band 7 (recruited as a Band 6) referred to wanting to know “the truth” (SSI11, NURS0610) so that this will enable her to challenge practice. Another felt like nurses “nag, nag, nag and then you just give up” (SSI7, NURS0618). In addition, junior nurses may not feel able to challenge more senior colleagues, with one example being given of a new nurse not feeling able to challenge a doctor not washing their hands, a practice which is considered “an absolute” (SSI11, NURS0610). If staff feel unable to challenge practices that they know are unacceptable, such as hand washing, it seems unlikely they will feel able to challenge practice that they are uncertain about.

Participants also recognised that making mistakes was part of being human and that there was a need to make it more acceptable to challenge each other. One consultant

recognised that explicitly communicating expectations may make it easier for staff to raise concerns:

> […] and perhaps prior to putting your line in, you can say to the nurse or the doctor with you, 'Keep an eye on it for me because I might not notice. Please tell me if you see that something's become desterilised,' and then that just takes that onus away from someone because actually then you can say it's all right, I'm expecting you to say that to me.
>
> **SSI3, DOC01**

8.5.3 Learning and Teaching

Participants across both professions felt that it was important to learn the right way to perform a task the first time it is taught. One consultant likened this to learning to drive, saying that it was important to not pick up bad habits (SSI12, DOC04). Another consultant recognised that it "tends to stay with you the way you've learnt it for the first time", which may be problematic if it was taught incorrectly (SSI15, DCO13). This is important given that in the ORIs, junior doctors were observed learning from each other. Learning from others continued to be referred to as the way in which both professions learnt central line practices, though some hoped the NICU had progressed from "you know how to put a cannula in, off you go" (SSI14, NURS0804). One consultant felt that sometimes this still happened:

> We just run through whether there is person is able to do it and let them do it on their own, which we shouldn't be doing.
>
> **SSI15, DOC13**

This also highlights the absence of monitoring and suggests that there is not always a second person. However, participants also identified formal training days and educational resources (simulation training and insertion videos). Visual aids and picture guides, such as those for Surgical ANTT and the AIPPs, were felt by nurses to improve implementation; however, it was recognised that these tended to get lost or "crumpled and thrown away" (SSI7, NURS018). Some staff experienced in central line insertion recognised that they are "a bit out of touch" (SSI14, NURS0804) with formalised training and "assume they get taught the way we do it" (SSI6, NURS0801). A Band 7 nurse was uncertain what was taught in nursing study days but admitted "we mostly learn from each other" (SSI11, NURS0610). Participants frequently suggested that refresher training would be useful.

There appeared to be a disconnect between how participants imagined the skills were taught, and how participants experienced it, particularly for central line insertion. Several consultants felt that doctors were taught how to insert central lines during their induction, however, no junior doctors in the ORIs referred to this training and it was recognised that attendance at these training days was often poor. Getting full attendance at training days was challenging for both professions, and this was felt to have an impact on knowledge dissemination. One member of the education team joked it would be great if the unit could close for a day and all staff provided with the same information at the same time (SSI7, NURS0618). Cascade training was frequently referred to as the way in which information was disseminated, and participants recognised that this brought challenges such as introducing variation. This adds to the degree of uncertainty, with one nurse recognising that “we make it confusing” by teaching new staff different things (SSI8, NURS0509). A member of the education team commented that she found teaching Surgical ANTT difficult and had to check what the correct process was. One consultant summarised the training challenges, showing the complex interplay of both individual and team influences on bundle adoption:

> So if I'm getting six people from the junior cohort who are absolutely vital, out of about 14 to 15 that are new, it then means that the remaining people have to be cascade trained. It's impossible for one person to cascade train, which means there are other people on the unit who are going to pass the practices on. Some of them missed the training completely, some of them come from other hospitals and bring their practice from other hospital into the unit. So the challenge there of ensuring a particular procedure like a central line insertion happens in a way that we would like it to happen from beginning to end, is really difficult.
>
> **SSI13, DOC04**

Cascade training and learning from each other is likely to influence the way in which the bundle is adopted. The challenges highlighted here that are related to training provision may also influence the degree to which staff feel able to monitor and challenge each other’s practice, further affecting bundle adoption. All the consultants interviewed believed that multi-disciplinary team training was important to understand each other’s roles, which would improve the ability of teams to monitor each other’s practice:

> So both faculties should be trained, because they play different roles with the lines. I think they should also have a sort of insight into each other's roles, because it helps that we are able to monitor each other's practice.
>
> **SSI15, DOC13**

This also demonstrates the interconnectedness of how the work is learnt, how it is divided between teams, and how it is monitored. Participants across both professions suggested that introducing regular assessments of practice, including the use of competency assessments, would be useful to improve adherence. Giving less experienced colleagues the opportunity to practice “not on real patients” (SSI1, NURS0617) was identified as important by both professions.

Improving access to information by making it more simple and easier to find was identified as a way to improve bundle adoption. This would address some of the challenges identified relating to understanding expectations (see 8.4.2). Suggestions included the use of visual aids, training videos, checklists, reminders and regular refresher training. It was suggested that it might be useful to incorporate the bundle into existing workflows, such as daily safety checklists, or have a visual aid incorporated into the electronic patient record that was “quick to pull up” (SSI7, NURS0618). Quicker access to information was felt to be important to participants; the central line insertion video was felt to be too long. Participants suggested regular monthly updates on infection rates or having a dedicated central line week. One nurse recognised the need for consistent information to be disseminated in a variety of formats:

> Some people will need a human to tell them; some people will read an email; some people will look at a poster in the gas room; some people will look at the AV system. Some people will look at none of it, but as long as you've captured, say, 80% of the people, they'll tell the ones that didn't look at anything.
>
> **SSI11, NURS0610**

8.6 Patient Factors

Participants described specific patient factors that changed the way practices were enacted. These included emergencies, life-saving lines and admissions.

8.6.1 Unavoidable Exceptions

There were specific patient-related circumstances in which central line practices may be adapted, corroborating the ORIs (see Appendix 29). In addition, the SSIs identified other patient factors such as the type of intravenous access a patient has. For example, if they only have one central venous line, the central line may be broken to administer life-saving treatments. Patients with difficult access were also cited as exceptions. This was the experience of both professions, with a consultant describing inserting a central line through a previously sited cannula as a life-saving measure.

One nurse describes her experience where a baby required multiple attempts, which had an impact on task performance:

> The last person tried and they basically wanted to finish it no matter what and how, and I think sometimes when we get to the point we're struggling or we're stressed about that, and I think everyone really gets pressure on it, I think at that point no one is watching, just let that person finish with whatever.
>
> **SSI8, NURS0509**

Emergencies, or deteriorating patients, were another exception, with nurses suggesting that corners may be cut when no one is watching, or that lines may be broken to add in new fluids rather than preparing all the fluids again.

8.7 Organisational Influences

This theme explores the wider organisational factors that may influence how the bundle is enacted by staff.

8.7.1 Resources

Human resources, such as insufficient staffing and workload demands, along with the accessibility of material resources, were both believed to be important moderators of bundle adoption.

Staffing and Workload Demands

Staffing was perceived by both professions to have a significant influence on bundle adoption, corroborating the ORIs (see Appendix 29). This was felt to be related to both insufficient staffing and having a high turnover of staff. Overwhelmingly nurses suggested reconfiguring the workforce to help accommodate the bundled practices, including creating a nursing ‘fluid shift’. Both professions felt that nurse staffing was a significant barrier to engaging nurses in central line insertions, as it is a long procedure and may also increase the workload of others. One consultant felt that insufficient staffing had become “normalised” (SSI3, DOC01); however, in contrast, another consultant felt this was “an easy card to play” (SSI12, DOC03). Some nurses felt that if nurse: patient ratios were improved, they would have time to assist with line insertions, whereas a consultant believed national recommendations had changed the perception of being busy. Competing demands, interruptions and distractions were a challenge for bundle adoption, corroborating with ORIs, with admissions highlighted specifically by both professions as a challenge:

> But if they've got more people then the focus is on making sure the other person is cleaning, or making sure a junior person is spending enough time cleaning the hub. I see all that happening, but then, obviously, if you've got admissions falling in and junior nurses working, it doesn't necessarily get done. That isn't to point fingers; it kind of happens, but I think that's somewhere where we're lacking.
>
> **SSI15, DOC13**

There were professional differences regarding the degree to which insufficient staffing influenced bundle adherence. For central line insertions, being busy was considered an acceptable reason to not have a second person, but not an acceptable reason for nurses to not scrub hubs appropriately (SSI15, DOC13). Staffing and competing workloads were considered appropriate reasons to adapt the insertion process:

> I mean, that speaks for itself, doesn't it? There's always going to be times when you can't necessarily adhere to it, particularly the two-person. There might not be enough staff around, the clinical environment might not support it, the patient need might not support it, because things need to be done quickly and appropriately, and you haven't got time. There might be other needs of patients on the unit, and it's not necessarily appropriate to pull two people away just to fulfil, because it says you need two people. It's more around competency level and skill.
>
> **SSI13, DOC03**

This was felt to be in contrast to nurses, who would leave the work undone if there was not a second person. These differences may be due to the perceived urgency of the need for the line, compared to routine fluid changes. In addition, one nurse felt that there were sufficient numbers of medics:

> I don't know if the medical team know that they are supposed to be using two people and be properly sterile […] There are frequently enough medics around, so I don't think too few staffing is a reason.
>
> **SSI11, NURS0610**

Availability of Material Resources

On the whole, most participants felt that there were sufficient material resources. However, these were not always easily accessible, corroborating the ORIs (see Appendix 29).

8.7.2 The Environment

The environment was frequently referred to by participants as a challenge to bundle adoption, again corroborating the ORIs (see Appendix 29). Participants suggested having a dedicated space with all the resources necessary for the task as a solution to the environmental challenges, including interruptions as well as the lack of space.

8.7.3 Infrastructure

It was recognised that the introduction of new infrastructure, in the form of the electronic record system (MetaVision), was one potential explanation for the retrospective use of the bundle checklist:

> I think the issue we have now we have MetaVision, is that the checklist is an after, not a before, or a concurrent thing, so you go through and there's a checklist, and you think well maybe I didn't do that. There would be the temptation just to tick it all off, or sometimes people don't complete them at all […] I think the issue is not the checklist, it's how it's built into our structure.
>
> **SSI3, DOC01**

8.8 Summary

The SSI results corroborated many of the ORI findings; however, they also identified additional influences on bundle adoption. Whilst the majority of junior doctors in the ORIs felt that the two-person technique was useful, the SSIs highlighted that both the problem (CLABSIs) and the solution (the bundle) may not have consistent endorsement across all professions. Despite agreement that reducing infection rates is important, implementing the bundle, and reducing infection rates, were not always believed to be achievable.

It was clear that reinforcement, along with surveillance and monitoring, were significant barriers to endorsement for some practices. Participants continued to seek reinforcement, corroborating the ORIs. However, the SSIs exposed an underlying complexity in apportioning responsibility for infections and being able to challenge poor practice. There was uncertainty around the expectations of central line insertion practices, which made it hard for nurses to challenge practice. It is not surprising that, in a high stakes setting where individuals may feel unable to monitor practice, in conjunction with a lack of reinforcement, they apportion responsibility externally to themselves.

In general, the SSIs highlighted a further disconnect between the *work as imagined* and the *work as done*. Whilst the ORIs highlighted that some practices were being performed

in opposition to an individual's beliefs, the SSIs highlighted that this disconnect occurs across a range of professional roles and between teams. The influence of local context and culture on the implementation of the bundle is important to consider; features of the local context, including the results of process and outcome measures as well as cultural insights from the qualitative data, will be explored in Chapter 10.

Chapter 9 Contextualising Implementation

9.1 Introduction

The previous chapters have presented the results of the NoMAD survey, observations of practice with retrospective interviews (ORIs) and semi-structured interviews (SSIs). The results of the NoMAD survey suggested that there were minimal changes in attitudes towards the bundle between surveys two and three. The ORIs found variations and uncertainties in the enacting of central line processes, as well as several influences on bundle adoption at an individual, team and organisational level, with some patient-specific factors also being important. The SSIs corroborated many of these findings; in addition, they found that buy-in for the problem and parts of the solution, was lacking, and that there was an externalisation of responsibility for infections.

However, in order to fully understand implementation, these results need to be interpreted in the light of the local context in which the bundle is being introduced. The importance of this has already been discussed in Chapter 2. To begin with, a brief description of the setting in which implementation occurred will be presented. Following this, outcome measures (local CLABSI rates) and process measures (bundle adherence data) will be presented in order to not only understand the success (or not) of implementation but also offer further explanations for the success (or not) of implementation processes. Following analysis of the ORIs and SSIs, both data sets combined provided information on specific cultural influences on implementation, that will be explored in section 9.5.

9.2 The Setting

Table 22 outlines annual admissions, average lengths of stay and patient turnover for the study periods. The NICU had slight reductions in admissions overall in 2018 and 2019, though the percentage of total admissions for ELBW infants remains consistent. The average length of stay appears to have reduced, though the range is consistently wide. Patient turnover, or the average number of admissions and discharges per day, also remained consistent.

Table 22 Local NICU Admission Data

Local NICU Data	**2017**	**2018**	**2019**

Total Admissions, n	887	761	777
ELBW <1000g	97	83	85
VLBW >= 1000g - <1,500g	87	72	51
Surgical (all babies)	88	95	83
% of Total Admissions			
ELBW <1000g	10.9	10.9	10.9
VLBW >= 1000g - <1,500g	9.8	9.5	6.6
Surgical	9.9	12.5	10.7
Length of Stay			
Length of stay, Mean (all babies)	36 days	14 days	14 days
Length of stay, Range (all babies)	0 to 96 days	0 to 96 days	0 to 97 days
Average number of admissions per day (all babies)	2.4	2.1	2.1
Average number of discharges per day (all babies)	2.3	2	2.1
Legend: ELBW= extremely low birth weight, VLBW= very low birth weight			

Demographics of all neonates admitted to the NICU with a central line between 2015 and 2019 are presented in Table 23. Median gestational ages and birth weights remained consistent, though there were fewer neonates with a central line in 2019.

Table 23 Demographics of all Neonates with a Central Line 2015-2019

	2015	**2016**	**2017**	**2018**	**2019**
Gestational age, median (IQR)	32.3 (27-39)	32.4 (27.5-38.6)	32.5 (28.1-37.5)	32.5 (28.2-38.1)	32 (27.4-38.1)
Birth weight, median (IQR)	1625 (882-3140)	1694 (998-2995)	1610 (1000-2874)	1724 (988-3089)	1590 (930-3100)
Gestational age n (%)					
<28 weeks, n (%)	93 (30)	93 (27)	81 (24.2)	75 (24.7)	81 (29)
28+1 – 32	58 (18.7)	74 (21.5)	79 (23.6)	73 (24)	59 (21.1)
32+1-37	48 (15.5)	67 (19.5)	78 (23.3)	64 (21.1)	51 (18.3)
>37+1	111 (35.8)	110 (32)	97 (29)	92 (30.3)	88 (31.5)
Total	310 (100)	344 (100)	335 (100)	304 (100)	279 (100)
Birth weight (g), n (%)					
<1000g	91 (29.4)	89 (25.9)	84 (25.1)	80 (26.3)	85 (30.5)
1001-1500g	56 (18.1)	68 (19.8)	72 (21.5)	58 (19.1)	42 (15.1)
1501-2500g	47 (15.2)	67 (19.5)	63 (18.8)	54 (17.8)	50 (17.9)
>2501g	116 (37.4)	120 (34.9)	116 (34.6)	112 (36.8)	102 (36.6)
Total	310 (100)	344 (100)	335 (100)	304 (100)	279 (100)

9.3 CLABSI Rates

Table 24 presents the annual NICU CLABSI data. It is important to note that the total number of central line days per year remained consistent during the study periods at between 3937 and 4582 days (see Table 24). Whilst 2016 had the highest number of central line days, the highest number of patients with a central line and the highest number of total positive blood cultures, the year with the lowest number of positive blood cultures (2018) did not have the lowest number of central line days nor did it have the lowest number of patients with a central line in situ.

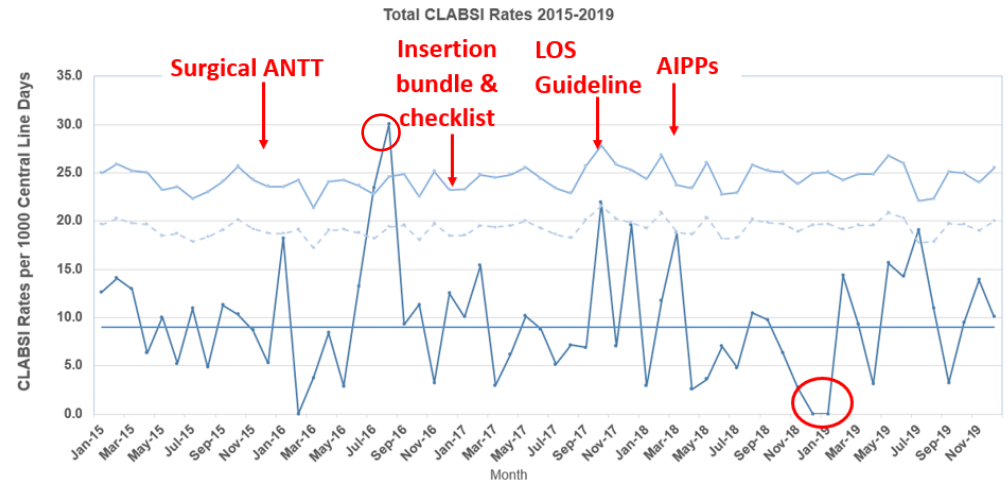
Table 24 Annual CLABSI Data 2015-2019

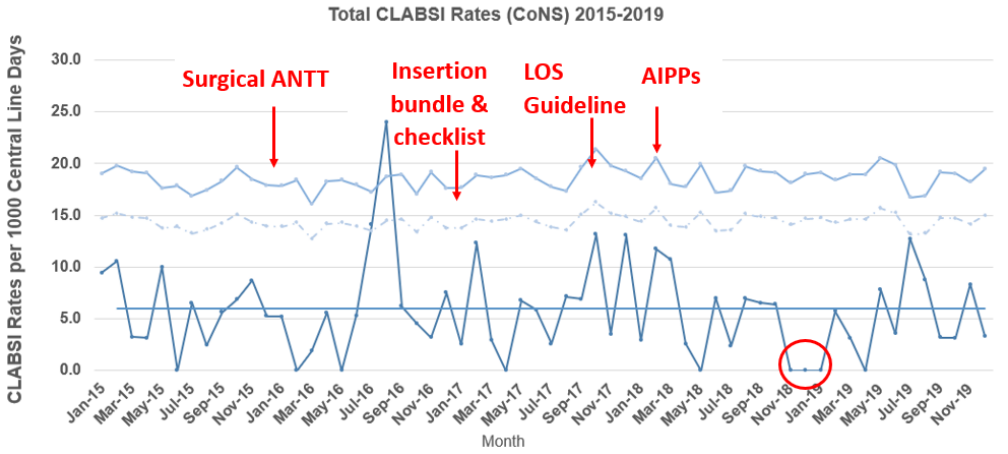
Year	**2015**	**2016**	**2017**	**2018**	**2019**
Central Line Days	4252	4582	3937	4078	4140
Total Positive Blood Cultures, n	39	52	38	27	43
Total Pathogens, n	14	23	14	8	20
Total CoNS, n	25	29	24	19	23
Total CLABSI Rates*	9.2	11.3	9.7	6.6	10.6
Total Pathogen Rates*	3.3	5.0	3.6	2.0	4.9
Total CoNS Rates*	5.9	6.3	6.1	4.7	5.7
*Rates reported per 1000 central line days					

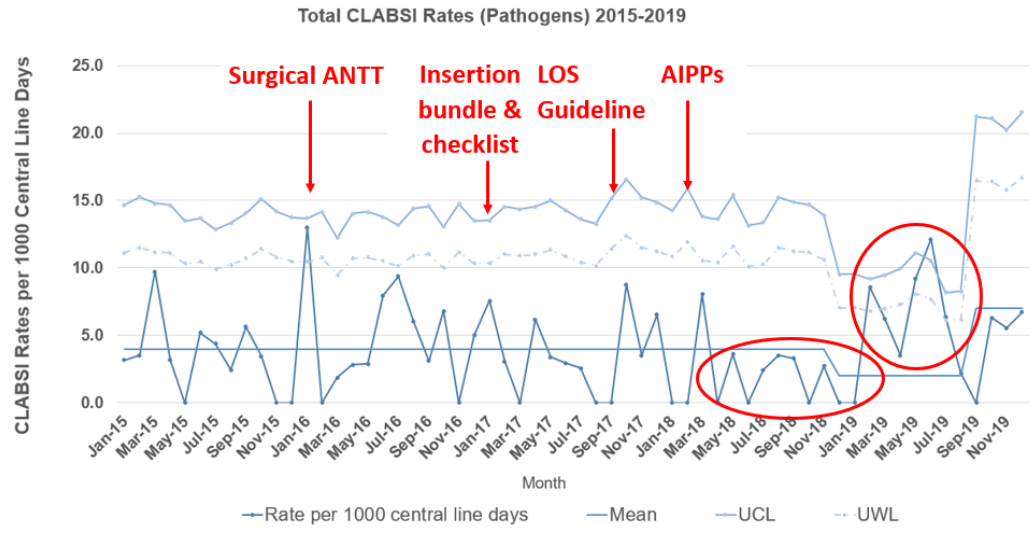
Overall, there was a 31% reduction in positive blood cultures in 2018, with 43% less pathogens and 24% less CoNS positive blood cultures compared to 2015. This was not sustained in 2019.

Figure 15 shows the statistical process control (SPC) charts for monthly CLABSI rates, mapped against intervention implementation for total CLABSIs, as well as CoNS and pathogen sub-groups. The mean rate is plotted along with the upper control limits (UCL) and the upper warning limits (UWL). The lower control limit was zero and therefore is not plotted. CLABSI rates outside of the normal variation are identified by a circle. As can be seen in Figure 15, there were no signals to suggest a trend outside of normal variation (see Chapter 5.6.2 for details of SPC methods). Two out of three consecutive points were close to the UWL during October to December 2017. Whilst there appears to be an initial decrease in rates after the introduction of the AIPPs, with two months of zero CLABSI rates, this was not sustained. Rule 1 is broken in July/August 2016 indicating special cause variation, with two data points outside the UCL. The period of December 2018 to January 2019 is the only period with two consecutive data points reaching the lower control limit of zero, also suggestive of special cause variation.

Figure 15 SPC Charts for CLABSI Rates







ANTT= Aseptic Non-Touch Technique, LOS= Late-Onset Sepsis, AIPP= Alcohol-impregnated port protectors

UCL= Upper Control Limit, UWL= Upper Warning Limit

↓ = Denotes when specific bundle elements were implemented

◯ = Highlights shifts, trends or unusual patterns in the data

There is special cause variation for the CoNS sub-group of CLABSIs in August 2016 when CLABSI rates peaked outside the UCL, and for 3 months from November 2018 to January 2019 where rates were zero for three consecutive months. This is the only time since 2015 that this occurred. For the pathogen sub-group, there was a decreasing shift from April 2018 to January 2019 with a run of 7 data points below the mean which signalled a recalculation of the mean. Whilst this reduction appears to follow after the introduction of the AIPPs in February 2018, this was not sustained, and the process appears to be in special cause variation in June 2019. The mean is recalculated again in August 2019 due to a run of 7 points above the mean. The SPC graphs indicate that local CLABSIs rates are in a state of normal variation, aside from occasional peaks outside the UCL. This indicates that the underlying processes need to change if there is to be a sustained reduction in CLABSI rates.

9.4 Bundle Adherence

Adherence to the local care bundle practices was measured in two ways; 1) by using prospective Trust audit data and 2) through a locally performed audit of NICU-specific practices.

9.4.1 Trust Audit Data

Figure 16 presents the Trust audit results for central line insertions on the NICU. The Trust audit consisted of between five and 10 observations of practice at each audit point. It should be noted that the use of ultrasound for insertions is currently not practiced on the NICU, so this audit measure is absent from the data. Adherence was 100% for all components across all observations, apart from on two occasions: one in March 2018 (documentation=60%), and one in July 2019 (eye protection=90%).

Figure 16 Trust Audit: Central Line Insertion

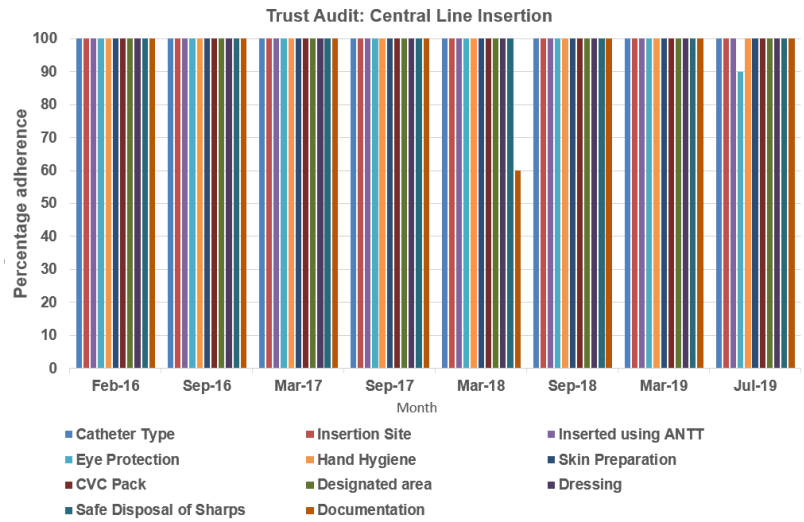
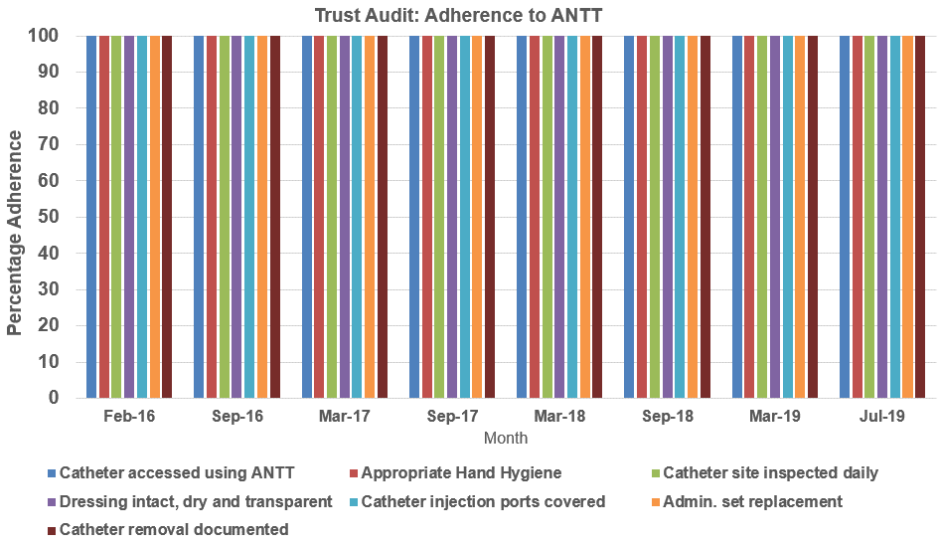


Figure 17 presents the results of Trust aseptic-non-touch-technique (ANTT) audits for central line care. The number of observations performed for each of the Trust audits on ANTT ranged from five to 10. According to this data, there has been 100% adherence to ANTT on the NICU for all observations.

Figure 17 Trust Audit: ANTT for Central Line Care



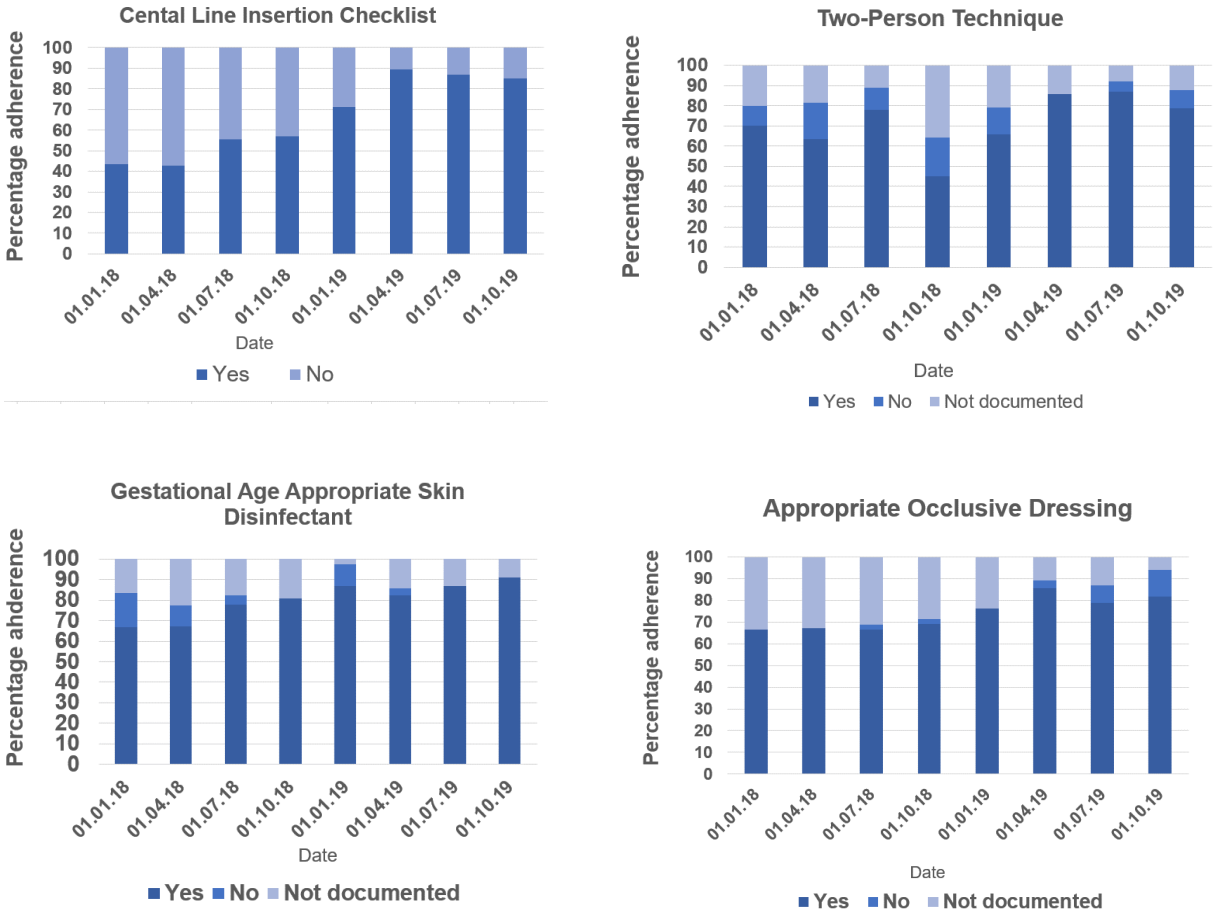
9.4.2 Local Audit Data

The records of 201 neonates with central lines, who were inpatients on the first day of each quarter between January 2018 and October 2019, were audited. This represents 34% of the total number of neonates admitted with a central line during this period. Median gestational age was 29+6 weeks (IQR 26+5 to 33+1 weeks), and median weight was 1140 grams (IQR 819-2026g). There were 88 females (44%) and 113 males (56%). There were 331 central line episodes audited, with 28 central lines excluded due to being inserted in another neonatal unit and therefore not subject to the local insertion practices.

- *Central line insertion processes*

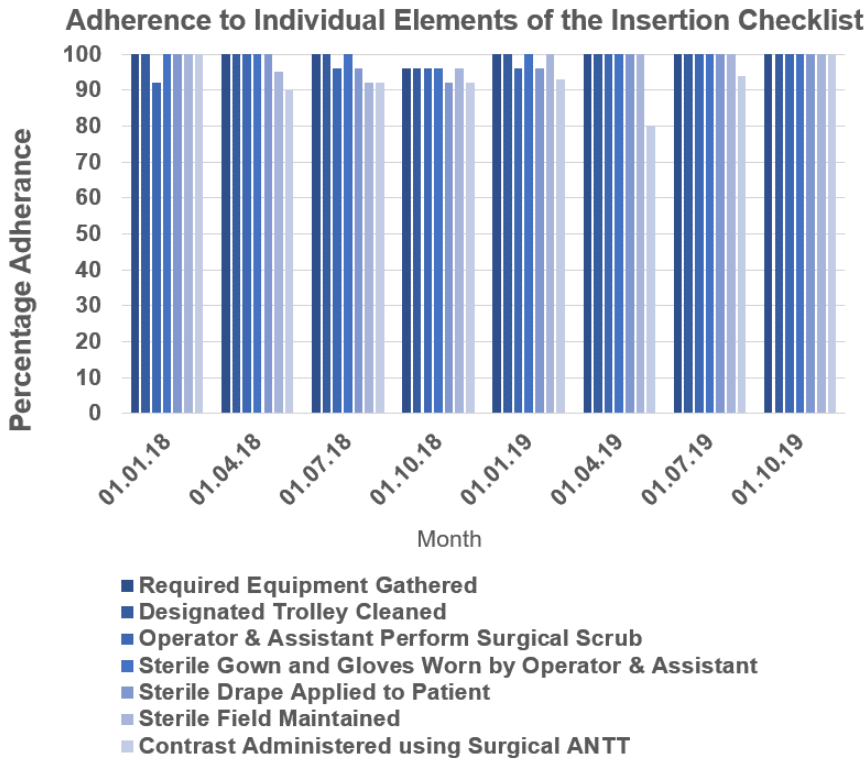
The audit of the central line insertion checklist comprised of two main sections on the electronic patient record. Part one asked for the insertion operator and assistant name, and included a tick box for the choice of skin cleaning agent according to gestational age (see Figure 18), whilst the second part of the checklist was composed of separate tick boxes for each key step in the procedure from start to finish (see Figure 19). Completion of the insertion checklist improved from 43% in January 2018 to 85% in January 2019 (see Figure 18). The documentation for having a second person improved slightly from 70% to 79%, though the lowest overall adherence was in October 2018 when adherence was 45%. It should be noted that between 8% and 36% were ‘not documented’.

Figure 18 Adherence to NICU Central Line Insertion Bundle



It was generally the case that if the checklist was completed, all the individual elements were documented as adhered to (see Figure 19). Two elements that were more frequently not recorded as being completed were ‘operator and assistant performing a surgical hand scrub’ and ‘administering contrast via Surgical ANTT. However, it should be noted that even for central lines that do not require contrast, such as umbilical lines, the component ‘administering contrast via Surgical ANTT’ was ticked as being completed. It is therefore unclear from this data if the contrast was being given unnecessarily or if it was being ticked and not done.

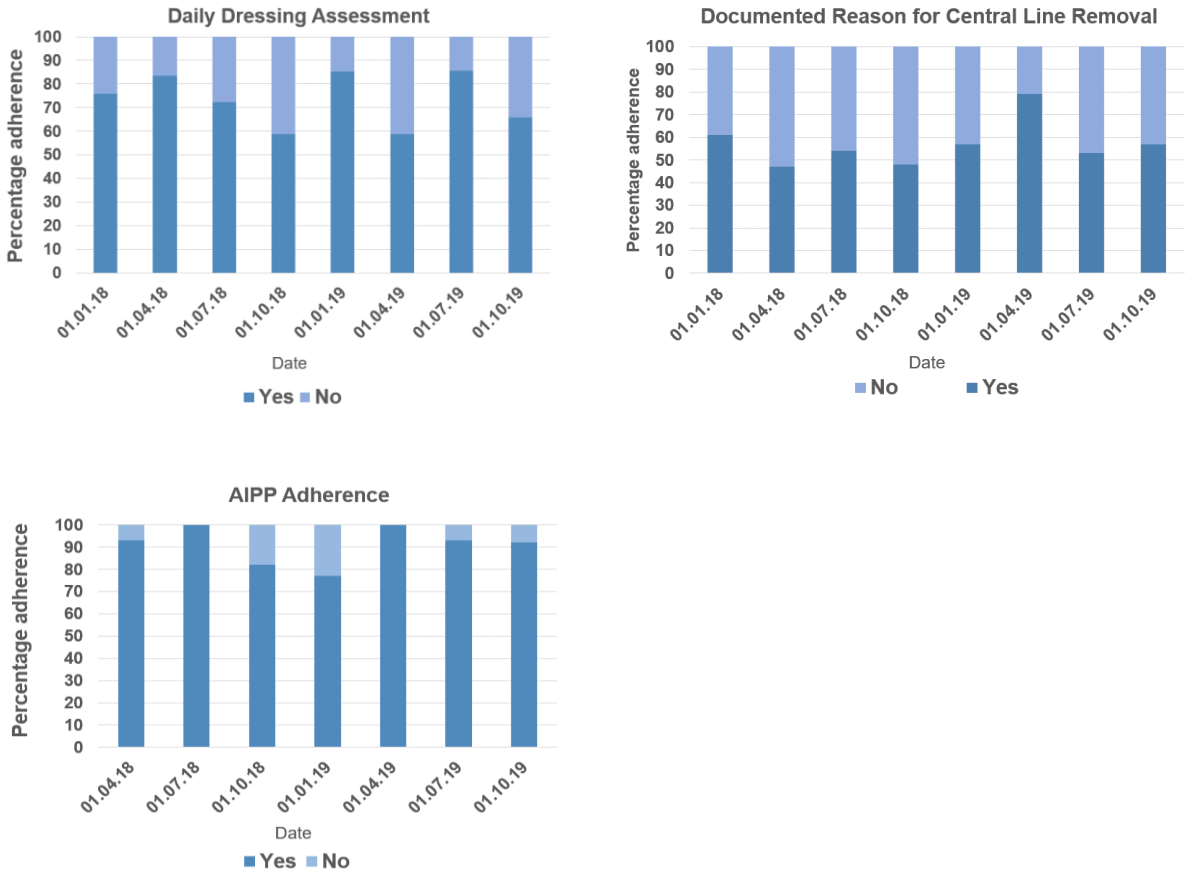
Figure 19 Adherence to Individual Insertion Checklist Elements



- *Central line maintenance processes*

Figure 20 presents the audit results regarding central line maintenance practices. The daily assessment of central line dressings had fluctuating adherence across the audit period, with the lowest adherence in October 2018 (59%) and the highest adherence in July 2019 (86%). The dwell times of central lines were audited; umbilical catheters had a median dwell time of 3.7 days (IQR 1.9-5.6) and peripherally inserted central catheters (PICCs) had a median dwell time of 15 days (IQR 8.8-24.9). Only one neonate had a PICC in situ for >6 weeks, which was discussed at senior medical level and risk assessed, in accordance with the central line guideline. Documentation of the reason for central line removal had lower adherence, with 153 central lines audited (46%) not having a documented reason for removal. Of the 180 central lines that did have a reason documented (54% of all central lines audited), 72% were documented as no longer needed, 16% were removed due to being dislodged or displaced, and 9% were removed due to the line being suspected as the source of infection. Infrequent reasons for removal included thrombosis (2%) and 'other' (1%). All neonates with a vascular access device that was not connected to a continuous infusion were included in the AIPP audit, including peripheral lines (total of 163 neonates). Adherence to using AIPP also improved over time, ranging from 77% to 100%. The poorest documented adherence for AIPPs was in October 2018 and January 2019. It should be noted that there were zero positive blood cultures in January 2019 (see Figure 15).

Figure 20 Adherence to Central Line Care Practices



9.5 Understanding Local Culture

Whilst reporting bundle adherence and CLABSI rates provides a context in which implementation can be situated, the observational and interview data analysed together provided insight into the local culture that warrants discussion. These manifestations of culture include social norms, shared values, and professional hierarchies that influence how the bundle is implemented.

9.5.1 Social Norms

Routines and rituals

For the nurses, there were historical, traditional ways of doing things that influenced the way care was organised and delivered. The nursing routine of changing central line fluids using Surgical ANTT and AIPPs was ritualistic; the process of handwashing and gelling hands, before donning an apron and gloves was enacted in the same way, in each observation. The act of an assistant putting an apron on the ‘clean’ nurse was reminiscent of a ceremony, with each actor having a clear role to play:

> but when you put those gloves on it's like a costume to like, 'This needs to be done sterilely. I mustn't touch anything,'
>
> **SSI4, NURS0707**

This process was performed daily as part of the “rooms routine” and was frequently referred to as “the way we do it here”. This created tension when other professions were not seen to be abiding by the same ‘rule’ or socially accepted way of practicing. Triangulation between researcher observations and participants experiences in semi-structured interviews, confirmed that nurses did not need to explain the process to each other with one participant saying that the nurses “catch up on stuff, they have a chin wag” (SSI6, NURS0801) during the task. This is a social practice. Whilst this suggests a familiarisation with a task, standardisation may lead to an ‘auto-pilot’ approach (Hall and Johnson, 2009). Indeed, some participants reported “not timing things” exactly as they were getting on with other things (ORI3, NURS0610).

Central line insertions did not have the same ritual or routine and were a contrast to the nursing processes. For insertions, the two participants involved may not have worked together in this way before; there were no conversational dialogues and no clear roles. The work itself is not part of daily routines. The application of maximal standard barrier precautions and a sterile field was not an easy or fluid process, having to navigate multiple obstacles in the environment. Whilst some of this may have been due to researcher presence, the dual interviews allowed participants to question each other- ‘I don’t know if that was right’, ‘Do you know a better way to do it?’, ‘Did you notice you put your gloves on first?- suggesting that this a procedure that they were less confident in and less familiar with. Routines and rituals may, therefore, promote the long-term embedding of new practices, though without reinforcement, variations and unintended adaptations may occur. Rituals and social norms may be harder to establish in teams that are undergoing frequent change.

Unwritten rules

There were some unwritten rules that had developed from the local NICU history, including serious adverse incidents. These included nurses not being allowed to flush central lines or change central line dressings, resulting in this being a medical team role. This may not be the case in other clinical areas, meaning that rotational staff have to learn these unwritten rules, though it is not clear how this is done. Similarly, it was suggested that nurses could not handle the needleless connector that attaches to the end of the central line, as nurses are not allowed to “fiddle with” central lines (ORI3, NURS0610). Again, this means that the responsibility for attaching this lies with the medical team at the point of insertion, and yet nurses have traditional ways of organising the attachments and

connections of central lines (including needleless connectors, needlefree extension sets and three-way taps) that the medical team were less familiar with. Not having the perceived ‘correct’ connections contributed to tensions between professional teams; nurses felt that the medical team were trying to be helpful but unknowingly created additional workload for the nurses who had to change the attachments, resulting in more handling of the central line:

> The medics. When they put a long line in, a lot of them will connect an Octopus to the end of it. I think that they think that they're doing us a favour. [Laughs]. […] I don't know when that has started or why that has started, but I think that they… I think it's because they think that that's what we'd like, but it's… But I don't know. I think that would be an improvement if nurses did that. Then again, that's us then flushing the line, so I guess it depends on how that is felt, because we were told we weren't allowed to.
>
> **SSI9, NURS0703**

The resulting impact of this is that those with the most appropriate knowledge and skill about accessing lines using Surgical ANTT (the nurses) are not always the ones who are allowed to perform the task (the medical team). As the medics may not be accessing lines in the same way, this variation results in professional tensions and confusion about best practice.

There were also unwritten rules regarding what to do if fluids have been disconnected from a central line, with experienced nurses believing that whilst “it’s not written down anywhere” they are “pretty sure we shouldn’t be doing that”, in reference to reattaching disconnected fluids (SSI, NUS0619). One consultant referred to a “mind-set shift” (SSI12, DOC03) in the acceptable number of attempts, and putting in long lines as a first option rather than umbilical lines. This suggests there has been a drift in socially acceptable practices.

Normalised deviance

There were examples throughout both the ORIs and the SSIs of practices that were performed knowingly against either local recommendations or what participants believed to be best practice, compared to some deviations which represented unconscious gaps in knowledge, or uncertainties. These are compared in Table 25.

Table 25 Normalised versus Unconscious Deviations.

Unconscious deviations	**Normalised deviations**
Nursing profession	
Handling of PN during aseptic procedure	Not checking PEP scores hourly Checking prescriptions after infusions prepared Attaching and reattaching fluids after breaking a line Sharing and storing diluted morphine Preparing groups of infusions for multiple patients Not waiting for one minute
Medical profession	
Using standard hand soap for a surgical scrub Not having a second person Accessing central lines differently to nurses	Not having a second person for line insertions Using the checklist retrospectively Wandering around the unit with sterile gloves and gown on Not wearing full standard barrier precautions

These normalised deviations were often referred to as things that "we know we shouldn't be doing but…" (SSI7, NURS0618). This suggests that there are socially acceptable deviances from best practice recommendations, and it partly explains the examples of cognitive dissonance between beliefs and behaviours that were both observed and discussed by participants (see 7.2.1, 7.9.1, 8.4.2, 8.5.3 and Appendix 29).

9.5.2 Shared Values, Beliefs or Attitudes

Autonomy versus standardisation

There was an underlying tension between professional autonomy and the standardisation of care. This manifested as balancing individual clinical judgement versus adherence to guidelines. Nurses believed that standardisation made their work easier including creating a shared mental model that made it easy to see when something was not performed as expected. However, standardisation seemed to stop nurses challenging individual aspects of practice that they had concerns about or did not understand. Several nurses questioned aspects of the Surgical ANTT process, such as the handwashing process and use of non-

sterile hand towels, but they still enacted the ritual. Being “written down in black and white” stopped some from challenging practice (SSI1, NURS0619). Most nurses felt that having ‘rules’ written down made it much easier to challenge each other’s practice. In a context where it was felt there were not always sufficient staff to supervise new or junior staff, participants felt that guidelines were important in providing safe care. One ANNP felt “torn by guidelines”, recognising the need for guidelines for safety but also being able, as a nurse who “has been around a while”, to recognise the need for “nursing creativity” (SSI14, NURS0804). This was in contrast to another ANNP who believed that trying to get “everyone to do things the same way” not only “reduces errors” but also “helps people” including making it easier to teach (SSI6, NURS0801).

In contrast, guidelines were seen as ‘just a guide’ by consultants, rather than as a protocol that must be strictly adhered to and therefore there was perhaps less endorsement for this to be implemented consistently (SSI12, SSI13, SSI15). However, when asked what advice they would give to other NICUs trying to reduce infection rates, “a standard practice of management”, “standardisation of the procedure” and sending them “our guidelines” were all suggested (SSI1, SSI12, SSI13). Whereas, on the whole, less experienced junior doctors felt that a two-person technique was appropriate, providing reassurance that the process was better for asepsis, experienced doctors didn’t necessarily seek this reassurance for central line insertion. It may be that these underpinning and deep-rooted professional cultures influence the extent to which bundled practices are endorsed by different professional groups. For example, if nurses were unable to find another nurse to help them perform their fluid changes, they would leave the fluids rather than not follow the rules, whilst medics would perform the procedure without a second person.

Perception of Busyness

The perception of being busy appeared to be a collective mindset on the NICU across both professions. The language surrounding central line tasks was often related to speed and completing tasks, with phrases such as “crack on”, “whip one in” “bang on” (ORI 4, 9,11,12) indicating that speed was important. There was a perceived need to “get on” with tasks with nurses feeling they need to “fit it all in”, despite also being able to rationalise that this was a “24-hour service” (ORI8, NURS0515). One consultant referred to an “unconscious need to keep going with tasks” (SSI3, DOC01). Another consultant suggested that this was a result of changing national recommendations:

> There's been a change in nursing standards ratios, expectations that intensive care babies should be nursed one to one […] So I think people's thresholds and tolerance, if you like, and ability to multitask or deal under stress has changed. So what [it] means to one individual what is busy may be very different to another person about what is busy.
>
> **SSI13, DOC03**

Some nurses talked about feeling “like a bad nurse” or “not doing their job properly” if central line fluids were not changed before the night shift (ORI 5,8, SSI4,9,14). Morale was deemed to be a ‘wibbly thing’ (SSI10, NURS0610) and there was a belief that being busy, as a result of poor staffing levels, increased absenteeism and incident forms had an impact on overall morale. The perceived pressure to get on with tasks may impact the implementation of the bundle, contributing to some of the normalised deviations outlined in Table 25. For example, one Band 7 nurse referred to a shared “mentality” of not wanting to hand over work undone (fluids and infusions) resulting in changing morphine infusions for groups of patients, as opposed to changing all the infusions for a single patient. When asked about the timing of fluid changes, one nurse replied:

> I think it’s just a culture that’s been embedded into the neonatal unit like it’s something that even when I was junior I felt like it’s something that everything has to be done on the day and it really doesn’t matter if it’s not done on the day, TPN can be left for the night.
>
> **SSI2, NURS0612**

9.5.3 Teamwork

There was a strong collective sense of teamwork in the nursing team, particularly during emergencies or busy periods. Nurses frequently referred to the unit “being a good team” (SSI5, 6, 7, 10) and a “good unit” was equated with being a team (SSI15). Teamwork, and not wanting to increase the workload for others, was a strong cultural influence on some practices, explaining some of the cognitive dissonance between beliefs and behaviours (see section 7.7.1, 8.5.1). Indeed, Surgical ANTT was felt to have improved nursing teamwork and therefore aligns with this shared professional value. Whilst there appeared to be a collective belief among nurses that minimising the number of times a central line is accessed is important, and there had been a previous shift in practice towards doing all fluid changes for a patient all together at a single time, this was felt to have not been sustained. Instead, one Band 7 nurse felt that practice had returned to a previous pattern of changing arterial line fluids in the morning, groups of infusions (such as inotropes or

morphine) in the afternoon and PN- commonly referred to by participants as TPN- in the evening.

One participant referred to “sneaky” potassium infusions (SSI1, NURS0617), those that have not been anticipated by the team changing the fluids, resulting in staff on the next shift having to break the line. ‘Sneaky’ suggests an element of deception or unfairness, suggesting that tensions arise when teams are perceived to not be working together. In contrast, several participants referred to a medical culture of being seen to be able to do everything yourself, which may partly reflect the underpinning professional culture of autonomous practice. In addition, there was a sense that medics did not want to be seen to fail, with one consultant recognising in his own experience as a junior doctor, “ego” (SSI12, DOC04) probably contributed to this. An ANNP referred to needing to change the “superhero” medical culture:

> Eugh…by trying to generate this more open culture of accepting, having help without it feeling like… How can I explain it? There is a culture, I don't know whether it's just our unit or just medicine in general, that you should be able to do everything on your own, you should be like a superhero and just get on and do everything and you don't need help, why do you need to help me? I know what I'm doing […] I think somehow, we need to change the culture of an assistant, not being a supervisor so to speak […] I don't know how you get to that, but I think it's quite an ingrained culture, maybe it's medicine in general, I think it's hard, isn't it? It's a hard career and you have to do a lot of stuff on your own. I don't know.
>
> **SSI14, NURS0804**

There appeared to be professional tensions between offers and refusals of help between professional groups. Medics appeared to not want to create additional workload for the nurses; some nurses felt like their offers of help were refused; and some medics felt like the nurses could offer to help but did not. Indeed, one participant believed that not only were they “always asking if they [doctors] need help with something”, they also “let them get on with it” (SSI8, NURS0509). These tensions may therefore have an impact on the integration of the two-person insertion technique as well as the monitoring of new practices. One registrar didn’t want to “go calling on some poor soul” (ORI11, DOC09) to get her things she had forgotten.

Changing the NICU culture to make it acceptable to make mistakes, and ask for help, was felt to be important, though it was recognised that this was difficult. Participants suggested that giving colleagues permission to challenge them may help make it more socially acceptable:

> I think that would help, that if I'm giving someone permission to tell me, and they know that's okay to do that, then that's helpful and explains the way I support them.
>
> **SSI3, DOC01**

Another potential challenge for team dynamics, and therefore bundle implementation, is the transitory, changing nature of the medical team. A discussion between an MTI and a junior doctor highlighted the differences in UK healthcare regarding cultural expectations, with the UK culture being described as “its more, you know, your line, you get the equipment out” (ORI11, DOC09), and so whilst nurses make an assumption that the doctors “know what they are doing” (SSI8, NURS0509) this may not always be the case. In the SSIs one participant highlighted that whilst MTIs may be very experienced in inserting lines, they may not be used to inserting them in incubators, as this may be very different to other countries they have worked in (SSI15). This may also be the case for junior doctors unfamiliar with NICU environments (ORI 10). Having to navigate this particular feature of UK NICUs may present challenges for maintaining asepsis.

There did not appear to be a shared collective approach to central line work, with challenges identified in organising work between teams. Improving teamwork between professional groups and creating a collective shared mindset towards central lines, may help implementation, with one consultant suggesting that central line education needs “a team” (SSI12, DOC04). Some participants believed that the new practices had improved teamwork on the unit; one ANNP felt that there was good teamwork between the two professions and that there was mutual appreciation for the work being done by each profession. Whilst another nurse believed that there was “a lot more teamworking” around central line insertions, this was related to the doctors being more “willing to help each other” and “doubling up as a pair” rather than related to teamwork between the two professions (SSI2, NURS0612).

9.5.4 Hierarchy

Hierarchies appeared to influence implementation on a variety of levels, including underpinning some of the cultural influences discussed so far. Asking for help, and feeling able to challenge poor practice, were notably felt to be influenced by hierarchies. Within the local NICU some hierarchies were visible, such as nursing uniforms that identified the power structures within the nursing team. Within the nursing team there were clear lines of escalation, and nurses felt they had a “strong” senior nursing team that would advocate for them. One nurse felt that her opinions were listened to more now she was wearing a

more senior uniform, having been promoted during the data collection period (SSI9, NURS0610); others felt that they were not always listened to or that they “nag, nag, nag, and then just give up” (SSI7, NURS0618). This is likely to have an impact on the continual reinforcement and monitoring that is important when implementing new practices or normalising new practices. Hierarchies were also provided as an explanation for some staff not wanting to ask for help:

> I think that the nurses probably find it okay to ask. The medics, I'm not sure. I feel there's a little bit more… Going back five or 10 years, I think we were a little bit a better team and we weren't necessarily a hierarchy as much. There's a bit more of a hierarchy at the moment.
>
> **SSI9, NURS0703**

Role-modelling desired behaviours and leading by example were felt to be important for challenging others and for performing Surgical ANTT. One consultant felt “it was vital” for them, as a team, to lead by example and role-model behaviours such as “bare below the elbow” (SSI3, DOC01); another admitted he could not expect his juniors to wear a hat and mask if he didn’t (SSI12, DOC04). One consultant recognised that junior doctors may not feel able to challenge senior colleagues, whereas if a nurse is present and “advocating” for their patient, “the hierarchy is not there” (SSI12, DOC04). This is in contrast to one doctor in the ORIs who recognised that having the nurse as the second person would only be effective if they felt able to challenge a doctor (ORI9, DOC09). Several participants provided examples of a senior clinician not role-modelling what they believed was expected in terms of cannulation. As participants believed they learn from each other, the hierarchical context here and the behaviours of senior staff may influence the degree to which there is buy-in or endorsement for the bundled practices, though this may be dependent on the authority of those individuals. Leadership, often considered a key part of an organisational culture, was infrequently discussed by participants.

Changing the NICU culture was strongly believed by all participants, across both professions, to be important to improve bundle adoption. Participants frequently suggested that there was a need to not only make it acceptable to challenge poor practice but also make it acceptable to make mistakes:

> It's all about changing the culture, isn't it? Everybody's perception of it and it being acceptable but I'm not quite sure how you get to that point. You can lead by example, but you're only one person in a big pond.
>
> **SSI14, NURS0804**

The influence of hierarchy on how staff ask each other for help, as well as how they challenge each other, is important for bundle implementation, and may explain some of the variations described by participants.

9.6 Summary

This chapter has explored features of the local context that are important for understanding the influences on implementation processes. It is clear that whilst there was some reduction in CLABSI rates, these have not been sustained, and this appears to be in spite of increased adherence to bundled components and no notable changes in contextual features such as admissions, patient demographics or central line days. The increasing adherence to some components of the bundle, such as the insertion checklist, appeared to be at odds with the findings of the observations in Chapter 7. However, local data also found that of the 180 central lines that had a documented reason for removal (54% of all central lines audited), 27% could be considered to be 'unplanned removals'; 9% were removed as they were considered to be the source of infection, 16% were dislodged and 2% due to thrombosis.

This chapter has also highlighted several features of the local culture that may have influenced the extent to which the bundle was implemented by staff. Routines, habits and rituals can be important safety features in healthcare though they may not always be effective, and distinct differences in professional cultures may result in tensions between teams. Whilst hierarchies are a natural structure of groups and communities, in this case they may have undermined and impeded implementation efforts. Cultural influences were not prospectively studied in the care bundle studies reviewed in Chapter 3, though some studies, performed after data collection for this research study had commenced, theorised that interventions such as the use of a checklist worked to flatten traditional hierarchies and enable the empowerment of nurses to stop the procedure (Hawes and Lee, 2018, Pharande et al., 2018, Savage et al., 2018, Hussain et al., 2020). It seems this has not occurred to the same extent in this context.

The following chapter will integrate the results of each method of data collection to address the research questions, including reference to the interaction between implementation, context and culture and the extent to which this has influenced bundle adoption.

Chapter 10 Discussion

10.1 Introduction

The results of this study have found that following the introduction of a care bundle there has been no sustained reduction in CLABSI rates, despite an apparent increase in bundle adherence. This is at odds with the results of the meta-analysis in Chapter 3, which suggested that the introduction of a bundle could reduce CLABSI rates by 62% (RR 0.38, 95% CI 0.31-0.47). Understanding why some interventions do not work in particular contexts is important to improve local implementation efforts and to tailor bundles to different contexts. Whilst the studies reviewed in Chapter 3 frequently described the setting, none of the studies were designed to understand implementation.

What follows in this chapter is the integration of the quantitative and qualitative results of this study in order to address the research questions, interpreted using the lens of NPT. The research questions being addressed are:

1. In the NICU, how do healthcare professionals implement a care bundle, aimed at reducing CLABSIs?
    a. How do healthcare professionals make sense of the nature and purpose of the care bundle?
    b. How do clinical teams integrate the care bundle into routine practice?
    c. To what extent does relational and normative restructuring occur?
    d. To what extent is the care bundle adapted by healthcare professionals, and how does the NICU adapt in order to accommodate the care bundle?

The constructs of NPT, with examples from this research study, can be found in Appendix 1.

10.2 How do healthcare professionals make sense of the nature and purpose of the care bundle?

NPT suggests that actors- those doing the work- need to understand how the new practices are different (coherence) and, through action, understand how they impact on their everyday work (reflexive monitoring).

10.2.1 Coherence

In general, buy-in for the bundled practices was not consistent across professional groups. All participants believed that reducing infections was important, and by the third

NoMAD survey there were high levels of agreement (80%) in beliefs regarding a shared understanding of the purpose of the bundle. However, the qualitative data suggests there were professional differences in the degree of buy-in for both the problem of CLABSIs and the solution (the bundled practices). Not all participants believed that completely eradicating infections this population group was achievable, nor that the bundle was appropriate for all staff.

Part of the problem appears to be that participants understood the purpose of the two-person technique differently. Some participants believed that an assistant primarily had a supervisory role to help insert the line, with very few participants believing the second person was there to monitor for asepsis and stop the procedure. This is strikingly different to the Michigan Keystone project, where the use of a prospective checklist acted as a mechanism of social control and that the empowerment of nurses to stop procedures was key to success (Pronovost et al., 2006). This was also retrospectively theorised in several neonatal studies published after the study in this thesis commenced (Hawes and Lee, 2018, Pharande et al., 2018, Savage et al., 2018, Hussain et al., 2020).

In order for actors to be able to implement and integrate new practices into their daily routines, they need to be able to make sense of what is expected of them- that is, the nature of the bundled components and their role in implementing them. There appeared to be professional differences here too; the nurses were unclear of the expectations for medical staff accessing central lines or indeed if it was essential for them to have two people during insertion. Whilst it was expected that medics could be ‘excused’ for not having a second person when they were busy, being busy was not a valid reason for nurses to not scrub the hub effectively.

An important part of sense making is understanding how the new work is different to previous practice. By survey three, agreement overall had improved (80%), though there was little difference between survey two and three, and a median construct score of 1 remained unchanged across all three surveys. Qualitative results revealed this cognitive work was easier for the nurses than the medics. Nurses could easily explain how current practice was different whereas some doctors felt that having a second person was “informally done” previously. Of course, the fact that not all survey respondents felt they understood the difference between new and previous practices may also be due to variable adherence to the two-person technique; if insertions are being performed alone, then there may not be any perceived difference in practice.

The findings from this research study agreed, to some extent, with the Matching Michigan study (Dixon-Woods et al., 2013), which found that a lack of buy-in was responsible for the programme stalling. The study in this thesis found that the degree of buy-in was

variable for different practices and between different groups, and what this study adds is that the underpinning professional cultures also influenced endorsement. Broadly speaking, nurses believed that guidelines were important and were highly valued, increasing endorsement for the new ways of accessing central lines, despite some individual elements of the process not making sense. In addition, some participants did not believe that eradicating CLABSIs was achievable in the NICU, which is also likely to influence the extent to which participants endorsed the new practices.

10.2.2 Reflexive Monitoring

Implementation is not linear, and as such, actors continue to appraise new practices once they are introduced; they work to determine if they are effective or require adaptation. Participants sought reinforcement on their practice; they were frequently uncertain if what they were doing was right and were unclear if the new practices had an impact on infection rates. This is likely to affect the extent to which reflexive monitoring can occur, as well as overall endorsement for the bundle. These results partly triangulated with the results from the NoMAD survey: in survey one only 61% were aware of the impact of the bundle on infection rates, though this had increased to 85% by survey three. The median construct score remained 1 across all three surveys. The time gap between survey three (October 2018) and the SSIs (July-August 2019) may explain the differences between the survey results and the qualitative data, where participants actively asked about infection rates.

Behavioural reinforcement in relation to infection control care processes is well known to be hard to deliver (Jenner et al., 1999). The invisibility of the problem (staff cannot see the problem) combined with the time lag between cause and consequence, are likely to make reflexive monitoring challenging. Participants recognised that providing feedback on these care processes was hard, and often negative. In addition, the absence of formal reinforcement meant that past experiences were relied upon as modifiers of behaviour; participants frequently described negative past experiences that influenced how they performed the task. However, this informal appraisal work is unlikely to result in sustained long-term organisational change in systems where teams and individuals, and the experiences and beliefs they bring with them, are frequently changing. The lack of reinforcement also resulted in participants questioning their own competence, making it hard to monitor colleagues' practice as a form of feedback.

Participants also apportioned responsibility for CLABSIs externally, either to other professional groups, specific types of patients, or to patients admitted from other NICUs, to explain local infection rates. It could be argued that given the high stakes nature of the context and the absence of formal reinforcement, projecting blame for the cause of these

infections is a psychologically protective strategy for staff. This is important, as if actors do not see their behaviour as contributing to the problem, then they will not perceive themselves to be part of the solution and buy-in for change may be reduced. This is in contrast to the findings of the Michigan Keystone project (Dixon-Woods et al., 2011), where it was theorised that the problem of CLABSIs was framed as being a social problem, that it was related to behaviour rather than a problem with a technical quick-fix solution (Dixon-Woods et al., 2011). In fact, in the study in this thesis, there was variable endorsement for the problem of CLABSIs, with some participants believing that an element of infection was inevitable.

The NoMAD survey respondents valued the impact that the bundle had on their work, with 95% of respondents agreeing or strongly agreeing by survey three, though the number of strongly agree responses had declined. Median scores remained consistent at 1 across all three surveys. However, the qualitative data revealed professional differences in how the work was valued. Nurses felt strongly that Surgical ANTT and AIPPs had improved their practice, whereas this was variable for those inserting central lines. In addition, the AIPPs reduced the perceived poor practice relating to scrubbing the hub, reducing potential conflict in having to challenge others. So, whilst Surgical ANTT takes longer to perform, the nurses valued the perceived benefits despite the lack of formal reinforcement. Interestingly, some components did not make sense to some nurses, and yet they still performed them. This may be because there was strong reflexive monitoring for these practices or because the shared professional culture of valuing standardisation was a strong influence. It has been recently highlighted that autonomy is a “cornerstone” of the medical profession, with guidelines being criticised as undermining professional identify (Runnacles et al., 2018). For the central line insertions, components that did not make sense or were not valued, such as hats and masks, or the insertion checklist, were dispensed with, viewed as being more useful for less experienced doctors, or adapted.

Participants felt that for new staff across both professions, the reconfiguration of previous knowledge was required, with staff having to go through a process of “unlearning” (ORI9 DOC05). This cognitive work may be hard for experienced clinicians who have well-established ways of doing things without having had any problems, for junior doctors who rotate between clinical areas or for temporary staff. It was felt that nurses quickly learnt “the way we do it here”, with one nurse realising she had forgotten how she used to change fluids in another unit. However, this was not the case for medics; one participant said that he wouldn’t change his practice as no one had ever told him that a line he had inserted had an infection. It can be seen clearly here that reinforcement is important for the reflexive monitoring work that is required when implementing new practices in order to reconfigure previous ways of doing things and improve endorsement for new practices.

In the absence of formal reinforcement, staff had to rely on individual appraisals of bundle efficacy, and this may have significant limitations. Nurses, for example, relied upon "feeling" like things were "cleaner", or that they were giving fewer antibiotics. This informal appraisal may provide false reassurance, particularly given that infection rates had not improved.

10.3 How do clinical teams integrate the care bundle into routine practice?

The results of this study suggest that there is variable integration of the bundle components into routine practice. Whilst some practices such as Surgical ANTT and AIPPs have become part of nursing routines, the insertion practices have not become normalised in the way that was intended. Despite audit data demonstrating improving adherence, qualitative data revealed adaptation and variation in how some practices were enacted, providing a possible explanation as to why a reduction in CLABSI rates has not occurred.

10.3.1 Cognitive Participation

This construct, outlined in Appendix 30, involves the work that actors do to build and sustain a community of practice around a new process. Median scores for questions relating to this construct were between one and two. In fact, this was the only construct in which some questions achieved a median score of 2. However, by survey three, the median score was 1 across all aspects of cognitive participation, suggesting a slight reduction overall. The qualitative data was able to offer explanations and illuminate the survey results, though sometimes the data was contradictory.

Central line fluid changes were a routine task, performed daily, and they appeared to be ritualistic in the observations of practice. Whilst ritual in nursing is often criticised for being associated with habitual and meaningless activities, rituals represent significant routines of care and as such may provide reassurance, avoid harm and identify sources of error (Wolf, 2013, Holland, 1993, Strange, 1996). In a high-stakes context with no formal reinforcement, ritual is likely to provide reassurance to nurses. In this situation, where nurses place value on the ritual of Surgical ANTT, it is unsurprising that there is tension when other professions do not subscribe to the same practice. To some extent, a community of practice had developed that had not occurred in the same way for line insertions.

Professional groups and individuals operationalised these aseptic practices differently. This may explain some of the variation observed in handling of the AIPPs, as participants

in both insertions and accessing lines made decisions among themselves regarding what was appropriate. Nurses also identified that the doctors did not operationalise the process of accessing central lines in the same way. Both professions described difficulties in trying to remain “sterile”; they referred to trying to assess risk, which was hard. It would appear that ‘mindlines’, or ‘guidelines in the head’ (Gabbay and Le May, 2004, Gabbay and le May, 2016) were used by participants as they worked together to establish socially acceptable standards of practice.

With limitations in coherence around certain central line practices, it is unsurprising that some did not feel it was appropriate for them to engage with the bundle. This weakness in legitimacy crossed both professions. For example, as the two-person technique was believed to be an educational or supervisory role, rather than monitoring bundle adherence and asepsis, involvement in central line insertions was not considered to be part of nursing work. Medics therefore did not enrol nurses in this work, not perceiving it as a nursing role either. Consequently, nurses valued *not* being enrolled in this process, as it allowed them to get on with other work that they believed to be more legitimately part of their role, furthering the endorsement of this as a medical role.

The qualitative results were partly contradictory to the survey findings, as by survey three, almost all respondents (98%) agreed or strongly agreed that involvement in the bundle was a legitimate part of their role. This may be because the survey referred broadly to the ‘bundle’ rather than specific practices. Qualitative data revealed that whilst nurses did not feel they should be involved in central line insertions, they did believe that they were the most appropriate members of the team to access central lines. As nurses were the largest group of survey respondents, this may explain the differences between the survey and interview data. The division of labour around Surgical ANTT was clear and there was clear legitimation for this as a nursing role.

Underlying cultural assumptions relating to the perception of busyness is an influence upon legitimacy in this context, with medics not wanting to be seen to increase the workload of nurses. In fact, there were fears during bundle development that making the assistant role a nursing role would be too burdensome for the nurses and would not be implemented. There is a striking difference here between the local bundle implementation and the Michigan Keystone project which had, as its central tenet, the empowerment of nurses as assistants who had the authority to stop the procedure if any part of the checklist was not completed (Dixon-Woods et al., 2011). The updated systematic review of neonatal studies (see Chapter 3.3) also emphasised the importance of nurse empowerment (Hawes and Lee, 2018, Pharande et al., 2018, Savage et al., 2018, Hussain et al., 2020).

There appeared to be a diffusion of responsibility between teams for some bundled practices, such as reviewing central line dressings. ANNPs, whose past experiences and previous training in both the nursing and medical aspects of central line care, believed that this was a collective responsibility but recognised this was not the case in practice, which was a source of tension. Similarly, it was unclear who was responsible for ensuring that the medics used two people when they inserted a line. Given that there was also a lack of coherence around this practice, it is unsurprising that monitoring it was hard. Without any clear responsibility, gaining endorsement for and subsequently adherence to, bundled practices may be challenging. Gaps in the bundle likely worsened this. In contrast, practices that had clear lines of responsibility, clear divisions of labour and clear responsibilities for monitoring, such as the AIPPs, were well embedded. The AIPPs clearly made sense to nurses and the impact on their work was valued. This, in addition, with their clear legitimation as a nursing role, contributed to their successful implementation.

Qualitative data also suggested that there were not key individuals driving change; there were very few references to leadership suggesting that this was missing from implementation plans. There were key individuals who were informally responsible for certain elements, such as teaching handwashing at doctors' induction or keeping the surgical hand scrubs visible on the unit, but these individuals had retired. Individual consultants were identified as primarily responsible for teaching central line practices to the junior doctors but not for monitoring practices. In survey one 59% of respondents agreed or strongly agreed that there were key individuals promoting the bundle, though this increased to 78% by survey three. May et al. (2016) argue that in complex-adaptive systems, where a high level of commitment for new practices is lacking, specialist practitioners or facilitators are required in order to help implement a new intervention as intended. Indeed, similar studies evaluating bundle implementation in other healthcare settings recognised the need for strong leadership (see Chapter 2).

10.3.2 Collective Action

This NPT construct, described in Appendix 30, involves actors mobilising skills and resources to enact a new process, which appeared to be challenging in this context. Median NoMAD survey scores for questions relating to this construct were between 0 and 1, and in fact this construct showed the most improvement in overall score as the median score was 1 across all aspects of collective action by survey three. Questions that showed improvement in median scores were related to the provision of training and resources, and qualitative data was able to explore these findings in more detail.

It was clear that there were some circumstances where those responsible for performing the task were not always the ones with the knowledge and skills to do so. Knowledge

about central lines was often role-specific, and unequally distributed, as not everyone had access to the same knowledge. For example, not all nurses attended governance meetings where infection rates were reported and not all nurses had an overview of infections on the unit. Some nurses did not know “the truth” about central line insertion practices. The division of labour between and within teams was not always appropriate, for example, those with the most knowledge regarding accessing lines- the nurses- were not allowed to access lines to flush them if the pressures were high or to administer contrast. This work was assigned to junior doctors and was frequently raised by nurses as an aspect where practice was variable and frequently perceived to be poor. Similarly, it was unclear whose skill set was most appropriate to redress central lines, with some feeling that experienced nurses would be better placed to do this than junior doctors. Local hierarchies and professional tensions likely weakened the overall relational and interactional integration, with participants referring to the work of others as separate from ‘their work’. The siloed division of labour in combination with these challenges may partly explain the variations observed. Moreover, the mismatch of the division of labour is likely to have an impact on bundle endorsement, resulting in practice variations influenced by the degree of experience individuals have.

Relational integration- the degree of confidence participants had in each other’s practice- was also a challenge. There was very little change in survey responses to this question; by NoMAD survey three only 67% of respondents agreed that they had confidence in their colleague’s abilities to use the bundle. Interviews revealed that whilst nurses on the whole had confidence in each other, some nurses lacked confidence in the medical teams’ abilities to access central lines according to the bundle. This may stem from differences in how the procedure was both conceptualised and operationalised by the two professions; nurses referred to medics not wearing sterile gloves or not using two people but did not refer to details of how the task was performed in regard to the key parts, which is integral to the process. Interestingly, one nursing pair recognised that they did not perform the pre-procedure hand wash in the same way as the medics. Equally, some medics felt that nurses did not always perform the scrub the hub technique appropriately. These professional tensions made surveillance and the monitoring of practice hard, though on the whole participants did not feel that working relationships were disrupted by these new practices. In fact, broadly speaking nurses felt that the bundled practices improved team working on the unit. Organisational support, or management supporting the bundle, was not explicitly discussed by participants, but the NoMAD survey identified that by survey three, 77% of respondents believed that the Trust supported the bundle, with an increase in both agree and strongly agree responses overall. It may be unclear what participants interpreted as the Trust in this context, or what support was expected.

Training is necessary so that staff are not only aware of the expectations of practice (the rules), but also to learn the skills that some participants felt were lacking in their colleagues. The NoMAD survey found that approximately a third of staff did not feel there had been sufficient training. There was triangulation here with the ORI data, as participants felt they learned the skills from each other and did not discuss any formalised training. Participants in both the ORIs and the SSIs questioned how staff were taught, or if they were taught the same way, and there was a difference between the teaching as imagined in the SSIs (how participants believed others were taught through formal educational sessions or induction training) and the teaching as done- how those enacting the task in the ORIs believed they had learnt the skills (learning from each other). There was also a lack of confidence in what was being taught to new staff or new doctors, with some participants questioning what others were taught, or if they were taught the same way.

Participants felt that there were insufficient resources to implement the bundle, and there was triangulation here between the survey, ORIs and SSIs. By survey three, 24% responded either neutrally, or disagreed, that there were sufficient resources to implement the bundle, though this had improved from survey one. The qualitative data was able to explore more fully the experiences of participants, finding that insufficient staffing, workload demands and the availability of resources, were all felt to make implementation difficult. Whilst nurses frequently referred to the challenges of having to find a second person or having to leave the nursery to locate additional resources, they felt that they always managed. They made the effort to mobilise and organise resources, even in difficult circumstances, and this may be because there was strong endorsement and buy-in for the bundled practices. However, this was limited to the practices where they felt it was legitimate for them to participate in, they did not organise or mobilise resources in the same way for the central line insertions, which they felt was not their role. Interestingly, there was a lack of communication between the teams regarding the organisation and prioritisation of care, and this experience was shared by participants in the SSIs. Medics did not appear to mobilise resources in the same way, with participants frequently recalling doing the process alone if there were insufficient staff.

Insufficient resources and competing workload demands may also have an impact on the monitoring of practice, as participants reported not necessarily watching each other closely. This is despite the belief that behaviour changes when someone is watching. It can also affect the formal monitoring of practice; Bannatyne et al. (2018) found that planned audit data had to be abandoned due to insufficient staff to collect it and a lack of commitment. This reaffirms the importance of getting buy-in from clinical staff for the bundle as well as the problem (CLABSIs). Indeed, LeMaster et al. (2014) found that the

most effective audit and feedback strategy was resource-intensive. This resonates with the findings from this research, where routinely collected clinical audit data was not performed prospectively as intended.

10.4 To what extent does relational and normative restructuring occur?

Normative restructuring relates to changes in the rules, social norms and resources that provide the capacity for change to occur within a setting, whilst relational restructuring refers to changes in the social interactions and relationships between actors. These social interactions provide the underpinning capacity for actors to engage, interact and mobilise the resources and knowledge required to implement new practices (May et al., 2016).

10.4.1 Relational Restructuring

Whilst a degree of relational restructuring occurred, it did not occur consistently for all aspects of central line care. The NoMAD survey suggested that relational integration and enrolment in the new practices were stronger aspects of local implementation: there was a consistent median score of 1 for being willing to work with colleagues in new ways, though there was a reduction in median score from 2 to 1 regarding having confidence in colleagues' abilities. The majority of respondents (75%) by survey three felt that the bundle did not disrupt working relationships, which appeared to be in agreement with participants' beliefs when asked in the SSIs, with most nurses responding that the bundle had improved relationships. However, some participants described professional tensions and a hierarchical culture, which may have resulted in some poor practices being un-challenged. When there are tensions between teams, the collective effort required to enact the work together to embed new practices may be harder. These findings are similar to the Matching Michigan study which found that professional norms went 'unchallenged' and the status quo remained the same (Dixon-Woods et al., 2013). It may be that a degree of disruption was required in the NICU in order to change the 'status quo', which contradicts question ten of the NoMAD survey, where the disruption of working relationships was perceived to be a barrier to implementation.

For nurses, the new practices were believed to have improved intra-professional dynamics between nurses, making it easier to challenge each other and as such reduce conflict between each other. This contributes to endorsement for the bundle, as it makes their day-to-day work easier. However, whereas nurses would have previously been an assistant in a central line insertion informally, formalisation of the two-person role has meant that nurses no longer see it as part of their role. Formalising this as a medical role

has ‘freed’ the nurses up to do ‘their own work’. The nurses endorsed the medical assistant role, and this has become the normalised way of working; this is the opposite of what occurred in the Michigan Keystone project in which nursing empowerment to stop the procedure was felt to be integral (Dixon-Woods et al., 2011).

Challenging poor practice was hard both within and between professional groups. New practices may be less likely to be embedded when actors are unable to effectively regulate each other’s practice, and this may be made worse where there is diffusion of responsibility, resulting in a lack of reinforcement. AIPPs, for example, were monitored daily during their implementation and it was considered unacceptable to not have them attached (SSI9, NURS0703). They were easily visible, making challenging practice easier and making nursing work easier, resulting in endorsement for the new practices. To some extent, it could be argued that the AIPPs flattened hierarchies within the nursing team, making it easier to challenge each other. These factors made it easier to reinforce and enforce the new practices. Dixon-Woods (2016, p. 225) argued that in systems without monitoring and accountability, some care processes can become normalised as optional:

> […] the absence of a forum responsible for monitoring its use and the inability of individual nurses to challenge (high status) physicians meant that sanctions for non-use or poor use were not applied. Ultimately the site abandoned the checklist altogether.

This quotation has clear resonance for this research study. Dixon-Woods (2016) argued that healthcare providers should not be afraid of providing reinforcement, accountability and sanctions for poor practice, though this needs to be appropriate and fair. Systems with harsh or punitive sanctions had a negative impact on challenging practice.

For central line insertions, disruption to working relationships had to occur in order to restructure social norms; staff needed to feel able to ask each other for help or challenge each other, both between and within professional groups. Uncertainties in understanding what was expected (the rules) and the underpinning hierarchical culture, meant that this disruption was, perhaps, hard to achieve. In the Michigan Keystone study, and several more recent neonatal studies, implementation success was attributed to flattening hierarchies, achieved through the introduction of a checklist and nurse empowerment (Hawes and Lee, 2018, Pharande et al., 2018, Savage et al., 2018, Hussain et al., 2020). Checklists have been argued as one way to democratise knowledge by providing a reliable translation of knowledge between different professional cultures, thereby improving communication (Winters et al., 2009). This degree of relational restructuring has not occurred: the checklist was not used prospectively; some nurses do not feel able to

challenge practice; and some referred to not being listened to when they did challenge practice.

Whilst nurses reported feeling able, for the most part, to challenge nursing colleagues, it would seem they do not always have the perceived authority to challenge other professions. In fact, when concerns were raised to the medical team, one nurse commented that part of the problem was “getting an appropriate response” (SSI11, NURS0610) whilst other nurses felt that they “nag, nag, nag and then just give up” (SSI7, SSI9, SSI11). Learned helplessness- where actors feel they have little control or authority over their work or environment- may be important here (French, 2011). Indeed, feeling like “one person in a big pond” may also have contributed to difficulties in relational restructuring (SSI14, NURS0804). Similarly, one consultant feels he does not have the authority to challenge the nursing practices of accessing central lines. This disconnect is likely to make the monitoring of bundle implementation hard. Indeed, in an recent ethnographic study of safety in a UK maternity unit, Liberati et al. (2019) found that monitoring and reinforcement of practice standards was important and occurred through social control. Informal monitoring of practice standards, alongside staff being prepared to use sanctions and intervene in order to bring behaviour “back in line”, were important in contributing to unit safety (Liberati et al., 2019, p. 69). It was also noted that non-adherence to standards was possible to allow for discretion, but that this was not an automatic privilege of status within a hierarchy. Instead, sapiential authority- authority based upon experience or having particular knowledge or skills- was considered important for patient safety (Liberati et al., 2019).

More widely, knowledge and authority hierarchies continue to be significant barriers to efforts to improve safety in healthcare (Green et al., 2017, Darbyshire and Thompson, 2018). Triantafillou et al. (2020) found that hierarchies were a barrier to infection prevention practices in a Greek NICU. As part of the local NICU’s implementation plan, it had originally been intended that the infectious diseases meetings would move to being a bedside ward round as a form of educational outreach, though this continues to take to place in the doctor’s office attended by the medical team. Knowledge hierarchies regarding the management of CLABSIs or discussions about the source of the infection, are therefore restricted to profession-specific roles on the NICU. Hierarchies may also make asking for help difficult for junior doctors, and there was a suggestion that not wanting to fail or wanting to be autonomous, may be also be a barrier to bundle implementation. Similar findings were reported by Lewis and Tully (2009) in regard to medical prescribing errors; junior doctors did not want to appear incompetent. None of the bundled interventions enabled junior doctors to navigate these challenges; the checklist did not give them permission to ask for help or to escalate, nor did the checklist reframe

being challenged as acceptable. However, ultimately the retrospective use of the checklist meant that there were no processes built into the system to empower others to stop the procedure.

10.4.2 Normative Restructuring

Whilst normative restructuring had occurred for the nursing practices, with there being clear rules regarding how central lines should be accessed, this restructuring of rules and norms had not occurred in the same way for the doctors. In fact, there were different inter-professional normative expectations that caused conflict, such as for accessing central lines. Lack of clarity over the division of labour and challenges with cascade training compounded these differences.

The introduction of an insertion checklist did not restructure social norms, and its retrospective use may have resulted in it becoming what one participant called a “tick-box exercise” (SS12, DOC04). Indeed, the audit data suggests that the checklist was not always completed accurately, despite increase adherence (see section 9.4.2). Checklists have been seen as a way to establish social norms by modifying peer group references for expectations of practice (Johnson and May, 2015). However, whilst participants acknowledged the checklists’ existence, it was apparent from the observations that these were not being prospectively used in practice. Indeed, several nurses also recognised that guidelines are not really used in their day-to-day work (SSIs 1,8,11,14). As such, participants appeared to be use mindlines, or “guidelines in the head”, negotiating between each other what was an acceptable standard of practice and way of working. An example of this was regarding who removed the AIPP during Surgical ANTT, with one participant saying, “we haven’t decided, as a unit, what do about that yet” (ORI8, NURS0511). Participants relied upon experiential and tacit knowledge to co-create normative standards of practice. This may be problematic if both actors involved in the procedure have limited experience and are unclear of the normative expectations on the NICU. Issues relating to relational and normative restructuring may mean that there were some normalised poor practices that were socially ‘accepted’ and went unchallenged, such as wandering around wearing maximal barrier precautions, preparing group morphine infusions, or not checking hourly percutaneous pressure scores. The inclusion of the AIPPs into the daily nursing checklist and regular auditing meant that accountability was built into the system for ensuring they were in place, in a similar way to the Michigan daily goals checklist (Pronovost et al., 2008). Using reminders that build accountability into the system may promote implementation *as intended*.

10.5 To what extent is the care bundle adapted by healthcare professionals, and how does the NICU adapt in order to accommodate the care bundle?

The degree to which an intervention can be adapted to suit its context (plasticity), and how flexible the context is to incorporate the new practices into daily routines (elasticity) are important mediators of bundle adoption.

10.5.1 Elasticity

The elasticity of context refers to the extent to which contexts can be stretched or compressed in order to accommodate new interventions. Contextual elasticity provides actors with the room to manoeuvre, whilst inelastic contexts can be characterised by rigid group processes or impermeable organisational structures (May et al., 2016). This NICU appeared to have a high degree of elasticity, providing actors with room to adapt and negotiate relational and resource components of implementation. However, in a context with high elasticity but without surveillance and monitoring, this may have resulted in some bundled elements not being implemented as intended. This flexibility perhaps fits well with those that valued individual clinical judgement rather than rigidly following guidelines; however, it brings some conflict for the nursing teams, which, on the whole, preferred standardisation. Indeed, the ritual of Surgical ANTT and the use of AIPPs appeared to have a good ‘fit’ with the nursing culture that valued standardisation. This elasticity of context has meant that the assistant role for insertion is considered optional, rather than something that is rigidly enforced, as actors navigate resource availability. However, in some cases, there were inelastic infrastructures, and it was felt that the electronic patient record system had resulted in the checklist being used retrospectively.

10.5.2 Plasticity

Interventional plasticity refers to how malleable an intervention is (May et al., 2016). The more plastic intervention components are, the more discretion actors have about how to use them in practice. AIPPs and Surgical ANTT were relatively un-plastic components; whilst nurses could adapt the role allocations, the procedural steps were felt to be structured. However, they had sufficient plasticity that they could be adapted in unavoidable exceptions, when it was perceived to be in the best interests of the patient, such as returning to standard ANTT. The two-person technique had a high degree of plasticity and actors had a large amount of discretion about how to implement this in practice. Local guidance implied that those unfamiliar with insertion should be supervised by someone with experience in the procedure, and outlines that nurses help prepare for

the procedure, provide patient comfort, monitor temperature and use the checklist (see Appendix 5). However, this initial *plasticity* appeared to result in both professions perceiving this to be a medical role, unintentionally causing a degree of rigidity imposed by actors themselves. This was in combination with an elastic (or flexible) context that did not provide monitoring or surveillance. This is likely to have resulted in the workarounds, variations and uncertainties that were both observed and discussed by participants. These variations in bundle adoption and integration may explain why CLABSI rates have not reduced.

Some components had too much plasticity- that is, there were no rules for staff to refer to or they were not enforced; as such, this represents a limitation in the workability of the bundle. It could be argued that in this context, providing staff with a large amount of freedom to make individual clinical judgements alongside differing inter-professional expectations of practice, contributed to staff uncertainty. Participants actively sought reinforcement about what they should do for certain aspects of central line care where there was no clear guidance. It is not surprising then, given that there were gaps in the bundle and a lack of reinforcement, that participants would externalise the blame for CLABSIs onto other professional groups, patient groups or healthcare settings. The insertion processes appeared to have a high intervention-to-context-fit to promote sustainability, but at the expense of intervention fidelity.

Participants discussed ways in which the bundle could be adapted in the future in order to improve its workability and integration into the context, and this supported the NoMAD results that feedback could improve the bundle. Examples including having paper versions of the insertion checklist and incorporating checking central line dressings into daily nursing checklists. Participants also discussed how the NICU could undergo adaptation in order to facilitate the integration of the bundle components more effectively, to help align the work as done with the work as imagined. These suggestions included strategies for providing reinforcement as well as for regular surveillance and monitoring. However, one of the challenges in this setting was the number of reminders and guidelines, with some participants recognising the risk of habituation.

10.6 A Conceptual Model of Implementation

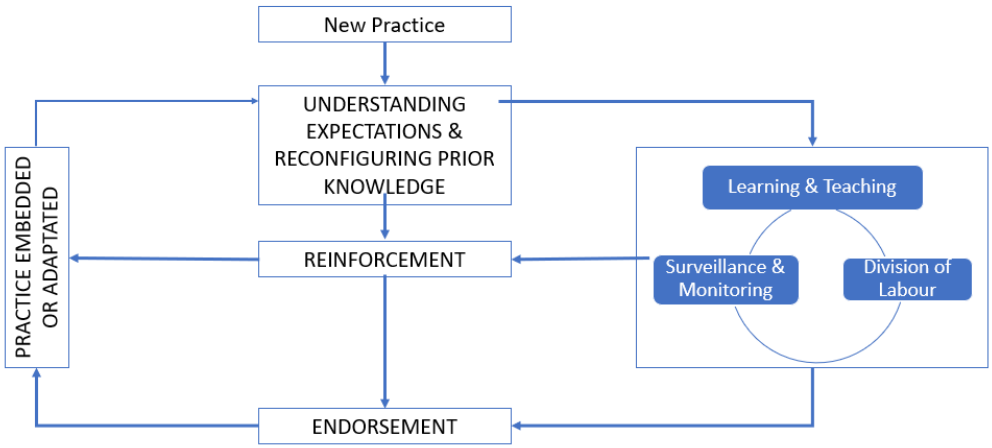
Implementation is not linear, and interactions between actors, the context and the intervention can result in variation and adaptation over time (May et al., 2016). Therefore, conceptualising implementation can be challenging given this unpredictability. Instead, implementation should be viewed as a continual evolving process, with interactions between context, actors and the intervention feeding back into the implementation

process. A conceptual model, described as providing an orderly and unified way of representing events or processes, can help understand not only what is happening but also *why* it is happening (Robson and McCartan, 2016, Mock et al., 2007). A conceptual model was developed using the findings of this study in order to describe the relationships between key concepts, and also to illustrate how the findings of this study fit (or not) with NPT, and identify any contradictions between them (see page 211). This enhances the study's ability to contribute further to the field of implementation science.

The conceptual model was developed in the following way: preliminary links between themes (or concepts) were initially identified during data analysis. After completion of analysis, all the key concepts identified in this study were collated. Then, connections between concepts and how they related to each other were identified. It was important at this point to take the widest view possible drawing upon not only the results of this study but also the pre-existing literature reviewed in earlier chapters of this thesis (see Chapter 1, Chapter 2, and Chapter 3). The development of the conceptual model was iterative, as relationships between concepts, and their influence on implementation, were identified. For ease of visual representation, the core concepts within the conceptual model have been presented as connected by a series of arrows; however, each of the concepts may both facilitate or hinder the adoption of a new practice, and to varying degrees. For example, whilst actors may initially understand what is expected of them, the way in which the work is enacted may result in more (or less) *Endorsement*.

Figure 21 demonstrates the conceptual model for implementation, which starts with the introduction of a new practice (or technology). At this point, actors need to be able to *Understand Expectations* (they need to know the 'rules') and may have to go through a cognitive process of *Reconfiguring Prior Knowledge*. This is important in ultimately contributing *to Endorsement*; if they do not understand how the new practice is different to their previous way of working, or do not understand it, it is unlikely they will enact it. Actors also need to perform a series of *actions* where they work together (or not) to enact the new practice; these including *Learning and Teaching* the new practice, the *Division of Labour* and *Surveillance and Monitoring*. Actors need to learn the new way of working and negotiate how to allocate the work, both between and within professional groups. *Surveillance and Monitoring* of each other's practice also needs to occur at this stage. All of these processes are interconnected and influence each other: *Learning and Teaching* may influence actors how actors *Divide the Labour*, and without training they may not feel able to confidently undertake *Surveillance and Monitoring* of practice. Indeed, how the work is divided may influence the extent to which the process is monitored effectively, and without *Surveillance and Monitoring*, the work may be allocated differently to how it was intended. Actors may consequently learn different ways of working from each other.

Figure 21 Conceptual Model for Implementation



All of these concepts influence the extent to which actors receive informal reinforcement on their practice through the work they do; as they enact the new practice, they are determining how worthwhile it is. *Reinforcement*- the process of encouraging or establishing a belief or pattern of behaviour- and *Endorsement*- the process of supporting or approving something- are related but independent concepts. Getting buy-in or support for a new practice is important though not contingent on reinforcement; practices may be endorsed without formal *Reinforcement,* and similarly *Reinforcement* may be used to enforce a practice or behaviour even if it lacks approval or support. Both of these concepts can be viewed as either positive or negative moderators of implementation; for example, whilst they may individually result in a practice being embedded or adapted in Figure 21, it could be that one enables routine adoption whilst the other may simultaneously hinder it. It could be argued that having both *Reinforcement* and *Endorsement* facilitating implementation is more likely to result in the adoption of a new practice. *Reinforcement* can be informal- through individual experiences and interactions- or formal- through specific interventions such as the provision of feedback or having an external observer. As implementation is viewed as a continual process, Figure 21 demonstrates how, following a practice being embedded or adapted, this will then go on to influence how actors make sense of it and how they work (collectively) with it.

As actors work together to embed a new practice through the *Division of Labour, Learning and Teaching,* and *Surveillance and Monitoring*, these concepts influence how much *Endorsement* or buy-in actors have for the new practice. If there is a lack of *Endorsement*, and no *Reinforcement*, then it is likely that actors will either adapt the new practice, develop ways to work around it, or simply not implement it at all. Adaptations or workarounds ultimately feed-back into actors' how actors understanding what is expected, and without *Reinforcement*, these adaptations may become the new 'rules' subsequently

altering how actors *Understand Expectations*. Adaptations may make more sense to those doing the work; they may be easier to teach, make the allocation of work easier, or be easier to monitor, and for a variety of reasons may have greater *Endorsement*. Without R*einforcement*, these adaptations may continue to be enacted and may no longer resemble the original intervention. Adaptation may, of course, be beneficial in embedding a new practice, but it may be at the expense of intervention fidelity, and so the practice may no longer work in the way it was intended.

Formal *Reinforcement* is important at every stage in this process; if actors do not receive any formal *Reinforcement*, or actors are having to rely solely on their own experiences, this will influence the extent to which they 'buy into' or *Endorse* the new practices. For example, if there is no feedback on the bundle's impact on CLABSI rates, then actors may be less motivated to implement the bundle, particularly if it requires significant resource mobilisation or goes against deep-rooted professional values. Equally, without *Reinforcement* actors may believe a new practice (or technology) is effective even if it is not, such as staff 'feeling' like they are giving less antibiotics.

As the results of this study have demonstrated, *Organisational, Cultural and Situational Influences* also impact on implementation. These could be considered to be 'local conditions' that exert external influence upon the process presented in Figure 21. As such, they are not represented in the conceptual model but instead should be viewed as the stage upon which this process is enacted by actors. Whilst actors may initially be able to *Understand the Expectations* of practice, factors such as resources, workload demands, professional cultures and professional hierarchies may all influence the extent to which actors enact, and subsequently have *Endorsement* for, the new practices. For example, some components of Surgical ANTT were not endorsed by all nurses, and yet they all still enacted it. This may be because nurses, on the whole, valued standardisation and disliked challenging others. This also explains why reinforcement strategies may need to take into consideration these 'local conditions' such as professional cultures or workload demands, and may require tailoring to different contexts (see section 10.8.1). In addition, the data has demonstrated that the degree of experience and uncertainty (*Situational Factors)* influence implementation. For instance, those with less experience may require a greater degree of reinforcement; they may have different training needs, require closer monitoring or a different division of labour.

In order to test the model for goodness of fit, it has been applied to two elements of the local bundle; the AIPPs (see Figure 22) and the two-person insertion technique (see Figure 23, page 210). Figure 22 shows that despite not receiving feedback on the impact of AIPPs on CLABSI rates, there was daily monitoring and immediate individual feedback (*Reinforcement*) to the responsible bedside nurse if AIPPs were not in place. 'Bundling'

together strategies such as visual aids, surveillance (audit and feedback) and a daily checklist (reminders), as well as the visibility of the intervention- the green AIPPs- acting as a reminder of the *Expectations*, could be argued to have successfully restructured social norms. Instead of disrupting working relationships, they made it easier for the nurses to monitor and reinforce the new social norm; as such, they restructured relationships, potentially flattening hierarchies and further improving buy-in.

Figure 22 Conceptual Model for Implementation applied to AIPPs

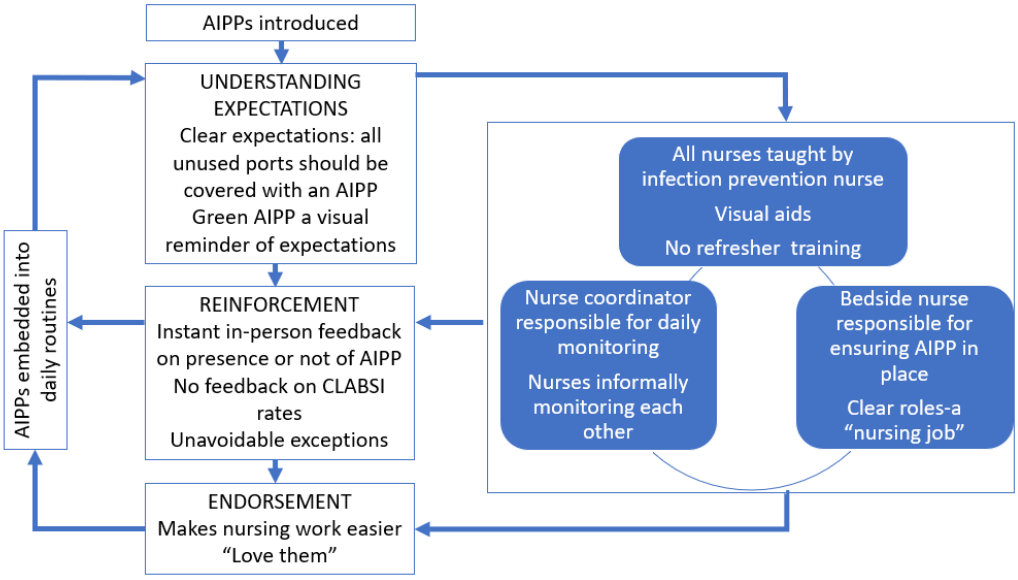
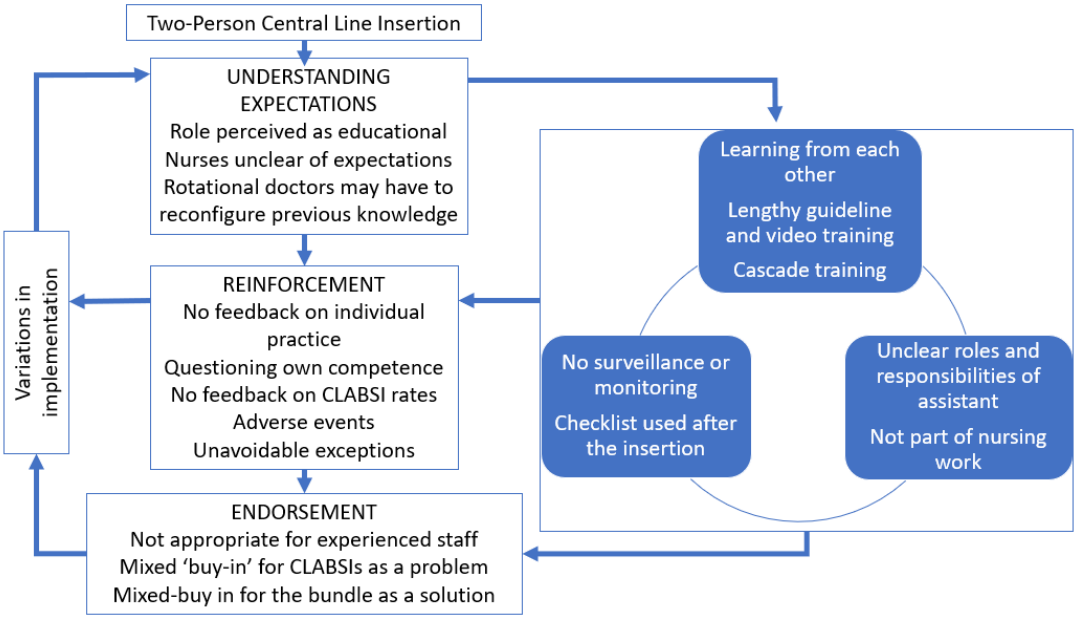


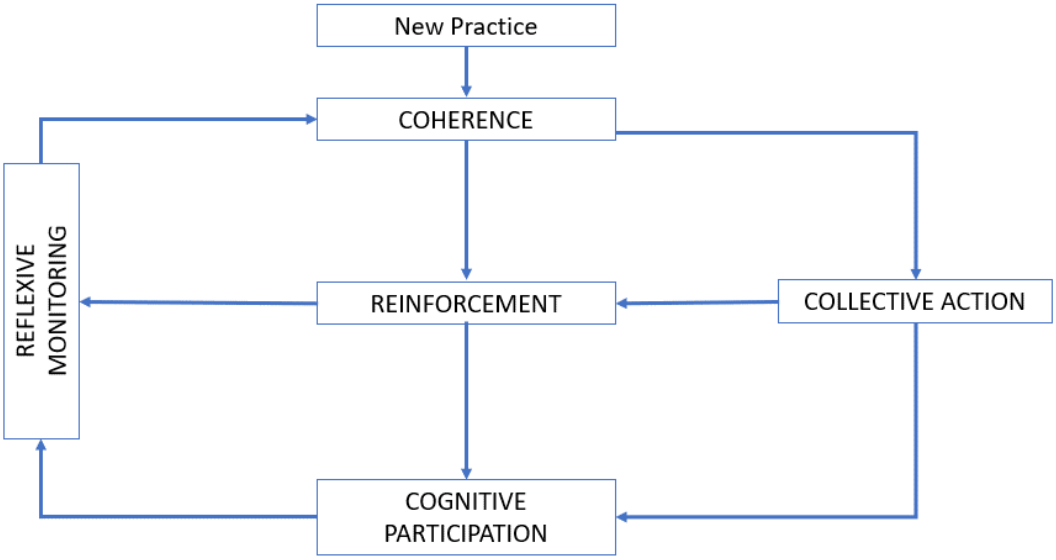
Figure 23 applies the conceptual model to the two-person technique for central line insertion. There were inter- and intra-professional differences in expectations of the two-person technique, being viewed almost exclusively as a medical role. This was influenced by actors learning the processes with unclear *Expectations*, a lack of clear roles, and the use of the checklist retrospectively, which may have resulted in challenges in *Surveillance and Monitoring*. The 'local conditions' (or the 'stage' for implementation) also made this process harder; professional hierarchies made it harder to monitor and subsequently *Reinforce* the new practice, and a deep-rooted professional culture valuing professional autonomy made getting full *Endorsement* for the practice tricky. Getting consistent support and approval for a new practice is likely to be key to the long-term sustainability and normalisation of new practices. This may be challenging in hierarchical contexts or where teams are frequently changing. Interventions that build in accountability and flatten hierarchies may work to change the cultural 'stage' that underpins (or undermines) implementation efforts.

Figure 23 Conceptual Model for Implementation applied to Two-Person Central Line Insertion Technique



In order to apply the results of this study within the wider field of implementation theory, Figure 24 applies the conceptual model to the constructs of NPT. It is important to reiterate here that there is likely to be movement both up and down these constructs. For example, the process of reflexive monitoring is likely to occur continually as actors enact new practices. However, by using NPT as a lens through which to interpret the findings of this study, it is apparent that there were weaknesses in some of the bundled components across all four constructs. There were inter- and intra- professional differences in how participants made sense of the bundle (coherence), how they worked to embed new practices and mobilised resources (collective action), and how they established a community around new practices (cognitive participation). The ability to appraise new practices (reflexive monitoring) was also different between professional groups. Without continual *Reinforcement*, variations and uncertainties resulted in a lack of *Endorsement* for some elements of the bundle.

Figure 24 Conceptual model applied to NPT



This thesis has identified the importance of behavioural *Reinforcement* in implementation and Figure 24 demonstrates the importance of this concept within NPT. *Reinforcement* is both a part of, and a precursor to, cognitive participation and reflexive monitoring. Cognitive participation- the work required to build and sustain a community of practice- ultimately requires those doing the work to endorse the new practice, to support or approve of it, particularly if the work requires substantial effort or mobilisation of resources. *Reinforcement*, therefore, is an important part of this cognitive work: it is required for actors to understand if their behaviour is socially acceptable and in line with expectations. In fact, without formal *Reinforcement*, variations in practice may actually be sustained. For example, for central line insertions, the role of the assistant was perceived as supporting or teaching less experienced actors, as opposed to monitoring asepsis or stopping the process. Without formal *Reinforcement* this has become the restructured socially accepted norm. As not all actors believe they need teaching or supporting, having a second person was not always considered appropriate nor was it seen as essential for patient safety. Indeed, whilst informal and communal appraisal work is part of reflexive monitoring- the appraisal work that people do to assess and understand the ways that a new set of practices affect them and others- and as such act as a form of *Reinforcement*, *Reinforcement* itself is also an important precursor to appraising a new set of practices. Without it, variations or adaptations may be valued or seen as more effective, and so may continue to be enacted. Whilst adaptation may aid sustainability, as interventions may be adapted to fit local contexts, this may be at the expense of intervention fidelity. Indeed, in an ethnographic study of patient safety in both developing and developed countries, Dixon-Woods (2016) concluded that systems require reinforcement to sustain new practices, and that in the absence of consequences, aspects of patient care tended to

become normalised as optional or be poorly performed. In addition, CLABSIs present a challenge for reinforcement due to the time delay between behaviour (for example, ineffective decontamination of needleless connectors) and consequence (developing a CLABSI), making apportioning responsibility hard. Indeed, whilst unavoidable exceptions such as emergencies were frequently cited as reasons for not always adhering to the bundle, this likely represents an accepted way of working. Issues related to the delay between behaviour and consequence, along with the lack of reinforcement, may have resulted in this norm having gone unchallenged.

In this study, participants raised concerns regarding how best to provide reinforcement, voicing concerns that negative reinforcement may damage morale or make people dislike their jobs, or that it may be perceived as harassment. They wanted to avoid attributing blame (see section 8.4.3). Whilst negative reinforcement has been argued to contribute to moral distress and burnout in healthcare (Smaggus, 2019), absent reinforcement may also have adverse effects. In fact, traditional hierarchical cultures rely on reinforcement as without it those in 'lower ranks' may feel undervalued and feel that their efforts go unrecognised (French, 2011). This may ultimately lead to reduced buy-in for new practices, particularly if effort is required to restructure working relationships or social norms. The absence of reinforcement, in this context, may have contributed to the variations, uncertainty and tensions found in this study, all of which are likely to undermine implementation efforts. However, simply providing more positive reinforcement may also be ineffective as participants in this study identified that reinforcement may not always be appropriate; feedback may sometimes be perceived to be inappropriate, being given for "just doing your job", or habituation may occur to repeated reminders (see section 8.4.3). Interventions that include a combination of fixed and variable reinforcement strategies, perhaps through regular monitoring and improving collective knowledge, may be more likely to improve endorsement. Furthermore, tailoring reinforcement strategies to different underpinning professional cultural values may be required (Kortteisto et al., 2010).

Johnson and May (2015) proposed that interventions that restructure practice norms, (through the use of opinion leaders, educational outreach, educational meetings and materials) along with those that restructure relationships (through the use of reminders, audit and feedback) are more likely to result in behaviour change. The restructuring of practice norms is argued to occur by providing clear expectations of behaviour, whilst relational restructuring occurs by reinforcing these group norms through an external reference group. The findings from this study support the hypotheses proposed by Johnson and May (2015) as there was a lack of normative and relational restructuring for some central line processes. There were unclear expectations for some practices and no clear external reference group monitoring practice. In fact, in this study there was a lack of

relational restructuring. In the absence of formal *Reinforcement*, previous normative ways of working (such as preparing groups of infusions or a single person central line insertion) continued to be informally reinforced and as such the status quo was often maintained. Without formal *Reinforcement* through professional interventions such as educational meetings, audit and feedback, or reminders, there may be a limited (if not absent) external frame of reference to help restructure group norms. Variations in the provision of educational training, difficulties in accessing educational resources, and participants learning the practices from each other, further resulted in an unclear understanding of 'the rules' (*Expectations)*. It may be, therefore, that bundles containing professional interventions that improve *Reinforcement* at various stages in the implementation process, result in a greater degree of normative and relational restructuring.

The second hypothesis proposes that interventions that seek to shape attitudes are less likely to result in behaviour change. The lack of changes between survey two and three suggests that attitudes have plateaued. It may be that different professional interventions are more effective at different stages in implementation timelines, with interventions targeting attitudinal components perhaps best suited to pre- implementation periods in order to create readiness for change. Participants in this study all believed that reducing infections was important and that they would continue to support the bundle, yet implementation of some of the bundled elements was variable despite these beliefs and intentions. This supports the work of Johnson and May (2015) who proposed that changes in behaviour results from changes in structure and action rather than changes in individual beliefs and intentions. Indeed, examples of cognitive dissonance- where an individual's behaviours were sometimes incongruent to their beliefs- were identified in this study. It may be that changes in structures and actions, through interventions that provide *Reinforcement*, contribute to building collective *Endorsement* for a new practice. In this way, it may be that *Reinforcement* is, in fact, also important in shaping collective attitudes towards a new practice over time.

The conceptual model developed from this study could be used to help design and deliver future iterations of the bundle by tailoring implementation to target specific mediators of bundle adoption, focusing upon improving reinforcement. Further testing of the conceptual model is required not only in order to further develop it but to also assess its utility in relation to the implementation of CLABSI care bundles in other healthcare settings.

10.7 Explaining CLABSI rates

This study has found that the introduction of a care bundle into a UK tertiary NICU has not reduced local CLABSI rates. This is at odds with the results of the meta-analysis in Chapter 3 which found that a care bundle could reduce neonatal CLABSI rates by 62% (RR 0.38, 95%CI 0.31-0.47). Statistical process control methods showed that rates were a result of normal cause variation, ultimately requiring a system change to reduce CLABSI rates. Whilst total CLABSI rates fell by 28% from 2015 to 2018 (9.2 to 6.6 per 1000 central line days), this was not sustained in 2019 and local rates remain above the EFCNI benchmark of 5.1 per 1000 central line days (EFCNI, 2019). The results of this research study suggest that there was only partial bundle implementation, and that the relational and sociocultural restructuring required in order to sustain change over time did not occur. When interventions 'fail' it may be because participants have been unable to perform the degree of restructuring that is necessary to do implementation work (May et al., 2016).

One possible explanation for the reduction in CLABSI rates seen in 2018 is that this is when the observations of practice with retrospective interviews were taking place, as were the NoMAD surveys. In fact, 50% of the observational data for this study was collected during the two months when there were zero bloodstream infections. This is the only time since 2015 that this has occurred. It could be theorised that observing practice not only provided the surveillance and monitoring that participants were seeking, but also gave participants an opportunity for reflexive monitoring and appraisal of their own practice.

Any potential improvements in rates have not been sustained- a phenomenon referred to by Bates (2008) as evaporation. This can be a symptom of an absent cultural component to change, and it appears that the bundle has not resulted in the same cultural change as was theorised in the Michigan Keystone project (Dixon-Woods et al., 2011). That said, the study in this thesis has arguably revealed weaknesses across other contextual factors, including fragmentation, (manifesting as variations in practice) and frustrations, (resulting in professional tensions) (Bates, 2014). Indeed, Richter and McAlearney (2018), having performed a cultural survey prior to the implementation of a CLABSI bundle, concluded that important cultural features for the successful reduction of CLABSI rates were communication openness, staffing, organisational learning, and teamwork. These features were significantly associated with zero or reduced CLABSI rates.

It appears that there has been partial implementation of the bundled practices. Some interventions were well embedded but did not appear to effect CLABSI rates, such as the AIPPs, whereas some interventions were not implemented as intended, such as the two-person insertion technique and checklist. Determining what counts as 'successful' implementation is hard, and the majority of the studies reviewed in Chapter 3 used bundle

adherence as a proxy for successful implementation, despite this being inconsistently associated with reductions in CLABSI rates (see Chapter 3.3.3). This is in keeping with the findings of this study where increasing adherence has not resulted in reductions in CLABSI rates. In fact, the adherence rates in this study were higher than many of the adherence rates reported in the literature which ranged from <15% up to 100%, and some studies found reduced CLABSI rates even with low levels of reported adherence (Balla et al., 2018). It could be argued, therefore, that it is not the percentage rates of adherence per se, but the process of surveillance and feedback that has an impact on behaviour. Prospective audits that involve observing staff and providing direct and instantaneous individual feedback may be more effective.

Since the study in this thesis commenced, very few negative studies have been published reporting a lack of CLABSI reduction following the introduction of a central line bundle (Karapanou et al., 2020). Karapanou et al. (2020) found that the implemented bundle did not resemble those implemented in previous studies; in particular nurses in this study were not empowered to stop the procedure and there was no necessity to complete the checklist. Mechanisms for implementation failure were retrospectively theorised, including insufficient nurse staffing and poor resource availability. It was concluded that checklists were more than a simple list of actions, and that implementation was context dependent. A recent systematic review of the barriers and facilitators that influence the sustainability of hospital-based interventions found that of the 32 included studies, sustainability was inconsistent, with inadequate staffing reported to be the most frequently identified barrier (Cowie et al., 2020). This review highlighted that clear roles and responsibilities, strong leadership and champions were key facilitators of sustainability. Whilst none of these studies investigated the implementation of CLABSI care bundles, the results appear to be consistent with the findings of this research study.

10.8 Recommendations for Practice

There are three main recommendations to improve bundle implementation on the NICU: improving reinforcement, building in accountability and improving knowledge management.

10.8.1 Improving Reinforcement

Surveillance of Practice

Building in regular surveillance of the bundled practices will help to address several problems found in this study, by outlining the standard of behaviour expected on the NICU, providing reinforcement of those behaviours, and promoting reflexive monitoring.

Regular walk-round audits and monitoring of practice will provide educational outreach to staff and allow those performing surveillance to evaluate the ongoing workability of the bundle. It will help highlight issues relating to the capacity of staff to meet expectations, either relating to gaps in knowledge or resources such as lack of clocks, hand soap and dressing packs. Weekly observations of central line access and insertion techniques, with individual feedback, would help provide reinforcement and may help to change social norms which has not occurred for all aspects of practice. The regular monitoring of practice may also empower other staff to feel more confident in challenging practice. The insertion checklist should be adapted to facilitate prospective use, with the 'assistant' role being reframed as a monitor or observer. Monitoring should be performed by all members of the multi-disciplinary team in order to establish a collective responsibility and help flatten hierarchies, and competency documentation should be incorporated into the training of all staff.

Understanding Measures

Reinforcement needs to be provided in a format that makes sense to those receiving it (Kwok et al., 2017). Whilst reporting CLABSI rates per 1000 central line days is required for national benchmarking, and also accounts for changes in activity level through its inclusion of central line days as a denominator, it may not always easily understood. In order for reinforcement to be effective, feedback on infection rates need to make sense to those receiving it, be provided regularly and be accompanied by an action plan. Having clear goals, such as achieving a number of infection-free days, for example, may also help motivate staff and could be used as a way to interpret CLABSI rates. Simple feedback strategies such as reporting percentage adherence assumes that staff will choose to behave differently having passively received the data, and hence providing feedback with an action plan, may be more useful. For example, if audits show a fall in checklist adherence, motivation may be improved if this is presented alongside an action plan such as re-education, increased monitoring, and a timeline for achievement, rather than presenting a percentage. Similarly, asking staff for suggestions on how infection rates may be improved, may also help improve buy-in and ownership of the problem.

The use of patient stories has been suggested as a strategy for generating buy-in for behaviour change (Fisher et al., 2013, Savage et al., 2018). Rehumanising CLABSIs and reframing them as preventable or avoidable rather than inevitable may improve motivation for change, though this would need to be implemented in a way that does not attribute blame. Two studies reviewed in Chapter 3 used patient stories, one used a video of a father talking about his experience of his preterm daughter dying from MRSA (Fisher et al., 2013), whilst another used personal stories regarding deaths from hospital-acquired infections (HAIs) which "became the catalyst for nursing leaders to become passionate

champions" for preventing CLABSIs (Savage et al., 2018, p. 32). Providing feedback to staff on specific CLABSI cases, for example, including the impact on the patient and their parents (for example, they required reintubation for five days, seven days of antibiotics, and four additional venepunctures or cannulations) may help provide buy-in for change. Patient stories could be shared as part of regular education days, short training packages, or as part of developing an 'avoidable infections' meeting (see section 10.8.3). Inviting the parents of babies who have had an infection (but are no longer an inpatient on the NICU) to share their experience may also be a powerful motivator for change.

Celebrating Successes

Smaggus (2019) suggest that striving for zero CLABSIs is unrealistic and is likely to contribute to burnout, though this is at odds with the plethora of studies reporting zero CLABSI rates both in adults and neonates (Pronovost et al., 2016, Erdei et al., 2015, Shepherd et al., 2015). Indeed, Hawes and Lee (2018) argue that the narrative surrounding CLABSIs should change from an accepted consequence to an adverse event that can be prevented. Changing the mental model from "inevitable to preventable" (Suresh and Edwards, 2012) may help improve buy-in.

One way to achieve this is through positive reinforcement. For instance, reporting infection-free line days, reporting the number of days since the last positive bloodstream infection or reporting lines that had completed their patient journey without an infection. Providing positive reinforcement may be more effective in a high-stakes setting such as the NICU. Foy et al. (2020) argue that the provision of feedback is context-dependent; positive feedback may have an adverse impact on motivation and negative feedback may result in defensive attitudes or disbeliefs in the data. Differences in professional cultures may mean that tailoring reinforcement is necessary; indeed, in a survey of healthcare professionals' intentions to use clinical guidelines, Kortteisto et al. (2010) concluded that perceived control was the strongest influential factor for doctors compared to subjective social norms for nurses. Reviewing cases where CLABSIs did not occur may also be useful in aligning the NICU culture with a Safety-2 approach, learning from when work is done well, rather than trying to enforce *the work as imagined* (Smaggus, 2019).

10.8.2 Building in Accountability

Building accountability into the bundle may help staff to have confidence in both their own and their colleagues' practice, helping improve buy-in for the bundle and facilitate the monitoring of practice.

Providing Leadership

In order to build accountability into a system, there needs to be clear leadership- an individual who is ultimately responsible for improving CLABSI rates on the NICU. There needs to be someone to whom concerns can be escalated, who can ensure feedback loops are maintained, and who can drive change forward (Ista et al., 2016).

Having a dedicated infection prevention or central line team could help to provide visible leadership and would contribute to the provision of reinforcement. This may further develop a community of practice, providing educational outreach, developing educational resources, working with staff 'on the shop floor' and contributing to CLABSI reviews. This would provide accountability for CLABSIs and reduce the diffusion of responsibility seen for some aspects of central line care. Seeing colleagues working towards the goal of reducing CLABSIs and monitoring practice may encourage others to challenge practice (Stroever et al., 2020). In a quality improvement study investigating the introduction of a bundle to reduce neonatal ventilator-associated pneumonias (VAPs), the building of a team of MDT 'champions' helped reduce the burden of work required and contributed to improved outcomes (Pepin et al., 2019). The inclusion of boundary spanners- healthcare professionals that span traditional professional boundaries- may be of benefit in helping to change behaviours across professional groups (Clack et al., 2018). This may include nurses developing extended roles for central line care.

Redefining the Problem

In order to improve accountability on the NICU, the narrative regarding CLABSIs needs to change. The language currently used to describe them does not help reframe the responsibility of healthcare professionals' behaviour. A recent national neonatal QI initiative to avoid term admissions (NHS Improvement, 2017a), has shifted the onus of these admissions onto healthcare professionals reframing them as preventable. Whilst CLABSIs are a hospital-acquired infection, redefining them as 'avoidable infections' may help to change the narrative from inevitable to preventable. Removing the sub-categorisation of local CLABSI data into CoNS and pathogens may help to shift the mindset that CoNS are not significant infections in this population.

Targeting the System

Recently, an interventional hierarchy has been developed that places person-focused interventions such as education at the bottom, reminders and checklist at mid-level, and interventions that force systems at the top (Soong and Shojania, 2020). System-targeted interventions focus on making it easy to do the right thing. The way in which resources are organised, for example, can help to nudge healthcare professional behaviours. The

introduction of a central line insertion trolley may help to provide clear expectations- for example, regarding appropriate hand scrub- and address issues relating to resource mobilisation.

In addition, forcing functions can help to reduce automatic or unconscious behaviours by working as prompts or reminders. These can build in accountability- for example, by requiring an electronic signature from the observer of a line insertion before data can be inputted. Whilst not all healthcare problems will have a system-forcing solution, reminders and checklists may be more effective than education alone. Prompting staff to consider the need for the central line on a daily ward round form is another example of how unconscious actions could be mediated. A daily review of the need of the line was not included in this bundled intervention; given audit data revealed that dwell times are twice as long as those in recently published studies, this area of practice warrants further consideration.

Staff need to be given permission to escalate unsuccessful attempts and to challenge poor practice. This would help address some issues relating to the number of attempts, using an assistant and a checklist as a form of monitoring, and ensuring clear expectations. Including phrases such as “I expect you to stop me if…” within the checklist may help facilitate this. Indeed, ‘stopping the process’ is a quality control method used in other industries, where responsibility is given to employees to provide quality control (Grout and Toussaint, 2010).

10.8.3 Improving Knowledge Management

Improving access to knowledge

Knowledge of local CLABSI rates should be accessible to all staff, as opposed to being presented only in governance meetings. It was planned as part of local implementation processes that the weekly Infectious Diseases meeting would take place at the bedside, rather than in the doctors’ office, as part of educational outreach, though this was never implemented. These meetings continue to take place in the doctor’s office and are an example of knowledge regarding patient care that remains situated within the medical domain.

Creating a ‘reducing avoidable infections’ multidisciplinary meeting may help provide educational outreach. Engaging all staff and involving them in the construction and dissemination of knowledge relating to CLABSs may empower staff and flatten knowledge hierarchies. Educational meetings would also provide staff with the opportunity for communal appraisal of the new practices and facilitate reflexive monitoring. Having a parent representative at these meetings may be very powerful and would promote the use

of parent perspectives to foster change. Learning from when things go right, balanced with traditional patient safety models such as root cause analysis, could help create useful knowledge to improve patient care (Smaggus, 2019).

Improving the accessibility of knowledge is also important. Lengthy guidelines, long video training and unwritten rules all create barriers to staff understanding what is expected of them. The insertion checklist needs to be re-designed and be separated from the documentation of line position forms that are incorporated into the electronic patient record. Temporary or rotational staff may be unaware of historical practices and staff do not have time to read extensive guidelines. Knowledge tools, such as visual aids and prompts built into existing infrastructures may help provide reminders. However, the risk of *habituation* to reminders is high in this context. A co-ordinated multi-disciplinary team approach to implementation is required to ensure that staff are not overwhelmed by change efforts. Guidelines should acknowledge uncertainties and recognise gaps in the evidence, providing some (but not too much) *plasticity,* which may reduce professional tensions (Elwyn et al., 2016, Wasserman, 2018).

Training the Multidisciplinary Team

Multi-disciplinary team training was identified by participants as being important in order to understand each other's roles. Providing opportunities to learn together may help provide insight into the division of labour between professional groups and help monitor practice. It would also allow for the redistribution of role-specific knowledge, flattening knowledge hierarchies. Simulation training would provide opportunities for staff to rehearse challenging each other or could be used to demonstrate the prospective use of the checklist and the second person role. Clarifying the role and responsibilities of the observer or 'monitor' role in central line insertions, whose role this is, and framing this a patient safety feature, is important. Given the concerns raised by participants regarding nurse staffing, it is important that there is buy-in for this role as a multidisciplinary one, and engaging staff across both professions and all job roles to feel able to do this is important.

Participants frequently asked for refresher training. In a recent survey of 180 registered nurses in Wales, 72% reported not having any follow-up training on ANTT in the past five years (Gould et al., 2017). Whilst cascade training is a common way to disseminate knowledge in the NHS, Clarke et al. (2013) found that cascade training did not reach all staff nor did it engage all staff. This is likely to reduce endorsement for new practices, and Pepin et al. (2019) found that repetitive education helped to get buy-in for reducing neonatal VAPs. Given that the local NICU has a large and frequently changing workforce, regular updates or mini educational sessions may improve the dissemination of knowledge.

10.9 Recommendations for Future Research

Further work is required in order to understand more about how to prevent avoidable infections in UK NICUs, including strategies to improve buy-in for these as preventable infections in the neonatal population. Understanding more about the influence of socio-cognitive factors on of healthcare professionals' beliefs and attitudes towards these avoidable infections may help to design strategies for targeting behavioural change. Therefore, a series of research studies is required to understand more about the phenomenon of care bundle implementation and infection prevention behaviour in the neonatal population.

Understanding the experience of caring for neonates with an avoidable infection

A qualitative study exploring the experiences of healthcare professionals who have cared for a patient with an avoidable infection who has died or become acutely unwell would help to understand more about the impact these infections have on those providing care, their beliefs about preventing them, and how to create endorsement for change. The way in which these experiences may contribute to other phenomenon raised in this thesis such as burnout, moral distress, nursing guilt and learned helplessness, may also be important. This could help tailor professional interventions, targeting specific beliefs, attitudes or cognitive biases, as opposed to adopting strategies that may contribute to further burnout or moral distress.

The experience of parents should also be explored. The concept of rehumanising avoidable infections through the use of real parent and healthcare professional stories, may be a powerful tool for behaviour change. The use of parent stories could be both a pedagogical and reinforcement tool; these have started to be explored in UK neonatal nurse education, though the impact of these on patient outcomes is yet to be determined (Petty et al., 2020). The 'Gabby' video used as part of the Perinatal Quality Collaborative Initiative (Fisher et al., 2013) and the use of parent stories reported by Savage et al. (2018) are examples of how these have been used in some NICUs to generate buy-in and endorsement for reducing preventable infections. Parent experiences have recently been used to support the scaling up of QI initiatives such as the Avoiding Term Admissions (ATAIN) programme (Upton, 2018) and the PReCePT2[4] study (Burhouse et al., 2017).

[4] A UK programme designed to improve the uptake of magnesium sulphate in preterm labour, to reduce rates of cerebral palsy.

Understanding the factors influencing central line removal in neonates

The prompt removal of central lines is one of the core components of the original Michigan bundle, featuring in some (but not all) of the studies reviewed in Chapter 3. This was not incorporated explicitly in the local bundle, and the retrospective spot audit performed as part of this study found that central line dwell times were potentially double those in recently published literature (Gilbert et al., 2019, Helder et al., 2020). Future research should investigate the factors influencing central line removal in neonates, including optimal timing for removal. Whilst a recent single centre study in the US has investigated factors influencing both urinary and vascular catheter removal in a medical-surgical ward (Quinn et al., 2020), it is important to understand this phenomenon in other clinical settings, particularly the NICU. Understanding clinician decision making regarding central line removal in high stakes setting like the NICU is likely to be important in future efforts to reduce avoidable infections.

Implementing a bundle of professional interventions to reduce avoidable infections in the NICU

A programme to re-design the bundle, including professional interventions targeted to address specific barriers to implementation identified in this thesis, should be developed. The conceptual model identified in section 10.6 could be used to tailor the professional interventions, aiming to facilitate bundle adoption by specifically targeting interventions that may improve reinforcement and increase buy-in. This would allow for further testing of the conceptual model. The *de-implementation* of some low-value practices- those lacking in evidence of efficacy- may also be required (Nilsen et al., 2020). It is now widely accepted that bundles should be small sets of evidence-based practices and many of the practices in the local bundle lacked a clear evidence base. Whilst it is unclear how many elements a bundle should contain, it may be that the bundle itself was too big. A plan for the re-design and implementation of the bundle is provided in Appendix 31, and should involve a range of professionals, and parents. A dedicated nurse and project lead should be employed to promote and facilitate implementation. Evaluation of the programme should be undertaken and could include further NoMAD surveys, observations of practice, and qualitative interviews alongside both process and outcome measures, to determine implementation success. Observations should include broader aspects of central line care, such as decision making around central line removal, and observations could also be used as a method of prospectively auditing practice. Criteria for determining success could be defined using the qualitative measures devised by Clack et al. (2018), as well as quantitative outcome and process measures.

More broadly, there is a need to develop a national agenda focusing on reducing avoidable infections in the NICU. If successful, the bundle could be scaled up, similar to the PROHIBIT study (Clack et al., 2018, Sax et al., 2013) or the Avoiding Term Admissions (ATAIN) programme (Upton, 2018). This future research could take the form of a larger-scale comparative case study. Studying NICUs that report low CLABSI rates would be equally useful to generate knowledge about what strategies work in different UK settings, and highlight potentially different contextual influences on behaviour. Determining the most effective reinforcement strategies for specific contexts would help tailor implementation and is a clear priority for future implementation research. Furthermore, technologies recommended for use in adults such as antimicrobial dressings and CVCs, should be the subject of rigorous evaluation in neonates.

10.10 Strengths

This is the first study to prospectively investigate the implementation of a care bundle aimed at reducing CLABSIs on a NICU. A recent survey of 134 neonatal units in England and Wales revealed 66% of neonatal units reported having a care bundle, and there was variation in bundled practices between units (Fraser et al., 2018). Given the variation in neonatal CLABSI rates in the UK despite the utilisation of care bundles, the findings from the study in this thesis can help other UK neonatal units implement or improve local practices.

One of the strengths of this study is its mixed-methods approach and ability to triangulate findings across data sources. This enabled the integration of both quantitative and qualitative data to illuminate individual data sets. Whilst quantitative research alone can help determine effect, it cannot explain the *how* of implementation. Mixed-methodology is useful for exploring complexity, where both paradigms provide insights into the *work as imagined* and the *work as done*. This research study incorporates many of the features of a complexity-informed approach to research, argued to be a necessary paradigm shift in studying health services (Greenhalgh and Papoutsi, 2018).

The use of multiple data collection methods had several benefits. Firstly, it enabled a broad range of staff to be recruited. In total, there were 26 eligible staff who did not respond to at least one of the three surveys; nine were no longer employed at the time of the SSIs, one participated in the ORIs and a further five were sampled in the SSIs. The question of sample sufficiency is one that often requires justification in qualitative research, unlike in quantitative research where a sample size calculation can be performed. This study has a sample size in keeping with similar qualitative studies investigating implementation, which sampled between five and 24 healthcare

professionals per site or ICU (see Chapter 2). The notion of data saturation suggests that qualitative studies continue recruitment until there is no new data, no surprises and no additional themes (O'Reilly and Parker, 2013). Whilst participants could continue to be recruited to the qualitative methods of data collection *ad infinitum*, with new data being found due to the uniqueness of individuals, it was clear that no new broad concepts or themes were being found in the data.

Secondly, the use of multiple methods enabled triangulation between data sets. Triangulation is one way to demonstrate rigour and adds to the overall credibility of the study findings. Whilst triangulation was able to provide confirmability, it also enabled some data to be refuted and explained. For example, a checklist was not used in any of the observations of central line insertion though the audit data suggested increasing adherence. The SSIs were able to explain this contradictory data. Similarly, whilst a two-person technique was used in every observation, audit and interview data refuted this, suggesting that it was not always implemented. The use of multiple methods has enabled a deeper understanding of the complexities of implementation than a single method, or paradigm, could achieve.

Another way in which rigour can be strengthened in mixed-methods research is the confirmability of the results. It is vital that research can demonstrate the goodness of fit between participant perspectives and the researchers interpretation of them (Nowell et al., 2017). Confirmability can be demonstrated through member checking. Transcripts were sent back to participants and the results of the ORI data analysis were sent to participants. The final results of the study were not only emailed to all staff, but also presented at both consultant and Band 7 nurse meetings as well as at a presentation that all staff were invited to. This helped establish confirmability and offered staff the opportunity to refute or challenge the study findings. No participants or staff raised concerns regarding the results. In addition, a series of observational site visits in December 2019 performed by the Trust IPC team, identified similar issues in practice that were recounted by participants. It was clear that the results from this research study had sufficient goodness of fit and that the results were credible. Presenting preliminary findings at professional conferences strengthened both the data analysis and the confirmability of the results.

The use of observations was another strength of this study, allowing the researcher to capture behaviour *in action* and revealing insights into the differences between participant beliefs and behaviours. The cognitive dissonance between the *work as imagined* and *the work as done* are important findings that could not have been found through interviews or audit alone. Some of the practices observed could be considered social milieus, only visible to insiders; whilst observation can enable this, an outsider may not have gained the

same insight (Guest et al., 2013). The clinician-researcher role, therefore, was invaluable at unlocking some of these 'hidden' practices.

Dual-participant interviews were a novel feature of this study. Whilst it could be argued that power hierarchies between the participants may influence their responses, this technique allowed participants to prompt each other, aiding memory recall. In addition, participants appeared to find comfort in being interviewed together. This dual technique also prompted reflexivity between the pairs, frequently asking each other what they thought or problem-solving together during the interview.

This reflexive process may have contributed to the reduction in CLABSI rates seen in 2018. A systematic review on optimising infection control practices concluded that behavioural change is more effective if experiential thinking is targeted (Suresh and Edwards, 2012). In the ORIs, participants reflected on their behaviour, identifying improvements they could make. It should be noted that 50% of the observation and retrospective interviews took place in December 2018 and January 2019, which were the only two consecutive months with zero CLABSI rates. The benefits of being involved within this type of research was particularly notable after the SSIs, when the senior nursing team developed and implemented an additional nursing role on the unit- a 'fluid nurse' role- to support central line fluid changes.

Finally, being an advanced neonatal nurse practitioner- whose background spans traditional professional boundaries- likely meant that the researcher was viewed as an 'insider' by both professions. This may have mitigated some of the risks of having a natural researcher bias towards a single professional group and may also have helped establish trustworthiness with both the professional groups being studied.

10.11 Limitations

One of the criticisms of mixed methodology is the expertise required in order to analyse both data sets, and the time required to both collect and analyse the data. This is particularly important where one data set informs the next. Each ORI was transcribed and analysed before the next observation was performed, and this, along with challenges in aligning consented participants, events to be observed, and researcher availability, meant that the ORI data collection took a year to complete. The length of time taken to collect and analyse data is also a limitation. Data collection began in January 2018 and ended in August 2019. Whilst this is a recognised challenge with ethnographic research, it does mean that participants experiences may have changed over time. However, triangulation between data sets suggests experiences were similar over time.

It has been argued that a focused ethnography undermines the ontological principles of the discipline which considers prolonged participant observation as the foundation for good ethnography. This academic debate was recently the focus of a series of editorial letters (Waring and Jones, 2016, Dixon-Woods and Shojania, 2016, Jowsey, 2016, Sales and Iwashyna, 2016). However, one of the benefits of the clinician-researcher role was that there was already a pre-established rapport with participants and the researcher was already 'immersed' in the field. This allowed a more rapid-ethnographic approach to take place, without necessarily encountering the challenges argued to normally limit a focused ethnography.

However, the presence of an observer-researcher, also a clinician on the NICU, is likely to have altered the behaviour of those being observed. One of the criticisms of observations is the extent to which behaviour reflects 'real life' behaviour or the degree to which there is reactivity (Robson and McCartan, 2016). Reactivity refers to the extent to which the observer affects the process being observed. It is important to recognise that, as healthcare professionals, it is likely they will have wanted to show 'the best version' of themselves and as such, observations may reveal what they think best practice is. This still provides useful data that illuminates and distinguishes *the work as done* from *the work as imagined.* The role of a clinician-researcher was beneficial in these observations, as participants knew that the researcher was familiar with the normative ways of working. Indeed, participants were familiar with the researcher; as such, this might mitigate some reactivity (Robson and McCartan, 2016). However, researcher presence may have prevented nurses from informally monitoring central line insertions, if they assumed there was already an observer (the researcher). The use of multiple methods allowed for triangulation between data sources to strengthen the credibility of the results, with interviews revealing that there isn't always a second person nor a nurse observing the procedure.

Unfortunately, the survey platform used was unable to track respondents which would have helped to identify any social desirability bias. In addition, the AIPPs were introduced in March 2018 after the first survey had taken place in January, and the changes seen in responses between surveys one and two may be a result of the implementation that took place around this particular component. This in itself highlights the challenges for those researching complex systems, highlighted by Greenhalgh and Papoutsi (2018), who argues the need for a complexity-informed paradigm. By survey three the response rate had reduced to 45%, and there may be responder bias as it may be that those who disagreed in the previous surveys were less likely to participate in survey 3. However, attempts were made to account for this in the SSIs, in sampling from a range of job roles and experience levels as well as to include those who may be 'disconfirming sources'. As

the survey was distributed to staff across a range of job roles, the responses may have been more illuminating if there had been a separate survey for central line insertion and central line access. However, this would have resulted in additional workload for already busy clinicians.

The survey also did not include junior doctors, who would not necessarily have experience of practices before bundle implementation. However, their responses may have provided useful insight into implementation processes. They were recruited into the ORIs, so their experiences of the *work as done* was captured. All junior doctors included had been on the unit for longer than six months either as a fellow or as part of the Medical Training Initiative (MTI) or had worked on the unit during a previous rotation. They therefore had some experience of central line practice on the unit, though this may have been some years previously. Additional research is required to explore junior doctors' experiences of both implementation and integration into NICU cultures. Similarly, this study did not include new staff, as participants had to have experienced practice before and after the implementation of the new practices. Given that participants referred frequently to new or junior staff influencing how the work was performed, it would be useful to understand the perspective of this group.

The NoMAD construct 'scores' should be interpreted with caution. Whilst applying quantitative values to the NoMAD tool has been used in this way previously (Scott et al., 2019), it is acknowledged that any such scoring needs to be interpreted within the local context and cannot be generalised to other settings (Finch et al., 2018). Indeed, it may be that in different settings the degree of influence each individual construct has on implementation varies depending upon the intervention and the '*Local Conditions'*. In this study, despite median scores of one across all sub-constructs in the final survey, for some elements of the bundle, implementation was inconsistent and buy-in was mixed. This suggests that attitudes towards the bundle, whilst positive, had plateaued, and it may be that patterns or changes in responses over time may be more useful than an absolute 'score'. As previously commented, there is a likely risk of responder bias.

A prospective audit of all patients with a central line would have provided a more comprehensive data set that may have been able to be used to test for any association between adherence and CLABSI rates. However, the overall trend was that adherence increased over time and timepoints included several rotations of junior doctors and new intakes of nurses. Whilst audit is a commonly used measure of process in the NHS, measuring adherence is not an accurate proxy for measuring implementation, and several studies have demonstrated reduced CLABSI rates with low bundle adherence (Fisher et al., 2013, Balla et al., 2018, Schulman et al., 2011, Piazza et al., 2016). Whilst reductions in CLABSI rates were used in this study as a marker of implementation success, future

research may want to also include qualitative definitions of implementation success which address aspects of intervention fidelity, intervention to context fit and acceptability of the programme being implemented (Clack et al., 2018).

As a clinician-researcher, there is a risk of social desirability bias within this research. As a nurse in a senior leadership position, and working in a medical role, credibility could be questioned due to participants wanting to acquiesce or provide the 'correct' answer in both interviews and in the NoMAD survey. Whilst participants were frequently reassured that this was not a test and that participating in the study would not influence the way they were treated on the NICU, this cannot be ruled out. However, triangulation between data sources strengthens the credibility of the findings.

10.12 The Role of Clinician-Researcher

A clinician-researcher is categorised as one who provides both direct patient care and conducts research, though not necessarily simultaneously or for the same workplace (Hay-Smith et al., 2016). There are well-documented challenges for clinician-researchers including professional socialisation, with deep-rooted values, skills and knowledge that can be difficult to separate (Hay-Smith et al., 2016). This was particularly pertinent in this study, where being a nurse could have influenced how the experiences of different professional groups was interpreted. However, working in a role that spans both medical and nursing boundaries provided a unique perspective with which to investigate implementation, and being in a dual role may have influenced participants perceptions of the researcher (see Appendix 32). Continual reflection on underpinning beliefs and values was crucial to ensure a balanced interpretation and presentation of the results.

However, not only did this research present challenges in regard to professional roles, it also took place within the researcher's workplace. This presented many challenges. Hiller and Vears (2016) reflexively report on some of the challenge's that clinician-researchers may face when studying their own profession or workplace. Participants expecting feedback on their practice or feeling judged were two frequent concerns, and as a researcher there were worries regarding being overly critical of colleagues. Indeed, there were several occasions where poor practice had to be addressed (see section 7.2.2); two were referred to senior colleagues and one was addressed at the time due to immediate safety concerns. These were hard but represented the broader challenges being faced in this particular NICU regarding social norms, divisions of labour and monitoring of practice. Indeed, some participants recalled similar examples of observed poor practice, unprompted, in interviews.

There was also an acute awareness of how busy participants were; taking them away from their work to interview them or complete surveys, was a frequent concern. However, the extent to which staff across both professions were willing to be involved and have their practice observed, was surprising and demonstrated their desire to improve the quality of care on the NICU. However, there were also staff that the researcher felt uncomfortable interviewing due to pre-existing professional relationships and power-dynamics. These interviews were scheduled for later in the data collection period, in order to develop confidence in interviewing technique.

Ethnographic researchers often feel the 'weight' of a duty to represent the experiences of those being studied (Dixon-Woods, 2003), and this was acutely felt studying colleagues in the researcher's workplace. Whilst there is a clear ethical duty to report the findings of this study, there were also concerns regarding the impact of these results on colleagues. Efforts were made to ensure member-checking of both the raw data and the data analysis as well as the presentation of data results at every stage of the research process. Opportunities were actively sought to disseminate results at a variety of professional educational and research meetings. At none of these opportunities did any staff disagree with the results; in fact, at a senior nurse meeting, all those in attendance felt the results accurately reflected their experiences. This should provide reassurance of the confirmability and credibility of the results of this study.

Being a clinician researcher within the local NICU conferred several advantages with regards to having pre-established interviewer-participant trust. As an 'insider', there were insights into some of the everyday workings of the NICU that may not have been seen by an outsider, there was already a pre-established rapport with staff. This is important, as it may have meant that participants felt able to respond honestly compared to talking to an 'outsider'. In addition, being familiar with the context being studied meant there was already an immersion 'in the field'. Whilst this requires a high degree of reflexivity, it also mitigates one of the criticisms of rapid ethnographic approaches. The clinician-researcher being already part of the 'tribe' being studied was helpful in understanding if participants were providing their experiences in a favourable light, or if they were providing honest accounts of unit practice. It does, however, require the insider researcher to be mindful of their own preconceived ideas regarding both practice and people both when collecting and analysing data. During the period of data collection, the researcher continued to work in clinical practice though not in a full-time capacity. As such, there was clearly a need to be reflective of the possible influence of the researcher on colleagues' practice during clinical shifts.

10.13 Summary

This Chapter has answered the research questions and put these findings within the context of wider literature. This study has found that, in this context, a care bundle did not result in a sustained reduction in CLABSI rates, despite apparently increasing adherence rates. However, the bundle was only partially implemented, and some practices were not implemented as originally intended. Individual, team, patient and organisational influences all moderated bundle adoption by influencing the degree to which professionals 'bought into' or endorsed new practices. Local hierarchies, along with deep-rooted professional cultures, influenced the way in which teams worked together and consequently the degree to which individuals endorsed new practices. As a result of the integration of qualitative and quantitative data, the complexities of implementation have been explored to a greater extent than one single paradigm alone could achieve.

In addition, the findings from this study have been used to develop a conceptual model of implementation, identifying relationships between concepts, and providing an explanation for the results found in this study. Recommendations have been made for future implementation strategies that are generalisable to those working in similar settings with similar contextual influences. Improving knowledge management and reinforcement as well as building accountability into systems across multi-disciplinary team boundaries are all likely to improve implementation. As such the findings of this research have been able to make a unique contribution to improving, and extending, the scientific knowledge of implementation in neonatal care.

Chapter 11 Conclusion

11.1 Introduction

This research study has highlighted the importance of reducing CLABSIs in order to reduce harm and improve patient outcomes by caring for patients in a safe environment. With the EFCNI (2019) recently publishing benchmarking standards for neonatal CLABSIs, with >5.1 per 1000 central line days considered a marker of poor performance, it will be interesting to see how UK, and European NICUs, respond to this. With the European Standards of Care for the Newborn recommending that all neonatal units have a care bundle to reduce CLABSIs, there is a risk that implementing a standardised bundle without consideration either for the context or the implementation strategy required for successful and sustained adoption, may result in a lack of effectiveness.

Through the use of a sequential, mixed-methods, focused-case ethnography design, this study has found that whilst care bundles do have the potential to reduce CLABSI rates, it is important to understand the way in which they are implemented and the settings in which implementation occurs. This research study has demonstrated that it is possible to use social sciences to study improvement in healthcare, resulting in broadly translatable findings that can be used to enhance the ability of future improvement work (Dixon-Woods, 2014). The use of NPT to underpin this work enabled the development of a conceptual model, which has resulted in recommendations that are transferable to a range of other healthcare settings and has therefore uniquely contributed to the field of implementation science.

11.2 Findings

This study has investigated the implementation of a care bundle designed to reduce CLABSIs in the NICU. It found that whilst the bundled practices had resulted in some normative and relational restructuring, this was not the case for all the bundled components and some implementation was not as intended. In short, there was partial implementation; some features were well embedded whilst others were not, and as such, reductions in CLABSI rates were not sustained.

There were influential factors at an individual level relating to beliefs and attitudes about the bundle, CLABSIs, and expectations of practice, and participants sought reinforcement regarding their practice. There were also team-level influences relating to training, the division of labour and how the new practices were monitored. Challenges in training and the division of labour influenced the ability to effectively monitor and challenge each

other's practice, and a lack of informal surveillance in combination with no formal, meaningful reinforcement, influenced overall endorsement for some practices. Patient factors sometimes required moderation of the bundle, and organisational factors such as resources and workload demands could make implementation challenging.

Understanding the influence of context has been argued to be vital to understanding implementation. Issues relating to professional hierarchies and deep-rooted professional cultures to some extent thwarted implementation efforts, meaning that the relational restructuring theorised to occur in the Michigan Keystone project did not occur in this context. Future research that takes place in complex adaptive systems such as modern healthcare organisations, can no longer remain acontextual (Bates, 2014).

Viewing these results through the lens of NPT, this study found that there were weaknesses across all four implementation constructs. There were inter- and intra-professional differences in how participants made sense of the bundle (coherence), how they established a community around new practices (cognitive participation) and how they worked to embed new practices and mobilise resources to do so (collective action). The ability to appraise new practices (reflexive monitoring) was also different between professional groups. Without reinforcement, variations and uncertainties ultimately resulted in a lack of endorsement for some bundled components.

11.3 Implications

The findings of this research study have been argued to have important implications not only for how implementation is performed in complex healthcare systems, but also for those trying to improve patient safety and risk management in the NHS. The way in which knowledge is created and managed in these complex systems with complex interacting teams, requires careful consideration. It has been argued that knowledge is unevenly distributed and poorly understood with a dissonance between the work as imagined by policy makers and the work as done (Braithwaite, 2018). This was frequently found in this study, and it was apparent that guidelines and checklists were not frequently used in practice for central line insertion and management. Simply introducing more guidelines, more checklists and more policies may be ineffective if the changes do not make sense to those implementing them. Meaningful and sustained change is unlikely to occur, as clinicians co-create informal rules about what is acceptable, together, in practice. Therefore, those making 'the rules' need to reconcile the idealised way of performing the work with the reality of those performing it, working towards a co-creation of knowledge and 'rule making' that can not only improve safety but also be embedded. Whilst these local rules were created by local clinicians, engaging those who routinely enact the tasks

or who may be responsible for monitoring everyday practice, is likely to be important for sustainability.

Those wishing to embed and sustain meaningful change need to consider the ways in which behaviour is reinforced and find strategies to do this without contributing to growing concerns regarding healthcare professional burnout. There is a delicate balance to be navigated here- between driving to improve safety and reduce avoidable infections such as CLABSIs, and the provision of feedback to reinforce behaviour without assigning blame or worsening morale. Learning from when things go right and reinforcing examples of good practice, may be a useful starting point.

For those wishing to embark on similar care bundle initiatives, care should be taken to ensure that bundles acknowledge areas of uncertainty. Expectations should be made clear for all staff involved to reduce tensions between professional groups, and multi-disciplinary working should be promoted. Enabling effective systems of surveillance and monitoring within a system of accountability is equally as important as avoiding blame in regard to culture; it is unfair to hold staff to account for systems failures. In a recent report investigating why babies die, only 5% of recommendations from mortality investigations targeted a system change (Kurinczuk et al., 2020). In order to sustain change, targeting individual education or behaviour is unlikely to be effective, and systems that monitor and reinforce expectations (fairly and consistently) are more likely to achieve sustainable change.

11.4 Summary

This research study started by exploring the challenges facing the evidence-based practice movement in regard to translating evidence into practice. Whilst evidence-based guidelines have become commonplace in healthcare, it has been argued that this has now reached a level that is overwhelming. Not only that, but these guidelines may be being infrequently used in practice, raising questions regarding their utility. In a post-guideline era, checklists, visual aids and clinical tools that have been co-created with those using them and that are short, accessible and integrated easily into current workflows, may be a solution for busy clinicians working in complex adaptive systems (Elwyn et al., 2016).

In summary, whilst care bundles may result in relational and normative restructuring, findings from one context cannot be simply translated into another. This research study has demonstrated that it is possible to use social science alongside local quality improvement work to generate meaningful knowledge regarding implementation processes to improve patient care. Understanding the context of implementation, the

mechanisms through which interventions are effective (or not), and in what specific settings is key to effectively embedding meaningful change.

Appendix 1 CLABSI Surveillance Definitions

Organisation	Vermont Oxford Network (VON, 2019)	National Neonatal Audit Programme (NNAP, 2020)	Centre for Disease Control (NHSN, 2021)
Population	Neonates <30 weeks or <1500gms After day 3 of life	Any neonate >72 hours of age	Any patient with a Laboratory-confirmed bloodstream infection (LCBI) with a central line in situ.
Definitions	Nosocomial Infections categorised as: Pathogens + CoNS CoNS only Any Late Infection= pathogens + CoNS + fungal	Any positive blood culture with a central line in situ	LCBI: any recognised pathogen identified from one or more blood specimens AND not related to infection at another site. In the case of a common skin commensal, patient must have one of 4 clinical signs (fever, hypothermia, apnoea, bradycardia) AND the organism Is not related to infection at another site AND the same common skin commensal is identified by culture from two or more blood specimens.
Organism categorisation	Pathogens do not include any CoNS species	In 2018-2019 Pathogens included *Staphylococcus epidermis* and *Staphylococcus capitis* In 2020: skin commensals excluded from “Clearly Pathogenic” list.	Pathogens do not include CoNS species
Dealing with potential contaminants	If CoNS positive blood culture need to also have received 5 days of antibiotics AND have additional clinical signs.	All positive BCs Need for clinical signs has been removed (2018)	If CoNS positive blood culture, two positive cultures are required taken on two separate occasions.
Measure	Percentages of babies Standardised Mortality Ratios	Per 1000 central line days	Per 1000 central line days

Appendix 2 Evidence Summary for the Prevention and Management of Neonatal CLABSIs

Preventative Strategy	Recommendation from Epic3 Guidance	Neonatal Application
General Strategies		
Hand hygiene and aseptic non-touch technique (ANTT) practices	Epic3 Guidance (Loveday et al., 2014) for children > 1 year and adults. Evidence available is of low quality (Class D recommendation) but recommendations are for all healthcare workers to be trained and competent in aseptic technique, and that it should be used for any procedure that breeches the body's natural defences including the insertion and maintenance of invasive devices.	There are no neonatal studies of the use of ANTT, however it is recommended as best practice for all healthcare workers (Taylor et al., 2015a).
Maintenance Strategies		
Scrubbing the hub	Scrubbing the needleless connector for 15-30 seconds with CHG 2% and 70% IPA and allowing it to dry for 15-30 seconds before accessing the line or connecting infusions. Minimum of 15 seconds is recommended in national guidance for adults and paediatric patients > 1 year of age (Björkman and Ohlin, 2015, Loveday et al., 2014).	In a before and after study, to reduce CoNS infections in neonates, Björkman and Ohlin (2015) found that scrubbing the hub for 15 seconds was an efficient way of reducing CoNS in neonates (from 9 cases to zero cases, during 25 month study period). Studies have shown that compliance with time-dependent infection control measures such as Scrub the Hub to be poor (McBeth, 2020, Caspari et al., 2017).

Preventative Strategy	Recommendation from Epic3 Guidance	Neonatal Application
Alcohol impregnated port protectors (AIPPs)	NICE (2019) reviewed evidence for AIPPs for needleless connectors and concluded that there was insufficient evidence for their routine adoption in the NHS and whilst they had potential to reduce hospital acquired infections, more research was required. This report was published after this study had been designed and data collected. Designed to reduce *S.aureus*, *S.epidermis*, *E.coli* and *P.aeruginosa* infections.	The use of alcohol impregnated port protectors (AIPPs) on unused hubs of central lines may be effective at reducing CLABSIs. In a systematic review of quasi-experimental studies across adult and paediatrics, AIPPs were found to reduce CLABSIs by 41% (IRR = 0.59, 95% CI = 0.45–0.77, P < 0.001) (Voor et al., 2017). However, the evidence reviewed were all before and after studies, with the risk of over-estimating the effect size and graded as moderate quality of evidence. Voor et al. (2017) also found a risk of publication bias.
Antibiotic locks for central line catheters	These should not be routinely used to prevent catheter-related infections.	In a meta-analysis on the use of antibiotic locks in neonates, Taylor et al. (2015b) found 3 studies eligible for inclusion, with a combined reduction in catheter related BSI (CRBSI) by 85% (95% CI 0.06-0.40). However, each study used a different antibiotic, and there was no assessment of antimicrobial resistance.
Central line dressing and maintenance	Class D evidence supports the following recommendations: • Using a sterile transparent and semi-permeable dressing to cover the site • Change it every 7 days or sooner if not intact or moisture under dressing	A Cochrane review (Lai et al., 2016) examined the evidence for anti-microbial dressings in neonates finding insufficient evidence to support a change in practice, either for chlorhexidine impregnated dressings or silver-alginate dressings. Chlorhexidine impregnated dressings reduced

Preventative Strategy	Recommendation from Epic3 Guidance	Neonatal Application
	Class B evidence supports the following recommendations: • Consider use of CHG impregnated sponge dressing in adult patients • Consider the use of daily cleaning with chlorhexidine in adult patients	catheter colonisation but had no significant effect on reducing CRBSIs. In addition, there was the potential for skin irritation. There has been a single before- and-after study investigating the use of chlorhexidine washcloths in neonates, finding a reduction in catheter-related bloodstream infections with no significant adverse reactions (Quach et al., 2014). This study excluded infants <1000grams and < 28 days old from the intervention.
Prophylactic antibiotics during central line removal	There is no evidence to suggest that prophylactic oral or parenteral antibiotics reduce catheter related infections.	In a retrospective study, Hoogen et al. (2008) found that the administration of cefazolin and gentamicin reduced the incidence of sepsis, diagnosed as clinical signs with a positive blood culture. Ratcliffe et al. (2015) found that a dose of antibiotic 12 hours prior to line removal reduced the incidence of clinical sepsis. However, this was a retrospective chart study, with infants receiving antibiotics already for treatment of sepsis as well as those who received a single dose prior to line removal. Infants in the antibiotics prior to line removal group also had longer dwell line dwell times. Another retrospective chart review found no difference between groups receiving a single dose of vancomycin versus those who did not (Bhargava et al., 2018). A Cochrane review found a single study that used 2 doses of Cephazolin prior to line removal and found no difference in the rate-ratio for late-onset sepsis or CLABSIs.

Preventative Strategy	Recommendation from Epic3 Guidance	Neonatal Application
		Prophylactic vancomycin is a risk factor for developing a vancomycin resistant enterococcus (VRE), and with current concerns regarding increasing antibiotic resistance, this likely outweighs the potential benefits.
Insertion Strategies		
Maximal Standard Barrier Precautions	MSB precautions involve wearing sterile gloves and gown, cap and mask, and using a full-body sterile drape during insertion of the catheter. A systematic review concluded that the lack of patient reactions, low cost and high cost of catheter-related infections, this will probably be a cost-saving intervention. Class C recommendation.	There is limited evidence specifically for the use of MSB in neonates, though they form the basis of many of the care bundles studying the reduction of CLABSIs (Payne et al., 2018, Taylor et al., 2015a).
Skin asepsis	Decontaminate the skin at the insertion site with a single-use application of 2% chlorhexidine gluconate in 70% isopropyl alcohol (or povidone iodine in alcohol for patients with sensitivity to chlorhexidine) and allow to dry prior to the insertion of a central venous access device. Class A recommendation.	There is limited evidence regarding the choice of skin antisepsis in neonates. Safety concerns have been reported regarding the use of chlorhexidine in preterm infants and the risk of severe skin burns (MHRA, 2014). A study comparing povidone iodine to chlorhexidine gluconate 2% found no different in CLABSIs but more thyroid function derangements in the iodine group, and do not recommend this be used for skin antisepsis in very low birth weight infants (Kieran et al., 2018). A recent pilot study (as yet unpublished) comparing 2% chlorhexidine gluconate to 2% chlorhexidine with 70% isopropyl alcohol found no

Preventative Strategy	Recommendation from Epic3 Guidance	Neonatal Application
		differences between groups, and no differences in adverse skin reactions (Clarke et al., 2019, {Clarke, 2020 #781).
Choice of site	A systematic review and meta-analysis found that there was no difference in catheter-related infections between insertion sites (femoral, sub-clavian and internal jugular). PICC lines inserted via the upper arm showed no difference in catheter-related infections compared to jugular or subclavian veins.	PICC lines inserted into upper arm and lower leg are standard in neonates. Jugular and femoral lines are rarely used. García et al. (2019) identified risk factors for CLABSIs in neonates finding that there were more CLABSIs in lines placed in the jugular vein and less in lines inserted into the upper limb. Umbilical venous catheters (UVCs) appear to have a higher risk of developing a CLABSI and early replacement with a PICC line is recommended (Sanderson et al., 2017).
Antibiotic impregnated central lines	The use of antibiotic impregnated central lines, whilst recommended in adults where a central line is likely to remain in place for greater than 5 days and CLABSI remains high.	Gilbert et al. (2019) found no difference in time to positive blood culture in neonates with rifampicin-miconazole impregnated catheters, compared to controls, but a slightly higher incidence of rifampicin resistant isolates.
Other strategies to reduce neonatal late-onset sepsis		
Speed of increasing feeds	N/A	Dorling et al. (2019) found that a quicker speed of increasing feeds (30mls/kg/day) compared to slower rates (18mls/kg/day) resulted in quicker establishment of full enteral feeds, less days of Parenteral Nutrition, and no differences in the rate of Necrotising Enterocolitis or Late-Onset Sepsis.

Preventative Strategy	Recommendation from Epic3 Guidance	Neonatal Application
Probiotics	N/A	Probiotics have been shown to reduce the risk of Necrotising Enterocolitis, one form of Late-Onset Sepsis that can result in translocation of bacteria from the gut into the bloodstream (Sharif et al., 2020). One of the challenges with the evidence for probiotics is that it is still unclear which strain of probiotic is the most effective, with a recent UK double- blinded RCT of a single strain of probiotic (Bifidobacterium) showing no difference in NEC or bloodstream infection rates (Costeloe et al., 2016). When it comes to reviewing the efficacy of probiotics in reducing Late Onset Sepsis, the evidence from systematic reviews is mixed. One strain-specific meta-analysis found that some strains of probiotics reduced the incidence of Late Onset Sepsis (van den Akker et al., 2018), one meta-analysis found this effect was only in human-milk fed VLBW receiving multiple strain probiotics (Aceti et al., 2015) and another meta-analysis of observational studies (Olsen et al., 2016) found that probiotics did not reduce episodes of sepsis, though the 95% CI was not greater than 1 (RR = 0.86, 95% CI, 0.74-1.00; p = 0.05).

Appendix 3 EPOC Taxonomy of Professional Interventions

Intervention	Description	Example
Educational materials	Distribution of published or printed recommendations for care	Guidelines related to the prevention and management of neonatal Late-Onset Sepsis.
Educational meetings	Participation in conferences, lectures, workshops or traineeships	Infectious Diseases or Governance meetings where cases are discussed, and lessons learnt.
Local consensus processes	Inclusion of providers in discussion to ensure that the agreed chosen clinical problem was important and the approach to management was appropriate	Formation of a multi-disciplinary team to design and develop local measures to reduce CLABSIs.
Educational outreach	Trained person who meets with providers in their practice setting to give information with the intent of changing the providers practice. The information may have feedback on performance	An infectious diseases or microbiology ward round that takes place at the bedside, to facilitate learning and education on CLABSI prevention and management.
Local opinion leaders	Nominated by colleagues as 'educationally influential'.	These could both facilitate or hinder implementation efforts. May include local infection prevention leads, or senior nurse leaders.
Patient-mediated interventions	Clinical information collected directly from patients and given to the provider	Parent involvement in monitoring asepsis.
Audit and feedback	Any summary of clinical performance of health care over a specified period of time. The summary may also have included recommendations for clinical action. The information may have been obtained from medical records, computerised databases, or observations from patients.	Auditing adherence to specific process measures such as checklist components.
Reminders	Patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health professional to recall information to perform or avoid some action to aid individual patient care.	Electronic alerts built within electronic record systems, or checklists to prompt healthcare professionals e.g. a checklist recommending the appropriate skin cleansing solution.
Marketing	Use of personal interviewing, group discussion ('focus groups'), or a survey of targeted providers to identify barriers to change and subsequent design of an intervention that addresses identified barriers	Informal group discussions at local meetings to determine beliefs regarding practice change or guideline.
Mass media	Varied use of communication that reached great numbers of people including television, radio, newspapers, posters, leaflets, and booklets.	Use of a variety of communication media such as audio-visual systems, emails, newsletters and posters to reach target audience.
Adapted from EPOC (2015)		

Appendix 4 Applying the Michigan CLABSI bundle to the NICU

Intervention	**Applicable (yes, no, partly)**	**Application to the NICU**
Hand hygiene	Yes	Hand hygiene known to be single most effective mechanism for reducing the transmission of HCAI
Maximal standard barrier precautions	Partly	Majority of neonates nursed in incubators or under radiant heaters, with ELBW nursed in >80% humidity. Makes the wearing MSB precautions uncomfortable for long periods. Incubators provide barrier between clinician and sterile field, ambiguity regarding necessity in this population.
Avoid the femoral site	Not applicable.	Femoral line site rarely used in this population.
CHG 2% + 70% Isopropyl alcohol (IA)	Partly	Evidence ambiguity ELBW have un-keratinised skin immediately after birth, so alcohol is avoided and 0.05% CHG recommended locally in < 28 weeks gestation population to avoid skin burns. >28weeks gestation 2% CHG + 70%IA used
Remove unnecessary catheters	Partly	Catheters rarely unnecessary in neonates. Limited evidence of benefit of peripheral versus central parenteral nutrition (PN) (Ainsworth and McGuire, 2015). However, peripheral PN can cause significant extravasation injuries. Gaining venous access in ELBW can be challenging. Immature glucose homeostasis mechanisms, lack of stores and inability to tolerate enteral feeds can result in increased central line dwell times. Whilst some studies suggest removing catheters at 120mls/kg/day enteral feed, there is a lack of information on balance measures such as growth and long term neurodevelopmental outcomes.

Appendix 5 Key Recommendations from Local Guidelines.

Central Venous Catheter Guideline

(Approved January 2016, review date January 2020).

Accompanying video available at: https://www.youtube.com/watch?v=nQHHnIS-CNk

The guideline aims to address:

- Aspects of insertion, ongoing use and care of CVC in the neonatal setting.
- Highlight early recognition of the rare but potentially fatal complications such as cardiac tamponade and umbilical venous catheter (UVC) extravasation.
- Help with implementation of a care bundle of practice for the multiprofessional team involved in the use of CVC's to ensure uniform practice with ongoing surveillance of complications (such as CVC related sepsis in neonates).

Operator competency

- Staff inexperienced in these procedures should only undertake the procedure under the direct supervision of a competent member of staff who is familiar with local practice. ST1-3s will complete their CVC access training within 8 weeks of joining. This includes a didactic and a simulated clinical component. Videos are available for standardisation and visual reinforcement. Additional clinical experiential learning will be supervised for ongoing proficiency in the procedure on neonates. ST1-3s should have a maximum of 2 attempts at a single site or a further attempt at consultant discretion.
- Staff members who have acquired skills in placing such catheters at other institutions should refer to the specific procedures as prescribed for this unit and have their technique approved by one of the unit's permanent medical staff before undertaking the procedure unsupervised or supervising others. In particular, attention should be given to
  - Types and lengths of lines available on unit
  - Preferred extension sets to connect to the line hub
  - Fluid used to keep line patent while position is confirmed
  - Documentation processes

The procedure should be undertaken by 2 people where possible (2nd person to assist, hold and monitor the patient and complete the ***Insertion Checklist.***

General Measures

- Choose appropriate vein and expose appropriately discussing how you want to restrain the baby.
- Manage pain appropriately. Consider oral sucrose, pacifiers, swaddling and if necessary, morphine as appropriate.
- Prepare your equipment. Don hat and mask prior to hand washing if outside incubator.
- The procedure requires meticulous attention to sterility. An assistant must be present during the procedure to ensure compliance with the insertion checklist. The assistant is required to stop the procedure if any breach in sterility is seen. This may involve the need to deglove and degown and prepare a new field as well as equipment depending on the nature of break in the process.
- Hand washing to be performed as a surgical scrub with Chlorhexidine 4% or Povidone-Iodine scrub.
- Maximal sterile barrier precautions, including the use of hair covering, face mask, sterile gown and gloves, and large sterile drapes have been shown to reduce the risk of infection by six to seven times over the use of sterile gloves and drapes alone if not in an incubator.
- Ensure you are double gloved for the procedure
- Create a wide sterile field to reduce risk of contamination
- Restrict traffic near the sterile field. Use curtains to ensure this.
- If there is accidental contamination of gloves or gown during the procedure de glove and de gown and repeat steps 4-7.

Asepsis

- Skin should be cleaned with aqueous Chlorhexidine 0.05 % for babies less than 28 completed weeks of corrected gestation using and up down and side to side motion. (See Video 4).
- Above this age, Chlorhexidine 2% in alcohol (Chloraprep) should be used. (See Video 5)
- Skin contact time required is 1 minute. After 1 minute, it is advisable to use saline soaked gauze to wipe the skin as the aqueous Chlorhexidine is soapy and may affect the occlusive dressing's ability to adhere to the skin. Iodine based preparations are not used.

- Clean the entire limb and ensure a wide sterile field when doing upper or lower limb veins as you might need to attempt further sites on the same limb.

Confirming position

- The position of the longline is confirmed on X-ray.
- For premicaths a water-soluble contrast (Neopam) should be injected into the line directly (distal to any multiport connectors). This means the line has to be broken using surgical ANTT gloved and gowned and no more than 0.2ml of contrast flushed through. Wait a few seconds and then take the X-ray.
- For lines 2fr and larger which are radiopaque routine contrast use cannot be recommended based on current evidence.

Care of lines

- All infusions should be sterile, prepared and connected using the surgical ANTT procedure. All access ports must be cleaned with 2% Chlorhexidine in 70% alcohol and allowed to dry for 1 minute before accessing.
- Lines should be removed as soon as is practical once they are no longer required.
- PICC lines may be left in place for up to 6 weeks provided there are no infection concerns. Use longer than this must be discussed at a senior medical level.
- Redressing: Dressings should only be changed if they are loose, have significant amounts of blood underneath or if there are concerns about skin integrity underneath hubs. Dressings should not be routinely changed for other reasons. This goes against the principles outlined in “Matching Michigan” but is necessary to protect fragile skin and displacement of the lines.
- All dressing changes must be done in a sterile manner, just as the insertion is. The skin should be cleaned as per Appendix 2 after the old dressing is removed. A new occlusive dressing should be applied following same principles as for insertion.

Sepsis

There are 6 key tenets to prevention of Central line associated blood stream infection enshrined in this guideline.

There should be:

- Sterile technique on insertion
- Monitoring of site and re-dressing where appropriate
- Surgical ANTT on checking line position & accessing lines

- Minimising line breakages, access, minimising use of line for bolus drug administration and use of endotoxin retaining in-line filter.
- Removal of the line when no longer indicated
- Use of antibiotics where clinically indicated as below and stopping antibiotics promptly as appropriate.
- Confirmed sepsis is in most cases an indication for CVC removal. In an infant with difficult access problems it may be possible to treat a line infection without removal, but this requires careful monitoring and the involvement of a Consultant in the decision making. Please see the guideline on Late Onset Sepsis for further management.

Communication Plan

- All ST1-3 to have training on central access as part of MPROvE Access Module within 8 weeks of training.
- For those trainees who cannot attend and ST4-8 the standardised videos produced as part of the MPROvE workshop to reinforce practice.
- Structured online MCQ to assess didactic knowledge to be completed within 8 weeks.
- Nursing training regarding ANTT to be through the infection control team. Medical training to be completed as part of induction package for all trainees.

Nursing Care of Central Lines

Assisting with insertion of central lines such as percutaneous inserted central catheter (PICC), umbilical venous catheter (UVC) or umbilical arterial catheter (UAC)

THIS IS A STERILE PROCEDURE

- Assist medical staff in preparing for the procedure and use the Checklist for central line insertion.
- Ensure infant is comfortable, paying attention to temperature control
- Assist medical staff in handing equipment, drawing up appropriate fluids, priming an Octopus and securing the line in place as per guideline

Preparation and administration of drugs via a central line

The procedure should take place using strict surgical aseptic non touch technique (ANTT) as per Southampton NHS Foundation Trust protocol.

- The bag of total parenteral nutrition (TPN) and the syringe containing lipid, which arrives from pharmacy is not sterile therefore great care should be taken that key parts are not touched as per ANTT guideline.
- The prescription must be checked, and drugs calculated prior to procedure
- Check if skin/dressing is secure, clean and dry and document in the nursing notes during every shift
- Change infusion set when changing infusion fluids
- TPN should have a designated port on the Octopus
- TPN filters should be changed every 96 hours/4days
- Lipid filters should be changed daily
- Filters for fluids with additives should be changed every 96 hours/4 days
- Octopi need changing every 96 hours/4days too and when continuous infusions (i.e. morphine, dopamine, insulin) have stopped. Discontinued 'continuous' drug infusions should be clamped and remain connected to the 'old' Octopus port which should remain clearly labelled till Octopus is changed. Do not disconnect and cover the ends of octopi with Elastoplast/tape
- Limit the number of octopi as far as possible on the central lines
- Changing pump pressures should be discussed with senior medical staff. The line should only be flushed by experienced medical staff.
- Check skin at infusion site, monitor infusion pump pressure, set rate and calculate prescribed rate, actual rate and total running rate hourly and document on observation chart
- Document how infusions have been running and comment on skin/site and note if dressing is intact/soiled/changed in the nursing notes during your shift

Guideline for the Prevention and Management of Late-Onset Sepsis (Approved October 2017)

Aim of guideline:

- To promote infection prevention on the neonatal unit and reduce rates of LOS and CLABSI
- To promote a consistent and standardised approach to the management of LOS and CLABSI
- To promote antibiotic stewardship and reduce unnecessary use of antibiotics

Accessing Central Lines

In order to reduce the risk of infection, central lines be accessed as little as possible. Ideally, theyshould be accessed only in the following circumstances

- In order to change IV fluids or PN as the existing fluids have expired or the prescription haschanged
- In order to add additional infusions that must be given centrally

- In order to administer antibiotics that need to be given centrally (usually for suspected central line infection)

Access times should be coordinated to allow all of the above to occur at the same time where possible and clinically appropriate. Ideally, central lines should not be used for the routine administration of drugs due to a lack of peripheral access, though this is acceptable if peripheral access cannot be obtained by a senior member of the medical team.

Fluids, drugs and infusions that are to be administered centrally should ideally be made up on a dedicated trolley, close to the patient's bedspace and away from any footfall through the room (screens should be used to facilitate this if necessary).

Removal of Central Lines

- Central lines should be removed as soon as possible in the following circumstances:
- The line is no longer needed. In the case of central lines used for providing PN, this will be 24 hours after the infants has been established on an amount of enteral feeds which will provide adequate nutrition for their needs.
- The line is felt to be a source of infection (i.e. the infection is a CLABSI). The decision that a line is infected will be a clinical one made by a senior clinician, but will usually be in a clinically unwell infant with a rise in CRP and a blood culture positive for an organism which is likely to have come from the line (eg CONS) or where the line may act as a reservoir for the organism (eg CONS and gram negative organisms). The threshold for removal should be lower if the CLABSI is a gram-negative organism, and fungal infection should always lead to line removal
- The decision to leave a line in situ, based on risk analysis, in the presence of likely systemic infection should be made by the duty consultant Neonatologist and the rationale for the decision should be recorded in the patient record along with guidance as to how the decision might be modified on the basis of a changing clinical picture.
- Where lines are removed for line sepsis, the line tip should be sent for microbiology after removal.

Management of Central Line Dressings

There is no evidence in the neonatal population to support the routine changing of peripherally inserted central line dressings every 7 days. The risks of line dislodgement, catheter damage, the possible introduction of infection, and the risk of epidermal stripping in the ELBW infant outweigh any potential benefits of routine dressing changes in this population at this time. Local consensus supports the change of central line dressings if

visibly soiled or there is potential for line exposure. Dressing integrity should be assessed and documented once per shift as a minimum. If a line dressing is coming away or damaged such that the insertion site is exposed, then it should be replaced using surgical ANTT, with the site cleaned prior to a new dressing being placed. If the insertion site is not exposed then the dressing should be supported using additional dressing materials. Opsite occlusive dressing should be used for central lines

Process for monitoring

Observations of practice, 6 monthly audits, all inpatients on a single day

Appendix 6 Local Central Line Insertion Checklist

(Adapted from the Prevention and Management of Late Onset Sepsis on the Neonatal Unit)

This checklist should be completed by an observer. The procedure must be stopped if any of the elements on this checklist are not followed.

Affix Patient Label:	Operator/s:
	Nurse Observer:

Before the procedure:

		Yes	No
1	Required equipment gathered		
2	Designated trolley cleaned (Clinell wipes)		
3	Operator and assistant should perform a surgical hand wash using		
4	Sterile gown and gloves worn by operator/assistant (theatre cap and mask should also be worn if infant is in an open cot rather than an incubator)		

During the procedure:

		Yes	No
5	Skin decontamination using gestation appropriate Chlorhexidine/70% Isopropyl Alcohol preparation & allowed to dry for 60 seconds		
6	Sterile drape to cover infant		
7	Sterile field maintained (if applicable sterile glove used for light source)		

After the procedure:

		Yes	No
8	Sterile dressing used (Opsite, Steristrips) Gauze beneath Long line/Cannula hub		
9	Attach infusion set		
10	Decontaminate hands after removal of gloves		
11	Ensure any contrast to check line placement is administered using surgical ANTT		

If any care bundle elements were not followed, please document why:

Operator Signed: Observer Signed:

Appendix 7 Implementation Search Strategy and Audit Trail

Search Question:

In all healthcare settings, how do healthcare professionals implement care bundles, aimed at reducing CLABSIs?

Key words:

Setting: All healthcare settings

Perspective: Healthcare professionals

Intervention: Care bundle* or bundle* or quality improvement or complex intervention

AND CLABSI, central line associated bloodstream infection, bloodstream infection

Comparison: No comparison

Evaluation: Implement* or evaluat* or barrier* or facilitat*

Sources Searched:

Medline, Psycinfo, Web of Science, CINAHL, Embase,

Non-database sources: Cochrane Library, Ethos, Clinicaltrials.gov

Inclusion Criteria	**Exclusion Criteria**
Any healthcare setting After 2006 (10 years at initial time of search) Evaluation of a care bundle or multi-faceted intervention	Studies investigating bundle efficacy only Studies focusing on a single intervention e.g. central line teams, reducing dwell times Studies focusing on a single implementation strategy e.g. education, simulation Specific microorganism outbreaks

Audit Trail: Updated Database Search January 2020					
Search terms	Medline	Web of Science	CINAHL	Embase	Psycinfo
Care bundle* or bundle* or quality improvement or complex intervention AND CLABSI OR central line associated bloodstream infection OR bloodstream infection AND Implement* or evaluat* or barrier* or facilitat* English Language limiter Jan 2006-Jan 2021	198	417	418	859	23
Database removal of conference abstracts	N/A	N/A	N/A	470	N/A
Total Database Hits	198	417	418	389	23
Non-database sources	Cochrane Library= 1 , Ethos= 0, Clinicaltrials.gov= 1				
	Total combined hits =1447				
After electronic duplicates (excluded n=597)	Total hits after duplicates removed n= 850				
Application of Inclusion/Exclusion criteria Total excluded n=843	Excluded by title, n= 347 Excluded by abstract, n =88 Excluded conference abstract, n =83 Excluded letters/commentary/editorial, n = 9 Excluded bundle efficacy, n =274 Excluded full text, n =42 Reasons for full text exclusion: Bundle efficacy, n = 11 Not bundles* , n =13 Not CLABSIs, n = 3 Culture/Patient safety programmes** =7 Michigan study , n = 1 Abstract only, n = 1 Not implementation= 1 Individuals knowledge of bundles/BSIs, n = 2 Not English language, n =1 Assessing adherence, n =1 Economic evaluations, n= 1				
Final Papers included: 7					

Appendix 8 Published Systematic Review Manuscript

TITLE PAGE

Care bundles to reduce central line-associated bloodstream infections in the neonatal unit: A systematic review and meta-analysis.

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WORD COUNT 2, 800

KEYWORDS Care bundles, central line-associated bloodstream infections, late-onset sepsis, neonates, neonatal intensive care

MeSH HEADINGS

Catheter-Related Infections, Newborn, Patient Care Bundles, Infection Control

What is already known:

Care bundles have been successful in reducing CLABSIs in adult ICUs, though replication in paediatric ICUs has been less successful.

Zero-CLABSI rates have been reported following the introduction of care bundles in some US NNUs

What this paper adds:

There is a substantial body of quasi-experimental evidence that care bundles may reduce CLABSIs in the NNU, though the magnitude of effect is variable.

There is widespread variation in the bundled elements used, though having a dedicated skin preparation protocol and education were the two most commonly used bundled elements.

Appendix 8

ABSTRACT

BACKGROUND

CLABSIs are associated with increased mortality, prolonged hospitalisation and increased healthcare costs. Care bundles have reduced CLABSIs in adult ICUs but replication in paediatric ICUs has had inconsistent outcomes. A systematic review was performed to assess the evidence for the efficacy of care bundles in reducing CLABSIs in the neonatal unit.

METHODS

MEDLINE, CINAHL and EMBASE were searched from January 2010 up to January 2017. The Cochrane Library, Web of Science, Zetoc and Ethos were searched for additional studies. RCTs, quasi-experimental and observational studies were eligible. The primary outcome measure was CLABSI rates per 1000 central line, or patient, days. A meta-analysis was performed using random effects modelling.

RESULTS

Twenty-four studies were eligible for inclusion; 6 were performed in Europe, 12 were in North America, 2 in Australia and 4 were in developing countries. Five were observational studies and 19 were before and after quality improvement (QI) studies. No RCTs were found. Meta-analysis revealed a statistically significant reduction in CLABSIs following the introduction of care bundles (Rate Ratio = 0.40 [CI 0.31-0.51], $p < 0.00001$), which equates to a 60% reduction in CLABSI rate.

CONCLUSION

There is a substantial body of quasi-experimental evidence to suggest that care bundles may reduce CLABSI rates in the NNU, though it is not clear which bundle elements are effective in specific settings. Future research should focus on determining what processes promote the effective implementation of infection prevention recommendations, and which elements represent essential components of such care bundles.

INTRODUCTION

Neonatal late-onset sepsis (LOS) is associated with increased mortality and morbidity and prolonged hospitalisation (Adams-Chapman, 2012, Payne et al., 2004, Rosenthal et al., 2013), with substantial additional healthcare costs (Payne et al., 2004). Neonates are especially susceptible to episodes of LOS due to an immature immune system, and they frequently require invasive devices, including central lines, to deliver life-saving medications and parenteral nutrition. The use of such devices significantly increases the risk of infection, and central line-associated bloodstream infections (CLABSIs) are an important cause of LOS (Zingg et al., 2017). Whilst there is some uncertainty regarding the impact of CLABSIs on neurological outcomes (Adams-Chapman, 2012) , recent evidence suggests that reductions in coagulase-negative staphylococcal (CoNS) infections may reduce cognitive disability in preterm infants (Davis et al., 2016).

The reported incidence of CLABSIs in neonates ranges from 3.2 to 21.8 CLABSIs per 1000 central line days (Folgori et al., 2013). The disparity in incidence possibly reflects the diverse definitions of CLABSIs which is demonstrated in Table 1. There are also variations in aspects of care and infection prevention practices and it seems that the variations in rates cannot be wholly explained by case mix between centres, with similar centres having differing CLABSI rates (Wynn et al., 2014, Balain et al., 2015). This suggests that studying the practice patterns of different neonatal units (NNUs) may provide insights into possible preventative strategies (Chien et al., 2002).

Care bundles, structured packages of evidence based practices aimed at improving the processes of care and patient outcomes, have been shown to be effective in reducing CLABSIs in adult ICUs. The Michigan Keystone project (Pronovost et al., 2006), a US state-wide quality improvement project in adult ICUs, introduced bundled evidence-based interventions alongside a patient safety programme, and was considered a major success, reporting zero CLABSI rates post-implementation. Matching Michigan, a UK 2-year, four-cluster, stepped non-randomised study conducted in adult and paediatric ICUs,

Table 1 Three definitions of central line-associated bloodstream infection

Source	Definition	Clinical signs	Laboratory Markers
NEO-KISS	Laboratory-confirmed bloodstream infection (LCBI) with coagulase negative staphylococcus (CoNS) isolated as sole pathogen AND 2 clinical signs AND 1 laboratory parameter OR Pathogen isolated from blood or cerebrospinal fluid culture, not related to infection at another site AND 2 clinical signs LCBI with non-CoNS pathogen isolated in blood culture or cerebrospinal fluid, and pathogen not related to infections at other site AND two clinical signs Clinical sepsis without proof of pathogen No pathogens isolated from blood or culture not taken Physician prescribes antimicrobials for at least 5 days No apparent infection at another site AND 2 clinical signs, without other recognised cause	Fever > 38 oC or temperature instability (frequent incubator adjustment) or hypothermia <36.5 oC Unexplained metabolic acidosis BE > -10 Tachycardia >200bpm and/or bradycardia <80bpm New or more frequent apnoeas Recapillarisation time >2 secs New hyperglycaemia >140mg/dl Other signs of infection: Colour (when recapillarisation time not use), apathy, CRP, interleukin, increased oxygen requirement (intubation) or unstable condition	C-Reactive Protein > 2,0mg/dl Thrombocytes <100/nl I/T ratio >0/2 * Leukocytes <5/nl (without erythroblasts) *immature granulocytes/total granulocytes
NNAP	The growth of a recognised pathogen in pure culture OR in the case of a mixed growth, or growth of skin commensal, the added requirement for 3 or more of 10 predefined clinical signs[5]	Tachypnoea/clinically relevant increase in oxygen or ventilation support Clinically relevant increase in apnoea, Bradycardias Hypotension Hypo or hyper-glycaemia Impaired peripheral perfusion, pallor, mottling, Capillary refill time >3 secs, toe-core gap >2 Lethargy, irritability, poor handling Temperature instability Ileus, feed intolerance Reduced urine output Metabolic acidosis Base Excess >-10	N/A
CDC	A laboratory- confirmed bloodstream infection (LCBI) where central line or umbilical catheter was in place for >2 calendar days on the date of event, with the day of device placement being Day 1, AND the line was also in place on the date of event or the day before.	Fever Hypothermia Apnoea, or bradycardia	N/A

[5] This definition has subsequently changed to no longer include the need for clinical signs NNAP (2018) *National Neonatal Audit Programme 2018 report on 2017 data.* London: RCPCH.

	LCBI: Patient of any age has a recognised pathogen identified AND organism identified in blood is not related to an infection at another site OR Patient <1 year of age has at least one clinical sign AND organism identified from blood is not related to an infection at another site AND the same common commensal is identified from 2 or more specimens.		

attempted to replicate this success and despite a 48% reduction in paediatric CLABSIs, this did not reach statistical significance (Bion et al., 2013). This was attributed to small numbers, large variations in paediatric CLABSI rates, and difficulties in outperforming the temporal trend. There was a failure to demonstrate, with confidence, that improvements were directly attributed to the intervention, with notable differences in team engagement (Dixon-Woods et al., 2013). These differences highlight the importance of understanding how various elements work to deliver improvements (Moore et al., 2015).

This systematic review was performed in order to assess the evidence for the efficacy of care bundles to reduce CLABSIs in infants with indwelling central lines in the NNU, compared to standard care, and to determine which bundled elements were most commonly used.

METHODS

The search protocol was registered in the PROSPERO international prospective register of systematic reviews (42016045321), and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines have been followed (Moher et al., 2009). MEDLINE, CINAHL and EMBASE databases were searched from January 2010 up to January 2017. The Cochrane Library, Web of Science, Zetoc and Ethos were searched for additional studies, and reference lists of relevant articles were searched. Two authors (VP, MJ) performed the search and selection process separately, and disagreements were resolved by discussion.

Studies were eligible for inclusion if they investigated the effect of a care bundle and were performed in an NNU of any care level. A care bundle was defined as any intervention with multiple interacting components and included both central line insertion and maintenance care bundles. Randomised controlled trials (RCT), non-randomised interventional studies and observational studies were all eligible for inclusion. Studies

were excluded if they investigated a single intervention, were performed in adult or paediatric populations or were focused on a specific pathogen outbreak. Studies not published in English, and conference abstracts, were excluded.

OUTCOMES

The primary outcome was the number of CLABSIs per 1000 central line or patient days. This denominator was chosen in order to reflect any potential changes in unit acuity or central line exposure that may result following the introduction of a bundle. The secondary outcome was to identify the frequency with which bundled technical and non-technical elements were used, the latter classified according to the Cochrane Effective Practice and Organisation of Care (EPOC) system.

DATA EXTRACTION AND RISK OF BIAS ASSESSMENT

Data were extracted using a standardised template. Study characteristics were collected including setting, study design, bundled elements, definition of CLABSI, change in CLABSI rate and measures of compliance. CLABSI rates were extracted from the published studies. Studies were categorised as observational or quality improvement (QI) based upon the classification provided in the original studies. The methodological quality of observational studies was assessed using the Newcastle-Ottawa Scale (NOS) (WHO, 2009). The Standards for Quality Improvement Reporting Excellence (SQUIRE) 18-item checklist was used for QI studies (Ogrinc et al., 2016).

STATISTICAL ANALYSIS

The bundled elements were summarised as frequencies and percentages. The rate ratio (RR) for the number of infections per 1000 central line days or patient days was calculated with 95% Confidence Intervals (CI), with a correction of 0.5 applied to zero rates as per

the methods in the Cochrane Handbook (Higgins and Green, 2011). This results in a more conservative estimate of the effect size. A meta-analysis was performed using random effects modelling (2011). Heterogeneity between studies was assessed using the I^2 test, with values >30% considered to represent moderate heterogeneity, >50% substantial heterogeneity, and >75% considerable heterogeneity (Higgins and Green, 2011). There were no *a priori* sub-group analyses planned, other than according to study design.

RESULTS

The search initially identified 439 articles, and following the removal of duplicates, 259 unique studies remained (see Appendix 9). Titles and abstracts were screened for relevance, and 40 full-text studies were assessed.

Study characteristics

Twenty-four studies were eligible for inclusion (Table 2). Twelve studies (50%) were performed in North America, 6 (25%) in Europe, 2 in Australia (8%) and 4 (17%) in developing countries. Sixteen (67%) were single centre, whilst 8 (33%) were multi-centre. Whilst 5 studies described themselves as observational studies, all 24 studies were non-randomised intervention studies. No RCTs were found.

Table 2 Study Characteristics

Author (date)	Setting	Location	Described Study Design	Definition	Results
Almeida et al. (2016)	Tertiary NICU	Portugal	Before/After	NEO-KISS	14.1 to 10.4
Arnts et al. (2015)	Tertiary NICU	Netherlands	Prospective Cohort	CDC	12.9 to 4.7 (CI 1.25–11.23)
Bizzarro et al. (2010)	Level IIIc 54 bed NICU	US	Before/After	CDC	8.44 to 1.7 (CI 0.08-0.45)
Bowen et al. (2016)	8 NICUs <29 weeks	Australia	Before/After	BSI infection where a central line was in situ or within 48 hours of removal of the central line, unless clearly identified source of infection.	9.9 – 5.4
Ceballos et al. (2013)	Level IIIb 50 bed NICU	US	Before/After	CDC	6.9-0.5
Chandonnet et al. (2013)	Level IIIc 24 bed NICU	US	Before/After	CDC	2.6 to 0.8
Erdei et al. (2015)	Level IIIc NICU	US	Before/After	CDC	4.1 to 0.94
Fisher et al. (2013)	3 Level II 10 Level III	US	Before/After	CDC	3.94- 1.16
Kime et al. (2011)	Level III NICU	US	Before/After	CDC	15.6-0.5
McMullan and Gordon (2016)	Level V NICU	Australia	Retrospective cohort	Proven BSI associated with a central venous line, when a central line has been in use 48 hours before signs and symptoms of infection.	8.5 to 2.3
Piazza et al. (2016)	17 IIIc NICUs	US	Before/After	CDC	1.33-1.076

Author (date)	Setting	Location	Described Study Design	Definition	Results
Rallis et al. (2016)	Level III NICU	Greece	Before/After	CDC	12-3.4
Resende et al. (2011)	NICU	Brazil	Before/After	CDC	24.1-14.9
Rosenthal et al. (2013)	4 NICUs	El Salvador, Mexico,Phillipines, Tunisia	Before/After	CDC	21.4-9.7
Salm et al. (2016)	34 NICUs	Germany	Cohort study	NEO-KISS	2.63-1.98
Schulman et al. (2011)	18 NICUs	US	Prospective cohort	CDC Definition change during study	3.5-2.1
Shepherd et al. (2015)	8 NICUs	US	Before/After	CDC	6-0.68
Sinha et al. (2016)	Level III NICU	UK	Before/After	BSI > 48 hours after birth, with central line in situ, or 48 hours previously	31.6-4.3
Steiner et al. (2015)	NICU	Austria	Before/After	NEO-KISS	13.9-4.7
Ting et al. (2013)	NICU Level III	Canada	Before/After	Canadian Nosocomial Infection Surveillance Program or NHSN	7.9-2.2
Wang et al. (2015)	NICU 110 VLBW	China	Case-Control	Not provided	3.1 control 0 intervention.
Wilder et al. (2016)	NICU Level IV	US	Before/After	Not provided	3.9-0.3
Wirtschafter et al. (2010)	13 NICUs	US	Before/After	CDC	4.3-3.2
Zhou et al. (2015)	NICU	China	Before/After	CDC	16.7-5.2

Risk of Bias Assessment

The mean NOS score across the studies was 7 (range 6-8, see Table 3) from a possible maximum of 9. Lower scores tended to be due to a lack of control for NNU centre and central line days, though all the observational studies controlled for birth weight and gestational age. In general there was limited reporting of data collection and verification processes. Those studies reported as QI studies tended to have longer intervals between the before and after groups, and only two studies used interrupted time series analysis to account for temporal trends (Sinha et al., 2016, Salm et al., 2016), with a further five using statistical process control (Fisher et al., 2013, Bowen et al., 2016, Shepherd et al., 2015, Erdei et al., 2015, Piazza et al., 2016).

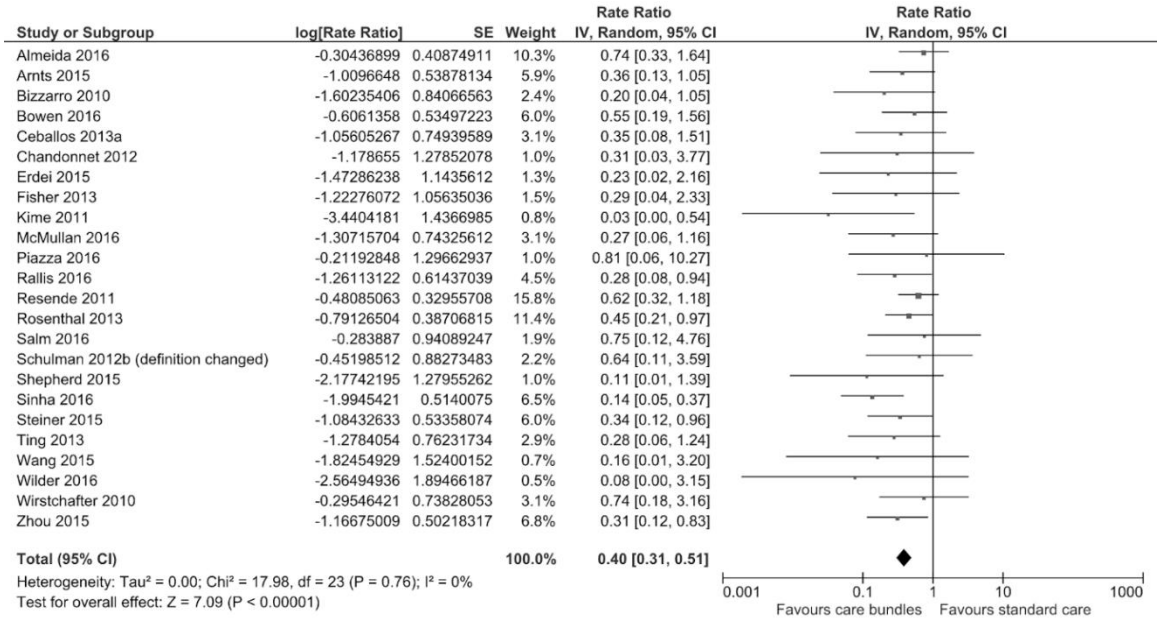
Using the SQUIRE reporting framework to assess the QI studies revealed that whilst the majority of studies provided detailed descriptions of the setting, the implementation process was not well documented (see supplementary material in). Few studies reported if the care bundle was implemented as intended (for instance by measuring compliance with bundle elements), and no studies reported any unintended consequences.

Reduction in CLABSI rates

Meta-analysis of all 24 studies revealed a statistically significant reduction in CLABSI rates following the introduction of a care bundle in the NICU (Rate Ratio = 0.40 [CI 0.31-0.51] p <0.00001, Figure 2). This equates to a 60% reduction in CLABSI rates. This effect remained for the separate analysis of the QI studies (RR= 0.40, CI 0.30- 0.52) and for the observational studies alone (RR=0.39 CI 0.20-0.79). There was no statistical heterogeneity amongst the studies, with I^2 = 0%.

Appendix 8

Figure 2 Meta-Analysis of 24 Included Studies



Baseline CLABSI rates ranged from 1.33 to 31.6 per 1000 catheter days. Following the introduction of a care bundle, CLABSI rates decreased to between zero and 14.9 per 1000 catheter days, with 7 studies reporting rates <1/1000 catheter days. All studies reported a reduction in CLABSI rates, though some were not as large as predicted (Kaplan et al., 2011, Piazza et al., 2016) and some did not find a reduction in rates in specific sub-groups, including neonates with birth weights <751 grams, 1000-1500grams and >1500 grams(Ceballos et al., 2013, Schulman et al., 2011, Wirtschafter et al., 2010). Several centres had starting rates that were already lower than the average National Health Surveillance Network rate (Piazza et al., 2016). In one multicentre study, one NNU reported 96% reduction in CLABSI rates, whilst another reported a 187% increase in rates (Schulman et al., 2011). Similarly, in a multi-centre study across 4 developing countries, only one NNU out of 4 reached a statistically significant reduction in CLABSI rates (Rosenthal et al., 2013).

Table 3 Assessment of bias using Newcastle Ottawa Scale										
	Selection				Comparability		Outcome			
Author	Representativeness of cohort	Selection of non-exposed cohort	Ascertainment of exposure	Outcome of interest	Controls for birth weight or gestational age	Controls for NICU centre, central line days	Assessment	Follow up duration >6months	Completeness of follow up	Total Score
Arnts	*	*	*	*	*	-	*	*	-	7
McMullan	*	-	*	*	-	-	*	*	*	6
Salm	*	-	*	*	*	*	*	*	*	8
Schulman	*	-	*	*	*	*	*	*	*	8
Wang	*	*	-	*	*	-	*	*	-	6

Bundled Elements

The technical and professional elements forming the care bundle in the included studies are shown in Table 4. The most common technical elements included the use of a specific skin preparation protocol (79%), maximal standard barrier precautions (71%), and a daily assessment of the need for the central line (67%). The choice of skin disinfectant varied, with chlorhexidine gluconate (CHG) and 70% isopropyl alcohol most commonly used (63%) though the strengths varied. Other preparations included povidone iodine (38%), or were unspecified (25%). Percentages do not total 100% due to some studies specifying multiple agents, determined according to gestational age. Despite hand hygiene resulting in significant reductions in hospital acquired infections (WHO, 2009), practices were poorly described, with only four studies specifying a product for hand cleansing (Schulman et al., 2011, Shepherd et al., 2015, Sinha et al., 2016, 'A national infection in critical care quality improvement programme for England: A survey of stakeholder priorities and preferences,' 2016), with the remainder making reference only to ensuring appropriate hand hygiene. Hand hygiene audits were reported in only 5 (20%) of studies.

The most common professional elements were education and training (100%), the use of checklists (67%), and audit and feedback (63%). Two studies attempted to associate specific elements with reductions in CLABSI rates, but were unable to isolate one single element (Sinha et al., 2016, Piazza et al., 2016). Bundle compliance was reported in 7 (29%) studies, and ranged from 10-100%. Studies that reported initial lower compliance rates of 10-30% generally reported improvement in rates over time. One study achieved a compliance rate of 55%, speculating this was lower than previously published rates due to anonymous bedside reporting (Fisher et al., 2013). One study concluded that CLABSI rate reductions were not associated with reductions in compliance rates (Piazza et al., 2016), whilst another study concluded that post-intervention CLABSI rates were better in those units that reported checklist compliance >15 % (Schulman et al., 2011). However, in this multicentre study 5 out of 18 units did not submit compliance data.

Table 4 Common bundled elements

Author **Technical Element**	Almeida	Arnts	Bizzarro	Bowen	Ceballos	Chandonnet	Erdei	Fisher	Kime	McMullan	Piazza	Rallis	Resende	Rosenthal	Salm	Schulman	Shepherd	Sinha	Steiner	Ting	Wang	Wilder	Wirtschafter	Zhou
Maximal standard barrier precautions	*			*	*	*		*		*	*	*	*	*	*	*			*	*	*		*	*
Skin Preparation	*		*		*	*	*	*	*	*	*	*	*		*	*	*	*		*	*	*	*	
Daily line need assessment		*		*		*	*	*	*	*	*		*	*	*	*	*				*		*	*
Scrub the hub	*	*		*			*	*	*		*			*			*	*		*			*	
Closed IV tubing	*		*					*														*	*	
PICC team			*				*										*				*	*		*
Central line trolley/ kit		*		*	*		*							*		*			*	*			*	*
Dressing protocol				*		*			*	*		*		*			*				*	*		
2 person technique				*	*	*	*			*		*										*		
Alcohol impregnated port protectors							*										*							
Professional Element																								
Education & training	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Multidisciplinary team		*	*	*	*		*	*	*	*	*						*			*		*	*	*
Audit & feedback		*	*	*	*	*	*		*	*	*			*			*	*		*		*	*	
Checklists		*	*	*	*			*	*	*	*	*			*	*	*		*	*	*		*	
Opinion leaders				*			*						*											
Rewards						*	*		*															
Root Cause Analysis				*	*	*	*		*		*						*						*	

DISCUSSION

This systematic review suggests that care bundles are associated with a statistically significant reduction in CLABSI rates in NNUs. This appears to be supported by a recent meta-analysis by Ista et al. (2016) which was the first systematic review to investigate CLABSI rates across all ages, performing separate sub-group analyses of adult ICU, PICU and NICUs. It found that care bundles statistically reduced CLABSI rates across all age ranges, including 14 neonatal studies (IRR 0.47, 95% CI 0.38-0.59). This is similar to the reduction found in the present study.

The lack of statistical heterogeneity is surprising, given that there is substantial heterogeneity amongst the included studies in terms of CLABSI definitions, setting and intervention. Moderate heterogeneity was found in the neonatal sub-group analysis performed by Ista et al. (2016), with an I^2 of 74%, though there were fewer studies included in their meta-analysis. Despite several studies being reported as cohort or case-control, the studies were all non-randomised interventional studies, which not only means there are multiple risks of bias,but may also partially explain the lack of statistical heterogeneity. Whilst the lack of statistical heterogeneity found in this study may suggest that the process of introducing a care bundle, regardless of its components, is effective, the absence of any negative studies strongly suggests a risk of publication bias within the literature. To date, no studies published in peer-reviewed journals have reported a negative effect of care bundles on CLABSI rates, and no studies reported unexpected or unintended consequences. Future QI should consider reporting relevant balance measures, such as any potential impact on skin integrity, nursing time, or infant growth.

There was no consensus definition for the primary outcome measure of CLABSI in the studies, although the majority of studies used the Centre for Disease Control (CDC) definition (see Table 1). The importance of a consistent definition cannot be underestimated, as a change in CDC definition in 2008, which required two or more positive cultures for a skin contaminant, drawn on separate occasions, was associated with a 40% reduction in adjusted CLABSI rates (Schulman et al., 2011). The practice of

obtaining two cultures following the growth of a skin commensal is likely to vary among neonatal units, due to both local practices and challenges associated with blood sampling, particularly in the extremely low birth weight population. In the case of a single culture of a skin commensal subjective judgement may be required in determining if it is a contaminant or a genuine infection, though arguably the aim should be to reduce the incidence of both genuine CLABSIs and contaminant cultures. Only one definition in Table 1 utilises laboratory markers, though in practice the use of markers such as white cells and C-reactive protein are likely to be used to distinguish genuine infection from contaminants.

Despite the use of an objective definition, inter-observer variability in the application of standardised definitions has been reported in the adult literature (Dixon-Woods et al., 2012, Leekha et al., 2013). Uncertainty attributing central lines as the cause of infection, variations in counting line days and logistical challenges in data collection means that this measure of reporting may be subject to measurement bias and local interpretation (Dixon-Woods et al., 2012). Whilst this study attempted to use a standardised primary outcome measure of bloodstream infections per 1000 line or patient days, selected in order to reflect changes in central line exposure and unit activity, this is not without limitations. However, this is the most frequently reported outcome measure and only two studies were excluded for reporting percentages (Davis et al., 2016, Kaplan et al., 2011).

There was variability within the bundled elements, though the commonest elements included education and training, using checklists, having a specific skin preparation protocol and using maximal standard barrier precautions (Table 4). Other practices potentially affecting the reduction of CLABSIs were not frequently reported, and it should be noted that 5 studies specified removing central lines at 120mls/kg/day enteral feed volumes. The study by Ista et al. (2016) found minimising central line access significantly contributed to reducing CLABSIs in the NICU. The authors did not contact the researchers for clarification on bundled elements, and are unable to ascertain if any bundled elements were used but not reported. It is often unclear why specific elements were chosen, and

absence of reported elements does not necessarily equate to absence in the neonatal unit. Unlike the study by Ista et al. (2016) this study has not attempted to associate specific bundled elements with reductions in CLABSIs, but instead identified the most frequently reported elements.

It is unclear is how consistently the bundled elements were implemented. None of these studies formally evaluated the implementation process to identify the most effective implementation strategy, though some did consider compliance with particular practices. The implementation of care bundles is often not successful or consistent (Sax et al., 2013, Moore et al., 2015). One of the challenges is that it is often uncertain whether the intervention, or the implementation, or both, has contributed to the success or failure of an intervention. It is unlikely that the success of a care bundle in one setting can be simply extrapolated to another (Nilsen, 2015, Dixon-Woods et al., 2013). Several studies retrospectively theorised the possible mechanisms through which care bundles may contribute to healthcare professional behaviour change, including repetitive social interaction, establishing communities of practice and the use of cognitive tools such as checklists and audit (Schulman et al., 2011, Ting et al., 2013, Wirtschafter et al., 2010). One study recognised that the implementation of measures not yet introduced, such as checklists, audit and feedback, commonly used in other care bundle studies, may help reduce CLABSI rates further in their unit (Almeida et al., 2016).

There are several additional limitations to this study. There were no RCTs, and only 2 studies used interrupted time series analysis to account for temporal trends though a further 5 studies used statistical process control methods. There has been a trend towards reducing CLABSI rates, with a 50% decrease in CLABSI between 2008 and 2014 (CDC, 2016) and one of the challenges of QI studies is outperforming temporal trends. Whilst this trend may be as a result of the plethora of QI projects that have been performed during this time, local practice variations and the change in CDC definition may have affected the results. Whilst non-randomised studies are traditionally not meta-analysed, they can provide pragmatic ‘real world’ solutions and can generate important knowledge

regarding systems of care, how best to change them, and identify potentially better practices. As future RCTs investigating the impact of a care bundle are unlikely, this study therefore provides a useful insight into current practices in neonatal units though further work should investigate how these bundles are implemented.

CONCLUSION

There is now a substantial body of evidence to suggest that care bundles reduce CLABSI rates in the NNU. However, it is not clear what bundle elements are most effective in specific settings, and individual centres should undertake local work to identify areas for improvement. This study highlights the potential effectiveness of a care bundle approach and common bundle elements that neonatal units might use to develop bundles specific to their local settings. Future research should focus on determining what processes promote the effective implementation of infection prevention recommendations, and which bundle elements represent essential components.

CONTRIBUTORSHIP STATEMENT

MH and VP contributed to the conception of the research. MJ and VP performed the search and selection process separately, and disagreements were resolved by discussion. VP performed data collection and analysis, and MJ assisted with data analysis. VP drafted the original manuscript. All authors were involved in critical revision of the article and approved the final version for publication.

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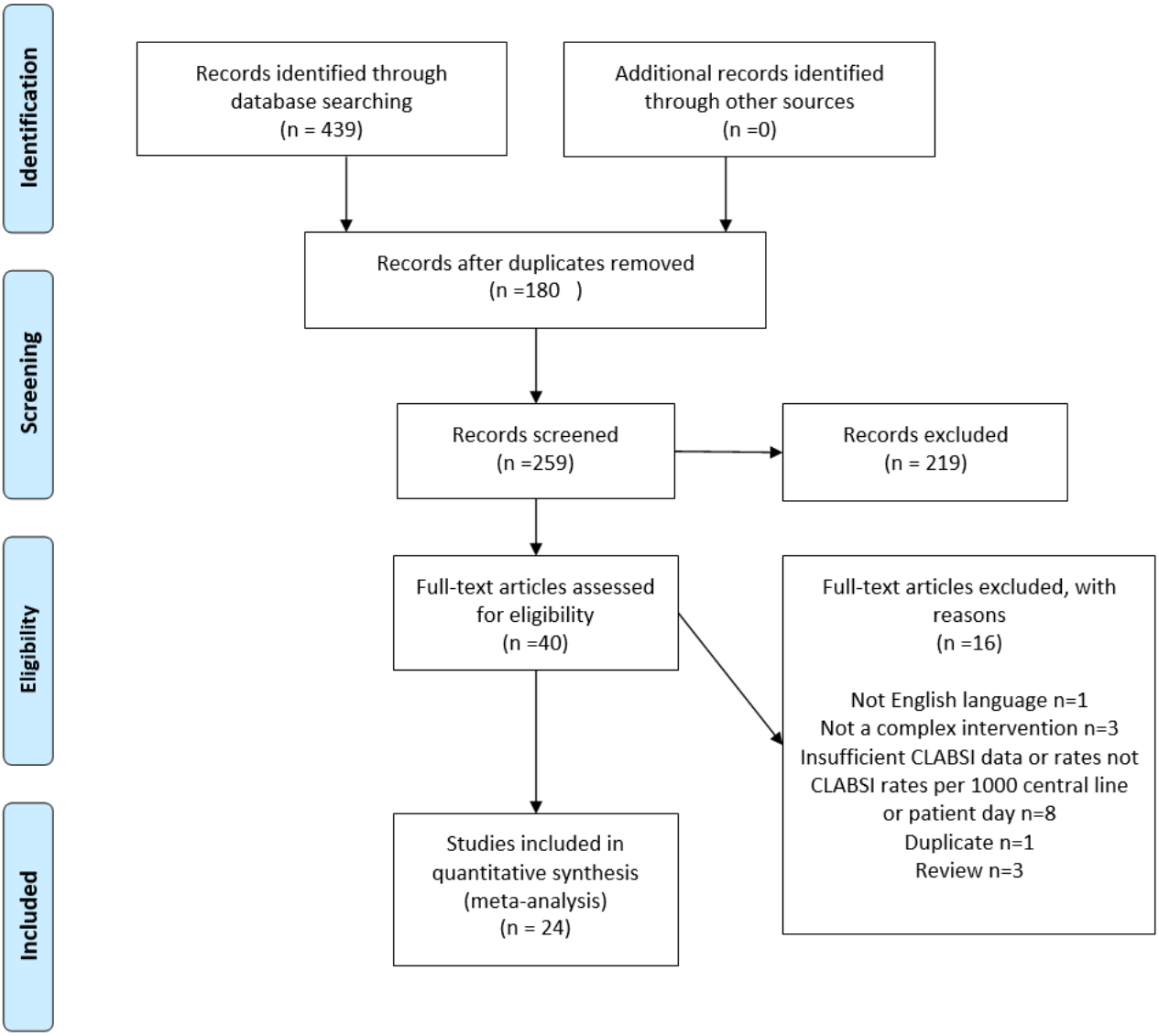
Appendix 9 PRISMA Flow Chart

Key words used and combined with Boolean operators (OR and AND) *neonatal intensive care, NICU, CLABSI, central line-associated bloodstream infection, late-onset sepsis, bloodstream infection, care bundle*, guideline*, complex intervention.*

Limiters applied: Publication date January 2010-January 2017, English Language



Appendix 10 Supplementary material: SQUIRE Appraisal

Author	Almeida	Bizzarro	Bowen	Ceballos	Chandonnet	Erdei	Fisher	Kime	Piazza	Rallis	Resende	Rosenthal	Shepherd	Sinha	Steiner	Ting	Wilder	Wirtschafter	Zhou
a. Indicates the article concerns the improvement of quality	N	Y	Y	Y	N	N	N	N	Y	N	N	Y	N	N	N	Y	Y	Y	N
b.States the specific aim of the intervention	Y	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y
c.Specifies the study method used	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N
2.Abstract																			
a.Summarises precisely all key information from various sections of the text using the abstract format of the intended publication	Y	Y	Y	P	Y	Y	Y	Y	Y	P	Y	Y	Y	Y	Y	Y	Y	Y	Y
3.Background knowledge																			
Provides a brief, non-selective summary of the current knowledge of the care problem being addressed and characteristics of the organisations in which it occurs	Y	Y	Y	Y	Y	Y	Y	Y	Y	P	Y	P	Y	P	P	Y	Y	Y	Y

4.Local problem																			
Describes the nature and severity of the specific local problem or system dysfunction that was addressed	N	Y	P	P	Y	Y	N	P	N	N	N	P	P	N	Y	P	Y	Y	N
5.Intended improvement																			
a)Describes the specific aim	P	Y	Y	Y	Y	Y	Y	Y	Y	P	Y	P	Y	Y	Y	Y	Y	Y	Y
b.Specifies who and what triggered the decision to make changes and why now	N	Y	N	Y	P	Y	Y	Y	P	N	N	P	P	N	P	Y	Y	P	P
6.Study Question																			
States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer	P	Y	Y	N	N	N	N	Y	P	P	P	N	N	Y	Y	Y	N	Y	Y
Methods *What did you do?*																			
7.Ethical issues																			
Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants physical well-being, and potential author conflicts of interest, and how ethical concerns were addressed	P	P	P	Y	Y	P	N	N	P	P	P	N	P	P	N	N	N	N	P

8.Setting																			
Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized	N	Y	N	N	P	P	N	Y	N	N	N	P	P	P	N	N	P	Y	N
9. Planning the intervention																			
a.Describes the intervention and its component parts in sufficient detail that others could reproduce it	P	Y	Y	Y	Y	Y	Y	Y	P	P	Y	Y	Y	Y	P	Y	Y	P	Y
b.Indicates main factors that contributed to choice of the specific intervention	N	Y	N	N	Y	P	N	Y	Y	N	Y	P	P	P	P	Y	Y	Y	P
c.Outlines initial plans for how the intervention was to be implemented (what was to be done and by whom)	N	Y	P	Y	P	P	Y	Y	P	N	N	P	Y	N	P	P	Y	P	P
10. Planning the study of the intervention																			
a.Outlines plans for assessing how well the intervention was implemented	N	N	N	N	Y	P	Y	P	P	N	N	P	Y	P	N	P	P	P	N
b. Describes mechanisms by which the intervention components were expected to cause changes, and plans for testing whether those mechanisms were effective	N	N	N	N	P	N	N	P	P	N	N	N	N	P	N	P	N	P	N

c. Identifies the study design chosen for measuring impact of the intervention on primary and secondary outcomes, if applicable	Y	Y	N	N	N	N	N	P	P	N	N	N	P	P	N	Y	N	Y	Y
d. Explains plans for implementing essential aspects of the chosen study design, as described in publication guidelines for specific designs, if applicable	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
e. Describes aspects of the study design that specifically concerned internal validity (integrity of the data) and external validity (generalizability)	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	P	N
11. Methods of evaluation																			
a. Describes the instruments and procedures (qualitative, quantitative or mixed) used to assess a)the effectiveness of the intervention b)the contributions of intervention components and the context factors to effectiveness of the intervention and c)primary and secondary outcomes	P	N	P	P	P	P	P	P	Y	N	P	P	P	P	P	P	N	P	P
b.Reports efforts to validate and test the reliability of assessment instruments	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	P

c.Explains methods used to assure data quality and adequacy (for example, blinding, repeating measurements and data extraction, training in data collection, collection of sufficient baseline measurements	N	N	P	N	P	N	Y	N	P	N	N	P	P	N	N	N	N	P	Y
12. Analysis																			
a. Provides details of qualitative and quantitative (statistical) methods used to draw inferences from the data	Y	Y	Y	N	N	Y	Y	P	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y
b. Aligns unit of analysis with level at which the intervention was implemented, if applicable	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
c. Specifies degree of variability expected in implementation, change expected in primary outcome (effect size), and ability of study design (including size) to detect such effects	N	N	N	N	N	N	N	N	P	N	N	N	N	N	N	P	N	P	N
d. Describes analytic methods used to demonstrate effects of time as a variable (for example, statistical process control)	N	N	Y SPC	N	N	Y SPC	Y SPC	N	Y SPC	N	N	N	Y SPC	Y ITS	N	N	Y	Y	N
Results *What did you find?*																			
13. Outcomes																			
a)Nature of the setting and improvement intervention																			

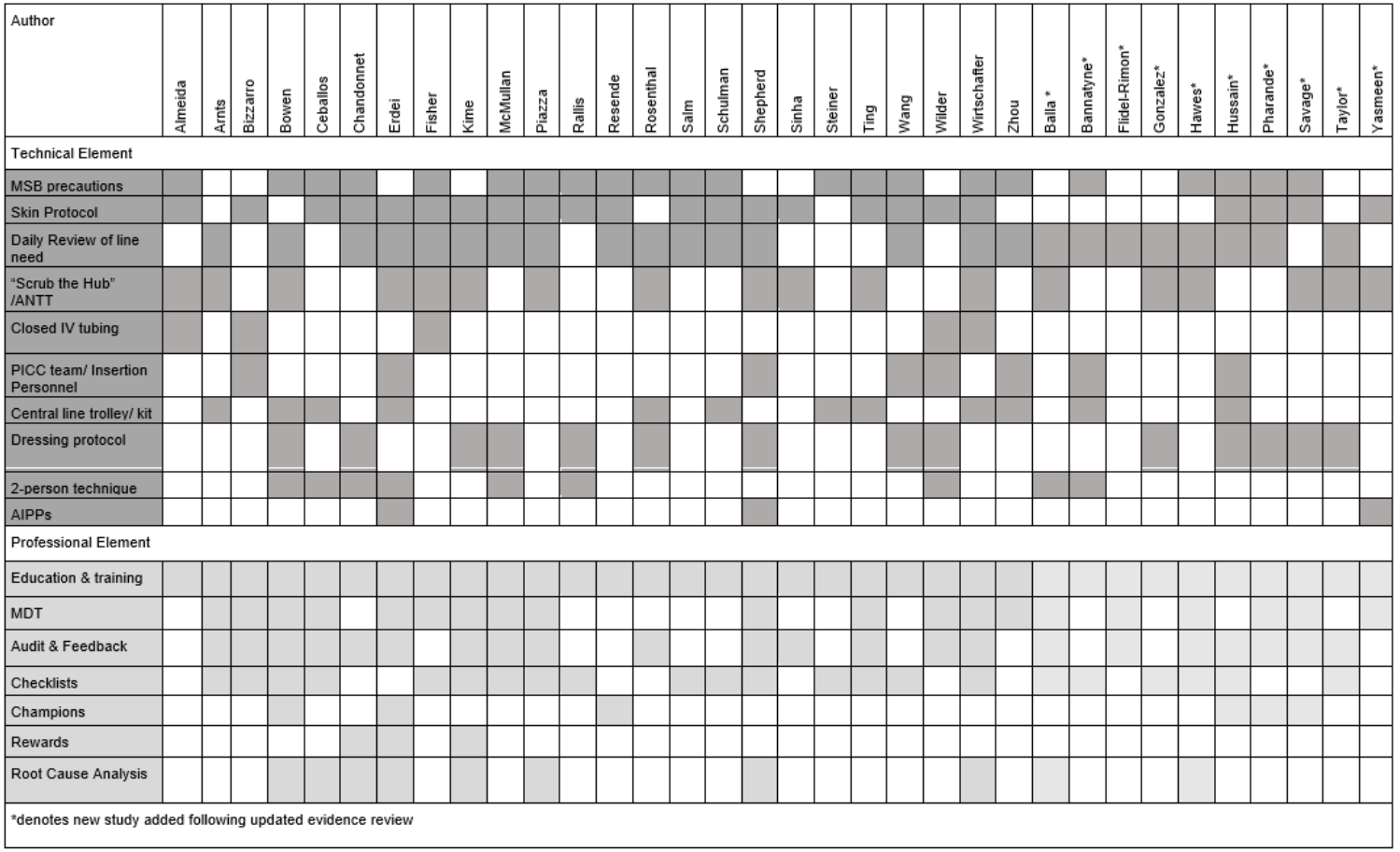
i. Characterizes relevant elements of setting or settings, and structures and patterns of care that provided context for the intervention	P	P	N	P	Y	P	P	N	P	N	N	N	P	P	N	P	P	N	P
ii. Explains the actual course of the intervention, preferably using a time-line diagram or flow chart	P	P	Y	N	P	Y	Y	P	N	N	N	P	Y	Y	N	P	Y	N	N
iii. Documents degree of success in implementing intervention components	N	N	N	P	P	P	P	P	P	N	N	P	P	N	N	N	N	N	N
iv. Describes how and why the initial plan evolved, and the most important lessons learned from that evolution, particularly the effects of internal feedback from tests of change (reflexiveness)	N	N	P	P	P	Y	P	N	P	N	N	N	P	N	N	N	Y	P	N
b)Changes in processes of care and patient outcomes associated with the intervention																			
i. Presents data on changes observed in the care delivery process	P	N	N	P	P	Y	Y	P	N	N	N	P	Y	N	N	P	Y	N	N
ii. Presents data on changes observed in measures of patient outcome	Y	Y	Y	Y	P	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
iii. Considers benefits, harms, unexpected results, problems, failures	N	P	N	P	N	Y	P	P	Y	N	N	N	N	N	N	N	P	N	N
iv. Presents evidence regarding the strength of association between observed changes/ improvements and intervention components/context factors	P	N	N	N	N	P	P	N	Y	Y	P	P	N	Y	P	P	N	P	P

v. Includes summary of missing data for intervention and outcomes	N	N	N	N	N	N	N	N	P	N	N	N	N	N	N	N	N	N	N
Discussion *What do the findings mean?*																			
14.Summary																			
a. Summarizes the most important successes and difficulties in implementing intervention components, and main changes observed in care delivery and clinical outcomes	N	P	Y	Y	P	Y	Y	P	Y	N	Y	P	Y	P	N	N	P	N	N
b. Highlights the study's particular strengths	P	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
15.Relation to other evidence																			
Compares and contrasts study results with relevant findings of others, drawing on broad review of the literature; use of a summary table may be helpful in building on existing evidence	Y	N	P	P	N	P	P	N	Y	P	P	P	N	P	P	Y	N	P	P
16. Limitations																			
a. Considers possible sources of confounding, bias, or imprecision in design, measurement, and analysis that might have affected study outcomes (internal validity)	Y	Y	Y	P	P	Y	P	N	Y	N	P	P	P	Y	P	N	N	Y	Y

b. Explores factors that could affect generalizability (external validity), for example: representativeness of participants; effectiveness of implementation; dose-response effects; features of local care setting	N	N	N	P	N	Y	N	N	Y	N	P	P	Y	N	N	N	Y	P	P
c. Addresses likelihood that observed gains may weaken over time, and describes plans, if any, for monitoring and maintaining improvement; explicitly states if such planning was not done	Y	N	N	Y	N	N	N	Y	N	N	N	N	P	N	N	N	Y	Y	N
d. Reviews efforts made to minimize and adjust for study limitations	N	Y	N	N	N	N	Y	N	P	N	N	N	Y	Y	N	N	N	P	N
e. Assesses the effect of study limitations on interpretation and application of results	N	Y	Y	Y	P	Y	P	N	Y	N	Y	N	Y	Y	P	N	N	Y	Y
17. Interpretation																			
a. Explores possible reasons for differences between observed and expected outcomes	Y	N	N	N	N	N	P	P	Y	N	N	N	N	P	N	N	N	P	N

b. Draws inferences consistent with the strength of the data about causal mechanisms and size of observed changes, paying particular attention to components of the intervention and context factors that helped determine the intervention's effectiveness (or lack thereof), and types of settings in which this intervention is most likely to be effective	N	N	P	N	N	Y	N	N	Y	N	P	N	P	P	P	P	N	P	P
c. Suggests steps that might be modified to improve future performance	Y	N	N	P	N	Y	N	P	N	N	N	N	Y	N	N	N	Y	P	N
d. Reviews issues of opportunity cost and actual financial cost of the intervention	N	N	N	Y	N	Y	P	N	N	N	N	N	N	N	N	N	Y	N	N
Other information ***Were other factors relevant to the conduct and interpretation of the study?***																			
19. Funding																			
Describes funding sources, if any, and role of funding organization in design, implementation, interpretation, and publication of study	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	Y	N	N	N	Y	N	N	P

Appendix 11 Updated Table of Bundled Elements.



Appendix 12 Estimated Local Costs of CLABSIs

Costing based on the National Institute for Clinical Excellence Antibiotics for Early Onset Neonatal Infection Costing Template (NICE, 2012)

Resource*	**Cost**	**Daily cost**	**Total cost per episode***	
CRP + Blood test	11.69	Variable, estimated 3 per episode	35.07	
Cannula insertion	23.97	Variable, estimate 2 per episode	47.94	
Vancomycin	29.25 (per vial)	BD 58.5 TDS 87.75	292.5 438.75	
Gentamicin	21.09 (dose)	24 hourly x 5 36 hourly x1	105.45 21.09	
Total resource cost			396.6– 627.21	
*This includes the time taken for staff to perform procedure/administer antibiotics **Based on a 5 day course of antibiotics. Potential higher costs incurred if 7-14 day course of antibiotics given and LP performed.				
	ICU cot £1,117/day	HDU cot £795/day	SCBU cot £480/day	Total per episode
Increased length of stay***	4,468	3, 180	1, 920	9, 568
*** Based on the INICC average of 12 days, split equally between all 3 care levels. This may be a conservative estimate, as the proportion of ICU cot days may be higher.				
Total estimated cost of a BSI per episode £9, 964.6 to £10, 195.22 Based on 30 'true' BSI per year annual cost of £298, 938 to £305, 856.6 Based on estimated 20 CLABSI per year annual cost of £199, 292 to £203, 904.4				

Appendix 13 NoMAD Survey

"A study investigating the implementation of a care bundle to reduce late-onset sepsis in the Neonatal Intensive Care Unit"

This survey aims to evaluate the implementation of the Late-Onset Sepsis Care Bundle, in order to identify what works, and what doesn't work, so that improvements can be made in the future. By completing this survey, your responses will enable us to make improvements and changes to the Care Bundle.

The survey consists of 16 tick-box questions, relating to the use of the Care Bundle. You will not be asked to provide any personal data, and all responses are anonymous. The confidentiality and privacy of all participants will be protected by the University of Southampton iSurvey, and no data will be accessible to third parties. For more details please see iSurvey (https://www.isurvey.soton.ac.uk/).

If you have any additional questions, please contact the researcher, Victoria Payne at vp1m14@soton.ac.uk

Do you agree to the above terms? ☐

By clicking Yes, you consent that you are willing to answer the questions in this survey. You may withdraw from the survey at any point.

We would be grateful if you could take a few minutes to answer the questions below.

Part A.

Please tick one of the boxes below that describes your role.	
Band 3 Nurse	
Band 4 Nurse	
Band 5 Nurse	
Band 6 Nurse	
Band 7 Nurse	
Band 8 Nurse	
MTI	
Consultant	
Other (please specify)	

1. How long have you worked on the neonatal unit (please tick the one which best applies)

< 1 year ☐

1-2 years ☐

<5 years ☐

< 10 years ☐

>10 years

Appendix 13

Part B

When you use the Care Bundle, how familiar does it feel?

0 1 2 3 4 5 6 7 8 9 10

Still feels very new Somewhat Feels completely familiar

Do you feel the Care Bundle is currently a normal part of your work?

0 1 2 3 4 5 6 7 8 9 10

Not at all Somewhat Completely

Do you feel the Care Bundle will become a normal part of your work?

0 1 2 3 4 5 6 7 8 9 10

Not at all Somewhat Completely

Part C: Please answer the following 16 questions below, providing an answer for Option A. If Option A is not relevant to you, please select an answer from Option B.

	Option A					Option B		
	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not relevant to my role	Not relevant at this stage	Not relevant to the bundle
1. I understand how the care bundle is different from my previous practices								
2. Staff on the neonatal unit have a shared understanding of the purpose of the care bundle								
3. I understand how the care bundle affects my own work								
4. I can see the potential benefits of the care bundle								
5. There are key people who promote the care bundle and get others involved								
6. I believe that using the care bundle is part of my role								
7. I am open to working with colleagues in new ways to use the care bundle								
8. I will continue to support the care bundle								
9. I can easily integrate the care bundle into my current practice								
10. The care bundle disrupts working relationships								
11. I have confidence in other people's ability to use the care bundle								
12. The work required by the care bundle is performed by people with the appropriate skills to do so								
13. Sufficient training has been provided to ensure staff can implement the care bundle								
14. Sufficient resources are available to support the care bundle								
15. The Trust supports the care bundle								
16. I am aware of the effects of the care bundle on the unit's bloodstream infection rates								
17. Staff agree that the care bundle is worthwhile								

	Option A					Option B		
	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not relevant to my role	Not relevant at this stage	Not relevant to the bundle
18. I value the effects the care bundle has had on my work								
19. Feedback about the care bundle can be used to improve it in the future								
20. I can change how I work with the care bundle								

Appendix 14 Example Unstructured Observation Form

Started 13:05 Ended 13:22
Process: PN on to newly inserted long line.
Patient: 2 day old 29 week infant 850g. No respiratory support. Incubator.
Location: Room 4 Space 7
Participants: Both Band 6 and Band 6 (recruited as a band 5)

How is the work organised? ***Who/Role negotiation/other competing demands?*** "it's your baby, you know where the lines are" (Band 6) to which Band 6 replies "sometime there seems to be a rule and sometimes there doesn't". Started by checking prescriptions, with junior band 6 washing hands, paper towel and gel, then sterile gloves, whilst senior band 6 gets an apron and puts it on her. The nurse that is considered "clean" is not the nurse looking after the patient. Competing demands- clean nurse aware of her patient alarms which she cannot see. Roles appear organised and clear to each person involved.	**Communication** ***Areas of agreement/uncertainty? Implicit/explicit?*** During the task communicating about things other than the task, personal family and social engagements. No explicit communication during the task about the task, other than "that's dirty I can't touch that"- in reference to the PN bag which is stock (lipid syringes considered to be sterile and handled by clean nurse) Communication as double-checking "does it have a bionnector?" "are they on anything else? Does it need an Octopus" Agreement/double checking of infusion rates "are you happy that is 0.4? I am going to write down what I am doing which other people don't want to do"
How is the work performed/enacted? ***Interruptions/technical challenges/adaptation?*** Scrubbing hub/connection of PN bag and letting it dry- watching clock Senior band 6 having to move computers and equipment out of the way to get to patient, and 'clean' nurse carrying sterile end with assistant carrying syringes and lines- lifting it all over head of computers and incubators (like multiple telegraph wires!) Senior nurse who is looking after the patient identifies the line, disconnects the fluid running and puts a curos cap on the bionnector. Clean nurse holds end with gauze, and keeps sterile end free/not touching anything. Senior band 6 takes off the curos cap and the clean nurses attached fluids to the long line bionnector. At which point a question is raised about needing an Octopus: "are they on anything else? Like vancomycin? Do they need an Octopus? Interruption of checking prescription to ask about milk feed plan for another patient.	**The context/environment** ***Resource allocation/organisation/adaptation?*** Unit over-capacity. Babies in bed spaces that do not exist (triplets born). Short staffed and nurses had to be called in as extra. Long line being pulled back by doctor in next cot space, multiple trolleys in the area. Lots of alarms beeping whilst syringes being changed.

Appendix 15 Retrospective Interview Prompts

Study Title: "A study investigating the implementation of a care bundle to reduce late-onset sepsis in the Neonatal Intensive Care Unit"

Retrospective Interviewing Guide

- Introduce myself and thank participants for their time.
- Explain the retrospective interview, and that the focus is not on what was right or wrong about the practice observed, but on the decision-making processes. Encourage participants to include all thoughts that had an impact on their decisions and actions.
- Explain the interview will be digitally recorded, and written notes may be taken, and that the process can be stopped at any time without needing an explanation.
- Confirm anonymity in transcripts and written reports.
- Confirm consent.

Retrospective Interview Prompts

Ask the participants to describe what they did, from the beginning of [the process] to the end. Encourage participants to discuss all the things that impacted on their decisions. Probing questions can be used following the participants description, to elicit information on:

- How the work was allocated (who performed the task, and why?)
- How were decisions about the task made? What influenced the decision?
- How the task is different to what they have done before
- What they may consider doing differently next time?

Offer participants the opportunity to add something further that has not been discussed.
Offer the participants the opportunity to ask any questions.
Thank the participants for their time.

Appendix 16 Semi-Structured Interview Guide

Introduction

- Explain purpose the interview
  The purpose of this study is to explore the implementation of the late onset sepsis care bundle. The aim of this interview is to identify what elements of the care bundle worked, and what didn't work, and identify how we might improve the care bundle in the future.
- Briefly introduce myself and interest in the topic
- Confirm participant will be anonymous in written reports
- How long the interview is likely to be
- Explain the interview will be digitally recorded and written notes may be taken. The interview will be recorded and transcribed, and the data will be anonymised. Once the study is completed, the recordings will be destroyed.
- Explain the interview can be stopped at any time without providing a reason.
- Ensure interviewee understands and confirm consent.
- So, before we start, can I just check that you have given your consent to participate, and that you understand that you can stop or withdraw from the interview at any point? Is there anything I can clarify for you before we begin?

Warm up

Thank participant. Explain that there are no right or wrong answers, this is about understanding staff's experience of the bundle.

- Can you begin by telling me about your role on the neonatal unit?

Appendix 16

Topic Guide

1.Exploring participants experiences

- Can you tell me about your experience of using the care bundle?

2.Exploring key results

- The survey results found that… [present participant with graph/chart] that shows [add results here]. What do you think about these results?
- Preliminary data suggests that local BSI rates are [add results here]. What do you think the reasons for this might be?
- Observations of clinical practice have suggested that [add themes here]. Does this reflect your own experiences of practice?

3.Exploring aspects of implementation

Thinking in particular about the main elements of the care bundle, can you tell me what it is like to put these into practice?

- Can you describe how your practice has changed following the introduction of the care bundle?
- How important do you think it was to introduce the care bundle?
- How has the care bundle changed how people/teams work together on the neonatal unit? Can you tell me what that is like/How do you feel about these changes?

4.Exploring barriers and facilitators to implementing the care bundle

- How easy was it for you to use the care bundle? What might make it easier to use?
- Were there things that made it difficult to use the bundle?
- Do you feel there are sufficient resources available in order to use the bundle? What other things do you think are needed to be able to use the bundle?

5.Improving the bundle

- How do you think the care bundle could be improved?
- What advice would you give to other neonatal units or neonatal teams wanting to introduce a similar care bundle to reduce infections in their unit?
- So, to finish with, is there something else you would like to discuss regarding the care bundle?

Ending the interview

- Offer the interviewee the chance to add anything further.
- So, before we end the interview, do you have any other comments?
- Offer to provide details of the study results. As discussed before the start of the interview, this recording will be now be transcribed and anonymised. The results will be sent to you to double-check my understanding and interpretation of the interview.

Thank the interviewee for their time.

I would like to take this opportunity to thank you again for agreeing to participate, and it is hoped that the results from this will contribute to improving practice on the neonatal unit.

Appendix 17 Participant Information Leaflet

University of Southampton

University Hospital Southampton NHS
NHS Foundation Trust

Participant Information Sheet

"The implementation of a complex intervention to reduce late-onset sepsis in the neonatal intensive care unit"

What is the purpose of the study?

The purpose of this study is to investigate what factors help or hinder the implementation of the late-onset sepsis care bundle. This is important as we know that episodes of late-onset sepsis contribute to increased neonatal mortality, morbidity, and prolonged hospitalisation. The use of antibiotics to treat episodes of late-onset sepsis may also contribute to increasing antibiotic resistance. However, we also know that implementing infection prevention recommendations can be challenging.

Research studies, mostly in the United States, have demonstated that care bundles can reduce central line-associated bloodstream infections in neonates, but there are differences in the size of these reductions in individual NICUs. It is not known what helps, or discourages, healthcare professionals using these care bundles. We know that there are many challenges to implementing new practices, so this study aims to evaluate what aspects of using the care bundle worked, and what didn't, so we can make changes to how we do this in the future.

It is hoped that this study will help us understand more about the implementation process in the NICU, so that we can improve the care bundle, as well as improving how we implement new evidence both locally, and potentially for other NICUs in the future.

Why have I been invited to participate?

You have been invited to participate because the care you provide involves central venous lines (including umbilical lines, and 'long lines'). This may be

inserting or re-dressing central lines, or accessing them for TPN, infusion, or medication administration.

Do I have to take part?

No, it is your choice to decide whether or not to take part in the study. If you do choose to take part, you can withdraw at any time. You do not need to provide a reason why you do not wish to take part. You can take part in one, two or all three parts of the study.

What will happen if I take part?

If you agree to take part, there are three different parts of the study. The first involves completion of an anonymous online survey. A link to the survey, will be emailed to all staff who are involved with the insertion of, or accesssing of, central lines. This does not require written consent, and by completing the survey, you have agreed to participate. However, you can withdraw your survey responses at any point, without giving a reason.

The second part of the study takes place on the neonatal unit, and is related to the use of the care bundle. During set times, I will ask you to inform me if there is a central line insertion, or central line maintenance procedure (such as Total Parental Nutrition and/or infusion changes) about to happen. If it is convenient for you and a colleague, I would then observe yourself and your colleague performing the procedures. I will take notes, and then when the procedure is completed, you, your colleague, and I, will go to a quiet room to discuss the processes involved that helps, or makes it difficult, to use the the care bundle. This will be digitally audio recorded. It is anticipated that this will last approximately 20 minutes. Both you and your colleague must consent in order to participate. You can participate in up to two observations with retrospective interviews, if they are with different colleagues.

This study is **not** looking at whether practice is 'right' or 'wrong', and it is not and audit of practice. This study is interested in looking at what helps or

hinders the care bundle being used by clinicians. The information will help us make improvements to the care bundle in the future.

The third part of the study is a semi-structured interview. This will take place 12 months after the start of the study, at at time that is convenient for you, and will discuss aspects relating to the implementation of the care bundle. It is not looking for right or wrong answers, but is aimed at understanding your experiences of the care bundle, and how we might improve this in the future. It is antipated that this will last no longer than 1 hour. This will also be digitally audio recorded and notes will be taken.

What are the possible disadvantages and risk of taking part?

It is not antipated there will be any risks in taking part in this study.

All efforts will be made to minimise disruption or interuption to your work, and even if you agree to participate and identify a suitable time for the observations, you are not obliged to continue if it is inconvienient or if you change your mind. In the event that there is a clinical emergency during the observations, then the process will be abandoned.

You do not have to give a reason if you choose to withdraw from the study. Your involvement in any parts of the study, or your decision not to be involved, will not make a difference to how you are viewed or treated by the the researcher/the Trust/Neonatal Unit management.

In the event that unsafe practice is observed this will be escalated to the relevant clinical managers including the nurse in charge and the on-duty Consultant Neonatologist.

Will the information I provide be confidential?

Yes. All the data from the observations and interviews will by anonymised, using codes of numbers and letters, so that only the researcher will be able to link you to your data.

The answers to the online survey will be anonymous, and so individual confidentiality will be maintained, and the researcher will not know how you have responded. iSurvey assigns each particpant a unique code, so the researcher will not be able to identify how you have answered the questions. Data is kept on a secure server, and no information is given to Third Parties. Please see iSurvey (https://www.isurvey.soton.ac.uk/) for more information on their privacy policy.

Audio recordings for the observations and interviews will be transcribed by a local transcription service, who have provided a non-disclosure agreement. All information captured will be anonymised and any identifiable data removed before being used to produce any research findings, reports, publications. Direct quotations may be used to support the findings, such as "Nurse 3 said that….".

Research data will be retained by the University of Southampton for a minimum of 10 years, in line with the University's Research Data Management Policy, after which the data will be securely disposed of. The researcher may be required to disclose confidential information to the appropriate authorities if the information is reportable by law, for example, if it is a criminal offence, or life-threatening circumstances.

What happens if I change my mind?

If you decide you no longer wish to participate, you may withdraw at any time, without giving a reason. This will not affect your legal rights, and will not influence how you are viewed or treated by the researcher, the Trust or management.

How will I know the results of the study?

The results of this study will form part of the researcher's PhD Thesis. The results will be published in relevant scientific journals, and presented at relevant academic conferences. The results will also be presented locally at

meetings, and circulated on noticeboards. Your involvement will remain confidential.

Who is undertaking and funding the research?

The research is being undertaken by Victoria Payne (Advanced Neonatal Nurse Practitioner) as part of her clinical PhD project. If you have any questions, or require more information about the study, please contact Victoria Payne using the following details:

Victoria Payne
Faculty of Health Sciences
F-120 Princess Anne Hospital
Tele: 02381 208 677 Email: vp1m14@soton.ac.uk

Who has reviewed the study?

The study has been peer-reviewed at the University of Southampton and reviewed by the University of Southampton's Ethics and Research Governance office. It has been approved by the NHS Health Research Authority, and sponsorship is being provided by the University Hospital Southampton NHS Trust.

What if there is a problem?

If you have a concern or a complaint about this study you should contact the Research and Development Office at University Hospital Southampton NHS Trust:

R&D office
E level, Southampton Centre for Biomedical Research
Laboratory and pathology block, mailpoint 138
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

Telephone: 023 8120 8215 Email: R&Doffice@uhs.nhs.uk

Appendix 18 Study Poster

University of Southampton | University Hospital Southampton NHS
NHS Foundation Trust

A study investigating the implementation of a care bundle to reduce CLABSIs in the Neonatal Intensive Care Unit

Why is this study needed?

The purpose of this study is to investigate how a care bundle to reduce central line-associated infections is implemented on the neonatal unit. This is important as we know that episodes of late-onset sepsis contribute to increased neonatal mortality, morbidity, and prolonged hospitalisation. There is evidence that care bundles can reduce CLABSIs, but there is variation in how well these bundles reduce infection rates across different NICUs.

We also know that implementing evidence can be difficult, so this study aims to evaluate what aspects of the implementation process worked, and what didn't, so we can make the care bundle better.

It is hoped that this mixed-methods study will help us understand more about the implementation process, and will benefit other projects, and other NICUs, in the future.

What does this study involve?

A survey-link will be emailed to all clinical staff who care for babies with central lines. You can choose whether or not to participate. This survey will be repeated 3 times in 12 months.

In addition, there is the opportunity to participate in observations of practice with retrospective interviews, to understand how the bundle fits into your everyday work. Semi-structured interviews will be used to get a better understanding of your experiences, and any additional barriers or facilitators not identified through the survey or observations.

How can I get involved?

If you would like the opportunity to be involved, please take an information leaflet. You can contact the research directly on the details provided.
If you want more information, or have any questions, you can also contact the researcher on the email address below, or in person when she is working on the neonatal unit.

Who should I contact about the study?

Victoria Payne
Advanced Neonatal Nurse Practitioner & Visiting Fellow
Tele: 02381 208 677
Email: vp1m14@soton.ac.uk

Study Poster_v1 5/2017
IRAS ID 208128
Poster take down date:12 /2018

Appendix 19 Summary of Observational Data and Field Notes

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
1 (Pilot) NURS0707 NURS0521	PN and needleless connector change using AIPPs.	Communicated and worked together well. Coped well with distractions and interruptions such as the “screaming baby on the end of the long line”. Some uncertainties regarding how to handle the needleless connector, disconnect and reconnect versus wipe and dry. Less experienced nurse feels able to teach it now she has seen it.	Handwashing process followed as taught. Some areas of explicit communication between pairs, when something unfamiliar or new. Band 5 asking “this is still what we do, isn’t it?” Some areas where process performed silently- running PN through giving set, attaching connections.	**Allocation of roles** **Clearly defined roles** **Checking with each other/ problem solving together.** Talking through the process “right, that’s clamped, that’s safe”.	**Environment:** Had to ask another nurse to move equipment out of the way- navigating environment. **Organising** work between different teams “we can’t do anything now” until prescription ready. Took 10 minutes. **Resources:** No hand gel readily available at cot side.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
			Uncertainty around best practice around disconnecting needleless connector from long line hub. Uncertainty around PN: "Different people do different things". Watching clock for timings of AIPP and when wiping end of PN bag.		Small trolley for the task! Having to leave room to get equipment. Competing demands such as other patient needs- nurse saying to a parent "I won't be long", patient vomited and had to ask another nurse to attend to patient.
2 NURS0603 NURS0604	New long line PN + infusions including morphine and insulin ELBW Incubator	Process ran smoothly. Organised and informed colleagues of the task Wouldn't do anything differently…Only difficulty was getting to the baby (equipment and incubator humidity) Questioned the use of a paper towel rather than sterile towel, hand	All equipment prepared and trolley cleaned. Parts of practice where still need to use Scrub the Hub process such as when reusing medication vials & for handling stock PN. Double checking with each other Uncertainty of how long insulin reused (1-2weeks or 1 month)	Hand hygiene as taught. Putting on apron etc. appears like a **ritual.** **Roles/responsibilities** Clear responsibilities allocated to clean and dirty roles. Asking who wants to do which. AIPP put on and removed by assistant.	**Environment:** Traffic in the nursery Walking from preparation area to cot side holding fluids/syringes **Resources:** Small trolley for complexity of task

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		hygiene process different to what the medics and ANNPs do. Questioning how frequently lines are accessed, rather than changing a single Octopus with all infusions attached (one key part). Uncertainty between participants about how best to manage this situation.	Cleaning & reusing of medication vials for central access. Not sterile 'stock' PN Variation in roles and task (who does the task, and who takes off the Curos Cap). Being clean or dirty.	**Environment:** Incubator doors down to navigate environment easier **Checking together:** Identifying lines together, problem solving together, navigating uncertainty together	Took 55 minutes from start to finish. **Uncertainty** Regarding certain aspects of the process e.g., how to handle PN, reusing medication vials
3 NURS0615 NURS0610	PN to new long line ELBW 17minutes Incubator stable	Forgetting equipment: Forgot giving set. Should have asked about extension set earlier.	All equipment prepared/trolley cleaned Timed cleaning of stock PN bag. AIPP not timed as doing other things- uncertainty about length of time required (intonation as a question).	**Routines:** Hand hygiene performed as taught-application of apron- ritualistic practice. **Roles:** clear roles for Surgical ANTT. Variation in **role allocation** for AIPP.	**Environment:** Lifting new fluids over computers and incubators (like telegraph wires!) **Resources**

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		Acknowledge variations in the roles (sometimes there is a rule, sometimes not) Lipid is made “not sterile but very clean” so key person can touch it. “I think we’ve stayed pretty clean”	Use of language noted here: being “good enough” or “pretty clean”- difficulties in assessing or appraising process.	AIPP on needleless connector by assistant who also disconnects fluid running (new long line) **Checking together:** Double checking drugs/prescriptions Identifying lines together	Competing demands (patient alarms, other procedures in the rooms)
4 NURS0612 NURS0609	Infusion changes. Long line Ex-preterm Ventilated	Discussion around who applies and removes the AIPP- considered “dirty” and not handled by clean person, but sometimes people try to do it with gauze. Calm environment-had time, a “quiet day”. Organise around needs of the room.	Morphine (CD) Focus was “did we pass”? Differences in PN being handled as sterile or clean Differences in who puts on/takes off AIPP-‘clean’ person tried to take AIPP off with gauze, asked assistant to do it. All equipment prepared/trolley cleaned. Waited a minute (specifically watched)	**Routine:** Hand hygiene process as taught. **Checking together:** Double checking drugs/prescriptions Identifying lines together **Workload:** A calm day	**Equipment** Small trolley **Uncertainty** **Poor practice:** Morphine pre-made and kept in fridge for reuse between patients.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
			Moved sterile field on trolley to patient bedside (prepared at bench)		
5 NURS0601 NURS0607	Infusion changes: morphine, vecuronium, dopamine, arterial line fluid Sick but stable Ventilated post op 31 weeks Overhead	Sometimes you end up checking prescriptions after you've made infusions up (if busy). Good to try and access lines only once a day (do it all together). Ideally should be prepared next to cot side but difficult if busy/parents present at cot side. Recognise that colleagues do some things differently but	All equipment prepared/trolley cleaned. Opening equipment individually for clean nurse (handing to her, not opening packed over sterile field) Discards morphine and diluted morphine after use- not stored in fridge. Used trolley to move to patient across room (not carrying it) Timed AIPP Monitoring BP during disconnection of inotropes	**Routine:** Hand hygiene process as taught. **Checking together:** Double checking drugs/prescriptions Identifying lines together **Environment:** space to move fluids on trolley to cot side.	**Environment:** Traffic Environment (Noisy, loud) **Competing demands**, needs of other patients (desaturating, "needs a suction").

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		"I'd say, on the whole, we are all very good at it" Senior team able to challenge even Consultants	Offering morphine for other patients in the room Nurse came to me to raise concerns about a medical colleague's practice but didn't challenge it herself- in interview, feels able to challenge practice. Sometimes behaviours go against 'rules': "which you shouldn't but sometimes you do"		
6 DOC02 DOC06	SVIA Term infant Stable Overhead Central line insertion 1hr 15mins	Could have asked for third person earlier on- for comfort and safety, but felt it was hard when everyone is busy. Removed blood as dressing wouldn't stick and acts as culture medium. Using a screen might have helped to maintain some calm.	No checklist used Walked across room with wet hands to dry and put on sterile gloves. Organisation and positioning of equipment in environment challenging.	**Roles/responsibilities**- **Patient comfort** Third doctor came to assist holding patient and administering sucrose. How is this normally managed, if two people both inserting the line? Who is responsible for this?	**Environment:** Space Very mobile sterile field! Traffic Distracting **Resource** intensive, needed third person to settle patient. **Patient:** active and very mobile!

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		SpR wouldn't change his practice as never been told his lines have had an infection. SpR- would be more vigilant of surroundings, something that less experienced may not be aware of.	Resource intensive procedure- required three people in order to have two people inserting and a third to comfort baby. Loss of sterile field (due to blankets e.t.c) Successful insertion Didn't wash hands after removing old gloves, just put on new gloves. Use of saline after using the chlorhexidine- not required in a term infant, only ELBW due to skin integrity. Consultant came to see if needed help (supervision)	Consultant **oversight**- checking in/ supervision. **Monitoring/checking**.	Not wanting to **increase the workload of others**. Busy day. No checklist used.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
			3rd person tasked halfway through to help hold and provide sucrose for analgesia. 2nd person re-gloved when sterility broke (baby kicked off sterile field). [Nurses discussing reusing prepared morphine, but told to be quiet-**researcher presence**!]		
7 DOC08 DOC10	LL insertion Ventilated fragile but stable 29 weeks Incubator	Uncertainties regarding practice- set up trolley with gloves on (thinks that's the right thing to do, not always done it that way) Very reflective- asking assistant- what would you have done, have you seen that done better? Lots of uncertainties regarding how best to clean the limb, moving in and out of incubator without contaminating hands, distance from hand scrubbing	Good hand hygiene and preparation of sterile field. Was going to be a single person insertion, Consultant sent a second person to assist. Person inserting line asking me "am I supposed to get a second person?". Cleaned off CHG with normasol triangulates with ORI 6. Multiple risks of contamination in environment: trolley set up and	**Roles/responsibilities**: Consultant ensured second person involved in procedure (may be influence of **researcher presence**?). Second person **role** recognised some potential 'breaches' in asepsis.	**Environment:** Traffic and space. Mobile sterile field! Leaving sterile field Incubator doors. Preparation including positioning and blankets e.tc. **Uncertainty**- is a second person required? How to set up trolley, use of non-sterile gloves? **Questioning own competence.**

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		to drying hands quite far (walked across nursery). 2nd person recognised tray slipping- being vigilant. Felt it was a good procedure because it was quick, and that multiple attempts may risk compromising asepsis. Having to assess risk- not sure how much of a risk for infection having blood underneath dressing is?	then left (participant went to bathroom). Little space in environment and moving trolley out of the way. Touched top of hands incubator- did not change gloves, tray off edge of sterile field. Blankets in the way etc. Had to reposition baby during process which was challenging in the incubator. Used nursing staff to reposition baby and asking them for help collecting equipment. Dressing a long line was challenging and dressing bloodstained.		**Roles and responsibilities:** who does what? **Resources**- availability of hand scrub, needing extra people to assist. Time- 55 minutes. Skin cleansing- wiping off chlorhexidine with saline. No checklist used.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
			Appeared to be stressful for participant. Participants very reflective and seeking assurance.		
8 NURS0515 NURS0511	Overhead Stable CPAP Term Infusions: morphine, midazolam and arterial line fluids UVC	Use of 'dirty' person to remove AIPP- different practices seen but most do it that way now. Felt allocation of roles was appropriate and safe. Confusion regarding PN sterile or not and uncertainty regarding AIPP- who does it, roles and responsibilities. Good to have a "clear cut" rule regarding practice. "We did pretty well" Sensible to do the transducer last. Difficult to let people know you're doing fluids, hectic. Can't do anything about movement- no better place for the trolley	Traffic Resources (organisation) All equipment prepared/trolley cleaned. Wheeled trolley to bedside Double check drugs/prescriptions Identifying lines to each other. Opening and passing equipment (rather than emptying onto sterile field) Waited a minute (specifically watched) Verbalising "no one touch this trolley". Note the language used again, "pretty well" and "pretty clean"- **lacking confidence in own practice.**	**Routine:** Hand hygiene process as taught. **Communication with room/organisation within nursery**: Communication to room- "no one touch this trolley". **Checking with each other**. **Resources** Organisation of resources	**Environment**- traffic past the trolley, space. **Roles/responsibilities** uncertain who handles AIPPs. **Uncertainties** Handling of PN remains confusing. Seeing others do things differently leads to **Questioning own competence**

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
9 DOC09 DOC05	Incubator 680g CPAP Stable Central line insertion	Selection of equipment perhaps not appropriate for vessel/patient Recognised difficulty of removing guidewire. Felt that dressing was “probably a bit suboptimal” but “that was the only way it could have been done”. Baby not getting containment holding. Potential for baby to be cold and ventilation coming off. Didn’t panic. Communicated well- but also suggested maybe they could have	Handwashing and organisation of sterile field. Initially started preparing a very small trolley which was actually what the nurses were using for their central line fluids. Researcher intervened to help with guidewire removal, and Consultant redressed the central line. Comfort and safety of patient- CPAP prongs off-nurse came to	**Checking together/ problem solving** Learning ‘in action’ from each other-navigating problems together, no obvious power dynamics, both similar experience levels.	**Environment** Trying to perform a surgical scrub under taps with a filter. Small trolley but did replace this. Maintaining asepsis **Resources** Time-1hr 10 mins Availability of hand scrub- had to go and find it Not wanting to throw away central line **Roles/responsibilities**

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		communicated better about a plan as to who was going to do what- unclear roles. Unease about line going in and out multiple times.	resecure them, no containment holding. Asepsis: Changing of gloves due to contact with incubator though hands not washed. Changed sterile field when contaminated with gauze packet. Increasing tension between participants towards end of procedure and securing the dressing was challenging: “this is why you need to just stick it down and not faff around”. Multiple attempts- instead of preparing a new sterile field, complicated process with drapes to avoid throwing away the central line.		Patient comfort and safety- **whose role?** **Uncertainty** Asking lots of questions- do you need hat/mask, what hand solution to use. Suggests not aware of local practices or general aseptic practices. Unsure how to remove guidewire. **Organising work** between teams and co-ordination- used a trolley being prepared by nurses for another task. Also organising work between each other-who is doing what, challenges sticking down dressing.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
					No checklist
10 DOC12 DOC11 (DOC12 only interviewed)	25+5wk 770g 40 mins. Incubator D2 with labile BP Ventilated Central line insertion (unsuccessful)	Challenges in maintaining sterile field. Blankets and rolls are challenging- prepare patient first! Difficult to maintain asepsis in incubator. Should have used a cold light to help- wasn't successful this time due to "rubbish veins". Procedure easier in bigger babies. Might be useful to have some nurses to keep an eye on you.	Labile BP and hypotensive at start of procedure Second person appeared to be 'policing' the operator- watching him set up his sterile field rather than helping him. Forceps touched incubator- not used, discarded. SpR not sterile, holding baby. First time seen assistant role used in this way Interruptions- assistant able to continue focusing on other	**Roles/responsibilities** Second person as a monitor of procedure (SpR supervising, not sterile assistant involved in process). More able to address other clinical patient needs as not sterile or cognitively engaged. Unable to interview this participant due to clinical demands- would have been useful to explore what she felt her role was here.	**Environment** Traffic Incubator- difficult to maintain asepsis, prepare environment, remove blankets etc. Interruptions and competing demands **Patient factors** Assessment of BP and perfusion pre-procedure may have been useful.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		Suggests using surgistrips might be better for securing line but not sure they can be used because of fragile skin	aspects of patient care (consultant telling information, asking nurses for a gas for another patient) Screen provided and a nurse brought in to hold when assistant needed to take over procedure. Traffic past sterile field Having to try and reposition and remove blankets when SpR took over and had an attempt.	Assistant keeping patient comfortable as non-sterile.	No checklist
11 DOC09 DOC07	Central line insertion Incubator 29wk, 2Fr line, 1.4kg HHHFNC	Very reflective in terms of dividing up the workload and communication required before hand, likened to a pre-**resuscitation 'huddle' (need for clear roles)**. Felt there was a need for clearly **designated roles**.	SHO uncertain of process for handwashing- used normal soap, stopped by SpR who went to get surgical hand scrub. SHO asked me if he could use normal hand towels to dry his hands.	**Environment/equipment** Organised/navigated environment differently. Used two trolleys, one for barrier precautions e.g gloves, gown. Closer to sterile field and not	**Lack of clear roles** Nurse observing process (task involved 3 people) to monitor patient but no one using a checklist. Unclear roles.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
	Stable	Organisation of equipment, grab bags in other places, it takes a lot time to prepare for the procedure.	Maintaining asepsis challenging. Hands touched top of portholes. Splitable needle removed and flushed to have another attempt rather than opening another needle. NOTE: equipment/resources need to be AVAILABLE and serve as <u>REMINDERS</u>	placed on a bin or other worksurface. **Roles** Patient comfort-nurse gave some sucrose. Nurse observing but unclear if this was for learning or if she was monitoring the process. **Communication/checking with each other** talked freely with each other negotiating and problem solving together- way of dealing with uncertainty. No obvious power dynamics here. Talking process through together. "I would usually do this…" communication with nurses about	At times it appeared that having two people was actually hindering the process- four adult hands all trying to access one very tiny foot! Clearly both participants cognitively engaged in task rather than monitoring the process. **Resources** Time 1hr 30minutes Availability of hand scrub and equipment **Environment**

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
				best way to attach infusions/giving sets.	Surgical hand scrub difficult under taps with filters on. Incubators **Organisation** and **timing** of procedure Started at 17:00 but called to handover so restarted at 18:10 **Uncertainty** Uncertainty about if a 2fr line would fit through a cannula (it doesn't!). How to connect equipment and infusions to the line. Uncertainty regarding use of hand towels as part of surgical scrub. No checklist used.

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
12 NURS0801 NURS0803	28+2 1.4kg Day 2 Ventilated Incubator Stable Active patient Central line insertion	Maintaining sterile field was very challenging due to traffic and nurses moving incubator past their sterile field. Used a spotlight and importance of preparing environment. Environment and equipment make the process difficult (incubators, guidewires, and traffic) 2 people can make the process challenging (time for both to be free) Poor perfusion-maybe should not have had second attempt- but both experienced and had expensive equipment out.	15mins gathering equipment. Use of additional resources (saline bolus, Astodia) Roles and workload of colleagues "we don't have a nurse anymore" and "you don't have to bother the nurses because its sterile". Traffic- nurses moving baby in incubator past the procedure!! Bumped light and disrupted procedure. Participants referred to "making sure you fill in the forms" but in reference to documenting the process after the event, no prospective use of checklist.	**Patient Factors** Assessment of **patient** pre-procedure- gave fluid bolus before starting. Links with ORI10-borderline blood pressure and perfusion not ideal. **Environment** -Got extra light source -Prepared environment- use of separate trolley for MSB **Equipment** -Use of Astodia and kept sterile.	**Resources** Time: 1hr 45mins (14:30-15:50 then second attempt 16:00-16:25) Increasing workloads of colleagues Competing demands Need for 2 people can make it challenging, delay procedure. **Links with ORI7-sometimes having 2-people is perhaps a hinderance?** **Environment** -Traffic -Incubator

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
		Busy and competing demands (100 other things to do in my head)	Some personal preferences in how procedure performed. Procedure needs flexibility. “do you not use these…”, “I don’t like that vein” and seldinger technique, use of Astodia. Interview provided clear triangulation with previous interviews about challenges with dressings but also leaving line exposed as dressed it along toes! This was actually observed in the previous observation. Provided triangulation with previous observations- medical staff do not always realise there are different types of lines and how they are used.		**Organising workloads/co-ordinating care** between teams- moving patient in incubator past sterile field. Traffic. Patient comfort-**whose role?** No checklist

Participant	Task	Participant Reflexivity	Researcher Observations	Positive Influences	Negative Influences
			Triangulation with other observations- importance of trying to stay calm and being busy. Language “I would normally do this but…just crack on with it”- compares to other procedures where participants talk about speed.		

Legend:

ELBW= extremely low birth weight, CPAP= continuous positive airway pressure, AIPP= Alcohol impregnated port protectors, PN= parenteral nutrition, SHO- senior house officer, SpR= speciality registrar

Appendix 20 Codebook

Theme	Sub-Themes	Description	Relevant Codes
Individual Level Influences			
Bundle Endorsement	Bundle Utility	Coded for when participants refer to factors relating to 'buy-in' for the new practices and their beliefs about the new practices. This includes codes relating to how they feel about the new practices.	Role of second person, making things easier, Surgical ANTT, AIPP, Scrub the Hub, being clean, not touching, routine, standardisation, ritual, routine, the way we do it here, evidence, variations, individual preferences, sense-making (treating like cannulas, making sense of the rules (questioning practice, doesn't make sense, importance, differences to previous practice, increasing awareness), perceptions of change, perceived benefits (not causing harm, reducing infections, reducing workload, number of attempts),
	Bundle Achievability	This is coded for when participants refer to how achievable they believe the bundle, and the purpose of the bundle, is. For example, this includes participants beliefs about how achievable it is to maintain asepsis, or how achievable it is to reduce CLABSIs to zero.	Getting to Zero, reducing infections, Role of second person, making things easier, Surgical ANTT, AIPP, Scrub the Hub, being clean, not touching
	Perceptions of guidelines	This relates to participants beliefs about how useful guidelines, bundles and protocols are in practice, more broadly. These underlying beliefs may influence the extent to which participants endorse the bundle. For	Perceptions of guidelines: standardisation, reconfiguring guidelines, being written down, standardisation vs 'art'

Theme	Sub-Themes	Description	Relevant Codes
		example, “guidelines are just a guide” or “they help standardise practice”.	
Expectations of Practice		Participant beliefs about what is expected of themselves and what they expect of others. Awareness of expectations. Incorporates beliefs about what practices are considered essential components of the bundle.	Expectations of practice- clear rules, lack of guidance, essential components, acceptability, uncertainty, variations, unwritten rules, mind-set shifts
Seeking reinforcement	Seeking reinforcement	Coded when participants refer to asking for feedback on both individual performance and unit performance on infection rates, as well the type of reinforcement they are asking for e.g. positive or negative, blame or feedback that is deemed inappropriate. Participants wanting to know if they are enacting the task correctly and are seeking confirmation on their practice.	Feedback on practice, feedback on infection rates, morale, blame, uncertainty, audit, observing each other,
	Questioning own competence	Coded for when participants refer to being unsure or uncertain of what they have done, or what they currently do. Participants reflect on if their actions or behaviours are appropriate, questioning their own abilities and actions.	Appraising own practice, questioning own knowledge, confidence in self, uncertainty, no other way, the only way, gaps, knowledge, doing this right, wanting to do the right thing, improvising, good enough, moral distress
	Past experiences	Participants refer to past experiences or adverse events that influence their behaviour.	Past experiences, adverse events, moral distress

Theme	Sub-Themes	Description	Relevant Codes
	Apportioning responsibility	Participants beliefs about where responsibility is apportioned for outcomes related to central lines. For example, explanations for infection rates, or reasons for failing at central lines.	Apportioning responsibility, explaining infection rates, explaining success or failure, blame, collective responsibility, individual responsibility
Reconfiguring prior knowledge		Participants refer to having to unlearn previous ways of doing things.	Reconfiguring knowledge, previous knowledge, being new,
Adapting the bundle		Participants refer to adapting or changing the bundle, improving it or modifying it. Suggestions for improving the bundle.	Adapting, reconfiguring, checklist, (too big, too long, too complex), perceptions of implementation
Team Level Influences			
Division of Labour	Roles and Responsibilities	Coded for when participants refer to how roles are allocated between teams and colleagues, who does the work and if the work allocation is believed to be appropriate. Examples include “their work” and “our work”. Related to how participants understand the work of others and the confidence they have in colleagues’ abilities to perform their role. Influenced also by experience.	Role-specific jobs, role-specific knowledge, historical rules, role allocation, role of second-person, nurses role in insertion, ownership (collective, individual), silo working, understanding the work of others, accountability, who is responsible, confidence in others, variations in colleagues, problem-solving, leadership
	Organising the work	How staff organise the work between each other and different teams. This involves negotiating and prioritising	timing of insertions, timing of fluid changes, needs of the nursery, around other things (asking colleagues, asking for help, not increasing

Theme	Sub-Themes	Description	Relevant Codes
		work with colleagues and between teams. Influenced also by experience.	the workload of others, prioritising tasks), Experience, skill, task-focused, teamwork (working with others, communication, working relationships), fluid nurse, having a team, traditional patterns of practice,
Surveillance and Monitoring	Monitoring practice	Refers to how participants monitor each other in practice and provide informal surveillance of practice. Participants refer to double checking with each other and being watched. Links with level of experience and uncertainty.	Checking together, watching each other, monitoring, self-monitoring, reminding, being vigilant, being watched, accountability, incident reporting, two-person technique, asepsis, waiting for one minute, documentation
	Challenging practice	Coded for when participants refer to having to challenge poor practice or challenge each other's practice.	Challenging others, being challenged, hierarchy, culture, feedback, communication, culture, being human, enforcing/policing, nurses as enforcers of rules, mental model, impact on colleagues
Learning and Teaching	Learning from others	Coded for when participants refer to learning from each other in practice. Learning in practice, see one-do one-teach one and cascade training all forms of learning from each other. Links with level of experience and uncertainty.	Learning from others, take your time, Skills, how do staff learn, cascade training, learning the right way, learning first time,
	Teaching and supervising	Coded for when participants refer to teaching or supervising others to learn the skills.	Supervising others, teaching others, 'see one, do one',
	Education and training	Coded for when participants refer to formalised teaching or educational resources on the unit.	Educational resources, written information, visual aids, multi-disciplinary team, having a team, simulation training, formalised training,

Theme	Sub-Themes	Description	Relevant Codes
			dissemination, reaching the workforce, regular updates, opportunities to practice, assessments, reminders, checklists, visual aids,
Patient Factors			
Unavoidable Exceptions	Illness severity	Coded for when participants refer to patient illness severity or perceived urgency of treatment may influence how they implement the bundle.	Inotropes, urgency, illness severity, breaking lines, not waiting one minute, two-person technique
	Patient characteristics	Coded for when participants refer to how patient characteristics such as size or gestation influence how they implement the bundle.	size, gestation, fragile, moving, activity, asepsis,
	Emergencies	Coded for when participants refer to how clinical emergencies influence how they implement the bundle.	Asepsis, organisation/preparation, breaking lines, urgency, emergency, admissions
Organisational Level Influences			
Resources	Staffing and Workload Demands	Coded for when participants refer to how staffing and competing demands influence their implementation of the bundle. Competing demands includes other patients, interruptions and admissions. Human resources.	Staffing, being busy, time, competing demands, staying calm, take your time, rushing, forgetting, interruptions, being quick, pressure, nursing guilt, fluid nurse role, patient ratios
	Accessibility of resources	Coded for when participants refer to having to go and find additional material resources, how accessible they are or how visible.	Preparation/organisation, clock, soap, resources, key individuals

Theme	Sub-Themes	Description	Relevant Codes
	Cost	Coded for when participants refer to cost influencing how they enact the bundle.	Cost
Environment		Coded for when participants refer to how the environment, or the equipment within in, influences how they implement the bundle.	Incubator, trolley, space, traffic, movement, maintaining asepsis, sterile field, separate, light, people
Infrastructure	External Agencies	Coded for when participants refer to how external agencies that contribute to NICU functioning influence the enacting of the bundle.	Pharmacy, bespoke PN, infection control
	Technology	Coded for when participants refer to how infrastructure such as technology influences how they enact the bundle.	MetaVision, prescriptions
Situational Factors			
Degree of experience		Coded for when participants refer to how experience influences how the bundle is implemented. Participants refer to being new, being junior or being experienced. This theme overlaps with several other themes.	Being new, being junior, experience level **Links with**: **Surveillance and Monitoring, Learning and Teaching, Division of Labour, Bundle Endorsement, Utility of Guidelines**
Degree of uncertainty		Coded for when participants refer to the level of uncertainty there is surrounding a particular aspect of the bundle, and how participants navigate this uncertainty.	Balancing risk, assessing risk, navigating competing rules, unclear rules, uncertainty,

Theme	Sub-Themes	Description	Relevant Codes
		This includes navigating conflicting rules and assessing risk. This theme overlaps with several other themes.	variation, dressings, PN, touching or not touching, asepsis, two-person technique, AIPP **Links with: Surveillance and Monitoring, Division of Labour, Learning and Teaching, Reinforcement, Understanding Expectations, Bundle Endorsement**
Culture			
Culture		Concept developed from re-analysing data from multiple sources and brought together frequently recurring codes from across multiple themes and observations. For example, the concept of ritual was developed from direct observation data, combined with interview data codes such as “the way we do it here” and “routine”.	Codes that spanned across multiple themes, across data sets. Together, these built a picture of culture and local context e.g. routine, ritual, standardisation, the way we do it here, traditional patterns of practice (fluid changes), historical rules, being busy (not increasing workload of others, asking for help) silo working, hierarchy, culture, workload demands, working with others and professional differences.

Appendix 21 Example of Grouping Qualitative Data

Sub-Theme	Data
Feedback on Practice	To be honest, probably not, we're not getting any feedback really. No, I think no one is kind of saying what we're doing really, or are we doing well or not. NURS0509, SSI8 For me, this is one of the kind of feedback, and also we have IP NURSE and she's always marking us, our infection marks are really bad or something, but I think it's slightly different I guess. It's a different kind of infection I think which I found from her. It's more environment, how we're washing hands and stuff, which also is important, but I think with a long line just because our babies, pretty much all of them are having central lines, and if we're still giving them infection through this I think we need to know where we are. NURS0509, SSI8 I suppose we get to know about when there's been a certain period of time without any line infections, we get told about that in emails. From day-to-day, we don't particularly get told about our practice, I don't think. NURS0601, SSI5 I don't think we do. As nurses we don't, I don't think, at all. I think the doctors get this kind of, 'Oh, well done for getting the long line in first time.' There's that kind of well done, tick it off your list - which is good - but it's about getting the line in; it's not about the practice involved NURS0703, SSI9 I mean we get very little feedback on specific areas of practice, unless something goes wrong, in general. Yes, I suppose we don't have a culture of saying, 'You did that very well, you did that very well,' every time you give an antibiotic! NURS0610, SSI11 I don't know how we should feedback about longline care. We don't get any now. NURS0610, SSI11

	Well, probably only if there's an infection in the line [laughs]. Depending on what it is, and if it's the same strain as somebody else has got then there's a bit of finger pointing, I guess. I don't think there's much positive feedback in terms of accessing central lines, but then I guess you wouldn't expect there to be because it's just an everyday job, isn't it? It's just what you do. […] I think we should celebrate the lines that have been in for six weeks without any problem! I don't know, it's a difficult one isn't it because there's a lot more celebration around other procedures like getting off the ventilator, or someone intubates a baby and you'll go, 'Really good skills, well done.' It's instant. I guess if someone gets a difficult long line and then you get to it and it's in a really good position, then you'll get some feedback then, 'Well done, you've got that in,' but more, 'You got it in and it's in the right place,' not around how you did it, if you know what I mean? It's more difficult procedure to give positive feedback on, I think. I don't know. NURS0804, SSI14 So I think there's various negative things that come back, in a very non-specific way, which means that no one does anything about it, because there's no ownership. […] There's also the collective ownership, with individual ownership of the nurses accessing the line, and them doing their bit, because if people, if practice is falling below a level it should be, but the only way of that being reported is a number in a governance meeting several months later, then it's not being fed back in a timely fashion, that we're waiting to find out we've got a problem, rather than being proactive about that. SSI3, DOC01 So for us, it's about imbibing that culture, for that we have to show people how that helps. I think the problem is, we haven't been able to show them results and I think that is why I can't put my hand on my heart and say that I want a two-person technique, and that's led to a reduction in infection rates and that is the problem. SSI12, DOC04 I know we very much live in a bit of a feedback culture, but actually there's a danger that you could just feedback for doing a job that you would be expected to do […] With any intervention, its not about what the intervention is, it's about continued awareness of - I guess feedback, in a

	way, of this is how we're doing, this is why you're doing it, this is why it's important, and positivity. SSI13, DOC03
Apportioning Responsibility	For us, I think infection, it could be really dramatic for babies, and sometimes if they're born with an infection that's fine, but if we're giving them so it's probably our fault and we can improve. It's good to know if we're doing something, if we're doing a good job or we're not doing that, or we still have some areas where we can improve. SSI8, NURS0509 Like, are the spikes when our medical staff change over? That would be a guess. […]I was going to say, like, August, September would be when we get a lot of new-start nurses as well. But I don't think they really do TPN changes and things quite so regularly but they might well look after a patient who has a central line. That would be my guess. SSI1, NURS0617 I think, from a challenging point of view, they may get immediate feedback, and then audits and things will tell us, but we never think it's us, do we? We always think, oh, well, that's the doctors, that's the surgeons do that. We haven't seen people washing their hands. As nurses, we always feel that we get the blame for when infection rates rise. I think, as a group of staff, we think that it's assumed that it's us, like I said, but it isn't. It's everyone, isn't it, and we're all responsible for it. We see it all over. We see nurses do it, we see doctors do it, we see surgeons do it, visitors, consultants from elsewhere. Obviously, random people just don't come in and access their long lines, but you know what I mean? SSI7, NURS0618 I can think of things like, actually if we identify that the baby has longline sepsis, then we ought to identify who the people who've been looking that baby are and at least let them know that the child that they've been looking after has developed a longline sepsis. Now, that may not specifically be their fault, but they may well have been involved in that. We know exactly who's been looking after each baby, so this isn't - it doesn't mean we know who's accessed the longline every time, but that's a blamey [sic] thing. Everything shouldn't be about blame, because then everyone just starts being very negative, which doesn't improve practice or morale, which doesn't improve coming to work! SSI11, NURS0610

	I think nurse staffing is a, for the two-person procedure, that's difficult. I think that is one area, I don't know whether that correlates with periods of high infection, I have not looked, and I certainly would be very wary of attributing blame in that area, but I think it's tricky when we don't have enough nurses, it does sometimes mean that juniors are having to do the procedures in a hurry. SSI2, DOC04

Appendix 22 Example of Coding and Thematic Development

Theme	Data	Codes
	What feedback do you think staff get in terms of their central line practices?	
Reinforcement Guideline utility	Well, probably only if there's an infection in the line [laughs]. Depending on what it is, and if it's the same strain as somebody else has got then there's a bit of finger pointing, I guess. I don't think there's much positive feedback in terms of accessing central lines, but then I guess you wouldn't expect there to be because it's just an everyday job, isn't it? It's just what you do. You wouldn't need to communicate it that really well because there's not really any room to do it really well or not well because if you follow the guideline you all do it the same. I guess the only feedback people get is when there is infection in the line.	Apportioning Responsibility Feedback on practice Standardisation
	Interviewer: How important is feedback do you think for you and your practice?	
Reinforcement Surveillance & Monitoring	Well, it is important obviously you prefer positive feedback that's quite nice, but you have to take the more constructively critical feedback as well, otherwise you can't improve your practice. I sit here saying this like it's easy to be challenged and just accept it and to have feedback and accept it, but that it's easier said than done isn't it? In practice, everybody has… No one wants to feel criticised even when it's not meant as a criticism.	Feedback on practice Challenging others
	Interviewer: How else could feedback be given to staff do you think?	
Reconfiguration Reinforcement	I think we should celebrate the lines that have been in for six weeks without any problem! I don't know, it's a difficult one isn't it because there's a lot more	Adaptation Feedback on practice

Division of labour	celebration around other procedures like getting off the ventilator, or someone intubates a baby and you'll go, 'Really good skills, well done.' It's instant. I guess if someone gets a difficult long line and then you get to it and it's in a really good position, then you'll get some feedback then, 'Well done, you've got that in,' but more, 'You got it in and it's in the right place,' not around how you did it, if you know what I mean? It's more difficult procedure to give positive feedback on, I think. I don't know. Especially if you're just changing the fluids you can't congratulate everybody. Actually, if you do say, 'Well done, you've got all your fluids done,' actually that is another whole area in itself, the pressure to get fluids changed on the day shift.	Pressure Timing of fluid changes
	Interviewer: Tell me a bit more about that then…	
Division of labour	From the nurse's point of view, I know they feel pressured to have all their infusions changed and they're PN up before the night shift come on.	Pressure Timing of fluid changes
	Interviewer: Why do you think that is?	
Division of labour	I don't know, because most of them work days and nights and when they come on a night shift, and there's fluids still to do, there's fluids still to do and they get on with them. I don't know where the pressure - I guess you want to be seen as a good, efficient nurse, getting everything done, I think it's self-imposed pressure. I was the same when I was - I didn't like the leave any fluids not done.	Timing of fluid changes Pressure “Nursing Guilt”
	Interviewer: When do you think, and I know that you don't do the role necessarily any more now, but when do you think is the best time for nurses to do their fluids?	
Division of Labour	It's difficult isn't it? Because I don't think there is an optimal time. From a medical point of view I quite like later afternoon because then you can implement your changes you've discussed on the ward round. If you've	Timing of Fluid Changes

Navigating Uncertainty Division of Labour Unavoidable Exceptions Reconfiguration	got a baby with a low sodium that you want to change the fluids for but then, the fluids don't go up until the night shift, then that's a long lag time from identifying a problem to making some changes. I also worry about doing things, like making infusions, in the night-time, it's a bit like blood transfusions isn't it? We try not to do blood transfusions overnight, because there's more risk of error, well, research has shown there's more risk of error and adverse outcomes. I worry the same about doing complicated infusions at night when the lights are dim [laughs], and I don't know. I can't see in the, at night anymore, I'm getting old [laughter]. I don't know, there's just a slight worry about that, yes, everyone should be on the ball at night as they are in the day, but your body functions very differently at night and I would worry about that being the norm. Yes, if things happen, emergencies, babies come in, you have to do stuff, but I think routine fluids at night, I'm not sure is a good idea. I think optimally it would be late afternoon, with another member of staff coming on to do an evening shift, a fluid shift	Balancing Risk Emergencies Fluid Nurse Role
	Interviewer: Tell me a bit more about that, how do you think that that would help?	
Reconfiguration	If you had somebody who, that was their role, to make up infusions and change PN, which wouldn't be a very exciting job, but if you didn't have to do it every week! I don't know, maybe somebody would like that job, I don't know. They could do with each person with their own baby, go round.	Fluid Nurse Role
	How do you think that would help? Or what do you think that would help with?	
Division of Labour Workload Demands	Well, then you'd always have your two people. Somebody who was designated to do it so they didn't have any other responsibilities. Because often I'll see that with the nurses, everything will be ready, and then something will happen, and they'll have to leave it, and	Roles and Responsibilities Interruptions

	sort out a baby that's having a bradycardia if there's no one else in the room and then come back to it. Yes, varies, interruptions. If it was somebody's sole job for that shift, like a twilight-type hours.	
	Do you think that interruptions impact on the aseptic practices?	
Environment Resources	Massively. It again goes back to that leaving a trolley unattended thing, that often happens. The nurseries are busy, they wear ‘don't talk to me I’m doing drugs aprons’, and everyone talks, 'I’m not talking to you because you've got an apron on, but can you just…?' All the time [laughter], then it takes longer and you've got to go back and double check what you've already done because you've been interrupted.	Environment Workload Demands Interruptions
	Do you feel that there are sufficient resources on the unit to be able to put these policies into practice?	
Resources	Not always and it's mainly a human resources issue. I think otherwise, yes, we've got all the equipment, we haven't always got all the bodies. I think that is the biggest barrier.	Staffing Equipment

Appendix 23 Example of Data Analysis Framework

Explanatory code Action	Temporal Influences	Resource Influences	Competing Demands (Links with Resources)	Working with others
Organising the work	Nurses talk about trying to get the task completed before the night shift, more people in the day time and felt to be safer. Nurses talk about just getting on or "crack on with it" because it is near the end of the shift. There is some pressure to get the task done before the end of the shift even though "its a 24 hour service!". They also talk about there being certain times of the day that are busier. Often it is fit into a spare 20mins, or don't usually have the time to organise it. One pair talk about doing "leisurely fluids" This fits with "taking your time"-nurses advice to colleagues would be to take their time and not to rush the process, yet this doesn't appear to translate into what people do. "you've got to make sure you have the time, and the room's ok to do it", just checking with the other person that they have time. Task is quicker easier if prepared beforehand. **Links to RESOURCES.**	Availability of resources is important, for example, running out of equipment- having to "run down the corridor because there's no syringes left". Easier to perform the task next to the drugs cupboard so you can get things if you have forgotten them (as opposed to doing it next to the patient as per the recommended practice). The availability of TWO NURSES to perform the task- this is an important part of how the task is organised- the appropriate time to do it because "you need two nurses". Poor preparation means you may need to ask someone else to go and get things (additional resources).	Nurses talk about checking with each other that they are both 'free' to do the task, free from distractions and 'up to date' with their workloads. Finding time to 'be clean' means that it is easier for nurses to organise fluids changes together into one task, rather than doing infusions separately during the day. Nurses recognise that if it is really busy (like preparing for a surgery) then there is less preparation, you get things out as you go along. One pair also recognise that when it is busy sometimes you make infusions up and check the prescription later- which is something they recognise they shouldn't do, but does happen.	Task should be organised in a way that doesn't increase the workload of others, so that you do not need to ask others to do things for your patients such as feeds and observations (though often other nurses do observations or go to get equipment whilst participants performing task.) Not having to ask others to 'do this and that and the other'. One nurse actually comments the opposite, that it was "quite nice" to have someone else available to go and get things for her. Nurses need to have prescriptions ready from the doctors (who can be busy as well, priority might not be to prescribe fluids) though this is only mentioned in the pilot.

Appendix 24 Letter of Support From BLISS

Bliss
for babies born premature or sick

Victoria Payne
Advanced Neonatal Nurse Practitioner
Princess Anne Hospital

21 April 2017

To whom it may concern,

Re: An investigation into the implementation of a complex intervention to reduce late-onset sepsis in the Neonatal Intensive Care Unit.

Many thanks for sharing your research plans with Bliss and for giving us the opportunity to discuss with you how we might support you in your proposed project.

Bliss supports Victoria Payne's application for a study to examine the implementation of a complex intervention to reduce late onset sepsis in the neonatal intensive care unit. Bliss believes that all premature and sick babies should have the best possible chance of survival and reaching their full potential.

Unfortunately poor infection control can reduce the chances of survival for all babies which is why Bliss recognises that further work is needed to understand how complex interventions such as the one stated above are key to optimizing outcomes for babies who are born premature or sick. How infection in preterm babies can be better prevented was also identified as a key priority by the pre-term birth priority setting partnership which identifies the need for this work.

Bliss supports this work and will help to disseminate results.

Yours sincerely,

Zoë Chivers
Head of Services

Appendix 25 Survey One: Responses to Questions 1 to 20

Question	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	NR	Invalid	Total	Median Score
Coherence									
Q1. I understand how the care bundle differs from usual ways of working	5 (5.6)	7 (7.8)	19 (21.1)	48 (53.3)	5 (5.6)	4 (4.4)	2 (2.2)	90 (100)	1
Q2. Staff on the neonatal unit have a shared understanding of the purpose of the care bundle	6 (6.7)	14 (15.6)	17 (18.9)	46 (51.1)	7 (7.8)			90 (100)	1
Q3. I understand how the care bundle affects my own work	3 (3.3)	2 (10)	12 (13.3)	49 (54.4)	14 (15.6)		2 (2.2)	90 (100)	1
Q4. I can see the potential benefits of the care bundle			12 (13.3)	39 (43.3)	36 (40)		3(3.3)	90 (100)	1
Cognitive Participation									
Q5. There are key people who promote the care bundle and get others involved	2 (2.2)	7 (7.8)	26 (28.9)	44 (48.9)	9 (10)		2 (2.2)	90 (100)	1
Q6. I believe that using the care bundle is a key part of my role	1 (1.1)	1 (1.1)	5 (5.6)	45 (50)	32 (35.6)		3 (3.3)	90 (100)	1
Q7. I am open to working with colleagues in new ways to use the care bundle			1 (1.1)	40 (44.4)	48 (53.3)	1 (1.1)		90 (100)	2
Q8.I will continue to support the care bundle			8 (8.9)	37 (41.1)	44 (48.9)		1 (1.1)	90 (100)	1
Collective Action									
Q9. I can easily integrate the care bundle into my current practice	1 (1.1)	3 (3.3)	17 (18.9)	49 (54.4)	17 (18.9)	3 (3.3)		90 (100)	1
Q10. The care bundle disrupts working relationships*	14 (15.6)	49 (54.4)	24 (26.7)	2 (2.2)			1 (1.1)	90 (100)	1

Question	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	NR	Invalid	Total	Median Score
Q11. I have confidence in other people's abilities to use the care bundle		1 (1.1)	6 (6.7)	28 (31.1)	49 (54.4)	5 (5.6)	1 (1.1)	90 (100)	1
Q12. The work required by the care bundle is performed by people with the appropriate skills to do so		1 (1.1)	23 (25.6)	52 (57.8)	13 (14.4)		1 (1.1)	90 (100)	1
Q13. Sufficient training has been provided to ensure staff can implement the care bundle	7 (7.8)	26 (28.9)	34 (37.8)	20 (22.2)	3 (3.3)			90 (100)	0
Q14. Sufficient resources are available to support the care bundle	4 (4.4)	7 (7.8)	37 (41.1)	40 (44.4)		1 (1.1)		90 (100)	0
Q15. The Trust supports the care bundle			32 (35.6)	49 (54.4)	7 (7.8)	1 (1.1)	1 (1.1)	90 (100)	1
Reflexive Monitoring									
Q16. I am aware of the effects of the care bundle on the units bloodstream infection rates	3 (3.3)	14 (15.6)	17 (18.9)	42 (46.7)	13 (14.4)	1(1.1)		90 (100)	1
Q17. Staff agree the care bundle is worthwhile		2(2.2)	22 (24.4)	48 (53.3)	18 (20)			90 (100)	1
Q18. I value the effects the care bundle has on my work		1 (1.1)	25(27.8)	47 (52.2)	14 (15.6)	2 (2.2)	1 (1.1)	90 (100)	1
Q19. Feedback about the care bundle can be used to improve it in the future			9 (10)	52 (57.8)	29 (32.2)			90 (100)	1
Q20. I can change how I work with the care bundle			16 (17.8)	50 (55.6)	22 (24.4)	2 (2.2)		90 (100)	1

Data presented as n (%)
NR= no response
*Reversed scoring, for example, strongly disagree= +2, disagree= +1

Appendix 26 Survey Two: Responses to Questions 1 to 20

Question	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	NR	Invalid	Total	Median Score
Coherence									
Q1. I understand how the care bundle differs from usual ways of working	2 (3)	3 (4.7)	9 (14)	41 (64)	7 (10.9)	2 (3)		64 (100	1
Q2. Staff on the neonatal unit have a shared understanding of the purpose of the care bundle	1 (1.6)	6 (9.4)	8 (12.5)	41 (64)	7 (10.9)	1 (1.6)		64 (100)	1
Q3. I understand how the care bundle affects my own work	1 (1.6)	2 (3)	4 (6)	40 (62.5)	16 (25)	1 (1.6)		64 (100)	1
Q4. I can see the potential benefits of the care bundle	1 (1.6)	0	2 (3)	29 (45)	31 (48)	1 (1.6)		64 (100)	1
Cognitive Participation									
Q5. There are key people who promote the care bundle and get others involved	1 (1.6)	6 (9.4)	9 (14)	33 (51.6)	15 (23.4)			64 (100)	1
Q6. I believe that using the care bundle is a key part of my role		1 (1.6)	3 (4.7)	32 (50)	28 (44)			64 (100)	1
Q7. I am open to working with colleagues in new ways to use the care bundle	1 (1.6)			32 (46.9)	30 (46.9)	1 (1.6)		64 (100)	1
Q8.I will continue to support the care bundle				31 (48.4)	32 (50)	1 (1.6)		64 (100)	2
Collective Action									
Q9. I can easily integrate the care bundle into my current practice	1 (1.6)	1 (1.6)	6 (0.4)	36 (56.3)	19 (29.7)	1 (1.6)		64 (100)	1
Q10. The care bundle disrupts working relationships	13 (20.3)	40 (62.5)	8 (12.5)	1 (1.6)	1 (1.6)	1 (1.6)		64 (100)	1

Question	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	NR	Invalid	Total	Median Score
Q11. I have confidence in other people's abilities to use the care bundle	4 (6.3)		19 (29.7)	37 (57.8)	3 (4.7)	1 (1.6)		64 (100)	1
Q12. The work required by the care bundle is performed by people with the appropriate skills to do so		1 (1.6)	4 (6.3)	53 (82.8)	5 (7.8)	1 (1.6)		64 (100)	1
Q13. Sufficient training has been provided to ensure staff can implement the care bundle	3 (4.7)	7 (10.9)	13 (20.3)	40 (62.5)	1 (1.6)			64 (100)	1
Q14. Sufficient resources are available to support the care bundle	1 (1.6)	7 (10.9)	10 (15.6)	46 (71.9)				64 (100)	1
Q15. The Trust supports the care bundle		1 (1.6)	14 (21.9)	43 (67.2)	6 (9.4)			64 (100)	1
Reflexive Monitoring									
Q16. I am aware of the effects of the care bundle on the units bloodstream infection rates	2 (3.1)	5 (7.8)	6 (9.4)	35 (54.7)	16 (25)			64 (100)	1
Q17. Staff agree the care bundle is worthwhile		1 (1.6)	6 (9.4)	42 (65.6)	14 (21.9)	1 (1.6)		64 (100)	1
Q18. I value the effects the care bundle has on my work	1 (1.6)	1 (1.6)	9 (14)	36 (56.3)	17 (26.6)			64 (100)	1
Q19. Feedback about the care bundle can be used to improve it in the future			1 (1.6)	37 (57.8)	25 (39.1	1 (1.6)		64 (100)	1
Q20. I can change how I work with the care bundle	1 (1.6)		7 (10.9)	43 (67.2)	13 (20.3)			64 (100)	1

Data presented as n (%)

NR= no response

*Reversed scoring, for example, strongly disagree= +2, disagree= +1

Appendix 27 Survey Three: Responses to Questions 1 to 20

Question	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	NR	Invalid	Total	Median Score
Coherence									
Q1. I understand how the care bundle differs from usual ways of working		1 (2)	8 (18)	32 (71)	4 (9)			45 (100)	1
Q2. Staff on the neonatal unit have a shared understanding of the purpose of the care bundle		4 (9)	5 (11)	35 (78)	1 (2)			45 (100)	1
Q3. I understand how the care bundle affects my own work				36 (80)	8 (18)	1 (2)		45 (100)	1
Q4. I can see the potential benefits of the care bundle			1 (2)	23 (51)	19 (42)	2 (4.4)		45 (100)	1
Cognitive Participation									
Q5. There are key people who promote the care bundle and get others involved		4 (9)	6 (13)	23 (51)	12 (27)			45 (100)	1
Q6. I believe that using the care bundle is a key part of my role			1 (2)	26 (58)	18 (40)			45 (100)	1
Q7. I am open to working with colleagues in new ways to use the care bundle			2 (4)	23 (51)	19 (42)	1 (2)		45 (100)	1
Q8.I will continue to support the care bundle				23 (51)	22 (49)			45 (100)	1
Collective Action									
Q9. I can easily integrate the care bundle into my current practice				30 (67)	14 (31)	1 (2)		45 (100)	1
Q10. The care bundle disrupts working relationships*	9 (20)	25 (55)	8 (18)	3 (7)				45 (100)	1
Q11. I have confidence in other people's abilities to use the care bundle		4 (9)	11 (24)	30 (67)				45 (100)	1
Q12. The work required by the care bundle is performed by people with the appropriate skills to do so		1 (2)	4 (9)	36 (80)	4 (9)			45(100)	1

Question	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree	NR	Invalid	Total	Median Score
Q13. Sufficient training has been provided to ensure staff can implement the care bundle		8 (18)	7 (16)	23 (51)	5 (11)	2 (4)		45 (100)	1
Q14. Sufficient resources are available to support the care bundle		2 (4)	9 (20)	28 (62)	4 (9)	2 (4)		45 (100)	1
Q15. The Trust supports the care bundle		1 (2)	8 (18)	29 (64)	6 (13)	1 (2)		45 (100)	1
Reflexive Monitoring									
Q16. I am aware of the effects of the care bundle on the unit's bloodstream infection rates		4 (9)	3 (7)	30 (67)	8 (18)			45 (100)	1
Q17. Staff agree the care bundle is worthwhile			5 (11)	32 (71)	8 (18)			45 (100)	1
Q18. I value the effects the care bundle has on my work			2 (4)	33 (73)	10 (22)			45 (100)	1
Q19. Feedback about the care bundle can be used to improve it in the future			1 (2)	30 (67)	14 (31)			45 (100)	1
Q20. I can change how I work with the care bundle			5 (11)	31 (69)	9 (20)			45 (100)	1

Data presented as n (%)

NR= no response

*Reversed scoring, for example, strongly disagree= +2, disagree= +1

Appendix 28 Example Field Notes

Field notes were recorded contemporaneously in a research notebook and transcribed electronically as a memo on NVivo.

December 2017: Participant Recruitment

During recruitment process, one nurse asked if I would be observing central line procedures at different times of day, or just the "controlled" procedures. I asked what this term meant to her, and she explained that when the unit is quiet, there is lots of time to do things properly. This prompted me to reflect on if this was a commonly used phrase on the unit, or this individuals perceptions.

During a presentation about this research project at an in-house nursing study day, I asked the attendees what this phrase meant to them. Staff attending agreed with the above conceptualisation of fluid changes as controlled and uncontrolled.

This led me to consider:

- Are there circumstances (time and context specific) where it is considered socially acceptable to staff to perform fluid changes in a way that is different to guidance?
- Are there issues here related to competing demands or patient illness/urgency of treatment that takes priority over central line guidance/practices?

During another recruitment period, two members of staff discussed fluid changes practices compared to other units they have worked. This related to changing fluid via Octopus' and switching these all individually rather than connecting the Octopus immediately to the line. This means that we are accessing Octopus multiple times, instead could change the Octopus only (one break in the line rather than several). Both nurses felt the latter was safer. Both nurses said they had tried to suggest this change in practice, but nothing had happened.

- Are we breaking the lines too often? How much is too often?
- When would it be acceptable to break lines? When is it perceived to be justifiable [socially acceptable]?
- Are there resource implications?

During the recruitment of a Consultant, they said they would "not be compliant" with the bundle, as they won't be using a two-person technique. This participant went on to say they were very experienced and didn't need a second helper.

- Important to emphasise this is not a study about compliance.
- What are staff's understandings of the role of the second person?

During the same recruitment episode, another Consultant said to me "oh you wouldn't have wanted to watch me put those lines in last week, I wasn't very sterile". Suggestion here that the implementation of the central line practices is not always performed using aseptic technique, or that there are things that influence the way it is performed, even though staff know they shouldn't do it that way. Provides further impetus/justification for the need for this study, to understand ***why*** this is the case.

Appendix 29 Semi-Structured Interview Data Corroborating ORI Findings

Theme	Sub-theme	Quotation	Commentary
Degree of experience		I suppose they're just performed slower, and with newly qualified you just have to make sure that they know what the key parts are and that they're not touching them (SSI5, NURS0601) If we've got newer doctors and they've not done that before and they don't seem to always maybe get shown exactly what they should do and I don't think it maybe always gets kept so sterile at that point. (SSI1, NURS0617) I suppose I know, I'm familiar enough with the guideline and the checklist, that I know what's expected, and I'm used to doing it, and it's really important to me that I do it as clean as possible (SSI3, DOC01) Or even if they could just have time to observe us doing it, which I guess they get during their supernumerary time, but then they're so…they must be so nervous and so worried about learning how to do everything else, that that's at the back of their mind really because you don't just start and automatically have to do all these infusions, and hopefully you're not left to do that as a newly-qualified nurse (SSI1, NURS0617) When you're teaching someone, like for example you're in special care and you need to show someone who just started recently, you're telling what to do and stuff and she's just saying, 'Oh, someone just did it differently,' and you think, yes, sometimes we do things differently. The most important thing, you're trying to point what is important (SSI8 NURS0509) Whereas I find it's the people that perhaps don't do it so often, don't do it as it should be done and touch bits or will hand you bits that shouldn't be… They	Data corroborated the ORI findings that the degree of experience was an influential factor on how the bundled practices were performed and how much participants endorsed the practices. Indeed, one Consultant recognised that she was very familiar with the guideline and the checklist, and is therefore aware of what is expected. It was felt that junior or new staff were felt to adhere more rigidly to guidelines compared to those perceived to be more experienced. This was similar across both professions and frequently caused confusion or tension for participants. This seemed to be particularly notable for nurses, as some colleagues were considered "sticklers for the rules" (SSI1, NURS0617), whilst some referred to wanting more room for "nursing art" (SSI14, NURS0804). In contrast, one nurse recognised that it was not just "junior" staff, and one Band 7 felt that it was those who do not perform the process often that might not perform Surgical ANTT appropriately.

Theme	Sub-theme	Quotation	Commentary
		shouldn't touch which I was quite surprised at, so there are some people that are unaware of what they should be doing (SSI4, NURS0707) I'm just talking about the odd occasions and the few people that you do have to keep saying things, and it's not just junior people, either. It's senior people, as well (SSI7, NURS0618) I just mean that some people are doing exactly how you're doing and they don't have any problem with this, but some people are doing different and you think, 'Oh well, okay, if you think it's better then fine'. I've found sometimes a more senior person doing differently and then you think, 'Well, okay' (SSI8, NURS0509) How to make that happen consistently? Just it is scary challenging people more senior than you, the more experienced, because you've got to be so confident in what you're saying. There's an element of fear that they're going to be cross with you, and they're more senior to you, so that could be a problem! (SSI11, NURS0610)	Degree of experience influenced other themes, such as being able to challenge others (those with more experience, or those who are senior), as well as overall endorsement for some bundled practices, for example, insertion bundle is not appropriate for more experienced colleagues.
Degree of uncertainty		So there's so many…it is written down but it's written down in so many places and there's different things written down that I don't think we ever come away feeling confident that we should be or shouldn't be mixing stuff with each other (SSI1, NURS0617)	Similar to the ORI results, participants described having to deal with different degrees of uncertainty. This uncertainty impacts on the extent to which participants endorsed the new practices, the way in staff worked together within and between teams, and how the task was taught by individuals.

Theme	Sub-theme	Quotation	Commentary
		they're all snuggly and cosy, we should be unwrapping them and looking at that site when we PEP score it, and I'm absolutely certain that we don't […] That's not to say everybody doesn't check, but I would say routine practice is not to hourly disturb the baby, which has got advantages as well, because we shouldn't be frequently disturbing premature babies! (SSI11, NURS0610) Well, there either is or there isn't. I figure there probably isn't, because there wouldn't be confusion if there was an actual rule, but I'm not quite sure where such a rule would be written down. A rule would irritate me enormously, but if there was one, it would be easier to follow (SSI10, NURS0610) So the only thing that I can possibly think of, and it's not that it's a clear practice, it's that it differs between the nurses and the doctors, is hand washing between the two.[…] Whereas the doctors and the nurse practitioners they do it properly where they do their iodine and they don't touch anything, and they dry with the thing in the sterile pack […]… so that would be my only observation and I don't really understand why we don't… (SSI5, NURS0601) Am I teaching this right, because people are challenging me and saying, "Well, I've not been shown how to do that,' and I'm saying, "Well, I think this is the right way.'" It makes sense in my head to not snap it off dirty, and then clean it. To clean it all first, and then break it off, things like that. There are lots of differences of opinion, and things keep changing. One minute we were	Nurses continued to refer to the challenges of having to predict patient deterioration regarding the decision to connect a needleless extension set. One nurse referred to “sneaky” potassium infusions (SSI1, NURS0617) suggesting that these are somehow deceptive or unfair. Participants across both professional groups felt that there was uncertainty around the management of central line dressings. Indeed, one Consultant recognised the significant “moral distress” (SSI3, DOC01) that can occur when staff behave with the best intentions but then inadvertently may cause harm to a patient, such as changing a central dressing which results in the line being dislodged. Individuals navigate uncertainty differently, making different decisions regarding best practice. This results in a variety of different practices and behaviours, which in turn influences how staff understand what is expected of them. Participants referred to “being told different things” (SSI8, NURS0509) or not “knowing the truth” (SSI11, NURS0610).

Theme	Sub-theme	Quotation	Commentary
		told that they were clean, and then we were told that they weren't sterile, or they were sterile, then they weren't (SSI7, NURS0618) How to clean that bag, for example. Another thing, when we're changing Octopus and Bionector on any central lines in the past, and I'm still actually not sure how to do it. Some people put Curos caps on it, some people clean with alcohol wipes. I just think from my point of view it's probably the same really, we're cleaning for a minute and stuff, but it's still a little bit confusing (SSI8, NURS0509)	Nursing participants provided examples of having to navigate conflicting information or conflicting rules which left them feeling unsure about what to do. These uncertainties contribute to participants questioning their own competence. This was primarily in relation to drug incompatibilities and documenting hourly PEP scores. Both a Band 6 and a Band 7 nurse discuss that central line sites and PEP scores are not checked hourly, though they know they should be, but that this has to be balanced against minimising the handling of preterm infants. There continued to be uncertainty regarding how to handle TPN bags as part of the surgical ANTT process. Multiple drug incompatibilities may result in babies requiring multiple venous lines, either peripheral or central venous access, increasing the risk of developing a CLABSI. Conflicting information about drug incompatibilities was problematic for nursing staff.

Theme	Sub-theme	Quotation	Commentary
Bundle Endorsement	Bundle utility	You have to work as a team, because one of you can't touch anything. Actually, it's challenging, but it's quite nice, as well, because you have to, whoever you're working with, whether you get on normally on not, on a personal level, you've got to be professional and get that job done, and work (SSI7, NURS0618) I think everyone has been really pleased with them. I mean, the Curos caps are great, because it's much quicker. You haven't got that wipe, you haven't got the, 'Oh, have I cleaned everything properly?' We were all taught how to do it, but everyone does it slightly differently. 'Have you cleaned all the areas?' (SSI7, NURS0618)	The new practices appeared to make nursing work easier; AIPPs made waiting for one minute easier as it reduced the workload involved in Scrubbing the Hub. These results support the findings from the ORIs. Surgical ANTT appeared to improve nursing team dynamics and there was strong buy in despite the fact that it requires additional human resources. Nurses felt that the new practices for accessing central lines were appropriate, with results supporting the ORI findings that previous Scrub the Hub techniques were believed to be poor. Surgical ANTT and the AIPPs were perceived to address these elements of poor practice and were highly valued by nurses. However, one nurse felt that the AIPPS do not attach directly to the end of the central line, and so using a sterile wipe “feels like you’re cleaning better” (SSI7, NURS0618).
Seeking Reinforcement	Seeking Reinforcement	We obviously get infection control who come round to see our general infection control practice and things like hand washing and putting on gel after taking off gloves and things like that would be picked up, but actually for the actual sterile procedure, we don't really have very much feedback, and whether we should be observing each other, having an outside observer (SSI4, NURS0707)	Participants felt that they did not know if what they were doing was right, compared to what was taught in formal study days or how others performed the task. Participants across all experience levels were seeking reassurance and participants felt they did not receive feedback.

Theme	Sub-theme	Quotation	Commentary
	Questioning own competence	I sort of think sometimes time just - obviously, you have an introduction of a protocol. Then I think sometimes a reinforcement somewhere down the line is a good idea and I don't know if that particularly happened in this case (SSI6, NURS0801) I do what I think is right, but I don't know if I am (SSI4, NURS0707) Are they meant to have two people, because sometimes we challenge them and they are like no, no it doesn't have to be (SSI9, NURS0703)	The uncertainty regarding two person techniques does not result from a gap in the bundle, as that is outlined in the CVC guideline and the checklist, and yet participants still experience varying degrees of uncertainty regarding its implementation. Practices that were not addressed within the bundle continued to be a source of anxiety, particularly in relation to central line dressings and having to navigate these uncertainties could cause "moral distress" (SSI3, DOC01). The debate between minimising the access of lines versus adding extra extension sets continued to be raised as an issue in the SSIs. The lack of clear guidance to staff, along with a perceived lack of reinforcement, may have resulted in confusion and tension between teams.
	Past experiences	So then we were all, like, "Oh god! That's terrible; I can't believe someone would leave it like that." But then at the back of my mind, what I'm really thinking was, "God, that could happen to me as well, I better make sure I actually am checking my dressings closely as I should be every hour." So I don't know if horror stories that shock you into doing your job properly are	Participants identified past experiences, usually adverse incidents, that they felt had changed their behaviour and moderated the extent to which they adhered to infection control practices. Participants could recall situations where central lines that had

Theme	Sub-theme	Quotation	Commentary
		really the way forward, but it certainly makes you think about it (SSI1, NURS0617) Not as, for instance, recently there was a particular longline that had very high pressures for three days, and the response was just consistently, 'Well, we'll flush it later.' 'Well, we'll flush it later.' 'We've flushed it.' 'Well, we'll leave it for a few hours.' That went on for three days. That child was subsequently ragingly septic and had the line removed. I don't know if it was the line, but the two don't hang together very nicely (SSI10, NURS0610)	been poorly dressed or had become dislodged that had not been checked hourly.
Reconfiguring prior knowledge		I'm speaking from experience of working somewhere else, and we had the benefit there of working in the same institution, whereas, that's not the case here. So people move around a lot, so some of them by the time they come here already know how to do a long line, and what we practice here is not necessarily what's practiced somewhere else. So they might have already learnt a different way of doing it, so it's a bit hard to overcome all that (SSI15, DOC13) So I think all that is very different, and for somebody who has trained somewhere else, who is already pretty good at putting lines in, they would have to revisit their practice to adapt it to the new environment, and that's not something which necessarily happens, because, obviously, if you think that somebody is skilled enough to put in a long line, people are pretty happy with you doing it without realising your environment might be unfamiliar, although you might be familiar with the skill (SSI15, DOC13)	Participants recognised that new staff have to reconfigure what they have previously been taught, or how they have previously enacted a procedure, corroborating with the ORI results, and this can be hard to overcome. One participant recognised that in other healthcare settings, staff remain in one particular hospital, and that the movement of staff between different hospitals is a challenge. This same participant recognised that doctors from other countries may not be familiar with inserting lines inside incubators, though they will be very experienced at inserting lines in neonates. Reconfiguring prior knowledge was felt be a challenge across both professions. When asked what might impact on the performance of asepsis, one nurse felt that having new staff, or agency staff, was a

Theme	Sub-theme	Quotation	Commentary
			challenge, as people come from “different units with their own practices” (SSI5, NURS0607).
Division of labour	Roles and responsibilities	When we used to use the wipe to wipe the line, whether it was done for that length of time because of lack of being able to see a clock, but it was their responsibility because they had the wipe in their hand, and they were actually wiping it […] think it was just clear that that was their responsibility because they had the wipe whereas if we made it somebody's responsibility, but because there is a variation in practice of who takes it [AIPP] off then I think that's probably perhaps where they don't actually wait for a length of time (SSI4, NURS0707)	The lack of clear roles regarding who removes the AIPP was highlighted again in the SSIs, corroborating the ORIs that there was uncertainty around this. More specifically, a Band 7 nurse felt that this impacts on how long the AIPP is left on for.
	Organising work between teams.	I also think sometimes, when the timings of the long lines, the timings of when those things take place, sometimes are not the best time for the nurse as well. It might be that you're like, 'Oh, it's two o'clock. I haven't had my lunch yet. I need to go,' and then that's the time that the decision is made that we're going to now have this attempt at a line. Then you feel like, well, I can't go, or I need to be here (SSI9, NURS0703) I don't know, because most of them work days and nights and when they come on a night shift, and there's fluids still to do, there's fluids still to do and they get on with them. I don't know where the pressure - I guess you want to be seen as a good, efficient nurse, getting everything done, I think it's self-	The timing of central line insertions, for example was not always discussed with the nursing teams, causing some tension for nurses between taking a lunch break, for example, or staying for the line insertion. Again, the way in the labour is organised between teams will impact on the way in which practices are being monitored; if nurses are not present, they cannot supervise practice. The division of labour between day and night shift teams was also raised in the SSIs, corroborating the

Theme	Sub-theme	Quotation	Commentary
		imposed pressure. I was the same when I was - I didn't like the leave any fluids not done (SSI14, NURS0804) So if I was to come onto the night shift and somebody in the day said, 'Oh, I haven't done my infusions, it's been really busy in there,' I'd go, 'Don't worry about it, I'll do them.' Just like if I hadn't done something at night they'd go, 'Don't worry about it' or 'New shift, new outlook,' but you do feel bad handing it over at the end of the day[…] I think that's just nursing guilt, isn't it? (SSI5, NURS0601)	findings of the ORIs. There continued to be a perceived need to change fluids before a night shift continued to be a source of tension and guilt. Handing over work undone, to the oncoming team, continued to be a source of guilt for some nurses. Indeed, there was a disconnect between the belief that central lines access should be minimised and completing fluid changes before the night team
Surveillance and monitoring	Challenging practice	And I still don't think those bags of 10% and 5%; I'm sure they're dust covers, but I got into so much trouble bringing that up in my old job, and it became this whole big drama that I daren't even open my mouth about it (SSI1, NURS0617) but actually if you put it somewhere, and then the nurses will see that as well, because we do go into that room. Then we will feel empowered, because we'll know the truth (SSI11, NURS0610)	The results from the ORIS suggested that nurses on the whole found policing and challenging poor practice uncomfortable, and the SSIs supported this. This was felt across both professions. Participants used terms like "being affronted" or a "personal slight" (SSI7, NURS0618), to describe how staff may feel when being challenged. Some participants were worried that strict enforcement may want to make staff leave their job, or that it might be viewed negatively.
Learning and teaching	Learning from others	Also, ideally, when it's a new person we like somebody senior to just teach them, or watch them do it for a couple of times before they actually do it on their own, and sometimes that doesn't happen. We just run through whether there is person is able to do it and let them do it on their own, which we shouldn't be doing (SSI15, DOC13)	Learning from others continued to be referred to as the way in which staff learnt the skills of central line management, across both professions, though it was hoped that this was with the support of someone experienced. One ANNP hoped that the unit had "moved on a bit" from "you know how to put a cannula

Theme	Sub-theme	Quotation	Commentary
		because sometimes then they rely on you and I think, “Well, I don’t know because I don’t put…that’s not what you’re meant to do,” so we don’t really know what their role is and then they’re kind of looking to us because we’re the only person in the room, so that can be a bit difficult (SS1, NURS0617)	in, off you go” (SSI14, NURS0804) but one Consultant felt that sometimes this still happened.
Unavoidable exceptions		Only in very, very, very sick patients that really don't cope when you take away their inotropes. But very rarely does it happen that you're taking away the baby's inotropes for long enough for them to notice. (SSI5 NURS0601) We tend to cut corners in emergencies, because it takes longer to do sterile fluids (SSI11, NURS0610) Yes, so emergency situations, so maybe doing intubation drugs, breaking lines. If you've got a baby on masses of infusions, and you're having to put something else up, so we will sometimes break the line to move. Rather than, 'Right, are we going to make everything fresh and start again, to add another Octopus in, or are we just going to break the line, add it to, while we're clean, add it on?' We know that we shouldn't be doing that (SSI7, NURS0618)	Nurses felt that babies on inotropes with unstable blood pressures was the most common situation in which practices are performed differently, not always waiting for one minute for the AIPPs. It was, however, felt to be a rare. This corroborated with the ORIs. There were other medications which were perceived to be both urgent and unavoidable, such as dextrose, insulin and potassium infusions, where levels may be “dangerously low” (SSI7, NURS0618). Emergencies were felt to result in central lines being inserted by one person (SSI6, NURS0804), or lines being accessed ‘without gloves on’ (SSI7, NURS0618). Not all participants agreed that it was acceptable to enact the processes differently during an emergency,

Theme	Sub-theme	Quotation	Commentary
		Obviously, when you have a life-threatening situation, yes, obviously, you don't think so much about asepsis, and I think that's totally acceptable (SSI15, DOC13)	and some felt that they were still able to perform adequate asepsis during resuscitations.
Resources	Staffing and workload demands	I think nurse staffing is a, for the two-person procedure, that's difficult. I think that is one area, I don't know whether that correlates with periods of high infection, I have not looked, and I certainly would be very wary of attributing blame in that area, but I think it's tricky when we don't have enough nurses, it does sometimes mean that juniors are having to do the procedures in a hurry. That means it might mean more unsuccessful attempts, but I do think that we do have a problem with our ability to be able to do the procedure as a two-person technique (SSI12 DOC04) and the other babies in the nursery, if they require care it's very hard to concentrate on doing something if you know a baby's deteriorating and needs help when you're sterile and you can't actually touch it! (SSI4, NURS0707) Massively. It again goes back to that leaving a trolley unattended thing, that often happens. The nurseries are busy, they're aware, they, don't talk to me and the doing drugs aprons, and everyone talks, 'not talking to you because you've got an apron on, but can you just…?' All the time [laughter], then it takes longer and you've got to go back and double check what you've already done because you've been interrupted (SSI14, NURS0804)	Competing workload demands were felt to result in interruptions and distractions. One nurse was concerned about the amount of time that would be required to assist in a central line insertion, as that would take her away from her other intensive care patient. Nurses explained the challenges of balancing multiple competing demands and performing Surgical ANTT, which was recognised as taking more time than standard ANTT. Having to stop to attend to another baby who may be “having a brady” (SSI11, NURS0610) was a frequently cited interruption, and nurses frequently reported having to stop to attend to another patient: One nurse recognises that the unit is “really bad” for interrupting each other, that it is an accepted way of working (SSI8, NURS0509). A Consultant also recalled being interrupted in the middle of inserting a central line, which was a source of tension. When asked if interruptions impact asepsis, one participant replied:

Theme	Sub-theme	Quotation	Commentary
		It's hard. It takes two people to do it, and we do always use two people to do it, but if you're working in a nursery that's got eight intensive care babies, and you've got four nurses, so theoretically you've got eight babies that each need a nurse at their bed space most of the time. You've only got four of you anyway, so you've got half the number of people you should have, and then you're taking another person out of that. The two people that should be looking after four babies, who are all critically ill, are both tied up slowly, carefully, making up fluids and then attaching them to the baby, and you can't stop in the middle of the process. Well, you can if there's an emergency. If you stop in the middle of the process, you have to wash and get a new pair of gloves, and a whole chunk of the process has to start again. If you do that, your trolley's lying around; the chance of somebody else touching it is high. Yes, if it's busy and we are trying to do fluids, it is challenging to give yourself the time to do it carefully and properly (SSI11, NURS0610)	Whilst the nurses felt that despite staffing being a challenge, they still always use two people to access central lines, the consequence of this was leaving work undone, resulting in some feeling 'nursing guilt'. Conversely the medical participants felt that poor staffing would be a reasonable reason to have a single person.
	Availability of resources	I think we need more clocks in the room. There's a clock missing in room three, so you need to be able to see a clock, and I just think that staff feel pressure to do things quickly (SSI7, NURS0618) Not being able to see a clock. I can think of plenty of places in the nursery that I can stand, and I can't see a clock, and I can't see my fob watch if my	Examples included not having access to clocks or appropriate hand scrub. This correlated with the participant in ORI11 who said he had never seen the "red stuff" (chlorhexidine) being used, though this is identified on the bundle checklist. Resources were not always stocked up such as dressing packs. These

Theme	Sub-theme	Quotation	Commentary
		hands are in an incubator, so I don't know how long it's been. I can imagine how long it's been, but I don't think many people imagine a minute correctly (SSI11, NURS0610) so finding the Hibiscrub is always a nuisance. We used to have it in every nursery in a pump on the wall. We don't have that any more, so I think that is a major issue in terms of new staff not asking for it, not realising they need it, I think that is a major issue (SSI3, DOC01) but the things that would slow us down, make us less likely to do something in a clean fashion, would for instance be there are no more wound-care packs in the cupboard. This needs to happen now, so I haven't got time to go and find another one, or we don't perceive that we have time to go and find another wound-care pack (SSI11, NURS0610) The dressing packs could have a better place to live! They don't really have a home, because when we set up how the nurseries are set up, we didn't use them. They're in completely different places in Room 3 and 4. I know must stuff is, but they are. They could probably do with being in the trolley, but there's so much stuff in the trolley, I don't think they'd fit unless we have a separate central line trolley that has only got the stuff we use for central lines (SSI11, NURS0610)	findings corroborate with the ORIs where participants were observed leaving the nurseries to collect equipment.
Environment		No, I don't think there are enough human hours. I'm fairly sure - I don't know, I haven't actually checked, but I'm sure there are enough gloves, aprons, longlines, wash, that sort of thing. There isn't enough space to have your	Incubators were described as a physical obstacle by one ANNP, and a Consultant recognised that whilst doctors may be very experienced in inserting central

Theme	Sub-theme	Quotation	Commentary
		trolley, actually have it clean and have it not bumped into 20 times while a longline is being put in. Yes, there's not enough people and there's not enough space (SSI11, NURS0610) Or disruptions when you're trying to do it, so because we don't have a separate treatment room or anything to make all the drugs up in, so then you're in the nursery and everybody's round about you and it's noisy and it's loud and there's distractions to doing things. (SSI1, NURS0617) Yes. I think we come from different places. Especially, I'm speaking as somebody who came from another country, so I know a lot of the equipment I was unfamiliar with, although, the line was pretty much the same, but all the connectors and everything else is different. We have babies inside incubators here, so coming from a hot country we don't have babies inside incubators, so learning to be sterile inside an incubator is like a big achievement. So it's not as easy as it looks. Well, I can do it with my eyes shut now, but it wasn't that way when I started (SSI15, DOC13)	lines, the process of doing this within an incubator may be unfamiliar. Portholes were identified as potential source of decontamination, providing triangulation with the ORIs. Space within the nurseries, and the traffic within this space, were all felt to be barriers to bundle implementation, again corroborating with the ORIs:

Appendix 30 Application of NPT constructs to this research study

Construct	Description	Sub-Constructs	Median Construct Scores for Survey 1, 2 & 3	Applied to the results of this study
Coherence	The sense making work actors do to operationalise new practices	**Differentiation:** Actors need to understand how new practices are different	1,1,1	Nurses can understand how the new practices are different from previous ones. They understand the importance of the new practices for reducing infections and standardising practice. Not all those inserting central lines see the difference to previous practice, nor do they see a second person as essential.
		Communal Specification: Actors work together to build a shared understanding of the aims, objectives and expected benefits of a set of practices	1,1,1	
		Individual Specification: Actors need to do things that will help them understand their specific tasks and responsibilities	1,1,1	
		Internalization: Understanding the value, benefits and importance of new practices	1,1,1	
Cognitive Participation	The relational work that actors do to build and sustain a community of practice around a new practice	**Initiation:** Are there key actors driving the new practices forward?	1,1,1	Nurses do not see their involvement in central line insertions as a legitimate part of their role. Medics do not see involvement in central line insertions as part of a nursing role. Work is described as role specific e.g. "Their work", "our work"
		Enrolment: Actors may need to reorganise themselves to collectively contribute to new practices	1,1,1	
		Legitimation: Actors need to believe it is right for them to be involved and that their contribution is valid	2,1,1	
		Activation: Actors need to collectively define the actions needed to sustain new practices	1,2,1	
Collection Action	The operational work that actors do to enact new practices.	**Interactional workability:** The work that actors do with each other, and artefacts, in order to operationalise them in everyday practice	1,1,1	The way in which some central line work is allocated is not always felt to be appropriate.

Construct	Description	Sub-Constructs	Median Construct Scores for Survey 1, 2 & 3	Applied to the results of this study
		Relational integration*: The knowledge work actors do to build accountability and confidence in practices and each other.	1,1,1	For example, some nurses do not believe the junior doctors are the most appropriate to be accessing central lines. Training and resource allocation were not always felt to be sufficient to enact the work. Guidelines for insertion were felt to be too long, and the insertion checklist was used *after* the procedure.
		Skill set workability*: The way in which work is allocated, which underpins the division of labour	0,1,1	
		Contextual integration*: Managing a set of practices through the allocation of different resources and protocols, policies and procedures.	1,1,1	
Reflexive Monitoring	The appraisal work that actors do to assess and understand the ways that a new set of practices affects them and others.	**Systemisation:** Actors seek to determine how effective and useful the new practices are for them and others.	1,1,1	Not all staff believed that the insertion bundle was appropriate for them or experienced colleagues. There was a lack of feedback on the impact of new practices on NICU infection rates. Actors informally evaluated the bundled practices, relying on experiences. The two-person technique was modified by actors, becoming an education and supervisory role.
		Communal appraisal : Actors work together formally or informally to evaluate the worth of new practices	1,1,1	
		Individual appraisal : Actors work experientially to appraise the effects of new practices on them and the context	1,1,1	
		Reconfiguration*: Appraisal work may lead to attempts by actors to modify practices.	1,1,1	
*Indicates results from two questions have been combined to provide single construct score. For example, the sub-construct of Relational Integration combines the responses from question 10 and 11 of the NoMAD survey				

Appendix 31 Future Programme of Bundle Development and Implementation

- The bundled technical interventions should be redesigned to ensure the bundle is simple, concise and based upon evidence. There should be de-implementation of AIPPs, with a re-focus on hub decontamination technique. Reassessing returning to standard ANTT (de-implementing Surgical ANTT) for accessing lines should also be considered-if other implementation strategies below are implemented to provide reinforcement. Current guidelines should be simplified and address areas of ambiguity in practice such as minimising access (changing fluids once per day, for each patient) and the role of the second person in insertion. Focus groups should engage all professional groups in bundle re-design.
- The insertion checklist should be re-designed, so it is simplified and separate from documentation of line position on the electronic patient record. It should be used by a member of staff not involved in the insertion process and should prompt the procedure to be stopped if asepsis is compromised. The person inserting the form should use the phrase “I expect you to stop me if…..” before commencing the procedure. The checklist should also specify the number of attempts permitted before escalation to a senior member of the team is expected. Visual aids should be provided on how to dress the central line.
- A daily nursing checklist to incorporate all aspects of central line care should be implemented, and checklists should require a signature by those completing them. Daily checklists and ward round forms should include prompts regarding the need for the central line, framed using the following phrase: “If we did not have a central line, would we put one in?”. Local guidance should be updated to include defined criteria for central line removal, and remove the need to keep the line in for an additional 24 hours after reaching “full feeds”.
- Comprehensive and regular multidisciplinary training should be developed, including short educational packages on avoidable infections and the evidence underpinning practice. Education should include parent stories and use clinical cases. There should be regular refresher sessions on all aspects of line care.
- A competency package for both central line insertions and ongoing central line care should be implemented. Training specific members of the MDT to perform or lead on specific aspects of central line management like dressing changes and accessing lines may help create a sense of ownership. For example, a central line access team, or a single designated team member on each shift who is

responsible, and accountable, for the process of scrubbing the hub at the point of attaching fluids.

- Infections should be renamed as avoidable and ensure this language is used consistently in training, educational resources, clinical aids/checklists and in any communication with staff including in clinical meetings. Champions should be enlisted across all professional roles, as avoidable infection ambassadors.
- A MDT should be established to tackle avoidable infections on the NICU and a named individual who has overall responsibility for this. The MDT should determine local goals and develop a system for monitoring avoidable infections on a day to day basis. This process should ensure that the MDT team are notified when a positive blood culture is obtained, with an individual allocated to undertake root cause analysis. These cases should be discussed at monthly avoidable infection meetings (open to all staff) and action plans for improvement made. Lessons learnt proformas should be used to monitor progress and promote further tailoring of the bundle. The weekly infectious diseases meeting should take place at the bedside.
- Reinforcement strategies should include positive reinforcement, such as studying cases where a patient with a central line did not develop an infection, promoting examples of good practice, celebrating successes when goals are met. Methods for feedback should be frequent and varied, including direct observation with individual feedback, the use of ultraviolet hand hygiene training, simulation, written materials, posters, and verbally in-person at handovers. The implementation of a central line insertion trolley may help provide easy access to resources and serve as a reminder of what is expected.
- Prospective and in-person audits should be performed twice weekly initially, with results presented monthly. Audits should include observations of clinical practice. Balance measures such as days of missed nutrition, or number of line-free days, should be included to assess for any unintended consequences associated with earlier line removal.
- Parents should also be educated and empowered to champion the prevention of avoidable infections. Parental experiences of infection prevention on the NICU should be sought and shared, and information leaflets on avoidable infections should be co-designed with parents. Parent stories should be used in educational materials.

- Additional human resources would be required to lead and support the implementation process. A nurse and a designated project lead should be employed to promote implementation.
- An evaluation of the bundle should be undertaken using surveys, unstructured observations, and qualitative interviews alongside patient outcome measures, to evaluate implementation success and test the conceptual model developed in this thesis. Observations should include broader aspects of central line care, such as flushing central lines and decision making around the timing of central line removal.

Appendix 32 Researcher Reflexivity

Reflection was facilitated using triangulated inquiry, from Rashid et al. (2019).

1.Myself:

What do I know? How do I know what I know? What shapes and has shaped my perspective? What do I do with what I have found?

As an ANNP, I am in a fairly unique position, that cross both medical and nursing professional boundaries. Whilst I do, of course, have a long history in the nursing profession, and my values, beliefs and attitudes are more aligned with the nursing profession, my role within a medical team means that I see both perspectives, have performed both jobs. Indeed, I know the challenges that come with both 'territories' and belong in both 'tribes'. It is hoped that this provides me with a degree of trustworthiness from both professions, reducing the risk of being overly 'biased' towards one profession. Certainly, I did not want to be seen as a nurse telling doctors what to do, or a nurse who had forgotten where she came from! What I hope I have achieved is a balanced and considered interpretation of the data, that instead of seeing 'tribes', instead recognises the challenges faced by both professions, as a result of a whole host of influencing factors, including how 'policy makers' or senior leaders contribute to the challenges faced by staff (such as through unclear policies, lack of training provision e.t.c.). Ultimately, all staff want to do the right thing; we have a duty to our staff to make that easy for them to achieve.

The broad issue of being an outlier for late-onset sepsis rates was introduced to me by a consultant colleague. Infection prevention was not something that had previously been "my thing", to be honest, but as I read more and more around the literature, and read about successes in other NICUs, the disparity between what I was reading, and clinical practice, felt like it got bigger and bigger. Continuing to work in a clinical role became increasingly hard at times, for example, when babies died with a *Staphylococcus aureus* infection, or *Enterobacter* sepsis not believed to be related to any abdominal pathology. This has, therefore, become an increasingly emotive topic for me. I quite passionately believe that being admitted to one hospital should not mean patients are more likely to get a late-onset sepsis infection compared to if you had been admitted to a different hospital. How would I feel if that was my child? I think therefore, there was always a risk of being overly critical in the interpretation of the data, and was something that I frequently revisited.

I worked clinically during the periods of data collection, though the clinical hours were significantly reduced. However, I cannot discount that my presence may have influenced

behaviour. For example, there were times when I would insert a central line. Whilst I would follow the bundled practices, including wearing a hat and mask, I would also sometimes have a nurse as an assistant. Whilst this is at odds with what was observed in the ORIs, actually ANNP colleagues also referred to using a nurse or a student nurse, as a second person, so in that way what I was doing was not particularly different to other ANNP colleagues. Of course, I also used the checklist retrospectively, completing it after insertion!! Indeed, I am 'native', part of the social norm and "the way it is done here". Having collected data for this research study, and analysed it, it prompted me to reflect on my own practice in a way that I have not done before, considering the reasons why I do not use the "intubation huddle" checklist, for example. As such it has prompted reflection on how I, as leader, contribute to the culture or practices on the NICU. Indeed, I found that staff would actively seek me out to discuss central line practices, share how their experiences of working in other units, and offered suggestions as to what the NICU might consider doing differently. After data collection had been completed, staff continued to seek out my opinions on practices they felt were poor, and still continue to discuss practice related issues related to infection prevention, across both professions.

As an Advanced Neonatal Nurse Practitioner (ANNP) I have knowledge that crosses the medical-nursing boundary, and as such am a 'member' of the both the nursing and medical teams. This puts me in a unique position having experience of both professions, as well as being viewed as part of both professions by others. Indeed, working as an ANNP on the unit being studied, had both advantages and disadvantages. I already had a pre-established rapport with the staff, though there was also power-dynamics which concerned me regarding interviewing senior members of the clinical team. Whilst I am sure that this pre-established rapport helped in facilitating and crafting the interviews, equally sometimes I would perhaps be too informal, and the tendency to respond encouragingly to participants was something I had to be really aware of!!! I had to work really hard at keeping myself neutral, not to unwittingly lead or encourage participants, and the process of crafting the interviews was often exhausting!! With practice, however, this did get easier, as I developed my interview style and technique. As an insider, staff knew to some extent that I had insight into what 'normal' practice looked like, so attempts to 'act up' for the researcher were likely to be recognised by me. I also felt a strong moral obligation to do right by those that participated. Staff were willing to give up their time to participate, and seemingly keen to share their experiences honestly. I felt, and still feel, a strong moral obligation therefore to reflect their experiences accurately and honestly. It was really important to me that I checked back with staff regarding my interpretation of what they had told me and presenting these findings at local meetings was a really helpful way of gauging this. I feel as though staff have put their trust in me, and I hope therefore that what I have found will be of use to them to improve patient care.

That being said, I did, at times, find myself being overly critical in my analysis, something that is documented in the literature when researching in one's own workplace. Checking in with supervisors for objective reviews of the data was helpful in mitigating this. In fact, multiple iterations of data analysis helped, as I found I came almost "full circle" back to my initial interpretations of the data, having explored and re-analysed, and explored and re-analysed through several stages. Having to raise concerns about poor practice was also hard, but clearly were not unique to individual participants, and as I would discover later on in the data collection process, represented the broader challenges faced in this particular NICU relating to social norms, how practices were learnt and how they were monitored. In fact, professional conversations with nurses and doctors from other NICUs suggested that some of the professional cultural influences highlighted in this study were not unique to the local NICU. Tensions relating to guidelines and professional autonomy are not new, and the desire for professional autonomy has been criticised as undermining guideline adherence (Runnacles et al., 2018).

Whilst it could be suggested that, as a researcher in one's own workplace, I would perhaps have certain professional biases, or that interpretations might be lacking in objectivity, I instead found that there were many aspect of central line practice that I simply had not considered until I actually took a step back, and set myself in a position that was almost 'outside' of the unit. This was almost like a reverse of the traditional ethnographic process, where I had to step outside of it in order to ***really see it***, rather than trying to go native. For example, having performed these procedures regularly myself until I started data collection, I had never quite appreciated the complexity of the tasks, the cognitive load that was required or the complexity of some the seemingly "normal everyday" decisions.

Indeed, performing this research challenged some of my own pre-conceived notions. Rightly or wrongly, before commencing data collection, I thought that staffing would be used as an excuse and that, staffing is not an easy or quick solution- we simply cannot get more staff as a solution, its not that easy. However, through undertaking this research the complexities and challenges for staff undertaking implementation work, the effort that is required and the unseen work that is done in order to make these practices work in challenging context, made me realise how difficult we, as 'policy makers' or senior leaders sometimes make the work. Through doing this research, my own beliefs, attitudes and values have changed, realising that we need to make the work easier for staff. This refers not just to the work of central line care, but making it easier to access resources, making it acceptable to challenge each other, and to "be the change you want to see". The fact that staff were actively asking for feedback made me reflect on how we train and educate both medical and nursing staff in clinical practice. Whilst staff may be wary of giving direct feedback, actually staff need this in order to feel confident in their practice. After data

collection and analysis for this study had been completed, many professional conversations (not instigated by me) highlighted that junior doctors find it hard to make decisions, go home, and not ever know if what they did was right. Moving forward, we, as senior nurse leaders, need to find ways of improving reinforcement, feedback, and supervision in practice. Emotional burnout is becoming an increasing concern for healthcare professionals and working in a high stake setting like the neonatal unit, without knowing if you are doing the right thing, must be hard for staff.

In fact, as data analysis continued, and I became 'immersed' in it, it was actually really hard for me to read about the tensions between colleagues. There were times it seemed overwhelming, reading about the feelings of nursing guilt, colleagues feeling like a bad nurse, and nurses nagging medical colleagues and then giving up. It was important, at these times, to focus on how these findings could improve patient care. It was also useful to speak to colleagues, peers, and researchers from other NICUs about their experiences, realising that these deep-rooted cultural components were not unique to this setting. Not only did this help during the difficult periods of data analysis, but it also highlighted the generalisability of the findings outside of the local setting.

In fact, sometimes I would go into work for clinical shifts, and see these tensions playing out in front of me. As an ANNP, with a background that is firmly situated in the nursing sphere, yet now working entirely within the medical sphere, these inter-professions were hard. And yet this work has helped me navigate these better in practice; more recently, I have able to provide pastoral support to nurses who might be feeling frustrated with how situations have panned out, and yet recognising that there are deep rooted professional cultures that are much bigger than any single individual, can help to depersonalise conflict. In fact, many of the tensions seen in this these have been seen on social media, with doctors 'tweeting' about being threatened with incident forms if they do not follow guidelines, for example. Indeed, a "them" versus "us" rhetoric is unhelpful and healthcare systems, and healthcare education, needs to try and remove some of these tribal narratives. Indeed, the results of research study support the argument that a unified approach and collective responsibility is needed to improve patient care.

What now? What to do with what I have learnt?

I cannot believe how much I have changed since starting on this journey, how much my own perspectives on the organisation and quality of care have evolved. The results of this research study have generated knowledge that can be used to create real, meaningful changes in practice to benefit not just our patients, but also improving the working environment for our staff. It is clear that there are aspects of the local culture that need to change as well as the technical central line practices, and this is likely to be hard. Creating

a psychological safe environment is key to being able to improve patient safety. I hope that in my role as an University lecturer, I have a deeper insight into the cultural complexities of healthcare (as well as research methods!) and so these insights can be used to engage in deeper discussions with students. In fact, frequently there are discussions in class that are reminiscent of the findings of this research study, and the ability to facilitate and navigate these classroom discussions is an added benefit of the journey I have been on during the research process.

Since data analysis has been completed, I have been contacted by 5 UK NICUs to discuss ways in which CLABSIS can be reduced their NICUs, and so this work has already been able to start contributing to improving neonatal care more widely in the UK. I am interested to hear back from these units, to see what they have implemented and how they have done it, and what impact these changes have had on their CLABSI rates. Being able to identify that the work that needs to be done is so much more than introducing a “bundle” or a “checklist” I think will be useful for units wanting to change their practice in the future. Again, professional conversations during discussion with some of these UK units highlights that the findings in this research study are not at all unique to this NICU, and as such represent challenges faced more broadly across UK NICUs.

List of References

Aceti, A., Gori, D., Barone, G., Callegari, M. L., Di Mauro, A., Fantini, M. P., Indrio, F., Maggio, L., Meneghin, F. and Morelli, L. (2015) 'Probiotics for prevention of necrotizing enterocolitis in preterm infants: systematic review and meta-analysis', *Italian Journal of Pediatrics,* 41(1), pp. 1-20.

Adams-Chapman, I. (2012) 'Long-Term Impact of Infection on the Preterm Neonate', *Seminars in Perinatology,* 36(6), pp. 462-470.

Adams, W. C. (2015) 'Conducting Semi-Structured Interviews', *Handbook of Practical Program Evaluation*, pp. 492-505.

Ainsworth, S. and McGuire, W. (2015) 'Percutaneous central venous catheters versus peripheral cannulae for delivery of parenteral nutrition in neonates', *Cochrane Database of Systematic Reviews,* (10).

Almeida, C. C. D., Pissarra da Silva, S. M. S., Flor de Lima Caldas de Oliveira, F. S. D. and Guimaraes Pereira Areias, M. H. F. (2016) 'Nosocomial sepsis: evaluation of the efficacy of preventive measures in a level-III neonatal intensive care unit', *Journal of Maternal-Fetal and Neonatal Medicine*, pp. 1-6.

Arnts, I. J. J., Schrijvers, N. M., Van Der Flier, M., Groenewoud, J. M. M., Antonius, T. and Liem, K. D. (2015) 'Central line bloodstream infections can be reduced in newborn infants using the modified Seldinger technique and care bundles of preventative measures', *Acta Paediatrica, International Journal of Paediatrics,* 104(4), pp. e152-e157.

Backes, C. H., Söderström, F., Ågren, J., Sindelar, R., Bartlett, C. W., Rivera, B. K., Mitchell, C. C., Frey, H. A., Shepherd, E. G. and Nelin, L. D. (2019) 'Outcomes following a comprehensive versus a selective approach for infants born at 22 weeks of gestation', *Journal of Perinatology,* 39(1), pp. 39-47.

BadgerNet Neonatal 2020. Edinburgh: Clevermed.

Balain, M., Oddie, S. J. and McGuire, W. (2015) 'Antimicrobial-impregnated central venous catheters for prevention of catheter-related bloodstream infection in newborn infants', *Cochrane Database of Systematic Reviews,* (9).

Balla, K. C., Rao, S. P., Arul, C., Shashidhar, A., Prashantha, Y., Nagaraj, S. and Suresh, G. (2018) 'Decreasing central line-associated bloodstream infections through quality improvement initiative', *Indian Pediatrics,* 55(9), pp. 753-756.

Bandura, A. (1998) 'Health promotion from the perspective of social cognitive theory', *Psychology & Health,* 13(4), pp. 623-649.

Bannatyne, M., Smith, J., Panda, M., Abdel-Latif, M. E. and Chaudhari, T. (2018) 'Retrospective cohort analysis of central line associated blood stream infection following introduction of a central line bundle in a neonatal intensive care unit', *International Journal of Pediatrics,* 2018.

Bates, P. (2014) 'Context is Everything', *Perspectives on Context: A selection of essays considering the role of context in successful quality improvement*. London: Health Foundation, pp. 1-30.

Bauer, M. S., Damschroder, L., Hagedorn, H., Smith, J. and Kilbourne, A. M. (2015) 'An introduction to implementation science for the non-specialist', *BMC Psychology,* 3(1), pp. 32.

Bergold, J. and Thomas, S. (2012) ' Participatory Research Methods: A Methodological Approach in Motion', *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research,* 13(1).

Bergström, A., Ehrenberg, A., Eldh, A. C., Graham, I. D., Gustafsson, K., Harvey, G., Hunter, S., Kitson, A., Rycroft-Malone, J. and Wallin, L. (2020) 'The use of the PARIHS framework in implementation research and practice—a citation analysis of the literature', *Implementation Science,* 15(1), pp. 68.

Bhargava, V., George, L., Malloy, M. and Fonseca, R. (2018) 'The Role of a Single Dose of Vancomycin in Reducing Clinical Sepsis in Premature Infants Prior to Removal of Peripherally Inserted Central Catheter: A Retrospective Study', *American Journal of Perinatology,* 35(10), pp. 990-993.

Bion, J., Richardson, A., Hibbert, P., Beer, J., Abrusci, T., McCutcheon, M., Cassidy, J., Eddleston, J., Gunning, K. and Bellingan, G. (2013) ''Matching Michigan': a 2-year stepped interventional programme to minimise central venous catheter-blood stream infections in intensive care units in England', *BMJ Quality & Safety,* 22(2), pp. 110-123.

Bizzarro, M. J., Sabo, B., Noonan, M., Bonfiglio, M.-P., Northrup, V. and Diefenbach, K. (2010) 'A quality improvement initiative to reduce central line-associated bloodstream infections in a neonatal intensive care unit', *Infection Control And Hospital Epidemiology,* 31(3), pp. 241-248.

Björkman, L. and Ohlin, A. (2015) 'Scrubbing the hub of intravenous catheters with an alcohol wipe for 15 sec reduced neonatal sepsis', *Acta Paediatrica,* 104(3), pp. 232-236.

BLISS (2020) *Neonatal Care Statistics*. London: BLISS. Available at: https://www.bliss.org.uk/research-campaigns/neonatal-care-statistics (Accessed: 30th December 2020 2020).

Borgert, M. J., Goossens, A. and Dongelmans, D. A. (2015) 'What are effective strategies for the implementation of care bundles on ICUs: a systematic review', *Implementation Science,* 10(1), pp. 119.

Bosk, C. L., Dixon-Woods, M., Goeschel, C. A. and Pronovost, P. J. (2009) 'Reality check for checklists', *The Lancet,* 374(9688), pp. 444-445.

Bowen, J. R., Callander, I., Richards, R. and Lindrea, K. B. (2016) 'Decreasing infection in neonatal intensive care units through quality improvement', *Journal of Paediatrics and Child Health,* 52, pp. 79.

Boyle, D. A. and Keep, D. J. (2018) 'Clinical audit does not work, is quality improvement any better?', *British Journal of Hospital Medicine,* 79(9), pp. 508-510.

Braithwaite, J. (2018) 'Changing how we think about healthcare improvement', *British Medical Journal* 361.

Braithwaite, J., Churruca, K., Ellis, L. A., Long, J., Clay-Williams, R., Damen, N., Herkes, J., Pomare, C. and Ludlow, K. (2017) *Complexity science in healthcare*, Sydney: Australian Institute of Health Innovation, Macquarie University.

Braun, V. and Clarke, V. (2013) *Successful qualitative research: A practical guide for beginners.* London: Sage.

Bucknall, T. and Aitken, L. (2015) 'Think Aloud Technique', in *The Research Process in Nursing*. pp. 442-454 [Online]. Version.

Burhouse, A., Lea, C., Ray, S., Bailey, H., Davies, R., Harding, H., Howard, R., Jordan, S., Menzies, N., White, S., Phillips, K. and Luyt, K. (2017) 'Preventing cerebral palsy in preterm labour: a multiorganisational quality improvement approach to the adoption and spread of magnesium sulphate for neuroprotection', *BMJ Open Quality,* 6(2), pp. e000189.

Burke, C., Jakub, K. and Kellar, I. (2020) 'Adherence to the central line bundle in intensive care: An integrative review', *American Journal of Infection Control*.

Burns, N. and Grove, S. K. (2010) *Understanding nursing research-eBook: Building an Evidence-Based Practice.* Missouri Elsevier

Cabana, M. D., Rand, C. S., Powe, N. R., Wu, A. W., Wilson, M. H., Abboud, P.-A. C. and Rubin, H. R. (1999) 'Why don't physicians follow clinical practice guidelines?: A framework for improvement', *JAMA,* 282(15), pp. 1458-1465.

Cailes, B., Kortsalioudaki, C., Buttery, J., Pattnayak, S., Greenough, A., Matthes, J., Russell, A. B., Kennea, N. and Heath, P. T. (2018) 'Epidemiology of UK neonatal infections: the neonIN infection surveillance network', *Archives of Disease in Childhood-Fetal and Neonatal Edition,* 103(6), pp. F547-F553.

Cantey, J. B. and Milstone, A. M. (2015) 'Bloodstream infections: epidemiology and resistance', *Clinics in Perinatology,* 42(1), pp. 1-16.

Caris, M. G., Labuschagne, H. A., Dekker, M., Kramer, M. H., van Agtmael, M. A. and Vandenbroucke-Grauls, C. M. (2018) 'Nudging to improve hand hygiene', *Journal of Hospital Infection,* 98(4), pp. 352-358.

Caspari, L., Epstein, E., Blackman, A., Jin, L. and Kaufman, D. A. (2017) 'Human factors related to time-dependent infection control measures: “Scrub the hub” for venous catheters and feeding tubes', *American Journal of Infection Control,* 45(6), pp. 648-651.

CDC (2016) *National and State Healthcare-Associated Infections (HAI) Progress Report* US: Department of Health and Human Services.

Ceballos, K., Waterman, K., Hulett, T. and Makic, M. B. F. (2013) 'Nurse-driven quality improvement interventions to reduce hospital-acquired infection in the NICU', *Advances in Neonatal Care,* 13(3), pp. 154-163.

Chandonnet, C. J., Kahlon, P. S., Rachh, P., DeGrazia, M., DeWitt, E. C., Flaherty, K. A., Spigel, N., Packard, S., Casey, D., Rachwal, C. and Agrawal, P. B. (2013) 'Health care failure mode and effect analysis to reduce NICU line-associated bloodstream infections', *Pediatrics,* 131(6), pp. e1961-e1969.

Chepkin, S., Prince, S., Johnston, T., Boby, T., Neves, M., et al (2019) *Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: First Annual Report.* Oxford: National Perinatal Epidemiology Unit.

Chien, L.-Y., Macnab, Y., Aziz, K., Andrews, W., Mcmillan, D. D., Lee, S. K. and Network, C. N. (2002) 'Variations in central venous catheter-related infection risks among Canadian neonatal intensive care units', *The Pediatric Infectious Disease Journal,* 21(6), pp. 505-511.

Chinn, C. A., Barzilai, S. and Duncan, R. G. (2020) 'Education for a “Post-Truth” World: New Directions for Research and Practice', *Educational Researcher,* 50(1), pp. 51-60.

Clack, L., Zingg, W., Saint, S., Casillas, A., Touveneau, S., da Liberdade Jantarada, F., Willi, U., van der Kooi, T., Damschroder, L. J. and Forman, J. H. (2018) 'Implementing infection prevention practices across European hospitals: an in-depth qualitative assessment', *BMJ Quality & Safety,* 27(10), pp. 771-780.

Clarke, D. J., Godfrey, M., Hawkins, R., Sadler, E., Harding, G., Forster, A., McKevitt, C., Dickerson, J. and Farrin, A. (2013) 'Implementing a training intervention to support caregivers after stroke: a process evaluation examining the initiation and embedding of programme change', *Implementation Science,* 8(1), pp. 96.

Clarke, P., Craig, J. V., Wain, J., Tremlett, C., Linsell, L., Bowler, U., Juszczak, E. and Heath, P. T. (2019) 'Safety and efficacy of 2% chlorhexidine gluconate aqueous versus 2% chlorhexidine gluconate in 70% isopropyl alcohol for skin disinfection prior to percutaneous central venous catheter insertion in preterm neonates: the ARCTIC randomised-controlled feasibility trial protocol', *BMJ Open,* 9(2), pp. e028022.

Conner, M. and Norman, P. (2017) 'Health behaviour: Current issues and challenges', *Psychology & Health,* 32(8), pp. 895-906.

Costeloe, K., Bowler, U., Brocklehurst, P., Hardy, P., Heal, P., Juszczak, E., King, A., Panton, N., Stacey, F., Whiley, A., Wilks, M. and Millar, M. R. (2016) 'A randomised controlled trial of the probiotic Bifidobacterium breve BBG-001 in preterm babies to prevent sepsis, necrotising enterocolitis and death: the Probiotics in Preterm infantS (PiPS) trial', *Health Technology Assessment,* 20(66), pp. 1-+.

Costeloe, K. L., Hennessy, E. M., Haider, S., Stacey, F., Marlow, N. and Draper, E. S. (2012) 'Short term outcomes after extreme preterm birth in England: comparison of two birth cohorts in 1995 and 2006 (the EPICure studies)', *British Medical Journal* 345.

Cowie, J., Nicoll, A., Dimova, E. D., Campbell, P. and Duncan, E. A. (2020) 'The barriers and facilitators influencing the sustainability of hospital-based interventions: a systematic review', *BMC Health Services Research,* 20(1), pp. 588.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M. (2008) 'Developing and evaluating complex interventions: the new Medical Research Council guidance', *British Medical Journal* 337.

Craig, P. and Petticrew, M. (2013) 'Developing and evaluating complex interventions: reflections on the 2008 MRC guidance', *International Journal of Nursing Studies,* 50(5), pp. 585-587.

Cresswell, J. W. 2016. Advances in Mixed Method Research. *In:* Methodology, I.I.f.Q. (ed.) *Advanced in Mixed Methods Research Webinar.* Alberta.

Creswell, J. W. (2014) *A Concise Introduction to Mixed Methods Research.* London: SAGE Publications.

Creswell, J. W. and Clark, V. L. P. (2011) *Designing and Conducting Mixed Methods Research.* London: SAGE Publications.

Crowe, S., Cresswell, K., Robertson, A., Huby, G., Avery, A. and Sheikh, A. (2011) 'The case study approach', *BMC Medical Research Methodology,* 11(1), pp. 100.

Cupit, C., Mackintosh, N. and Armstrong, N. (2018) 'Using ethnography to study improving healthcare: reflections on the 'ethnographic' label', *BMJ Quality & Safety,* 27, pp. 258-260.

Dahan, M., O'Donnell, S., Hebert, J., Gonzales, M., Lee, B., Chandran, A. U., Woolsey, S., Escoredo, S., Chinnery, H. and Quach, C. (2016) 'CLABSI risk factors in the NICU: potential for prevention: a PICNIC study', *Infection Control & Hospital epidemiology,* 37(12), pp. 1446-1452.

Darbyshire, P. and Thompson, D. (2018) 'Gosport must be a tipping point for professional hierarchies in healthcare—an essay by Philip Darbyshire and David Thompson', *British Medical Journal* 363, pp. k4270.

Datta, J. and Petticrew, M. (2013) 'Challenges to evaluating complex interventions: a content analysis of published papers', *BMC Public Health,* 13(1), pp. 568.

Davis, J. W., Odd, D., Jary, S. and Luyt, K. (2016) 'The impact of a sepsis quality improvement project on neurodisability rates in very low birthweight infants', *Archives of Disease in Childhood: Fetal and Neonatal Edition,* 101(6), pp. F562-F564.

de Silva, D., Foundation, T.H. (2015) *Whats Getting in the Way: Barriers to improvement in the NHS.* London.

De Souza, D. E. (2013) 'Elaborating the Context-Mechanism-Outcome configuration (CMOc) in realist evaluation: A critical realist perspective', *Evaluation,* 19(2), pp. 141-154.

Degraeuwe, P. (2018) 'Research on infection prevention bundles: hidden risk of bias?', *Archives of Disease in Childhood-Fetal and Neonatal Edition*.

Dixon-Woods, M. (2003) 'What can ethnography do for quality and safety in health care?', *BMJ Quality & Safety,* 12(5), pp. 326-327.

Dixon-Woods, M. (2014) *The problem of context in quality improvement*, London: Health Foundation.

Dixon-Woods, M. (2016) 'What is the role of individual accountability in patient safety? A multi-site ethnographic study Emma-Louise Aveling, Michael Parker and', *The Sociology of Healthcare Safety and Quality*, pp. 36.

Dixon-Woods, M. (2019) 'How to improve healthcare improvement—an essay by Mary Dixon-Woods', *British Medical Journal* 367(l5514).

Dixon-Woods, M., Bosk, C. L., Aveling, E. L., Goeschel, C. A. and Pronovost, P. J. (2011) 'Explaining Michigan: developing an ex post theory of a quality improvement program', *Milbank Q,* 89(2), pp. 167-205.

Dixon-Woods, M., Leslie, M., Bion, J. and Tarrant, C. (2012) 'What counts? An ethnographic study of infection data reported to a patient safety program', *The Milbank Quarterly,* 90(3), pp. 548-591.

Dixon-Woods, M., Leslie, M., Tarrant, C. and Bion, J. (2013) 'Explaining Matching Michigan: an ethnographic study of a patient safety program', *Implementation Science,* 8(1), pp. 70.

Dixon-Woods, M. and Martin, G. P. (2016) 'Does quality improvement improve quality?', *Future Hospital Journal,* 3(3), pp. 191-194.

Dixon-Woods, M. and Shojania, K. G. (2016) 'Ethnography as a methodological descriptor: the editors' reply', *BMJ Quality & Safety,* 25(7), pp. 555-556.

DOH (2014) *The NHS Outcomes Framework 2015/16.* London: HMSO.

DOH, Health, D.o. (2019) *Tackling Antimicrobial Resistance 2019–2024.* London: HMSO.

Donovan, E. F., Sparling, K., Lake, M. R., Narendran, V., Schibler, K., Haberman, B., Rose, B. and Meinzen-Derr, J. (2013) 'The investment case for preventing NICU-associated infections', *American Journal of Perinatology,* 30(3), pp. 179-184.

Dorling, J., Abbott, J., Berrington, J., Bosiak, B., Bowler, U., Boyle, E., Embleton, N., Hewer, O., Johnson, S., Juszczak, E., Leaf, A., Linsell, L., McCormick, K., McGuire, W., Omar, O., Partlett, C., Patel, M., Roberts, T., Stenson, B. and Townend, J. (2019) 'Controlled Trial of Two Incremental Milk-Feeding Rates in Preterm Infants', *New England Journal of Medicine,* 381(15), pp. 1434-1443.

Dyson, S. and Brown, B. (2006) *Social Theory and Applied Health Research.* McGraw-Hill Education.

Eccles, M. P., Hrisos, S., Francis, J., Kaner, E. F., Dickinson, H. O., Beyer, F. and Johnston, M. (2006) 'Do self- reported intentions predict clinicians' behaviour: a systematic review', *Implementation Science,* 1, pp. 28.

Edwards, J. D., Herzig, C. T., Liu, H., Pogorzelska-Maziarz, M., Zachariah, P., Dick, A. W., Saiman, L., Stone, P. W. and Furuya, E. Y. (2015) 'Central line–associated blood stream infections in pediatric intensive care units: Longitudinal trends and compliance with bundle strategies', *American Journal of Infection Control,* 43(5), pp. 489-493.

EFCNI (2019) *European Standards of Care for Newborn Health Toolkit.* Munich: European Foundation for Care of the Newborn Infant.

Elwyn, G., Wieringa, S. and Greenhalgh, T. (2016) 'Clinical encounters in the post-guidelines era', *British Medical Journal* 353, pp. i3200.

England, N. (2015) *Patient Safety Alert: Supporting the introduction of the National Safety Standards for Invasive Procedures.* London: NHS England.

EPOC (2015) *EPOC Taxonomy*. Available at: epoc.cochrane.org/epoc-taxonomy (Accessed: 31st December 2020).

Erdei, C., McAvoy, L. L., Gupta, M., Pereira, S. and McGowan, E. C. (2015) 'Is zero central line-associated bloodstream infection rate sustainable? A 5-year perspective', *Pediatrics,* 135(6), pp. e1485-e1493.

European Centre For Disease Control (2018) *Incidence and attributable mortality of*

healthcare-associated infections in intensive care units in Europe, 2008-2012. Stockholm: ECDC.

Finch, T. 2018. *RE: NoMAD Survey.* Type to Payne, V.

Finch, T. L., Girling, M., May, C. R., Mair, F. S., Murray, E., Treweek, S., McColl, E., Steen, I. N., Cook, C. and Vernazza, C. R. (2018) 'Improving the normalization of complex interventions: part 2-validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT)', *BMC Medical Research Methodology,* 18(1), pp. 135.

Finch, T. L., Mair, F. S., O'Donnell, C., Murray, E. and May, C. R. (2012) 'From theory to'measurement'in complex interventions: methodological lessons from the development of an e-health normalisation instrument', *BMC Medical Research Methodology,* 12(1), pp. 69.

Fisher, D., Cochran, K. M., Provost, L. P., Patterson, J., Bristol, T., Metzguer, K., Smith, B., Testoni, D. and McCaffrey, M. J. (2013) 'Reducing central line-associated bloodstream infections in North Carolina NICUs', *Pediatrics,* 132(6), pp. e1664-e1671.

Flidel-Rimon, O., Guri, A., Levi, D., Ciobotaro, P., Oved, M. and Shinwell, E. S. (2019) 'Reduction of hospital-acquired infections in the neonatal intensive care unit: A long-term commitment', *American Journal of Infection Control,* 47(8), pp. 1002-1005.

Folgori, L., Bielicki, J. and Sharland, M. (2013) 'A systematic review of strategies for reporting of neonatal hospital-acquired bloodstream infections', *Archives of Disease in Childhood: Fetal and Neonatal Edition,* 98(6), pp. 518-523.

Foy, R., Skrypak, M., Alderson, S., Ivers, N. M., McInerney, B., Stoddart, J., Ingham, J. and Keenan, D. (2020) 'Revitalising audit and feedback to improve patient care', *British Medical Journal* 368.

Fraser, C., Harron, K., Dalton, L., Gilbert, R. and Oddie, S. J. (2018) 'Variation in infection prevention practices for peripherally inserted central venous catheters: A survey of neonatal units in England and Wales', *PLoS One,* 13(11), pp. e0204894.

French, R., Rayner, C, Rees, G, Rumbles, S. (2011) *Organizational behaviour.* 2nd edn. Chichester: Wiley.

Gabbay, J. and Le May, A. (2004) 'Evidence based guidelines or collectively constructed “mindlines?” Ethnographic study of knowledge management in primary care', *British Medical Journal* 329(7473), pp. 1013.

Gabbay, J. and le May, A. (2016) 'Mindlines: making sense of evidence in practice', *British Journal of General Practice,* 66(649), pp. 402-403.

García González, A., Leante Castellanos, J. L., Fuentes Gutiérrez, C., Lloreda García, J. M., Fernández Fructuoso, J. R., Gómez Santos, E. and García González, V. (2017) 'Five steps to decreasing nosocomial infections in very preterm newborns: A quasi-experimental study', *Anales de Pediatría (English Edition),* 87(1), pp. 26-33.

García, H., Romano-Carro, B., Miranda-Novales, G., González-Cabello, H. J. and Núñez-Enríquez, J. C. (2019) 'Risk factors for central line-associated bloodstream infection in critically ill neonates', *The Indian Journal of Pediatrics,* 86(4), pp. 340-346.

Garg, A. X., Hackam, D. and Tonelli, M. (2008) 'Systematic review and meta-analysis: when one study is just not enough', *Clinical Journal of the American Society of Nephrology,* 3(1), pp. 253-60.

Gaube, S., Fischer, P. and Lermer, E. (2021) 'Hand(y) hygiene insights: Applying three theoretical models to investigate hospital patients' and visitors' hand hygiene behavior', *PLOS ONE,* 16(1), pp. e0245543.

Gesser-Edelsburg, A., Cohen, R., Halavi, A. M., Zemach, M., van Heerden, P. V., Sviri, S., Benenson, S., Trahtemberg, U., Orenbuch-Harroch, E. and Lowenstein, L. (2018) 'Beyond the hospital infection control guidelines: a qualitative study using positive deviance to characterize gray areas and to achieve efficacy and clarity in the prevention of healthcare-associated infections', *Antimicrobial Resistance & Infection Control,* 7(1), pp. 1-10.

Gilbert, R., Brown, M., Rainford, N., Donohue, C., Fraser, C., Sinha, A., Dorling, J., Gray, J., McGuire, W. and Gamble, C. (2019) 'Antimicrobial-Impregnated central venous catheters for prevention of neonatal bloodstream infection (prevail): an open-label, parallel-group, pragmatic, randomised controlled trial', *The Lancet Child & Adolescent Health,* 3(6), pp. 381-390.

Gillham, B. (2000) *Case Study Research Methods.* London: Continuum.

Gokce, I. K., Kutman, H. G. K., Uras, N., Canpolat, F. E., Dursun, Y. and Oguz, S. S. (2018) 'Successful implementation of a bundle strategy to prevent ventilator-associated pneumonia in a neonatal intensive care unit', *Journal of Tropical Pediatrics,* 64(3), pp. 183-188.

Gominet, M., Compain, F., Beloin, C. and Lebeaux, D. (2017) 'Central venous catheters and biofilms: where do we stand in 2017?', *Apmis Journal of Pathology, Microbiology and Immunology,* 125(4), pp. 365-375.

Gonzales, R., Handley, M. A., Ackerman, S. and O'Sullivan, P. S. (2012) 'A framework for training health professionals in implementation and dissemination science', *Academic Medicine,* 87(3), pp. 271-278.

Gould, D., Chudleigh, J., Purssell, E., Hawker, C., Gaze, S., James, D., Lynch, M., Pope, N. and Drey, N. (2017) 'Survey to explore understanding of the principles of aseptic technique: Qualitative content analysis with descriptive analysis of confidence and training', *American Journal of Infection Control,* 46.

Green, B., Oeppen, R., Smith, D. a. and Brennan, P. (2017) 'Challenging hierarchy in healthcare teams–ways to flatten gradients to improve teamwork and patient care', *British Journal of Oral and Maxillofacial Surgery,* 55(5), pp. 449-453.

Greenberg, R. G., Cochran, K. M., Smith, P. B., Edson, B. S., Schulman, J., Lee, H. C., Govindaswami, B., Pantoja, A., Hardy, D. and Curran, J. (2015) 'Effect of catheter dwell

time on risk of central line–associated bloodstream infection in infants', *Pediatrics,* 136(6), pp. 1080-1086.

Greenhalgh, T. (2020) 'Will COVID-19 be evidence-based medicine's nemesis?', *PLOS Medicine,* 17(6), pp. e1003266.

Greenhalgh, T., Annandale, E., Ashcroft, R., Barlow, J., Black, N., Bleakley, A., Boaden, R., Braithwaite, J., Britten, N. and Carnevale, F. (2016) 'An open letter to The BMJ editors on qualitative research', *British Medical Journal* 352.

Greenhalgh, T., Howick, J. and Maskrey, N. (2014) 'Evidence based medicine: a movement in crisis?', *British Medical Journal* 348.

Greenhalgh, T. and Papoutsi, C. (2018) 'Studying complexity in health services research: desperately seeking an overdue paradigm shift', *BMC Medicine,* 16(1), pp. 95.

Greenhalgh, T. and Swinglehurst, D. (2011) 'Studying technology use as social practice: the untapped potential of ethnography', *BMC Medicine,* 9(1), pp. 45.

Grimshaw, J. M., Eccles, M. P., Lavis, J. N., Hill, S. J. and Squires, J. E. (2012) 'Knowledge translation of research findings', *Implementation Science,* 7(1), pp. 50.

Grout, J. R. and Toussaint, J. S. (2010) 'Mistake-proofing healthcare: Why stopping processes may be a good start', *Business Horizons,* 53(2), pp. 149-156.

Guba, E. G. and Lincoln, Y. S. (1982) 'Epistemological and methodological bases of naturalistic inquiry', *Educational Communication and Technology; A Journal of Theory, Research, and Development,* 30(4), pp. 233-252.

Guest, G., Namey, E. and Mitchell, M. (2013) *Collecting Qualitative Data: A Field Manual for Applied Research.*

Guest, J. F., Keating, T., Gould, D. and Wigglesworth, N. (2020) 'Modelling the annual NHS costs and outcomes attributable to healthcare-associated infections in England', *BMJ Open,* 10(1), pp. e033367.

Gurses, A., Seidl, K., Vaidya, V., Bochicchio, G., Harris, A., Hebden, J. and Xiao, Y. (2008) 'Systems ambiguity and guideline compliance: a qualitative study of how intensive care units follow evidence-based guidelines to reduce healthcare-associated infections', *BMJ Quality & Safety,* 17(5), pp. 351-359.

Hagel, S., Ludewig, K., Pletz, M., Frosinski, J., Moeser, A., Wolkewitz, M., Gastmeier, P., Harbarth, S., Brunkhorst, F. and Kesselmeier, M. (2019) 'Effectiveness of a hospital-wide infection control programme on the incidence of healthcare-associated infections and

associated severe sepsis and septic shock: a prospective interventional study', *Clinical Microbiology and Infection,* 25(4), pp. 462-468.

Hall, J. M. and Johnson, M. (2009) 'When Should a Process Be Art, Not Science?', *Harvard Business Review*.

Haraden, C. (2021) *What is a Bundle?* Boston: Institute for Healthcare Improvement. Available at: http://www.ihi.org/resources/Pages/ImprovementStories/WhatIsaBundle.aspx (Accessed: 31st December 2020).

Hasson, F., McKenna, H. and Keeney, S. (2015) 'Surveys', in Gerrish, K. & Lathlean, J. (eds.) *The Research Process in Nursing: Vol. 19*. Oxford: Wiley-Blackwell, pp. 255-266.

Hawes, J. A. and Lee, K.-S. (2018) 'Reduction in central line-associated bloodstream infections in a NICU: practical lessons for its achievement and sustainability', *Neonatal Network,* 37(2), pp. 105-115.

Hay-Smith, E. J. C., Brown, M., Anderson, L. and Treharne, G. J. (2016) 'Once a clinician, always a clinician: a systematic review to develop a typology of clinician-researcher dual-role experiences in health research with patient-participants', *BMC Medical Research Methodology,* 16(1), pp. 95.

Heale, R. and Twycross, A. (2015) 'Validity and reliability in quantitative studies', *Evidence-Based Nursing,* 18(3), pp. 66-67.

Helder, O. K., van Rosmalen, J., van Dalen, A., Schafthuizen, L., Vos, M. C., Flint, R. B., Wildschut, E., Kornelisse, R. F. and Ista, E. (2020) 'Effect of the use of an antiseptic barrier cap on the rates of central line–associated bloodstream infections in neonatal and pediatric intensive care', *American Journal of Infection Control*.

Heron, T. J., Faraday, C. M. and Clarke, P. (2013) 'The hidden harms of Matching Michigan', *Archives of Disease in Childhood-Fetal and Neonatal Edition,* 98(5), pp. F466-F467.

Higginbottom, G. M., Boadu, N. and Pillay, J. (2013) 'Guidance on performing focused ethnographies with an emphasis on healthcare research', *The Qualitative Report,* 18(9), pp. 1-6.

Higgins, J. P. T. and Green, S. (2011) *Cochrane Handbook for Systematic Reviews of Interventions* The Cochrane Collaboration. Available at: www.handbook.cochrane.org (Accessed: 9th January 2021).

Hiller, A. J. and Vears, D. F. (2016) 'Reflexivity and the clinician-researcher: managing participant misconceptions', *Qualitative Research Journal,* 16(1), pp. 13-25.

Hirsch, E. and Gellner, D. (2001) 'Introduction: ethnography of organisations and organisations of ethnography.', in Gellner, D. & Hirsch, E. (eds.) *Inside Organisations: Anthropologists at Work.* Oxford: Berg, pp. 1-15.

Holland, C. K. (1993) 'An ethnographic study of nursing culture as an exploration for determining the existence of a system of ritual', *Journal of Advanced Nursing,* 18(9), pp. 1461-1470.

Hollnagel, E., Wears, R. L. and Braithwaite, J. (2015) *From Safety-I to Safety-II: a white paper*, University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia: Resilient Healthcare Net.

Hoogen, A., Brouwer, A. J., Gerards, L., Fleer, A. and Krediet, T. (2008) 'Removal of percutaneously inserted central venous catheters in neonates is associated with the occurance of sepsis', *Acta Paediatrica,* 97, pp. 1250-2.

Horbar, J. D., Edwards, E. M., Greenberg, L. T., Morrow, K. A., Soll, R. F., Buus-Frank, M. E. and Buzas, J. S. (2017) 'Variation in performance of neonatal intensive care units in the United States', *JAMA Pediatrics,* 171(3), pp. e164396-e164396.

Hsieh, H.-F. and Shannon, S. E. (2005) 'Three Approaches to Qualitative Content Analysis', *Qualitative Health Research,* 15(9), pp. 1277-1288.

Huddlestone, L., Turner, J., Eborall, H., Hudson, N., Davies, M. and Martin, G. (2020) 'Application of normalisation process theory in understanding implementation processes in primary care settings in the UK: a systematic review', *BMC Family Practice,* 21(1), pp. 52.

Hunt, K. and Lathlean, J. (2015) 'Sampling', in Gerrish, K. & Lathlean, J. (eds.) *The Research Process in Nursing: Vol. 13.* Seventh ed. Chichester: Wiley-Blackwell, pp. 173-184.

Hussain, A. S., Ahmed, A. M., Arbab, S., Ariff, S., Ali, R., Demas, S., Zeb, J., Rizvi, A., Saleem, A. and Farooqi, J. (2020) 'CLABSI reduction using evidence based interventions and nurse empowerment: a quality improvement initiative from a tertiary care NICU in Pakistan', *Archives of Disease in Childhood,* 106(4), pp. 394-400.

Ista, E., van der Hoven, B., Kornelisse, R. F., van der Starre, C., Vos, M. C., Boersma, E. and Helder, O. K. (2016) 'Effectiveness of insertion and maintenance bundles to prevent central-line-associated bloodstream infections in critically ill patients of all ages: a systematic review and meta-analysis', *Lancet Infectious Diseases,* 16(6), pp. 724-734.

Jenner, E. A., Mackintosh, C. and Scott, G. (1999) 'Infection control–evidence into practice', *Journal of Hospital Infection,* 42(2), pp. 91-104.

Johnson, M. J. and May, C. R. (2015) 'Promoting professional behaviour change in healthcare: what interventions work, and why? A theory-led overview of systematic reviews', *British Medical Journal Open,* 5(9), pp. e008592.

Johnson, T. J., Patel, A. L., Jegier, B. J., Engstrom, J. L. and Meier, P. P. (2013) 'Cost of morbidities in very low birth weight infants', *The Journal of Pediatrics,* 162(2), pp. 243-249. e1.

Jones, J. and Smith, J. (2017) 'Ethnography: challenges and opportunities', *Evidence-Based Nursing,* 20, pp. 98-100.

Jowsey, T. (2016) 'Watering down ethnography', *BMJ Quality & Safety,* 25(7), pp. 554-555.

Jun, J., Kovner, C. T. and Stimpfel, A. W. (2016) 'Barriers and facilitators of nurses' use of clinical practice guidelines: an integrative review', *International Journal of Nursing Studies,* 60, pp. 54-68.

Kahneman, D. (2011) *Thinking, fast and slow. Thinking, fast and slow.* New York, NY, US: Farrar, Straus and Giroux.

Kan, M. P. H. and Fabrigar, L. R. (2017) 'Theory of Planned Behavior', in Zeigler-Hill, V. & Shackelford, T.K. (eds.) *Encyclopedia of Personality and Individual Differences*. Cham: Springer International Publishing, pp. 1-8.

Kaplan, H. C., Brady, P. W., Dritz, M. C., Hooper, D. K., Linam, W. M., Froehle, C. M. and Margolis, P. (2010) 'The influence of context on quality improvement success in health care: a systematic review of the literature', *The Milbank Quarterly,* 88(4), pp. 500-559.

Kaplan, H. C., Lannon, C., Walsh, M. C. and Donovan, E. F. (2011) 'Ohio Statewide Quality-Improvement Collaborative to Reduce Late-Onset Sepsis in Preterm Infants', *Pediatrics,* 127(3), pp. 427-435.

Karagiannidou, S., Zaoutis, T., Maniadakis, N., Papaevangelou, V. and Kourlaba, G. (2019) 'Attributable length of stay and cost for pediatric and neonatal central line-associated bloodstream infections in Greece', *Journal of Infection and Public Health,* 12(3), pp. 372-379.

Karapanou, A., Vieru, A.-M., Sampanis, M. A., Pantazatou, A., Deliolanis, I., Daikos, G. L. and Samarkos, M. (2020) 'Failure of central venous catheter insertion and care bundles in a high central line–associated bloodstream infection rate, high bed occupancy hospital', *American Journal of Infection Control*.

Kaushik, V., Walsh, C. and Lai, D. (2019) 'Pragmatism as a Research Paradigm and Its Implications for Social Work Research', *Social Sciences,* 8, pp. 255.

Kibiswa, N. K. (2019) 'Directed qualitative content analysis (DQlCA): A tool for conflict analysis', *The Qualitative Report,* 24(8), pp. 2059-2079.

Kieran, E. A., O'Sullivan, A., Miletin, J., Twomey, A. R., Knowles, S. J. and O'Donnell, C. P. F. (2018) '2% chlorhexidine–70% isopropyl alcohol versus 10% povidone–iodine for insertion site cleaning before central line insertion in preterm infants: a randomised trial', *Archives of Disease in Childhood-Fetal and Neonatal Edition,* 103(2), pp. F101-F106.

Kime, T., Mohsini, K., Nwankwo, M. U. and Turner, B. (2011) 'Central line "attention" is their best prevention', *Advances in Neonatal Care,* 11(4), pp. 242-248.

Knoblauch, H. 'Focused ethnography'. *Forum Qualitative Sozialforschung/Forum: Qualitative Social Research*.

Knobloch, M. J., Thomas, K. V., Patterson, E., Zimbric, M. L., Musuuza, J. and Safdar, N. (2017) 'Implementation in the midst of complexity: Using ethnography to study health care–associated infection prevention and control', *American Journal of Infection Control,* 45(10), pp. 1058-1063.

Kono, Y., Yonemoto, N., Nakanishi, H., Kusuda, S. and Fujimura, M. (2018) 'Changes in survival and neurodevelopmental outcomes of infants born at< 25 weeks' gestation: a retrospective observational study in tertiary centres in Japan', *BMJ Paediatrics Open,* 2(1).

Kortteisto, T., Kaila, M., Komulainen, J., Mäntyranta, T. and Rissanen, P. (2010) 'Healthcare professionals' intentions to use clinical guidelines: a survey using the theory of planned behaviour', *Implementation Science,* 5(1), pp. 51.

Koshy, E., Koshy, V. and Waterman, H. (2011) *Action Research in Healthcare* London: SAGE Publications LTD. Available at: https://sk.sagepub.com/books/action-research-in-healthcare (Accessed: 3rd January, 2021).

Kramer, H. S. and Drews, F. A. (2017) 'Checking the lists: A systematic review of electronic checklist use in health care', *Journal of Biomedical Informatics,* 71, pp. S6-S12.

Krein, S. L., Damschroder, L. J., Kowalski, C. P., Forman, J., Hofer, T. P. and Saint, S. (2010) 'The influence of organizational context on quality improvement and patient safety efforts in infection prevention: a multi-center qualitative study', *Social Science & Medicine,* 71(9), pp. 1692-1701.

Kuppala, V. S., Meinzen-Derr, J., Morrow, A. L. and Schibler, K. R. (2011) 'Prolonged initial empirical antibiotic treatment is associated with adverse outcomes in premature infants', *The Journal of pediatrics,* 159(5), pp. 720-725.

Kurinczuk, J., Boby T., Prince, S., Johnston, T. and Neves, M., et al 2020. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: Second Annual Report. Oxford: National Perinatal Epidemiology Unit.

Kvale, S. and Brinkman, S. (2009) 'Interview quality', *Interviews: Learning the Craft of Qualitative Research Interviewing*, pp. 161-175.

Kwok, Y. L. A., Harris, P. and McLaws, M.-L. (2017) 'Social cohesion: the missing factor required for a successful hand hygiene program', *American Journal of Infection Control,* 45(3), pp. 222-227.

Lai, N. M., Taylor, J. E., Tan, K., Choo, Y. M., Ahmad Kamar, A. and Muhamad, N. A. (2016) 'Antimicrobial dressings for the prevention of catheter-related infections in newborn infants with central venous catheters', *Cochrane Database of Systematic Reviews,* (3).

Lamprell, K., Tran, Y., Arnolda, G. and Braithwaite, J. (2020) 'Nudging clinicians: A systematic scoping review of the literature', *Journal of Evaluation in Clinical Practice*.

Lang, E. S., Wyer, P. C. and Haynes, R. B. (2007) 'Knowledge translation: closing the evidence-to-practice gap', *Annals of Emergency Medicine,* 49(3), pp. 355-363.

Laurent, F. and Butin, M. (2019) 'Staphylococcus capitis and NRCS-A clone: the story of an unrecognized pathogen in neonatal intensive care units', *Clin Microbiol Infect,* 25(9), pp. 1081-1085.

Lavallée, J. F., Gray, T. A., Dumville, J., Russell, W. and Cullum, N. (2017) 'The effects of care bundles on patient outcomes: a systematic review and meta-analysis', *Implementation Science,* 12(1), pp. 142.

Lee, R., Ward, N., Azares, R., Fife, A. and Bhat, R. (2016) 'Central line associated blood-stream infections; a study of outcomes in length of stay, respiratory and gastrointestinal support in a neonatal intensive care population', *European Journal of Pediatrics,* 175 (11), pp. 1871-1872.

Lee, Y. S., Stone, P. W., Pogorzelska-Maziarz, M. and Nembhard, I. (2018) 'Differences in Work Environment for Staff as an Explanation for Variation in Central Line Bundle Compliance in ICUs', *Health Care Management Review,* 43(2), pp. 138.

Leekha, S., Li, S., Thom, K. A., Preas, M. A., Caffo, B. S., Morgan, D. J. and Harris, A. D. (2013) 'Comparison of total hospital-acquired bloodstream infections to central line-

associated bloodstream infections and implications for outcome measures in infection control', *Infection control and hospital epidemiology,* 34(9), pp. 984-986.

LeMaster, C. H., Hoffart, N., Chafe, T., Benzer, T. and Schuur, J. D. (2014) 'Implementing the central venous catheter infection prevention bundle in the emergency department: experiences among early adopters', *Annals of Emergency Medicine,* 63(3), pp. 340-350. e1.

Leslie, M., Paradis, E., Gropper, M. A., Reeves, S. and Kitto, S. (2014) 'Applying ethnography to the study of context in healthcare quality and safety', *BMJ Quality & Safety,* 23(2), pp. 99-105.

Lewis, P. J. and Tully, M. P. (2009) 'Uncomfortable prescribing decisions in hospitals: the impact of teamwork', *Journal of the Royal Society of Medicine,* 102(11), pp. 481-488.

Liberati, E. G., Tarrant, C., Willars, J., Draycott, T., Winter, C., Chew, S. and Dixon-Woods, M. (2019) 'How to be a very safe maternity unit: An ethnographic study', *Social Science & Medicine,* 223, pp. 64-72.

Logan, R. M. and Dormire, S. (2018) 'Finding My Way: A Phenomenology of Fathering in the NICU', *Advances in Neonatal Care,* 18(2), pp. 154-162.

Lohm, D. and Kirpitchenko, L. 2014. Interviewing pairs: Discussions on Migration and Identity. SAGE.

Long, K. M., McDermott, F. and Meadows, G. N. (2018) 'Being pragmatic about healthcare complexity: our experiences applying complexity theory and pragmatism to health services research', *BMC Medicine,* 16(1), pp. 94.

Loveday, H. P., Wilson, J. A., Pratt, R. J., Golsorkhi, M., Tingle, A., Bak, A., Browne, J., Prieto, J. and Wilcox, M. (2014) 'epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England', *Journal of Hospital Infection,* 86, pp. S1-S70.

Mannion, R. and Davies, H. (2018) 'Understanding organisational culture for healthcare quality improvement', *British Medical Journal* 363.

Marlow, B., Keeble, H., Onita, R. and Chetcuti-Ganado, C. (2014) 'Mismatching michigan?', *Archives of Disease in Childhood,* 99, pp. A52.

May, C. (2013a) 'Agency and implementation: understanding the embedding of healthcare innovations in practice', *Social Science & Medicine,* 78, pp. 26-33.

May, C. (2013b) 'Towards a general theory of implementation', *Implementation Science,* 8(1), pp. 18.

May, C., Sibley, A. and Hunt, K. (2014) 'The nursing work of hospital-based clinical practice guideline implementation: an explanatory systematic review using Normalisation Process Theory', *International Journal of Nursing Studies,* 51(2), pp. 289-299.

May, C. R., Cummings, A., Girling, M., Bracher, M., Mair, F. S., May, C. M., Murray, E., Myall, M., Rapley, T. and Finch, T. (2018) 'Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review', *Implementation Science,* 13(1), pp. 80.

May, C. R., Finch, T., Ballini, L., MacFarlane, A., Mair, F., Murray, E., Treweek, S. and Rapley, T. (2011) 'Evaluating complex interventions and health technologies using normalization process theory: development of a simplified approach and web-enabled toolkit', *BMC Health Services Research,* 11(1), pp. 1-11.

May, C. R., Johnson, M. and Finch, T. (2016) 'Implementation, context and complexity', *Implementation Science,* 11(1), pp. 141.

Mazza, D., Chapman, A. and Michie, S. (2013) 'Barriers to the implementation of preconception care guidelines as perceived by general practitioners: a qualitative study', *BMC Health Services Research,* 13(1), pp. 36.

McAlearney, A. S. and Hefner, J. L. (2014) 'Facilitating central line-associated bloodstream infection prevention: a qualitative study comparing perspectives of infection control professionals and frontline staff', *American Journal of Infection Control,* 42(10 Suppl), pp. S216-22.

McBeth, C. L. (2020) 'Scrub the Hub:: CLABSI Prevention Through Nurse Leader, Staff Engagement', *Nurse Leader,* 18(2), pp. 116-119.

McIntyre, S. A., Francis, J. J., Gould, N. J. and Lorencatto, F. (2020) 'The use of theory in process evaluations conducted alongside randomized trials of implementation interventions: A systematic review', *Translational Behavioral Medicine,* 10(1), pp. 168-178.

McMullan, R. and Gordon, A. (2016) 'Impact of a central line infection prevention bundle in newborn infants', *infection control & hospital epidemiology,* 37(9), pp. 1029-1036.

MetaVision ICU, i.-S. 2017. Tel Aviv: iMD-Soft.

MHRA (2014) *Chlorhexidine solutions: reminder of the risk of chemical burns in premature infants*. London: Crown Copyright. Available at: https://www.gov.uk/drug-safety-

update/chlorhexidine-solutions-reminder-of-the-risk-of-chemical-burns-in-premature-infants (Accessed: 20th February, 2021 2021).

Michel, J. B. (2019) 'Thinking fast and slow in medicine', *Proceedings (Baylor University. Medical Center),* 33(1), pp. 123-125.

Milstone, A. M., Reich, N. G., Advani, S., Yuan, G., Bryant, K., Coffin, S. E., Huskins, W. C., Livingston, R., Saiman, L. and Smith, P. B. (2013) 'Catheter dwell time and CLABSIs in neonates with PICCs: a multicenter cohort study', *Pediatrics,* 132(6), pp. e1609-e1615.

Minary, L., Trompette, J., Kivits, J., Cambon, L., Tarquinio, C. and Alla, F. (2019) 'Which design to evaluate complex interventions? Toward a methodological framework through a systematic review', *BMC Medical Research Methodology,* 19(1), pp. 1-9.

Mock, V., St Ours, C., Hall, S., Bositis, A., Tillery, M., Belcher, A., Krumm, S. and McCorkle, R. (2007) 'Using a conceptual model in nursing research--mitigating fatigue in cancer patients', *Journal Advanced Nursing,* 58(5), pp. 503-12.

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G. and Group, P. (2009) 'Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement', *PLoS Medicine,* 6(7), pp. e1000097.

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T. and Wight, D. (2015) 'Process evaluation of complex interventions: Medical Research Council guidance', *British Medical Journal* 350.

Morton, P. (2006) 'Using Critical Realism to Explain Strategic Information Systems Planning', *Journal of Information Technology Theory and Application (JITTA),* 8(1).

'A national infection in critical care quality improvement programme for England: A survey of stakeholder priorities and preferences', (2016) *Journal of the Intensive Care Society,* 17(1), pp. 27-37.

Neubauer, B. E., Witkop, C. T. and Varpio, L. (2019) 'How phenomenology can help us learn from the experiences of others', *Perspectives on Medical Education,* 8(2), pp. 90-97.

Newell, A. and Simon, H. A. (1972) *Human Problem Solving.* Prentice-Hall Englewood Cliffs, NJ.

NHS Improvement (2017a) *ATAIN Avoiding Term Admissions.* London: NHS Improvement.

NHS Improvement (2017b) *A Guide to Creating and Interpreting Run and Control Charts Turning Data into Information for Improvement.* Coventry: NHS Institute for Innovation and Improvement.

NHS Improvement (2018) *Statistical Process Control.* London: NHS England.

NHSN (2021) *National Healthcare Safety Network (NHSN) Patient Safety Component Manual* Washington: U.S Department of Health and Human Services.

NICE (2012) *Neonatal Infection (Early Onset): Antibiotics for Prevention and Treatment (CG149).* Manchester: NICE.

NICE (2019) *Curos for preventing infections when using needleless connectors*, London: NICE. Available at: https://www.nice.org.uk/guidance/mtg44/resources/curos-for-preventing-infections-when-using-needleless-connectors-pdf-64372055777989 (Accessed: 30th January 2021).

Nilsen, P. (2015) 'Making sense of implementation theories, models and frameworks', *Implementation Science,* 10(1), pp. 53.

Nilsen, P., Ingvarsson, S., Hasson, H., von Thiele Schwarz, U. and Augustsson, H. (2020) 'Theories, models, and frameworks for de-implementation of low-value care: A scoping review of the literature', *Implementation Research and Practice,* 1, pp. 2633489520953762.

NNAP (2016) *National Neonatal Audit Programme 2016 report on 2015 data.* London: RCPCH.

NNAP (2017) *National Neonatal Audit Programme 2017 report on 2016 data.* London: RCPCH.

NNAP (2018) *National Neonatal Audit Programme 2018 report on 2017 data.* London: RCPCH.

NNAP (2020) *National Neonatal Audit Programme (NNAP) 2020 annual report on 2019 data.* London: RCPCH.

Nowell, L. S., Norris, J. M., White, D. E. and Moules, N. J. (2017) 'Thematic analysis: Striving to meet the trustworthiness criteria', *International Journal of Qualitative Methods,* 16(1), pp. 1609406917733847.

O'Cathain, A., Croot, L., Duncan, E., Rousseau, N., Sworn, K., Turner, K. M., Yardley, L. and Hoddinott, P. (2019) 'Guidance on how to develop complex interventions to improve health and healthcare', *BMJ Open,* 9(8), pp. e029954.

O'Cathain, A., Murphy, E. and Nicholl, J. (2007) 'Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study', *BMC Health Services Research,* 7(1), pp. 1-11.

O'Reilly, M. and Parker, N. (2013) ''Unsatisfactory Saturation': a critical exploration of the notion of saturated sample sizes in qualitative research', *Qualitative Research,* 13(2), pp. 190-197.

Ogilvie, D., Adams, J., Bauman, A., Gregg, E. W., Panter, J., Siegel, K. R., Wareham, N. J. and White, M. (2020) 'Using natural experimental studies to guide public health action: turning the evidence-based medicine paradigm on its head', *Journal of Epidemiology and Community Health,* 74(2), pp. 203.

Ogrinc, G., Davies, L., Goodman, D., Batalden, P., Davidoff, F. and Stevens, D. (2016) 'SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process', *BMJ Quality & Safety,* 25(12), pp. 986-992.

Olsen, R., Greisen, G., Schrøder, M. and Brok, J. (2016) 'Prophylactic probiotics for preterm infants: a systematic review and meta-analysis of observational studies', *Neonatology,* 109(2), pp. 105-112.

Östlund, U., Kidd, L., Wengström, Y. and Rowa-Dewar, N. (2011) 'Combining qualitative and quantitative research within mixed method research designs: a methodological review', *International Journal of Nursing Studies,* 48(3), pp. 369-83.

Øvretveit, J., Leviton, L. and Parry, G. (2011) 'Increasing the generalisability of improvement research with an improvement replication programme', *BMJ Quality & Safety,* 20 Suppl 1(Suppl_1), pp. i87-91.

Pammi, M., Thapa, S., Balderas, M., Runge, J. K., Venkatachalam, A. and Luna, R. A. (2020) 'Microbiome signatures in neonatal central line associated bloodstream infections', *PloS One,* 15(1), pp. e0227967.

Paparini, S., Green, J., Papoutsi, C., Murdoch, J., Petticrew, M., Greenhalgh, T., Hanckel, B. and Shaw, S. (2020) 'Case study research for better evaluations of complex interventions: rationale and challenges', *BMC Medicine,* 18(1), pp. 301.

Paton, J. Y., Ranmal, R. and Dudley, J. (2015) 'Clinical audit: still an important tool for improving healthcare', *Archives of disease in Childhood, Education and Practice Edition,* 100(2), pp. 83-8.

Patton, M. Q. (2011) *Developmental evaluation: Applying complexity concepts to enhance innovation and use.* New York, NY, US: Guilford Press.

Pawson, R., Greenhalgh, T., Harvey, G. and Walshe, K. (2004) *Realist synthesis: an introduction*, Manchester: ESRC Research Methods Programme, University of Manchester. Available at: https://www.betterevaluation.org/sites/default/files/RMPmethods2.pdf#:~:text=Realist%20synthesis%20is%20an%20approach%20to%20reviewing%20research,%28or%20don%E2%80%99t%20work%29%20in%20particular%20contexts%20or%20settings. (Accessed: 20th April, 2021).

Payne, N. R., Carpenter, J. H., Badger, G. J., Horbar, J. D. and Rogowski, J. (2004) 'Marginal Increase in Cost and Excess Length of Stay Associated With Nosocomial Bloodstream Infections in Surviving Very Low Birth Weight Infants', *Pediatrics,* 114(2), pp. 348.

Payne, V., Hall, M., Prieto, J. and Johnson, M. (2018) 'Care bundles to reduce central line-associated bloodstream infections in the neonatal unit: a systematic review and meta-analysis', *Archives of Disease in Childhood Fetal Neonatal Edition,* 103(5), pp. F422-f429.

Payne, V., Hall, M., Prieto, J. and Johnson, M. J. (2020) 'Reply to:‘Research on infection prevention bundles: hidden risk of bias?'', *Archives of Disease in Childhood Fetal and Neonatal Edition,* 105(1), pp. 112.

Pepin, B. J., Lesslie, D., Berg, W., Spaulding, A. B. and Pokora, T. (2019) 'ZAP-VAP: A Quality Improvement Initiative to Decrease Ventilator-Associated Pneumonia in the Neonatal Intensive Care Unit, 2012-2016', *Advances in Neonatal Care,* 19(4), pp. 253-261.

Perry, C., Chhatralia, K., Damesick, D., Hobden, S. and Volpe, L. (2015) 'Behavioural insights in health care', *London: The Health Foundation*, pp. 18-29.

Petty, J., Jarvis, J. and Thomas, R. (2020) 'Exploring the impact of digital stories on empathic learning in neonatal nurse education', *Nurse Education in Practice,* 48, pp. 102853.

Pharande, P., Lindrea, K., Smyth, J., Ward, M., Lui, K. and Bolisetty, S. (2014) 'Trends in late onset sepsis in a neonatal intensive care unit following implementation of infection control bundle: A 10 year audit', *Journal of Paediatrics and Child Health,* 50, pp. 102-103.

Pharande, P., Lindrea, K. B., Smyth, J., Evans, M., Lui, K. and Bolisetty, S. (2018) 'Trends in late-onset sepsis in a neonatal intensive care unit following implementation of infection

control bundle: A 15-year audit', *Journal of paediatrics and child health,* 54(12), pp. 1314-1320.

PHE (2020) *UK Standards for Microbiology Investigations: Identification of Staphylococcus species, Micrococcus species and Rothia species*, London: Public Health England.

Piazza, A. J., Brozanski, B., Provost, L., Grover, T. R., Chuo, J., Smith, J. R., Mingrone, T., Moran, S., Morelli, L., Zaniletti, I. and Pallotto, E. K. (2016) 'SLUG Bug: Quality improvement with orchestrated testing leads to NICU CLABSI reduction', *Pediatrics,* 137 (1), pp. 1-12.

Plsek, P. E. and Greenhalgh, T. (2001) 'The challenge of complexity in health care', *British Medical Journal* 323(7313), pp. 625-628.

Portela, M. C., Pronovost, P. J., Woodcock, T., Carter, P. and Dixon-Woods, M. (2015) 'How to study improvement interventions: a brief overview of possible study types', *BMJ Quality & Safety,* 24(5), pp. 325-336.

Prestwich, A., Webb, T. L. and Conner, M. (2015) 'Using theory to develop and test interventions to promote changes in health behaviour: evidence, issues, and recommendations', *Current Opinion in Psychology,* 5, pp. 1-5.

Prieto, J. (2016) 'Guest editorial', *Journal of Research in Nursing,* 21(1), pp. 5-7.

Proctor, E. K., Powell, B. J. and McMillen, J. C. (2013) 'Implementation strategies: recommendations for specifying and reporting', *Implementation Science,* 8(1), pp. 1-11.

Pronovost, P., Needham, D., Berenholtz, S., Sinopoli, D., Chu, H., Cosgrove, S., Sexton, B., Hyzy, R., Welsh, R., Roth, G., Bander, J., Kepros, J. and Goeschel, C. (2006) 'An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU', *New England Journal of Medicine,* 355(26), pp. 2725-2732.

Pronovost, P. J., Berenholtz, S. M., Goeschel, C., Thom, I., Watson, S. R., Holzmueller, C. G., Lyon, J. S., Lubomski, L. H., Thompson, D. A. and Needham, D. (2008) 'Improving patient safety in intensive care units in Michigan', *Journal of Critical Care,* 23(2), pp. 207-221.

Pronovost, P. J., Watson, S. R., Goeschel, C. A., Hyzy, R. C. and Berenholtz, S. M. (2016) 'Sustaining reductions in central line–associated bloodstream infections in Michigan intensive care units: A 10-year analysis', *American Journal of Medical Quality,* 31(3), pp. 197-202.

QSR International Pty Ltd 2018. NVivo Qualitative Data Analysis Software v12. 12 ed.

Quach, C., Milstone, A. M., Perpête, C., Bonenfant, M., Moore, D. L. and Perreault, T. (2014) 'Chlorhexidine bathing in a tertiary care neonatal intensive care unit: impact on central line–associated bloodstream infections', *Infection Control & Hospital Epidemiology,* 35(2), pp. 158-163.

Quinn, M., Ameling, J. M., Forman, J., Krein, S. L., Manojlovich, M., Fowler, K. E., King, E. A. and Meddings, J. (2020) 'Persistent Barriers to Timely Catheter Removal Identified from Clinical Observations and Interviews', *The Joint Commission Journal on Quality and Patient Safety,* 46(2), pp. 99-108.

Rallis, D., Karagianni, P., Papakotoula, I., Nikolaidis, N. and Tsakalidis, C. (2016) 'Significant reduction of central line–associated bloodstream infection rates in a tertiary neonatal unit', *American Journal of Infection Control,* 44(4), pp. 485-487.

Rapley, T., Girling, M., Mair, F. S., Murray, E., Treweek, S., McColl, E., Steen, I. N., May, C. R. and Finch, T. L. (2018) 'Improving the normalization of complex interventions: part 1-development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT)', *BMC Medical Research Methodology,* 18(1), pp. 133.

Rashid, M., Caine, V. and Goez, H. (2015) 'The encounters and challenges of ethnography as a methodology in health research', *International Journal of Qualitative Methods,* 14(5), pp. 1609406915621421.

Rashid, M., Hodgson, C. S. and Luig, T. (2019) 'Ten tips for conducting focused ethnography in medical education research', *Medical Education Online,* 24(1), pp. 1624133.

Ratcliffe, C., Abelian, A. and Reynolds, R. (2015) 'Prospective re-audit of central line associated bloodstream infections on the neonatal unit following guideline implementation', *Archives of Disease in Childhood,* 100, pp. A236-A237.

Resende, D. S., do O, J. M., de Brito, D. V., Abdallah, V. O. S. and Gontijo, P. P. (2011) 'Reduction of catheter-associated bloodstream infections through procedures in newborn babies admitted in a university hospital intensive care unit in Brazil', *Revista Da Sociedade Brasileira De Medicina Tropical,* 44(6), pp. 731-734.

Richter, J. P. and McAlearney, A. S. (2018) 'Targeted implementation of the Comprehensive Unit-Based Safety Program through an assessment of safety culture to minimize central line-associated bloodstream infections', *Health Care Management Review,* 43(1), pp. 42-49.

Robson, C. and McCartan, K. (2016) *Real World Research.* Chichester: Wiley.

Rosenthal, V. D., Duenas, L., Sobreyra-Oropeza, M., Ammar, K., Navoa-Ng, J. A., Casares, A. C. B., Machuca, L. J., Ben-Jaballah, N., Hamdi, A., Villanueva, V. D. and Tolentino, M. C. V. (2013) 'Findings of the International Nosocomial Infection Control Consortium (INICC), Part III: Effectiveness of a multidimensional infection control approach to reduce central line-associated bloodstream infections in the neonatal intensive care units of 4 developing countries', *Infection Control and Hospital Epidemiology,* 34(3), pp. 229-237.

Runnacles, J., Roueché, A. and Lachman, P. (2018) 'The right care, every time: improving adherence to evidence-based guidelines', *Archives of Disease in Childhood, Education & Practice Edition,* 103(1), pp. 27-33.

Saint, S., Howell, J. D. and Krein, S. L. (2010) 'Implementation science: how to jumpstart infection prevention', *Infection Control and Hospital Epidemiology,* 31(Suppl 1), pp. S14.

Sales, A. and Iwashyna, T. J. (2016) 'Comment on ‘Ethnography asa methodological descriptor: the editors reply'', *BMJ Quality & Safety,* 25(7), pp. 558-558.

Salm, F., Schwab, F., Geffers, C., Gastmeier, P. and Piening, B. (2016) 'The Implementation of an Evidence-Based Bundle for Bloodstream Infections in Neonatal Intensive Care Units in Germany: A Controlled Intervention Study to Improve Patient Safety', *Infection Control and Hospital Epidemiology,* 37(7), pp. 798-804.

Samarasekara, S. I., Booth, D. and Clarke, P. (2012) 'Devastating coagulase-negative staphylococcal septicaemia in an extremely low birth weight infant', *Case Reports,* 2012(bcr2012007407).

Sanderson, E., Yeo, K., Wang, A., Callander, I., Bajuk, B., Bolisetty, S., Lui, K., Bowen, J., Sedgley, S. and Carlisle, H. (2017) 'Dwell time and risk of central-line-associated bloodstream infection in neonates', *Journal of Hospital Infection,* 97(3), pp. 267-274.

Savage, T., Hodge, D. E., Pickard, K., Myers, P., Powell, K. and Cayce, J. M. (2018) 'Sustained reduction and prevention of neonatal and pediatric central line-associated bloodstream infection following a nurse-driven quality improvement initiative in a pediatric facility', *Journal of the Association for Vascular Access,* 23(1), pp. 30-41.

Sax, H., Clack, L., Touveneau, S., da Liberdade Jantarada, F., Pittet, D., Zingg, W. and Group, P. S. (2013) 'Implementation of infection control best practice in intensive care units throughout Europe: a mixed-method evaluation study', *Implementation Science,* 8(1), pp. 24.

Schulman, J., Stricof, R., Stevens, T. P., Horgan, M., Gase, K., Holzman, I. R., Koppel, R. I., Nafday, S., Gibbs, K., Angert, R., Simmonds, A., Furdon, S. A. and Saiman, L. (2011) 'Statewide NICU central-line-associated bloodstream infection rates decline after bundles and checklists', *Pediatrics,* 127(3), pp. 436-444.

Schunk, D. H. and DiBenedetto, M. K. (2020) 'Motivation and social cognitive theory', *Contemporary Educational Psychology,* 60, pp. 101832.

Scott, J., Finch, T., Bevan, M., Maniatopoulos, G., Gibbins, C., Yates, B., Kilimangalam, N., Sheerin, N. and Kanagasundaram, N. S. (2019) 'Acute kidney injury electronic alerts: mixed methods Normalisation Process Theory evaluation of their implementation into secondary care in England', *BMJ Open,* 9(12), pp. e032925.

Shah, N., Castro-Sánchez, E., Charani, E., Drumright, L. and Holmes, A. (2015) 'Towards changing healthcare workers' behaviour: a qualitative study exploring non-compliance through appraisals of infection prevention and control practices', *Journal of Hospital Infection,* 90(2), pp. 126-134.

Sharif, S., Meader, N., Oddie, S. J., Rojas-Reyes, M. X. and McGuire, W. (2020) 'Probiotics to prevent necrotising enterocolitis in very preterm or very low birth weight infants', *Cochrane Database of Systematic Reviews,* (10).

Shepherd, E. G., Kelly, T. J., Vinsel, J. A., Cunningham, D. J., Keels, E., Beauseau, W. and McClead, R. E. (2015) 'Significant reduction of central-line associated bloodstream infections in a network of diverse neonatal nurseries', *Journal of Pediatrics,* 167(1), pp. 41-46.e3.

Sinha, A. K., Murthy, V., Nath, P., Morris, J. K. and Millar, M. (2016) 'Prevention of late onset sepsis and central-line associated blood stream infection in preterm infants', *Pediatric Infectious Disease Journal,* 35(4), pp. 401-406.

Smaggus, A. (2019) 'Safety-I, Safety-II and burnout: how complexity science can help clinician wellness', *BMJ Quality & Safety,* 28(8), pp. 667-671.

Soong, C., Cho, H. J. and Shojania, K. G. (2020) 'Choosing quality problems wisely: identifying improvements worth developing and sustaining', *BMJ Quality & Safety,* 29, pp. 1-2.

Soong, C. and Shojania, K. G. (2020) 'Education as a low-value improvement intervention: often necessary but rarely sufficient', *BMJ Quality & Safety,* 29, pp. 353-357.

Srigley, J. A., Corace, K., Hargadon, D. P., Yu, D., MacDonald, T., Fabrigar, L. and Garber, G. (2015) 'Applying psychological frameworks of behaviour change to improve

healthcare worker hand hygiene: a systematic review', *Journal of Hospital Infection,* 91(3), pp. 202-210.

Stang, A. (2010) 'Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses', *European Journal of Epidemiology,* 25(9), pp. 603-605.

Steiner, M., Langgartner, M., Cardona, F., Waldhor, T., Schwindt, J., Haiden, N. and Berger, A. (2015) 'Significant reduction of catheter-associated blood stream infections in preterm neonates after implementation of a care bundle focusing on simulation training of central line insertion', *Pediatric Infectious Disease Journal,* 34(11), pp. 1193-1196.

Strange, F. (1996) 'Handover: an ethnographic study of ritual in nursing practice', *Intensive and Critical Care Nursing,* 12(2), pp. 106-112.

Stroever, S., Boston, K., Ellsworth, M., Cuccaro, P. and McCurdy, S. (2020) 'Qualitative process evaluation of a central line-associated bloodstream infection (CLABSI) prevention team in the neonatal intensive care unit', *American Journal of Infection Control*.

Sturgiss, E. A. and Clark, A. M. (2019) 'Using critical realism in primary care research: an overview of methods', *Family Practice,* 37(1), pp. 143-145.

Suresh, G. K. and Edwards, W. H. (2012) 'Central Line-Associated Bloodstream Infections in Neonatal Intensive Care: Changing the Mental Model from Inevitability to Preventability', *American Journal of Perinatology,* 29(1), pp. 57-64.

Tabak, R. G., Khoong, E. C., Chambers, D. A. and Brownson, R. C. (2012) 'Bridging research and practice: models for dissemination and implementation research', *American Journal of Preventive Medicine,* 43(3), pp. 337-350.

Taylor, J. E., McDonald, S. J., Earnest, A., Buttery, J., Fusinato, B., Hovenden, S., Wallace, A. and Tan, K. (2017) 'A quality improvement initiative to reduce central line infection in neonates using checklists', *European Journal of Pediatrics,* 176(5), pp. 639-646.

Taylor, J. E., McDonald, S. J. and Tan, K. (2015a) 'Prevention of central venous catheter-related infection in the neonatal unit: A literature review', *Journal of Maternal-Fetal and Neonatal Medicine,* 28(10), pp. 1224-1230.

Taylor, J. E., Tan, K., Lai, N. M. and McDonald, S. J. (2015b) 'Antibiotic lock for the prevention of catheter-related infection in neonates', *Cochrane Database of Systematic Reviews,* (6).

The Health Foundation (2013) *Quality Improvement Made Simple*, London: The Health Foundation.

The Joint Commission (2012) *Preventing Central Line–Associated Bloodstream Infections: A Global Challenge, a Global Perspective.* Oak Brook, IL: The Joint Commission Resources.

Thorne, S. (2000) 'Data analysis in qualitative research', *Evidence-Based Nursing,* 3(3), pp. 68-70.

Ting, J. Y., Goh, V. S. K. and Osiovich, H. (2013) 'Reduction of central line-associated bloodstream infection rates in a neonatal intensive care unit after implementation of a multidisciplinary evidence-based quality improvement collaborative: A four-year surveillance', *Canadian Journal of Infectious Diseases and Medical Microbiology,* 24(4), pp. 185-190.

Ting, J. Y., Synnes, A., Roberts, A., Deshpandey, A., Dow, K., Yoon, E. W., Lee, K.-S., Dobson, S., Lee, S. K. and Shah, P. S. (2016) 'Association between antibiotic use and neonatal mortality and morbidities in very low-birth-weight infants without culture-proven sepsis or necrotizing enterocolitis', *JAMA Pediatrics,* 170(12), pp. 1181-1187.

Triantafillou, V., Kopsidas, I., Kyriakousi, A., Zaoutis, T. and Szymczak, J. (2020) 'Influence of national culture and context on healthcare workers' perceptions of infection prevention in Greek neonatal intensive care units', *Journal of Hospital Infection,* 104(4), pp. 552-559.

Upton, M. (2018) 'Avoiding Term Infants Into Neonatal units

Insights from the Atain programme'. *UK Midwifery Study System Study Day*, Birmingham, 2018: NPEU.

van den Akker, C. H., van Goudoever, J. B., Szajewska, H., Embleton, N. D., Hojsak, I., Reid, D. and Shamir, R. (2018) 'Probiotics for preterm infants: a strain-specific systematic review and network meta-analysis', *Journal of Pediatric Gastroenterology and Nutrition,* 67(1), pp. 103-122.

Van Someren, M., Barnard, Y. and Sandberg, J. (1994) *The Think Aloud Method: a practical guide to modelling cognitive processes. Academic Press* London.

Vindrola-Padros, C. and Vindrola-Padros, B. (2018) 'Quick and dirty? A systematic review of the use of rapid ethnographies in healthcare organisation and delivery', *BMJ Quality & Safety,* 27(4), pp. 321-330.

VON (2019) *Manual of Operations: Part 2*

Data Definitions & Infant Data Forms. Vermont: Vermont Oxford Network.

Voor, A. F., Helder, O. K., Vos, M. C., Schafthuizen, L., Sülz, S., van den Hoogen, A. and Ista, E. (2017) 'Antiseptic barrier cap effective in reducing central line-associated bloodstream infections: a systematic review and meta-analysis', *International Journal of Nursing Studies,* 69, pp. 34-40.

Vougioukalou, S., Boaz, A., Gager, M. and Locock, L. (2019) 'The contribution of ethnography to the evaluation of quality improvement in hospital settings: reflections on observing co-design in intensive care units and lung cancer pathways in the UK', *Anthropology & Medicine,* 26(1), pp. 18-32.

Wang, W., Zhao, C., Ji, Q., Liu, Y., Shen, G. and Wei, L. (2015) 'Prevention of peripherally inserted central line-associated blood stream infections in very low-birth-weight infants by using a central line bundle guideline with a standard checklist: A case control study', *BMC Pediatrics,* 18.

Waring, J. and Jones, L. (2016) 'Maintaining the link between methodology and method in ethnographic health research', *BMJ Quality & Safety,* 25(7), pp. 556-557.

Wasserman, S., Messina, A. (2018) *Guide to Infection Control in the Healthcare Setting: Bundles in Infection Prevention and Safety*, Massachusetts: International Society for Infectious Diseases. Available at: https://isid.org/wp-content/uploads/2019/06/ISID_GUIDE_BUNDLES_IN_INFECTION_PREVENTION_SAFETY.pdf (Accessed: 31st December 2020).

WHO (2009) *WHO Guidelines on Hand Hygiene in Health Care.* Geneva: WHO.

WHO (2020) *Standards for improving the quality of care for small and sick newborns in health facilities.* Geneva: WHO.

Wilder, K. A., Wall, B., Haggard, D. and Epperson, T. (2016) 'CLABSI Reduction Strategy: A Systematic Central Line Quality Improvement Initiative Integrating Line-Rounding Principles and a Team Approach', *Advances in Neonatal Care,* 16(3), pp. 170-177.

Williams, L., Burton, C. and Rycroft-Malone, J. (2013) 'What works: a realist evaluation case study of intermediaries in infection control practice', *Journal of Advanced Nursing,* 69(4), pp. 915-926.

Wilson, A. D., Onwuegbuzie, A. J. and Manning, L. P. (2016) 'Using paired depth interviews to collect qualitative data', *The Qualitative Report,* 21(9), pp. 1549.

Winters, B. D., Gurses, A. P., Lehmann, H., Sexton, J. B., Rampersad, C. J. and Pronovost, P. J. (2009) 'Clinical review: checklists-translating evidence into practice', *Critical Care,* 13(6), pp. 210.

Wirth, T., Bergot, M., Rasigade, J. P., Pichon, B., Barbier, M., Martins-Simoes, P., Jacob, L., Pike, R., Tissieres, P., Picaud, J. C., Kearns, A., Supply, P., Butin, M. and Laurent, F. (2020) 'Niche specialization and spread of Staphylococcus capitis involved in neonatal sepsis', *Nature Microbiology,* 5(5), pp. 735-745.

Wirtschafter, D. D., Pettit, J., Kurtin, P., Dalsey, M., Chance, K., Morrow, H. W., Seid, M., Byczkowski, T. L., Huber, T. P., Milstein, J. M., Bowles, S. M., Fichera, S. and Kloman, S. (2010) 'A statewide quality improvement collaborative to reduce neonatal central line-associated blood stream infections', *Journal of Perinatology,* 30(3), pp. 170-181.

Wolf, Z. (2013) *Exploring Rituals in Nursing: Joining Art and Science.* New York, US: Springer

Woods-Hill, C. Z., Papili, K., Nelson, E., Lipinski, K., Shea, J., Beidas, R. and Lane-Fall, M. (2020) 'Harnessing implementation science to optimize harm prevention in critically ill children: A pilot study of bedside nurse CLABSI bundle performance in the pediatric intensive care unit', *American Journal of Infection Control*.

Writing Group for the CHECKLIST-ICU Investigators (2016) 'Effect of a Quality Improvement Intervention With Daily Round Checklists, Goal Setting, and Clinician Prompting on Mortality of Critically Ill Patients: A Randomized Clinical Trial', *JAMA,* 315(14), pp. 1480-1490.

Wynn, J. L., Wong, H. R., Shanley, T. P., Bizzarro, M. J., Saiman, L. and Polin, R. A. (2014) 'Time for a neonatal-specific consensus definition for sepsis', *Pediatric Critical Care Medicine,* 15(6), pp. 523-8.

Yee, L., Marlow, B., Belani, P. and Chetcuti-Ganado, C. (2016) 'G580 (P) CONS control: Fully implementing Matching Michigan to reduce CONS infection', *Archives of Disease in Childhood,* 101, pp. A345-A346.

Zachariah, P., Furuya, E. Y., Edwards, J., Dick, A., Hangsheng, L., Herzig, C. T. A., Pogorzelska-Maziarz, M., Stone, P. W. and Saiman, L. (2014) 'Compliance with prevention practices and their association with central line-associated bloodstream infections in neonatal intensive care units', *American Journal of Infection Control,* 42(8), pp. 847-851.

Zhou, Q., Lee, S. K., Hu, X. J., Jiang, S. Y., Chen, C., Wang, C. Q. and Cao, Y. (2015) 'Successful reduction in central line-associated bloodstream infections in a Chinese neonatal intensive care unit', *American Journal of Infection Control,* 43(3), pp. 275-279.

Zingg, W., Hopkins, S., Gayet-Ageron, A., Holmes, A., Sharland, M. and Suetens, C. (2017) 'Health-care-associated infections in neonates, children, and adolescents: an analysis of paediatric data from the European Centre for Disease Prevention and Control point-prevalence survey', *Lancet Infectious Diseases,* 17(4), pp. 381-389.

Zingg, W., Walder, B. and Pittet, D. (2011) 'Prevention of catheter-related infection: toward zero risk?', *Current Opinion in Infectious Diseases,* 24(4), pp. 377-384.