University of Southampton

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School of Health Sciences

Reporting Medical Device-Related Pressure Ulcers: An International Consensus and Feasibility Study

by

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Abstract

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Pressure ulcers (PUs) develop when the skin and soft tissues are exposed to prolonged periods of mechanical load. They reduce patients' quality of life and represent a high cost for the individual and healthcare providers. Recent research revealed that up to a third of PUs are caused by medical devices, where critical care units represent the highest risk areas. Despite raised awareness, medical device-related pressure ulcers (MDRPUs) are not routinely reported, creating a substantive gap in knowledge for both healthcare providers and device regulators.

The doctoral programme of research aimed to systematically develop a MDRPU reporting tool underpinned by an international consensus and followed a sequential mix-methods design. The methodological approach included five phases: (1) a narrative review of reporting practice, (2) an international qualitative study exploring reporting practice with 17 participants from 11 countries, (3) a first–in–kind international consensus study with experts from 23 countries, (4) a preliminary MDRPU reporting form pre-testing using vignettes, incorporating four cognitive interviews and three focus groups with clinical nurses, and (5) a pilot study to evaluate the proposed MDRPU reporting form feasibility with tissue viability teams in two large acute university hospitals.

The findings revealed variation in policy and practice of reporting PUs between countries and organisations. Clinicians in the qualitative study reported that MDRPU data are not routinely collected, and when they are, the device information is extremely limited. The international consensus study facilitated the agreement of thirty items for inclusion in MDRPU reporting across five themes: medical device care, MDRPU data, device data, ulcer-specific reporting, and general patient data. Cognitively pre-testing of the novel MDRPU reporting form with anticipated end-users confirmed the form's content and face validity. Subsequently, the form was piloted in two hospitals in England, to assess its feasibility and acceptability. Overall, the participants found the form clear and comprehensible. However, challenges in the usability of the preliminary reporting form were identified, associated with shortcomings of data availability and time for completion.

The new MDRPU reporting form is an important contribution to the international field of tissue viability. It addresses the lack of a standardised data collection relating to MDRPUs. Furthermore, its use can facilitate cooperation with device regulatory bodies, resulting in improved communication with manufacturers to identify which devices are no longer fit for purpose. The form requires further research to assess its reliability and to identify facilitators to data acquisition, e.g., asset tagging technologies to digitally document devices used in clinical settings.

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Research Thesis: Declaration of Authorship

Author name: Ewa Agnieszka Crunden

Title of thesis: **Reporting Medical Device-Related Pressure Ulcers: An International Consensus and Feasibility Study.**

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;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. Parts of this work have been published as:

Crunden, E. A., Schoonhoven, L., Coleman, S. B. and Worsley, P. R. (2021) 'Reporting of pressure ulcers and medical device related pressure ulcers in policy and practice: A narrative literature review', *Journal of Tissue Viability*, 31(1), pp. 119-129. DOI:10.1016/j.jtv.2021.10.010

Crunden, E. A., Worsley, P. R., Coleman, S. B. and Schoonhoven, L. (2022) 'Barriers and facilitators to reporting medical device-related pressure ulcers: A qualitative exploration of international practice', *International Journal of Nursing Studies,* 135, pp. 104326. DOI:10.1016/j.ijnurstu.2022.104326

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Definitions and Abbreviations

(s)DTI .....(suspected) Deep Tissue Injury

AHRQ.....Agency for Healthcare Research and Quality

BiPAP .....Bilevel Positive Airway Pressure

CCU.....Critical Care Unit

CMS .....Centres for Medicare and Medicaid (USA)

CPAP .....Continuous Positive Airway Pressure

DoH .....Department of Health

DS .....Data set

EMR .....Electronic Patient Record

EPUAP.....European Pressure Ulcer Advisory Panel

ETT.....Endotracheal Tube

FDA.....Food and Drug Administration

HAPU .....Hospital Acquired Pressure Ulcer

HPRA .....Health Products Regulatory Agency

ICU.....Intensive Care Unit

IIMS .....Incident Information Management System

IPR .....Interpercentile range

IPRAS .....Interpercentile range adjusted for symmetry

IRS .....Incident Reporting System

IT .....Information Technology

LTC.....Long Term Care

MD.....Medical Device

MDRPU.....Medical Device-Related Pressure Ulcer

MHRA .....Medicines and Healthcare products Regulatory Agency

NG tube .....Nasogastric Tube

NGT .....Nominal Group Technique

NHS ..... National Health Service

NHSI ..... NHS Improvement

NIH ..... National Institutes of Health

NPIAP ..... National Pressure Injury Advisory Panel (previously NPUAP – National Pressure Ulcer Advisory Panel)

NRLS ..... National Reporting and Learning System

OECD ..... Economic Co-operation and Development

POA ..... Present on Admission

PPPIA ..... Pan Pacific Pressure Injury Alliance

PU ..... Pressure Ulcer

PUWA ..... Pressure Ulcer and Wound Audit

QI ..... Quality Improvement

RAM ..... Rand Corporation/ University of California Appropriateness Method

RCA ..... Root Cause Analysis

SAC ..... Severity Assessment Code

SI ..... Serious Incident

STEIS ..... Strategic Executive Information System

STh ..... Safety Thermometer

TICD ..... Tailored Implementation for Chronic Diseases

TVN ..... Tissue Viability Nurse

VHIMS ..... Victoria Health Incident Information System

WOCN ..... Wound, Ostomy, and Continence Nurse

Chapter 1 Background

1.1 Introduction

This chapter presents an overview of this PhD Thesis. It provides a general outline of pressure ulcers and medical device-related pressure ulcers, providing definitions, classification based on severity, the extent to which they prove a problem to healthcare organisations and systems, their financial impact and their effect on patients' quality of life. Pressure ulcer incidence used as a proxy measure for quality and safety of patient care is introduced. Medical device-regulatory bodies' role in monitoring the quality and safety of medical devices is discussed.

1.2 Thesis overview

This thesis provides a detailed report on the research undertaken to develop an MDRPU reporting tool to be used routinely to collect data on any incident of device-related skin damage. To understand why creating an MDRPU reporting tool requires exploring the main challenges of pressure ulcers and MDRPUs. It is essential to understand why such a tool is needed, how it can improve clinical practice and its impact on the quality and safety of patient care in the acute sector. Thus this thesis explores the need for a reporting tool, describes its development, and discusses its feasibility in clinical practice.

This thesis provides a critical account of the adopted programme of research, which includes 5 phases:

1) Narrative review of pressure ulcers and medical device-related pressure ulcers reporting in policy and practice
2) Qualitative exploration of reporting practice in eleven countries
3) Consensus study involving participants from 23 countries
4) Design and pre-testing using cognitive testing methods
5) Feasibility testing of the MDRPU reporting tool in 2 acute hospital trusts.

Work in each phase was conceptualised and undertaken by the researcher.

1.3 Definitions of pressure ulcer, medical device-related pressure ulcer and classification

A pressure ulcer (PU), also called a pressure injury, bedsore or decubitus ulcer, is a localised injury to the skin and/or underlying tissue, usually over a bony prominence due to pressure or pressure in combination with shear (EPUAP NPIAP & PPPIA., 2019). Pressure ulcers were first detected thousands of years ago, with the ancient Egyptians depicting a wound treated with gazelle skin (Agrawal and Chauhan, 2012). However, the understanding of aetiology has changed in the last two centuries. In the 19th century, it was believed that pressure ulcers developed as a result of damage to the nervous system, and their development was associated with imminent death (Agrawal and Chauhan, 2012). In recent years, research into the biomechanics of skin and underlying tissues led to a better awareness of the factors leading to PU development. It is now understood that mechanical load type, magnitude, duration, individual tolerance and susceptibility, and risk factors, all, play a role in PU development (Coleman et al., 2014b).

The most common body sites where PUs develop include sacrum and heels (VanGilder et al., 2009), although they may present at any anatomical location, especially over a bony prominence (EPUAP NPIAP & PPPIA., 2019). The traditional view that pressure ulcers only occur when an individual is lying down or sitting is changing. It has been recognised that medical devices may also become implicated in pressure ulcer development. Although the first mention of a medical device-related pressure ulcer (MDRPU) appeared in The Lancet in 1972 (Glaser, 1965), it was not until 2010, when a seminal paper by Black et al. (2010) was published, that the spotlight shone on MDRPUs**.** This study concluded that 34.5% of all hospital-acquired pressure ulcers (HAPUs) were attributed to a medical device and that patients with devices were 2.4 times more likely to develop a PU of any kind (Black et al., 2010).

A more recent study of medical device-related pressure ulcers (MDRPUs) in long-term acute care hospitals by Arnold-Long et al. (2017) indicated that out of all HAPUs experienced by patients, 47% were medical device-related. The most commonly reported devices related to PUs are respiratory devices, splints and braces, and tubing (Arnold-Long et al., 2017). Moreover, MDRPUs may be difficult to prevent and treat as the device cannot always be moved or removed. Medical devices themselves create pressure, humidity and heat that develops between the skin and the device affecting the local microclimate. They often need to be secured tightly to assure appropriate seal, and the materials used to secure the devices may hinder skin inspection (Black et al., 2010, Bader and Worsley, 2018).

The specific factors impacting MDRPUs development are (Bader et al., 2019):

1) Devices are based on generic designs and do not accommodate patient variability in body size and shape.
2) Devices employ materials, which are relatively stiff and do not match the mechanical compliance of the skin and sub-dermal tissues.
3) Inadequate guidance is provided regarding device application.
4) Many individuals exhibit skin and sub-dermal tissues with impaired tolerance to loading, e.g. associated with ageing, malnutrition, neuromuscular compromise or diabetes.

Following these studies and international consensus meetings, a definition of MDRPU was established as:

> "pressure ulcers resulting from the application of medical devices, necessary for diagnostic and therapeutic purposes, which take shape or pattern of the device" (EPUAP NPIAP & PPPIA., 2019).

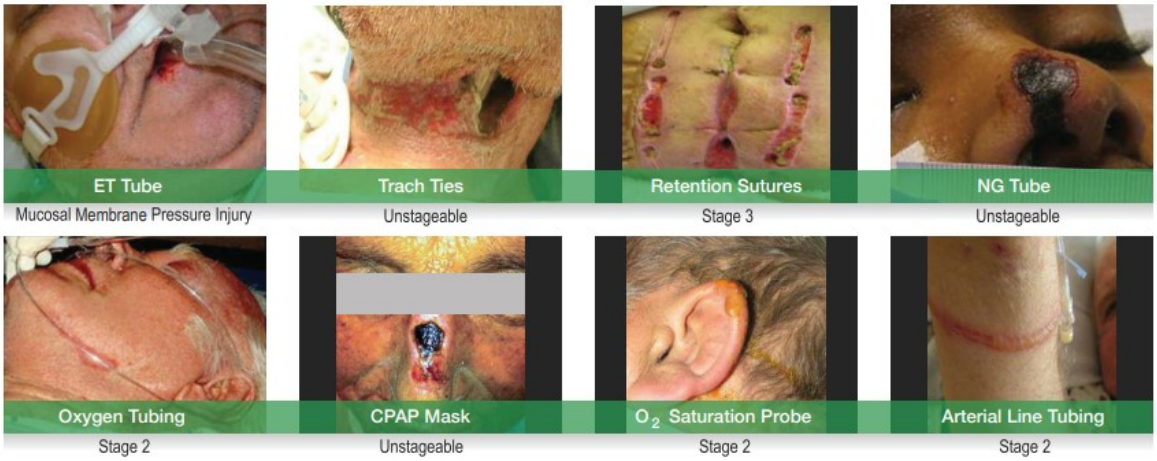


Figure 1.1 Examples of MDRPUs, with device implicated in their development and MDRPU stage. Source: NPIAP

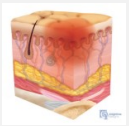
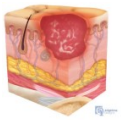
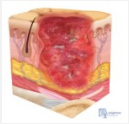
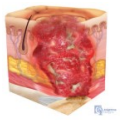
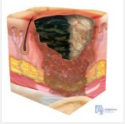
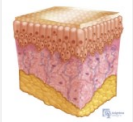
In contrast to PUs, MDRPUs can cause skin damage where the device was attached to the patient's body (Figure 1.1), including not only bony prominences but also soft tissues and mucous membranes (EPUAP NPIAP & PPPIA., 2019). Although the aetiology of PUs and MDRPUs is similar, MDRPUs primarily develop due to friction in combination with shear from ill-fitted and poorly positioned medical device (MD) which constantly moves or rubs the skin and causes forces parallel to the skin (Apold and Rydrych, 2012, Young, 2017). Devices most often implicated in patient harm are presented in Table 1.1.

Table 1.1 Examples of devices associated with MDRPU development, adapted from Gefen et al. 2022.

Device & Medical purpose	**Examples**
Respiratory devices	Oxygen face masks, continuous / bilevel positive airway pressure masks (CPAP / BiPAP), nasal prongs and tubing, extracorporeal membrane oxygenation
Access devices	All types of lines (e.g. catheters & associated tubing), chest lines & tubes
Feeding and nutrition	Nasogastric tubes, orogastric tubes, percutaneous endoscopic gastrostomy incl. external bumper and clamps
Patient monitoring	Oxygen saturation probes/pulse oximeter, blood pressure cuffs, electrocardiogram dots, leads and lines, wearable monitoring devices, movement sensors
Treatment	Tubing and lines (e.g. dialysis, negative pressure wound therapy, intra-aortic balloon pumps), aircast boots, plaster casts
Prosthetics and orthotics	Above- and below-knee, arm and hand prostheses, braces, ankle foot orthoses, dental prostheses
Compression and deep vein thrombosis prevention	Compression hosiery, sequential compression devices, thromboembolic deterrent stockings, heel offloading devices
Faecal and urinary devices	Urinary catheters, bedpans, condom catheters, penile clams, bowel management systems

PUs and MDRPUs are categorised according to the depth of the wound, from non-blanchable erythema to full-thickness tissue loss (EPUAP NPIAP & PPPIA., 2019, EPUAP NPIAP & PPPIA., 2014). This classification system includes four numerical stages, as well as unstageable pressure ulcers and suspected deep tissue injury (Table 1.2). It is worth noting, that staging MDRPUs can be challenging, since they often occur over sited with minimal tissue coverage, e.g. bridge of the nose from continuous positive airway pressure (CPAP) masks. It was also recognised that mucosal pressure ulcers are predominantly caused by MDs, but because of a different development mechanism to other MDRPUs, they cannot be staged using a classification system (EPUAP NPIAP & PPPIA., 2019, NPUAP, 2008).

Table 1.2 International Pressure Ulcer Classification System (EPUAP NPIAP & PPPIA., 2014), definition of mucosal PU and DRPU from the EPUAP NPIAP & PPPIA. (2019) guideline. Images source: NPIAP

Category & schematic drawing	**Description**
Category 1 	Intact skin with nonblanchable redness of a localised area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area. The site may be painful, firm, soft, warmer, or cooler compared to adjacent tissue.
Category 2 	Partial-thickness loss of dermis presenting as a shallow open ulcer with a red/ pink wound bed, without slough. It May also present as an intact or open/ruptured serum filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.
Category 3 	Full-thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunnelling. The depth of a Category/ Stage III pressure ulcer varies by anatomical location.
Category 4 	Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunnelling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location.
Unstageable: Depth unknow 	Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, grey, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/ Stage, cannot be determined.
Suspected deep tissue injury 	A purple or localised maroon area of discoloured intact skin or blood-filled blister due to underlying soft tissue damage from pressure and shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones.
Mucosal membrane pressure ulcer 	Mucosal membrane pressure ulcer is found on mucosal membranes with a history of medical device use at the site of the ulcer. These pressure ulcers cannot be staged.
Device-related pressure ulcer (DRPU)	A pressure ulcer resulting from use of medical devices, equipment, furniture and everyday objects that have applied pressure to skin. The shape of pressure ulcer usually conforms to the shape or pattern of the device. Device related pressure ulcers are staged using the same classification system as other pressure ulcers.

1.4 Prevalence, Incidence, and Cost

Prevalence and incidence data are used most commonly to describe the extent of the problem of pressure ulcers. Prevalence indicates the proportion of a given population with a specific condition (e.g. pressure ulcer) at a given point in time (Polit and Beck, 2017). This includes all pressure ulcers – those that might have originated outside the healthcare setting and those that developed during the inpatient stay. This measure allows us to understand the extent of the pressure ulcer issue in the healthcare system and subsequently its financial burden (Baharestani et al., 2009). The incidence rate is defined as a rate of new cases with the specified condition, which is calculated by dividing the number of new cases which occurred over a specified time period by the number of patients free of the condition at the outset of that time period (Polit and Beck, 2017). The incidence of pressure ulcers is often used as a proxy measurement for the quality and safety of nursing care. It shows the rate of facility-acquired pressure ulcers and thus can be directly linked to preventive care (Gunningberg et al., 2008).

Pressure ulcers are a significant problem worldwide. They involve all patient groups, although those in critical and intensive care are most at risk of PU development. A summary of prevalence and incidence rates across different healthcare settings is displayed below in Table 1.3.

Table 1.3 Ranges of PU prevalence and incidence in different settings (EPUAP NPIAP & PPPIA., 2019).

Setting/ population		**Prevalence rates**	**Incidence rates**
Acute care		6% - 18.5%	0% - 12%
Critical care – 95% Confidence Interval (CI)		10% – 25.9%	16.9% - 23.8%
Older adults		4.1% - 32.2%	1.9% - 59%
Paediatric care	Primary health care	1.75% (95% CI: 1.71 – 1.73)	-
	General acute care	1.8% - 4%	0.57% - 21.4%
	Critical care	32.8%	0.25% - 27%
	Mixed setting	0.47% - 7.1%	0.29% - 27.7%
Operating room		-	5% - 53.4%

MDRPUs were given relatively little attention until the last decade and the seminal publication by Black et al. (2010). A recent systematic review and meta-analysis undertaken by Jackson et al. (2019), which included 13 studies from ICUs, estimated the pooled incidence of MDRPUs was

12%, and prevalence was 10%, with some studies reporting prevalence as high as 45% depending on the setting (high incidence in ICU wards). A systematic review investigating MDRPU incidence in acute settings revealed an incidence of 28.1% (Brophy et al., 2021). Rashvand et al. (2020) have reported that incidence of MDRPUs to be 20.5% in Iran. However, they have also highlighted that in many facilities, MDRPUs are not included in PU statistics. The majority of MDRPUs were Category 1 and 2 (Barakat-Johnson et al., 2019, Black et al., 2010, Rashvand et al., 2020). Barakat-Johnson et al. (2019) concluded that mucosal pressure ulcers were most often reported in incidence studies, whereas prevalence studies reported most often ear and nose MDRPUs. A recent integrative review of MDRPUs indicated that the most frequently affected body sites were the back of the head (66%) and nose (40%) (Galetto et al., 2019) which is in line with Apold and Rydrych (2012) who reported 70% of MDRPU occurring on the head, face, and neck in comparison to only 8% of PUs developing withing these anatomical locations (Figure 1.2).

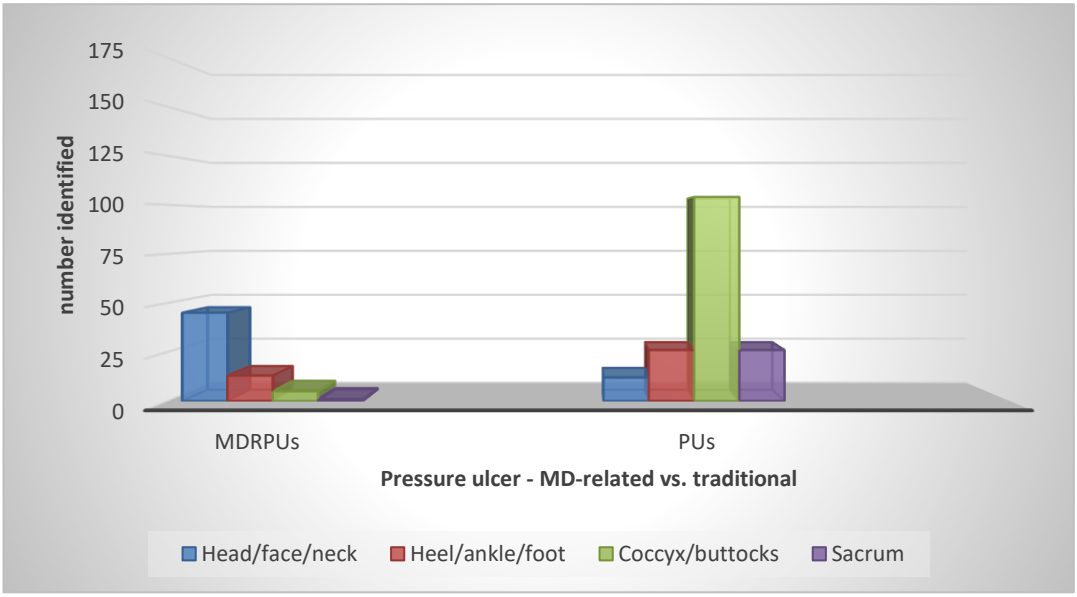


Figure 1.2 Most common anatomical locations of MDRPUs in comparison to PUs (Apold and Rydrych, 2012)

Nevertheless, direct comparison between prevalence and incidence studies is difficult due to different methodologies used for data collection. Several systematic reviews highlight high heterogeneity, with some studies based on a review of medical records only and exclusion of Category 1 PUs (Al Mutairi and Hendrie, 2018, Barakat-Johnson et al., 2019, Chaboyer et al., 2018). These issues in data collection are important, especially considering that most MDRPUs recorded in the studies that did report them were Category 1 and 2. Without their inclusion, direct comparison is impossible, and moreover, it may lead to underestimating the problem of those wounds. Relying on routinely collected data rather than the 'gold standard' of skin inspection may also prohibit accurate estimation of prevalence and incidence since those data are

known to be affected by underreporting (Baharestani et al., 2009, Meddings et al., 2013). Notwithstanding the measurement methodology problems, the issue of PUs and MDRPUs is a clear burden for all healthcare settings, especially those that serve the most vulnerable patient populations, such as intensive and critical care, paediatrics and neonate units whose patients have reduced tolerance of the skin to load (Oranges et al., 2015, Visscher and Narendran, 2014), and where clinicians rely heavily on medical devices for patient monitoring and treatment.

1.5 PU and MDRPU burden on quality of life

Pressure ulcers are a multifaceted and complex issue and are associated with high mortality, morbidity and need for extended hospitalisation (Bates-Jensen, 2001, Bennett et al., 2004, Shahin et al., 2009). Furthermore, patients who suffer from PUs have a diminished quality of life, suffer from pain, discomfort (Gorecki et al., 2011, Gorecki et al., 2012), and often psychosocial issues (Degenholtz et al., Essex et al., 2009, Galhardo et al., 2010). The development of a pressure ulcer is also linked to an extended hospital stay (Dealey et al., 2012b).

Although there are no publications exploring the impact of MDRPUs on patients' quality of life, taking into consideration that majority of MDRPUs occur on patient's head, face, and neck (Figure 1.2), it is reasonable to assume that changes relating to the possibility of scarring and balding due to scar tissue may change person's appearance, would have a negative psychological impact, and decrease the reported quality of life.

1.6 Financial burden of PUs

A recent retrospective cohort analysis used patients' records in The Health Improvement Network to estimate the 2012/2013 annual NHS cost of managing all wounds and associated comorbidities. After adjusting for comorbidities, the cost varied between £4.5 and £5.1 billion (Guest et al., 2017). Indeed, there were an estimated 2.2 million patients with wounds managed by the UK NHS in 2012/2013, including pressure ulcers, diabetic foot ulcers and leg ulcers (Guest et al., 2017). Guest et al. (2018) estimated the annual cost of managing pressure ulcers to be £531 million, and the mean UK NHS cost of wound care over 12 months from the initial presentation to be £8,700 per pressure ulcer, ranging from £1,400 (category 1) to >8,700 (other categories). Similarly, Dealey et al. (2012b) estimated the cost of healing a PU in the UK varies between £1,214 and £14,108, depending on the severity of the ulcer. A recent study in the USA investigating the cost of Hospital Acquired Pressure Ulcers estimated expenditures in excess of $26.8 bn (Padula and

Delarmente, 2019). These numbers show a great economic burden of PUs to healthcare systems. Managing MDRPUs is likely to include a range of expenses, such as (Gefen et al., 2022):

1) Medical costs
2) Health professional costs
3) Reimbursement withheld for HAPUs
4) Financial penalties in some jurisdictions
5) Litigation costs
6) Potential court-ruled damages and settlements
7) Cost of insurance policies, which are affected by the institution's litigation history
8) Cost of device abandonment (e.g., prosthetics and orthotics)
9) Cost of changing medical intervention (e.g., when CPAP fails in neonates, some need to be re-intubated, alternative securement is required).

Furthermore, the cost of treatment increases due to the healing time and the increase in the chance of associated complications (e.g., wound infection) and associated increased length of hospital stay.

1.7 Pressure ulcer rates as quality of care indicator

Pressure ulcer prevalence and incidence measurements are used in healthcare organisations and healthcare systems as indicators of quality of care. MDRPUs are mostly hospital-acquired and included in the PU metrics. However, often they are not reported separately to the 'traditional' PUs, therefore there is little insight to the true burden of these wounds. Recently the UK NHS introduced new guidance on PU reporting, where it is required to differentiate the MDRPUs from other PUs in the incident reporting (NHS Improvement, 2018).

Incidents of pressure ulcers, including MDRPUs, are routinely reported at the organisation level and in many countries on the national level (Jackson et al. 2016, Smith et al. 2016). These reports include prevalence rates and serious incidents reporting. However, limitations to those data collection systems, such as variation in local implementation of the systems and difference in methodologies used, lead to inconsistencies in reporting of PUs. The systems lack standardisation and are characterised by under-reporting and erroneous reporting (Smith et al., 2016, Barakat-Johnson et al., 2018).

Notwithstanding those limitations, those reports are often used for benchmarking and quality and safety of care indicators. In some countries (e.g. the USA and Australia), PU incidence rates are

linked with financial consequences such as lack of reimbursement for the care provided or potential loss of accreditation (Gefen et al. 2022).

1.8 Problem statement & subsequent chapters

Worldwide, patient safety and quality of care are high on the healthcare agenda (WHO, n.d., Third Global Ministerial Summit on Patient Safety, 2018), with PUs cited as key care quality indicator (Gunningberg et al., 2008). In the USA, category 3 and above HAPUs are described as “never events” (Zaratkiewicz et al., 2010, Patient Safety Network, 2019) and their development leads to financial sanctions (Center for Medicare and Medicaid Services [CMS], 2019). Similarly, in England, pressure ulcers category three and above are on the list of reportable adverse incidents. There has been much emphasis on the prevention of those wounds. Many Quality Improvement (QI) initiatives and policies to improve patient safety and outcomes have been implemented (Padula et al., 2017, Niederhauser et al., 2012), although to date their incidence remains unacceptably high.

In a recent publication, the Organisation for Economic Co-operation and Development (OECD) concluded that 15% of hospital expenditures were consumed by the cost of treatment of safety failures, PUs being the most costly (Slawomirski et al., 2017). As discussed, MDRPUs are considered to represent a substantive proportion of PUs, particularly in critical care settings. Despite medical devices primary function being therapeutic and monitoring patients' health state, they are the source of patient safety incidents, increased costs to organisations, and high costs to patients alike. But despite national drivers to improve patient safety, MDRPUs are not routinely reported. Consequently, there is uncertainty whether indeed MDRPUs represent substantive proportion of PU prevalence and cost presented to date, or those figures in fact underestimate the impact of MDRPUs.

Currently, due to the low frequency of reporting, and despite both mandatory and voluntary reporting tools being available, there is no quality standardised data that can identify which devices would benefit from a further study into their design and safety for use with vulnerable patient groups (Groeneveld et al., 2004).

To provide high quality and safe patient care, data relating to MDRPUs and associated medical devices implicated in skin damage are required. The rigour and consistency of these reports must be ensured to maximise patient benefit. This doctoral research programme will address the need

to standardise reporting of MDRPUs. It will establish a robust, evidence-based, internationally agreed data set, which will underpin a novel reporting tool for use in clinical practice.

In the subsequent chapter (Chapter 2), a narrative review of literature is presented. It offers analysis and synthesis of international academic and grey literature relating to the policy, guidance and practice of reporting PUs and MDRPUs. The findings of this review further guided the development of this doctoral research design and methodology used, which will be presented in Chapter 3. This will be followed by four empirical studies chapters (Chapter 4, 5, 6 and 7), where we will offer a detailed research report of each of the study phases as described in Section 1.2.

The final chapter (Chapter 8) will offer a general discussion of findings and their consequences for policy and practice. They will discuss the strengths and limitations of the research programme and how the novel reporting tool could be used to enable standardised data collection of MDRPUs, and medical devices implicated in patient harm. The potential impact on patient safety and nursing care quality will also be explored.

Chapter 2 Narrative literature review

2.1 Introduction

This chapter presents the finding of a narrative literature review which underpinned the development of the proposed MDRPU reporting form and its content. The review was undertaken to explore and understand the practice of reporting PUs and MDRPUs around the world, using all available written evidence – both academic and grey literature (e.g. guidance, policies, and reporting tools). This chapter provides details of the methodological approach and aims of the review, presents results, and discusses the implications of the findings, as well as limitations of the reviewed literature and methods used.

2.2 Methods

Aim :

To review scientific and grey literature pertaining to PU and MDRPU reporting practice, policies, and guidance.

2.2.1 Design

A narrative literature review approach has been chosen to explore both the scientific and grey literature on reporting practice. This approach was selected due to its flexibility and inclusion of all available sources, both from research and non-research publications (Mays et al., 2005). A five-stage framework for review of the evidence was used, as described by Mays et al. (2005). The stages are not necessarily linear but occurred iteratively. The stages are:

1) define the aim of the review,
2) specify the review question,
3) perform a scoping review to map the evidence,
4) define the search strategy,
5) select studies and other evidence types for the review.

2.2.2 Search strategy

The search for relevant literature relating to reporting practices for pressure ulcers, with a special interest in MDRPUs was completed in two stages: 1) searching research databases and 2) searching for grey literature.

A comprehensive literature search was undertaken in January 2021. Databases searched included: CINAHL Plus with Full Text (Ebsco), Medline (Ebsco), EMBASE Classic + Embase 1947-2021 wk2 (Ovid), PubMed, Web of Science Core Collection, and ProQuest Dissertation and Theses A&I. Search terms were developed using concept mapping (Table 2.1) and applied in using truncation, adjacency and Boolean operators, formatted to each specific database (Appendix A).

Table 2.1 Concept mapping.

CONCEPT	**Reporting**	**Pressure ulcers**
SYNONYMS	Policy Guideline Procedure Document Report	Pressure injuries Bedsore Decubitus Pressure sore Deep tissue injury

All study designs were included. Exclusion criteria included those studies not written in the English language and studies which did not relate to pressure ulcer reporting (local or national). Further literature was identified by screening the publications' reference lists and searching using the names of the key authors, to ensure exhaustiveness of the search. A search of grey literature was performed by scrutinising the following sources: OpenGrey, National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel website, and Google search engine. Simplified search terms were used: "pressure ulcer" or "pressure injury" and "reporting".

In addition to the search for scientific and grey literature, a search for medical device regulatory agencies reporting systems and guidelines was performed. This was based on the data (specifically names of organisations) obtained from academic and grey literature and was undertaken at a later stage.

2.2.3 Quality appraisal

Formal quality appraisal was not performed since the aim of the review was to illustrate pressure ulcer reporting systems, rather than reviewing their quality or appropriateness. A hierarchy of evidence was referred to in relation to academic journal articles (Polit and Beck, 2017). However,

no publications were excluded based on the design or purpose. This decision was made due to the paucity of literature meeting the inclusion and exclusion criteria.

2.2.4 Data extraction and synthesis

A data extraction form was developed based on Gray et al. (2017), which includes methodological elements and study outcomes, as well as details relating to reporting, enabling relevant information to be captured for analysis and synthesis (Popay et al., 2006). Results of studies, policies, procedures, guidelines, white papers, and reporting tools were narratively reported. Following data extraction, synthesis was performed in stages described by Mays et al. (2005):

1) development of a preliminary synthesis of findings of all the included literature,
2) exploration of relationships in findings,
3) assessment of the robustness of the synthesis produced.

To identify patterns and themes in the data, thematic analysis with constant comparison was applied (Glaser, 1965). This technique permits findings from a diverse range of literature to be summarized and organized (Popay et al., 2006). The themes were developed theoretically (Braun and Clarke, 2006) and this a-priori approach was informed by the scoping review of literature. Academic literature review focused on how pressure ulcers were reported in practice (i.e., by whom, in what circumstances, of what severity), and whether, and how, medical device-related pressure ulcers were included in reporting. Whereas when reviewing policy and guidance documents, the themes of interest covered the intended audience, what was the indication for PU and MDRPU reporting, whether the reporting was mandatory or voluntary, and whether it included any guidance on reporting medical device data.

2.3 Results

A search for published academic papers yielded 4,806 hits. After removing duplicates 3,443 titles were screened broadly. A focused abstract review was conducted on 183 articles, out of which 37 articles were read in full (Figure 2.1). Fifteen journal articles were included in the review. Searching reference lists returned one additional academic journal article.

Search of OpenGrey database did not yield any hits. Examination of websites of pressure ulcers advisory organisations and Google yielded 12 policy documents/ guidelines (6 on national level), and 3 reporting tools for review (Figure 2.1).

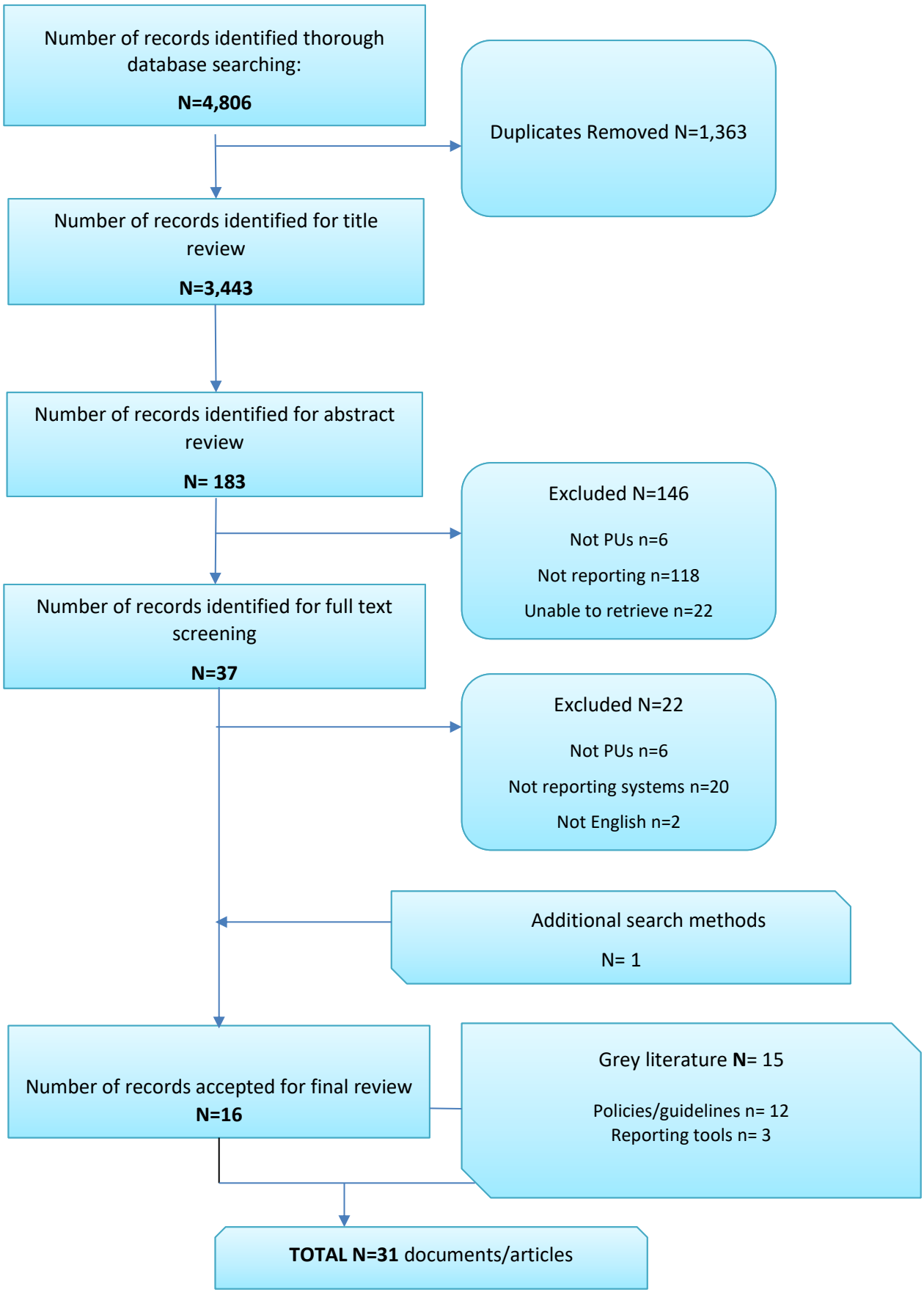


Figure 2.1 PRISMA flowchart.

2.3.1 Type of literature: Academic

A summary of academic literature is being presented, with common elements highlighted and data synthesised to illustrate reporting practice of PUs and MDRPUs. Two main themes were identified in the academic literature: (1) variation and inconsistency in reporting pressure ulcers, and (2) organisational issues in reporting medical device-related pressure ulcers. Reviewed studies focused mostly on organisational (6/16) and local (4/16) reporting practices and half of the publications reported on a quality improvement initiative or a clinical audit. Table 2.2 provides a summary of the literature included in the narrative review, presenting the findings regarding reporting practices.

2.3.1.1 Theme: Variation and inconsistency in reporting pressure ulcers

Academic literature identified PU reporting variation within and between countries. Systems currently in use locally, regionally and nationally lack standardisation, and as reported by Smith et al. (2016) are characterised by high levels of under-reporting. Owing to these inconsistencies it is almost impossible to interpret and compare data between organisations, but also use the data to assess performance. In some cases, the performance has financial implications (Coleman et al., 2016b). Correspondingly, Jackson et al. (2016) highlighted that financial penalties are imposed on healthcare facilities in Australia, and USA Centres for Medicare and Medicaid Services operate a policy of non-payment for HAPUs.

Results of an audit monitoring system in England, surveying 24 National Health Service (NHS) Trusts were reported by Smith et al. (2016) and Coleman et al. (2016b). Smith et al. (2016) aimed to assess accuracy of the reporting systems used in the in-patient facilities, Coleman et al. (2016b) gave recommendation for their improvement. The studies included a Pressure Ulcer and Wound Audit (PUWA) and compared results with clinical records and reports made to Safety Thermometer (STh), Incident Reporting System (IRS) and Strategic Executive Information System (STEIS), which are national reporting databases. A range of issues were identified regarding the definitions of pressure ulcer and quality of reporting metrics, with results revealing patient records were often incomplete. Indeed, PUs were under-reported across all three surveillance systems, and often mis-classified. The collection of data by clinical staff to inform monitoring systems was a further issue, which may have impacted on the quality and completeness of data. The PUWA undertaken by Smith et al. (2016), did not identify a number of PUs which were reported in STh and IRS. Reports to IRS were made based on patient records, rather than physical assessment, and this study observed issues with identification of PU harm from this source. Moreover, the submission to IRS was not readily identifiable in the clinical record. These inaccuracies in reporting are confirmed in the study by Barakat-Johnson et al. (2018), who

examined hospital-acquired PUs reported in the Incident Information Management System (IIMS), by one tertiary hospital in Australia. The results have shown that over 75% of HAPUs were erroneously reported, which may cause concern about the quality of care and patient safety (Barakat-Johnson et al., 2018), although this study limitation relates to its focus on already reported HAPUs, therefore the lack of the opportunity to assess rates of over- or under-reporting. Moreover, inconsistencies between patient records and audit data were found (Barakat-Johnson et al., 2018, Hansen and Fossum, 2016, Li, 2016). Backman et al. (2016) discovered a large proportion of PUs may not be reported in administrative data due to poor documentation in the patient record.

Jackson et al. (2016) in their analyses of PU policies in six countries, highlighted that there is no consensus regarding data collection and reporting, which in turn contributes to variation in data reporting, limiting the possibility for comparison and introducing reporting bias. These findings correspond with results of Dealey et al. (2012a) and Smith et al. (2016), who found similar issues in practices and reports made by healthcare institutions from the same country. Jackson et al. (2016), in contrast to Smith et al. (2016), revealed that the NPUAP/EPUAP classification system was widely used across the countries. An audit of UK monitoring systems shown variance in implementation of this classification system between organisations (Coleman et al., 2016b). Authors also highlighted substantial variation in local implementation of the national policy framework for reporting adverse incidents. Different definitions, data collection methods, and different validation processes have been used by different healthcare facilities.

2.3.1.2 Theme: Organisational issues in reporting medical device-related pressure ulcers

As in the case of traditional PUs, there is a lack of standardised guidance for reporting MDRPUs. Despite using hospital acquired PU metrics as quality of care indicators, the awareness of MDRPUs is low and the processes of reporting underdeveloped (Barakat-Johnson et al., 2017, Chavez et al., 2019). Barakat-Johnson et al. (2018) concluded that the records were not a reliable source of information for MDRPUs since clinical staff would only record skin integrity. They also noted that documentation of prevention and skin monitoring under devices was not available until skin damage occurred. While it has been argued that the proportion of PUs caused by medical devices is small, and as such has small impact on national figures (Smith et al., 2016), this is contradictory to findings of Black et al. (2010), Arnold-Long et al. (2017), and Jackson et al. (2019).

Apold and Rydrych (2012) auditing data of reportable PUs found that nearly a third of the wounds were device-related, and 70% of those occurred on the head or neck. The authors stated that with changes to the reporting documentation, which was implemented in 2009, it was mandatory to

report the category (e.g. tube) of the device implicated in PU development, as well as the type of the device (e.g. nasogastric tube).

A report from a quality improvement project concerned with MDRPUs associated with respiratory equipment, Padula et al. (2017) found differences in how PUs were categorised and documented by different staff groups (e.g. nurses and respiratory technicians). Smith et al. (2016) found MDRPUs reporting varied between monitoring systems and organisations. This was further explored by Coleman et al. (2016b), who revealed a large proportion of trusts do not distinguish MDRPUs in their documentation, even though the majority included them in reports to national databases.

The problems of reporting also relate to technical limitations of the electronic medical record. Chavez et al. (2019) reported that the Electronic Medical Record system used in the Veteran Affairs Nursing Outcomes Database had limited usability. It was not designed for recording MDRPUs or mucosal PUs. Nevertheless, some progress in reporting has been made at local levels. For example, Apold and Rydrych (2012) described how a state-wide intervention initiated by the Minnesota Hospital Association, with support from the Minnesota Department of Health, led to the development of a data collection tool for medical device-related pressure ulcers. From its inception in 2009, reporting requires the identification of MDRPUs, along with information about category and device type.

Dealey et al. (2012a) published proposed guidance on pressure ulcer reporting, collated through an international consensus meeting. The proposed framework offered a uniform set of statements to allow the collection of accurate, meaningful, and consistent data (Dealey et al., 2012a). This has been adapted and implemented nationally in England since 2019 (NHS Improvement, 2018). According to this guidance, MDRPUs have to be reported to national and local incident reporting systems as a separate category (NHS Improvement, 2018).

Table 2.2 Summary of reviewed journal articles included in the literature review.

Author (year)	Topic/ Focus/ Question	Design (Research OR policy)	Setting/ Country	Level of reporting (Organisational (hospital), local, national)	Target population	Type of reporting (mandatory (M)/ voluntary (V))	Standardised staging /definition of PU?	MDRPUs as subsection
Apold, J. and Rydrych, D. (2012)	MDRPUs prevention	audit	Hospitals in Minnesota **USA.**	Local	Nursing staff	M	NPUAP 2007	yes – cat. of device AND specific type of device
Ayello, E. (2017)	Centres for Medicare & Medicaid Minimum Data Set 3.0	Clinical management, education	**USA**	National	Physicians, nurse practitioners, specialist nurses	M	CMS, adapted from NPUAP 2007	No
Backman, C., et al. (2016)	Accuracy of reporting in one healthcare centre	Retrospective analysis of records and prevalence survey	**Canada**	Organisational	Physicians or clinician with primary care responsibility	M	NPUAP n.d.	No
Barakat-Johnson, M. et al. (2017)	MDRPUs management and prevention	Exploratory descriptive	acute tertiary hospital, 800 beds, **Australia**	Organisational	Nursing staff	M	NPUAP/EPUAP /PPPIA 2014	Yes
Barakat-Johnson, M. et al. (2018)	MDRPUs management and prevention	Exploratory descriptive	acute tertiary hospital, 800 beds, **Australia**	Organisational	Nursing staff	M	NPUAP/EPUAP /PPPIA 2014	Yes
Chavez, M., et al. 2019	PU documentation practices	Quality improvement	31 Department of Veteran Affairs facilities **USA**	Local	Nursing staff	M	WOCN 2016	Yes
Coleman, S. et al. (2016)	Variation of PU reporting practices	Audit	24 NHS trusts **England**	Organisational & local	Nursing staff & Trusts	M & V	NPUAP/EPUAP /PPPIA 2014 or adaptation.	varied

Author (year)	Topic/ Focus/ Question	Design (Research OR policy)	Setting/ Country	Level of reporting (Organisational (hospital), local, national)	Target population	Type of reporting (mandatory (M)/ voluntary (V))	Standardised staging /definition of PU?	MDRPUs as subsection
Collier, M. (2015)	Variation of PU reporting practices	Editorial	**England**	Organisational and national	Nursing staff	M	n/a	No
Dealey, C. et al. (2012)	TVS consensus meeting 2011	White paper	All UK h/c organisations **UK**	3 levels of reporting	Nursing staff & Trusts	M	NPUAP/EPUAP 2009	No
Hansen, R. and Fossum, M. (2016)	Accuracy of reporting	Cross sectional, descriptive – nursing documentation audit and patient examination	Nursing homes in **Norway**	Organisational	Nursing staff	M	EPUAP 2009	No
Jackson, D. et al. (2016)	PU prevention & treatment policies in 6 countries	Comparative review and synthesis	Policies re PUs in: **Australia, England, Hong Kong, New Zealand, Scotland, USA**	n/a	n/a	M & V	NPUAP/EPUAP /PPPIA 2014 Definition & terminology – varied.	n/d
Li, D. (2016)	Hospital-acquired PUs in ICUs – accuracy of reporting	Retrospective, comparative, descriptive, correlational – records audit	560-bed medical centre in Florida, convenience sample of ICU patients (n=196) **USA**	Organisational	Nursing staff	M	NPUAP 2007	No
Padula, C. et al. (2017)	PU prevention	QI	16-bed ICU & 19-bed intermediate care unit, Rhode Island **USA**	Organisational	Nursing staff & respiratory therapists	M	NPUAP/EPUAP/ PPPIA 2014 & NPAUP 2016	yes – type of device

Author (year)	Topic/ Focus/ Question	Design (Research OR policy)	Setting/ Country	Level of reporting (Organisational (hospital), local, national)	Target population	Type of reporting (mandatory (M)/ voluntary (V))	Standardised staging /definition of PU?	MDRPUs as subsection
Pokorna, A. et al. (2019)	PU analysis based on a nationwide data	Pilot analysis	Central Adverse Event Reporting System **The Czech Republic**	National	Health care organisations	M	n.d	No
Smith, I. L., et al. (2016)	Accuracy of reporting systems in England	Audit	NHS Trusts **England**	Local & national	Nursing staff	M& V	NPUAP/EPUAP /PPPIA 2009	*STh* – no *IRS* – yes Locally - varied
Zaratkiewicz, S. et al (2010)	Incidence tracking system for HAPUs	QI	Harborview Med Centre, Seattle- level 1 trauma/burn centre **USA**	Organisational	Nursing staff, respiratory technicians & physicians	M	NPUAP 2007	n/d

2.3.2 Type of literature: Grey - Policy and guidance

Healthcare policy and clinical guidelines aim to standardise and improve quality, process and outcomes of care provided for patients. By locating and surveying these documents it was planned to review the guidance for best practice of reporting device related and more traditional pressure ulcers.

Through a grey literature search we identified policy documents from three European countries (England, Wales, and Republic of Ireland), Australia (New South Wales and Southern Australia) and USA (Table 2.3). The primary focus of those documents was to summarise evidence regarding pressure ulcer prevention and provide advice to clinicians on prevention and management of PUs. They offered a brief guidance on how PUs should be reported and mostly concentrated on local level reporting procedures. Policies focusing on reporting adverse incidents presented information on documenting practices relating to pressure ulcer harm which has been deemed to meet adverse event/ serious incident criteria and required escalation to national reporting systems.

Another aim of policies was to guide reporting (NSW Government, 2019, Government of South Australia [SA], 2014). There were cases, for example the All Wales policy (NHS Wales, 2018), published explicitly to promote standardisation of PU reporting to guide performance and improve learning. Three exemplars of reporting systems (Australia, UK, USA) were investigated more closely to analyse how they inform clinical reporting practice. Additionally, where publicly available, medical device harm databases were compared to assess how skin damage and associated devices were recorded.

2.3.2.1 Theme: Learning from incidents

Pressure ulcer incident reports have been developed to share learning and improve quality of care (NSW Government, 2019, Government of South Australia [SA], 2014, Health Service Executive, 2018b, Agency for Healthcare Research and Quality [AHRQ], 2014). Reports might be also submitted to patient safety committees within a central government, for example in Ireland, where they are sent to the Quality and Patient Safety Committee. In some countries, such as USA or Australia, reports are also linked to cost reimbursement and accreditation. Worldwide, reporting of MDRPUs is a relatively new concept included in policies and mandatory systems, providing a limited picture of prevalence and incidence of these wounds.

2.3.2.2 Theme: Variation in staging and definitions

The reviewed policy documents advised using the international staging system and definitions as published by EPUAP, NPIAP and PPPIA in 2014 (Government of South Australia [SA], 2014, NHS Improvement, 2018, NHS Wales, 2018). However, national and local variation in the adoption of the international guideline exists. For example, the Irish policy referred to the international guidelines published in 2009 (Health Service Executive, 2018b). In some countries, there appears to be regional differences in reporting policy. For example in Australia, in contrast to New South Wales, the Southern Australia policy is underpinned by the Pan Pacific Clinical Practice Guideline for The Prevention of Pressure Injury (Australian Wound Management Assoc., 2012).

There are also other variations in the use of staging systems and definitions. In Ireland and Wales, despite policies being underpinned by the international guideline, definitions of avoidable and unavoidable ulcers are taken from the UK Department of Health (DoH). The 2018 NHS Improvement (England) guidance, however, rejected the use of the DoH definitions, to align practices in other patient safety incidents (NHS Improvement, 2018). Additionally, the Health Service Executive (HSE) 2018 guidance (Ireland) used the 2009 EPUAP staging system for categories 1-4 (Health Service Executive, 2018a), but also introduces a “suspected deep pressure and shear induced tissue damage, depth unknown” category, and advises that a stable eschar on patient’s heel should be staged as a category 3 pressure ulcer (until this is proven otherwise). Moreover, for reporting purposes, category 1 PU is defined as a non-blanchable erythema that does not disappear after 24 hours (Health Service Executive, 2018a).

Table 2.3 Summary of reviewed policies and national guidance documents.

Country	PU reporting policy/ guidance	Aim of reporting	Definition and staging standard	PUs reported nationally	MDRPUs reported locally/ nationally	MD Reg body	MDRPUs reported to regulatory body?	Serious incidents & never events
England	NHS Improvement 2018 Guidance	Quality improvement	NPUAP/ EPUAP/ PPPIA 2014	All PUs >= cat. 2	Yes, as a separate category	MHRA	Voluntary	PU cat. 3 & 4
Wales	NHS Wales 2018 Policy	Quality improvement	Definition: NPUAP/EPUAP /PPPA 2014 Staging: Essential Elements of Pressure Ulcer Prevention and Management	All PUs >= cat. 2	Yes, as a separate category	MHRA	Voluntary	PU cat. 3, 4, SDTI & unstageable
Ireland	Health Service Executive 2018 Guidance	Quality improvement	Definition: NPUAP/EPUAP /PPPA 2014 Staging: NPUAP/EPUAP /PPPA 2009	All categories	n/a	HPRA	Voluntary	PU cat. 3 & 4
Australia New South Wales	Pressure Injury Prevention and Management Guideline 2014	Quality improvement Accreditation	NPUAP/ EPUAP/ PPPIA 2014	All categories	n/a	TGA (Australian Government)	Voluntary	PU cat. 3,4, SDTI & unstageable
South Australia	Pressure injury prevention and management 2016	Quality improvement Accreditation	PPPIA 2012	All categories	n/a	TGA (Australian Government)	Voluntary	PU cat. 3,4, SDTI & unstageable
USA	CMS	Reimbursement	NPUAP 2016	All stages	n/a	FDA	Voluntary	PUs cat. 3 & 4

2.3.2.3 Theme: Variation in pressure ulcer reporting

All national and local reporting guidelines instruct pressure ulcer status to be reported on admission to hospital. However, escalation of reporting differs considerably between countries. The New South Wales (NSW) [Australia] policy instructs that all PUs, including Present on Admission (POA), new PUs and wounds which deteriorated during admission are recorded in an Incident Information Management System (IIMS) and reported to the appropriate medical team locally. Similar rules can be found in the guideline published by the Royal Children's hospital Melbourne, Victoria (using Victoria Health Incident Information System (VHIMS)). In Ireland, similar policy is adopted, although a 24 hour deadline for reporting is stipulated.

The Welsh system requires all identified PUs must be recorded and reported through a local reporting system and device related pressure damage is to be reported separately. Although, NHS Wales policy requires all PUs to be investigated (at a certain level), as a minimum it sets out all PUs category 2 and above, unstageable, and suspected Deep Tissue Injury (sDTI) should be investigated using a national (Welsh) review tool. This recommendation echoes in the UK NHS Improvement (NHSI) guidance (NHS Improvement, 2018) for local reporting.

In USA, reporting of pressure ulcers nationally is mandatory since it is necessary for review those data for decisions regarding the commissioning of care. The reviewed California Department of Public Health guidance (California Hospital Association, 2015) and the Minnesota Hospital Association (2019) guidance only discuss reporting of the Hospital Acquired PUs (HAPUs), since occurrence of these PUs have impact on the organisation's funding. No explicit policies or guidance on local reporting of pressure ulcers have been located through internet search.

2.3.2.4 Theme: Reporting serious incidents and never events

Pressure ulcer can meet criteria of Serious Incident (SI) which is defined as an event with grave consequences to patients, families and carers, staff, or organisations, and where the potential for learning warrants using additional resources to investigate the event fully (NHS England, 2015). Pressure ulcer categories reportable as a serious event according to the reviewed policies are presented in Table 2.3.

The reviewed documents show a similar approach to reporting SIs in different countries. Process initiation, however, varies between different nations. Reporting a PU as a Serious Incident is preceded by Root Cause Analysis (RCA) (NHS England, 2015, NSW Government, 2019) and often a severity assessment (Ireland; NSW; South Australia).

However, there is no standard at which a PU is considered a SI. NSW's Pressure Injury Prevention and Management guideline advises that a Severity Assessment Code (SAC) 2 rating is applied to PU category 3 and above (NSW Government, 2019). Akin directive has been included in the Government of South Australia's Clinical Guideline for 'Pressure injury prevention and management" (Government of South Australia [SA], 2014). However, the SA policy instructs, PUs category 2 or greater, should be given a SAC rating 2 or 3 and thus warrant RCA. The rating is given to an incident based on the impact of the harm on patient (additional treatment, disfigurement) and health services (length of stay) (NSW Government, 2019, Government of South Australia [SA], 2014).

In Ireland, the HSE policy requires PU category 3 and above to be classified as Serious Reportable Events if they were acquired after admission. In similar manner to Australian policies discussed above, incidents receive classification (also 3-stage) based on their severity and consequences. Subject to the category, a review is carried out – comprehensive, concise, or aggregate, and results are fed back to the healthcare organisation. This protocol is similar to that in Wales, where additionally all unstageable PUs and suspected DTI require a SI report, which is submitted to the national government. All reviewed policies emphasized that the investigations are followed by a report with a set of recommendations, which are implemented to improve patient safety. Results of investigation are to be used to share learning and quality of care improvement, which is similar to other national systems (e.g. National Reporting and Learning System [NRLS], UK). Implementation of recommendations are monitored and evaluated to assess improvements.

In USA, where the health service is based on insurance, CMS are medical insurance providers that pay patients' hospital costs. Since 2008 the cost of care of hospital acquired pressure ulcers stage 3 and 4 are not paid by Center for Medicare and Medicaid Services (CMS) (Center for Medicare and Medicaid Services [CMS], 2019) and are defined as 'never events' (Agency for Healthcare Research and Quality [AHRQ], 2019). Unstageable pressure ulcers, which developed during hospital stay are subsequently staged as category 3 pressure damage (California Hospital Association, 2015, Minnesota Hospital Association, 2019). All policies regarded reporting SIs as a route to learning and quality improvement. In the UK, reports are made to a National Reporting and Learning System (NRLS) (NHS Improvement, 2019). However, the incident reports are often held and shared only within an organisation or a group of associated organisations.

2.3.2.5 Theme: Variation in MDRPU reporting

The grey literature offered little guidance about reporting MDRPUs. On an organisation level MDRPUs are recognised as a separate category of PUs and local reporting systems allow for collecting information about them. However, there is no standardisation as to what details are

documented. In most cases, the healthcare staff records a narrative account of what has been found and what device type might have been implicated in patient harm.

The most detailed set of instructions was included in the HSE Incident Management Framework (HSE, 2020). It identified that any deterioration in the characteristics and/or performance of a device, and any inadequacy in the instructions of use which led to patient harm, should be reported to the Health Products Regulatory Agency (HPRA). Responsibility for such reporting falls on the manager where the incident occurred, however, this is a voluntary reporting scheme. Guidance to this reporting system does not directly refer to reporting device-related PUs, although there is acknowledgement that the list of incidents that is provided in the document is not complete (Health Products Regulatory Authority [HPRA], 2012).

The Royal Children's hospital Melbourne, Victoria, published a 'quick reference' of clinical pressure ulcer management guideline for communication and documentation of PUs. Any clinical incident has to be reported through the Victoria Health Incident Information System (VHIMS). This reporting system allows to report a MDRPUS and select the device type (e.g. endotracheal tube [ETT]) with space for clinicians narrative (The Royal Children's Hospital Melbourne, 2019).

More detailed report can be submitted through the All Wales DRPU Investigation tool. It collects data on risk assessment score which includes category of device, its name, prevention strategies, skin assessment under device, if staff were familiar with the device, if the device was the right size and applied according to the manufacturer's guidance.

The new NHSI guidance in England requires the MDRPUs to be recorded as a separate category for national reporting. However, it does not include any data about the device. Such information can only be found in the local reporting, although as mentioned previously, there is no standard as to what details are recorded. In Wales, the All Wales Device Related PU Investigation tool is available, although healthcare facilities are at liberty to decide its use alongside a national general PU reporting tool.

2.3.3 Regulatory Agencies

A search for medical device regulatory agencies' reporting guidelines and systems have been undertaken separately. Three regulatory bodies have been used as exemplars (US Food & Drug Administration [FDA], UK Medicines and Healthcare products Regulatory Agency [MHRA] & Australian Therapeutic Goods Administration [TGA]) of how surveillance of medical devices is carried out, in what circumstances and how reports of device harm can be/is reported.

FDA in US, MHRA in UK and Australian Department of Health TGA developed voluntary reporting systems for device related harm (MedWatch, Yellow Card, and IRIS respectively). These reporting interfaces are available online and in print (downloadable from the organisation's website). All three reporting systems allow anyone to report a harm or malfunction of a medical device. However, because these reporting systems are generic and as such contain open mandatory fields and free- text replies, reporting is not standardised, not providing specific data fields relating to pressure ulcer harm (Table 2.4).

In the UK there is no mandatory system of reporting device harm to the regulatory body – the MHRA. However, such reports can be made through the Yellow Card Scheme (MHRA, 2019). Reports can be made online, or a hard copy can be submitted by the reporter. Despite the MHRA advising the report can be made regarding a medical device harm (such as PU), the details the form collects relate mostly to medications (e.g. dose or administration route).

Table 2.4 Summary of medical device and incident data collected by voluntary reporting systems in chosen countries.

	MedWatch (USA)	**YellowCard (UK)**	**IRIS (Australia)**
ID data		▪ Reporter name & address (can decline forwarding to manufacturer)	
Incident	▪ Patient data ▪ Type of incident/outcome ▪ Pre-existing medical conditions/history	▪ Type of incident <u>*Not required:*</u> ▪ Date ▪ Current location of device ▪ Type of injury	▪ Patient data ▪ Type of incident *(no PU option available),* ▪ Medical reason for the device use
Device	▪ Brand name or Common device name	▪ Type/intended use	▪ Name ▪ Brand ▪ If it was sterile ▪ Reusable ▪ For single patient use ▪ Supplier ▪ Manufacturer
Not mandatory	▪ Manufacturer details ▪ Model/catalogue/serial/lot/ unique identifier ▪ Operator of device ▪ Expiry date ▪ Single use AND/OR reprocessed & reused ▪ Details of reprocessor	▪ Supplier ▪ Manufacturer ▪ Serial number ▪ Name or model number ▪ Batch/lot number	▪ Device model ▪ Serial number ▪ Batch & lot number ▪ Expiry date

	MedWatch (USA)	YellowCard (UK)	IRIS (Australia)
	▪ Concomitant products ▪ Reporter's details & background		

The US FDA requires user-facilities to report any adverse event related to the use of a medical device annually and any occurrence of device-related harm or a serious injury if manufacturer of the device is unknown. MHRA and TGA also put a legal obligation on a manufacturer or sponsor to report any adverse incident related to use of a medical device. However, there is no such obligation on clinicians or other healthcare professionals for reporting pressure damage, which are not considered to be an adverse incident.

The difference between the US, Australian and UK systems are the public availability of the reports. The UK YellowCard and the MHRA reports data are not available publicly. The FDA Manufacturer and User Facility Device Experience (MAUDE) and TGA Database of Adverse Event Notifications (DAEN) databases, however, are searchable and publicly available, thus allowing for retrieval of any incidents related to a device in question (Table 2.5). Additionally within the US MAUDE database, manufacturer often offers a reply to the report (U.S. FDA, 2019).

Table 2.5 Characteristics of MD - related harm databases

	MAUDE (USA)	DAES (Australia)
Searchable by device	Yes	Yes
Searchable by injury	Yes	-
Manufacturer' comments	Yes	-
Source of reporting (system)	Voluntary & mandatory	Voluntary & mandatory

Five reports from the MAUDE website have been accessed and analysed to evaluate the details reported. The results revealed that individuals completing the reports were not directly involved in the care of a patient – they were manufacturers. Report contents were based on data supplied by a healthcare professional, or patient, and their own investigation. The event descriptions were most likely originating from the patient files, and very brief. The main body of report focused on details listed in Table 2.5 presented above. Manufacturers were able leave response to the report on file. In reports reviewed, one report had no response, one stated a report will be issued on receipt of further details, one stated biocompability testing of the device was successful, and the last one stated there was no evidence the device malfunctioned.

2.4 Discussion

This literature review aimed to synthesise current scientific and grey literature regarding pressure ulcer reporting systems and processes. We found a paucity of publications on reporting pressure ulcers, especially device-related pressure ulcers. Similarly, policy documents are not readily available. A significant degree of variation was observed in scientific and grey literature.

Worldwide, patient safety and quality of care are high on the healthcare agenda (WHO, n.d., Third Global Ministerial Summit on Patient Safety, 2018). PU prevalence and incidence rates are indicators of the quality of nursing care (Gunningberg et al., 2008). In the USA, HAPUs category 3 and above are described as "never events" (Zaratkiewicz et al., 2010, Patient Safety Network, 2019). In England, PU category 3 and above are on the list of reportable adverse incidents. There has been much emphasis on the prevention of those wounds, and many quality improvement (QI) initiatives and policies to improve patient safety and outcomes have been implemented (Sullivan and Schoelles, 2013, Padula et al., 2017, Niederhauser et al., 2012). However, to date, their incidence in both the acute and community care settings has remained unacceptably high, resulting in a significant burden to patients and healthcare providers.

The fundamental premise of policies and clinical guidelines is to promote standardised practice and improve the quality of patient care (Woolf et al., 1999, Jackson et al., 2016). Nonetheless, despite the emphasis of policies on collecting national prevalence data for pressure ulcers, the lack of consistency in the data collection standards was apparent both within and between countries (Barakat-Johnson et al., 2018, Coleman et al., 2016, Jackson et al., 2016, Smith et al., 2016). In addition, inconsistency of hospital coding systems and classification limits the capacity to use data for pressure ulcer prevention and collate care quality indicators (Backman et al., 2016). This was despite the instruction of most of the reviewed policies to use the international guidelines published by NPUAP, EPUAP and PPPIA as an underpinning document for PU categorisation, prevention, and management (NHS Improvement, 2018, NHS Wales, 2018, NSW Government, 2014).

Moreover, there is also a significant paucity of research for reporting device-related pressure ulcers. There are no easily available policies on reporting MDPUs either. The data are fragmented and scattered, often creating more questions than gives answers. Reviewed literature shows a lack of standardisation of reporting on different levels (Barakat-Johnson et al., 2018, Coleman et al., 2016b, Dealey et al., 2012a, Jackson et al., 2016, Smith et al., 2016). Therefore, it is impossible to compare organisations within a healthcare system or between healthcare institutions. This severely limits shared learning from the MDRPU incidents. On inspection, the mandatory systems often do not record contextual details regarding devices. Even if MDRPUs are recorded and

reported within mandatory systems, the reports omit important details of the device implicated in patient harm (NHS Improvement, 2018, Center for Medicare and Medicaid Services [CMS], 2019). In cases where the specialist nursing teams decide to collect data about devices, they are kept at a hospital level for intelligence and educational purposes (Apold and Rydrych, 2012, Chavez et al., 2019, Padula et al., 2017). However, as evidenced by the lack of reports in the UK's Yellowcard scheme (MHRA, 2019) and the limited number of reports in the MAUDE database (U.S. FDA, 2019) the data are not being regularly submitted to medical device regulatory bodies by healthcare professionals and/ or organisations. This severely limits shared learning from the MDRPU incidents. There is no one database accessible nationally or worldwide that records full details of MDRPUs. It is internationally agreed that devices which cause skin damage often would benefit from a further study into their design and safety features for high-risk patients (Groeneveld et al., 2004) and should be managed through better regulation and evidence (Gefen et al., 2020).

2.4.1 Limitations

The most important limitation of this narrative literature review was reliance of the grey literature being published in English language. It is highly likely there are other publications in the public domain which we were unable to track and review because they were written in their national languages. Using internet for searches of grey literature also poses limitation on what can be retrieved, because of the ever-changing nature of Google's search algorithms.

2.5 Conclusion

Currently, there is much variation how pressure ulcers are recorded and reported between organisations, regions, and countries. These differences make benchmarking difficult, and as such have a negative impact on potential improvement to patient care and safety. Even more challenging circumstances surround medical device related pressure ulcers. Here, the disparities are even more pronounced. It is not only about what details are reported, but the most basic issue of reporting MDRPUs as a separate category. Thus, due to the low frequency of reporting, there is no standardised database of devices which have been implicated in MDRPUs, and as such improvement in care, safety, and device design is based on local knowledge rather than a robust evidence-based policy.

2.6 Aims and objectives of the doctoral programme of research

The gap identified by the literature review determined the following doctoral research **aim**:

To systematically develop a MDRPU reporting tool underpinned by an international consensus in readiness for clinical practice settings.

To achieve this aim, a research pathway consisting of four distinctive phases was developed with the following **objectives**:

- To explore clinicians' experiences of pressure ulcer reporting systems, with emphasis on medical device-related pressure ulcers and to derive barriers and facilitators to reporting pressure ulcers in practices - Chapter 4.
- To define a list of MDRPU reporting criteria from the literature review and interviews - Chapter 5.
- To establish international consensus on a data set which can be used to design a form to facilitate routine and standardised reporting of Medical Device-Related Pressure Ulcers (MDRPUs)– Chapter 5.
- To assess and improve the usability and acceptability of the Medical Device – Related Pressure Ulcer Reporting Form with its intended end-users using cognitive pre-testing – Chapter 6.
- To assess the usability and feasibility of a Medical Device Related Pressure Ulcer (MDRPU) reporting form, derived from an internationally agreed Data Set, in clinical practice – Chapter 7.

The overview of methods used to address the doctoral programme of research aim will be introduced in the ensuing Chapter 3. Detailed account of the aims, methods and results of each of the sequential studies will be given in subsequent chapters of the Thesis.

Chapter 3 Methodology

3.1 Introduction

The literature review presented in Chapter 2 identified the lack of a standardised way of reporting MDRPUs in clinical practice and the need for a reporting tool to be established. This chapter describes and discusses the overall methodological approach taken, which forms the basis for achieving the aims of this programme of doctoral research. Detailed methods used in each of the studies are described in each of the ensuing thesis chapters preceding specific results.

3.2 Research design overview

This doctoral research thesis combines qualitative and quantitative research methods to arrive at the pre-defined aim of developing a MDRPU reporting tool. With such focus, this PhD programme of research is grounded in pragmatism.

Pragmatism is a worldview that focuses on applying the best methods to investigate real-world issues. It accepts the use of different sources of data to answer research questions. It is linked with mixed-method research, where the researcher uses both qualitative and quantitative approaches within a study or multi-phase project to reach the research aim (Creswell and Clark, 2018, Polit and Beck, 2017). Although there was a criticism that such 'what works' approach is not systematic enough in ensuring that the evidence is legitimate or valuable (Teddlie and Tashakkori A., 2003, Hesse-Biber, 2015), others highlighted that the choice of the method leading to the evidence discovery is underpinned by academic rigour (Kelly and Cordeiro, 2020). Despite the paradigm being criticised for over-emphasising what is practical, it gives attention to theory and practice (McKenna et al., 2011) and knowledge is directly linked with experience (Hildebrand, 2011).

3.2.1 Methods for developing health measurement instruments

Currently, there is no methodological approach to developing and validating reporting tools. As a result, health status and patient-reported outcome measures instrument development methods were considered and critiqued. Those methods typically have widely accepted and cohesive theoretical framework, methods for development, and validation (Lohr, 2002). Indeed, guidance for the review and evaluation of patient-reported outcome measures has been established (U.S. FDA., 2009), as well as criteria for evaluating the health status and quality of life instruments

(Lohr, 2002). In the field of skin health, this guidance influenced the development and validation of a novel pressure ulcer risk assessment instrument (Coleman et al., 2016a) and, more recently, a patient-related outcome measure for all types of chronic wounds (Klassen et al., 2020). Consequently, it was found to be relevant for the development and validation of the proposed MDRPU reporting tool.

In wider literature, the terms 'instrument' and 'tool' are used interchangeably as a measure of the quality or quantity of a health outcome of interest (Prinsen et al., 2016). The term 'instrument' covers an array of measures that aim to collect data to evaluate health status through a clinician's assessment or patient report (Polit and Beck, 2017). This may be a single score (obtained through physical examination or a laboratory test), scale, questionnaire, or measurement (Prinsen et al., 2016). Table 3.1 presents the key terms commonly used in the literature in the context of health and patient outcomes measurement.

Table 3.1 Key terms used in the health measurement literature, based on (Polit and Beck, 2017)

Term	Definition
Instrument	A device or tool used for the purpose of data collection. The term **'device'** includes any apparatus or object that indicates the amount, quantity, or degree of a construct. The term **'tool'** includes forms, checklists, and surveys. It aims to collect data for specific purposes and offers instruction/ guidance for use.
Form	Standardised document with fields in which to write or select. Used for data collection for an specified purpose, i.e. incident reporting.
Measurement	The process of allocating scores (numbers) to represent how much of a construct under investigation is represented in a person or object and based on prescribed rules.
Scale	A composite measure of an attribute, where data from multiple items are converted into a single number (value) representing where a person places on a continuum representing the attribute.

The term '(reporting) form' was adopted for the purpose of this research. By this, the researcher refers to an organised and systematic data collection sheet/ document. The difference in this doctoral programme of research is, that the reporting form is not designed to measure any aspect of health or illness but to enable robust MDRPU data acquisition in a new standardised way to improve the reporting practice. This caveat is essential when considering the validity and reliability of the proposed reporting form (Table 3.4).

3.2.2 Conceptual framework

This doctoral research aims to develop a robust, evidence based MDRPU reporting tool. Hence, well-established methodologies are drawn upon, where a sequential mixed methods design is shown to provide a sound basis for investigation (Figure 3.1). Within this sequence of development steps, important aspects of validity and reliability are considered. This programme of doctoral research will utilise the most important elements of this framework to design the research studies, which will result in a meaningful, evidenced based tool design and evaluation.

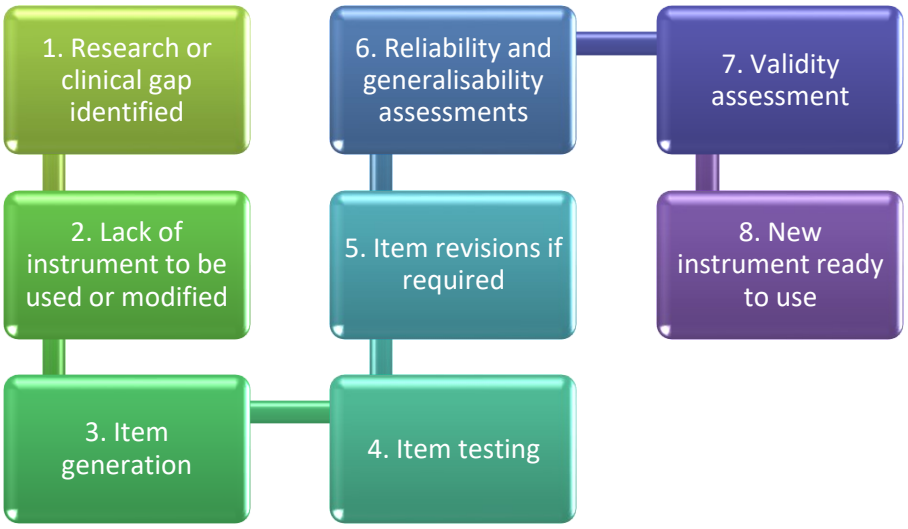


Figure 3.1 Process of developing a new health measurement instrument, adapted from Streiner et al. (2015).

In recent years, there have been several new instruments developed in the area of skin health, including PU risk assessment tools (Coleman et al., 2016a, Coleman et al., 2014a), attitudes and knowledge questionnaires (Beeckman et al., 2010), pressure ulcer prevalence (Vanderwee et al., 2007), and to classify and measure incontinence-associated dermatitis (Beeckman et al., 2018). These publications provided exemplars of the application of health and patient-related outcome measurement methodologies and provided a frame of reference when considering the approach to developing and validating the MDRPU reporting tool. Table 3.2 presents methods used in developing those novel instruments.

Table 3.2 Phases of instrument development

Authors & Focus / Phases	Vanderwee et al. PU prevalence measurement	Beeckman et al. Attitudes towards PU prevention measurement	Coleman et al. PU risk assessment instrument
Literature review	-	Yes	Yes
Expert discussion on the content of the instrument	Yes	Yes	Yes
Formal consensus process to agree on the content of the instrument.	-	Yes	Yes
Approvals by expert groups and stakeholders	Yes	-	Yes
Pre-testing (cognitive methods)	-	-	Yes
Pilot testing	Yes	Yes	Yes
Reliability	Inter-rater	Stability reliability	Reliability
Validity	Face and content	Face, content and construct	Convergent and known groups
Additional psychometric tests	-	-	Data completeness, clinical usability

The framework for developing the MDRPU reporting form is informed by the methodology used for developing health measurement and patient-related outcome instruments (Streiner et al., 2015, Polit and Beck, 2017, U.S. FDA., 2009). However, a critical difference in the MDRPU reporting form is to collect data in a standardised way but not to yield scores. As a result, different psychometric characteristics are relevant to this research (Table 3.4) and this is reflected in the design and methods used in this programme of research.

3.2.3 Considering psychometric properties of the MDRPU reporting tool

In general terms, when a health measurement or patient-reported outcome measure is constructed, it yields scores (e.g. continuous scores, categorical scores). Some instruments may be generic (i.e. applicable across patient populations) and some may be patient population specific (e.g. self-efficacy scale for patients with leg ulcers). However, when choosing what measure to use in practice, the quality of their measurement properties, i.e. validity and reliability is the guide (Streiner et al., 2015).

Validity and reliability can be explored in cross-sectional and longitudinal domains, depending on whether the measurement is done at one point of time (cross-sectional) or over a series of time points (longitudinal) (Prinsen et al., 2016). In this doctoral study, however, we are interested in the cross-sectional domains since the MDRPU reporting form collects data corresponding to an incident of skin damage.

Table 3.3 Cross-sectional measurement property domains based on Polit and Yang, as published in Polit and Beck.

Validity domain	**Reliability domain**
Content and face validity	Reliability (test-retest, inter-rater, intra-rater, parallel test)
Criterion validity (concurrent, predictive)	Internal consistency
Construct validity	Measurement error

The taxonomy and definitions of psychometric properties that are usually used for assessments of new health and patient-related outcome measure instruments are shown in Table 3.3. However, owing to the aim of the MDRPU reporting, not all of the parameters are applicable or can be used to ascertain the psychometric properties of the form (Table 3.4).

Table 3.4 Validity and reliability taxonomy and definitions, summarised based on Polit and Beck (2017) and Streiner et al. (2015)

Property	**Definition**	**Applicability to the MDRPU reporting form**	**Justification**
Validity	The degree to which the instrument measures the construct it claims to measure.	Yes	The form collects relevant MDRPU data
Content and face validity	**Face validity** refers to whether the instrument looks like it measures the construct under investigation.	Yes	The form will collect specific data on MDRPUs
	Content validity refers to the extent to which the instrument's content adequately captures the construct under investigation.	Yes	The form content needs to reflect key domains of MDRPU reporting
Criterion validity	It is concerned with the degree to which the scores are a good reflection of a 'gold standard' (i.e. criterions being an ideal measure of the construct). Where the 'gold standard' does not exist, the measure cannot be validated using this approach.	No	There is no 'gold standard' and no scores are yielded
Construct validity	The degree to which evidence about the measure's scores, relative to other scores, supports the conclusion that the	No	The form items do not yield any scores

Property	Definition	Applicability to the MDRPU reporting form	Justification
	construct is appropriately represented.		
Responsiveness	The ability to detect changes over time in the construct being measured.	No	The form items do not measure changes over time
Reliability	The extent to which scores obtained from the same participants have not changed.	Partially	Although the from does not yield any scores, the expectation is that the same data are collected when evaluating reproducibility.
Test-retest	The same measure is administered to the same rater on two occasions.	Yes	The reporter completes the form regarding the same MDRPU occurrence (where there was no change in medical condition) in the same way on two different occasions.
Inter-rater	The same measure is administered simultaneously to two or more raters.	Yes	Two different reporters, at the same time) produce report with the same data recorded.
Parallel test	The same attributes are measured using an alternate version of the same instrument with the same raters.	No	There is no other reporting form/ tool available.
Internal consistency	The extent to which scores obtained from the same participants have not changed across items during the exact application of the instrument.	No	The form items do not yield any scores.
Measurement error	The systematic and random error in scores obtained cannot be attributed to actual changes in the construct under investigation.	No	The form items do not yield any scores.

Property	Definition	Applicability to the MDRPU reporting form	Justification
Data quality & usability / acceptability	The extent to which items of the form are completed by the reporter (quality of data) & the form use is deemed usable and acceptable for use in clinical practice by the end users.	Yes	The form items collect relevant & necessary data about MDRPUs; to obtain robust / quality data, the form needs to be usable, acceptable & completed in full (or nearly).

The psychometric characteristics addressed in the studies to be undertaken at each phase of this doctoral research, which will consequently lead to the development of a MDRPU reporting form, will be content and face validity, data quality, and usability.

Instrument design can be performed through sequential studies, including determining content domain, sampling from content (item generation) and instrument construction (Nunnally, 1967). The first step is determining the content domain of a construct that the form is made to assess. Content domain is the content area related to the variables that being measured (Beck and Gable, 2001). It can be identified by literature review on the topic, interviewing with the respondents and focus groups. Through a precise definition on the attributes and characteristics of the desired construct, a clear image of its boundaries, dimensions, and components is obtained. The qualitative research methods can also be applied to determine the variables and concepts of the pertinent construct. The Delphi technique has also emerged as a popular method for assessing instrument content validity (Murphy et al., 2017, van Rijssen et al., 2019). It seeks to obtain consensus on the opinion of experts through a series of structured survey rounds (Hasson et al., 2000).

Content validity will be confirmed by a consensus study, where the items relevant and necessary for inclusion in MDPRU reporting will be decided upon. During cognitive pre-testing, the face validity will be tested and confirmed by clinicians who experienced in the field of tissue viability as well as reporting practices and policies. Finally, evaluation of data quality and usability will be undertaken during a feasibility study (Polit and Beck, 2017). The usability of a tool is confirmed if it is easy to interpret and use, thus can be completed as intended (Brooke, 1996b), hence impacting positively on data quality. At the same time, acceptability concerns whether the end-users consider the tool appropriate for the task, are satisfied with it or any of its elements, and to what extent they felt overburdened by the data collection (Polit and Beck, 2017). Usability and acceptability testing is important for the MDRPU reporting tool since we are developing and proposing a novel, standardised way of collecting data.

Assessment of reliability will not be undertaken due to the constraints on resources of this doctoral project. Reliability will be best assessed when the form has been more fully developed. Thus the previous studies must be completed first prior to future studies evaluating the test re-test- and inter-rater reliability. The form will be designed to optimise reliability through drop down options, clear instructions and logical flow of items. Any future study should focus on confirming reproducibility of data gathered using the MDRPU reporting form to confirm the form's reliability.

The process of developing a new health measurement instrument (Figure 3.1) was modified for the purpose of developing an MDRPU reporting form. The changes made, were underpinned by the purpose of the form, i.e. collecting facts about the MDRPU. Some psychometric characteristics will not be tested since the motivation for the design and subsequent measurement requirements are driven by the aim of the tool being developed, here – the form (Greenhalgh et al., 1998).

Furthermore, the importance of including end-users (i.e. clinical nurses) in the development and evaluation of the MDRPU reporting form (Greenhalgh et al., 1998) is recognised and implemented as an important part of this PhD doctoral programme of research. Using pertinent studies published in skin health and instrument development allowed for constructing a frame of reference that further informed the framework and design for this programme of research. Consequently, an MDRPU reporting form will be developed systematically, ready for use in clinical practice to collect robust and comparable data on MDRPUs incidents.

3.3 General Approach

In this research programme (Figure 3.2) the design of each phase was carefully considered, and methods were chosen based on the research aims and objectives (Chapter 2, section 2.6), i.e. what is the best approach to answer each of the research questions posed. Qualitative methods were used to explore participants' experiences and issues they might encounter in their routine practice. These data informed the consensus study, where the quantitative findings informed the content of the proposed reporting tool. Cognitive pre-testing methods enabled improvements of the draft form resulting in a more cohesive and clearer tool for pilot feasibility testing. In this final phase, we used a mixed-method, sequential exploratory approach. Thus, allowing early identification of issues, which were then discussed with participating nurse teams during focus groups. Such mixing of methods is in line with the pragmatic paradigm and aims to use the best research method for the problem under the investigation (Creswell and Clark, 2018).

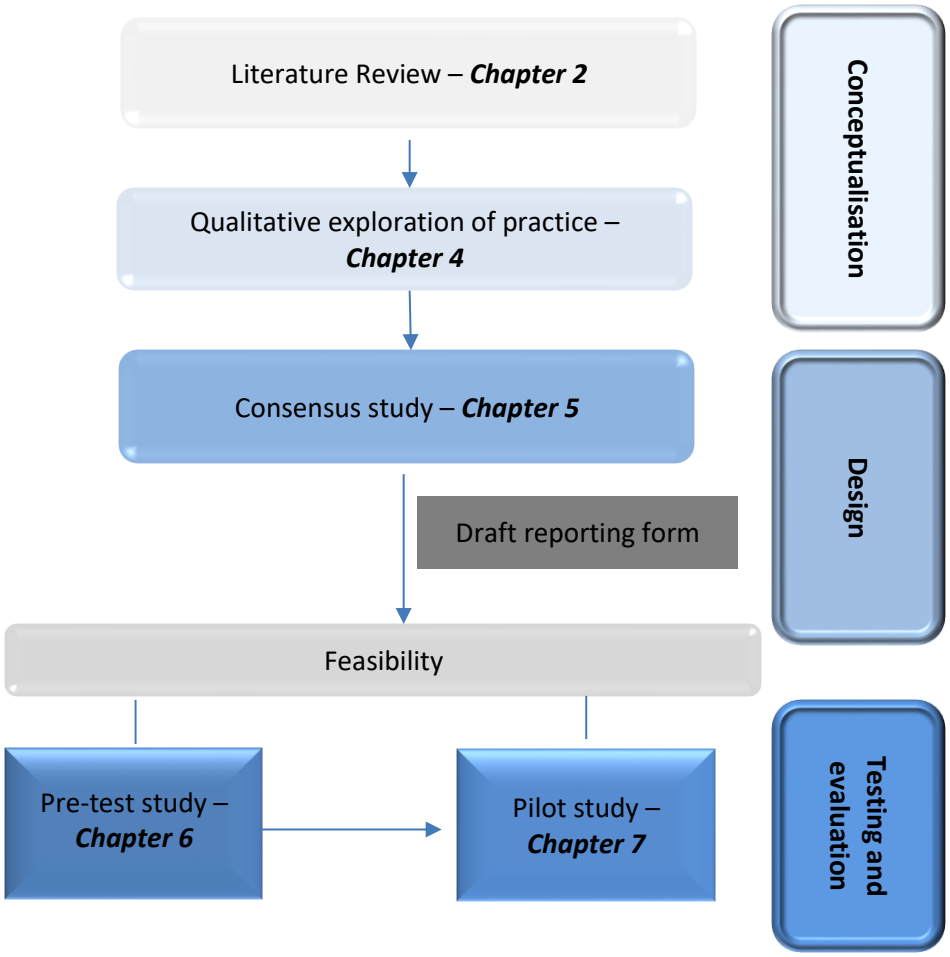


Figure 3.2 The design of the programme of doctoral research.

3.4 Summary

This chapter presented the approach to undertaking the doctoral programme of studies. Drawing on methodologies used for health measurement and patient-reported outcome measure instruments development, a methodology for developing the MDRPU reporting form was developed. Following this, the design of the doctoral programme of research was described, as well as how this systematic approach led to achieving the overarching aim of developing an evidence-based MDRPU reporting form.

Subsequent chapters, organised sequentially, will detail the design and methods used in each of the phases of this doctoral programme of research. Finally, the novel MDRPU data reporting form will be introduced (Chapter 7). Lastly, a general discussion of all study findings will be presented and examined against the overall aim and objectives in Chapter 8. Which will also offer suggestions on how it might be used in clinical practice and what further research might be required.

Chapter 4 Qualitative exploration of reporting practice

4.1 Introduction

There is a paucity of literature on MDRPU reporting practices in different clinical settings, with reports of under reporting and a lack of reliability for general PU reporting. Therefore, qualitative exploration of reporting of pressure ulcers, especially those which are medical device-related, was undertaken to complement the narrative literature review (Chapter 2) and provide a source of data for the future design of the reporting tool (Chapter 5). The reporting of MDPRUs in current clinical practice is explicitly addressed and opinions of healthcare professionals about an 'ideal world' data set for collating information are elicited.

Aims:

To explore clinicians' experiences of pressure ulcer reporting systems, with emphasis on medical device-related pressure ulcers.

To explore barriers and facilitators to reporting pressure ulcers in practice, with emphasis on MDRPUs.

Objectives:

- To identify and recruit a range of international clinical, academic, and industrial experts in pressure ulcer reporting
- To perform a series of interviews with the experts to derive information regarding their experiences of reporting systems in different countries.
- To collect opinions on the content of an 'ideal world' data set for reporting MDRPUs.
- To perform qualitative analysis on the interview transcripts to identify key determinants for reporting practices.

4.2 Methods

A descriptive design using semi-structured interviews was used, which allows exploration of different perspectives and produces in-depth, rich data for analyses (Bowling, 2014, Barbour, 2014). Interviews were selected as an appropriate methodology as they are considered the 'gold standard' of qualitative research (Barbour, 2014) and are the most commonly used technique in qualitative research (Britten, 1999, Legard et al., 2003). This method of data collection allowed

participants to express their experiences and unique views in a confidential environment, and to elicit their wider views on the topic of MDRPU reporting.

The Tailored Implementation for Chronic Diseases (TICD) (Flottorp et al., 2013) framework was used to systematically report barriers and facilitators to PU and MDRPU reporting. The TICD is a checklist of 12 determinants relevant for change implementation in healthcare settings which was developed through systematic review and consensus process. It constitutes 7 domains: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organisational change, and social, political, and legal factors.

4.2.1 Participants and recruitment

Leading organisations in tissue viability (Table 4.1) were identified based on their engagement in developing international guidelines for pressure ulcer prevention and treatment (EPUAP NPIAP & PPPIA., 2014). Their representatives were recruited as gatekeepers, who were contacted via email to introduce the study and ask for their support. Simultaneously, the team pursued experts who were in their professional networks, asking for support of the study. Recruited members of organisations and experts signed a consent form indicating their willingness to act as gatekeepers.

Table 4.1 Organisation approached for the purpose of participant recruitment

Organisation	**Summary of membership**
European Pressure Ulcer Advisory Panel	Health professionals, researchers, academics, industry representatives.
National Pressure Ulcer Advisory Panel	Health professionals, industry representatives, governmental agencies representatives.
Pan Pacific Pressure Injury Alliance	Wounds Australia: health professionals, researchers and academics. Hong Kong Enterostomal Therapists Association Society: Stoma, wound and continence nurses. New Zealand Wound Care Society: Health care professionals, from a range of disciplines. Wound Healing Society Singapore: health care professionals and industry representatives.
European Wound Management Association	Wound management organisations, health care professionals, researchers and academics.
Wound, Ostomy and Continence Nurses Society	US Wound, ostomy and incontinence health care professionals.
Tissue Viability Society	Health care professionals, researchers, academics and industry representatives.
NHS Improvement	Tissue viability and critical/intensive care health professionals

Participants were purposefully sampled to represent a range of experiences and expertise in tissue viability and/or wound assessment or reporting, as well as have a good working knowledge of policy and practice stemming from their healthcare roles. The research was not guided by a sample size or saturation, rather we looked to include representatives from as many countries as possible, to allow us to have a better general overview of factors impacting on reporting practices.

After receiving confirmation from gatekeepers, an information leaflet was distributed to potential study participants representing different regions under their membership. Those who expressed an interest in taking part in the study were then contacted directly by the researcher to confirm eligibility and check if they fulfil inclusion criteria (Table 4.2). If they met these criteria, an appropriate day, time, and mode of the interview was agreed between the lead researcher and participant. A participant information sheet was included in the email correspondence, as well as a consent form , which was signed and returned prior to the interview taking place.

Table 4.2 Inclusion and exclusion criteria applied – interview participants

Inclusion criteria*	**Exclusion criteria**
10 years' experience working within the domain of tissue viability.	Inability to communicate in English
Healthcare professions Council Registered or General Medical Council Registered.	
Clinical practice including wound assessment and/or reporting within the last 2 years.	
Research/publication track record on pressure ulcers and/or medical device-related pressure ulcers.	
Industry experience working with medical devices which interface with the skin or prophylactic dressings to protect the skin.	

***Healthcare professionals to meet at least 2**

4.2.2 Data collection

One-on-one, semi-structured interviews were conducted based on a topic guide (Appendix B). The topic guide was developed based on the themes from the narrative literature review (Chapter 2), i.e. variation in reporting of PUs and MDRPUs, organisational issues in MDRPU reporting, learning from incidents, variation in staging and definitions used, variation in PU reporting practice, and reporting serious incidents and never events. At this stage the TICD was not used to guide the development of the interview questions. Interviews lasted between 30 and 60 minutes and were audio recorded and transcribed verbatim by the doctoral researcher and anonymised.

Due to the geographical spread of participants, the majority of interviews were carried out online, via Skype for Business (www.skype.com/en/business) or an online conferencing platform available at https://www.zoom.us/. These platforms offer free online meetings, accessed via a dedicated link, and can be accessed from any device (Windows, Apple, Android). It provided a secure and flexible means to conduct the interviews, reducing inhibitions and supporting anonymity (Polit and Beck, 2017). Online interviews were audio recorded only (not video), to ensure anonymity in the subsequent analysis. Some of the interviews were also carried out via telephone and face-to-face. In such case, interviews were undertaken in a private room for confidentiality purposes. Similarly, they were audio-recorded, transcribed verbatim by the researcher, and after a check for accuracy, the recording was deleted.

4.2.3 Data analysis

Thematic analysis with a codebook approach (Braun and Clarke, 2019) was used to analyse the data. Initially the researcher immersed herself in the data through systematic reading and familiarisation. Open coding was undertaken independently by the doctoral researcher. This was followed by focused coding. The researcher chose the initial codes making most analytical sense to categorize data (Charmaz, 2014) and themes were presented as domain summaries (Braun and Clarke, 2019). The codebook was developed by the researcher based on analysis of first three interviews. The initial themes were developed inductively and at this early stage the researcher avoided 'fitting' barriers and facilitators into the TICD domains. It was at the stage of reporting of the determinants of practice that the inductively developed themes were positioned as sub-domains in the TICD and highlighted as a barrier or facilitator for the reporting practice (Table 4.5). To ascertain, as much as possible, that there was no bias in developing themes relating to barriers and facilitators of MDRPU reporting, the researcher did not examine the TICD framework until the themes were ready to scrutinise them against the framework.

Coding and analysis started immediately after the first interview, with new data added to the analysis as it emerged. NVIVO software (NVIVO 12 PRO, QSR International) was used to facilitate data analysis.

4.2.4 Reflexivity and trustworthiness

Different strategies were used to ensure the quality of the research. The researcher kept a reflexive journal to examine her own values, identity, and background since they may affect the research process (Polit and Beck, 2017). As a non-clinician, the researcher had no pre-conceived

ideas about pressure ulcer reporting. Nevertheless, as a researcher, the author recognised the need for improved reporting.

An audit trail was developed, and investigator triangulation (Polit and Beck, 2017) was used, where a small subsection of transcripts, coding and analysis was crosschecked by the supervisory team to ensure consistency and accuracy. There were no disagreements during this process, which was an opportunity for the researcher to reflect and share reflections and thought about the data and their analysis with the supervisors.

4.2.5 Ethical considerations

Institutional approval was obtained from University of Southampton Ethics Board (ERGO 2 49718) prior to study recruitment (Appendix C) .

All participants had at least 48 hours to consider their participation after they received their information sheet. They also had ample opportunities to ask questions relating to the study. Indeed, some asked several questions through email exchange, before committing to participating. In all bar one instances, electronic versions of the consent form with e-signatures were used and shared through password protected emails.

All data were stored and kept secure in compliance with University of Southampton protocols, the European Union general Data Protection regulation and the UK Data Protection Act (2018). To ensure good data management practice, the sound files were downloaded securely to a university password-protected server, and the external recordings were deleted immediately.

4.3 Results

During October 2019 to February 2020, 17 semi-structured interviews were conducted. The majority of interviews (11/17) were undertaken using Skype, telephone (3/17) and Zoom (2/17). One interview was undertaken face-to-face. Participants represented eleven countries, and the majority (13/17) identified themselves as tissue viability/wound and ostomy care nurses. Background and professional credential of interview participants are presented in Table 4.3.

Table 4.3 Characteristics of interview participants.

Participant's ID	Country	Setting	Position	Years of experience
P1	UK	Acute	TVN lead	Less than 10
P2	Czech Republic	Acute/Academia	Professor of nursing	More than 10
P3	USA	Paediatrics/ acute	WOCN	More than 10
P4	USA	Long Term Care (LTC)	APN, WOCN, clinical professor	More than 10
P5	Italy	Paediatric/ acute	RN	More than 10
P6	UK	Acute	TVN Lead	More than 10
P7	Hong Kong	Private hospital	WOCN lead	More than 10
P8	Thailand	Military hospital	APN, WOCN lead	More than 10
P9	USA	LTC	VP skin integrity/ certified wound specialist	More than 10
P10	Switzerland	Acute	Wound care specialist	More than 10
P11	Finland	Acute/ ICU	RN, Wound care specialist	More than 10
P12	Australia	Academia/ Acute	Senior research fellow & lecturer	More than 10
P13	Italy	Paediatric/ acute	Plastic surgeon/ wound care specialist	More than 10
P14	Belgium	Acute	Clinical nurse specialist in wound care	Less than 10
P15	Brazil	Academia/ acute	RN/ professor of wound care	More than 10
P16	UK	Paediatrics/ acute	TVN lead	Less than 10
P17	UK	Industry representative	Engineer/ designer	n/a

APN – advanced nurse practitioner; **WOCN** – wound and ostomy nurse; **RN** – registered nurse; **TVN** – tissue viability nurse; **VP** – vice-president.

Three main themes were developed during the analysis - '*reporting systems and processes'*, *determinants of reporting practice*, and '*emergent issues in MDRPU reporting'*. These are presented with subthemes, in the Table 4.4, and discussed in depth with participant's quotes for illustration. In 'reporting systems and processes' and 'determinants of reporting practice' themes,

findings about PUs and MDRPUs are presented within subthemes together, the way in which they were developed from the interview data.

Table 4.4 Themes and subthemes.

Theme	Subtheme
1. Reporting systems and processes	Routine reporting of incidents and prevalence
	Reporting based on the level of harm
	Staff responsibility of reporting
2. Determinants of reporting practice	Education
	Perception of consequences
	Knowledge
	Attitudes
	Openness & teamwork
	Peer influence
	Financial disincentives
	Device procurement
	Workload
	Time
	Staffing
3. Emergent issues in MDRPU reporting	Variation in reporting
	Internal negotiations of MD safety
	Future directions of reporting

4.3.1 Pressure ulcers reporting systems and processes

This section presents PU reporting systems and processes with sub-themes within. The findings describe different levels of reporting, reporting based on the level of harm and reporting responsibilities of staff in different countries as recalled by the participants.

4.3.1.1 Routine reporting of incidents and prevalence

4.3.1.1.1 Incident reporting

Most of the participants use an electronic patient record (EMR) to record an incident of pressure ulcer. Of the participants interviewed from eleven countries, half reported using only the

electronic patient record for reporting PUs. In countries such as Brazil, the Czech Republic, Italy, Thailand, and US long-term care centres' (LTC) documentation of a pressure ulcer occurrence is completed on paper, which then is kept within the patient file or in a separate database.

"*So my point is, is in long term care, I mean, in US up until this moment in time, it's been pretty much all on paper. So the rest of the EMR is electronic, but skin stuff is generally in a binder somewhere*" (P9).

In the Czech Republic, for example, PU data are collected from the patient file by a designated person – e.g. manager of quality, for analyses. Groups of hospitals may create a Trust and have their own database from which they draw comparisons and use for benchmarking.

"Each hospital trust, we have four or five in our country, they have a special collection database, just focusing on their own hospitals" (P2).

The reporting practice may also be different between private and national hospitals. Indeed, in some countries, private hospitals do not share data with other institutions. It was reported that National hospitals collect data and present yearly reports.

"*Because we are in a private hospital, our system is different from the government [public] hospital. In the government [public] hospital they have to report within the cluster [of public hospitals depending on their location] and to the Department of Health in Hong Kong. They will collect all the data and consolidate into a yearly report. But because we are in a private hospital, we report to our hospital administration only"* (P7).

Similar practice exists in other countries, where PUs are only reported locally (i.e. Thailand and Switzerland). Policies are published by hospitals and reporting guidelines are managed by them, with HAPUs being considered adverse incidents and reported within the organisation.

"*Beside the annual prevalence that is obligatory to do for Switzerland hospitals and clinics, there is no policy about reporting PU. (It) depends on the hospital."* (P10).

4.3.1.1.2 Prevalence reporting

Most of the participants (9/17 representing of 6/11 countries) reported national PU prevalence studies taking place. In some countries, such as Finland, the concept of national prevalence data collection is relatively new, being initiated in 2018 by a University Hospital and a group of local hospitals. Frequency of data collection was reported to vary between countries, between once a year (e.g. Czech Republic, Switzerland) and quarterly (Belgium). One of the participants from the US reported prevalence data are sent monthly to the National Database of Nursing Quality

Indicators. Some countries (like England and Czech Republic) publish prevalence data online, which can be accessed by the public as well as healthcare professionals. In the majority of countries MDRPUs are not a separate category in prevalence data collection and analysis but are included within the numbers. Participants representing Finland, Thailand, USA and UK confirmed MDRPU prevalence is calculated separately to other PUs.

4.3.1.2 Reporting based on the level of harm

Participants reported that investigations of serious incidents aim to improve the quality of patient care, and to share learning, and that those reports are organised separately to those in internal reporting systems. In most cases, HAPU category 3 and above are reported as serious incidents, or never events (e.g. in USA). UK-based clinicians said that since the new guidelines have been introduced in England by NHS Improvement (NHSI), serious incidents are being assessed according to the impact they have on care provision and patient. The new guidelines require to report pressure ulcers category 2 and above (including DTI and unstageable). PUs which developed due to medical device use, have to be further categorised as device related.

"*So we still do the [SI] investigation the same, but we now look for the level of harm against the patient safety framework and for serious incidents. So we give [allocate] a level of harm to all of those [PUs] that have been developed in the hospital of low, moderate, or high." (P6)*.

For the purpose of reporting a serious incident (SI) in England, there is no separation in the reported numbers between PUs and MDRPUs. However, in the report to care commissioners, context of the incident is included.

It was reported by participants that in the Czech Republic adverse incident data is automatically sent to a national database, and that in the private hospital in Hong Kong only serious incidents are reported to the Department of Health. Another participant highlighted that in Switzerland serious incidents are still only reported within the organisation and not shared nationally. In Belgium, there is no national reporting system available.

"*That's a very sad thing, that in Belgium there's no common organ [institution] [or] system that collect data. It's everybody by themselves*" (P14).

Although most participants identified that reporting serious events is mandatory, in countries such as Brazil, it is voluntary and relies on the leadership of the organisation.

"*It's recommended that each hospital has a patient safety committee, and each patient safety committee has to report these. However, it's not mandatory yet, because there's no punishment or anything*" (P15).

4.3.1.3 Reporting responsibility of staff

Pressure ulcer care and reporting was perceived to be a nursing task. Participants stated that in countries like US, staging of PUs is done by a specific member of the team, but because PUs are considered a medical diagnosis, they can be diagnosed only by a nurse practitioner or physician.

"*Then they have to notify whoever is their particular team, who does the staging. Some institutions have WOCN, or some don't even have that, and they bring that to the attention of the physician, because in the US it is a diagnosis, and the only people who can diagnose are nurse practitioners or physicians*" (P3).

Another participant indicated that data are collected by a wound care team coordinator collating information for the whole hospital.

"*We have a wound care team coordinator who will collect all PU related injuries from the whole hospital. And then we will submit the data every month to each wards and also report to nursing administration*" (P7).

Many participants reported a significant involvement with identification, treatment, and reporting PUs by specialist teams such as tissue viability or wound and ostomy. Participants (tissue viability nurses) from hospitals in England, reported they also keep a separate database, where additional information is kept about pressure ulcer incidents, for example details of devices implicated in patient harm. In contrast, a participant from Switzerland stated, that even as a tissue viability lead, there was no arranged access to PU reports and had to ask for access to those data.

"*There's only this report [serious incidents] and what's funny about it is that as a wound specialists we don't get the reports*" (P10).

4.3.2 Determinants of reporting practice

Exploring barriers and facilitators of reporting practice for PUs and MDRPUs allows for better understanding of factors impacting the practice, and thus supports implementing practice improvements.

Our results show the barriers and facilitators group in four domains of the TICD as presented in Table 4.4, below. Each of the domains with corresponding inductive themes are reported on in turn in the section below.

Table 4.5 Barriers and facilitators to reporting PUs and MDRPUs (based on Flottorp et al. (2013)).

DOMAIN	**SUBDOMAIN (themes)** **B – barrier** **F - facilitator**
Individual health professional factors	(F) education
	(B) perception of consequences
	(B) knowledge
	(B) attitudes
Professional interactions	(F) openness & teamwork
	(B) peer influence
Incentives and resources	(B) financial disincentives
	(B) (F) device procurement
Capacity for organisational change	(B) workload
	(B) time
	(B) staffing

NB. Barriers and Facilitators reported by Flottorp et al (2013) are denoted (F). Other barriers are reported as (B).

4.3.2.1 Individual health professional factors

4.3.2.1.1 Subdomain 1 - Education

Specialist nurses in this study suggested that education of staff to be able to correctly identify MDRPUs would improve reporting of these wounds. Participants indicated that often a quality improvement project led to such improvements.

"*So after I rolled out the project in 2017 for the BiPAP [Bilevel Positive Airway Pressure] prevention, they [staff] started to recognise [the medical device-related pressure ulcers] and they know how to report them*" (P7).

4.3.2.1.2 Subdomain 2 - Perception of consequences

Participants described how nurses are often nervous about missing a pressure ulcer and hence they report anything that might be pressure damage. On the other hand, because HAPU incidents are considered a reflection of quality of nursing care, there is the worry that the unit will be judged to have 'too many' of them and be seen in a negative light.

"*So even though it's not a financial impact, the wards and ourselves feel that most keenly*" (P1).

There is also a notion that the person reporting a PU, is the person responsible for its development. Although this corresponds with the culture prevalent in the unit or hospital, it makes staff consider implications of reporting for themselves. To illustrate this issue, one of the participants reflected that an agency nurse who discovers a PU, might weigh pros and cons to reporting.

"*What's the risk for me if I report it and it wasn't reported, are they going to think I did it? What does that mean for my job*?" (P9).

4.3.2.1.3 Subdomain 3 - Knowledge

Lack of knowledge relating to PUs and MDRPUs was reported in the interviews as one of the main barriers to reporting Category 1 PUs may be not reported at all beyond the institutional system, because staff are unsure of the diagnosis.

"*Grade 1 we don't report to the government [national level reporting] because there's too much wrong with reporting them, and they are mixed with Incontinence Associated Dermatitis"* (P14).

Medical device associated wounds were reported to be often not recognised or not identified as pressure ulcers.

"*I think that the biggest issue is people [staff] recognising that devices do cause pressure damage. I think that's a new concept that we haven't got our heads around yet*"(P6), and "*I think (…) nurses still think that MDRPUs are not really PUs and they think they can misdiagnose them with other skin wounds*" (P2).

Clinical staff also lack the knowledge of the risk factors and might not appreciate long-term consequences of device related skin damage.

"(…) too many people, especially in paediatrics say [they] don't know what the big deal is because kids heal quickly. Kids scar, and they have lifelong scars [and] that's a big deal" (P3).

Another barrier discussed was the disparity between educational MDRPU publications, and devices that are in clinical use in less-well funded healthcare systems.

"*Some devices that we see in the picture or in the literature are not used in [our country]"* (P15).

Hence it was suggested that the knowledge might not be transferable between high- and low-income settings.

4.3.2.1.4 Subdomain 4 - Attitudes

There was a belief that MDRPUs are not an issue on general wards. In some cases clinicians reported that these wounds do not occur often and their focus was on prevention of traditional pressure ulcers.

"*I don't think it's a huge problem in our hospital*" (P14)

MDRPUs may also not be reported, because of the perception that after relieving the patient from the device, the pressure ulcer category 1 or 2 will heal quickly and therefore is not worth reporting.

" I think if you've got something, say, on the ears or on the nose and the patient then had that tubing or mask removed, they're just going to heal up fairly quickly and go away, I don't think all of those [pressure ulcers] are reported" (P1).

MDRPUs on critical and intensive care units were reported to have become normalised and perceived as something that cannot be avoided. Medical devices are expected to cause skin harm because they always have done.

"*I think that a lot of the time people just expect them [medical devices] to cause problems and they've always caused problems. So people don't think of it as a problem because it's just expected*" (P1).

Moreover, because incidents of MDRPUs are expected, not all of them are being reported.

"*People only report the most serious issues and not everyday issues*" (P4).

Medical devices regulatory authorities were identified to be predominantly used to support the management of serious incidents relating to device malfunction or injury. Participants reported that MDPRUs first has to be investigated by the organisation, before it is escalated.

"*If it's urgent [problem with a device causing PUs], it will be an urgent withdrawal in our hospital. But if it's indeed serious, then it will be reported to the higher instances [MD regulatory body] for sure*" (P14).

Not only the severity of the incident is taken into account when a decision to report is made, but also there is a perception that it should be more than one incident, otherwise it will not be taken seriously by the regulatory body.

"*They [the regulatory body] might think the device is not dangerous if they didn't get any other complains. If there were more cases, then they [would] have to do something, take some action*" (P2).

However, in countries that have established procedures for submitting reports to regulatory agencies (i.e. Australia and USA), doubt in their willingness to be proactive in acting upon reports have emerged.

"*I think it is possible to communicate with them [regulatory authority], but they are a bit of a 'toothless tiger', and they've been exposed and criticized in recent years (…). I'm not sure about their effectiveness, to be honest. I'm not sure if that would be the first port of call if there was a complaint about devices"* (P12).

Moreover, transparency of the US FDA has been questioned as well.

"*It turns out that the manual medical manufacturers actually have a different site, that they report data to the FDA that is not accessible by the public. So even if we check the MAUDE site, it may not be comprehensive because of this protected site between the FDA and the manufacturers" (P4).*

4.3.2.2 Professional interactions

4.3.2.2.1 Subdomain 1 - Openness and teamwork

Openness and lack of fear of reporting, followed by a process of investigation and feedback, meant staff could learn from incidents and improve practice.

"*How our policy is, is learn and practice and do better the next time. And that is not a shame that will cause any problem. That is this is a problem related to the whole system of care, not just about a single person*" (P13).

This climate of openness is also about receiving positive feedback, so the staff can celebrate and share good practices. Involving other clinicians, such as doctors, opens another communication channel. Nurses being able to ask questions on how they treat patients, make MDRPUs a 'visible' nursing problem.

"*We can say 'doctor, I have this lesion and I'm treating it this way. Is it the right way?' We are not isolated, there's a team*" (P5).

However, it might be difficult for a junior member of staff to verbalise opinions that are opposite to the more senior staff.

"*Another problem is also that even if they reported as medical device-related pressure ulcers, it won't be accepted and the rest of the group in the unit will say 'oh you're joking. It's not like this.' I have experience for a student from master's degree who came to me and said: 'I want to report it and they said I was stupid, and that it was not true [the presence of medical device-related pressure ulcer]'"* (P2).

Open communication between wound nurses and staff from operating theatres was mentioned to be especially important. Operating theatres have specific ways of positioning the patient, especially prone position is shown to lend itself to patients developing MDPRUs.

"Sometimes they do the spinal surgery for more than 10 hours, but they can't turn the patient back and see [the] face. Sometimes maybe they move a little bit of the patient, but they never know whether it [the head] is on the right position on the device. It is a bit difficult for us because we are not operation room nurses and we usually have to use imagination about what had happened to the patient with the devices" (P7).

4.3.2.2.2 Subdomain 2 - Peer influence

Despite the emphasis of policies on safety and learning from incidents the blame culture on hospital wards still exists.

"*Although we concentrate very much on the learning, (…) I think when you've suffered years, if not decades of the blame culture, you can't get rid of that overnight*" (P1).

Clinicians discussed how the peer influence interlinks with the blame culture, where staff might be less likely to report because they feel pressured not to put their unit in jeopardy.

"*The is a lack of transparency because they [staff] are afraid to report the truth, because they feel that their jobs or budgets will be in jeopardy*" (P4).

Participants agreed that shift in this attitude requires ongoing education.

4.3.2.3 Incentives and resources

4.3.2.3.1 Subdomain 1 - Financial disincentives

A fear of reporting exists where incidence of PUs is linked with funding, like in the USA. Transparency in presenting pressure ulcer data can also lead to negative perceptions of the organisation and financial repercussions. Those, who are open and frank about PU rates can be

seen as those who have 'problems' with their prevention, whereas those who lack transparency can be judged as issue-free.

"*I have other consultations in U.S. hospitals where typically the Safety Committee or Quality Committee is completely transparent, and their numbers are significantly higher than those institutions in the surrounding area. And everybody thinks that that place has a problem when in fact it's the other places that have no transparency*" (P4).

High rates of HAPUs can lead to loss of contracts, loss of accreditation, or lower cost reimbursement. There is also fear of litigation, which is common in countries such as USA.

"*I don't think a lot of people put that data [adverse event] into the MAUDE database [voluntary reporting of medical device harm provided by US Food and Drug Administration] or report it back to the manufacturers because they feel that some of that information is now disclosable in case of a lawsuit. If it stays within the quality department, it doesn't have to be disclosed" (P4).*

4.3.2.3.2 Subdomain 2 - Device Procurement

Procurement of medical devices required for patient care was described as cost driven.

"*So there's a very cheap one [dressing available from a supply chain], medium one and a little bit better one. And then we have to use one of them because you can't get in any others. It's causing an awful lot of upset in the tissue viability world, because the concern is it will be the same with devices*" (P6).

However, the inner context of the organisation's ability and readiness to dedicate resources to support MDRPUs reporting, might support the reporting practice seeing as the feedback might have impact on what devices are purchased by the organisation.

"*There's of course the hospital purchase office. They are the ones that decide which medical device we can use in the hospital and so we of course give the feedback, and then we have to explain and show the evidence that it doesn't work*" (P11).

4.3.2.4 Capacity for organisational change

4.3.2.4.1 Subdomain 1 - Workload

In the pursuit for effectiveness and efficiency patient records have been moved into electronic systems in many countries. Some participants however reported that a proportion of data capture or reporting might still be undertaken using paper records.

"My nurses like to write [report] on paper and after that they put the information in the electronic file" (P8) and *"(…) in long term care, in the U.S. up to this moment in time, it's been pretty much all on paper [reporting of PUs]. [Although we use EMR] the skin 'stuff' is generally in a binder somewhere"* (P9).

This coexistence of traditional, paper records and EMR in the same organisation means data double-entry. But, in some countries (e.g. Australia or UK) this process might involve use of more than one reporting system, since the applications lack interoperability.

"*Nurses have to put that information into a (…) surveillance program that helps the hospital monitor pressure injuries that is being assessed and identified. But it doesn't speak to the integrated electronic health record. Nurses then have to go back to that record (…) [and] they then have to code each of these*" (P12).

4.3.2.4.2 Subdomain 2 - Time

Clinical environment is increasingly busy, and sometimes lack of time may lead to underreporting. Moreover, the length of time it takes to make a report was identified to have impact on the decision-making.

"So there's no time. So people only report the most serious issues and not everyday issues" (P4).

Competing priorities in intensive care units and workload were also mentioned as factors impacting MDRPUs occurrence and reporting.

"*It is the time that is lacking, because they [nurses] have many job bundles that are really heavy. And so there are many reason why for the pressure ulcer onset is not just the fault of a single person. Is the whole system" (P13).*

4.3.2.4.3 Subdomain 3 - Staffing

Not all institutions employ nurses specialising in tissue viability (e.g. in Czech Republic or USA). Also, turnover of staff has been pointed at as a barrier to reporting. Organisations may struggle to train everyone to a standard, when the changes in staff numbers and abilities are fast and dynamic. Similar problems were discussed outside of an acute care.

"*[B]ecause of turnover, we experience deficit in education, or we are waiting for education and the overwhelm of other priorities in the nursing home, means sometimes that [reporting] gets missed" (P4).*

4.3.3 Emergent issues in MDRPU reporting

4.3.3.1 Variation in reporting

Reporting MDRPUs is a relatively new practice, with some participants indicating it has started sometime in 2015/16 (P7), 2019 in UK, some countries are yet to introduce mandatory reporting of these wounds (e.g. Brazil, Switzerland). Some participants indicated the practice starting with identification MDRPUs becoming an apparent burden to the hospital.

"*But from 2018 [when reporting of MDRPUs started] and to right now, two years, we have also collected the whole hospital skin injuries incidents, because we find that from the operation theatres, they have increased numbers of skin injuries, some due to the medical devices*" (P7).

Practice of reporting MDRPUs varies between countries and organisations within the countries.

"*Some hospitals, they have a special code for identification [of MDRPUs] in their reporting sheet, but not in every [hospital]*" (P2).

In countries where an EMR is used, an electronic report is completed and automatically forwarded to a specialist team for review and support. Contextual details, such as a type of device that caused the wound, can be found in a free-text box of the report. At the same time, for example in England, since the new reporting guideline has been introduced, a drop-down box is included in the electronic document, where the reported has to indicate whether the PU is device related or not, but there is no requirement to indicate which device was implicated in the MDRPU development.

"[*A] drop-down box is included in the electronic document indicating if the PU was device-related - select category, [then] select MDR yes [or] no), and the information about what device it was is put in a comment section*" (P1).

Still, each report has to be validated by a senior or lead nurse, which requires auditing data and actually denoting the PU as MDR. It is not an automatic process. Mostly, those HAPUs are recorded and reported as a subcategory to PUs.

"[*Do you collect that data on MDRPUs separately?] No. So we're starting to*" (P9).

Similarly, in US (Minnesota) under the PU category in the report, an indication is made (yes/no) if PU is MDR. Additionally, some institutions report MDRPUs separately because of the type of the setting.

"*Yes, we have reporting it. We are recording it separately. Just because the devices as more related to the intensive care settings*" (P13).

4.3.3.2 Internal negotiations of MD safety

In Finland, the electronic record of MDRPUs includes devices that a specific unit uses for patient care, it also allows to add a device not included in the catalogue.

"*We have a list of different medical devices, which we use in our unit, and also there's an empty space if it's another one that we haven't listed already*" (P11).

Nonetheless, other reporting systems rely on details recorded as 'free text' and thus not standardised. Most often, participants mentioned that the category of the device was recorded. Additional information focused on PU location, stage, prevention, and treatment. Some participants indicated that the investigation that ensues reported on the application of the device, including if it was the correct device, correct size, applied correctly, and if the staff were trained to use it. This is completed in a form of a narrative statement.

Those data and reports are used internally to educate staff. Participants described how the reports are reviewed by specialist nurses or quality department to identify root causes for MDRPU development and provide education for staff or initiate quality improvement initiatives.

"The nurses from the quality department would analyse [reports] and work with persons from the [unit] to improve the care." (P15)

Those reports usually kept in an internal database and used by the specialist team to advise the procurement office on the safety of the device and influence the purchase process.

"Now I get a better documentation about which device was the reason so it can influence what kind of devices we buy" (P11).

The majority of participants said that a recurrent issue with a device was reported internally to a quality department or similar. At the same time, such report is sent to the manufacturer by an official route but omitting the regulatory agency.

"So when there's a problem with one or other products, we have a system in our online system that requires to fill in a file. It goes automatically to the purchase organisation [department]. They will contact the company and they will search for a solution" (P14).

Such feedback can have an impact on future acquirement of devices from a specific manufacturer.

"I [would mention] to the hospital [issues with a device leading to MDRPU development], in the future if they want a medical device from the company that I don't recommend the company" (P8).

Many participants reported giving feedback to manufacturers directly when they find an issue with a device. The responses they received were varied. Some reported the representatives not being interested and implying there must have been an issue with how the device was used.

"I would say most of the time they say, 'we've never heard this before'. 'This has never happened'. 'I can't believe it. What did you do?'.' Do you think your staff was using this properly?'" (P4).

"*A lot of time the manufacturers will come back and say, 'well, we haven't had that problem elsewhere'*" (P6).

Some were offered a 'comforting' assurance the information will be forwarded to a relevant team in the company. A few participants reflected, that the issues they raised and possible solutions they gave to the company representatives, have resulted in the device improvement.

"*I've given feedback to companies how they could improve or just point out the problem and they can figure out how to improve it*" (P11).

All participants were asked if they have ever reported a medical device to a regulatory authority. None of the clinicians conducted this process. Reasons given were unawareness of such possibility.

"*I might have actually forgotten that I could make complaint myself*" (P11).

Reports concerning medical devices were considered to be a task of managers and undertaken according to organisational policies. However, despite following the prescribed procedures by the clinician, the internal report may not be escalated as presumed.

"*[Reporting a medical device] was something that I thought that Risk [hospital department responsible for reporting to MHRA (Medicines and Healthcare Products Regulatory Agency)] did. And then I found out that Risk didn't [report]*" (P1).

On the other hand, some participants reported lack of policy for reporting problems with devices beyond the organisation. Moreover, a perception that the regulatory authority is not effective in dealing with device issues was also discussed.

"I think it is possible to communicate with them [device regulatory authority] but they are a bit of a 'toothless tiger' and they've been exposed and criticised in recent years (…).So I'm not so sure

about their effectiveness (…). I'm not sure this would be a first point of call if there was a complaint about devices" (P12).

However, participants talked about a specific department within the organisation whose task it was to make reports to the regulatory authority. Although it was also stated by one of the interviewees, that the department was not actually making such reports.

"*That is something (…) we should be doing [reporting through the YellowCard scheme]. And that it's something that I thought that risk [a hospital department] did. And then I found out that risk didn't do it*" (P1).

Medical device regulatory authorities also deal with for example medication errors, and participants were more aware of that role of the bodies, than the role they could play in regulating the manufacturing and use of devices.

"*We can do it [report an issue with a MD] directly to the Ministry of Health. First, you have to advise your institution. And the institution will deal with the Ministry of Health. And then it happens sometimes, but which drugs normally, not with devices*" (P13).

4.3.3.3 Future direction for MDRPU reporting

Development of a database for medical devices related to development of pressure ulcers was suggested to be useful for clinicians, who would be able to make an informed decision about which devices should be purchased and used for patients. Having such data would also allow the discussion with manufacturers about improving devices.

"*If I could go to look at a national database and see how many other people have had issues with that particular device, I think that would give us knowledge that maybe we need to look for something different. But also it would show that we need to go back to the manufacturer and say, 'there is a lot of cases [of skin damage] happening" (P6).*

It was suggested that internal, hospital databases holding MDRPU data and including MD data, should be linked to an external, independently maintained one, where any alerts would be accessible across all healthcare institutions.

"*If I am a staff nurse and I see something, I go to my electronic medical record and I just tick the box, that would alert perhaps an authority outside the institution as well as within the institution that there was a device related issue*" (P4).

All participants were asked what data should be reported. We asked to list all items they thought would be useful to collect, with a caveat there was no time restriction on staff recording that

data, and there were no financial barriers. As a result we obtained a list of items presented in Table 4.6.

The specific data about the type of device, manufacturer data were suggested to be important, because collating those data would allow to provide evidence that certain product needs looking into.

"*I would like to get manufacturer and the type of the product. So that the governing body can see that there is always the same product that causes that and maybe they can go to the manufacturer to say you have to do something, you have to change this" (P3).*

The immediate and future impact on the patient were suggested as elements that should be included in the data set. This was talked about by participants who worked with paediatric population and/or neonates.

"*I would also send how it looks [MDRPU] like once it's healed. Because too many people, especially in paediatrics they always say I don't know what the big deal is because kids heal quickly. Kids scar, and they have lifelong scars, that's a big deal*" (P3).

But this was also reflected upon by a participant from an adult inpatient setting.

"*What is the effect on the patient of that pressure ulcer, if the pressure ulcer is on the nose and half the nose is intact, but there is a wound and there will be a scar and it's a baby, I guess the effect is not the same. What will be the consequence of the pressure ulcer*?" (P10).

One of the participants reflected that data on all stages of MDRPUs should be collected.

"*I would say that all pressure ulcers related to devices should be reported, not just stage 3 or higher, unstageable or deep tissue. Because I think that's how we start changing practices with data*" (P4).

Table 4.6 Elements of the Data Set proposed by the participants of the qualitative study

Item	**Number of participants suggesting the item**
Device type	10
Manufacturer or Distributor	6
Location of PU	4
Prevention used	3
Regular patient data	3
Type of material used in device	3
Category/stage of PU	3

Item	Number of participants suggesting the item
Exact name of device	3
Effect on patient	3
Clinical issues	2
How long used for/in place	2
Operating Room/Theatre OR Ward	2
Potential effect	2
Size of PU	2
Type of damage	2
Application technique	1
Comfort	1
Communicated to patient (when possible)?	1
If MD still in use	1
If used as prescribed or off label	1
Indication for use	1
Other devices in situ?	1
Patient's response when informed about PU	1
Photos	1
Photos after healed	1
Record of repositioning	1
Time of finding	1
When first applied	1
When the PU occurred	1

It has been highlighted that the reporting form should be easy to fill in, and easily accessible. It was mentioned that positive feedback should be included.

"*Somewhere that you could just give feedback easily on a product and everything could be collated. So positive feedback as well as negative. Something that was easily accessible and quick and easy to fill in*" (P1).

4.4 Discussion

The literature review, presented in Chapter 2, identified issues in general pressure ulcer reporting (e.g. variation in practice and uptake of the international guidance). Moreover, it acknowledged a paucity of evidence about MDRPU reporting in practice. This study aim was to explore pressure ulcer reporting systems, and barriers and facilitators for reporting PUs and MDRPUs. In addition an investigation into how reporting of MDRPUs could be improved was undertaken.

The results show that despite the focus on improving the quality of care, there is an overwhelming lack of standardisation in pressure ulcer data collection. This problem is not only

present between the countries, but also within the countries, nations, and states. Jackson et al. (2016) likewise concluded, in their comparative review of pressure ulcer policies, that there is no consensus on data collection and reporting. Similarly, Coleman et al. (2016b) in a survey of monitoring systems in England found, that there are disparities in recording and reporting of pressure ulcers between hospital trusts. This study found that the practice differs between public and private providers, and acute and long-term care setting (possibly due to private ownership).

Reporting of MDRPUs is not yet mandatory in all healthcare systems. The practice of recording and reporting of medical device-related pressure ulcers was found to be different between organisations, which is in line with other studies (Coleman et al., 2016b, Smith et al., 2016). Furthermore, where reporting is mandatory, the data collected do not include specific information about the device, except for the name of the manufacturer.

Most often reports of devices implicated in PU development are not forwarded to a MD regulatory body but dealt with internally. Yet when they are, there is a perception those organisations are not prepared to execute their regulatory powers towards manufacturers. This finding is in line with those of Jewett and de Marco (2019) , who uncovered that the US FDA failed to investigate reports on medical device harm. This raises questions regarding the role regulatory bodies play in reporting systems, since there might be a perception the manufacturers suffer no consequences.

This study identified several barriers and facilitators to reporting of MDRPUs in clinical practice. The findings revealed that out of seven domains of the TICD, the identified determinants of reporting practice concentrate on four key areas: (1) individual healthcare professional factors, (2) professional interactions, (3) incentives and resources, and (4) capacity for organisational change. Given the paucity of available literature examining barriers and facilitators to reporting PUs and MDRPUs, the researcher turned to the literature looking at general incident reporting (e.g. medical errors). The main findings corroborate findings in this area and suggest that despite the policy move towards openness and transparency (Francis, 2013, GMC and NMC, 2015, Wu et al., 2017), clinicians still experience fear of feeling the blame and disciplinary sanctions (Health Quality Ontario, 2017, Pfeiffer et al., 2010, Rashed and Hamdan, 2019), legal penalties (Asgarian et al., 2021, Health Quality Ontario, 2017, Pfeiffer et al., 2010, Rashed and Hamdan, 2019), and have anxieties over own competency being questioned with potential risk to employment (Asgarian et al., 2021, Pfeiffer et al., 2010, Rashed and Hamdan, 2019). These issues were reported by many of the clinicians in this study and represent a significant barrier to reporting facility acquired pressure ulcers.

This research also shows there is a strong agreement that improved data on MDRPUs is necessary for improved patient care. This echoes the recently published consensus study on MDRPUs by Gefen et al. (2020) who stated there is a need for an evidence-based policy for reporting MDRPUs. Similar conclusion was reached by Barakat-Johnson et al. (2018), who asserted that national and international guidelines supporting reporting and documentations are required. Similarly, this study also found participants calling for a database, where information about devices causing PUs would be recorded. Searchable databases provided by medical device authorities are only available in a few countries (e.g. USA, Australia), and they are difficult to use and do not hold systematically collected data. Developing a robust database would enable informed decisions as to what medical devices are most suitable, what prevention should be used, and most importantly to provide undeniable evidence to initiate medical devices redesign.

4.4.1 Strengths and limitations

To the author's knowledge this study is the first international evaluation of MDRPUs reporting practice and exploration of barriers and facilitators to MDRPUs reporting.

The recruitment strategy resulted in involvement of individuals with a vested interest in MDRPUs. Participants of this study were mostly specialist nurses who held a leadership role or were also involved in research and teaching. This enabled us to get an overview of the current clinical practice and illicit the content of the 'ideal data set' from a leadership point of view. However, not involving the 'bedside' nurses in this study might have limited our results relating especially to barriers and facilitators to reporting.

Because MDRPUs are more prominent in intensive and critical care, the participants were mostly representing those settings, and this is another limitation to this study. We did not have the opportunity to further explore MDRPUs reporting in other settings.

In this study almost all interviews were conducted remotely. This can be a strength, because the researcher was able to reach individuals from different countries, healthcare systems, and experiences and thus have a better understanding of the PU and MDRPU reporting practice. However, it also might be a limitation, since there is an evident physical barrier between the interviewer and participant, that may have a negative impact on developing a rapport between the two. This may result in sharing less than in a face-to-face interview. It may also influence the interview especially when it is conducted beyond usual working hours and the participant is in their home environment. In this study there was one participant who was in such situation. However, despite a slight feel of unease at the beginning of the interview, the participant was keen to explain their experiences and how their organisation reports all PUs, including MDRPUs.

4.4.2 Implications

This study gives us an insight into how PUs and MDRPUs are recorded and reported in different settings and different countries. It also offers a systematic report on what determines reporting practice. Based on this study findings we were able to conceptualise a list of items that would be relevant for reporting MDRPUs and in what format and how the new MDRPU reporting might be implemented in the future in clinical practice

4.5 Conclusions

This qualitative study explored the current practice of reporting PUs and MDRPUs in eleven countries to describe the systems and processes that are used in clinical practice. The study revealed that collection of high-quality data on MDRPUs is necessary for improvement of quality and safety of care. Equally it is necessary to collect robust data to enter a conversation with manufacturers of medical devices aiming to improve medical devices that are in circulation and influence development of new, safer devices. Data should be collected in a pragmatic and non-burdensome fashion by nurses supported by information technology systems. Notwithstanding the clear need for standardised reporting of MDRPUs, there is no data collection tool available for clinicians to use to record and report MDRPU incidents. To address this gap, a consensus study was undertaken, where results of this qualitative study, including the feedback we gathered on the 'ideal' data set for reporting MDRPUs, and along with the narrative literature (Chapter 2) formed the evidence base for the consensus study. The design, methods, and results of the consensus study are described in the chapter that follows (Chapter 5).

Chapter 5 Consensus study

5.1 Introduction

This chapter provides an overview of consensus methods and the prospective international survey findings. The Delphi and the RAND/UCLA appropriateness methods are critically examined, and their similarities and differences are discussed. A rationale for using a consensus study designed to develop a data set for reporting MDRPUs is summarised, specifying the methodological approach to define items considered important for MDRPUs. Findings presented in this Chapter will be used to define the data set for reporting MDRPUs, as agreed by a substantive panel of international experts, preceding a cognitive pre-testing of a reporting form (Chapter 6) and its pilot feasibility evaluation in the clinical setting (Chapter 7). Developing consensus is an important step in achieving international agreement on reporting practice for MDRPUs, prior to any evaluation in clinical practice.

5.2 Overview of consensus methods

Structured consensus methods are often used where there is a lack of evidence on the issue under consideration, to test questions of clinical relevance, and to achieve agreements on disputed topics (Jones and Hunter, 1995, Iqbal and Pipon-Young, 2009). They aim to determine the level of agreement regarding a topic of investigation. Consensus methods allow for synthesising a range of evidence and the knowledge and views of experts in the field (Hasson et al., 2000). Additionally, they offer methodological advantages and overcome limitations of informal group decision-making methods, such as the dominance of one individual or a group with a strong interest in the subject matter (Dalkey, 1967, Jones and Hunter, 1995). This is achieved through key methodological choices:

1) Considering panel structure – limiting the influence of dominating personalities and inclusion in the panel based on expertise (i.e. knowledge and/ or experience)
2) Allowing participants to change their opinion in the view of the panel scores and/or discussions
3) Anonymity
4) Clear presentation of results, with decisions based on pre-defined methods.

There are several consensus methods available. However, the most often used in health research are the Delphi method, the Research and Development/ University of California at Los Angeles

(RAND/UCLA) Appropriateness Method (Fitch et al., 2001), the Nominal Group Technique (NGT) (Delbecq and Van de Ven, 1971), and the US National Institute of Health's Consensus Development Conference (Ferguson, 1996, Fink et al., 1984). There are many modifications of these methods in the literature, which are flexible enough to facilitate different study aims (Hasson et al., 2000, Iqbal and Pipon-Young, 2009, Jones and Hunter, 1995). A summary of consensus methods used in health research, summarised from Nair et al. (2011) are presented in Table 5.1 below.

Table 5.1 Summary of main features of formal consensus methods (Nair et al. 2011)

Component of a consensus method	**Classic Delphi**	**Classic Nominal Group Technique**	**RAND/ UCLA Appropriateness Methods**	**Consensus development conference**
Explicit review/ use of evidence	No	No	Yes	Yes
Structured interaction	Yes	Yes	Yes	No
Mailed questionnaire	Yes	No	Yes	No
Rating of statements	Yes	Yes	Yes	No
Private rating/ decisions	Yes	Yes	Yes	No
Opportunity to re-rate (re- consider own scores)	Yes	Yes	Yes	No
Formal feedback of group decisions	Yes	Yes	Yes	No
Explicit method of synthesis of group decisions and judgements	Yes	Yes	Yes	No
Face-to-face interaction	No	Yes	Yes	Yes

5.2.1 The Delphi method

The Delphi method originates from the RAND Corporation for forecasting in defence research in the USA (Dalkey, 1967, Murphy et al., 1998). The Delphi is a consensus method often used in decision making in healthcare when there is insufficient information available (Powell, 2003, Jones and Hunter, 1995, Keeney et al., 2006). It is an iterative group process that seeks to establish consensus on the opinions of individuals who are perceived as 'experts' in a studied field. It consists of a series of questionnaires completed anonymously by the experts. The task associated with each of the questionnaire rounds are presented in Table 5.2. As a part of the

process, the results of each questionnaire round are summarised and fed back to participants (Hasson et al., 2000, Keeney et al., 2006). This method includes several stages (Jones and Hunter, 1995, Murphy et al., 1998):

1) Identification of the research problem,
2) Participant selection,
3) Questionnaire items development,
4) Iterative rounds of anonymous questionnaires, with group feedback and
5) Summary of results after each round.

Table 5.2 Delphi rounds and associated tasks

Round	**Task**
1	The initial questionnaire is developed by recruited experts OR by the researcher.
2	Participants rank their agreement with statements in the questionnaire. The researcher summarises the rankings and includes them in the subsequent version of the questionnaire.
3 and subsequent	Participant's re-rank their agreement with each statement and can change their score based on the summary of the group responses. The rankings are summarised and evaluated for agreement. Items where agreement is reached may not be presented in the subsequent round. The third round is repeated until consensus criteria are met (these should be agreed a priori).

The classical Delphi allows for the inclusion of experts from diverse regions, without the need to meet physically (Keeney et al., 2006, Murphy et al., 1998). This method allows for expressing opinions without peer pressure and enables to change judgements in light of the group's feedback (Hasson et al., 2000). The feedback given is controlled, which means participants are focused on the task at hand. Nonetheless, the critics of this method highlight the lack of a face-to-face meeting may preclude the identification of reasons for disagreement between experts and have a negative effect on establishing compromise acceptable for all parties involved (Murphy et al., 1998). Moreover, some argue that this may lead to a lack of accountability for expressed opinions (Sackman, 1974, Iqbal and Pipon-Young, 2009).

5.2.2 Classic Nominal Group Technique

The Classic Nominal Group Technique (NGT) is a structured small group discussion aiming to achieve agreement between participants. It was first developed to enable effective committee decision-making and since its inception it has been successfully used in health research (Delbecq

et al., 1975). The guidance suggests this face-to-face meeting involves between 9 and 12 experts, who follow a highly prescribed procedure for eliciting information about a given topic (Jones and Hunter, 1995). As with the Delphi technique, panellists are chosen based on their knowledge and/ or experience in the subject matter. Table 5.1. summarises the key principles of the NGT, and the process of achieving consensus is shown in Table 5.3.

Table 5.3 Classic NGT process for achieving consensus after the question for the panel is generated (Nair et al., 2011)

Task	Round 1 and subsequent
1.	Silent and independent generation of ideas
2.	Round-robin listing of ideas
3.	Series of brief discussions facilitated by a skilled moderator aiming to clarify ideas / statements
4.	Independent ranking or rating of ideas on a scale 1-5 or 1-10
5.	Solutions with highest ranking / rating are kept and the lowest are discarded.

The strengths of the NGT are its structured process and interaction between the panellists, who all take an active part in contributing towards new ideas and discussions (Jones and Hunter, 1995). This structured approach to the process mitigates the threat of more dominant personalities controlling the meeting (Murphy et al., 1998), as does the involvement of a skilled facilitator. Another positive of this approach is the separation of the idea generation component from the discussion, which enables more ideas to be vocalised and as such prevents following only one way of thinking and rushed decision making (Delbecq and Van de Ven, 1971). In addition, the ideas generated can be evaluated and clarified if necessary (Fink et al., 1984). The main limitations with the NGT are associated with the small number of experts involved, limiting the generalisability and reliability. Indeed, views of a small number of panellists may not be representative of the wider community. Another important issue is the lack of explicit focus on available evidence in the group decision making of the classic NGT, although some modifications of this technique incorporated evidence (i.e. RAND/UCLA Appropriateness Method) (see Table 5.1) which is discussed in the section 5.2.3 below.

5.2.3 RAND/ UCLA Appropriateness Method

The RAND/UCLA Appropriateness Method (RAM) originated as a part of the RAND Corporation and University of California Los Angeles (UCLA) Health Services Utilisation Study in the 1980s and was used as an instrument to measure overuse and underuse of medical and surgical procedures (Fitch et al., 2001). It was developed as a response to the lack of randomised clinical trials – 'the

gold standard' for evidence-based medicine or sufficiently detailed evidence to support decision making in clinical care. This method aimed to combine the best available scientific evidence with expert judgement to obtain a statement relating to the appropriateness of undertaking procedures for specific groups of patients and in the light of patient-specific symptoms, medical history, and test results (Fitch et al., 2001).

The key characteristics of the RAM in relation to other methodologies are shown in Table 5.1. Fitch et al. (2001) described the overview of the process, which is presented below in Figure 5.1. The outcomes of the RAM process are used to inform and improve clinical decision making to increase appropriateness and can be used retrospectively to compare clinical records against criteria outcomes (Fitch et al., 2001).

The RAM combines some constructive aspects of the nominal group technique (NGT) and Delphi method, such as private rating of indications/statements and a face-to-face meeting of experts during the second round (prior to re-rating of the indications/ statement). This allows for areas of disagreement and uncertainty to be discussed and clarified, which potentially may facilitate a final agreement. Moreover, this method emphasises the importance of consideration of the synthesised research evidence in the field of enquiry. This element of the RAM process is stressed more than in the classical Delphi or NGT.

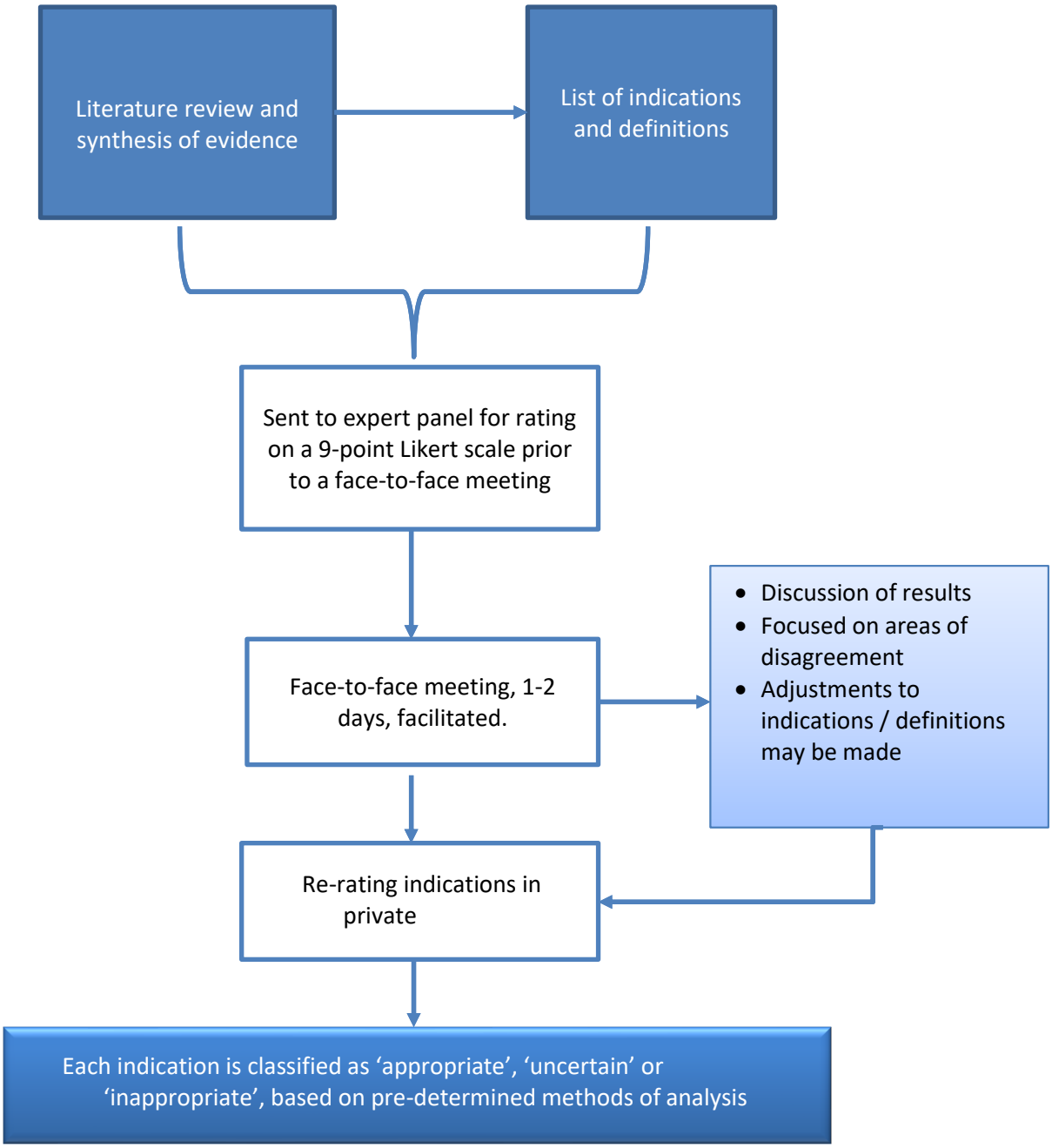


Figure 5.1 RAM process overview based on Fitch et al. (2001)

5.2.4 Consensus development conference

The Consensus development conference was established by the US National Institutes of Health (NIH) (Fink et al., 1984) and guidelines for running the conference have been modified with time (Murphy et al., 1998). The main characteristics of this method are summarised in Table 5.1. Broadly speaking, the process involves approximately ten people, who meet face-to-face in a chaired meeting over several days (Murphy et al., 1998). They are presented with evidence by various experts who are external to the panel. After hearing the evidence the panellists retire to

consider the questions underpinned by the evidence they were presented with, in order to reach consensus (Murphy et al., 1998).

This approach can be criticised for a small number of experts involved. However, drawing on elements of judicial decision-making, it aims to hear out available evidence on which the panel later deliberates to achieve consensus (Lomas, 1991). Moreover, members of the public are invited to participate in discussions, an element which is absent from other consensus methods, since the conference method was not developed for the purpose of research but achieving a resolution (consensus) on a subject matter (Murphy et al., 1998). Currently, however, this methodology has been used infrequently, with the other consensus methods, described previously, taking precedence (Black, 2006).

5.3 Methodological issues in consensus studies

5.3.1 Validity

In consensus studies, it is difficult to ascertain the validity of a judgement (i.e. determine whether the judgement made is 'good') at the precise time when it is being made (Murphy et al., 1998). Although there are several ways of assessing validity, including comparison with the 'gold standard', predictive validity, and concurrent validity (Murphy et al., 1998), their use in assessment of judgements is limited.

Where there is no evidence readily available, or it is insufficient or contradictory, consensus studies are usually undertaken to synthesise the knowledge and practice of experts in a given field of enquiry (Jones and Hunter, 1995). By implication, there is no 'gold standard' with which the comparisons can be made at the time of the study takes place. Similarly, although consensus studies used for forecasting can be assessed for predictive validity as the new evidence is produced, this is impossible to ascertain during the conduct of a consensus study. To assess concurrent validity any decision (judgement) made, should be evaluated alongside the research evidence. If the decision (judgement) and evidence do not align without a good reason – the decision should be deemed invalid (Murphy et al., 1998).

5.3.2 Reliability

Consensus methods can be criticised for lack of reliability, namely difficulty obtaining the same results with different groups of participants (Keeney et al., 2006, Sackman, 1974). However, it has been observed that the Delphi method which includes a larger group of participants shows

greater within- and between-group reliability than panels with fewer participants. (Raine et al., 2005).

5.3.3 Panel composition

The choice of participants and the best composition of the consensus study panel has been debated by methodologists. It has been agreed that an expert panel should consist of knowledgeable individuals - experts (McKenna, 1994, Dalkey, 1967). An 'expert' has been defined as a person who has a specialist knowledge, qualification and/ or proven track record in the field (Keeney et al., 2001) and an individual who is representative of their profession, is able to implement the findings, and is an expert in the field (Fink et al., 1984). Identifying such persons is an area of procedural concern (Hasson et al., 2000). Moreover, the potential for selection bias was identified as another issue since panel composition can affect results (Jones and Hunter, 1995, Keeney et al., 2006). The selection process of participants has to be transparent and reflect the research question (Keeney et al., 2006). The credibility of results can be enhanced by ensuring the expert group's heterogeneity. Hence, the panel composition reflects who (what stakeholder groups) are concerned by the study results, and a range of views can be included (Boulkedid et al., 2011).

There are no written rules about the number of participants, but the methodology used will guide the decision of the size of the panel (Hasson et al., 2000, Jones and Hunter, 1995, Keeney et al., 2006). The Delphi method can be effectively used with large and very large panels because it does not require face-to-face interactions. Moreover, Delphi's reliability increases with the number of experts (Fink et al., 1984). However, the more participants there are, the more data are produced, and more skills and resources are required to manage the study (Hasson et al., 2000, Keeney et al., 2006). Methods that rely on face-to-face interactions are more prescriptive in how many experts should be involved, because the group discussions have to be chaired or facilitated. It would be impractical and difficult to facilitate discussions with large number of participants. However, when a fewer number of experts is involved in the consensus, the questions of reliability of results may be raised (see sections 5.2.2 and 5.3.2).

5.3.4 Use of evidence

A review of available literature summarising evidence pertinent to the particular topic under study is essential (Fitch et al., 2001). All participants must have access to the same body of knowledge to support their decision-making process (Murphy et al., 1998). Lack of access to synthesised evidence may lead to the participants relying explicitly on their own experience,

which may be insufficient (Fink et al., 1984). Availability and use of evidence impacts on validity of the decisions made during the consensus process. Consequently, in practice, the process of the systematic evidence review and consideration is regularly incorporated into consensus studies (Edsberg et al., 2014, Lovegrove et al., 2020, Coleman et al., 2014a, Haesler et al., 2018).

5.3.5 Definition of consensus

Two issues need to be considered regarding achieving consensus. First, how the consensus should be determined and second, how it should be defined. Different methods will predetermine when the consensus is reached. Classical Delphi can have three (possibly four) rounds of questionnaires (Jones and Hunter, 1995, Powell, 2003). In contrast, the RAM includes two rounds (which might be followed by a third-round after the panel meeting, if necessary) (Fitch et al., 2001). The key concept of importance is that the panellists have the opportunity to change their views in the light of feedback and a summary of panel results. Therefore at least two rounds of rating should take place. However, it is recognised that more rounds can result in participant fatigue and dropout (Hasson et al., 2000).

There are many ways that researchers define consensus (Fink et al., 1984). Principally, the levels of agreement that are considered are two-fold: agreement with the statement and the extent to which the participants agreed with each other.

A central tendency measure is required when analysing the level of agreement with the statement. An ordinal, 9-point Likert scale was used in this study, and median was reported as a measure of central tendency (Black, 2006). Group median responses are categorised into tertiles, which guide indications including:

- Disagreement with the statement (1-3),
- Uncertainty (4-6), and
- Agreement (7-9).

A measure of dispersion typically assesses the extent to which participants agree with each other. Most often utilised in consensus studies are:

1) The interquartile range (Black, 2006) -

   IQR =Q3 - Q1, where:

   Q3 – third (upper) quartile

   Q1 – first (lower) quartile

2) The mean absolute deviation from the median (MADM) (Hutchings et al., 2005) –

   MADM = Median ($|x_i - \tilde{x}|$), where:

   x_i = each value

   $\tilde{x}$ = average value

3) The disagreement index (DI) used in the RAM (Fitch et al., 2001) –

   DI = $\frac{IPR}{IPRAS}$, where:

   IPR – interpercentile range

      IPR = 2.35 (value that best reproduces 'classic' definition as per Fitch et al., 2001)

   IPRAS – IPR + (AI *CFA), and

      AI – asymmetry index

         AI = (5 – central point of IPR), where central point of IPR = (Lp + Up)/2

         Lp – Lower limit IPR

         Up- Upper limit IPR

   CFA – Correction Factor for Asymmetry, and

      CFA =1.5 (value that best reproduces 'classic' definition as per Fitch et al. 2001)

The MADM is preferable over standard deviation, because it does not give extra weight to outliers in the data set (although they are still included), and it measures variation around the median, which is the most common measure of central tendency in consensus studies (Hutchings et al., 2005). The IQR is said not to be as sensitive as MADM, hence is less desirable.

The DI addresses the issue of applying the classic definition of consensus in panels where there were more than nine panellists (Fitch et al., 2001). This classic definition states that in a nine-person panel, disagreement exist when at least three panellists rated the item in the 1-3 tertile, and at least 3 rated the item in the 7-9 tertile (Fitch et al., 2001).

5.4 Comparison of consensus methods

There is a lack of research comparing different formal consensus approaches on study results. Some literature suggests there is little difference to study outcomes between mail only and in-person panels (Washington et al., 2003), equally other publications assert the opposite. In the field of clinical guideline development Hutchings et al. (2006) compared four Delphi and four NGT panels, and found that the nominal groups have closest within group agreement, whereas the Delphi have improved reliability. The authors concluded that a hybrid of NGT and Delphi would facilitate a technique which enables close consensus whilst simultaneously ensuring greater reliability (Hutchings et al., 2006).

The mail only (Delphi) panels offer several advantages such as lower cost, speed, flexibility, and inclusion of participants from different geographical areas (Holliday and Robotin, 2010, Powell, 2003). Furthermore, the lack of face-to-face interaction in the Delphi method enables much larger panels, which in turn is shown to improve the reliability of the study findings (Raine et al., 2005). A larger panel is more likely to represent all stakeholders interested in the study results, ensuring a range of different perspectives on the issue under investigation (Kezar and Maxey, 2016). Consequently, to enhance credibility and acceptance, the panel should incorporate all groups with a vested interest in the study findings (Boulkedid et al., 2011). Nonetheless, there are also disadvantages of Delphi studies, which are concerned with the lack of face-to-face interaction (see section 5.3.1) and the definition of 'expert' and potential bias in participant selection (see section 5.3.3).

An approach where the Delphi method is combined with RAM, would enable gaining consensus from a large panel representing different settings and opinions (including those which might have been otherwise marginalised), using a robust approach of defining agreement within the group and with the statements proposed. This hybrid approach should allow for gaining a close consensus with maximum reliability.

5.5 Rationale for consensus study

The narrative review (Chapter 2) and the qualitative exploration of reporting practice (Chapter 4) have identified variation and inconsistencies in the routine practice of PU and MDRPU reporting. This variation exists not only between countries but also between organisations in the same country and potentially within the same healthcare institution (e.g. general wards and critical care units or paediatric intensive care units). Furthermore, the information collected in MDRPU reporting is not standardised and lacks details of the medical device implicated in patient harm

(beyond the type). In the UK, since the variation has been reported by researchers, NHS Improvement developed a guidance for national reporting specifying that any PU which developed due to application of a medical device, should be distinguished from the 'traditional' PU (NHS Improvement, 2018). It did not go any further than that in requiring any contextual data round MDRPUs to be recorded and reported (as discussed in Chapter 2). In addition, the internal electronic reporting systems often do not support effective and efficient recording of these wounds. They lack data fields to input relevant information, relying often on 'comment' boxes only and do not provide an opportunity for a structured reporting beyond gross prevalence estimates.

Reflecting on these shortfalls and recognising that reporting of MDRPUs is a relatively new practice, we have an opportunity to improve the current reporting practice through designing a novel reporting tool for MDRPUs, where all necessary data items could be recorded and reported. Having a standardised data set would improve the evidence we have, providing the basis for improved guidelines for prevention. It would also enable better comparison and benchmarking, facilitate dialogue with device manufacturers to improve devices' design and develop new, safer devices. This may also have an economic impact on organisations and support more efficient resource allocation. It can be achieved by purchasing devices that although they might be more expensive, are also safer and do not require investing into resource-intensive prophylactic interventions and in a long run may spare organisations costs of lawsuits or compensations for patients who suffered with MD-related harm during an inpatient stay. Those savings can be then redirected into areas where investment is most needed.

Currently, there is no available or internationally agreed recommendations on what data are relevant for reporting of MDRPUs. Hence there is a need to consult with experts in the field of tissue viability, medical device manufacture and research to establish a list of items to be used for standardised reporting on MDRPU incidents. This was undertaken through a robust and transparent process of structured consensus methods.

5.6 Aim of the study

To create an internationally agreed data set which can be used to design a form to facilitate routine and standardised reporting of Medical Device-related Pressure Ulcers (MDRPUs). The form will subsequently undergo pre-testing (Chapter 6) and feasibility evaluation in clinical practice (Chapter 7).

Objectives:

- To identify a list of reporting criteria derived from the literature review and interviews.
- To recruit an international panel of experts with informed knowledge and interest in MDRPUs to conduct the consensus study
- To agree a list of items to form a Data Set for the collection of data relating to medical device-related pressure ulcers
- To develop a clinical reporting form incorporating the agreed Data Set.

5.7 Study design

A modified Delphi study drawing on RAND/UCLA (University of California, Los Angeles) Appropriateness Method (RAM) methodology (Fitch et al., 2001) was selected to define the MDRPU dataset (Figure 5.2). This approach was chosen to maximise reliability and content validity through combining of the key features of a traditional Delphi study (i.e. structured interaction (but not face-to-face), rating, decisions made in private, formal feedback, opportunity to change decision (re-rate), explicit synthesis of judgement and group decisions) with the strength of RAND/UCLA RAM method, which lies in combining research evidence with expert opinion for developing consensus (Table 5.1). An important motivation for the design of this consensus study was the inclusion of a large, international panel of experts, and the possibility to include additional items as suggested by the participants (in feedback section of the questionnaire), as well as rounds targeted at reducing the number of items. The design of this consensus study is shown in Figure 5.2. It includes RAM elements such as an evidence (literature) review, individual appropriateness and necessity scoring rounds. The item is defined as appropriate if the expected benefit of inclusion in the data set exceeds the expected negative consequences, i.e. that collecting data on an item will overall be more beneficial because of the insights it provides, than the burden it may put on the reporter (Brook et al., 1986). Whereas necessity was operationalised (and the definition given to the participants within the survey text) as a data item that is needed for a desired result, a prerequisite. Which means that not collecting data on an data set item would be considered improper, since it would benefit the aim of the data collection (Fitch et al., 2001).

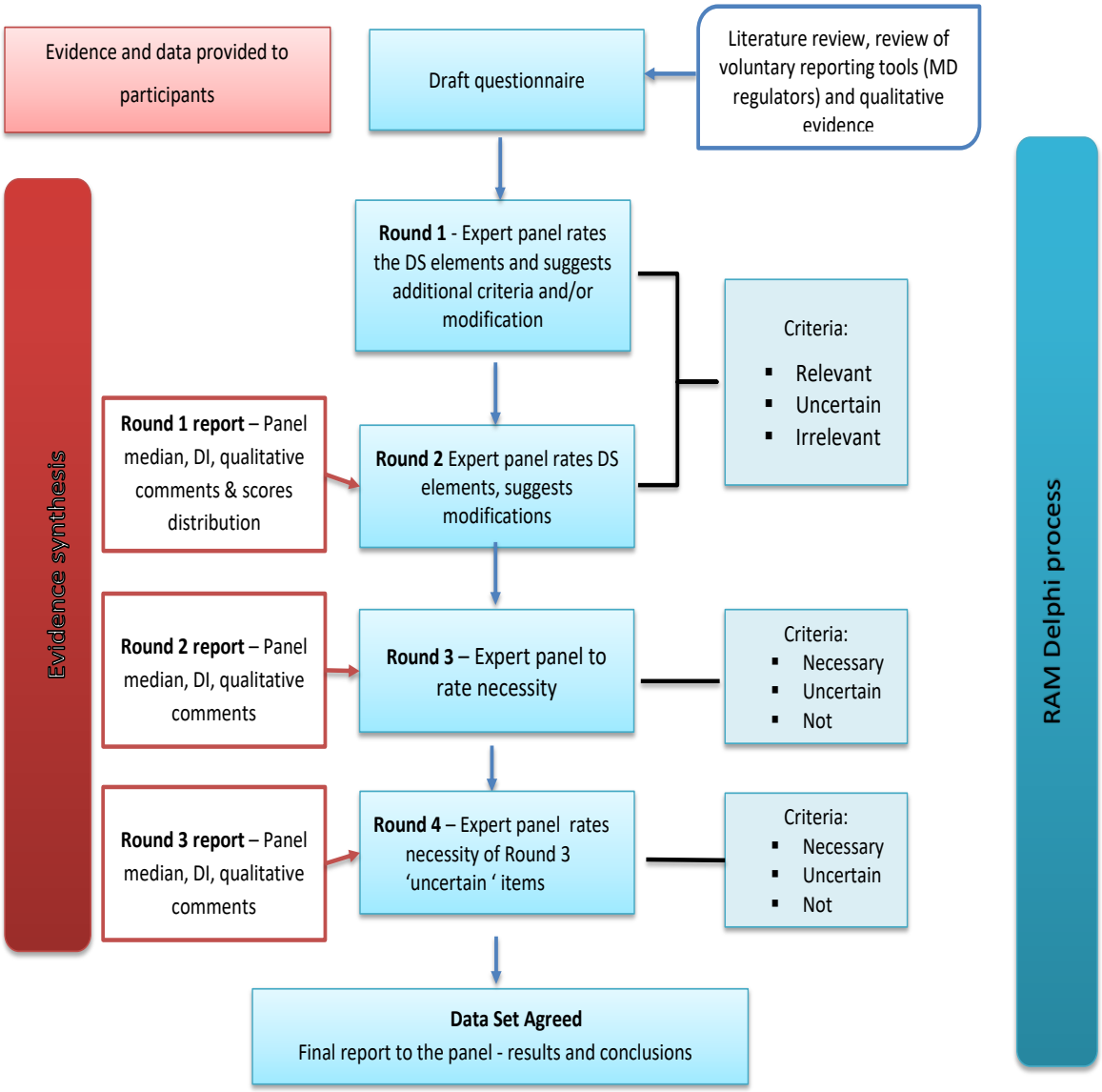


Figure 5.2 Design of the consensus study drawing on the RAM methodology and an overview of evidence provided to the panel.

In this study combination of the two techniques allowed for:

1) Explicit inclusion of the evidence
2) Inclusion of a large group of experts through the use of mailed questionnaires to enhance reliability and content validity (no face-to-face interaction which is a feature of RAM due to the large number of experts)
3) Questionnaire completion using a 9-point Likert scale enabling analyses of levels of agreement.
4) The initial study design was based on 3 rounds of statement scoring to agree the data set for reporting MDRPUs. However, it emerged that the uncertainty remained (i.e. items were classified as 'uncertain') after scoring in round 3. Any item which achieved a median 4-6 OR any median with disagreement in round 3, although according to RAM should be excluded, was included in the round 4 scoring round. Since the consensus process did not include a face-to-face meeting and hence the areas of uncertainty could not be explored via discussion, the decision to proceed to a fourth round was an attempt to clarify the panel's judgement and potentially come to an agreement to include or exclude those items.
5) Other items were included or excluded as per round 3 indication. The decision of initiating of a fourth round of questionnaires was made based on the necessity to clarify the panel's consensus on the necessity of their inclusion in the data set.

Rounds 1 and 2 of the scoring cycle were concerned with how relevant items were for inclusion in the data set. In round 3, the expert panel was asked to rate items' necessity. i.e. if their inclusion in the minimum data set was required to achieve the data collection aim. Additionally, any new items included after feedback from round 2 were scored for both: relevancy and necessity. In the final round, only statements classified as uncertain at the end of round 3 were presented to the panel for final consideration of necessity (Figure 5.2).

5.8 Participants/ sample

Following guidance on best practice in consensus studies, indicating that a multi-speciality group was favoured (Hutchings and Raine, 2006), participants were purposively sampled to include perspectives of clinicians, academics and device manufactures' representatives (inclusion criteria are presented in Table 5.4). Furthermore, it was considered that participation of international experts may facilitate wider adoption of the data set and reporting tool in the future.

Table 5.4 Exclusion and Inclusion criteria – consensus study.

Inclusion criteria – Healthcare professionals to meet at least two of the criteria (1-3).	**Exclusion criteria**
1. Ten years' experience working within the domain of tissue viability.	Inability to communicate in English
2. Healthcare professions Council Registered or General Medical Council Registered.	
3. Clinical practice, including wound assessment and/or reporting within the last two years.	
4. Research/publication track record on pressure ulcers and/or medical device-related pressure ulcers.	
5. Industry experience working with medical devices which interface with the skin or prophylactic dressings to protect the skin.	

Following the qualitative study data collection (Chapter 4), participants were asked if they were interested in taking part in the consensus study (the inclusion criteria in both studies were the same). Accordingly, eleven potential participants were approached to establish whether they would consider taking part in the consensus study. Nine of these clinicians expressed interest in participating and were added to the expert panel.

Other expert clinicians and/or researchers were recruited using a purposive sampling approach and employing the set inclusion criteria. We aimed to recruit from the same group of international organisations as in the qualitative study (Chapter 4, Table 4.1). However, a different recruitment strategy was used. Here, an invitation to participate in the consensus study with an explanation of the study's aims and objectives, was sent to members of organisations by the researcher. The organisations were asked to advertise the study to their membership according to their rules and regulations. The email address of the researcher was supplied in the text of the advertisement and on receipt of the expression of interest, potential participants were contacted to establish eligibility. If they fulfilled inclusion criteria, they were included in the mailing list.

The panel sample was partly determined by practical and logistical factors, namely the resources available and the scope of the MDRPU consensus task (Hasson et al., 2000, Keeney et al., 2006). And partly by the recognition that a higher number of panellists improves the reliability of composite judgements (Murphy et al., 1998) which was found important for the acceptability of judgements made during the consensus process.

In this study, the sample size was initially guided by other consensus studies in the field of skin health (Beeckman et al., 2018, Coleman et al., 2017) and aimed to recruit 20 to 30 experts to the panel. Although these studies are not Delphi studies, they worked as a practical indication of how many participants can be recruited from the relatively small field of skin and wound health field.

As mentioned in section 5.3.3, it is difficult to determine the exact number of participants required in a consensus study. In recognition that this study was concerned with an issue of international importance, and delivered online, the recruitment strategy employed was wide-reaching and ambitious, and the number of participants extended beyond the first estimation.

Consequently, the recruitment strategy employed in this study enabled to convene a large panel of clinicians and industry representatives, making the panel heterogeneous. Moreover, experts represented a range of settings and healthcare systems, which ensured a range of opinions was enabled to be expressed and considered in the process. This range, however, might have also led to differences in appropriateness ratings, due to different organisation of healthcare and availability of resources (Hutchings and Raine, 2006).

5.9 Data collection

The consensus study was undertaken between October 2020 and March 2021 and consisted of 4 questionnaire rounds administered to an anonymous international panel of experts (Figure 5.2).

Questionnaires were administered and completed electronically using a commercial online survey platform (LimeSurvey https://www.limesurvey.org/). In the absence of guidance as to how long each round should take to complete (Hasson et al., 2000), participants in this study were given on average two weeks to complete the questionnaire in each round, with a period of one month to collate the responses and analyse the data. In round 2, the experts had this period extended to four weeks due to the holiday period and the impact of the Covid-19 pandemic on their workloads.

Participants were provided with a summary of findings (Appendix D) of the narrative literature review (Chapter 2) and the international qualitative study exploring reporting practice (Chapter 4) in each of the study questionnaire rounds. The summary was accompanied with full reports for both of the studies added in appendices, in the event of any participant interested in details of either of the studies. The evidence synthesis was supplied in a separate document to the questionnaire.

Following the traditional Delphi design, experts did not meet in person. However, the RAM advises a group meeting following the statements' ranking. In order to mitigate the lack of in-person meeting and the chance to share valuable feedback, (Iqbal and Pipon-Young, 2009), the questionnaires in rounds 1 and 2 included the possibility of adding new items and/ or comments if the participant wished to do so. The qualitative feedback was also shared with the panel in subsequent round reports. This allowed for observations about the content of the questionnaire

and more general comments about the data set or the reporting tool to be collected for consideration by the study team.

5.9.1 Questionnaire design

The questionnaire items, developed in preparation for the study, included the proposed data set extrapolated from the qualitative study results (Chapter 4) and items aggregated from medical device regulatory bodies' voluntary reporting schemes (Chapter 2, Table 2.5). The items were grouped thematically and ordered to improve the logical flow and thus understanding of the questionnaire:

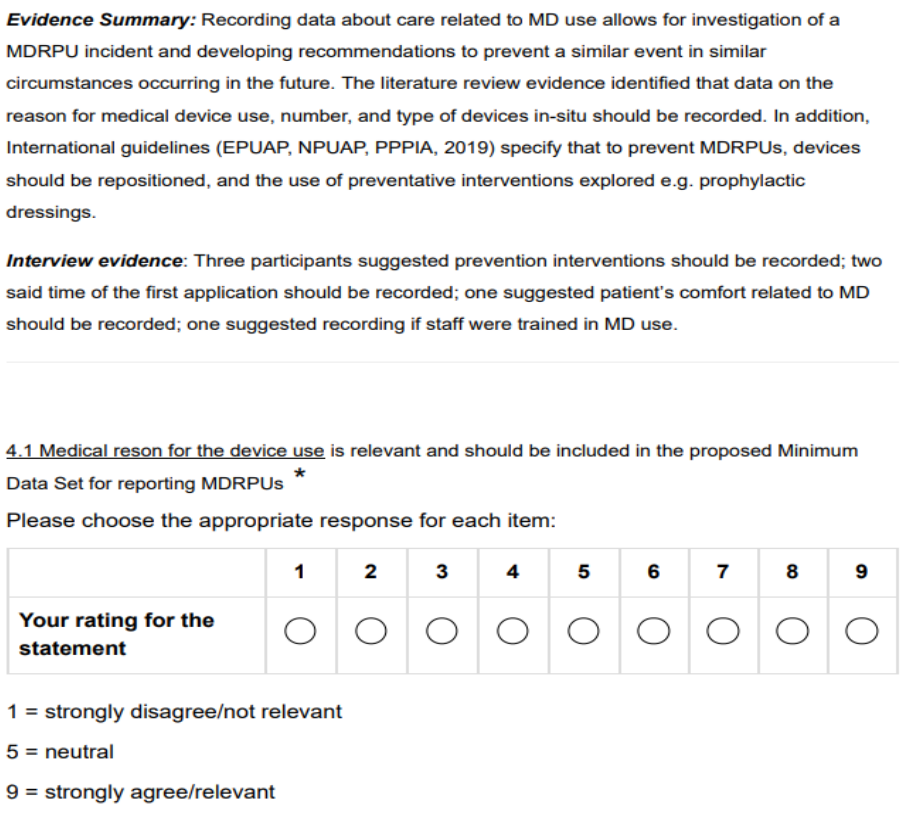
1) Recording medical device care
2) Reporting medical device-related pressure ulcers
3) Medical device-specific reporting
4) Ulcer-specific reporting
5) General patient and co-morbidity data
6) Other items – free-text box to suggest any items relevant but missed in the questionnaire or any modifications (this was available in rounds 1 and 2).

The themes were the same throughout voting rounds 1 to 3, with the exception of the final qualitative theme 'Other items'. Qualitative data were only collected in rounds 1 and 2 (Appendix E presents Round 1 questionnaire as an illustration). Panellists were encouraged to add any items they considered relevant for reporting MDRPUs that were not included in the proposed data set. They were also invited to share any comments they might have had about MDRPU reporting or the future format of the reporting tool.

In the final, fourth round, experts were presented with a list of items they had not reached consensus on and were asked to re-rate them. Those items were simply presented in a list which followed the order of the themes from previous rounds.

In the body of the online questionnaire, each theme or distinctive group of questions was introduced by a short introduction of evidence to support experts' decision making. Experts rated their agreement with each statement on a 9-point Likert scale (where 1 indicate no support and 9 indicates strong support) (Figure 5.3). The group median for each item was categorised into three tertiles. In this study categories were - median 1-3 disagree, 4-6 uncertain, and 7-9 agree. In round two, there was an additional option to keep the score the same as in round 1, and the distribution of scores for each item was presented. Rating of all statements was mandatory. There was an opportunity to add any items otherwise missing from the list of items and a space for comments

at the end of each set of questions, as well as a separate open-ended question box at the end of the online questionnaire. Although the open text boxes were not compulsory to complete.



Evidence Summary: Recording data about care related to MD use allows for investigation of a MDRPU incident and developing recommendations to prevent a similar event in similar circumstances occurring in the future. The literature review evidence identified that data on the reason for medical device use, number, and type of devices in-situ should be recorded. In addition, International guidelines (EPUAP, NPUAP, PPPIA, 2019) specify that to prevent MDRPUs, devices should be repositioned, and the use of preventative interventions explored e.g. prophylactic dressings.

Interview evidence: Three participants suggested prevention interventions should be recorded; two said time of the first application should be recorded; one suggested patient's comfort related to MD should be recorded; one suggested recording if staff were trained in MD use.

4.1 Medical reson for the device use is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Figure 5.3 Example questionnaire item from Round 1, including evidence in survey text, and Likert scale used in appropriateness rounds (1&2).

In the final two rounds (rounds 3 and 4), experts were asked to rate the necessity of including items they previously agreed were relevant to reporting MDRPUs. The scoring used a 9-point Likert scale presented in the Figure 5.4. Similar to rounds 1 and 2, the group median response for each of the items was categorised into three tertiles (1-3 disagree, 4-6 uncertain, 7-9 agree).

Feedback from Round 1: One of the experts stated there are situations when repositioning of the MD is not safe for the patient, and this should be recorded.

"It might be useful to have something about whether it was a "lifesaving intervention" and whether it in fact could be repositioned or pressure relieving devices beneath it be used as many occur in these situations but staff cannot prevent them occurring despite trying repositioning/monitoring etc."

4.N3. Including a record if the medical device could be safely repositioned is ***necessary.***
*

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/ definitely **does not have to** be included

5 = neutral

9 = strongly agree/ definitely **has to be** included

Figure 5.4 Example questionnaire item from Round 3, including evidence in survey text, and Likert scale used in the necessity rounds (3&4).

5.9.2 Round reports

In each round, starting from round 2, all participants were provided with a report of the previous round. Each participant received a personalised report (including their scores and panel's median score or their choice of answer and how the panel answered in the case of questions pertaining to the use of the proposed data set for measuring MDRPU prevalence) as well as the next round's questionnaire to complete, and separate document with evidence synthesis (as in round 1). All items were tabulated, the individual's score was presented along with the panel median and disagreement index (see Appendix F for an example report). In rounds 2 and 3, we presented any comments received for the item verbatim. Lastly, an initial indication of inclusion, exclusion or uncertainty were shown. Any additional comments received at the end of each section (in rounds 2 and 3) were also reported. New items added in rounds 2 and 3 as a response to the feedback were presented with the number of experts proposing the item and direct quotes. After the last round, the experts received a final report with the results of the consensus study and conclusions.

5.10 Data analysis

In traditional Delphi a cut-off point to establish an agreement is decided at the study design stage (as prescribed by best practice). Nonetheless, there is no guidance available about the level of

agreement necessary for achieving consensus, some suggest a minimum value of 75% (Keeney et al., 2006), others suggest 70% (Humphrey-Murto et al., 2017). Overall, there is a great variability in a thresholds used to ascertain consensus, with a range 51 – 80% (Hasson et al., 2000). In this study, these features were decided a priori to the data collection and analysis, which is considered a good practice (Keeney et al., 2006, Jünger et al., 2017). This also addresses the perceived robustness and clarity of cut-off point, which in Delphi studies, may impact trustworthiness of the results (Keeney et al., 2006).

RAM provides clear rules on determining the level of agreement (Fitch et al., 2001), with less reliance on achieving arbitrary thresholds. In the RAM process an item is classified as 'appropriate', 'uncertain' or ' inappropriate' based on two variables (Fitch et al., 2001) (see also section 5.3.5), hence the questionnaire statements were summarised with:

1) The median panel rating;
   and
2) A measure of dispersion of panel ratings, which is considered to be an indicator of the level of agreement between the panellists with which the ratings were made, in RAM this is the Disagreement Index (DI), which is based on the classic definition of disagreement.

The DI was found most suitable for this consensus study, in comparison to other measures of dispersion (section 5.3.5). It considers the dispersion of individual scores within the group and identifies areas of disagreement. To detect disagreement, the inter-percentile range (IPR: 0.3-0.7) was calculated, and IPR was adjusted for symmetry (IPRAS), see section 5.3.5 for the formula used for the calculation.

Disagreement was established by calculating the ratio of IPR and IPRAS. Thus, there is disagreement if DI >1, and if DI<1, there is an agreement (Fitch et al., 2001).

Using those two parameters, and following the established RAM, items were included and excluded in Round 2, with the corresponding thresholds presented in Table 5.5 below.

Table 5.5 Round 2 - Panel's support criteria.

Panel median	**Disagreement Index (DI)** DI > 1 indicates disagreement	**Indication**
1 - 3	DI < 1	Exclude
4 - 6	Any	Uncertain
Any	DI > 1	Uncertain
7 - 9	DI < 1	Include

It is worth noting that the rules in Round 3 differed from the ones used in Round 2 (Table 5.6). In this round any item that in Round 2 would have been regarded as 'uncertain' was excluded from the list of statements. Consequently, participants had the opportunity to revise their judgement, before an item was excluded from the data set, and refinement of the number of items included was anticipated. It is possible, when the panel consist of an even number of participants, that decimal medians are obtained and in such case the item was included in the higher appropriateness/ necessity category (e.g. median of 6.5 would be classified as appropriate/ necessary) (Fitch et al., 2001).

Table 5.6 Round 3 - Panel's support criteria.

Panel median	**Disagreement Index (DI)** DI > 1 indicates disagreement	**Indication**
1 - 3	DI < 1	Exclude
4 - 6	Any	Exclude
Any	DI > 1	Exclude
7 - 9	DI < 1	Include

Qualitative data collected in rounds 1 and 2 were narratively summarised. Any new items that any panellist suggested were tabulated, and any duplication was noted. The addition of an item in the subsequent round of questionnaire was based on how frequently the experts mentioned the item in their feedback, in the free - text boxes. Any other qualitative comments were coded, thematically categorised as topic summaries, and analysed using content analysis.

5.11 Validity

Determining the validity of consensus judgements at the time they are made is difficult. Hence it is paramount for the consensus process to be as rigorous as possible (Raine et al., 2005). To achieve this goal, good practice guidelines were followed in designing and undertaking this study. Namely, the panel consisted of experts from different specialities and backgrounds (Hutchings and Raine, 2006). Questionnaires were developed based on the most up to date available evidence, round reports included their own score for each of the items, panel median, disagreement index, and any qualitative feedback received. In the questionnaire itself, when re-scoring items a table showing distribution of scores was also provided, for reference. Additionally, participants were informed when to expect results of each of the consensus questionnaire rounds.

Each questionnaire was a subject of piloting to ensure content validity. As a result, language and choice of vocabulary was improved upon to ensure clarity. All questionnaires were expected to be

completed in private, without the external pressures of others who might have had strong convictions regarding the subject. Moreover, we enabled written feedback not only regarding additional items that were not included in the proposed list of statements, but also other feedback participants might have felt was necessary to give. Lastly, a measure of the dispersion of scores and the measure of central tendency were included in reporting of the study results (Murphy et al., 1998).

5.12 Ethics

This study has already obtained University of Southampton Ethics Board approval via the same application as the qualitative study reported in Chapter 4 (ERGO 2 49718 Appendix C). At the start of the online questionnaire, participants were asked if they read the study information sheet and to confirm their consent to participate, which was confirmed by ticking a box next to the consent statement. They were also reminded they had the right to withdraw from the study without giving reasons.

5.13 Results

Initially, 95 international experts expressed willingness to participate in the consensus study. They all met the inclusion criteria and were subsequently invited to complete the first round of the study questionnaires. The number of participants in each round and response rates are summarised in Table 5.7. Despite attempts to maintain the number of experts throughout the rounds, numbers decreased by just over 50% by the final round. However, overall response rates were high for each corresponding round (74-96%).

Table 5.7 Participant numbers and response rates.

Round #	Number of invited experts	Number of responses	Response rate	Responses received vs ***initial*** (95) invitations sent
1.	95	75	79%	79%
2.	75	65	87%	68%
3.	65	48	74%	51%
4.	48	46	96%	48%

In Round 1, 75 out of 95 recruited experts completed the questionnaire (79% response rate). The panel of experts represented twenty-three different countries, with the highest number of participants being based in the UK (24%), the USA (19%), and Australia (11%) (Table 5.8)

Table 5.8 List of countries and number of participants in Round 1 consensus study.

Country	**Number of participants**
Australia	8
Belgium	1
Brazil	4
Canada	1
China	4
Croatia	1
Czech Republic	1
Finland	1
Germany	2
Greece	1
Hong Kong	4
Iran	1
Ireland	1
Kingdom of Bahrain	1
New Zealand	2
Philippines	1
Portugal	2
Saudi Arabia	3
Sweden	2
Switzerland	1
Turkey	1
United Kingdom	18
USA	14

Participants in Round 1 represented academia (25%), acute sector (63%), industry (7%), health service regulatory body (1%), and community sector (3%), with one participant identifying with both community sector and industry (Table 5.9). There were no representatives of medical device regulatory agencies.

Table 5.9 Number of expert participants in each round according to their workplace sector.

Sector	Round 1 N (%)	Round 2 N (%)	Round 3 N (%)	Round 4 N (%)
Academia	19 (25%)	15 (23%)	12 (25%)	11 (24%)
Acute	47 (63%)	44 (68%)	34 (71%)	33 (72%)
Community & industry	1 (1%)	1 (1%)	1 (2%)	1 (2%)
Industry	5 (7%)	4 (6%)	1 (2%)	1 (2%)
Heath service regulatory body	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Community	2 (3%)	1(1%)	0 (0%)	0 (0%)
TOTAL	**75 (100%)**	**65 (100%)**	**48 (100%)**	**46 (100%)**

Fifty-nine panellists (79%) had ten or more years' experience in tissue viability or related research and sixty-nine participants (92%) had ten or more years' experience in wound assessment and/ or reporting (Table 5.10).

Table 5.10 Experts' characteristics – experience

	Round 1		**Round 2**		**Round 3**		**Round 4**	
Years' experience	Tissue viability/ related research **N (%)**	Wound assessment and/ or reporting **N (%)**	Tissue viability/ related research **N (%)**	Wound assessment and/ or reporting **N (%)**	Tissue viability/ related research **N (%)**	Wound assessment and/ or reporting **N (%)**	Tissue viability/ related research **N (%)**	Wound assessment and/ or reporting **N (%)**
1 - 15	28 (37%)	27 (36%)	25 (38%)	24 (37%)	18 (38%)	18 (38%)	17 (37%)	17 (37%)
16 – 25	30 (40%)	28 (37%)	26 (40%)	24 (37%)	19 (40%)	17 (35%)	18 (39%)	16 (35%)
Over 25	14 (19%)	17 (23%)	12 (18%)	15 (23%)	10 (21%)	13 (27%)	10 (22%)	13 (28%)
No data	3 (4%)	4% (n=3)	2 (3%)	2 (3%)	1 (2%)	0 (0%)	1 (2%)	0 (0%)

5.13.1 Consensus development – the content of the Data Set

In the first round of questionnaires, experts rated 36 items (Table 5.11). After the first two rounds four items were removed, since they did not meet the criteria for inclusion in the data set. Two of those items related to medical device data, i.e. expiry date and whether device was sterile. The experts also agreed that photographs of a healed MDRPU and patient gender are not relevant to reporting. In the first round, there was no agreement between experts whether the risk assessment score was relevant for MDRPU reporting (median 5, DI=2.26), however after the second round the disagreement resolved and the item eventually was included in the data set. Additionally, experts in the first round suggested three more items to be included in ensuing voting rounds – the type of MD securement used and its frequency of change, and whether the MD could be safely repositioned. Consequently, all three items were included in the subsequent questionnaire rounds and reached the consensus criteria for inclusion in the proposed data set.

After four rounds of voting, 30 items met criteria for inclusion in the data set for reporting MDRPUs and subsequently were used to develop a reporting tool (form) that could be used in clinical practice. Table 5.11 shows items included or excluded through the rounds and the final proposed data set.

Table 5.11 Consensus development results and final list of items

	Proposed Item	**Relevancy**		**Necessity**		
#		**Round 1 Panel Median (DI)**	**Round 2 Panel Median (DI)**	**Round 3 Panel Median (DI)**	**Round 4 Panel Median (DI)**	**Items included in the proposed DS**
	Theme 1: Recording medical device care					
1.	Medical reason for the device use	9.00 (0.16)	9.00 (0.13)	8.00 (0.75)		√
2.	The number and type of medical devices in situ	9.00 (0.00)	9.00 (0.00)	9.00 (0.27)		√
3.	The prevention used (e.g. type of prophylactic dressings	9.00 (0.13)	9.00 (0.13)	9.00 (0.13)		√
4.	A record of when an MD was first applied	9.00 (0.16)	9.00 (0.00)	9.00 (0.13)		√
5.	A record of the type of securement ‡		9.00 (0.13)	8.00 (0.29)		√
6.	How frequently the securement was changed ‡		9.00 (0.26)	8.00 (0.29)		√
7.	Documenting if the MD could be safely repositioned ‡		9.00 (0.13)	8.00 (0.29)		√
8.	A record of device repositioning	9.00 (0.13)	9.00 (0.00)	9.00 (0.29)		√
9.	Recording comfort associated with the medical device	7.00 (0.65)	7.00 (0.37)	6.00 (1.61)	6.00 (0.37)	
10.	Information whether the Staff were trained to use the medical device	7.00 (0.65)	7.00 (0.69)	6.00 (0.91)	6.00 (0.52)	
11.	Whether the MD is used as prescribed or 'off label.'	7.00 (0.37)	7.00 (0.49)	6.50 (0.99)		√
12.	Documenting patient communication regarding the MDRPU presence and/or development	8.00 (0.23)	8.00 (0.29)	7.00 (0.37)		√
	Theme 2: Reporting medical device-related pressure ulcer					
13.	Pressure Ulcer category †	9.00 (0.00)	9.00 (0.00)	9.00 (0.00)		√
	Theme 3: Medical device - specific reporting					
14.	The type of MD	9.00 (0.00)	9.00 (0.00)	9.00 (0.13)		√
15.	The name of the manufacturer	7.00 (0.67)	8.00 (0.59)	5.00 (1.70)	5.50 (0.52)	

	Proposed Item	Relevancy		Necessity		
#		Round 1 Panel Median (DI)	Round 2 Panel Median (DI)	Round 3 Panel Median (DI)	Round 4 Panel Median (DI)	Items included in the proposed DS
16.	The exact name/product	7.00 (0.65)	7.00 (0.75)	5.00 (0.99)	6.00 (0.52)	
17.	Recording if the device was single-use or reusable	5.00 (0.52)	5.00 (0.65)			
18.	Recording expiry date	5.00 (1.02)	5.00 (0.97)			
19.	Recording the device was sterile	5.00 (0.65)	5.00 (0.69)			
20.	Recording the batch & lot number	5.00 (1.08)	5.00 (1.04)			
21.	If the MD is still in place	8.00 (0.29)	9.00 (0.19)	8.00 (0.29)		√
22.	The type of material the MD is made of	7.00 (0.75)	7 .00 (0.75)	5.50 (1.70)	6.50 (0.52)	√
	Theme 4: Ulcer - specific reporting					
23.	The body site where the MDRPU is located	9.00 (0.00)	9.00 (0.00)	9.00 (0.00)		√
24.	Size of the MDRPU	8.00 (0.75)	9.00 (0.13)	9.00 (0.13)		√
25.	The date and time of finding the MDRPU	9.00 (0.02)	9.00 (0.00)	9.00 (0.00)		√
26.	Including photographs of the MDRPU	7.00 (0.67)	8.00 (0.59)	7.00 (0.72)		√
27.	Including photographs after the MDRPU healed	5.00 (0.65)	5.00 (0.65)			
28.	The environment (i.e. Ward OR theatre location) in which the MDRPU was first observed	9.00 (0.00)	9.00 (0.00)	8.00 (0.29)		√
29.	The short-term effect of the MDRPU on current patient care	7.00 (0.45)	8.00 (0.29)	6.50 (0.65)		√
30.	A potential longer-term consequence of the MDRPU on the patient	6.00 (0.45)	7.00 (0.65)	6.00 (1.04)	6.00 (0.52)	
	Theme 5: General patient and co – morbidity data					
31.	Patient's age	9.00 (0.54)	9.00 (0.13)	8.50 (0.29)		√

	Proposed Item	Relevancy		Necessity		
#		Round 1 Panel Median (DI)	Round 2 Panel Median (DI)	Round 3 Panel Median (DI)	Round 4 Panel Median (DI)	Items included in the proposed DS
32.	Patient's gender	5.00 (1.70)	6.00 (0.75)			
33.	Patient's weight	7.00 (0.67)	8.00 (0.29)	7.00 (0.74)		√
34.	Patient's nutritional status	8.00 (0.19)	9.00 0.19)	8.00 (0.49)		√
35.	Patient's primary diagnosis	7.00 (0.75)	8.00 (0.59)	8.00 (0.29)		√
36.	Patient's co-morbidities	7.00 (0.67)	8.00 (0.37)	7.50 (0.47)		√
37.	Pressure Ulcer Risk Assessment score	5.00 (2.26)	8.00 (0.75)	8.00 (0.49)		√
38.	Skin assessment	9.00 (0.33)	9.00 (0.00)	8.00 (0.13)		√
39.	When the patient was last repositioned	8.00 (0.75)	8.00 (0.29)	8.00 (0.49)		√
40.	Patient's skin tone*			7.00 (0.74)		See below
	Including the record of the patient's skin tone *			6.00 (0.99)	6.50 (0.22)	√
42.	Recording if the patient was proned with a medical device*			8.00 (0.29)		See below
	Recording if the patient was proned with a medical device in situ*			8.00 (0.29)		√

‡ Item added to round 2 due to feedback in round 1.
† In rounds 1 and 2, panels voted on the relevance of all categories of pressure ulcers. In round 3, the question was shortened to a general statement because the panel agreed in round 2 that all categories should be included.
*Questions added to round 3 due to feedback in round 2. Both relevance and necessity were scored in round 3.
NB. Greyed out boxes mean that the item was not considered at a round, because it was either included after feedback, excluded based on panel consensus, or included based on panel consensus.

After data analysis from the 3rd Round, seven items panel median fell into the 'uncertain' category, and out of those, there were four items where a disagreement between the experts was present (Table 5.12). A fourth-round was initiated to clarify whether those items were necessary or not for inclusion in the list of items that the MDRPU reporting tool. In the survey, participants were offered evidence from the international qualitative study (Chapter 4) and feedback from previous rounds of the consensus study to consider, along with details of the panel median and disagreement index for each of the seven items and asked to re-rate their necessity of inclusion. Scores from Round 4 are presented in the Table 5.12.

Table 5.12 Round 3 & 4 results - uncertain items

		Round 3		Round 4	
#	**Proposed item**	**Panel Median**	**Disagreement Index (DI)**	**Panel Median**	**Disagreement Index (DI)**
1.	The name of the manufacturer or distributor	5.00	1.70*	5.50	0.52
2.	The exact name/product number of the MD	5.00	0.99	6.00	0.52
3.	The type of material the MD is made of	6.00	1.70*	6.00	0.52
4.	Patient's skin tone	6.00	0.99	6.50^	0.22
5.	The comfort associated with the medical device	6.00	1.61*	6.00	0.37
6.	A potential longer-term consequence of the MDRPU on the patient	6.00	1.04*	6.00	0.52
7.	Information whether the Staff were trained to use the medical device	6.00	0.91	6.00	0.52

*Indicates disagreement
^reached inclusion threshold

Results of the final, fourth round indicated that consensus was reached on including the record of the patient's skin tone in the data set (median 6.5 and DI=0.22). Six other items were left uncertain and hence were excluded from the final list of items for reporting MDRPUs (Table 5.11 and Table 5.12).

5.13.2 Inclusion of pressure ulcer categories in reporting

In rounds 1 and 2, participants were asked to decide which pressure ulcer categories should be required to be reported using the data set under development. There was a good level of support for the inclusion all of the categories and mucosal MDRPUs. In round 3, it was confirmed that this represented a necessary data entry and should be included in the proposed data set (Appendix G).

5.13.3 Prevalence data collection using the proposed data set

In addition to using the proposed data set for reporting incidents of MDRPUs, the panel was asked to consider an opportunity to use the data set for a standardised prevalence data collection. In rounds 1 and 2, experts were asked whether they would support using the data set for this purpose and where (on what level) data should be collected. The vast majority supported utilising

this data set for collecting prevalence data (Round 2 – 86%, Table 5.13), and on all three levels of reporting: unit/ department, hospital, and national level (Table 5.14).

Table 5.13 The use of the proposed data set for MDRPU prevalence data collection - panel responses.

	Round 1		**Round 2**	
	Yes [%]	**No [%]**	**Yes [%]**	**No [%]**
The proposed DS' purpose is to collect incident data, would you consider using it to collect regular MDRPU prevalence data as well?	63 [84]	12 [16]	56 [86]	9 [14]

Table 5.14 Overall panel scores regarding the support for the use of the proposed data set for the prevalence data collection of three levels of reporting (unit, hospital, national).

Question	**Round 1**		**Round 2**	
Do you support reporting prevalence (using the proposed DS) on a:	**Panel Median**	**DI (>1 = no agreement)**	**Panel Median**	**DI (>1 = no agreement)**
▪ Unit/department level	9.00	0.00	9	0.00
▪ Hospital level	9.00	0.00	9	0.00
▪ National level	9.00	0.13	9	0.00

Experts were of the opinion that unit-level data should be collected monthly (50% respondents), on hospital-level prevalence data should also be collected monthly, and nationally this should be collected yearly, see Table 5.15 for details.

Table 5.15 Overall panel scores regarding the preferred frequency of prevalence data collection using the proposed data set.

Questionnaire item	**Frequency**	**Round 1 -** Count [%]	**Round 2-** Count [%]
What would be the ideal frequency of reporting MDRPU prevalence on unit/department level?	every week	16 [25]	15 [27]
	every 2 weeks	1 [2]	0 [0]
	monthly	**27 [43]**	**28 [50]**
	quarterly	8 [13]	6 [11]
	every 6 months	3 [5]	3 [5]
	yearly	3 [5]	2[4]
	other	5 [8]	2 [4]
	every week	5 [8]	1 [2]

Questionnaire item	Frequency	Round 1 - Count [%]	Round 2- Count [%]
What would be the ideal frequency of reporting MDRPU prevalence on hospital/organisation level?	every 2 weeks	1 [2]	1 [2]
	monthly	**25 [40]**	**29 [52]**
	quarterly	22 [35]	19 [34]
	every 6 months	2 [3]	1 [2]
	yearly	5 [8]	3 [5]
	other	3 [5]	1 [2]
What would be the ideal frequency of reporting MDRPU prevalence on national level?	every week	0 [0]	1 [2]
	every 2 weeks	0 [0]	0 [0]
	monthly	7 [11]	3 [5]
	quarterly	12 [19]	15 [27]
	every 6 months	7 [11]	10 [18]
	yearly	**31 [49]**	**25 [45]**
	Other	6 [10]	2 [4]

5.13.4 Qualitative data

New items proposed by participants were tabulated with supporting evidence, and consideration has been given to the frequency with which the same suggestion appeared in the data. As a result of this analysis, three items were added to the round 2 questionnaires and two items were added to the round 3 questionnaires (Table 5.16).

Table 5.16 New items suggested in Rounds 1 and 2 of the consensus study

#	Proposed item	Round	Number of comments	Quote(s)
1.	What type of securement has been used	1	2	▪ *"Securement - type of securement (tape, dressing, plaster etc), frequency of change of device securement." (P15)* ▪ *"Most importantly to intubation would be how it is secured and when the tube is moved. Securement devices should be noted in the record and they become another MD." (P92)*
2.	How frequent was the securement changed	1	1	As above

#	Proposed item	Round	Number of comments	Quote(s)
3.	Could the MD be repositioned safely	1	1	▪ *"It might be useful to have something about whether it in fact could be repositioned or pressure relieving devices beneath it be used as many occur in these situations, but staff cannot prevent them occurring despite trying repositioning/monitoring etc." (P87)*
4.	Patient skin tone (or ethnicity)	2	2	▪ *"Note no mention of skin tone – given challenges in darker skin tone, should this not be included?" (P8)* ▪ *"Does there need to be a question related to the skin tone of the patient? It may be possible that we miss earlier pressure damage on patients with darker skin tones". (P23)*
5.	Patient proned with MD in situ	2	2	▪ *"(N)ow that COVID is part of our care - and proning injuries are now becoming more frequent - do we include an item about whether or not this patient was proned with the MDRPU in place?" (P75)* ▪ *"Just remember that rules change when dealing with covid-19 especially with regards to devices in place and patients in prone position. Double vigilance is needed on both device management and risk assessment". (P5)*

Experts had the opportunity to add any general comments regarding the data set or its use. The dominant theme of the feedback revolved around the feasibility of collecting the data. The concern expressed by several experts was to develop a reporting tool that is short and easy to complete.

"A minimum data set is important to be clear and concise to ensure staff will use it." (P40)

and

"*I think the minimum data set for reporting should be a sleek list (…)*" (P7)

It was emphasised that the nursing staff work under time pressure and asking them to complete a lengthy report may lead to a lack of compliance.

'*We have to be really careful about setting nurses up to fail*.' (P14)

and

'*There is a danger that if too much data is included that staff will find it too complicated and will not fill it in.*' (P86),

where access to some data may be restricted due to the quality of the patient record.

'*I find documentation where I work is appalling in terms of comprehensive skin assessments, particularly under MD [medical device] and in relation to offloading of areas and repositioning patients. I'm currently trying to change this but feel there needs to be a cultural shift* (…).' (P72)

and lack of easily accessible data in relation to, e.g. medical device data, may lead to missing data.

'*The challenge with the above [recording medical device data], is this is a lot of information that the staff may not have to hand* '. (P17)

and

'*Recording of medical device [data] can be very time consuming, to make it a routine recording may not be feasible'* (P55)

5.14 Discussion

This consensus study was a first in-kind undertaken in the area on medical device-related pressure ulcers and involved a large international community of experts. A panel of experts, representing 23 countries agreed for 30 items across 5 Themes to be included in the reporting tool, in readiness for the future evaluation of a standardised tool for practice.

The RAND UCLA structured consensus process was adapted for this study which enabled consideration of evidence gathered through a narrative literature review and international interview study, as described in previous chapters. It allowed for a data set for a draft MDRPU reporting tool to be agreed and underpin its content validity. Experts also supported the use of the agreed data set for prevalence studies and supported its use on different levels for reporting (unit, hospital, and national) which presents an opportunity for standardised reporting, meaningful comparisons, and evidence-driven medical device improvements.

The consensus study was underpinned by the evidence from a narrative literature review (Chapter 2) as well as the evidence from the international interview study (Chapter 4), where clinicians described and discussed reporting practices in their healthcare systems. Experts in this study, were able to privately review the evidence and make their judgements related to the proposed data set items without peer pressure. Consensus definition determined a priori and based on the RAND/ UCLA Appropriateness Method [RAM] (Fitch et al., 2001) set out clear rules on what level of support was required in order for an item to be included in the proposed data set for reporting MDRPUs and contributed towards methodological strength of this study. This approach worked well and enabled the expert panel to reach an agreement on the most relevant

and necessary to be included in the proposed data set for reporting MDRPUs. However, despite the final two rounds aiming to limit the number of items to be included in the data set, through necessity rating, this did not yield anticipated results.

There were, however, items which did not reach the required threshold for the inclusion in the proposed data set but may still be considered as relevant for reporting MDRPUs, e.g. the name of the medical device manufacturer (Gefen et al., 2022). The qualitative comments signal, that this exclusion might be based on feasibility of collection of those data by the nurse reporter. Many comments received in rounds 1 and 2 were concerned with the volume of data that would be included in the reporting. Indeed, nurses' primary concern is patient care, and it is well documented in literature that pressures (including administrative burden) lead to patient care being missed, which in turn has negative impact on staffs wellbeing and job satisfaction (Senek et al., 2020, Ball et al., 2014, Harvey et al., 2020). The feedback highlighted the fact that nurses are extremely busy with clinical work, thus any reporting needs to be fit for purpose, with clear objectives, and any form that may be designed, should be easy and quick to complete. Gathering information on medical device, such as e.g. name of manufacturer and device make and model, was suggested to be difficult for a nurse to undertake. It is, however, important to consider, that without standardised collection of data relating to the devices (i.e. the device manufacturer and the name/ product number) it is impossible to know which devices would benefit from change in their design or materials used to manufacture them (Gefen et al., 2022). Routine collection of those data would enable coordinated work with medical devices regulatory bodies, such as MHRA in UK.

The study design did not include face-to-face interaction at any stage of the consensus process. The classical Delphi starts with exploration of the panel's opinions on the issue under investigation and based on that a survey is constructed (Jones and Hunter, 1995). To mitigate this potential design limitation, the possibility of adding suggestions and comments in the first two rounds of the voting cycle was added. This was a successful addition and experts engaged with it. As a result, five additional items were added and subsequently included in the agreed data set. These included patient's skin tone, whether the patient was proned with the device in situ, securement and its change frequency, and record of repositioning of the device. It has been recognised that skin tone variance may affect timely recognition (EPUAP NPIAP & PPPIA., 2019). Patients with dark skin tones rarely show a non-blanchable erythema (category 1 PU), instead presenting either increased or reduced pigmentation in the areas of skin irritation (Grimes, 2009). Clinicians have to be aware of the skin tone to provide individualised care and avoid healthcare inequality between patients (Gee and Ford, 2011). It is worth noting, that even though in medical device research the focus here is on ethnicity, it has been acknowledged that ethnicity cannot be

used as proxy for skin tone (Everett et al., 2012, McCreath et al., 2016). Including the 'skin tone' item in the reporting data set and form, may lead to improved awareness of MDRPUs in different ethnic groups, as well as robust data on devices which could benefit from improvement in design.

Furthermore, association between incidents of MDRPUs and devices are relevant for enquiry in the light of research on facemasks, respiratory protective equipment, and the Black, Asian, and minority ethnic persons. Literature suggests there are significant differences in anthropometrics between ethnicities (Manganyi et al., 2017, Brazile et al., 1998, Zhuang et al., 2010). However, the device designs are based on predominantly white, Caucasian male face measurements (Institute of Medicine (IOM), 2007).

This consensus study was undertaken at a time, when the Covid-19 pandemic was spreading around the globe posing new challenges for the nursing staff, who had to treat large numbers of patients with acute respiratory distress syndrome (ARDS). ARDS requires invasive mechanical ventilation and prone position is used to manage lung injury and help with oxygenation (Barakat-Johnson et al., 2020, Chua et al., 2021). It was suggested that with a raising number of MDRPUs relating to placing patients in prone position, a record whether a MDRPU development was related to proning should be reflected in the data set. Patients remain in the prone position in intensive/ critical care units for prolonged periods of time and have many life-supporting devices. A recent study found that patients with pressure ulcers showed correlation between days of mechanical ventilation and time spent in prone position (ρ=0.47, P=0.042) ,prevalence of patients with pressure ulcer related to proning was approximately 30% (CI=18.8-41.5) and that most affected body site was the face (59%, 32/54) (Binda et al., 2021). Therefore it is important to raise awareness of the medical device care, appropriate prevention, and skin care of those patients (Barakat-Johnson et al., 2020).

The final two items included into the rating cycle, which subsequently reached the level of support required for inclusion in the data set related to data about securement and repositioning of the device. Repositioning of the device is a recognised and advised strategy for the prevention of MDRPU development (EPUAP NPIAP & PPPIA., 2019). There is also evidence that securement devices may lead to MDRPU development (Worsley et al., 2016). Experts consequently agreed that data relating to those items should be explicitly reported.

As discussed previously (see Section 5.11), it is challenging to determine validity at the time of undertaking the study. To ensure we addressed this problem, the methodology and conduct of the study was as rigorous as possible. To ensure validity and reliability of the results, a large panel from a geographically large area was established to take part in the consensus process. The inclusion of different backgrounds, a range of experiences, and the most up-to-date evidence

ensured all opinions and point of views were included and therefore the results are as reliable as possible and the validity is increased.

However, the lack of an in-person meeting, where the areas of uncertainty or lack of agreement could have been explored in an open discussion (Coleman et al., 2014a) is a methodological limitation of this study. This is important especially in relation to medical device items details such as the name of the manufacturer, the exact name or number of the device, and record of the device material. In-person meeting may have facilitated discussion and debate increasing the opportunity for resolving those areas of uncertainty and disagreement. Those data are necessary to be able to investigate which devices should benefit from improved design or change in the materials used for their production. It is possible that, despite the researcher's effort, these arguments were not put clearly enough. Equally, face-to-face interaction would allow for the reasoning against including those data items in the reporting data set, to be put forward and the reasons for that, understood.

Another limitation of this study was being reliant on participants having internet access, which may have led to the study not being accessible to potential participants from less wealthy countries where internet access is not universal. In addition, involving participants with significant knowledge and experience, who are also members of leading international skin and wound care organisations, may have led to selection bias and questions whether the results are truly representative of the opinions of other experts and clinicians. To minimise those issues, further studies exploring which data should be collected at minimum, and which could be non-mandatory should be undertaken in the future with a range of clinicians involved in PU and MDRPU reporting. Furthermore, assessments should be undertaken beyond the UK to assess feasibility of the agreed data set.

The interest from the members of wound and tissue viability organisations proved to be very high. As a result, 95 participants were sent the initial invitation, evidence on reporting, and first cycle questionnaire. Although through the rounds a number of participants reduced due to dropout, overall the study retained a relatively large panel incorporating a range of clinical, academic and industrial participants. Dealing with such large group of participants, good organisation and record keeping were necessary. Participants had to be tracked and individual contact had to be made to ensure questionnaires were returned. The study went through two periods of time where the workloads had to be more appreciated than at any other time. First, it was the time of Christmas holidays, when even though not all participants would have had celebrated, many would take vacation. Second, the COVID-19 pandemic was declared, and clinicians were required to re-evaluate their priorities. This was particularly difficult from the point of view of undertaking

this study and may be why the number of participants dropped in round 3, since the majority of participants were active clinicians in the acute care sector. Nonetheless, the number of experts who remained in the study was high and the panel reached consensus on the content of the data set for MDRPU reporting. The fact that this study continued and was not overly delayed can be viewed as an evidence to how important the issue of reporting MDRPUs is to those who are active in the field of skin and wound care.

Although the consensus study resulted in a list of items relevant and necessary for inclusion in MDRPU reporting, further development work was required to design a reporting form and improve its usability and pre-testing with clinical nurses to assess acceptability and clarity of the form (Chapter 6). Indeed, while this method was suitable to establish the content of the proposed data set for reporting MDRPUs, wording of questions or statements within the reporting form could not be considered. Moreover, we need to explore whether collecting data on medical device-related pressure ulcers and medical devices will be as burdensome and difficult as some of the experts indicated. Further feasibility testing was also required to assess the form and its use in clinical practice (Chapter 7).

5.15 Conclusions

In this study was first of its kind international consensus on MDRPU reporting and agreed a data set of 30 items which will underpin a novel MDRPU reporting form for use in clinical practice. This study used a modified Delphi technique drawing on the RAND/UCLA appropriateness method, incorporating most recent academic and grey literature, alongside the evidence from a qualitative study exploring reporting practices in eleven countries worldwide. Further development of a reporting form underpinned by this data set is reported in the chapters that follow.

Chapter 6 Pre-testing of a medical device-related pressure ulcer reporting form

6.1 Introduction

This chapter will critically examine further development of an MDRPU reporting form, underpinned by the list of items agreed through an international consensus study presented in Chapter 5. It will demonstrate how the reporting form was assessed by clinical nurses and improved in a pre-test study prior to a feasibility evaluation in two hospital trusts (Chapter 7).

6.2 Design of the MDRPU reporting form incorporating the Data Set

The initial design of the reporting form incorporated all thirty items that reached consensus in the Delphi study (Chapter 5). In addition, the researcher decided to include three more items which related directly to medical devices' information. The narrative feedback from the consensus study participants relating to those further 3 items, namely the name or product number, name of manufacturer or distributor, and material the device was made out of, indicated that uncertainty about these items was based on the perceived difficulty of collecting those data and not their irrelevancy to MDRPU reporting. The consensus process that was followed did not incorporate a face-to-face meeting where areas of uncertainty could have been discussed and resolved. Since collecting those data is necessary to gain oversight of the devices that are repeatedly included in patient harm, are not fit for purpose, and hence would benefit from design update, the researcher decided to test the feasibility of collecting these data in a future pilot study and confirm whether data could be gathered during routine reporting.

The design of the form followed the survey format from the consensus study (Chapter 5). The data items were grouped thematically for ease of completion. The themes of the form included:

1) patient,
2) medical device-related pressure ulcer,
3) device-related care,
4) device data.

The items agreed through the consensus process were transformed into form items. The language and construction of the items were based on the reporting tools, which were examined as a part of the literature review (Chapter 2, section 2.4.2). The drafted reporting form was then pre-tested with specialist nurses.

6.3 Pre-test study aims

Aim

To assess and improve the usability and acceptability of the Medical Device – Related Pressure Ulcer Reporting Form with its intended end-users (critical care and tissue viability nurses) using cognitive pre-testing methods.

Objectives

- To gather feedback from critical care and tissue viability nurses following them using the reporting form with vignette case studies.
- To confirm the content validity of the reporting form items based on completion of the MDRPU reporting forms using vignette case studies.
- To assess and improve the design, clarity, comprehension, and completion of the MDRPU reporting form.

6.4 Overview of Methods

Cognitive pre-testing methods are considered essential for establishing and improving clarity, understanding, and confirming the content validity (Boeije and Willis, 2013). This methodology is well-established in the development of health status and patient reported outcome measures (Boeije and Willis, 2013, Coleman et al., 2016a). This study has drawn upon this methodology in the absence of formal methodologies for developing forms, which allowed for a systematic and evidence-based development of the draft reporting form. Drawing on this methodology was considered important, since it enhances precision, allows conformation of content validity, as well as that the proposed MDRPU reporting form was understood by the target population and fit to be tested in clinical practice (Lohr, 2002, U.S. FDA., 2009).

Cognitive pre-testing methods were used to explore the clarity and design of the reporting MDRPU form (Figure 6.1). The reporting form was pre-tested in two iterative cycles. First, think-aloud interviews were used to assess and improve quality, clarity, comprehension, completeness, and language for the items agreed through the consensus study. This method asks the participant to vocalise all and any thoughts they have whilst completing the form based on a simulated patient case (Ericsson and Fox, 2011). Second, focus groups were undertaken to determine the acceptability and feasibility of future use in clinical practice. After each pre-test cycle, data were analysed, results reviewed, and necessary amendments were made to the reporting form (e.g. layout, flow, language, and/or vocabulary).

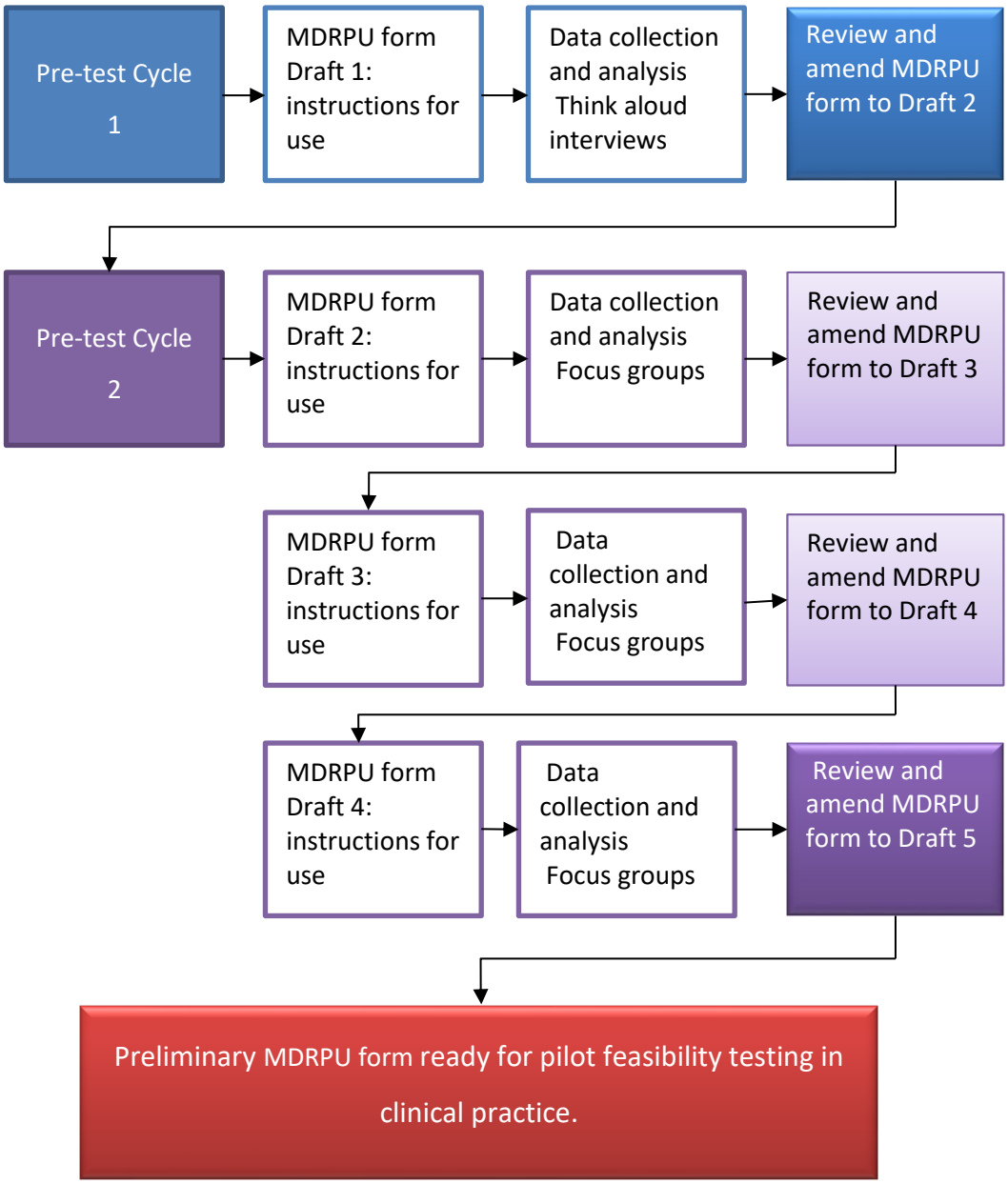


Figure 6.1 Pre-test cycles based on Coleman et al. (2016a)

6.4.1 Cognitive interviews

Individual cognitive interviews, where the participants were encouraged to 'think aloud' whilst simultaneously completing the task (Ericsson and Simon, 1980, Ericsson and Fox, 2011), were used to identify any issues with form flow, vocabulary, and comprehension and to elicit areas for improvements. They are an active pretesting method where the researcher probes the participant about how they answer the questions (Willis, 2005). As an example, when a participant was silent during the task, the researcher asked what they were thinking about, what were they considering, and reminded them that all their thoughts are important. After the task finished, the researcher

followed up with questions relating to comprehension, flow, any items that might have been redundant or missing, whether the language mirrored practice, and invited any other comments about the form and its completion. All interviews were undertaken remotely, using MS Teams (Microsoft Office 365 v. 1.1.1), and took approximately 1 hour.

6.4.2 Focus groups

A focus group is a planned discussion focused around an issue and guided through a designed set of questions (Krueger and Casey, 2015). This method is valuable for gathering data in design phases and evaluation (Krueger and Casey, 2015). The use of focus groups in this study was expected to lead to a better understanding of the reporting form usability issues, with participants engaging in an open discussion and following up on each-other's ideas to evoke a rich debate about the reporting form. Focus groups work best when the group is homogenous as participants feel able to speak more openly and interact with other group members (Krueger and Casey, 2000), which leads to clarification of views (Kitzinger, 1995). Therefore, an effort has been made to arrange each focus group with clinicians of similar background.

Focus groups were conducted remotely, using MS Teams (Microsoft Office 365 v. 1.1.1), and took approximately 1 hour. At the beginning of each of the focus groups (and after recording consent), a randomly assigned vignette was shared via screen-share on MS Teams. Participants were sent the draft MDRPU reporting form prior to the meeting with request not to open it beforehand. Then 15 minutes were given to the participants to complete the form based on the vignette case study and note any areas that were problematic from their point of view.

6.4.3 Vignettes

Vignettes are a research tool in the form of a fictional scenario. Their purpose is to be an aid for the participant to respond to the task they have been invited to. A vignette requires enough detail for the participant to imagine the situation and thus collect enough data on group norms, beliefs, and values. Additionally, vignettes can be used for pragmatic and ethical reasons (Quigley et al., 2020) which were relevant due to a lack of access to patients with MDRPUs, especially during the Covid-19 pandemic, potential delays in patient care review, and the limited pool of potential participants locally.

This study used three vignettes to elicit feedback on the novel MDRPU reporting form (Appendix H). Two were based on literature and published case studies (Hughes and Huby, 2004) and reviewed by experts in the pressure ulcer field, with changes made (where appropriate) to ensure anonymity, clarity, and enough possible detail, and to de-identify the medical device. One

vignette was designed directly by an expert in the neonatal tissue viability field. All vignettes were approximately half-a page long and accompanied by a photograph of the MDRPU and the medical device described in the vignette.

6.4.4 Participants

The researcher used a convenience sampling strategy to recruit nurses who were members of an NHS Improvement pressure ulcers taskforce. This group consisted of tissue viability nurses, critical care nurses, and nurses interested in preventing MDRPUs. Participants were nurses who, in their daily practice, were involved in the investigation and reporting of MDPRU (Table 6.1).

The literature suggests a sample of 5-15 participants should be recruited to participate in one-to-one cognitive interviews (Willis, 2005). However, it is also proposed that the number of participants should depend on the complexity of the evaluated tool and its items, as well as on the ongoing analysis of the cognitive interviews (Miller et al., 2014). Consequently, the researcher did not pre-plan the number of cognitive interview participants, but it was data saturation that guided the data collection (Legard et al., 2003).

The ideal size of focus group is between five and eight participants (Krueger and Casey, 2015); hence the aim was to recruit a minimum 5 participants in the second cycle. However, due to organisational issues (such as workload of TVNs, other commitments, or issues created by the COVID-19 restrictions), smaller groups i.e. triads were arranged for. Similarly to cognitive interviews, the number of focus groups were guided by data saturation (Legard et al., 2003), i.e. the assumption was that the focus group which did not add anything new to the analysis would be considered the final one.

Participants were randomly allocated either to the cognitive interview or the focus group (https://www.random.org/ was used for this purpose). Those who participated in cognitive interviews (cycle 1) did not participate in a focus group (cycle 2). This decision was made at the point of design of the study and aimed to ensure the participants in focus group were 'untainted' by previous version of the MDRPU reporting form and hence could give initial impressions of the form. This approach also minimised research burden on participants, who were active clinicians and gave up their time to participate in the study. Although assignment to cognitive interview or focus group was made at random, when arranging the focus groups, the researcher made an effort for those groups to be as homogenous as possible, to support open disclosure (Krueger and Casey, 2000).

6.5 Ethics

This study recruited tissue viability specialist nurses and critical care nurses, and the ethical issues related mainly to establishing a convenient time to arrange an interview or a focus group. No risks to participants were anticipated. The study was approved by the University of Southampton (ERGO 2 60764, Appendix I), which provided sponsorship for the study. Potential participants were given a participant information sheet and invited to ask any questions they may have had. Written consent was collected before data collection, and participants were free to withdraw from the study without giving their reasons at any point.

6.6 Data collection

Due to participant geographical spread and the COVID-19 pandemic, the one-to-one cognitive interviews and focus groups were undertaken online, using MS Teams (Microsoft Office 365 v. 1.1.1). The researcher shared both parts of the vignette (description and photograph) through screen sharing.

Participants were randomly assigned one of three vignettes (using a https://www.random.org/ to generate the vignette number) to work with the MDRPU reporting form during both data collection rounds (cognitive interviews and focus groups). Prior to data collection, the participants were emailed the vignette and the MDRPU reporting form (Figure 6.2 and 6.3), although they were asked not to open the files until the meeting, so that their first impressions could also be vocalised to the researcher.

The researcher provided a short demonstration of completing the MDRPU reporting form using the vignette at the beginning of the interviews and focus groups, before participants were invited to fill in their forms.

6.6.1 Cognitive interviews (cycle 1)

Before the data collection started, the think aloud technique was described to the participant. After the participant confirmed they understood the approach, they were asked to complete the reporting form using a vignette.

Participants needed approximately 15 minutes to complete the reporting form before commencing the cognitive interview. The researcher used the probing technique a posteriori (i.e. after the task was completed) meaning that the participant was not interrupted during the task

and maintained their thoughts' flow. However, when the participant was less vocal, the interviewer asked probing questions concurrently (Appendix J).

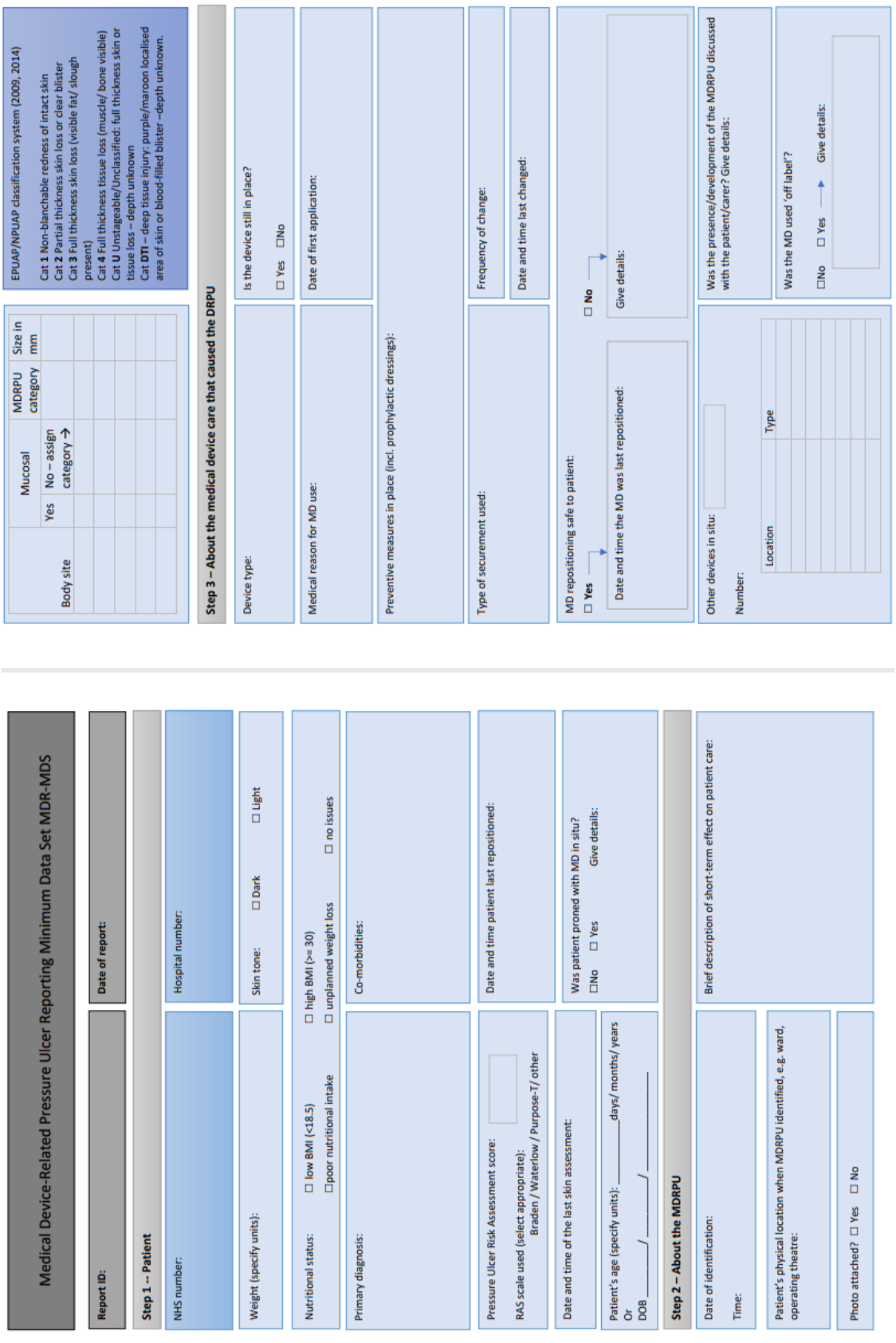


Figure 6.2 MDRPU reporting form before cognitive interviews (cycle 1 of the cognitive pre-testing) – pages 1 and 2

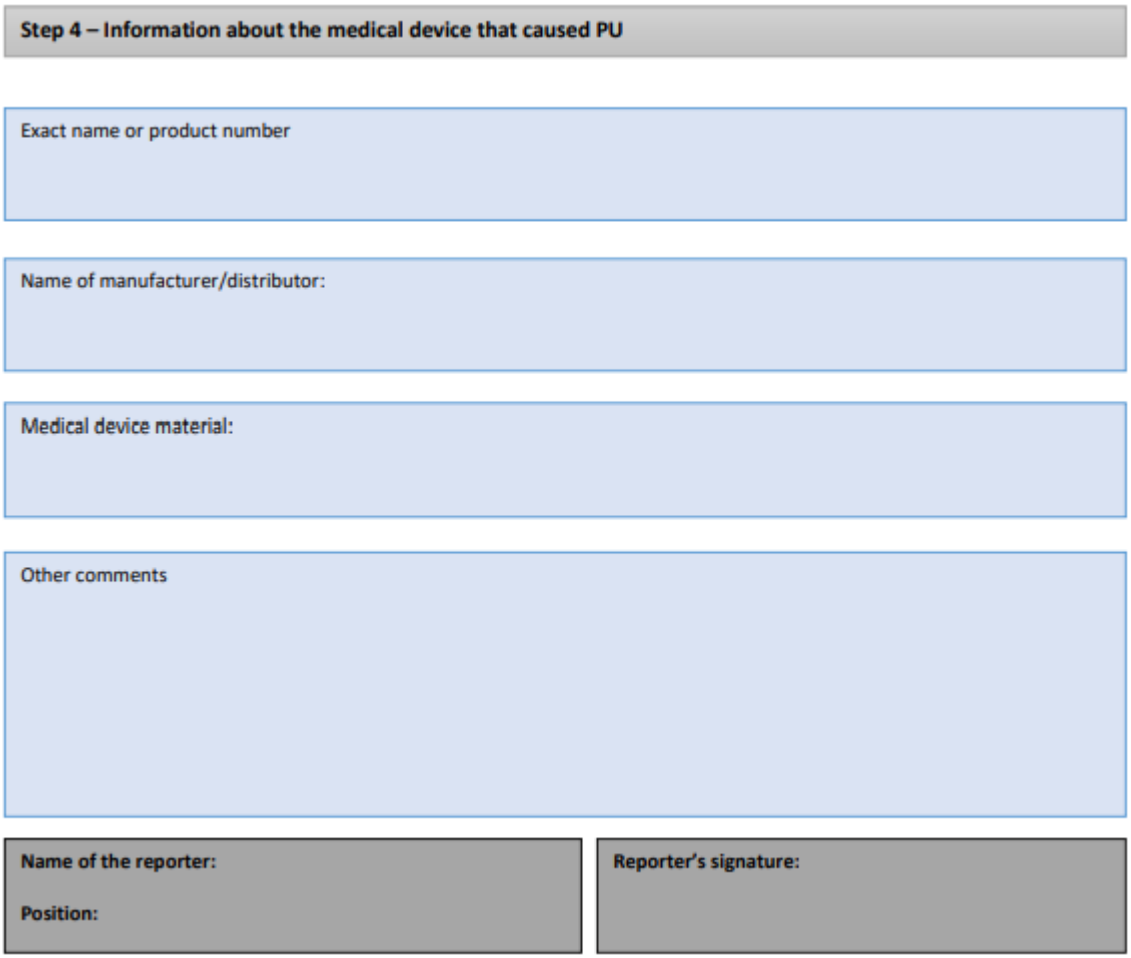


Figure 6.3 MDRPU reporting form before cognitive interviews (cycle 1 of the cognitive pre-testing) - page 3.

6.6.2 Focus groups (cycle 2)

Similar to the cognitive interviews, the participants used approximately 15 minutes to complete the reporting form before commencing the focus group discussion. Participants of the focus groups were also asked to note any areas they found unclear. The topic guide (Appendix K) based on the form items and feedback from cognitive interviews, was then used to focus the discussion. In this cycle, the acceptability and feasibility of future use of the reporting form were explored.

6.7 Data analysis

The researcher audio-recorded cognitive interviews and focus groups and transcribed verbatim. After the researcher confirmed the accuracy of the transcription (through re-listening to the recording and comparing it with the transcript), recordings were deleted. Anonymised transcripts were then coded by the researcher. Coding was directed by the MDRPU form items, following the directed content analysis methodology (Hsieh and Shannon, 2005). The NVIVO (version 12 Pro)

package was used to support the analysis. The focus was to identify commonalities across the cognitive interviews and focus groups which could have impact on the use of the proposed form in clinical practice. Adjustment were made after the cognitive interviews (cycle 1), then pre-tested during focus groups (cycle 2). Completeness of the MDRPU reporting forms was not investigated in this study, however it was explored in the subsequent feasibility study (Chapter 7).

6.8 Results

Cognitive interviews and focus groups were undertaken between April and June 2021. Twelve clinicians participated, with four one-to-one interviews and three focus groups. Two first focus groups comprised of 3 participants, the last focus group was planned to also be a triad, however one of the participants was ultimately unable to join in. Demographic data of participants and their allocation to cognitive interviews or focus groups are presented in Table 6.1.

Table 6.1 Demographic data

Data collection method	**Gender**	**Role**	**Sector**
Interview 1	F	senior sister CCU	acute
Interview 2	F	TVN	acute
Interview 3	F	TVN consultant	acute
Interview 4	F	senior clinical advisor	NHS
Focus Group 1	F	Tissue Viability CNS	acute
	F	lead ANP Tissue Viability	acute
	F	deputy sister	acute
Focus Group 2	M	consultant nurse Critical Care	acute
	F	matron	acute
	F	consultant nurse	acute
Focus Group 3	F	TVN	acute
	F	TVN lead	acute

CCU – critical care unit, TVN – tissue viability nurse, CNS – clinical nurse specialist, ANP – Advanced Nurse Practitioner.

The changes made in response to the feedback received during cognitive interviews and focus groups related to the wording of specific items, document flow, understanding, and timely completion of the forms are shown in Table 6.2. The modifications made led to combining all medical device information under one section and developing such items as device type,

prevention, and securement type to include a list of possible items for the clinician to choose from. Summary of changes the reporting form went under are presented in Table 6.2 below, details can be found in Appendix L.

Table 6.2 Changes to the MDRPU reporting form following each pre-testing cycle

	Changes made based on feedback
Cycle 1 – cognitive interviews	Items removed: ▪ Deleted item relating to recording the type and number of other devices in situ – time consuming and most likely irrelevant to the report. ▪ Removed item asking the reporter to indicate what the MD's material, as this would be speculative. Changes impacting clarity and ease of use: ▪ Added a pre-defined (check) list of preventive measures to help with completion. ▪ Added a pre-defined (check) list of potential securement options. ▪ Added a 'non applicable' option to the 'securement' item as some devices do not require securement (e.g., anti-embolic stockings). ▪ The 'off label device use' item raised questions about what 'off label' means, hence an aide memoir was added with definition. ▪ Item relating to communicating with patient / carer regarding MDRPU was developed to include details with whom and what was discussed, and if details were not discussed – to give rationale why not. ▪ Split the item asking for the MDRPU photograph to include photograph of the device. ▪ Added classification of skin status to the recording of date and time of the assessment, since recording only those data does not give enough insights as to the MDRPU development ▪ Added the Fitzpatrick's scale to the skin tone item to assess with assessment ▪ Item recording safe repositioning of the MD – changed 'give details' to 'clinical rationale' to clarify what details should be noted ▪ Changed the item recording 'MD name **or** product number' to **and/or** as both details should be ideally reported, if possible, but at least one is necessary ▪ Changed wording in MDRPU characteristics: 'body site' to 'anatomical location' and changed the dimensions from millimetres to centimetres as per usual practice and language used in practice ▪ Defined 'short term effects on patient care' as to reflect what changes might have to be implemented by adding 'planned [patient care]'
Cycle 2 – Focus groups	Items removed: ▪ MD 'off label use' removed. This item was considered confusing, unfamiliar to nurses, and staff would not use device against its prescription. ▪ Short term effect on planned care was removed as it deemed speculative Changes impacting clarity and ease of use: ▪ Added 'rotated' to the item asking whether the device could have been safely repositioned ▪ Device type item was developed to include a list of most commonly used devices and ordered alphabetically

	Changes made based on feedback
	▪ In the item asking whether the device is still in place, a further question was added to indicate whether the device is required for the patient and thus initiate review of the care plan ▪ Patient weight – added units to ease completion ▪ Patient's comorbidities item was modified to indicate inclusion of medical conditions that are relevant for MDRPU development ▪ Pressure ulcer risk assessment score was simplified to only indicate whether the patient was or was not at risk ▪ Skin assessment (date and time) item was clarified by adding wording 'under the device' ▪ Device type item was further clarified by change to 'type of device that caused MDRPU' ▪ Moved BMI item to the patient weight section, since they relate ▪ Nutritional status item was further refined by changing 'poor' to 'insufficient' nutritional intake – wording is less open to interpretation ▪ Skin tone item was improved by dividing into two categories (light and dark – which is reflective of the language used in the literature) and guiding attribution of the colour by indicating which skin tones would fall into those categories using the Fitzpatrick's scale.

All participants in cognitive interviews highlighted recording patients' skin tone as problematic. The reasoning given was concerning the subjectivity of such assessment. The need for a reference was expressed. When a simple scale was added to the item, i.e. The Fitzpatrick Scale (Orazio et al., 2013, ARPANSA, n.d), no issues with completing this item were raised during subsequent focus groups. Instead, the feedback was positive because the included scale was straightforward to use and assess the skin tone.

Furthermore, four items were removed from the form based on the results of the pre-testing study: 'other devices in situ', 'MD material' (after cognitive interviews), and 'short-term effects on patient care, and 'off-license' use of the medical device (after focus groups).

Clinicians emphasised that listing all devices and their anatomical locations (item 'other devices in situ) would not be possible, especially in intensive or clinical care settings. It was stressed that the completion of this item would be very time-consuming. Although knowing what other devices the patient is supplied with may be relevant for the prevention of further MDRPU development, it is not appropriate for incident reporting. It is more suitable for an investigation or root cause analysis.

The item focusing on recording short-time effects of the MDRPU on patient care was found to be confusing. The feedback highlighted lack of clarity how to define 'short-term'. Moreover, there was a discussion about what elements of 'patient care' would need to be captured and whether it

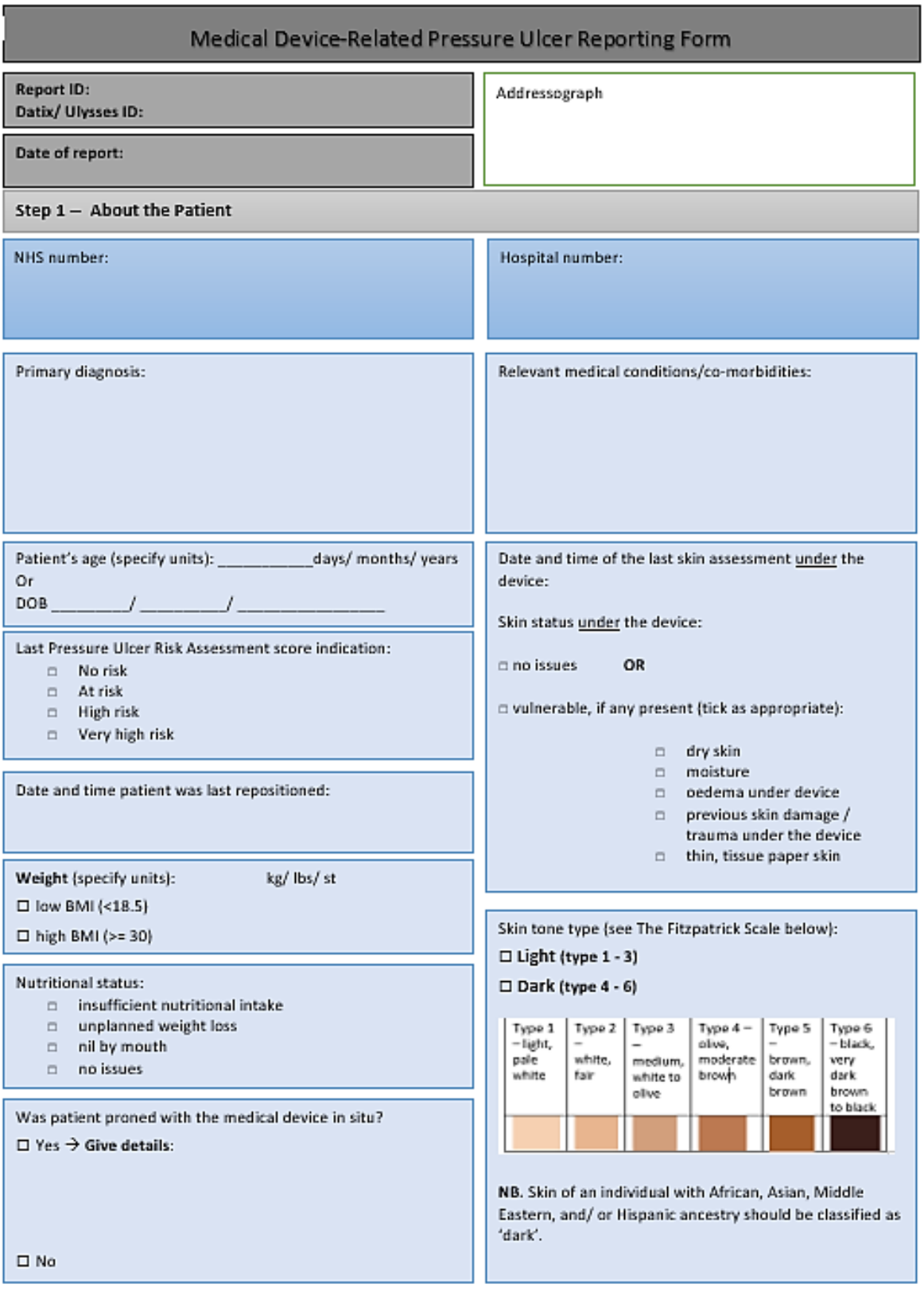
means ‘current’ or ‘planned’ patient care. Despite attempts to clarify this item it was found to be subjective, and at risk of not being completed by the reporter.

During the pre-testing, it became clear that asking a clinician about what material the medical device was made of was not feasible. It is difficult to ascertain this characteristic without referring to the device leaflet or packaging. The staff completing the report most likely would not have access to the packaging or be the ones who applied the device in the first place and were able to examine the packaging.

Participants in the first cycle of the pre-test reported that clinical staff might not understand what off-license use of the medical device is and that it may be challenging to ascertain whether it was the case. As a response, a definition of off-license use was provided. However, in the second cycle of pre-testing, participants felt that the ‘off-license use’ item should not be a part of the reporting form because clinical staff would not have enough knowledge to record this correctly. The use of ‘off-license’ is always agreed upon by medical staff (e.g. consultant). Hence, the inclusion may pose an undue burden on reporters and should be considered part of the investigation rather than routine reporting.

Overall, the form was considered to have a good flow and to be of logical order before any changes were made. The changes made based on the cognitive pre-testing improved clarity of questions, items usability in terms of completion (tick boxes), as well as removed items which were perceived to be irrelevant for routine reporting, subjective, or overly burdensome without clear benefit to the report itself. In the final attempt to order the form after the pre-testing, the researcher merged Step 4 – ‘Detailed information about the medical device’ with Step 3 – ‘About the medical device that caused the pressure ulcer’, since having the vital details about the device felt more logical (the initial division followed the structure of the consensus study questionnaire). It was also ensured that the items maintained a logical flow.

There were no significant changes impacting directly on the length of the reporting form. The figures below illustrate the initial draft (Figure 6.2 and 6.3) which was tested during cognitive interviews (cycle 1 of pre-testing) and the final draft form (Figure 6.4 – page 1, Figure 6.5 – page 2, Figure 6.6 – page 3), which incorporates all the changes made during the pre-testing and will be consequently piloted in clinical practice.



Medical Device-Related Pressure Ulcer Reporting Form

Report ID:
Datix/ Ulysses ID:

Date of report:

Addressograph

Step 1 – About the Patient

NHS number:

Hospital number:

Primary diagnosis:

Relevant medical conditions/co-morbidities:

Patient's age (specify units): _____days/ months/ years
Or
DOB _____/ _____/ _____

Last Pressure Ulcer Risk Assessment score indication:
- ☐ No risk
- ☐ At risk
- ☐ High risk
- ☐ Very high risk

Date and time patient was last repositioned:

Weight (specify units): kg/ lbs/ st
☐ low BMI (<18.5)
☐ high BMI (>= 30)

Nutritional status:
- ☐ insufficient nutritional intake
- ☐ unplanned weight loss
- ☐ nil by mouth
- ☐ no issues

Was patient proned with the medical device in situ?
☐ Yes → **Give details**:

☐ No

Date and time of the last skin assessment under the device:

Skin status under the device:

☐ no issues **OR**

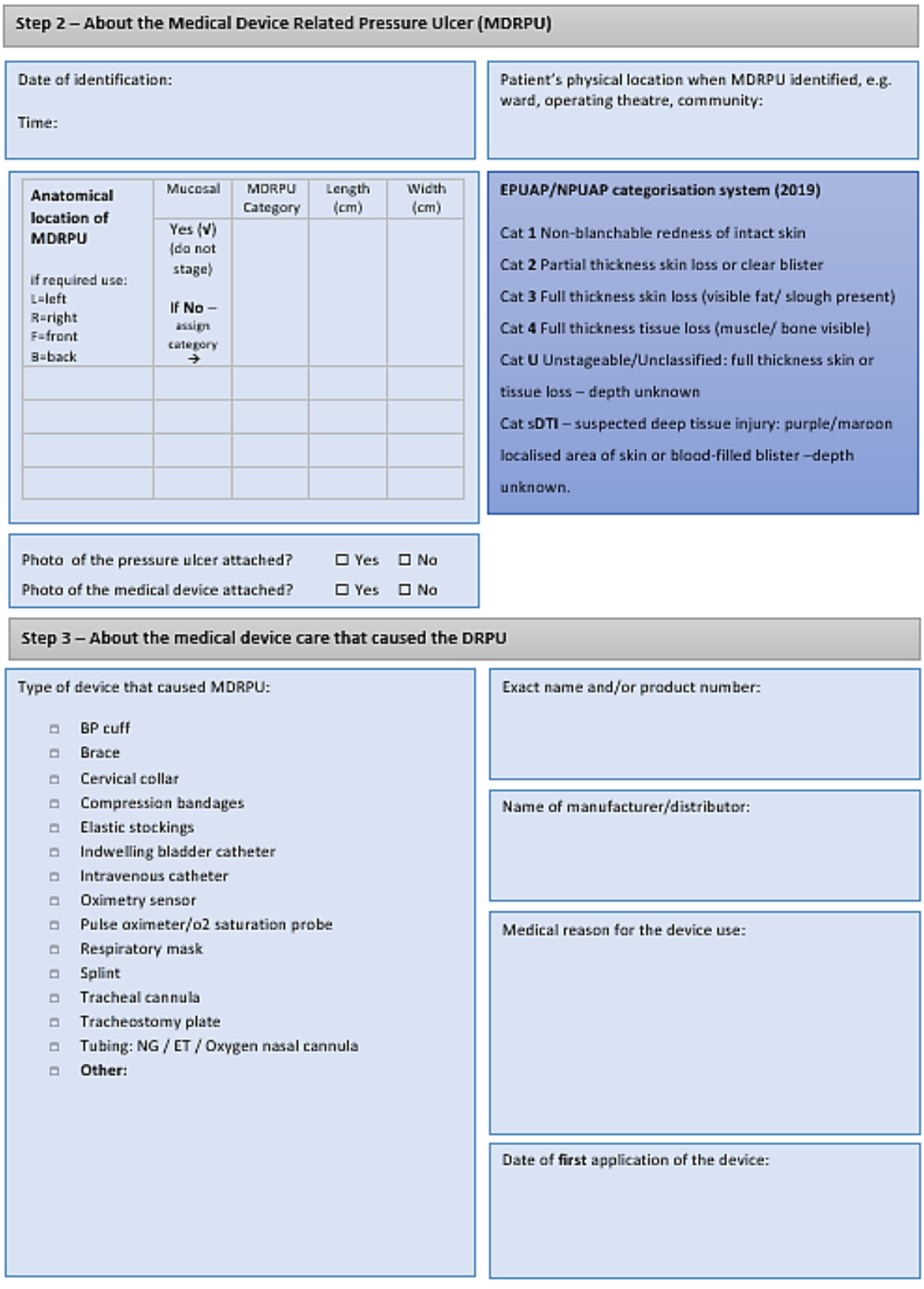
☐ vulnerable, if any present (tick as appropriate):
- ☐ dry skin
- ☐ moisture
- ☐ oedema under device
- ☐ previous skin damage / trauma under the device
- ☐ thin, tissue paper skin

Skin tone type (see The Fitzpatrick Scale below):
☐ **Light (type 1 - 3)**
☐ **Dark (type 4 - 6)**

Type 1 – light, pale white	Type 2 – white, fair	Type 3 – medium, white to olive	Type 4 – olive, moderate brown	Type 5 – brown, dark brown	Type 6 – black, very dark brown to black

NB. Skin of an individual with African, Asian, Middle Eastern, and/ or Hispanic ancestry should be classified as 'dark'.

Figure 6.4 MDRPU reporting form after the pre-testing (i.e. both cycles) and in readiness for piloting in clinical practice - page 1.



Step 2 – About the Medical Device Related Pressure Ulcer (MDRPU)

Date of identification:

Time:

Patient's physical location when MDRPU identified, e.g. ward, operating theatre, community:

Anatomical location of MDRPU if required use: L=left R=right F=front B=back	Mucosal Yes (√) (do not stage) If No – assign category →	MDRPU Category	Length (cm)	Width (cm)

EPUAP/NPUAP categorisation system (2019)

Cat **1** Non-blanchable redness of intact skin

Cat **2** Partial thickness skin loss or clear blister

Cat **3** Full thickness skin loss (visible fat/ slough present)

Cat **4** Full thickness tissue loss (muscle/ bone visible)

Cat **U** Unstageable/Unclassified: full thickness skin or tissue loss – depth unknown

Cat **sDTI** – suspected deep tissue injury: purple/maroon localised area of skin or blood-filled blister –depth unknown.

Photo of the pressure ulcer attached? ☐ Yes ☐ No

Photo of the medical device attached? ☐ Yes ☐ No

Step 3 – About the medical device care that caused the DRPU

Type of device that caused MDRPU:

- ☐ BP cuff
- ☐ Brace
- ☐ Cervical collar
- ☐ Compression bandages
- ☐ Elastic stockings
- ☐ Indwelling bladder catheter
- ☐ Intravenous catheter
- ☐ Oximetry sensor
- ☐ Pulse oximeter/o2 saturation probe
- ☐ Respiratory mask
- ☐ Splint
- ☐ Tracheal cannula
- ☐ Tracheostomy plate
- ☐ Tubing: NG / ET / Oxygen nasal cannula
- ☐ **Other:**

Exact name and/or product number:

Name of manufacturer/distributor:

Medical reason for the device use:

Date of **first** application of the device:

Figure 6.5 MDRPU reporting form after the pre-testing (i.e. both cycles) and in readiness for piloting in clinical practice - page 2.

Could the **medical device** be safely repositioned/ rotated?

☐ **Yes** → Date and time the device was last repositioned/ rotated:

☐ **No** → Please give clinical rationale:

Is the device still in place?

- ☐ Yes
- ☐ No

If **Yes** →

Is the device still required for patient's care or treatment?

- ☐ Yes
- ☐ No

Preventive measures in place (tick applicable):

- ☐ Barrier products
- ☐ Dermal pads
- ☐ Film dressings
- ☐ Hydrocolloids
- ☐ Hydrophilic foam
- ☐ Silicone foam dressing
- ☐ Other, **give details:**

Type of securement used:

- ☐ Tape
- ☐ Elastic straps
- ☐ Dressings
- ☐ Not applicable
- ☐ Other, **give details:**

Frequency of change of the **securement:**

- ☐ Not applicable

Was the presence/development of the MDRPU discussed with the patient/carer?

☐ Yes → **Give details – when** and **with whom** this was discussed and **what** information was given:

☐ No → rationale:

Other comments

Name of the reporter:

Position:

Reporter's signature:

Figure 6.6 MDRPU reporting form after the pre-testing (i.e. both cycles) and in readiness for piloting in clinical practice - page 3.

6.9 Discussion

The MDRPU reporting form design was underpinned by the results of the consensus study and designed by the researcher, based on other reporting forms available in the field of skin health and medical device incidents (MHRA, 2019, HPRA, 2019, NHS Wales, 2018, The Royal Children's Hospital Melbourne, 2019). This first draft of the form was the subject to the pre-test study.

The applied cognitive pre-testing methods were used to improve the flow, language, and understanding of the reporting form. A similar approach has been used to refine outcome measures (Elliott and The Bluebelle Study Group, 2017, Gorecki et al., 2013) and develop a pressure ulcer risk assessment instrument (Coleman et al., 2016a). Although pre-testing methods are not usually used in designing reporting forms, this step in the design was necessary since the researcher had to 'translate' items agreed through the consensus study. Consequently, areas of confusion were identified and improvements were made to enhance the form's usability and acceptability. Furthermore, the cognitive pre-test confirmed the content validity with the anticipated end-users of the form – tissue viability and critical care nurses.

The consensus study yielded a list of data relevant and necessary for MDRPU reporting, however those items had to be transformed into straightforward instructions for completion by end-users. The reporting form design process required consideration of the format and order of the items. The researcher followed the order of the consensus study survey, adapting the items and ordering them into a logical order. Some items were contextualised by adding decision support for the end-users, since the time constraints were previously identified as a barrier to reporting (see Chapter 4, section 4.3.2.4.2, and Chapter 5, section 5.13.4). The reporting from is underpinned by the international consensus relating to the items that had to be included, however the way in which this information was constructed and presented in the form could impact how it was understood by end-users and its usability in clinical practice. Hence it was necessary to apply pre-testing methods to assess and improve the form. Adopting this approach resulted in the form possessing a logical flow, following an order to which the reporter is accustomed, hence improved the form's usability.

To best simulate a real case scenario and put the clinician into a reporting mindset, the researcher used vignettes. Vignettes have been previously used in a range of fields by social scientists (Barter and Renold, 2000), as well as in health care research (Sheringham et al., 2021), and to develop a novel pressure ulcer risk assessment tool (Coleman et al., 2016a). Using vignettes as a basis for MDRPU reporting form completion enabled further identification of areas where clarity was lacking. As a result, areas requiring improvements to enhance usability and acceptability were uncovered and addressed.

Although vignettes have been used as simulated patient cases in healthcare research (Sheringham et al., 2021), they are limited in their potential to illustrate a real-life incident fully (Evans et al., 2015). An effort was made to design the vignettes to closely resemble clinical cases, with attention paid to details and realism added through the supply of photographs of the MDRPU and the device associated with the wound. To achieve this the researcher developed two vignettes based on published case studies, which then were further improved by specialists in the field, and the third vignette was developed by a nurse with experience in neonatal patient's skin harm. These steps were taken to ensure the case of MDRPU was as close as possible to real-life incidents to indicate internal, external, and construct validity (Evans et al., 2015, Finger and Rand, 2005). Using vignettes as a basis for cognitive pre-testing was considered logical for assessing and improving the form before feasibility testing in clinical practice. However, recognising that a vignette is not a true representation of a real-life event (Evans et al., 2015), the form will undergo further testing in clinical setting.

Focus groups were arranged by the researcher to avoid any hierarchical issues which might have had a negative impact on the willingness of participants to share their opinions and experiences (Krueger and Casey, 2000). Consideration was also given to the order in which the data collection was designed. Cognitive interviews enabled quick identification of confusing, unclear, or difficult to complete items. Following the participant's trail of thought' (Ericsson and Simon, 1980) helped to notice how the design of the form could facilitate easy completion. In contrast, the focus groups were expected to give insight into general usability issues, as the participants were interacting with each other and 'sparking ideas' from each other (McColl, 2005), discussing any arguments they made.

Although some of the comments received in cognitive interviews overlapped with those generated in focus groups, the two distinct approaches identified separate sets of issues. One had to do with 'technical' problems of the form itself, i.e. design, and second – issues of usability and feasibility of use. Consequently, we were able to address all aspects of the design and usability of the reporting form and confirm content validity with clinicians who are the anticipated users of this form.

The main limitation in this study was the necessity for online interviewing. The study was undertaken during the Covid-19 pandemic and there was no possibility to organise face-to-face meetings. This possibly led to sampling bias, because the researcher had to rely on participants having access to a computer, with video-conferencing software, and the ability to dedicate uninterrupted time to the video call. In person interviews or focus groups usually put the onus on the organiser to ensure the location of the meeting is quiet and private, however when organising

this online, the participant is responsible for their own arrangements. As a result, some potential participants with a wealth of knowledge and experienced might have been inadvertently deprived of the opportunity to participate. However, relying on remote interviews, also allowed the inclusion of participants from a wider geographical region in comparison to what would have been possible if in-person meetings were to be arranged. There is little or no evidence that the mode of the interviews (or focus groups) has impact on the quality of data (Krouwel et al., 2019, Thunberg and Arnell, 2021), hence using remote interview might be also considered a strength of this study.

6.10 Conclusions

The draft MDRPU reporting form was a subject of cognitive pre-testing with clinical nurses to assess and improve its usability. The nurses were coached on completing the reporting form and then invited to a cognitive interview or focus group. Based on analyses of collected data, the flow, language, and comprehension were improved upon. Using cognitive pre-testing methods for reporting form development helped identify and resolve relevant usability issues. It also facilitated confirmation of content validity of the MDRPU reporting form. Testing the form in clinical practice, discussed in the forthcoming Chapter 7, will further explore its feasibility.

Chapter 7 Pilot feasibility of the MDRPU reporting form

7.1 Introduction

This chapter explores the work that was undertaken to assess the feasibility of using the MDPRU reporting form in clinical practice. It builds on the consensus study (Chapter 5) which identified the most important data that should be included in the MDRPU reporting and cognitive pre-testing study (Chapter 6) where the form underwent amendments to improve its flow, language, and clarity. Subsequently, a pilot feasibility study was conducted in two large acute hospitals, which is presented in this chapter.

7.2 Aim of the pilot study

Aim:

To assess the usability and feasibility of a Medical Device Related Pressure Ulcer (MDRPU) reporting form derived from an internationally agreed Data Set in clinical practice.

Objectives:

- To pilot and evaluate the usability of the preliminary version of the MDRPU reporting form with tissue viability nurses in hospital settings.
- To analyse the MDRPU reporting forms for completeness of data.
- To explore the factors affecting the completion of the MDRPU reporting form items in routine NHS practice.

7.3 Methods

In this study, a mixed-methods, explanatory sequential design was used to assess the usability and feasibility of using the MDRPU reporting form (Creswell, 2014). A quantitative component, the System Usability Scale (SUS) (Brooke, 1986) and assessment of data completeness guided the subsequent qualitative component – focus groups with the tissue viability teams (Figure 7.1). The tissue viability teams were introduced to the preliminary MDRPU reporting form and asked to use it alongside usual practice for three months. In month two SUS questionnaire data were collected and analysed before the completed anonymised MDRPU reporting forms were evaluated for completeness in month four. After this analysis, two focus groups were arranged (one at each participating trusts) to explore usability and feasibility of the reporting from. This approach worked well since it allowed further exploration and discussions about challenging areas which

were identified through the completion of the form over time and provided adequate opportunity to explore the usability and feasibility of the MDRPU reporting form.

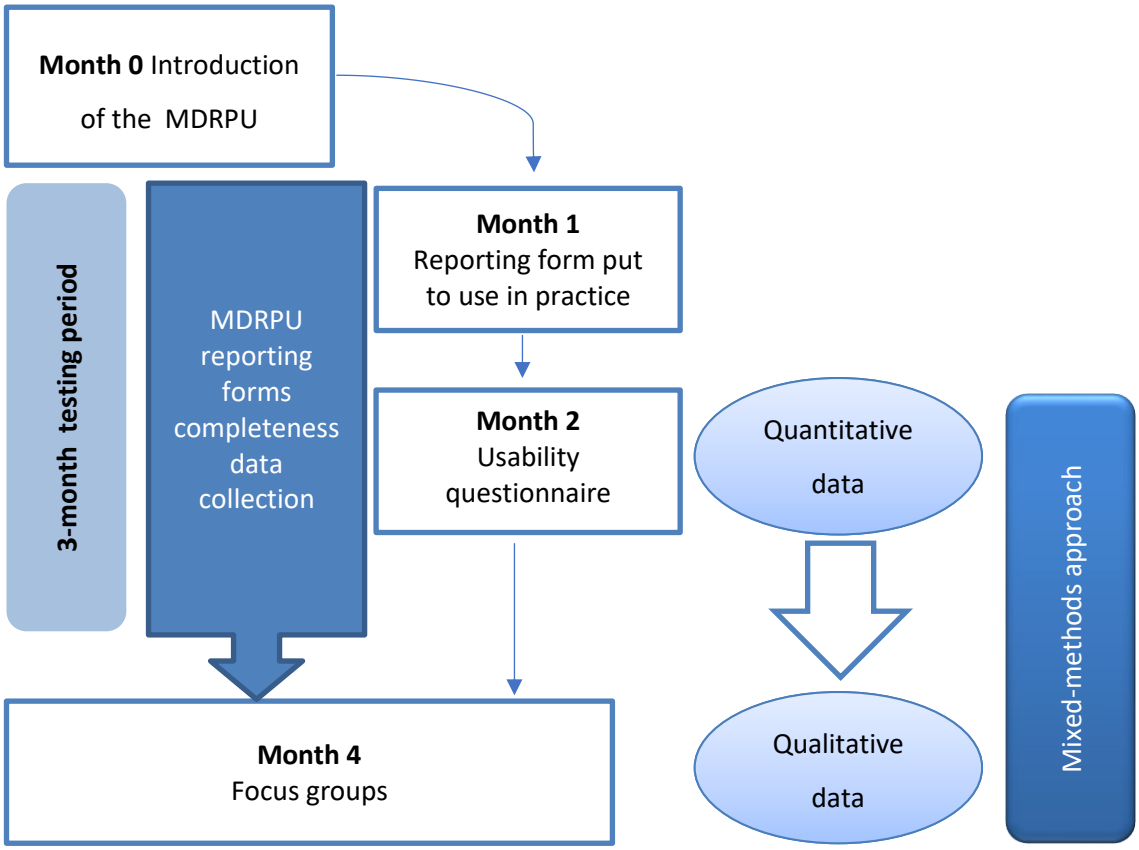


Figure 7.1 Schematic of the pilot study elements and methods.

7.3.1 Feasibility and usability studies design

Currently, there is no universally agreed and systematically applied definition of a feasibility or pilot study (Polit and Beck, 2017). In this study the Medical Research Council's (MRC) guidelines and terminology were adopted (Craig et al., 2008, Skivington et al., 2021). The MRC does not distinguish between pilot and feasibility studies, which are defined as a studies that test the intervention for its acceptability, adherence, capacity of providers to deliver the intervention or evaluate design (e.g. recruitment, data collection, retention, outcomes, analysis) (Skivington et al., 2021). The MRC guidance states in their guideline that feasibility study does not need to be a scaled-down model of the future large scale intervention (Craig et al., 2008). It should, however, address the uncertainties that were identified during the intervention's development stage and for this reason the MRC recommends undertaking feasibility studies (MRC, 2018). In health measurement and outcome measures instrument development, it is also widely accepted that after theoretical development and pre-testing, the instrument is then assessed for further psychometric properties, which are relevant based on its future use (Lancaster and Thabane,

2019). Feasibility studies are used in questionnaire development (Skinner et al., 2018), technology-based assessment (Khetani et al., 2018), the use of electronic Patient Reported Outcome Measures (O'Connell et al., 2018), as well as complex intervention development (Sugg et al., 2017, Winder et al., 2017), and mobile and online health interventions (Korpershoek et al., 2020, Gianfrancesco et al., 2018).

Although there is no definitive guidance as to designing feasibility studies, with the MRC indicating that the most suitable and available methods should be used, even if they are not theoretically optimal (MRC, 2018). As such mixed-method research was identified as the most appropriate paradigm to address the aim of this study. The combination of quantitative and qualitative data is most likely to give a full picture of the MDRPU reporting form usability and feasibility since it allows for determining perceived usability and acceptability through collecting quantitative data but also offers an exploration of those data through qualitative data collection and analysis methods.

7.3.2 Participants

Tissue Viability Nurses (TVNs) from two Trusts in the South of England were approached to participate in the study. The gatekeeper support (lead tissue viability nurse) was ascertained to establish a working relationship and ensure the MDRPU reporting form was used along with the usual practice and by all TVNs who consented to take part.

The researcher ensured the gatekeepers (TVN leads) and all the members of the TVN team had detailed information about the research and ample opportunities to ask questions about the research study. An online meeting (via MS Teams) took place with the tissue viability nurses to discuss the study and answer any potential questions. Informed consent was collected prior to the MDRPU reporting forms being supplied to the teams. A separate written consent was recorded prior to the qualitative data collection. During the testing period, the researcher was in contact with the lead TVNs from each of the Trusts to monitor progress and answer any questions or queries from the team.

7.3.3 System Usability Scale Questionnaire

When the TVNs gained experience using the reporting form, in month two, data on its usability were collected. A validated and reliable System Usability Scale (SUS) (Brooke, 1996a, Lewis, 2018) was used. The SUS is composed of 10 statements which are scored on a 5-point Likert scale (1= strongly agree; 5= strongly disagree) and is converted to a total score out of 100, where a score >70 is considered acceptable (Bangor et al., 2009). It is a simple tool used to establish the

general usability of a varied range of products and services (Bangor et al., 2009). It is shown to have excellent reliability (coefficient alpha >0.90) (Lewis, 2018), validity, and sensitivity to a wide variety of independent variables (Sauro and Lewis, 2016). Appropriate modifications to the wording of the questionnaire were made, replacing the word 'system' with 'reporting form' and 'cumbersome' with 'awkward' (Appendix M). The term 'awkward' was reported to be often used by SUS administrators in instructions for the questionnaire use and, overall more often used word in the English language (Bangor et al., 2008). It has been previously reported that such changes have no impact on resulting scores (Lewis and Sauro, 2009). The results provided discussion points for the subsequent focus groups.

7.3.4 Completeness

MDRPU reporting form completeness was assessed by accessing anonymised carbon copies of the form and checking each criterion for their respective completion. All forms returned by the TVNs were reviewed and whether the item was completed, not completed, or completed with feedback was recorded. Patient data were not transferred to the researcher and were not used for the purposes of this research. The percentage of completeness was calculated for each form to enable comparison between raters and hospitals.

7.3.5 Focus groups

After three months of testing (in month four), two focus groups (one with each of the participating TVN teams) were undertaken to explore experiences of using the MDRPU reporting form and any potential implementation issues. This group interview method facilitated interactions to enhance the exploration of participants' experiences (Krueger, 1998). The timeframe of 3 months gave the TVN teams enough experience with the reporting form to discuss their views on the usability and feasibility of use.

7.4 Ethics

The study was registered on the University of Southampton Ethics system (ERGO 2 64253), and the University provided sponsorship for the study. Research and Development Departments at each site confirmed their capacity and capability to undertake the study following HRA approval (21/HRA/4099 Appendix N).

The questionnaire's completion was assumed as a proxy for consenting to taking part in this element of the study. In the case of the qualitative data collection, written consent was collected before the focus groups or interview(s) was undertaken. The data collection was undertaken

online, hence consent was obtained through the participant scanning the signed form and forwarding it to the researcher's university email address. MDRPU reporting forms were anonymised at the source before the researcher collected data on form completeness.

7.5 Data collection

Hard copies of the preliminary MDRPU reporting form were provided to the Tissue Viability Teams by the researcher with the support of the Tissue Viability Nurse (TVN) lead. Due to restrictions relating to the Covid-19 pandemic the researcher conducted all data collection activities remotely, via MS Teams (Microsoft Office 365 v. 1.1.1). TVNs were given a presentation by the researcher on how to complete the reporting form, based on a simulated patient (a vignette which was also used in the cognitive pre-testing study presented in Chapter 6). The teams were asked to use the reporting form to record MDRPUs they review on any hospital ward they visit for a period of 3 months alongside the usual reporting practice.

Many of the reporting items in the new form are already included in common incident reporting mechanisms such as Datix, for example, the stage and size of the MDRPU and data on medical devices (which is not a part of the national prevalence data collection) are already collated by the tissue viability teams for their use (see Chapter 4, section 4.3.3.2). Prior to the MDRPU reporting forms being printed and supplied to the tissue viability team, the researcher sought feedback on whether there were any items that the teams already collected the data in their existing routine practice. This was to assure that the nurses do not need to replicate the work they already routinely complete, and the form was a more detailed addition to the practice. Trust 1 did not indicate any changes to the form were required, whereas Trust 2 identified two items (MDRPU identification date and patient location in the hospital on identification) that they already report. As a result, those items were removed from the reporting form to mitigate any potential duplication and reporting fatigue. The TVNs completed the MDRPU reporting on paper, where the original form was kept by the team and the anonymised copy was collected for the purpose of this study.

The Covid-19 pandemic restrictions required that the focus groups data collection had to be undertaken online, as opposed to the well accepted, "gold standard" face-to-face data collection methods (Deakin and Wakefield, 2014). This study was conducted when teams working within the UK NHS had already experienced using online tools, such as MS Teams, for meetings and training. Familiarity with online communication platforms has been quotes as necessity when conducting remote interviews or focus groups (Deakin and Wakefield, 2014, Hanna, 2012, Sedgwick and

Spiers, 2009). The TVNs were experienced in using the platform and the researcher did not have to make allowances for a trial run as some literature suggests (Murray, 2022).

When arranging focus groups what had to be considered was the day and time of the meeting. The researcher made it clear that this should be guided by the team, given their small numbers and the workloads they were experiencing. This also helped to facilitate building rapport with the TVN lead and the team, who inadvertently would know that they are respected and valued as participants. At the beginning of the focus groups the researcher made notes on the TVN names and used them to direct questions, in return the TVNs would also use the researcher's name at times, which shows certain familiarity and being relaxed in the situation. A drawback of this mode of data collection in this study was that one of the teams were gathered wearing facemasks, which limited the non-verbal cues that the researcher could respond to. Nonetheless, some non-verbal cues such as hand gestures, nodding or furrowed brow could be observed. Moreover, guided by the work of Sandelowski (2000), the researcher focused more on listening to participants, than talking, which again supported the rapport-building. Additionally, the researcher paid attention to speak slowly, asking follow-up questions carefully, and listening to the tone of voice of the speaker (Deakin and Wakefield, 2014, Hanna, 2012).

Another issue to consider was the collection of signed informed consent forms. The researcher sent at least two reminders to each of the team' leaders to ask for the forms to be returned just before the focus group. This was more time-consuming than when conducting data collection face-to-face.

7.5.1 Quantitative Data

Due to the Covid-19 restrictions, the SUS questionnaire was emailed to the gatekeepers, who distributed them to the participating nurses. This was a preferred mode by the TVNs, the researcher set up the questionnaire online, using Google Forms, however this opportunity for completion was not taken up by the TVNs. TVNs either edited the MS Word document (Microsoft Office 365) or printed the form, completed, and scanned back to the researcher. The questionnaires were returned within 2 weeks and prior to the qualitative data collection, during month 3 of testing.

Apart from data relating directly to the study aims, demographic data for participant description (i.e. professional qualifications, years of experience in tissue viability, years of experience in reporting) were also collected.

7.5.2 Completed MDRPU reporting forms

MDRPU reporting forms with carbon copies were supplied by the researcher to the TVN teams in both Trusts. They were delivered in person by the researcher, the Trusts' rules about meeting on site were taken into consideration. The gatekeepers were instrumental in distributing the forms to the team and collecting carbon copies for the study. The form was designed to facilitate nurses' reporting aims, and the team were invited to retain forms as part of their routine clinical data collection.

Yet again, due to the Covid-19 restrictions, the researcher was unable to visit the teams' offices to collect data on the form completeness, instead, copies of the anonymised and completed reporting forms were sent to the researcher using a University of Southampton SafeSend service (https://safesend.soton.ac.uk/). This service ensures that all transferred files are encrypted and data are stored on equipment managed by the University of Southampton and their staff, rather than being a "cloud" service. Moreover, the uploaded data is held only for 32 days, after which they are deleted automatically.

The researcher requested a data transfer from the tissue viability lead nurse at an agreed time, to minimise burden and the need of 'remembering' to initiate the transfer. After data collection the files were deleted, to reflect what would happen if the researcher examined the forms whilst on the Trust premises. No patient data were transferred to the researcher, all forms were anonymised.

7.5.3 Qualitative focus groups

The focus groups were undertaken online, using MS Teams (Microsoft Office 365 v. 1.1.1). At the point of data collection and due to the Covid-19 pandemic, the Trusts did not allow for external visitors and onsite meetings for the purpose of research.

Focus groups discussions were semi-structured, based on a topic list guided by the study aim Appendix O), which was developed based on the content of the form and results of the quantitative data analysis which provided further lines of enquiry. The focus groups were audio-recorded and transcribed verbatim by the researcher. After transcripts were checked for accuracy, the recordings were deleted. Transcripts were then anonymised before being analysed by the researcher.

7.6 Data analysis

7.6.1 Quantitative Analysis

To define the participants' characteristics, descriptive statistics were used.

Data collected through the SUS questionnaire were manually entered to an MS Excel sheet (Microsoft Office 365). The SUS has its own scoring system, providing a single number representing a composite measure of overall usability (Brooke, 1996a). The process of calculating the SUS scores is as follows (Brooke, 1996a):

- Sum scores of each item where:
    - even number items' contribution is five minus the scale position
    - odd number item's contribution is scale position minus 1
- Multiply the sum of the scores by 2.5 to obtain the overall SUS score.

Each item score varies between 0 and 4, and the overall SUS score ranges between 0 and 100 (Brooke, 1996a). Non-parametric descriptors including median and range values of the SUS scores were then calculated in Microsoft Excel. Score of 70 or over indicates perceived usability threshold is achieved.

The analysis facilitated further development of a topic guide subsequently used in the qualitative strand, where issues of implementation and feasibility were explored. The measure of central tendency (i.e., median) provided a starting point for identifying potential problems with the implementation and feasibility of using the MDRPU form. Although individual item scores are not meaningful on their own (Brooke, 1996a), they highlighted particular areas of concern, which were then discussed during a focus group. The researcher evaluated which questions scored the highest and the lowest, reflected on the questionnaire question, and noted down a prompt to use during the subsequent focus group. The prompts were targeted at specific focus group, i.e., the group of participants who raised the issue in question.

7.6.2 Completeness of MDRPU reporting forms

The researcher examined the extent to which the MDRPU reporting form items were completed, i.e. (%) of item-level data missing, what items (if any) were left blank, and what, if any, additional data were consistently added to the form by the participants. The analysis also looked at trends regarding specific items that were consistently not completed. For each of the form questions/ statements to complete, a value of 1 was assigned if item was completed, 0 if it was not completed, 3 if a nurse did not complete the item but made a comment as to why. Item was

considered completed if the response to was given, regardless of what answer it was, i.e. an effort was made to ascertain the form item was addressed. If the item was missed out all-together, it was considered not completed. The distinction between item not completed (0) and not completed with feedback (3) was made to make clear, that the reporter did in fact consider the item but could not complete it for a reason given in the feedback.

7.6.3 Qualitative Analysis

The anonymised transcripts were initially coded line-by-line. The NVIVO (version 12 Pro) package was used to support analysis. Initial codes and categories were based on the MDRPU reporting form items, using a directed content analysis methodology (Hsieh and Shannon, 2005). As the coding and categorising progressed, additional codes and categories were added. To ensure consistency and quality of data, the researcher re-coded part of each of the focus group transcripts after 14 days of the initial coding (Schreier, 2012). Although the coding frame was prescriptive as it followed the content of the reporting form, this double-coding ensured that the meaning of the material is understood in the same way after a period of de-attachment from it. This was especially important where new codes were generated inductively and allowed to consider the coding frame to be reliable. In addition, because the additional categories were driven by data, we may also conclude the coding frame was valid (Schreier, 2012).

7.6.4 Data integration

In this study data integration has been accomplished at the design level and the interpretation and reporting level (Fetters et al., 2013). The intention of integration on the design level was to build the qualitative element data collection and analysis (focus groups) on the results of the quantitative element (SUS and data completeness results) (Ivankova et al., 2006). The integration on the interpretation and reporting level was achieved through the contiguous approach to integrating through narrative (Fetters et al., 2013). Using this approach, quantitative and qualitative results are presented separately, in different sections, and brought together at the interpretation stage.

7.7 Results

Four nurses from Trust 1 and five nurses from Trust 2 consented to the use the MDRPU reporting form alongside their usual practice. Eight nurses (four from each site) completed the usability questionnaire (SUS). Those participants also took part in subsequent focus groups. One of the participants from Trust 2 was unable to complete the SUS questionnaire and participate in the

meeting. Demographic data of the participants were collected alongside the SUS questionnaire and are presented in Table 7.1. The researcher collected twenty-three completed MDRPU reporting forms - twelve from Trust 1 and eleven from Trust 2.

Table 7.1 Demographic characteristics of study participants

Participant ID	**Trust ID**	**Highest qualification held**	**Years' experience in tissue viability**	**Years' experience in wound reporting**
01	1	Diploma in nursing	10	15
02	1	Master's Degree	15	30
03	1	Advanced diploma in Nursing	2	20
04	1	Advanced diploma in Nursing	9	9
05	2	Bachelor's Degree	2	1
06	2	Bachelor's Degree	2	10
07	2	Bachelor's Degree	1	8
08	2	Bachelor's Degree	1	3.5

7.7.1 System Usability Scale Questionnaire

The scores and the final SUS score are presented in Table 7.2 below. The SUS questionnaire used in this study is presented in Appendix M.

Eight SUS questionnaires were returned, and the scores ranged from 45 to 70, with median of 65 (Table 7.2). System Usability Scale results did not meet the usability threshold of 70.

Table 7.2 System Usability Scores for MDRPU reporting form (Brooke, 1996a)

	Questions	Participant number									
#		**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**Median**	**Range**
1.	I think that I would like to use this reporting form frequently.	2	2	1	2	1	2	2	2	2	1 - 2
2.	I found the reporting form unnecessarily complex.	3	3	1	2	0	2	2	3	3	1 - 3
3.	I thought the reporting form was easy to use.	3	3	1	2	1	3	3	2	3	1 - 3
4.	I think I would need the support of a technical person to be able to use this reporting form	3	3	3	4	3	3	3	4	3	3 - 4
5.	I found the various functions in the reporting form were well integrated.	2	2	2	2	2	2	2	2	2	-
6.	I thought there was too much inconsistency in this reporting form.	3	2	2	4	3	2	4	3	3	2 - 4
7.	I would imagine most people would learn to use this reporting form very quickly.	3	2	2	3	1	4	3	2	3	2 - 3
8.	I found this reporting form awkward to use.	3	3	1	2	1	4	2	3	3	1 - 3
9.	I felt very confident using the reporting form.	3	2	2	3	1	2	2	2	3	2 - 4
10.	I needed to learn a lot of things before I could get going with this reporting form.	2	4	3	4	3	4	1	3	4	2 - 4
	Sum of scores	27	26	18	28	16	28	24	26		
	SUS SCORE (sum of scores *2.5)	**68**	**65**	**45**	**70**	**40**	**70**	**60**	**65**	**65**	**40-70**

7.7.2 Evaluation of the completeness of the MDRPU reporting form

Table 7.3 shows results of the data completeness data analysis, showing the distinction between items where no attempt was made to record data, and where the data were not recorded, not through omission, but lack of available information. Close examination of the data revealed a trend for some items where nurses would leave feedback as to why they were unable to complete them. Mostly, the TVNs indicated they could not complete an item due to lack of data recorded in nursing notes either due to poor quality of the nursing notes or the data not being routinely recorded by the staff.

Table 7.3 MDRPU forms data completeness analysis

Form #	Total number of items in the form	Completed [%]	Missing/ no attempt [%]	Missing with feedback [%]
1.	32	22 [69]	9 [28]	1 [3]
2.	32	23 [72]	8 [25]	1 [3]
3.	32	23 [72]	8 [25]	1 [3]
4.	32	21 [66]	10 [31]	1 [3]
5.	32	24 [75]	8 [25]	0 [0]
6.	32	26 [81]	5 [16]	1 [3]
7.	32	30 [94]	2 [6]	0 [0]
8.	32	28 [88]	3 [9]	1 [3]
9.	32	26 [81]	5 [16]	1 [3]
10.	32	25 [78]	7 [22]	0 [0]
11.	32	26 [81]	2 [6]	4 [13]
12.	32	29 [91]	1 [3]	2 [6]
13.	30*	22 [73]	8 [27]	0 [0]
14.	30*	21 [70]	2 [7]	7 [23]
15.	30*	18 [60]	4 [13]	8 [27]
16.	30*	23 [77]	2 [7]	5 [17]
17.	30*	20 [67]	2 [7]	8 [27]
18.	30*	20 [67]	4 [13]	6 [20]
19.	30*	23 [77]	7 [23]	0 [0]
20.	30*	19 [63]	4 [13]	7 [23]
21.	30*	24 [80]	4 [13]	2 [7]
22.	30*	20 [67]	9 [30]	1 [3]
23.	30*	23 [77]	5 [17]	2 [7]
Mean (Std deviation)		23 (3)	5 (3)	3 (3)

*Trust 2 reporting forms were tailored to avoid duplication of reported data (see section 7.3).

None of the returned forms were 100% complete. The highest level of completion was 94% (30 out of 32 items). When considering that a completed item also included any item that the nurse attempted to find data and left feedback to such effect, the highest level of completion was 97% (31 out of 32 items). There was some difference in completion rates between the two trusts, where TVNs from Trust one completed on average 79% of the form items, whereas in Trust 2 on average 71% of items were completed.

On average 5 items were left blank on each form, and additional 3 were left incomplete with written feedback from the nurse making the report. The maximum number of items missing was 10, which is approximately a third of all those required for completion. Table 7.4 illustrates the

level of missing items (%) and gives an overview of what items were consistently missed or left incomplete. No additional items were added by the nurses to the forms.

Analyses of the level of completeness of each of the MDRPU reporting form items revealed that there were several items that were completed by the nurses 100%. They mostly related to data that were observable when the nurse was at the bedside, e.g., patient's skin tone, MDRPU category, device type, and whether device repositioning could be safely accomplished. By contrast, only four (4/23) reports included the name of the manufacturer or distributor and only 9/23 included the device's name.

Table 7.4 Item-level analyses of MDRPU reporting form data completeness.

	Item	Completed (1) [%]	Missing (0) [%]	Missing with feedback (3) [%]
Step 1: All about the patient	Primary diagnosis	22 [96]	1 [4]	0 [0]
	Co-morbidities	21 [91]	2 [9]	0 [0]
	Last PU assessment score	22 [96]	0 [0]	1 [4]
	Last skin assessment date and time	11 [48]	6 [26]	6 [26]
	Skin status	13 [57]	10 [43]	0 [0]
	Patient repositioning	12 [52]	4 [17]	7 [30]
	Weight	10 [43]	2 [9]	11 [48]
	Nutritional status	20 [87]	2 [9]	1 [4]
	Skin tone	23 [100]	0 [0]	0 [0]
	Patient proning w/ device in situ	23 [100]	0 [0]	0 [0]
Step 2: About the Medical Device – Related Pressure Ulcer (MDRPU)	MDRPU identification date and time*	12 [100]	0 [0]	0 [0]
	Patient's location on MDRPU identification*	11 [92]	1 [8]	0 [0]
	MDRPU anatomical location	21 [91]	2 [9]	0 [0]
	MDRPU category	22 [96]	1 [4]	0 [0]
	MDRPU dimensions	21 [91]	2 [9]	0 [0]
	Photo of MDRPU attached	16 [70]	7 [30]	0 [0]
	Photo of device attached	15 [65]	8 [35]	0 [0]
Step 3: About the Medical Device that caused the Device - Related Pressure Ulcer	Device type	23 [100]	0 [0]	0 [0]
	Device name or product number	9 [39]	6 [26]	8 [35]
	Manufacturer / distributor	4 [17]	8 [35]	11 [48]
	Reason for device use	21 [91]	1 [4]	1 [4]
	First application date	13 [57]	5 [22]	5 [22]
	Possibility of safe repositioning	23 [100]	0 [0]	0 [0]

	Item	Completed (1) [%]	Missing (0) [%]	Missing with feedback (3) [%]
	Repositioning date and time / rationale if impossible	11 [48]	6 [26]	6 [26]
	Whether device still in place	19 [83]	3 [13]	1 [4]
	Whether device still required	12 [52]	10 [43]	1 [4]
	Prevention used	21 [91]	2 [9]	0 [0]
	Securement used	20 [87]	2 [9]	1 [4]
	Frequency of securement change	18 [78]	5 [22]	0 [0]
	Duty of candour y/n	22 [96]	1 [4]	0 [0]
	Duty of candour – description	20 [87]	3 [13]	0 [0]
	Other comments	2 [9]	21 [91]	0 [0]

*Item only in Trust 1 form, see section 7.3 for information.

7.7.3 Qualitative data (focus groups)

Online focus groups (MS Teams) were undertaken in April 2022 (Trust 1) and May 2022 (Trust 2). Each of the meetings took approximately 40 minutes. In this section results of the qualitative content analysis are presented in three sections.

1) the general usability,
2) the completion of some of the form items, and
3) view of the feasibility of the reporting form use in clinical practice.

7.7.3.1 Overall usability of the form

All participants found the form easy to use, with logical flow, and clear questions / items. The use of tick boxes was appreciated as they increased the speed of the reporting process. The participating tissue viability nurses also confirmed that some of the data items would be considered by them when completing their regular reporting.

In Trust 1 completion took about 15 – 20 minutes, in Trust 2 it was less, only about 5- 10 minutes. Trust 2 did not have to collect data relating to the date and time of MDRPU identification and where the patient was located within the hospital at that point. Trust 1 reported that as standard they have 40 minutes to complete a total patient review. The extended time for completion of the MDRPU reporting form was associated with attempts to find and extract data from nursing documentation.

"*We don't have a lot of time. Yes, I tried to rummage around to find the information that is already somewhere else is quite difficult and in relation to the form, if you see, it's quite time consuming*" (P4).

However, it was also reflected that the form was new to the team and hence took longer to complete. Nurses suggested that with time and experience this task could take less time.

"*So when completing on the ward, it probably would take a good 15, 20 minutes to do, you have to dig and find the information, because it's not all there. (…) So, you kind of have to go through lots of paperwork. It takes a long time. So that they're not the quickest forms to fill in, but I suppose also once you get used to doing them, that will become quicker,*" (P3).

The team from Trust 2 who were completing forms in a shorter time, did recognise it most likely was due to the unavailability of data and were concerned about the quality of their report.

"I *think it's an acceptable time to fill it [the form] in [the 5-10 minutes it took on average], but I do feel like I couldn't still complete the forms properly because the ones that I've done, I wasn't able to give the information about the manufacturers etc. And I was just a bit concerned when I was sort of saying, 'Well, my form's done', that actually, I hadn't done the job properly because I wasn't able to really give you all of those details*" (P5).

7.7.3.2 Form items

The MDRPU reporting form items guided the data collection and analysis. This section presents findings related to those discussed during focus groups.

7.7.3.2.1 Step 1. All about the patient

Skin tone

The teams disagreed on whether it is a useful item to be reporting on. Team 1 stated that all the patients they have seen were of light skin. They suggested that this item does not provide any new insights into MDRPU development. It was, however, recognised that this item might relate to how easy or difficult it is to identify skin damage on darker-pigmented skin. One of the participants implied that skin colour has no influence on PU / MDRPU development, i.e., light skin tone is not more susceptible than dark skin tone, or vice-versa. Seasonal changes in skin tone and self-tanning product use were also highlighted as confounding factors.

"*I think the proper basis and are you looking at it from people with darker skin tones or lighter skin tones more prone to damage? Because if you're looking at that, then I can see why you want figures nationally, but again, you don't know. You don't know the situation with the medical device*

and whether that actually [has any impact]. You could have somebody with light coloured skin that had a device on for a day and they develop damage, or you could talk to somebody with dark skin has had the device on for six weeks and they develop damage. (…) I'm not sure how useful those data would be. I think there would be seasonal changes in colour, as well. Some people are much darker [skin] tone in the summer than they are during the winter. So, and the use of fake tanning products are going to make people look darker than they actually are." (P2).

Despite reporting on only light-skinned patients, the team from Trust 2 declared they appreciated this item being in the form. All of the TVNs agreed this was a good reminder that on darker skin the early damage and deep tissue injuries can be difficult to identify and will look different to what can be seen on patients with light skin colours.

"(…) [P]articularly, as you were looking at a category one [pressure ulcer] or a suspected deep tissue injury (…) because it can be quite hard to tell the difference between two in some of the darker skin tones. I did think that [skin tone item] was useful to be on the form" (P5) and "*I try to be aware that skin damage has a different look, on different skin [tones] and that was a good reminder for myself [having the skin tone scale]*" (P7).

Skin assessment and skin status

The view of the tissue viability nurses from both trusts was that the date and time of skin assessment were hard to ascertain and often required the nurses to look through the documentation to deduce when the last assessment was completed (e.g., by finding out when was the MDRPU identified, or device repositioned/ changed).

"[T]*here's no clear documentation, particularly for things about like a skin status under the device. [This] is not documented every two hours, as we would check a pressure area for a patient [who is] on a repositioning schedule, for instance. So that information was quite difficult to actually find out, [or] if anything was documented at all. Sometimes the only way was to actually identify on the day where maybe there was no damage documented. And then the next day, when it was first documented at sometime within that 24-hour period, that's when the device would have been moved and the area would have been seen*" (P3).

Skin assessment under the device was reported to be rarely completed by the ward nurses. The TVNs completing a report at the bedside are able to assess the skin status easily, however, there might be a significant time difference between the initial identification of MDRPU by the ward

nurse, and when the TVN sees the patient. It was indicated that there are difficulties to gather objective data that would reflect what the skin status when the MDRPU was first discovered.

"*But you [are] assuming [when completing the report] that's what it [skin] looked like at the moment you saw the damage. Not at the time when the nursing staff noticed the damage and then referred it to us. And you know, with the way we are at the moment, it may be some time before we get to see that patient. So, things might have changed a little*" (P2).

BMI & weight

This item is not seen as relevant in MDRPU development and reporting. Completion of this item was time-consuming and involved the nurse reviewing patient documentation for, what they would consider considerable time. Moreover, often those details are not recorded for immobile patients.

"*So, if a patient has a device related pressure ulcer, is it useful for us to tell you how much the patient weighs? So, all these things take a lot of time [to find in nursing documentation]. Do we actually need that? Is that actually helpful in relation to the type of pressure ulcer that that patient has? If it's something maybe that is related to the physical size of the patient, then yes, I could understand that*" (P1).

By contrast, Trust 2 nurses thought this item was good to have the weight of the patient recorded but they do not routinely report it.

"I think it was quite good [recording weight and BMI]. F*or us to actually write down about somebody's weight or BMI on the form, that's not necessarily something that we would capture in an investigation for any of our other pressure ulcers, it's more 'has it being considered', but we don't actually write if they were underweight or if they were obese*" (P8).

Nutritional status

Participants from Trust 2 considered this item to be useful, reasoning that it brings awareness of the importance of nutrition for PU healing. They suggested that as a result, the care plan would be more likely to include additional interventions relating to patient nutrition.

"When you review it again [the form], you can kind of reflect on the plan that you put in place as well, for instance, when it says about let the nutritional status [the nutritional status of the patient], it [the item] kind of makes you think about the care plan and if there is anything additional, we need to put in place. It was great to sort of evaluate the whole scenario (…)" (P8).

Risk assessment score

Nurses felt that the risk assessment score should be removed from the form because most of the patients will be in the high-risk category – "*I think that's a little bit [risk assessment score] pointless as well to be on there because most of them will be high risk*" (P4). Moreover, having a medical device in situ automatically puts any patient at risk of MDRPU development, even if the patient moves independently and hence the risk is not captured by the risk assessment score.

"*They [patients] might be at risk [even if] they're walking around, but they may have an NG tube stuck up their nose and taped in the wrong place. So, their pressure ulcer risk [assessment score] may not have any bearing on whether they developed medical device related pressure ulcer*" (P1).

Patient repositioning

This item was not seen as relevant for MDRPUs and what should be reported is MD repositioning.

"*The date and the time the patient was last repositioned, I'm not really sure that that's completely relevant to the medical device because actually. Because actually, if it's an NIV [non-invasive ventilation] mask, actually that patient repositioning makes completely no difference*" (P4)

7.7.3.2.2 Step 2. About the MDRPU

Photograph of MDRPU

This activity can only be done if the patient consents to it. Consent may be difficult to obtain, especially with patients who lack mental capacity or are unconscious. Moreover, if the MDRPU is on a patient who is Covid-19 positive, taking photos is impossible due to infection control measures.

"*A lot of difficulty with that in some of these cases is some of the wounds on COVID patients because it's a therapeutic device that's required for the patient. And you can't take photographs because it's infection control. So that's difficult from that point of view to give that that evidence*" (P2).

Photograph of MD

Neither of the teams take photos of the MD as routine and they did not do this for this study.

7.7.3.2.3 Step 3. About the device that caused the PU

Device name/ number & manufacturer/ distributor

Both Tissue Viability Teams reported it was very difficult to find data relating to MD. Nurses struggled to complete those items and were often left to make an estimated guess regarding the manufacturer's name and product's name or had to leave the item incomplete.

"*It's really difficult [to find out details of the MD]. And often you find the damage, when [the device] taken off and thrown in the bin. And then you don't really know what caused the damage, but you're making an estimated guess*" (P1).

Large trusts, represented by the TVN teams, were said to rely on a range of equipment supplied by different manufacturers, which makes it difficult to identify the exact make and manufacturer of the device, where those data are not recorded when the device is applied to the patient. Nurses reported this was especially difficult with devices such as straps and tubes (e.g., nasogastric [NG] and oxygen [O2]).

"*I found, particularly in a large hospital with different suppliers of different equipment, it's quite difficult to be able to identify what make, manufacturer and [other data], in a particular the strapping on the oxygen mask and tubing*" (P5).

Where different sources (manufacturers) of the same device type exist, it may be difficult to identify which device was implicated in the PU development (unless the packaging is available). This is because devices look similar and the stock rotation in the storage areas can further confuse staff who try to ascertain which device was in use.

"*With the oxygen tubing et cetera because it's all been put on already [on the patient] and all the packets have been thrown away, we can't guarantee which type [of device] it's going to be [that caused the pressure ulcer]. And you know what it's like with NHS supply chain, you're not always getting [the same device] from the same manufacturer*" (P5).

Moreover, different wards often use different devices, which are often removed before the TVN reviews the case, and no data relating to the medical device is logged in nursing documentation.

"*The issue with the device as well is unfortunately, different wards, could use different types of devices and because the device is going to come off before we [tissue viability nurses] get there, then you don't know what you know. So, for example, you know, it [pressure ulcer] has been caused on the ears by the nasal cannula. But you don't know what nasal cannula. You can't tell what the product is because the patient is no longer on the nasal cannula or has something else*

[different device] and that is a bit of an issue for us. But having said that, the information about that is really important because we've just found that we're using four different brands of nasal specks that we thought we were using a totally different one within the trust. (…) But I can't see the nurses on the wards documenting what products they're going to put on [the patient] at the time that they put it on." (P1).

Some patients may be admitted with a device in place which then may be replaced during their inpatient stay. This also was reported to create a problem when attempting to report which device caused the MDRPU. Similarly, the devices might come from different hospital settings which, with the lack of comprehensive records and computer systems that do not work together, means the MD cannot be identified.

In addition, TVNs acknowledged that when devices are applied in an emergency situation there is no time for recording device data, so subsequent reporting on the device data is impossible. MDRPUs may be developing after several devices of the same type (but not necessarily from the same manufacturer) are used. In such case, and without data of device change in nursing documentation, the nurses stated it is almost impossible to ascertain which device was implicated in MDRPU development.

"*It can sometimes be really difficult to get that actual information, especially of things that are put on in emergency situations. And actually, they [the medical devices] just sometimes appear [on the patient] and you just simply don't know sometimes [what is the manufacturer or any other data]*" (P5).

One of the participants, who used to work as a ward nurse reflected that they would not consider the recording of a device change, especially not if it was to a device of the same type.

"S*peaking from past experience, working as a nurse on the ward the brand of that oxygen tube wasn't something that ever crossed my mind. It was just in that moment 'is it the right one?'"* (P6).

Participants also expressed their doubt over ward nurses recording such information or reporting on them, due to time pressures and prioritising workload as well as the lack of awareness of medical devices and MDRPUs in general. Often, when there are no data, the TVNs draw on their experience (and use clinical judgement), and knowledge about what devices are used in the trust to assert which device caused MDRPU.

"*I think that your general nurse on the ward wouldn't even be thinking, 'Oh, I'll have to change that to a different type [of device]. I better write it down because they might get a pressure sore'.*

So, I think it's just something it wouldn't cross their mind because they're just focusing on what they need to do to keep that patient well at the time" (P5).

"*I don't think that the nurses on the wards be very happy if they were having to write down the exact sort of manufacturer and batch numbers every time, they use the piece of equipment because it's going to add time when they're already trying to prioritize care*" (P8).

"*I don't think they would be filled in properly by ward nurses. And I'm saying this from the point of view with the paperwork and the risk assessments that they need to do already aren't always done properly. So, to add an extra bit in there, I just I don't think it would get done*" (P6).

Nonetheless, for some devices, e.g., catheters, a label with a barcode is applied in the patient record, which gives the MD data such as manufacturer and batch number. It was suggested by nurses that such an approach would help with an easy recording of medical devices dispensed to a patient. It was also recognised by the participants, that this would involve a whole system change.

"*It's about what is available, but which stock is being used for which patient. I think that's the hard bit to try and capture because you might have tubing from two different manufacturers because you've got some [stock] that came in last week and then some [stock] that come in this week, but you don't necessarily know that the stocks being rotated in the cupboard. So, you wouldn't know which one was picking up. So, I think the only way you get around it is when a medical device is being fitted to a patient. [For example] [w]hen a patient has a catheter and you [the nurse] stick[s] the label in the medical notes. So, if it's a catheter, we can tell you the actual batch number of the catheter that's gone on [onto the patient]. So, something like that would work, but it would have to go into practice that that happens every time a medical device goes on to somebody*" (P5).

Repositioning of the MD

MD repositioning was seen as an important preventive measure, often overlooked by the ward nurses. However, even when there is a record of repositioning, it rarely includes time. It was mentioned that repositioning of NG or O2 tubes is rarely recorded in nursing documentation.

"*I think it's important to capture whether the medical device can be repositioned or rotated just as in a 'yes' or 'no', and we want to know the last time it was repositioned. But if it is oxygen or NG tube, we quite often don't have that information to add*" (P4).

Securement devices

Again, the securement of devices was rarely reported in nursing notes and difficult to find out what the type/nature of securement was, especially when the device is not in place anymore. When there is a record of the device, nurses draw on their knowledge of devices and practices in the hospital to make a judgment call about what securement might have been used.

"*Some things [items] can sometimes be difficult [to complete]. To find out how the device was actually secured [can be difficult] because what we find is that actually that can change quite often through the time that they [the patient] have it on. And especially for those [devices] which would be removed by the time you get there [to assess the pressure ulcer]. Nurses [on the ward] would have to be really very good at documenting how devices are actually secured. So that's one thing that was often found challenging to find out the actual details. I know that we need to be able to get the data. But that was something that can be quite challenging to find [type of securement]. I like the way I could document it to see what type of device it was and knowing what sorts of devices were used in the trust. So, whether it's got elastic head straps or it's got some head straps close with Velcro, that kind of thing, it's just knowing the device rather than specifics, I couldn't give any specifics [about the device or securement when the device was removed prior to TVN's reporting]"* (P3).

Duty of candour

This item was seen as not relevant for reporting MDRPUs as it does not give any details about the device or the PU development.

"*I don't know what we would achieve by having it on this form [duty of candour data], because actually that doesn't tell us anything about the medical device or how it the pressure are actually developed, which is that more data side of things that we are getting. So I don't think it adds think to the quality of the information that you're gathering*" (P1).

7.7.3.3 Form feasibility

Participants reported that using the form during this pilot study made them more conscious of their practices and more reflective when considering which device caused MDRPU. However, the teams were unanimous that the form requires further work to make its use feasible.

"*I think that it did [completing the form] make us stop and think about what the device actually was, why it was what we use and may just stop and think a little bit about the device (…)It makes you stop and think about what the different devices are, and I think it could be something that*

could be useful in a more simplified form so that we know if we get in pressure from all the same devices. So that we can make change and think 'why are we getting them?' " (P1).

A simpler version of the form could be used within the team to track devices that cause the majority of PUs. Participants suggested that the form should be more succinct and suggested it should include data on MDRPU and the device implicated (Steps 2 and 3 of the form). Some items would be difficult to complete, but overall those parts of the form were seen as the most important for TVNs' practice.

"*The form is useful, but I think it should be a bit more succinct because actually, if we just get data on actually what was the device, what was the pressure ulcer that it caused? How long have the device been on? Do we need to be going around gathering all like medical conditions and that sort of thing? Is it going to make that much of a difference if we are wanting it more to know more about what the device is that caused the pressure ulcer?*" (P1).

"*The second to last page, I think, is the page that has all the most information on it, that is probably the most useful page, which is the Step 2: about the medical device related pressure ulcer. The bit is probably the most useful, it is difficult to find some of that information but... We got a reason as to why we've used the device, because actually, we're not just using something for the sake of it*" (P5).

Items in Step 1 (All about the patient) were seen as irrelevant for MDRPU reporting (e.g. patient weight, diagnosis, co-morbidities) and data difficult to find, hence not usable or feasible in practice.

This preliminary form as it stands, is not feasible for use in clinical practice due to the information not being recorded in routine practice. Nonetheless, all participants agreed that the overall aim of the data collection facilitated by this reporting form is important for improvements in the quality and safety of care.

"*I think, at the moment [the form is not feasible]. I think it is too long too in depth form, that I just can't see either us or the nursing staff having the time to complete and also having the information to complete all of that*" (P1).

"*So it's I think it's really important to know which products are causing the damage so that we can say we've got evidence and we can go forward to get a different product in use, which is what this whole the whole point of the measuring medical device-related pressure ulcers process is. However, it's not always very easy for us[the process of completing the form]*" (P3).

7.8 Discussion

This study aimed to assess usability and feasibility of the draft MDRPU reporting form. It builds on the work of the pre-test study which was undertaken using vignettes (Chapter 6), where the draft form usability and acceptability were evaluated. However, vignettes have been criticised for their internal and external validity (Evans et al., 2015) and despite best effort to design vignettes used in the pre-test study to reflect real-life cases, it was recognised that piloting the reporting form in clinical practice is the natural progression in the attempt to evaluate usability and feasibility.

Usability of the MDRPU reporting form was assessed using a short and simple questionnaire – System Usability Scale (SUS) (Brooke, 1996a). The SUS results indicated the scores did not reach the threshold necessary to confirm usability. The reporting form median score was 65 (range between 40 and 70), whereas the guidance indicated the score should be > 70 to confirm the perceived usability (Bangor et al., 2009).

There was a notable difference in the experience of the TVNs between the two participating trusts. TVNs in trust 1 were more experienced (on average 9 years in tissue viability and 9 years in wound assessment/ reporting) than nurses in trust 2 (on average 1 year in tissue viability and 6 years in wound assessment/ reporting). The more experienced team spent longer on completing the reporting form (15 - 20 mins vs. 5-10 mins) and had greater rate of MDRPU reporting form completion (79%) when compared to the less experienced team (71%). When analysing the SUS results, the average score from each team was similar, trust 1 team's score was 66 (range 45-70) and trust 2 was 63 (range 40-70).

The team's experience had minor impact on the perceived usability of the MDRPU reporting form, however the results suggest that the experience had a positive impact on data completeness of the form. It is possible that the experience in the processing reports meant that the nurses were more likely to know where to look for information that was not immediately available in nursing documentation or were more comfortable with making an 'estimated guess' about the data they were unable to find out because they were unavailable. Data regarding the medical device's name (or product number) and the name of the manufacturer were most often unavailable to the TVNs, because they are not routinely recorded in nursing notes, yet they are fundamental to being able to work with the manufacturers to improve medical devices that are being used in healthcare settings. Consequently, this potential area of practice development and education should be investigated in further research.

The SUS results revealed that the two questions that scored the lowest on average asked whether the participant would like to use the form frequently and whether the elements of the system

were well integrated (both items score median=2, 'disagree'). Although, as discussed in section 7.6.1, individual SUS item scores do not bear any meaning, they indicate there might be an issue necessitating further investigation. When the TVNs were asked about why they would not want to use the MDRPU form and what the key issues were, they have indicated that the data required to complete the reporting form is not routinely recorded (e.g. the medical device data) or missing from nursing documentation (e.g. Last patient repositioning, patient weight, details of skin assessment under the medical device), the form itself is too lengthy, and there is a lack of information flow between care settings. Consequently, it is difficult to collate all necessary data to complete the MDRPU reporting form and as such its usability in practice is questioned.

Analyses of data completeness of the MDRPU reporting forms confirmed that the most problematic items were clustered in 'Step 3 – About the medical device that caused PU' and included the name of the manufacturer (or distributor), name and / or number (product code) of the device. Items looking for details about first application of the device and last repositioning were completed in only approximately half of the reporting forms. Interestingly, all forms included the type of device. This item was developed during the previous pre-test study to include a long checklist of possible devices to facilitate reporting.

In contrast, the TVNs almost always completed items which are: always recorded in nursing documentation, such as patient's medical history and patient's proning with device in situ, easily observable, e.g., patient's skin tone, or those that are directly related to their expertise and do not require nursing documentation. Those were date and time of MDRPU identification, where the patient was located at that time, the MDRPU anatomical location, category and dimensions, type of device, possibility of safe repositioning, reason for use and whether the device was still in place when the report is being completed, as well as any prevention, securement of device, and duty of candour (whether the patient of patient's representative was informed about MDRPU development).

As mentioned above, the most often repeated reason why the reporting form had an impaired usability in clinical practice, was the lack of recording data relating to medical devices in the patient record. Participants described, how devices are usually applied, repositioned, and changed by ward nurses, who are also tasked with completing routine skin assessments. Although pressure ulcer prevention, treatment, and reporting, is a multidisciplinary team effort, it has been traditionally assigned to nurses (Samuriwo, 2012, Tan et al., 2020, Ursavaş and İşeri, 2020). Ward nurses are often faced with time pressures and competing priorities (Barakat-Johnson et al., 2018). As a result, they might not perceive that recording data about medical devices is a priority. Moreover, a couple of participants confided that when working on busy wards in the past, they

did not consider recording any MD related data at all. The tissue viability nurses reflected that the ward staff would not have time, or indeed willingness, to record every device they apply onto the patient. Indeed, sometimes that list might be long. Hence, participants suggested recording could be improved if barcodes could be scanned to an electronic patient record. Nevertheless, this resolution would require a system change, where procurement would have to be involved, as well as a change to routine nursing practice, and would require a decision whether MDRPUs are an important enough issue to warrant such resource-intensive change.

The perception that reporting is too time consuming, adds to workload, and is not integrated into work has been cited as some of the barriers for incident reporting (Evans et al., 2006, Pfeiffer et al., 2010). Although the participants in this study, the TVNs, were completing the form for the testing purposes, they agreed that it was too lengthy, took too long to complete, and it was difficult to find the information required for the purposes of the MDRPU reporting. As a result, the use of the MDRPU reporting form was adding to the documentation burden experienced by nurses. The TVNs relied on nursing documentation to inform some of the MDRPU reporting form items, yet some of the data are not routinely recorded by the ward nurses. Since the focus of nursing care is the provision of high quality and safe patient care (Senek et al., 2020) re-routing the time from direct care to collating data for reporting may lead to some care left undone, leading to increased patient mortality (Ball et al., 2014, Ball et al., 2018). Moreover, inability to perform the nursing duties to the best of one's abilities, may lead to poor wellbeing and burnout, which has been shown to be associated with poor patient safety outcomes (Hall et al., 2016).

When designing the MDRPU reporting form draft, a lot of thought was put into ensuring that whilst incorporating the items agreed through international consensus, the form was as easy as possible to use. Aide memoirs were added to remind reporters the international PU classification system (EPUAP NPIAP & PPPIA., 2019), and the Fitzpatrick's scale defining skin tones was also provided (Fitzpatrick, 1988).

The concern of the consensus study participants, as well as the participants in the pre-testing study, was to ensure the reporter is not attempting an impossible task, i.e., the form is usable in practice. Some literature suggests that when designing a reporting form to use open-ended questions and include only 'must-have' list of items to emphasise the 'story' of the event and allow to understand all the factors that impacted on the event occurring, including human factors (Health Quality Ontario, 2017). This might not be necessarily suitable for MDRPU reporting, where we are looking at the incident as a 'matter of fact' to ascertain characteristics of MDRPU incident. As a result, it is important to extract all aspects of the wound development and what might have had impact on it.

Clinicians' narrative of the event is important; however, some participants suggested the more narrative items (e.g., record of duty of candour) are more suitable to an investigation. Not including open-text boxes also might have a positive impact on the time that the form completion might take, i.e., takes less time, because the reporter answers direct questions / completes direct items, rather that decide what they should include in the report. It may also facilitate future digitalisation of the reporting form. Open questions, without an easily accessible guidance as to what to write down, do not allow for standard reporting. Our findings support this notion, since the nurses appreciated items with check-boxes, and the free-text box for comments was most of the times left blank with participants confessing they did not what to write in that section.

The inability to extract data from the nursing documentation might be related to the quality of the record, as well as to the lack of integration between electronic systems used in hospitals. Insufficiencies of nursing documentation have been identified in previous research (Li, 2013, Barakat-Johnson et al., 2018, Barakat-Johnson et al., 2017) and participants in this study found this issue prevalent and having direct negative impact on their reporting activities. Moreover, even if those data were reported in one of the many electronic systems that the trust uses, participants stated that the lack of interoperability makes it impossible to effectively collect relevant information.

Although the feasibility study identified challenges in the usability of the preliminary reporting form in clinical practice, it was mostly due to the shortcomings of data available to the TVNs. The participants found the reporting form clear, comprehensible, and with a logical flow. If changes in nurse practices were implemented and supported by procurement and IT departments, recording device data could be much easier and as a result - available for reporting. This change should also be supported by manufactures who could enable automatic recording of devices through e.g., improving MD packaging and provision of self-adhesive labels (with the device information/ barcode) that can be easily put into nursing documentation or scanned directly to an electronic patient file.

The main limitation of this study was relying on paper copies of the MDRPU reporting form. Most of nursing documentation has moved into electronic systems and completing a paper form might not reflect current practice. Moreover, completing the MDRPU reporting form may have been burdensome on the TVNs, since they had to remember to take the form with them when reviewing a patient case. Subsequently, for the future it would be beneficial if the form became an extension to an incident reporting form (such as Datix) which is completed online. Additionally, it might reduce the volume of data that would have to be transcribed from patient notes into the report and minimise duplication.

The approach to conducting this research overall worked well. Nonetheless, the online data collection in this study was more time-consuming for the researcher because more preparation had to be made, and the dialogue with the team leaders was asynchronous. This issue was deepened because of the leaders' workloads and priority being patient care. Trust 2 had to reschedule the planned focus group three times due to staff shortages and workload pressures, and although it might be easier to cancel an online meeting (Deakin and Wakefield, 2014), it was clear that such decision had to be made. Admittedly, rescheduling focus groups may be somewhat easier when they are undertaken online and there is no requirement to secure a safe and confidential room on the Trust's premises owing to the tissue viability teams have offices on the premises, which are for their sole use.

7.9 Conclusions

The MDRPU reporting form design was supported by international consensus and pre-testing to assess and improve its usability. The draft reporting form was then piloted in two hospital trusts by corresponding tissue viability teams, to assess and explore the ease of use and feasibility in clinical practice. Although a number of challenges to the form usability and feasibility have been revealed, this study findings are relevant for the future research into changes of nursing and reporting practice, as well as collaboration with manufacturers to enable some of those changes.

Chapter 8 Discussion

8.1 Introduction

Currently, there is no national or international standard for reporting medical device-related pressure ulcers (MDRPUs). Where changes have been made, for example, the UK prevalence reporting guidelines for pressure ulcers, which includes a requirement for separate recording of the device-related pressure ulcers, no contextual data (e.g. type of device) are included. Internationally, the practice varies between countries, states, and organisations. This doctoral programme of research aimed to create an internationally agreed set of items and develop a form to enable a standardised approach to reporting MDRPUs.

The overall methodology drew on approaches used in relevant research fields where clinical reporting tools have been established. It consisted of distinct phases, including a narrative review of academic and grey literature on pressure ulcer reporting (Chapter 2), an international qualitative study exploring reporting practice (Chapter 4), a large international consensus study (Chapter 5), cognitive pre-testing of draft reporting form (Chapter 6), and pilot feasibility study in two large acute hospitals in the South of England (Chapter 7). The work was completed over the course of four years, accommodating the challenges associated with the COVID-19 pandemic.

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8.2 Summary of key findings

8.2.1 Narrative review of literature

<u>Aim 1</u>: To review scientific and grey literature pertaining to PU and MDRPU reporting practice, policies, and guidance.

The narrative review synthesised current scientific and grey literature relating to pressure ulcer reporting systems and processes and provided the rationale for the PhD research. The review included 31 sources – 16 journal articles and 15 policy and guidance documents, which identified a variation in reporting practices. It was important to capture not only academic research in this review but also policies and guidance documents to gather a range of evidence to explore and understand reporting of pressure ulcers and especially MDRPUs in healthcare settings. The most appropriate method to synthesise this literature was through a narrative approach.

The narrative synthesis revealed that MDRPUs are often not identified and reported as a separate category from other PUs in local and national reporting systems. Policies relating to patient safety reporting varied across all reporting levels, with the more severe pressure ulcers being reported more consistently. Devices implicated in patient harm are not included in mandatory reporting, nor are they reported to medical device regulatory bodies as a standard. This is despite national efforts to create reporting platforms such as the MAUDE website developed by the FDA (U.S. FDA, 2019).

This narrative review highlighted that the reporting processes in place are inadequate and do not facilitate the collection of meaningful data about MDRPUs. Moreover, the paucity of published literature on MDRPU reporting made it difficult to capture the most critical characteristics of medical devices, which are frequently implicated in patient harm. The review's key recommendation was to establish a standardised data collection tool for reporting MDRPUs. Standardised data collection would enable improvements in the quality of care, improve transparency, and allow data sharing with regulatory agencies and the industry to make necessary changes to improve device design and application guidance. This would make it possible to determine the impact on healthcare systems and systematically collect data on harmful devices.

The narrative literature review underpinned the future research undertaken in the PhD to create a novel tool for the reporting of MDRPUs.

8.2.2 Qualitative exploration of reporting practice

<u>Aim 2:</u> To explore clinicians' experiences of pressure ulcer reporting systems, with emphasis on MDRPUs.

<u>Aim 3</u>: To explore barriers and facilitators to reporting pressure ulcers in practice, with emphasis on MDRPUs

Due to little written evidence about the processes of reporting of MDRPUs in clinical practice and no publications on determinants of reporting practice, an international interview study was undertaken. This study was the first of its kind to explore reporting practices with 17 participants from 11 countries worldwide. This study further confirmed the disparities in reporting of MDRPUs between countries as well as within the countries. Participants agreed that standardised reporting of MDRPUs is necessary to improve the quality of care and facilitate meaningful comparisons between organisations and benchmarking. Moreover, the study explored barriers and facilitators to reporting of MDRPUs and found that education, openness, and teamwork enable reporting. However, factors such as the perception of consequences, knowledge and attitudes, peer

influence, financial disincentives, workload, time, and staffing have a negative impact on clinicians reporting behaviours. This study's findings were significant for further research being undertaken, where barriers and facilitators would need to be addressed to create a meaningful reporting tool, which can be translated into practice. The qualitative findings also confirmed the results of the literature review and guided the design development of the consensus study.

8.2.3 International consensus study

<u>Aim 4</u>: To create an internationally agreed data set which can be used to design a form to facilitate routine and standardised reporting of Medical Device-related Pressure Ulcers (MDRPUs).

The consensus study used a modified Delphi technique based on the RAND/UCLA Appropriateness Method. An international expert group consisting of 75 participants (in round 1 of the consensus process) from 23 countries reviewed the evidence on reporting medical device-related pressure ulcers generated through the narrative literature review (Chapter 2) and the qualitative exploration of reporting practice (Chapter 4). Each participant of the consensus study was asked to make a judgement on a list of relevant items necessary for reporting of MDRPUs. The consensus study consisted of 4 rounds of questionnaires delivered online, with an opportunity in the first two rounds to provide qualitative feedback and suggest new items that could be included in future reporting.

This first-in-kind consensus study enabled a structured and transparent consideration of the initial 36 items (Chapter 5). Consequently, an international agreement on the content of a data set for reporting MDRPUS has been achieved. The agreed data set included thirty items, which were thematically organised and included data about the patient, the medical device-related pressure ulcer, the care related to the pressure ulcer, and data relating to the device that caused the pressure ulcer. This underpinned the draft of the MDRPU reporting form.

8.2.4 Pre-testing of the draft MDRPU reporting form

<u>Aim 5:</u> To assess and improve the usability and acceptability of the Medical Device – Related Pressure Ulcer Reporting Form with its intended end-users using cognitive pre-testing methods.

The draft MDRPU reporting form was underpinned by the consensus study, and the design was influenced by other relevant reporting forms identified through the narrative literature review (Chapter 2). The construction was guided by the item themes as presented in the consensus study (Chapter 5). The draft was then cognitively pre-tested with clinical nurses from critical care and

tissue viability backgrounds to assess and improve its usability and acceptability. These groups of nurses were considered end-users of this reporting form. Hence their experiences of completing them were instrumental in ensuring the reporting form is fit for use. The pre-test used vignettes as simulated patient cases and was undertaken in two cycles, including cognitive interviews using the 'think-aloud' method and focus groups. These pre-testing methods are used in health measurement instruments' testing and allow the participant to address a real-life case scenario. As such, the researcher was able to identify any shortcomings in the style or language used and modify the form accordingly. Changes to the draft MDRPU reporting form were made after each cycle. The key changes made during this pre-test study related to the content, language and wording of specific items. As a result, the form was further developed and improved in preparation for piloting in clinical practice. This was a critical component of the research since it directly addressed the aim of this doctoral programme of research.

8.2.5 Pilot feasibility of the MDRPU reporting form

Aim 6: To assess the usability and feasibility of a Medical Device Related Pressure Ulcer (MDRPU) reporting form, derived from an internationally agreed Data Set, in clinical practice.

In this study, the MDRPU reporting form was used in practice in two large acute hospitals in the South of England. The study was approved by institutional (ERGO 2 64253) and HRA ethics (21/HRA/4099) and tissue viability nurses were recruited to use the new MDRPU reporting form alongside their routine practice. Using an exploratory mixed-method approach, the general usability and feasibility of the reporting form were investigated. The results revealed that the reporting form was easy to follow and comprehend. However, the completion of the form was challenging due to the quality of nursing records and the lack of routine recording of medical device data. Currently, the MDRPU reporting form completion in current practice was found to have compromised usability and feasibility. Nevertheless, systemic changes to clinical practice, supported by information technology, and working with manufacturers to allow easy recording of devices, may have a positive impact on the usability and feasibility of standardised MDRPU reporting.

8.2.6 Summary of original findings

- The first international investigation of MDRPU reporting practice was undertaken.
- The mixed methods approach enabled the exploration of barriers and facilitators to reporting MDRPUs with experienced international participants from clinical practice, academia and industry.

- Subsequently, one of the largest international consensus studies in the field of pressure ulcers was conducted to create a novel data set for reporting MDRPUs.
- A first-in-kind MDRPU reporting form was developed, drawing upon rigorous principles of health measurement instruments development methodology.
- The MDRPU reporting form content validity was confirmed by the clinical nurses in the cognitive pre-testing of the MDRPU reporting form.
- Pilot testing of the MDRPU reporting form was completed in two large university hospital trusts where face validity was confirmed.
- A number of barriers to the MDRPU reporting form completion were also identified, compromising feasibility where the unavailability of data was a significant factor.

8.3 Contribution to the knowledge

In the last decade, reporting of Medical Device-Related Pressure Ulcers has become more prominent in the field of tissue viability, following seminal papers highlighting their high prevalence and incidence (Black et al., 2010). Yet to date, little is known about the true burden of those wounds and the medical devices that cause them.

The literature review established that clinicians do not routinely report medical device-related pressure ulcers (Chapter 2). When the MDRPUs are included in the overall pressure ulcer numbers reported on the local and national levels, no details relating to the devices implicated in patient harm are recorded. Although pressure ulcer rates (including MDRPU data) are used as a proxy measure of nursing care quality and safety of care (Gunningberg et al., 2008), not collecting data relating directly to the main risk factor, namely the use of the medical device, renders the data limited. The primary aim of this thesis was to establish an international consensus on the catalogue of items relevant and necessary for reporting MDRPUs and design a data collection form which could be used in clinical practice. The novelty of this thesis is the approach taken, where to systematically develop a reporting tool, methodologies used for developing health measurement instruments were drawn upon (Chapter 3). To the researcher's knowledge, this approach has not been used for reporting form development. Consequently, a robust, incremental, and critical approach was taken to arrive at the thesis aim (Figure 8.1).

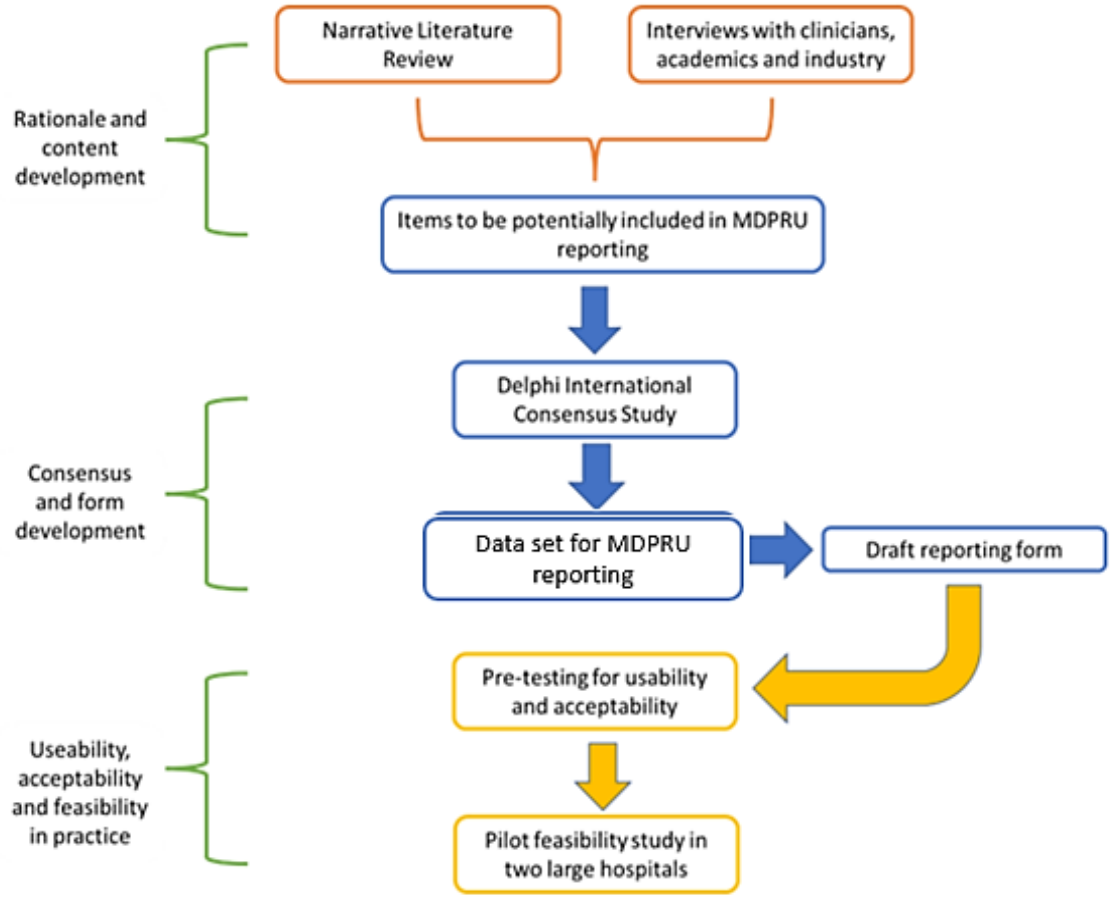

Figure 8.1 Process of the doctoral programme of research.

The narrative review gave a limited picture of the MDRPU reporting practice. Hence a qualitative study (Chapter 4) incorporating views of clinicians and researchers from countries worldwide was undertaken. The findings of this study enhanced the understanding of what, how, and to whom the MDRPUs are reported. Joining the literature review results and the qualitative study also facilitated a better understanding of how the reporting practices have evolved in different countries and what the differences and similarities were. Overall, there is still an overwhelming disparity in pressure ulcer data collection within and in-between countries, despite the policy drive to improve quality of care (Coleman et al., 2016b, Jackson et al., 2016). Moreover, the practice also differs between public and private, and acute and long term settings (section 4.3.1.1). Reporting of MDRPUs is not mandatory in all healthcare settings, and where it is, the data collection does not include specific information about the medical device beyond the name of the manufacturer. Furthermore, MDRPU incident reports with associated device information are not routinely forwarded to medical devices regulatory bodies, such as U.S. FDA or UK MHRA. The perception is that the regulatory bodies are ineffective in dealing with reports (Jewett and de Marco, 2019). Yet unless there is standardised and routine reporting withing healthcare

organisations, supported by policy changes regarding sharing data, those institutions are limited in what influence they may have over device manufacturers.

To the researcher's knowledge this is the first study to explore factors affecting MDRPU reporting. The results showed that the fear of potential consequences may have negative impact of reporting practice, and there is a need for a clear policy and guidelines for reporting those wounds to provide support to the staff. Moreover, to motivate staff to report MDRPU incidents, the impact should be clearly visible and feedback given.

The qualitative study data provided a list of 29 potential items for MDRPU reporting (see Table 4.4), which underpinned the subsequent consensus study (Chapter 5) survey questions. The majority of those items were not identified from the literature review, and included contextual data about the patient health status, potential effects of the MDRPU, data about the ulcer, and data about the device including name and manufacturer, application's date and preventive measures in place. Indeed, as far as the researcher is aware, this was the first attempt to collate a list of items that clinicians would find useful in MDRPU reporting.

The consensus study was a structured process and informed by evidence. It allowed 75 experts from 23 countries (from Europe, North and South America, Asia, Australia and New Zealand), to express their judgement about what should be routinely reported about MDRPUs. The remote design of the consensus study enabled participants from all over the world to take part, which was crucial for a couple of reasons. Firstly, the tissue viability community is small and opening the participation to clinicians wherever they might be located may positively impact the validity and reliability of findings (Boulkedid et al., 2011, Kezar and Maxey, 2016, Raine et al., 2005). Secondly, experts that took part in the consensus process might be a driving force in their own countries (Fink et al., 1984) to implement the standardised and routine reporting of MDRPUs as agreed. As a result, when MDRPU data are routinely collected in a standardised way and available from different healthcare systems and organisations, this may strengthen the arguments for improvement in MDRPUs prevention, care, and device improvements.

The consensus study established a list of 30 items relevant and necessary for inclusion in a standardised routine reporting of MDRPUs. Some experts warned about the number of items and suggested limiting those, which was relayed to the entire panel in the final round of consensus. Despite this, the expert panel did not further limit the items list.

The number of the items agreed for inclusion in the reporting of MDRPUs can be perceived as a drawback of an all-remote consensus process. This remote process allowed for including participants who otherwise would not be able to take part to give their opinion and judgement

(Holliday and Robotin, 2010, Powell, 2003). Conversely, the lack of face-to-face interactions potentially disallowed discussion over unclear and contentious items and clarified which are the core items necessary to include in routine reporting (Coleman et al., 2014a). For example, some medical device data items did not reach a consensus for inclusion nor were eliminated from the list of items by the panel. Having the opportunity to carefully consider arguments for the inclusion of those items and discuss what the hesitations may have been, may have led to increased consensus and different outcomes. The qualitative comments given indicated clearly that the experts were concerned about the feasibility of collecting those data rather than not agreeing / disagreeing on the importance of their inclusion. It is well documented, that staff experience documentation fatigue (Hall et al., 2016, Senek et al., 2020, UK Parliment House of Commons, 2021).

One criticism of the MRDRPU reporting form identified in the feasibility study was that it was too long and involved duplication of already collected data. However, if the form was integrated into an electronic reporting system, some of the data (e.g. data relating to the patient and their medical state) could possibly be omitted and instead transferred from the main patient record. Additionally, the current incident reporting system could be enhanced so that if the incident involved a medical device, additional fields would automatically be generated for completion. Integrating the MDRPU reporting form into the existing reporting system would allow easier access to data and instantaneous feedback. NHS trusts operate several reporting systems, which also may vary between organisations (e.g., using Datix and Ulysses for reporting incidents). Creating a universal recording and reporting system would be challenging, nonetheless healthcare is moving towards digitalisation (Cummins and Schuller, 2020) and the Covid-19 pandemic highlighted the need for updates to the clinical care delivery systems and digital technologies used in healthcare (Keesara et al., 2020). Moreover, to improve reporting and lessen the burden of reporting, duplication and coordination of reporting systems should be improved, with ideally only one system in place which should be then accessible to different stakeholders (Pronovost et al., 2008).

The cognitive pre-testing with a group of end users as well as clinicians responsible for reporting and policy-making, using vignettes as case studies to complete the MDRPU report using the draft form, confirmed its face and content validity (Chapter 6). Participants in this study found the form to have a logical flow, and some items were adjusted to align vocabulary to what is used in clinical practice. Three items have been removed from the form (Chapter 6, table 6.2), two due to their speculative nature (what material the medical device was made of, short term effect on patient care), and one (off label use) was found to be unfamiliar to nurses, since they would not use a device against its prescription. Despite those improvements, the results from the pilot study

where the form was tested in clinical practice (Chapter 7) have shown that the proposed form's feasibility is compromised and requires further consideration.

The main concern for the proposed reporting form development was making it as easy as possible to complete. Throughout the programme of research, the participants highlighted this requirement at each stage. Similar to other research (Ball et al., 2014, Senek et al., 2020, UK Parliment House of Commons, 2021) it was found that workload and time constraints were important barriers to reporting being completed by the ward nurses. However, during the piloting of the proposed form, it was established that the tissue viability nurses were also unable to complete the form in the time allocated to them for making an individual report. This was caused by the information regarding a number of items on the reporting form not being easily accessible and requiring time and effort to locate.

Another well-known issue identified in the literature is the poor quality of nursing documentation, where data relating to skin care, prevention and device use are often not recorded by ward nurses in routine clinical practice. This would need to improve to facilitate and enhance MDRPU incident reporting. However, it is clear that with the pressures widely described in the literature (Recio-Saucedo et al., 2018, Harvey et al., 2020, Ball et al., 2014) there has to be a systemic change to facilitate and support the recording of the data relating to MDRPUs and especially MDs by the bedside nurses who are engaged with the patient care on a daily basis.

Despite the majority of the devices not being recorded in patient notes, there are some medical devices which indeed are documented. For example, catheters have the barcode taken from the packaging and applied directly to patient notes. Tissue viability nurses reported that if such a possibility were extended to all medical devices, that would enable easy and timely recording of devices dispensed and applied to the patient. Using barcodes can improve patient safety through a more accurate and complete data collection and reduce manual workload of recording devices in organisations' databases and reporting systems (Morocutti et al., 2002).

Nonetheless, such change would have to involve a universal change in how the medical devices are packaged (to include a barcode and/or a peel-off barcode), procurement systems which hold a database of available (purchased) devices in the organisation, and clinical practice, where the nurses are aware of the practice of logging devices. Since organisations are moving away from paper-based records, scanning barcodes straight to electronic patient records should also be considered to facilitate and ease nursing practice. Another area that might be explored is asset tagging using a radio frequency identification (RFID), where radio signals are used to access data stored on a MD tag and does not require barcode scanners (Fritzsche et al., 2020). The RFID system was found to enable medical staff to efficiently and accurately locate and record medical

devices (Tsai et al., 2019). However, the issue of the lack of interoperability of hospital electronic systems needs to be addressed. The ability to easily move information from one electronic application to another and select relevant information for the specific report would save time, limit data duplication, lead to more effective reporting, and minimise reporting burden (Pronovost et al., 2008).

The change has to also involve the institution's procurement database. Once medical devices are ordered and delivered to the site, they have to be registered (recorded) in such a way that the nursing reporting systems have access to the stock data. As we know, different units and wards use different devices, and some will utilise a broader range of devices than others (e.g. general wards vs critical care). Hence there needs to be a targeted list of medical devices for specific wards or units. This would also facilitate easier reporting of the devices of interest with the manufacturer's data (such as a name) would be automatically populated. If, at the same time, improvements in recording of the devices by ward staff are in place, then collecting data during reporting should be much improved because it would not involve making a judgement call by the reported on what medical device might have caused the MDRPU.

There is uncertainty over how the incident reports impact clinical practice and whether they are used for clinical benefit (Revere et al., 2017). This research found that transparency from the healthcare organisations and national agencies is necessary to show that the reports do in fact lead to changes and acts as a facilitator to reporting (Chapter 4). MDRPU data needs to be analysed and translated into safety and quality improvement initiatives, and the procurement departments need to be responsive to data on devices that cause MDRPUs. Although cost can be a barrier to purchasing more advanced, newer and better-designed devices, it is possible that by doing so, the incidents of MDRPUs will be reduced. Furthermore, ensuring clinical staff are aware that incident reporting can lead to improvements in patient care, as well as ensuring feedback mechanisms are in place, are necessary (Health Quality Ontario, 2017, Rashed and Hamdan, 2019).

8.4 Strengths and limitations

The main strength of this doctoral programme of research is the development of an original MDRPU reporting form underpinned by an international consensus on its content. The MDRPU reporting form is novel and unique because it was developed through the use of systematically acquired evidence and data from around the world. The well-established methodologies employed to develop patient health status and quality of life instruments and patient-reported outcome measures (Mokkink et al., 2010, Reeve et al., 2013, U.S. FDA., 2009, Lohr, 2002), are not

usually used for reporting form development. Anchoring the proposed MDRPU reporting form in research data and developing it in a sequential manner, ensures its robustness and validity. Involving international stakeholders in the first two studies (qualitative exploration of reporting practice – Chapter 4 and consensus study – Chapter 5), which laid the ground for the content of the form, can further facilitate uptake of the agreed data set (items), and thus the implementation of standardised reporting of MDRPUs worldwide. Moreover, a pilot study (presented in Chapter 7) examined the feasibility and usability of the proposed reporting form and explored barriers and facilitators to its use in clinical practice. This enables targeted research into refining the reporting form and improving the capabilities and resources in readiness for more widescale adoption.

The limitations of this programme of research are concerned with the paucity of academic literature on reporting PUs and MDRPUs. The researcher aimed to balance this issue by including grey literature. However, this resulted in the inability to undertake a quality appraisal of included publications. To offset this issue the international qualitative study was designed and completed, aiming to enrich and validate the findings of the narrative review.

Another limitation is concerned with selection bias. Although the aim was to reach as widely as possible, international wound care organisations were targeted to identify participants for the qualitative study and then subsequently for the consensus study. Members of those organisations are predominantly English language speaking and probably affluent since they had to be able to participate in online data collection, which requires access to a computer and an internet connection. This means an exclusion of a vast population of experts and researchers interested in MDRPU reporting improvement who would not participate due to language and connectivity barriers. It is also likely that they were unaware that such research was actually undertaken. And although some participants represented the low- and middle-income countries in both of the studies (Table 4.3 and Table 5.8), there might be further issues (e.g., relating to access to medical devices) in different countries of this group, that were not explored due to the recruitment design and methods.

The consensus process developed and conducted in this programme of research was undertaken rigorously. Nonetheless, there are limitations that have to be acknowledged. Although consensus methods drawn upon provided a structured process underpinned by evidence to enable valid decisions to be made, in fact, it is difficult to establish the validity of the judgement at the time of it being made (Black et al., 1999). Equally, it might be questioned whether the opinions of the experts that took part in the consensus study are representative of other experts in the field (Raine et al., 2005), even though the literature suggests that a larger expert panel is more likely to

represent all stakeholder groups interested in the study results (Kezar and Maxey, 2016) and produces more reliable results (Raine et al., 2005). Additionally, although using a purely remote approach to conducting the consensus process meant no limitation to the geographical spread of the participating experts and the inclusion of a large sample, it also meant that a face-to-face meeting was impossible to organise. As a result, the areas of the lack of agreement between the experts could not be discussed to arrive at a decision on the inclusion or exclusion of certain items. Consequently, the researcher put forward the 'uncertain' items for inclusion in the draft MDRPU reporting form so that the pre-testing and feasibility study results could validate whether they should and could be reported on.

The reporting form itself and the statements herein included were designed by the researcher based on other reporting forms (see Chapter 2). Cognitive pre-testing of the draft form was considered a rational next step in ensuring the content validity and usability of the form, despite the vignette method being considered somewhat artificial (Bradbury-Jones et al., 2014). Undertaking the pre-test ensured that the form was designed as well as it could for piloting in clinical practice by tissue viability nurses.

The consensus study, cognitive pre-testing, and pilot feasibility study were significantly impacted by the Covid-19 pandemic pressures on nursing teams. The final two rounds of the consensus study were undertaken when the pandemic was first identified. It is likely that the participants' dropout was associated with this since the vast majority of experts were practising clinicians. At that point in time, they had to prioritise their clinical work over research.

Undertaking a research study during a pandemic is challenging when the population involved are nursing staff. With all the guidance and precautions in place, the researcher made an effort to design the form pre-testing study to be completed remotely. It was paramount to develop a strong working relationship with the gatekeeper of the organisation the participants were recruited from. They were able to identify potential participants and offer a link to them. Without this endorsement, recruitment would be lengthy and difficult. It is plausible, however, that this selection bias that was introduced through recruiting from a pressure ulcer working group had an impact on the results of the study. A different recruitment strategy might have included participants with different experiences, possibly less engaged in research and influencing policy. Nonetheless, the target groups being similar would be expected to, in general, produce similar comments and feedback as they share knowledge and experience relating to MDRPUs and reporting as a part of their practice.

Another problem relating to recruitment was the coordination of arranging focus groups. As it is widely accepted, the ideal focus group size is between 5 and 8 participants (Krueger and Casey,

2000), and the aim of this type of interview is to stimulate discussion about the topic of interest (Krueger and Casey, 2015). As a result of the anticipated issues with recruitment and arranging a day and time suitable to all, it was decided that triads will be arranged if required. Indeed, all three focus groups were set up as triads. Regrettably, in the final group, one of the participants suddenly dropped out without any time given to arrange a replacement for them. Fortunately, throughout all three focus groups, participants were engaged in the discussions, and rich data were collected.

Although the majority of this programme of research was completed during the pandemic, the feasibility pilot study was difficult to undertake due to restrictions put in place by the NHS Trusts and the deployment of tissue viability nurses into other areas of clinical care. As a result, the study start was delayed and communication with the teams was more challenging than it would be in normal circumstances. Arranging focus groups with each of the teams was problematic, as it was difficult to gather the whole team at the same place and time for discussions. Nevertheless, there was a true understanding of the value of this research withing the tissue viability team and the researcher was committed to supporting the TVNs and facilitating data collection. Despite the administrative burden, data were collected as planned, and the issues provided further insight into the usability and feasibility of the proposed MDRPU reporting form.

8.5 Implications for practice

The presented programme of research puts forward a change in practice can be seen as profound, and will hinge on health care professionals, especially nurses knowledge and skills. It has been proposed that any clinician should possess core competencies to deliver patient-centred care within a multidisciplinary team, where the practice is underpinned by evidence, quality improvement approaches, and use of technologies (Institute of Medicine (US) Committee on the Health Professions Education Summit, 2003). All strands of the presented research subscribe to this vision.

The MDRPU reporting form was developed in a novel way and enables the collection of data relating not only to the pressure ulcer itself but also to the medical device that caused the skin damage. It has been developed to be used in clinical practice for any patient population. However, it might have to be tailored to use in specific patient groups, for example neonates, where the devices and their attachment methods are often bespoke to the patient. The form is underpinned by the most current evidence base and the knowledge, experience, and views of experts and clinicians in the field of wound care and tissue viability. As a result, this first-of-its-kind form has improved content and face validity.

To date, healthcare organisations do not routinely collect standardised data on MDRPU incidents. Pressure ulcer rates are used as a proxy measurement of the quality and safety of nursing care, and the MDRPU reporting form captures the patient medical state, nursing preventative interventions and care, but also details of medical devices and care relating to its application. Thus data collected using the MDRPU reporting form gives a more complete picture of each of the reported MDRPU incident. This will allow to better understand factors contributing to MDRPU development and therefore with the potential to improve practice, prevention, and education. It will also enable identification of devices which would benefit from improved design.

Separating the medical device data from pressure ulcer data recognises that there is another element in the MDRPU development – the device itself and that oftentimes regardless of the prevention put in place by the clinical team, this might be the main contributing factor. Implementing the proposed MDRPU reporting form would allow an insight into the true burden of those pressure ulcers and enable a better understanding of which devices that are commonly used in patient care would benefit from design or material improvements. It is imperative to remember that it is not only the direct cost of treatment and management of MDRPUs, but those wounds have a real physical and psychological impact on patients, as mentioned in Chapter 1, section 1.5. Being able to collect routinely a standardised data set relating to MDRPUs would also facilitate cooperation with device regulatory bodies, and thus open a communication channel with device manufacturers aiming to identify which devices are no longer fit for purpose.

Moreover, the MDRPU reporting form novelty also comes with the inclusion of recording patient's skin tone. Collecting those data might inform MDRPU prevention in the dark skin patient population, since those data are not routinely collected in practice.

Another positive change that could be achieved by implementation of the MDRPU reporting form is the improved ability to compare and benchmark healthcare organisations. Currently, the variation between organisations, states, and countries exists (see Chapter 2) which precludes any meaningful comparisons and hence sharing good practices in the area on MDRPU prevention and treatment. It can also address the challenge associated with different devices being used around the world and different nursing practice. Furthermore, wide implementation of the MDRPU reporting form in routine practice would allow for a more standardised means of procuring the most safe devices and creating common learning for how to attach and monitor them in-situ to prevent skin damage (Gefen et al., 2022).

The MDRPU reporting form could be integrated to the standard reporting that is currently in place in healthcare organisations. In the UK NHS, where any MDRPU is identified for the national reporting (NHS Improvement, 2018), it could be an extension to the electronic incident reporting

generated if the reporter identifies the pressure ulcer as medical device – related. Furthermore, introduction of new technologies such as FRID (discussed in section 8.3) would lead to more efficient and effective recording of devices, availability of relevant data, without undue burden on clinical staff.

8.6 Future research

The pilot study was undertaken with local teams in acute hospitals to establish the feasibility of the reporting form. There is, however, scope to test the form's content validity and feasibility in other settings (e.g. community), nationally and internationally (in different healthcare systems). This would facilitate adoption of the reporting form, resulting in the collection of data that could be pooled and evidence used to inform prospective development of a registry of MDRPUs. It would enable shared learning and improvements in patient safety, as well as to support collaboration with medical device manufacturers. This approach has been shown to create improvements in practice at both a national and international level through reporting e.g. National Joint Registry (NJR) for orthopaedic devices (Porter et al., 2019).

The development of the MDRPU reporting form uncovered complexities of implementation in clinical practice (Chapter 7). The issue which needs addressing is the number of items included in the reporting form. This matter was not addressed by the consensus study. However, as discussed above, to ensure the form is usable and not adding to the reporting fatigue, refinement of the content of the form is required. Following from this, a the MDRPU reporting form should be tested in a large sample of trusts and patient populations, as well as the community setting, to confirm its feasibility. Using the form as a standard ensuring it is usable and brings benefits to the practice, as examined above in section 8.5, would require changes encompassing policy, guidance, standard procedures, and practice. Nevertheless, owing to diversity and complexities of healthcare systems it is likely that the content of the data set will have to be adjusted to suit each of the settings. The aim would be to decide which data elements are the core 'must haves' and which elements could be considered to be reported voluntarily if there was a scope to do so. Gathering even limited data on MDRPUs and devices would enable progress in the field, and this process could be further supported by additional techniques, such as root cause analysis.

Using a theoretical underpinning, such as Grol and Wensing (2013) Implementation of Change Model, the MDRPU reporting form should be further evaluated in practice as a complex intervention (MRC, 2018). This evaluation should take into account the barriers and facilitators to reporting as demonstrated in Chapter 4, carefully consider the research design, and the choice of methods. Furthermore, health systems would need to review their existing practice against the

data set so it can be appropriately integrated into their systems and avoid duplication that may hamper implementation. The IT systems should also be made compatible to reduce the data duplication burden and improvements allowing the use of new technologies (such as asset tagging) should be made.

8.7 Conclusion

This programme of research resulted in a first in kin MDRPU reporting form, addressing a clear gap identified through the current scientific and grey literature. It has taken a standardised sequential approach to systematically collect evidence, explore practice, define barriers and facilitators to reporting and build an international consensus about what data should be reported for any MDRPU incident. A draft reporting form was evaluated through cognitively pre-testing, and pilot feasibility study with tissue viability nurses (the envisaged end- users in the UK NHS). This work makes a substantive contribution to the field of tissue viability and is first to draw from wider instrument development methodologies to establish a MDRPU reporting form.

The proposed MDRPU reporting form now requires further refinement and evaluation in different settings and healthcare systems to further assess its reliability and usability. Following from this, a larger implementation study should be undertaken to systematically address all the challenges and changes required for the standardised reporting to be implemented through policy and guidance. This will enable close collaboration between healthcare providers, regulatory agencies and industry to improve the prevention of these wounds and improve patient care.

Dissemination

Results of research described in this Thesis has been presented at:

1) EPUAP 2021 Virtual Meeting "**Defining a Data Set for Reporting Medical Device-related Pressure Ulcers**" (18-19 October 2021) – Oral presentation awarded Best Oral (Free Paper) Presentation.
2) Tissue Viability Society 2021 Conference "**Working towards consensus in reporting Medical Device-Related Pressure Ulcers**" (24 September 2021) – Oral presentation.
3) EPUAP 2021 Virtual Meeting "**We don't have a problem here. International perspective on reporting Medical Device-Related Pressure Ulcers**" (18-19 October 2021) – Poster presentation
4) EPUAP 2022 Annual Meeting "**Development of a reporting tool for Medical Device Related Pressure Ulcers: Cognitive pre-testing, usability, and feasibility assessment**" (14-16 September 2022) – Oral presentation (presented by Dr Peter Worsley in absentia).

Published manuscripts are listed in the Declaration of Authorship (page **xiii**).

Planned publications:

1) International consensus study – Chapter 5
2) Pre-test and feasibility pilot of the preliminary MDRPU reporting form – combined Chapters 6 and 7.

Appendix A Search strategy

Databases searched included: CINAHL Plus with Full Text (Ebsco), Medline (Ebsco), EMBASE Classic + Embase 1947-2021 wk2 (Ovid), PubMed, Web of Science Cole Collection, and ProQuest Dissertation and Theses A&I.

1) report*
2) polic*
3) procedure*
4) document*
5) guid*
6) OR/ 1-4
7) “pressure ulcer*”
8) “pressure injur*”
9) bedsore*
10) decubit*
11) “pressure sore*”
12) “deep tissue injur*"
13) "bed sore"
14) OR/6-12
15) 5 AND 13

Appendix B Qualitative study interview topic guide

Setting the scene: Now that we've discussed the general intent of the study with informed consent, let's get started with the questions. Let me pre-empt that with saying that we're completely neutral when it comes to your answers and we come from a place of genuine curiosity. Every person has his/her own opinions and values things differently, and we would like to hear yours.

Please be assured your participation is confidential and you have the right to stop the interview without giving me any reasons, and at any point of our conversation. If you do not want your interview to be included in the data analysis, please contact me via email and I will destroy on relevant information.

Collect data regarding occupation, length of employment in the position, and country.

Questions:

1. **Can you tell me about your experiences of reporting PUs?**
2. **What systems do you have to interact with when reporting PUs?**
3. **Can you describe the process as you see it?**
4. **Are MDRPUs included in the reporting?**
5. **Are they reported separately in the numbers?**
6. **Have you ever reported a device-related harm to a regulatory agency in your country?**
7. **What details do you include in the report of MDRPUs?**
8. **How should those data be used in your opinion?**
9. **In your opinion, what are the main problems in reporting MDRPUs?**
10. **In your opinion, how could we improve MDPRU reporting?**
11. **If you had all the time in the world, what would you think should be reported in relation to MDRPUs?**
12. **What impact do you think it would have if we were better at reporting MDRPUs?**

Industry stakeholders:

Manufacturer or sales representative?

1. **Do you receive any feedback about potential harm MD you offer may have caused?**
2. **Do you think it is/would be beneficial to receive such feedback?**
3. **If you get feedback, what details do you receive?**
4. **If you don't get feedback – what information would you need (to improve your product)?**
5. **Would there be an ideal pathway for such report to reach you?**
6. **How accountable do you think industry should be for reporting and regulating MDRPUs?**
7. **How do you think you could work with clinicians to improve reporting and make safer devices?**

Appendix C Qualitative and consensus study ethical approval

Approved by Faculty Ethics Committee - ERGO II 49718

ERGOII <ERGOII@soton.ac.uk>
Tue 03/09/2019 15:54
To: Ewa Crunden <E.A.Crunden@soton.ac.uk>

Approved by Faculty Ethics Committee - ERGO II 49718

ERGO II – Ethics and Research Governance Online https://www.ergo2.soton.ac.uk

Submission ID: 49718
Submission Title: Reporting of Medical Device-Related Pressure Ulcers
Submitter Name: Ewa Crunden

Your submission has now been approved by the Faculty Ethics Committee. You can begin your research unless you are still awaiting any other reviews or conditions of your approval.

Comments:

•

Click here to view the submission

TId: 23011_Email_to_submitter___Approval_from_Faculty_Ethics_committee__cat_B___C_ Id: 189140

eac1g14@soton.ac.uk coordinator

Appendix D Summary evidence provided to experts in the consensus study

Introduction

Prevalence of pressure ulcers (PUs) have been a healthcare quality indicator worldwide. They are universally reported, and metrics are often used for benchmarking and in some countries institutionally acquired PUs can have financial implications. Medical device related pressure ulcers (MDRPUs) have gained recognition over the last decade, with a number of clinical and lab based studies on the topic. As a relatively new area of interest, there is a paucity of studies into these wounds. However, the recent research shows the prevalence and incidence are high, especially in intensive care settings, with some reports revealing they constitute up to 30% of all hospital acquired pressure ulcers. Prior to the forthcoming consensus study, we have conducted a narrative literature review and an interview study, to gather all possible data on reporting MDRPUs. The narrative review enabled us to synthesise documents from a wide spectrum of sources. To enrich the data we were getting from those sources, sixteen experts and/or clinicians in the field of tissue viability (from 11 countries) and one representative of the industry were interviewed. Details of design and methods of those two studies are available for your review in the Appendix. In this document, we will present summary of evidence, regarding the reporting of MDRPUs.

Published academic literature

Databases search returned 29,013 articles, but after the screening process, only 9 focussed on the reporting of device related pressure ulcers criteria. Additional 3 articles were identified through additional search methods. We have also identified 18 policy and guidance documents using Google search engine (see Figure 1). The literature revealed variation and inconsistency in reporting. This is the case not only between countries, but also between organisations within countries. It is, therefore, exceedingly difficult to interpret and compare data between organisations. Moreover, different definitions were reported to be used and the quality of metrics was questioned. To add to this, relying on patient records rather than physical assessment for reporting purposes was highlighted as an issue, because patient records were incomplete, or data were not easily identifiable. The lack of agreement on data collection and reporting methodologies has resulted in data which limits the possibility for a meaningful comparison. At the time of the review, there was lack of national guidance for reporting MDRPUs. Again, there was variation in how those wounds were reported, and medical records were found to have inaccurate or missing data on prevention and skin assessment.

Appendix D

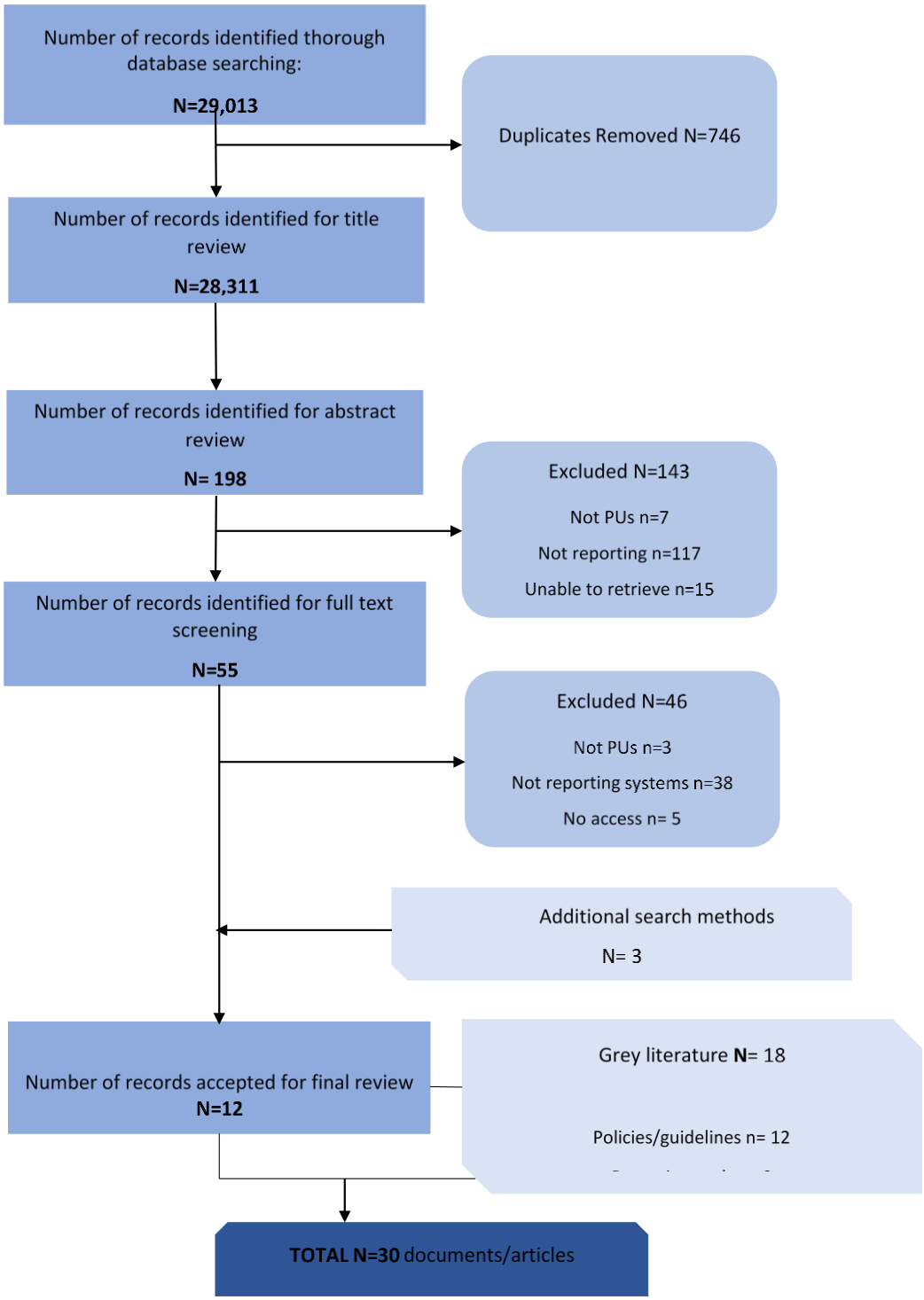

Figure 1 PRISMA flowchart

Polices, guidelines, and guidance – what do they say?

Policies and guidelines which we reviewed were mostly focused on prevention and management of pressure ulcers. The majority were local guidelines and as such reporting was limited specific institutions or regions. There is also a body of policy concentrating on reporting serious incidents and escalation to national reporting systems. Although, in general terms, aims of the reviewed documents were similar – learning and improvement, some were also linked to reimbursement and accreditation. However, what we found is variability in use of staging and definitions, and no standard way of collecting and reporting data. The reviewed documents offered little guidance as

to reporting medical device-related pressure ulcers. Only on an organisational level MDRPUs were recognised as a separate category. Their reporting was limited to attribution to a medical device (MD). Some organisations operate a list of devices in use at the facility, and thus allowing the clinician to select the type of MD implicated in PU development. Most often though, such data is recorded in a free-text box, and as such not standardised.

Reporting practices (Literature and Interviews)

Pressure ulcer status was reported to be universally recorded on patient's admission to the care facility. When a hospital acquired pressure ulcer (HAPU) is identified by a clinician (typically nurse) a report is triggered. Across healthcare organisations interview participants identified differences in how this report is both detailed and escalated. In most cases it is forwarded to the specialist nurses' team, who usually triage patients and attend the most difficult cases. Their involvement ranges from seeing all pressure damage, to seeing patients when they are specifically asked for their input. HAPUs can be classified as a serious incident if they meet specified criteria, typically at category 3 pressure ulcer or above. Those criteria, however, are different in different healthcare systems and countries. There is also some subjectivity when the report is made, since an assessment of severity of the wound is required. Ultimately, the report offers recommendations for improvement. Implementation of those measures were said to be monitored and evaluated to assess improvements. Serious incident data is most often held in a national database, however in some countries they are held locally only.

MDRPUs reporting is a relatively new practice and many countries are still to introduce mandatory reporting of these wounds. Where they are routinely reported, the practice varies between organisations and countries. Some use a coding system on patient file level; some mark a PU as MDR using a yes/no question. Some institutions were found to report MDRPUs separately to other PUs because of the type of the setting, i.e. intensive/critical care. Most of the organisations rely on MD details recorded narratively by a clinician. As such documented details of the device are not standardised. Most frequently found is a record of the device type. Other details include PU location, stage, prevention, and treatment. If the MDRPU is investigated, application of the device, its size, application, and staff competency is reported.

However, these reports are usually kept internally only. Data on devices that are implicated in PU development recurrently might be used by the specialist teams to advise organisation's quality department or similar, as well as a procurement office. The latter may take those data into consideration when purchasing decisions are made, whereas the former was said to send official reports to manufactures. Interestingly, this process may by-pass regulatory agency. It is not certain which department within an organisation is equipped to make such reports to MD regulatory body, and indeed if they are routinely made. Moreover, despite the possibility of directly reporting a MDRPU to a MD regulatory body, as it is possible in many countries, clinicians are unlikely to complete this process. This has been reported to be the case due to unawareness of this being possible, lack of policies for reporting beyond the organisation, but also lack of awareness of the role the MD agencies could play in regulating the manufacturing and use of devices.

Appendix D

Ideal Reporting Practice (Interviews)

During interviews, all participants were asked to consider what they would want to be reported about MDRPUs, if there were no time or financial restraints. Summary of elements discussed are presented in Table 1 below. Those data, in combination with data from the literature review guided the development of the consensus study questionnaire (see also Table 3).

Table 1 Elements of the Minimum Data Set suggested by interview participants

Item	Times mentioned
Device type	10
Manufacturer or Distributor	6
Location of PU	4
Prevention used	3
Regular patient data	3
Type of material used in device	3
Category/stage of PU	3
Exact name of device	3
Effect on patient	3
Clinical issues	2
How long used for/in place	2
Operating Room/Theatre OR Ward	2
Potential effect	2
Size of PU	2
Type of damage	2

NB n=1 for: Application technique; Comfort; Communicated to patient (when possible)?; If MD still in use; If used as prescribed or off label; Indication for use; Other devices in situ?; Patient's response when informed about PU; Photos; Photos after healed; Record of repositioning; Time of finding; When first applied; When the PU occurred

Barriers and facilitators to MDRPU reporting

Our study identified a number of barriers and facilitators to the practice of reporting MDRPUs. They were categorised into four distinct groupings, which are presented in Table 2 below.

Table 2 Barriers and facilitators to reporting of MDRPUs

Determinants of practice DOMAIN	SUBTHEME B – barrier F - facilitator
Individual health professional factors	**(F) education**
	(B) perception of consequences
	(B) knowledge
	(B) attitudes
Professional interactions	**(F) openness & teamwork**
	(B) peer influence
Incentives and resources	**(B) communication**
	(B) financial
	(B) cost-driven procurement
Capacity for organisational change	**(B) workload**
	(B) time
	(B) staffing

Majority of identified barriers are concerned with high level organisation of work. These are not easily modifiable. However, an emphasis was put on the culture of openness, teamwork, peer support, and influence. If open culture were present, the attitudes towards reporting would be more positive. This could drive MDRPU reporting. Nonetheless, recognising different context in which clinicians operate is equally important. How consequences of high HAPU rates are perceived in a healthcare systems where financial penalties are imposed, might be quite different than in healthcare systems which emphasises organisational learning. In conclusion, despite some of the barriers are systemic, how teams and clinicians are educated and/or trained, and what values they present, have an impact on PU and MDRPU reporting.

Summary

Guidance on reporting MDRPUs was inadequately described both in the scientific papers and the grey literature. Where it was offered, it was limited to recording the MDRPU as a subcategory to PU and adding contextual information in a free-text box. In most countries, there is no obligation to report MDRPU and the device implicated to any national database, or in fact to a regulatory authority. In Table 3 below, we presented data reported regarding MDRPUs and medical devices, as found through literature review and interviews with experts. Collecting a high-quality, standardised data on MDRPUs is pivotal for the improvement of quality and safety of care. It has the ability to open a constructive conversation between clinicians, manufacturers, and MD regulatory bodies. Such change may also lead to more openness and less stigma, that clinicians still feel when they report those wounds. Detailed reports of both studies we have discussed in this brief documents are available in Appendices A & B.

Table 3 Items reported regarding MDRPUs in mandatory and voluntary systems – synthesis

	Literature review	**Interviews**
MDRPUs reporting	▪ Category of pressure ulcer ▪ Device type (e.g. tube) ▪ Specific device (e.g. nasogastric tube) ▪ Risk assessment score ▪ Prevention used ▪ Skin assessment under device ▪ Whether staff familiar with the device ▪ Correct size of MD ▪ MD applied according to manufacturer's guidance	▪ Type of device usually recorded in a free text box and not standardised ▪ MDRPU is a sub-category of PU, "select **category** -> "select **MDR** -> **yes/no**" ▪ Location ▪ Stage/category ▪ Prevention ▪ Treatment
MD reporting voluntary systems	▪ Reporter name & address and profession ▪ Patient data ▪ Type of incident/outcome ▪ Pre-existing medical conditions/history ▪ Medical reason for the device use ▪ Brand name or Common device name ▪ Type/intended use ▪ Name OR model number ▪ Serial number OR unique identifier ▪ Batch & lot number ▪ If it was sterile ▪ Reusable ▪ Manufacturer ▪ Supplier ▪ Operator of device ▪ Expiry date ▪ Details of reprocessor[1] ▪ Concomitant products	**No data** – devices implicated in PU development were not reported to MD regulatory authorities by interview participants. **MD** – medical device **MDR** – medical device-related **PU** – pressure ulcer

Disclaimer

Results of the two studies we have presented underpin the consensus (Delphi) study you have agreed to participate in. Please keep the information in this document confidential. When each element is published a publicly available version will be disseminated.

[1] person responsible for cleaning and disinfecting/sterilising of a reusable MD device

Appendix E Consensus study questionnaire Round 1

Round 1 MDRPU reporting consensus study

Thank you for agreeing to participate in this consensus study to agree on a Minimum Data Set (the minimum set of elements that should be used for mandatory data collection) and reporting guideline for Medical Device-Related Pressure Ulcers (MDRPUs).

This study is being undertaken as a part of a PhD programme of research by Ewa Crunden, under the supervision of Professor Lisette Schoonhoven (University Medical Center Utrecht & University of Southampton), Dr Peter Worsley (University of Southampton) and Dr Susanne Coleman (University of Leeds).

We have provided you with an Evidence Synthesis on the policy and practice of reporting Medical Device-Related Pressure Ulcers. This was developed by a narrative review of literature to identify current policy and practice (Appendix A) and a qualitative exploration of medical device-related pressure ulcer reporting practice in 11 countries (Appendix B). This research facilitated a list of potential data items for inclusion in the Minimum Data Set (MDS) and we will seek your views and levels of support for these in this questionnaire. The Delphi (consensus) study will be conducted over three iterative rounds. In this first round we have included a comprehensive list of statements for you to express your views upon. However, we envisage with each following round this number will decrease and the survey will become shorter as consensus of items is reached.

Following completion of the Delphi we will create a reporting tool and guidelines for MDRPU incidents and test this in clinical settings in the UK, using a feasibility design. The tool, guidelines and findings from the feasibility study will be made publically available for use.

There are 68 questions in this survey.

Part 1: Introduction and instructions for use

In the email with the active link to a survey platform, you have received a ***synthesis of evidence*** pertraining to reporting of medical device pressure ulcers (with Appendices). This is to offer you the most up-to-date overview of evidence in the field and support the consensus process.

For the purpose of this research the term ***incident*** is defined as an occurrence of a medical device-related pressure ulcer, regardless of its stage/category.

Please complete the questionnaire by **14th October 2020**. This will allow time for analysis in time for Round 2 of the consensus study.

Format of the Initial Questionnaire

The questionnaire is divided into seven parts:

Part 1 introduces the questionnaire and provides instructions for use

Part 2 provides a summary of medical device use and current issues

Part 3 participants demographic information

Parts 4 - 6 present proposed items for the Minimum Data Set [MDS]:

Part 4: Recording medical device related care (9 items + 1 optional)

Part 5: Reporting Medical Device-Related Pressure Ulcers (19 items + 1 optional)

Part 5A: Medical device-specific reporting (9 items + 1 optional)

Part 5B: Ulcer-specific reporting (8 items + 1 optional)

Part 6: General patient and co-morbidity data (9 items + 1 optional)

Each part will comprise of the following information:

- Statements will have an explanatory text taken from the literature and/or the interviews. The full report of literature review and the interview study can be found in the Appendix A & B of the Evidence Synthesis. You can access any part of the document using the Table of Content, by simply selecting the item of interest.

- Statement regarding inclusion of the proposed items for MDRPU recording for which you are asked to rate your level of support on a 9 point Likert scale (where 1 indicates item is not relevant and 9 indicates the item is very relevant).

- An optional comments box to describe your reasoning and/or suggest changes to the item.

Part 7 offers a comment box to provide further statements and suggest other items to be included in the MDS, which were not identified in the prior literature review of interviews.

N.B. For the purpose of this study, we are concerned with medical devices rather than other devices that may cause a pressure ulcer (i.e. object or product without a medical purpose).

If you have any problems with the survey, or any questions, do not hesitate to email the researcher at: **eac1g14@soton.ac.uk**

Part 2: Summary of medical device use and current issues

Medical devices (MDs) are used for therapeutic and diagnostic purposes. They often need to be secured tightly to maintaing functionality and the materials used to secure the devices may hamper skin inspection (Black et al., 2010, Bader and Worsley, 2018). In some cases medical devices cannot often be moved or removed frequently, exposing the underlying skin to prolonged pressure, humidity, and heat that puts tissue viability at risk. This may lead to the formation of pressure ulcers, which typically form the shape of the device interfacing with the skin. Although many factors are implicated in MD related pressure ulcer (MDRPU) development, specific issues include (Bader et al., 2019, Gefen et al., 2020):

- Devices being based on generic designs and not accommodating patient variability in body size or shape
- Devices employing materials, which are relatively stiff and do not match the vulnerable skin and sub-dermal tissues
- Inadequate guidance on device application
- Individuals' skin and sub-dermal tissues have impaired tolerance to loading associated with e.g. age, malnutrition, neuromuscular compromise, or co-morbidities.
- Lack of clinicians' understanding of the importance of medical devices repositioning, rotation, offloading, and correct fitting.

Although MDPRUs are most prevalent in intensive care (Barakat-Johnson et al., 2017, Barakat-Johnson et al., 2019), they can occur in any setting. Patients managed with medical devices are more likely to develop any pressure ulcer during their hospital stay (Black et al., 2010). Pediatric and neonate patients are acutely vulnerable to MDRPU development, due to skin immaturity and low levels of subcutaneous tissue (García-Molina et al., 2018).

There is a high association between PU development and respiratory devices, regardless of setting. Continuous and bilevel positive airway pressure devices are linked to facial pressure ulcers occurring on the bridge of the nose and/or nasolabial fold (Clay et al., 2018). In newborns mechanical ventilation devices may severely affect nasal cartilage (Gefen et al., 2020). Other devices often implicated in skin harm are endotracheal and nasogastric tubes, oxygen tubing, urinary catheters, cervical collars, and casts (Arnold-Long et al., 2017).

MDRPUs also have negative impact on patients' quality of life and mental health, extending beyond hospital stay, since often patients are left with visible scars and permanent hair loss (Gefen et al., 2020). Notably, many MDRPUs occur on the face or neck, resulting in long term social and psychological trauma associated with scarring.

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Part 3: Participant demographic information

Please complete the participant demographic information: *

Part 4: Recording medical device related care

Please review the presented evidence and provide your support for the statement using the Likert scale.

Further details/evidence can be found in the Evidence Synthesis sent in the email which provided you the link to this survey.

Evidence Summary: Recording data about care related to MD use allows for investigation of a MDRPU incident and developing recommendations to prevent a similar event in similar circumstances occurring in the future. The literature review evidence identified that data on the reason for medical device use, number, and type of devices in-situ should be recorded. In addition, International guidelines (EPUAP, NPUAP, PPPIA, 2019) specify that to prevent MDRPUs, devices should be repositioned, and the use of preventative interventions explored e.g. prophylactic dressings.

Interview evidence: Three participants suggested prevention interventions should be recorded; two said time of the first application should be recorded; one suggested patient's comfort related to MD should be recorded; one suggested recording if staff were trained in MD use.

4.1 Medical reson for the device use is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.2 The number and type of medical devices in situ is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.3 The prevention used (e.g. type of prophylactic dressings) is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.4 A record when a MD was first applied is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.5 A record of device repositioning is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.6 Recording comfort associated with the medical device is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.7 Information whether the Staff were trained to use of the medical device is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: Medical devices may occasionally be used off-label, in a manner not specified by the manufacturer and approved by MD regulatory body.

Interview evidence: "*Products are produced for some reason, but people use it in other indications. So it would be interesting to know how the product is used as it should be used. For the right indications*".

4.8 Whether the MD is used as prescribed or 'off label' is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs.

*

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: Healthcare organisations strive to the culture of openness and transparency, whilst providing patient-centred care. Public have easy access to knowledge relating to health, prevention, and treatment of a wide range of health ailments, including pressure ulcers. Openness towards the patient about their care is important to providing high quality service.

Interview evidence: *"And if a patient is able to communicate, we also should record what the action of the patient and how it was communicated with him or her, because I think in the last few years patients are more and more educated, their health literacy is higher. So they are able to recognize that they were harmed by others or injured by other."*

4.9 Documenting patient communication regarding the MDRPU presence and/or development is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

4.10 Optional comments box to explain your reasoning or to suggest changes to any item in this section as required.

Please, note the question number if you have comments about specific items.

Please write your answer here:

Part 5: Reporting Medical Device Related Pressure Ulcers

Please review the presented evidence and provide your support for the statement using the Likert scale.

Further details/evidence can be found in the Evidence Synthesis sent in the email which provided you the link to this survey.

Evidence Summary: National and international rules of reporting incidents of pressure ulcers and medical device-related pressure ulcers vary. This variation is present also in reporting through to different levels within and outside healthcare institutions. To understand MDRPUs development and their association with devices and to change practice, data needs to be collected in a standardised way, accounting for all categories of ulcers.

Interview evidence: Four participants expressed opinion all MDRPUs (all categories/stages) should be reported through the levels. "*I would say that all pressure ulcers related to devices should be reported, not just stage 3s. The state should examine all medical device related injuries, not just any injury that's a 3 for unstageable or deep tissue. Because I think that's how we start changing practices with data.*"

5.1 Category/stage I MDRPUs reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.2 Category/stage I MDRPUs should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.3 Category/stage II MDRPUs reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.4 Category/stage II MDRPUs should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.5 Category/stage III MDRPUs reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.6 Category/stage III MDRPUs should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.7 Category/stage IV MDRPUs reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.8 Category/stage IV MDRPUs should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.9 Unstageable MDRPUs reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.10 Unstageable MDRPUs should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.11 Mucosal membrane MDRPU reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.12 Mucosal membrane MDRPUs should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.13 Suspected Deep Tissue Injury attributed to MD reporting should be included in the proposed Minimum Data Set *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.14 Suspected Deep Tissue Injury related to a MD should be reported at: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.15 The proposed MDS' purpose is to collect ***incident*** data, would you consider using it to collect regular MDRPU ***prevalence*** data as well?

Please see definition of the terms below:

Incident – unplanned event resulting in an injury or damage; here: any MDRPU occurrence.

Prevalence – proportion of patients with MDRPU on the day of the census.

*

Please choose **only one** of the following:

○ Yes

○ No

5.16 Do you support reporting prevalence on a: *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Unit/department level	○	○	○	○	○	○	○	○	○
Hospital level	○	○	○	○	○	○	○	○	○
National level	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5.17 What would be the ideal frequency of reporting MDRPU prevalence on unit/department level?

Please explain why.

*

Please choose **only one** of the following:

- ○ every week
- ○ every 2 weeks
- ○ monthly
- ○ quarterly
- ○ every 6 months
- ○ yearly
- ○ other - please add comments

Make a comment on your choice here:

5.18 What would be the ideal frequency of reporting MDRPU prevalence on hospital/organisation level?

Please explain why.

*

Please choose **only one** of the following:

- ◯ every week
- ◯ every 2 weeks
- ◯ monthly
- ◯ quarterly
- ◯ every 6 months
- ◯ yearly
- ◯ other - please add comments

Make a comment on your choice here:

5.19 What would be the ideal frequency of reporting MDRPU prevalence on national level?

Please explain why.

*

Please choose **only one** of the following:

- ◯ every week
- ◯ every 2 weeks
- ◯ monthly
- ◯ quarterly
- ◯ every 6 months
- ◯ yearly
- ◯ other - please add comments

Make a comment on your choice here:

5.20 Optional comments box to explain your reasoning or to suggest changes to any item in this section as required.

Please, note the item question if you have comments about specific items.

Please write your answer here:

Part 5a: Medical device-specific reporting

Please review the presented evidence and provide your support for the statement using the Likert scale.

Further details/evidence can be found in the Evidence Synthesis sent in the email which provided you the link to this survey.

Evidence Summary: Medical Device regulatory bodies' e.g. MHRA or FDA, provide voluntary reporting systems to collect a range of data relating to the device information and characteristics to ascertain the right device is investigated.

Interview evidence: three participants suggested recording what material the device is made of is important, and one participant suggested recording if the device is still in-situ when the incident report is complied.

5A.1 The type of MD is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.2 The name of the manufacturer or distributor is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.3 The exact name/product number of the MD is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.4 Recording if the device was single use or reusable is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.5 Recording expiry date of the device is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.6 Recording the device was sterile is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.7 Recording the batch & lot number is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.8 If the MD is still in place is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.9 The type of material the MD is made of is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5A.10 Optional comments box to explain your reasoning or to suggest changes to any item in this section as required.

Please, note the question number if you have comments about specific items.

Please write your answer here:

Part 5b: Ulcer specific reporting

Please review the presented evidence and provide your support for the statement using the Likert scale.

Further details/evidence can be found in the Evidence Synthesis sent in the email which provided you the link to this survey.

Interview Evidence: Interview participants suggested the same data should be reported on MDRPU as it is reported on the 'traditional' pressure ulcers. Two participants suggested taking photographs of the MDRPU and after the wound healed should be included in reports; "*I would also send [a photograph] how it looks like once it's healed. Because too many people, especially in paediatrics they always say I don't know what the big deal is because kids heal quickly. Kids scar, and they have lifelong scars that's a big deal*"

5B.1 The body site where the MDRPU is located is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5B.2 Size of the MDRPU is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5B.3 The date and time of finding the MDRPU is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5B.4 Including photographs of the MDRPU is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5B.5 Including photographs **after** the MDRPU healed is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: Some clinical settings are more associated with MDRPUs than others, for example Intensive Care Units.

Interview evidence: two participants suggested reporting where (physical location of the patient) the MDRPU was first found was important.

5B.6 The environment (i.e. Ward OR theatre location) in which the MDRPU was first observed is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	◯	◯	◯	◯	◯	◯	◯	◯	◯

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: In some cases device related pressure ulcers stop the intervention of monitoring from being delivered effectively, thus requiring a change in medical management.

5B.7 The short-term effect of the MDRPU on current patient care is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs
*

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: Many MDRPUs occur on the face and neck with long term social and psychological consequence.

Interview evidence: *"What is the effect on the patient of that pressure ulcer, if the pressure ulcer is on the nose and half the nose is intact, but there is a wound and there will be a scar and it's a baby, I guess the effect is not the same. What will be the consequence of the pressure ulcer?"*

5B.8 Potential longer term consequence of the MDRPU on the patient is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs
*

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

5B.9 Optional comments box to explain your reasoning or to suggest changes to any item in this section as required.

Please, note the question number if you have comments about specific items.

Please write your answer here:

Part 6: General patient and co-morbidity data

Please review the presented evidence and provide your support for the statement using the Likert scale.

Further details/evidence can be found in the Evidence Synthesis sent in the email which provided you the link to this survey.

Evidence Summary: Pressure Ulcers are influenced by both intrinsic (e.g. age, nutrition status) and extrinsic factors (pressure, shear, moisture). Therefore the inclusion of patient data is highly relevant to the potential cause of the device related pressure ulcer.

Acuity of illness which influences perfusion and sensation may be associated with the risk of developing MDRPUs.

Interview evidence: *"Characteristics of the patient too because some devices can hurt one kind of patient, but not other. Like the weight of the patient."*

6.1 Patient's age is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.2 Patient's gender is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.3 Patient's weight is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.4 Patient's nutritional status is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.5 Patient's primary diagnosis is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.6 Patient's co-morbidities are relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: Risk assessment scales are typically used to monitor pressure ulcer risk e.g. Waterlow, Braden, PURPOSE-T or Norton Scale

6.7 Pressure Ulcer Risk Assessment score is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.8 Skin assessment is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

Evidence Summary: In practice it is sometimes difficult to position a patient off a device, for example tubing can get trapped under the patient. Repositioning of the patient allows for skin assessment and prevents skin damage from occurring.

Interview evidence: *"If the patient is on top of the device, I would question how long this patient is on the top of the device without changing the position. Because it's not only the device but also the position, repositioning of the patient that was missed. Because if you change you can see the device, and you can see the skin before the harm would have been too bad."*

6.9 When the patient was last repositioned is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs *

Please choose the appropriate response for each item:

	1	2	3	4	5	6	7	8	9
Your rating for the statement	○	○	○	○	○	○	○	○	○

1 = strongly disagree/not relevant

5 = neutral

9 = strongly agree/relevant

6.10 Optional comments box to explain your reasoning or to suggest changes to any item in this section as required.

Please, note the question number if you have comments about specific items.

Please write your answer here:

Part 7: Other items

7.1 Could you provide further statements and/or suggest other proposed items to be included in the MDS?

Please, could you also briefly explain why the item(s) is/are relevant in your view.

If you have nothing to add, just type 'N/a' *

Please write your answer here:

Thank you for taking part in the Round 1 of the consensus study to elicit elements of minimum data set for reporting of medical device-related pressure ulcers.

Your responses will now be analysed. You will receive Round 2 questionnaire in approximately 3-4 weeks. It will present the items and your scores, and summarise the support given by the panel. We will also present any modifications to items. You will be then asked to reconsider your scores. In the meantime, if you have any questions, please do not hesitate to contact the researcher via email eac1g14@soton.ac.uk.

Thank you for your time and expertise!

Appendix F Example of a report from the consensus study round

Introduction

Seventy-five experts who took part in round 1 of the consensus study were invited to complete round 2 questionnaire. We received a total of 65 completed surveys from participants based in twenty-two countries (87% response rate). The largest body of experts were represented by the UK (22%), USA (17%), and Australia (12%). The panel mostly comprised of specialist, advance practice, and consultant nurses (71%), academics (22%), and industry representatives (6%). The vast majority (90%) of panellists have 5 or more years' experience in tissue viability or related research.

The round 2 results of each of the five main parts of the survey were tabulated providing summary data in accordance with the RAND/UCLA Delphi methodology including:

- Panel median score, which indicates the group's initial support for the inclusion of each of the statements in the proposed minimum data set,
- Disagreement Index (DI). DI indicates the level of agreement between experts as to the inclusion or exclusion of each of the items. If the DI is larger than 1, it suggests disagreement between panel members exists.
- The initial indication for inclusion or exclusion (or uncertainty) of the proposed MDRPU MDS.

The criteria detailed in Table 1 were applied to give the groups initial indication of inclusion/ exclusion/uncertainty.

Table 1 Panel's initial support criteria

Panel median	Disagreement Index*	Initial indication
1 - 3	DI < 1	**Exclude**
4 - 6	Any	**Uncertain**
Any	DI > 1	**Uncertain**
7 - 9	**DI < 1**	**Include**

**DI > 1 indicates disagreement*

Round 1 Results summary

Sections below relate directly to the proposed Minimum Data Set for reporting MDRPUs. Each section includes the item number (corresponding with the numbering in

the survey), description of the item, your individual score from Round 2, summary statistics from panel responses, and any comments made by panellists.

NB. Structure of the online questionnaire:

Part 1 – Instructions for use

Part 2 – Summary of MD use and current issues

Part 3 – Participant demographic information

Part 4 – Survey questions

Survey Part 4: Recording Medical Device-Related Care

Table 2 Overall panel scores to item #4.1 to item #4.9, feedback, and individual score from Round 1. Items marked *have been added after Round 1 feedback.

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
4.1	**Medical reason for the device use** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.13	▪ *"Although I agree that the reason for the MD may be self-evident for cases such as intubation however, it would be good to know of the reason for MD where it is less obvious. Knowing the reason can help to play a part when we are discussing the importance of MD use with patients if there is some reluctance to its use. I think reasons should be recorded in notes, too".* ▪ *"1 I still feel that in the vast majority of incidence the medical reason for the use/application of the device is self-evident".*	**INCLUDE**
4.2	**The number and type of medical devices in situ** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00		**INCLUDE**
4.3	**The prevention used** (e.g. type of prophylactic		9	0.13		**INCLUDE**

	dressings) is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs					
4.4	**A record when a MD was first applied** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00	▪ *" (…) to ask a bedside nurse when the device was first applied or when it was re-tapped is not easy information to find in a chart".*	**INCLUDE**
***4N.1**	**A record of type of securement** used is relevant and should be included in the proposed MDS for reporting MDRPUs		9	0.13		
***4N.2**	**How frequently the securement was changed** is relevant and should be included in the MDS for reporting MDRPUs		9	0.26	▪ *"Frequency of change of the device is not documented in the clinical notes and therefore the data from this will not be captured".*	
***4N.3**	**Documenting if the MD could be safely repositioned** is relevant and should be included in the proposed MDS for reporting MDRPUs		9	0.13	▪ *"Not all medical devices can be repositioned".* ▪ *"There are medical devices which cannot be repositioned, for example different plasters and ecmo".* ▪	
4.5	**A record of device repositioning** is relevant and		9	0.00		**INCLUDE**

	should be included in the proposed Minimum Data Set for reporting MDRPUs					
4.6	**Recording comfort associated with the medical device** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		7	0.37	▪ *"I acknowledge some of the points raised around recording of comfort and that it may not always be possible to do if the patient is sedated. However where a patient can provide this information, I think it should always be explored and recorded and every attempt must be made to maximize comfort. The comfort is so important to note as, if the device is causing discomfort the patient is more likely to not want to use and may remove it or fiddle with it which may cause more harm".* ▪ *"Comfort associated with the medical device should not be included because all devices that are of therapeutic use or used as life-sustaining equipment. The issue whether they are comfortable or not are not relevant. Any comfort is not a measurement or risk factor for pressure injury*	**INCLUDE**

					development. Devices are used for a reason. If a device is no longer indicated, it should be removed". ▪ *"A large majority of our population (paediatrics) is unable to verbalize if a medical device is causing discomfort and it is not feasible to explain to a paediatric patient why a medical device is needed. To the parents/caregivers, but not the patient".* ▪ *"It should be noted that patient comforted should be recorded where possible".*	
4.7	**Information whether the Staff were trained to use of the medical device** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		7	0.69	▪ *"to record is a staff member has been trained on a medical device is not useful information as to whether or not a PI occurs. What they should be trained on are prevention measures regardless of the device".* ▪ *"How will this data be feasibly collected? And for every device? Training and caring for particular devices goes to scope of practice. So if RNs/clinicians are managing devices that do not have*	**INCLUDE**

					adequate training for this become I legal issue".	
4.8	**Whether the MD is used as prescribed or 'off label'** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs.		7	0.49	▪ *"If device is used off label this should be documented by exception".* ▪ *"(…)"off label" use of device may not put patient at a higher risk of pressure injury if preventive measures (e.g. Prophylactic dressing) are taken. And at this moment there is NO scientific evidence suggesting that off-label use of medical device will lead to more pressure injury. If knowing how a product is used is just for interest, it should not be included in the minimum data set".* ▪ *"Many MD are used off label because we have no choice. There isn't a paediatric option".* ▪ *"It tends to be nurses that perform and record PU preventative care, if a device is used 'off label' it is more likely that this will be initiated by medical staff, but I don't know if nurses would*	**INCLUDE**

					always know if a device is being used as designed or not".	
4.9	**Documenting patient communication regarding the MDRPU presence and/or development** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		8	0.29		**INCLUDE**

ADDITIONAL COMMENTS	▪ ***"Not all proposed data sets will be easy to collect and record, so this is reflected in some responses. Some is data we would look at for RCA but not collect for reporting externally due to it being very time consuming to collect (if that data are even available)."*** ▪ ***"I think the information is important but think it would be difficult and time consuming to collect".*** ▪ ***"All of these items are important. Not only for real-time evidence-based patient care but also for the collection of data which over time can be seen to inform and improve practice".***

Survey Part 5: Reporting Medical Device-Related Pressure Ulcers

Table 3 Overall panel scores to item #5.1 to item #5.14, feedback, and individual score from Round 2

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
5.1	**Category/stage I [1]** MDRPUs reporting should be included in the proposed Minimum Data Set		9	0.00	▪ *"Stage 1 pressure injuries should be reported by the local level because the data provide information for ongoing quality improvement. Stage 1 pressure injuries are often an early sign of*	**INCLUDE**

					pressure-induced injury that can be acted on". ▪ *"Category 1 should be reported and then this could be passed to the specialty to go assess and offer support. Braces/splints - physio support Casts - plaster technician ICU equipment could be an MDT This could then hopefully reverse the category 1 and prevent further damage".*	
5.2	**Category/stage I** [1] MDRPUs should be reported at:					
	Unit/department level		9	0.00		**INCLUDE**
	Hospital level		9	0.10		**INCLUDE**
	National level		9	0.45		**INCLUDE**
5.3	**Category/stage II [2]** MDRPUs reporting should be included in the proposed Minimum Data Set		9	0.00		**INCLUDE**
5.4	**Category/stage II** [2] MDRPUs should be reported at:					
	Unit/department level		9	0.00		**INCLUDE**
	Hospital level		9	0.00		**INCLUDE**
	National level		9	0.00		**INCLUDE**
5.5	**Category/stage III [3]** MDRPUs reporting should be included in the proposed Minimum Data Set		9	0.00		**INCLUDE**
5.6	**Category/stage III** [3] MDRPUs should be reported at:					

	Unit/department level		9	0.00		INCLUDE
	Hospital level		9	0.00		INCLUDE
	National level		9	0.00		INCLUDE
5.7	**Category/stage IV [4]** MDRPUs reporting should be included in the proposed Minimum Data Set		9	0.00		INCLUDE
5.8	**Category/stage IV** [4] MDRPUs should be reported at:					
	Unit/department level		9	0.00		INCLUDE
	Hospital level		9	0.00		INCLUDE
	National level		9	0.00		INCLUDE
5.9	**Unstageable** MDRPUs reporting should be included in the proposed Minimum Data Set		9	0.00		INCLUDE
5.10	**Unstageable** MDRPUs should be reported at:					
	Unit/department level		9	0.00		INCLUDE
	Hospital level		9	0.00		INCLUDE
	National level		9	0.00		INCLUDE
5.11	**Mucosal membrane** MDRPU reporting should be included in the proposed Minimum Data Set		9	0.00		INCLUDE
5.12	**Mucosal membrane** MDRPUs should be reported at:					
	Unit/department level		9	0.00		INCLUDE
	Hospital level		9	0.00		INCLUDE
	National level		9	0.00		INCLUDE
5.13	**Suspected Deep Tissue Injury** attributed to MD reporting should be included in the proposed		9	0.00	▪	INCLUDE

	Minimum Data Set					
5.14	**Suspected Deep Tissue Injury** MDRPUs should be reported at:					
	Unit/department level		9	0.00		**INCLUDE**
	Hospital level		9	0.00		**INCLUDE**
	National level		9	0.00		**INCLUDE**

ADDITIONAL COMMENTS	▪ ***"There is a difference between using data categories for clinical use and diagnosis, and the use of data to support learning and function of an organisation. The burden on organisations to report all levels of pressure damage without a clear outcome points should not be supported. Unstageable is at least cat 3, but they can be used by some areas as a default if the level of tissue damage is unknown due to lack of the assessment skills i.e. cat 2 or sDTI. sDTI will eventually evolve into either cat 1,2, or deeper and will skew reporting figures through double reporting".*** ▪ ***"In order to understand prevention of PI, we have to know how many PI's of each stage, and where they are occurring. The unit and hospital location is very important. To exclude any of this data is to not obtain a true picture of what is occurring".***

Table 4 Panel response to item #5.15 - using the proposed MDS for prevalence data collection

Item number	Question	Your Round 2 response (yes/no)	Yes [%]	No [%]
5.15	The proposed MDS' purpose is to collect incident data, would you consider using it to collect regular MDRPU prevalence data as well? **Please see definition of the terms below:** *Incident – unplanned event resulting in an injury or damage;* ***here: any MDRPU occurrence****.* *Prevalence – proportion of patients with MDRPU on the day of the census.*		86	14

The following section of the survey (items #5.16 to #5.19) was only available to those participants who supported using the proposed MDS as an instrument for prevalence data collection (question #5.15).

Table 5 Overall panel scores to item #5.16 - support for using the proposed MDS for prevalence data collection on different levels of reporting (unit, hospital, national)

Item number	Question	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Initial indication
	Do you support reporting prevalence (using the proposed MDS) on a:				

Item number	Question	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Initial indication
	Unit/department level		9	0.00	INCLUDE
	Hospital level		9	0.00	INCLUDE
	National level		9	0.00	INCLUDE

Table 6 Overall panel scores to item #5.17 to item #5.19 - frequency of prevalence data collecting using the proposed MDS

Item number	Question	Frequency	Your Round 2 response (marked by *)	Count	[%]
5.17	What would be the ideal frequency of reporting MDRPU prevalence on **unit/department** level?	every week		15	27
		every 2 weeks		0	0
		monthly		**28**	**50**
		quarterly		6	11
		every 6 months		3	5
		yearly		2	4
		other		2	4
5.18	What would be the ideal frequency of reporting MDRPU prevalence on **hospital/organisation** level?	every week		1	2
		every 2 weeks		1	2
		monthly		**29**	**52**
		quarterly		19	34
		every 6 months		1	2
		yearly		3	5
		other		1	2
5.19	What would be the ideal frequency of reporting MDRPU prevalence on **national** level?	every week		1	2
		every 2 weeks		0	0
		monthly		3	5
		quarterly		15	27
		every 6 months		10	18
		yearly		**25**	**45**
		Other		2	4

Part 5a: Medical Device-Specific Reporting

Table 7 Overall panel scores to item #5a.1 to item #5a.9, feedback, and individual score from Round 2

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
5a.1	**The type of MD** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00	▪ *"As industry (and) having read about this topic the past 2 months (…) - the type of device could be highly important to support technology design advancements".* ▪ *"The type and manufacturer is important to collect to track trends in any particular type and make".*	**INCLUDE**
5a.2	**The name of the manufacturer** or distributor is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		7	0.75	▪ *"Reporting manufacturer name and product name is irrelevant because a higher incidence rate associated to a single manufacturer or product does not mean the product is associated to a higher risk of pressure injury development. It can also mean that particular manufacturer or product is of a more common use locally or worldwide. On the other hand, in some underprivileged countries, there is no alternative or replacement".* ▪ *"The first step is to identify what is causing the issue and who the*	**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
					manufacturer is - once we know that we can start a deeper dive with aggregate data".	
5a.3	**The exact name/product** number of the MD is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		7	0.75	▪ *"I can see the relevance of adding this information to investigate if the product had some fault etc. But again I feel people wouldn't have time to do this. I'm unsure of the value of this being included".*	**INCLUDE**
5a.4	Recording if the device was **single use or reusable** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		5	0.65	▪ *"MDRPUs If the name of the manufacturer and the name of the device has been documented, one will know is the product for the single use or not. On the other hand even if the MD would be only for single use, it might have been used before, cleaned, and used again. We do not know from the report if a single use device is really used for the first time".*	**EXCLUDE**
5a.5	Recording **expiry date** of the device is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		5	0.97	▪ *"There are devices like intravenous cannulas which cannot be used after expire date, but there are devices which do not have expire date like ECG cables".* ▪ *"Batch number, expiry date and sterility is not*	**EXCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
					relevant to pressure injury development". ▪ *"(…) some of these are not something that should be collected under the banner of pressure related e.g. sterility; if re-useable or single use -it shouldn't matter should be fit for purpose regardless".*	
5a.6	Recording the device was **sterile** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		5	0.73		**EXCLUDE**
5a.7	Recording **the batch & lot** number is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		5	0.95		**EXCLUDE**
5a.8 ***5a.4 in round 3**	If the **MD is still in place** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.26		**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
5a.9 *5a.5 in round 3	The **type of material** the MD is made of is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		7	0.75	▪ *"This would be important to know, but very difficult task for the staff. If we have the name of the manufacturer and the name of the device, someone can figure it out what kind of material MD is made of".* ▪ *"what material it is made of whilst very important staff will have to spend time finding that information and if we have manufacturer/device type then this is sufficient for them to trace this themselves to review their own products".* ▪ *"I agree the staff may not know the material but agree that this knowledge would be useful when preparing a report on the injury".* ▪ *"I'm not convinced the nurses would know what material the device was made from. This would involve them having to look this up which will take time that they don't have".* ▪ *"If the manufacturer, batch, and lot number are recorded in the MDS then the material of the device can be determined. If you include type of material in the MDS*	**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
					it will be open to interpretation or guessing".	

ADDITIONAL COMMENTS	▪ ***"All suggests above are relevant HOWEVER many will not be able to be collected for reporting and so for an element of practicality".*** ▪ ***"Details about the specific device (manufacturer, lot number etc...) May be "overkill" and unduly burdensome for the purposes of this minimum data set; however at some point facilities, in the process of balancing cost and efficacy of devices should have information which devices meet minimal standards and which devices are "cheaper" but maybe causing greater harm due to 'cheaper construction'".*** ▪ ***"This information regarding the product is not something that is readily available to the bedside clinician. How is anyone expected to obtain that information"?*** ▪ ***"If information is kept on the brand of the product, then other information such as batch numbers, expiry dates etc should be able to be found in an incident investigation. We need to be realistic about how much data busy health professionals can collect".*** ▪ ***"Nurses will get frustrated with having to include too much data".*** ▪ ***"The type of material/batch and lot number/sterility - many staff will become too frustrated in reporting some of these details and not want to complete the MDS or thy don't know the information or have access to it (like batch/lot number which is on the package which most likely be thrown away - especially in an emergent situation)".*** ▪ ***"It worries me that assumptions are made about the quality and characteristics of medical devices. Including basic details re. Use type, expiry date, sterility, batch/lot no - promotes patient safety, increases awareness about products and how they should be assessed before use, provides evidence when examining causes of injury and streamlines logistical processes".***

Appendix F

Part 5b: Ulcer Specific Reporting

Table 8 Overall panel scores to item #5b.1 to item #5b.8, feedback, and individual score from Round 2

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
5b.1	**The body site** where the MDRPU is located is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00		**INCLUDE**
5b.2	**Size of the MDRPU** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.10		**INCLUDE**
5b.3	**The date and time of finding** the MDRPU is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00		**INCLUDE**

5b.4	**Including photographs** of the MDRPU is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		8	0.69	▪ *"Photographs whilst good practice would not always be possible for all Trusts to produce so including them would be detrimental as a data set. Plus we would need a large amount of IG regulations and consent of the patient which is not always possible".* ▪ *"Photographs are associated with liability and patient confidentiality issues. However, if they can be de-identified, they offer excellent insights into the prevention, treatment, and long-term consequence of medical device related injuries".* ▪ *"mdrpus I agree with one comment about legal and regulatory issues (from Round 1 report). It is not always possible to take a photo. This should be voluntary".* ▪ *"Photographs is tricky not everybody is allowed to take photographs".* ▪ *"Can only see the relevance of this for education purposes, as this would highlight the long term effects on patients of PI's but I'm not really sure of the value in their documentation".* ▪ *"Photograph is not a mandatory documentation method although it is getting more common and is promoted. It has its limitation e.g. In reporting institutional and national data, it is not possible to attach photographs of every*	**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
					patient because of the large patient volume".	
5b.5	**Including photographs after the MDRPU healed** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		5	0.65	▪ *"(…) patient might have been transport to another unit or hospital, so the follow up might be challenging. Is the purpose to take a photo of the healing wound or the scar or the intact skin? It might confuse people".*	**EXCLUDE**
5b.6 *5B.5 in round 3	**The environment** (i.e. Ward OR theatre location) in which the MDRPU was first observed is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00		**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
5b.7 *5B.6 in round 3	**The short-term effect** of the MDRPU on current patient care is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		8	0.29	▪ *"(…) knowing the long term consequence can be difficult especially a skin can take up to 18 months to finish maturing in adults and can be different again in paeds and so this is not data that is easy to obtain or follow up on. Immediate damage is easily reportable and available but longer term will be difficult to obtain".*	**INCLUDE**
5b.8 *5B.7 in round 3	**Potential longer term consequence** of the MDRPU on the patient is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		7	0.65	▪ *"How would the long term consequence be determined? I think this is too subjective".* ▪ *"This would be too difficult to complete. If I worked in an integrated Trust. A process could involve a follow up but not possible in all areas".* ▪ *"Long-term effects and obtaining photos after the MDRPU is healed is extremely difficult from a logistics point of view - many of these patients are transferred to other health systems (…) with the MDRPU and are lost to follow up. Also - how do you handle those patients who have died".*	**INCLUDE**

ADDITIONAL COMMENTS	▪ ***"It (sic) should be reported. Regardless if injuries are preventable or not, a policy of total transparency should be adopted to ensure impacted patients have access to treatment and support".***

Appendix F

Part 6: General Patient and Co-morbidity Data

Table 9 Overall panel scores to item #6.1 to item #6.9, feedback, and individual score from Round 2

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
6.1	**Patient's age** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.13		**INCLUDE**
6.2	**Patient's gender** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		6	0.75	▪ *"Studies are mixed on the effects of gender on pressure injury risk. Think you can delete this from an MDS unless gender is important for other reasons".* ▪ *"Gender (…) assumes a binary, which is no longer appropriate".* ▪ *"Gender may not be relevant to MDRPI, but it is necessary for the collection of basic information of patients with MDRPI".*	**EXCLUDE**
6.3 ***6.2 in round 3**	**Patient's weight** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		8	0.29	▪ *"Weight may only be relevant depending on the device and site - I would be concerned that weight may be given a bigger attribution/factor than it actually could be".* ▪ *"Patient BMI is probably more important than weight".*	**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
6.4 ***6.3 in round 3**	**Patient's nutritional status** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.13		**INCLUDE**
6.5 ***6.4 in round 3**	**Patient's primary diagnosis** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		8	0.45	▪ *"Primary diagnosis and comorbidities are important, but difficult to standardize. Would look at general categories of comorbidities like the Charlson Comorbidity Index or the comorbidities identified in the international guideline which are associated with pressure injury development".*	**INCLUDE**
6.6 ***6.5 in round 3**	Patient's **co-morbidities** are relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		8	0.29		**INCLUDE**
6.7 ***6.6 in round 3**	**Pressure Ulcer Risk Assessment score** is relevant and should be included in the proposed		8	0.75	▪ *"PU RAS are not sensitive or specific to MDR PU. All MDs carry a risk for PU development".* ▪ *"The current risk assessments used nationally are not*	**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
	Minimum Data Set for reporting MDRPUs				*looking at risk for MDRPU but general risk for bony prominences and so including them could be misleading as I have several patients with a very low risk factor when risk assessed but developed device related damage due to the device not their risk so I don't see the current Risk Assessments and being useful for Device related damage indication therefore including them would be misleading (potentially)".* ▪ *"I understand that not all clinicians are enthusiastic about risk assessment scales. However, the subscales of risk assessment scales that are associated with tissue tolerance (e.g. Nutrition, moisture) are probably also relevant to medical device related injuries.... As are perfusion and oxygenation deficits (also measures of tissue tolerance). The mechanical boundary conditions associated with medical device related injuries are probably more strongly associated with fit, securement,*	

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
					material properties and duration of the device application". ▪ *"- Risk assessment should be completed and if a device the patient is already at risk. If it is correct is a different question".* ▪ *"Pressure Ulcer Risk Assessment score does not reflect the risk of development of medical device associated pressure injury".* ▪ *"Also feel regardless of the patients' risk level a medical device can cause a PI so is irrelevant".* ▪ *"Risk assessment scores are useful in identifying the 'potential' for MDRPI".*	
6.8 ***6.7 in round 3**	**Skin assessment** is relevant and should be included in the proposed Minimum Data Set for reporting MDRPUs		9	0.00	▪ *"Skin assessment is vitally important assuming that the skin under any removable device is assessed with routine skin assessment. In patients with increasing edema, the skin under removable medical devices should be assessed more frequently".* ▪ *"Skin assessment and repositioning are only relevant in regard to the device".*	**INCLUDE**
6.9 ***6.8 in round 3**	When **the patient was last repositioned** is relevant and should		8	0.49	▪ "*When the patient was last repositioned may not indicate that the device has been repositioned or a relevant factor unless*	**INCLUDE**

Item number	Proposed Item	Your score in Round 2	Panel Median	DI (>1 = no agreement)	Panel comments	Initial indication
	be included in the proposed Minimum Data Set for reporting MDRPUs				*you specify if the device was repositioned and if it was 9or could be) how often and so when would be more relevant) BUT this would be part of the RCA rather than whether it needs to be part of the initial data collection set".* ▪ *"Body repositioning may not be relevant to the development of some MDAPI, e.g. Pressure injury at nasal bridge due to application of oxygen mask or mask for non-invasive ventilation, pressure injury at nostril due to application of nasal endotracheal tube or nasogastric tube".* ▪ *"Repositioned and skin assessment under medical device is probably more important than general body repositioning".*	

ADDITIONAL COMMENTS	▪ ***"I changed comment(s) as feel we could be collecting too much data".***

Survey part 7: Other items

Individual members on the Panel have suggested additional items that might be relevant for the proposed Minimum Data Set. We have reviewed those items and taking into consideration the aim of the MDS and general comments (burden on staff, time, access to data, and duplication of data), two items have been added to the Round 3 survey. These are summarised below for you to consider.

Table 10 List of new items proposed items to include in the proposed MDS

#	Proposed item	# comments	Quote(s)
1	Patient skin tone (or ethnicity)	2	▪ *"Note no mention of skin tone – given challenges in darker skin tone, should this not be included?" (P8)* ▪ *"Does there need to be a question related to the skin tone of the patient? It may be possible that we miss earlier pressure damage on patients with darker skin tones". (P23)*
2	Patient proned with MD in situ	2	▪ *"(N)ow that COVID is part of our care - and proning injuries are now becoming more frequent - do we include an item about whether or not this patient was proned with the MDRPU in place?" (P75)* ▪ *"Just remember that rules change when dealing with covid-19 especially with regards to devices in place and patients in prone position. Double vigilance is needed on both device management and risk assessment". (P5)*

Appendix G PU categories in MDRPU reporting

		Round 1		Round 2	
Item number	Proposed Item	Panel Median	DI (>1 = no agreement)	Panel Median	DI (>1 = no agreement)
5.1	**Category/stage I [1]** MDRPUs reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.2	**Category/stage I** [1] MDRPUs should be reported at:				
	Unit/department level	9	9.00	9	0.00
	Hospital level	9	9.00	9	0.10
	National level	7	9.00	9	0.45
5.3	**Category/stage II [2]** MDRPUs reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.4	**Category/stage II** [2] MDRPUs should be reported at:				
	Unit/department level	9	0.00	9	0.00
	Hospital level	9	0.00	9	0.00
	National level	9	0.37	9	0.00
5.5	**Category/stage III [3]** MDRPUs reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.6	**Category/stage III** [3] MDRPUs should be reported at:				
	Unit/department level	9	0.00	9	0.00
	Hospital level	9	0.00	9	0.00
	National level	9	0.00	9	0.00
5.7	**Category/stage IV [4]** MDRPUs reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.8	**Category/stage IV** [4] MDRPUs should be reported at:				

	Unit/department level	9	0.00	9	0.00
	Hospital level	9	0.00	9	0.00
	National level	9	0.00	9	0.00
5.9	**Unstageable** MDRPUs reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.10	**Unstageable** MDRPUs should be reported at:				
	Unit/department level	9	0.00	9	0.00
	Hospital level	9	0.00	9	0.00
	National level	9	0.00	9	0.00
5.11	**Mucosal membrane** MDRPU reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.12	**Mucosal membrane** MDRPUs should be reported at:				
	Unit/department level	9	0.00	9	0.00
	Hospital level	9	0.00	9	0.00
	National level	9	0.29	9	0.00
5.13	**Suspected Deep Tissue Injury** attributed to MD reporting should be included in the proposed Minimum Data Set	9	0.00	9	0.00
5.14	**Suspected Deep Tissue Injury** MDRPUs should be reported at:				
	Unit/department level	9	0.00	9	0.00
	Hospital level	9	0.00	9	0.00
	National level	9	0.00	9	0.00

Appendix H Vignettes

Case study 1 -ICU

Oz is a 55-year-old Asian man who lives at home with his wife and 3 grown-up children. He is a non-smoker, is overweight (BMI 35) and following an over 50s health check was diagnosed with type 2 diabetes which he has managed to control with diet and medications (metformin). He works as a plumber but over the last year has been finding his work increasingly difficult due to general fatigue and episodes of cardiac-sounding chest pain which led to an acute admission for a suspected Myocardial Infarction. Investigations reveal he had f ischaemic heart disease and heart failure). and he was scheduled for elective coronary artery bypass grafting (CABG)

He underwent CABG with no immediate complications, but 7 days post-op while on the surgical ward he suffered a cardiac arrest. He was successfully resuscitated, intubated with a *** endotracheal tube, ventilated and transferred to a cardiac surgical ICU. He had a central and arterial line inserted, was catheterised and administered Inotropes and insulin and underwent continuous cardiac monitoring. For the first 48 hours in ICU, he remained very unstable and so was nursed in a supine position, making full skin assessment of his back area difficult. He was nursed on an alternating pressure mattress. On day 3 of his ICU stay when changing the position of the ET tube, the nurse noticed that he had a category 3 PU on the back of his neck where the tube had been secured with tape.

Case study 2 - PICU

Emma* was born at full term by Caesarean section. Trisomy 21 was diagnosed antenatally. A diagnosis of long-gap oesophageal atresia was confirmed following birth.

Emma required surgery after birth. At two days of age she was transferred to a paediatric intensive care unit for surgery to place a gastrostomy. Prior to the surgery she was nasally intubated. Emma was extubated during her stay on PICU and transferred back to the neonatal unit at five days old. There were no surgical complications.

On return to the neonatal unit, Emma did not require supplemental oxygen or other respiratory support. She was haemodynamically stable. Emma was cared for in an intensive care cot due to the care needs associated with her Replogle tube, including saline flushes every 15 minutes. The Replogle tube remained in situ as the defect had not yet been surgically repaired. Emma was fed expressed breast milk via her gastrostomy. Her nappy changes and other cares were cue-based.

Once Emma returned to the unit, a pressure ulcer was observed on her right nare (see Figure A), associated with the nasal endotracheal tube. The wound was not documented until Emma returned to the neonatal unit. By this point the wound had begun to heal, making it difficult to determine the depth of the original wound or the date on which it first occurred. No active management of the wound occurred. The Replogle tube visible in the left nare required re-siting every few days. In this situation the nursing staff chose to continue re-siting the replogle tube to minimise the risk of a second PU, at the risk of potentially aggravating the original wound. Emma required several weeks of Replogle nursing to allow her oesophagus time to lengthen.

Other device-related skin damage was also observed in Emma, namely a wound of unclear aetiology associated with her gastrostomy (Figure B). It is unclear whether this is skin irritation or a category I PU. After the wound was observed, the area around the gastrostomy was protected with a foam dressing. No visible damage was present when the wound was reassessed after three days.

Case study 3

Jonny is a 29-year-old male, who has been admitted to the ICU following a bike accident. Jonny is divorced and works for the city council as a finance assistant. He has no previous medical history and is a healthy BMI. Due to the accident, he suffered multiple trauma and subdural haemorrhage. He was fitted with an *** rigid collar at the site of the accident by emergency service technicians. After 6 days in the ICU, physicians ordered the removal of the cervical collar as the spinal clearance process was completed. After the removal of the collar, nurses discovered two stages 4 pressure ulcers. One developed in occiput, second on the chin.

*** stands in place of a manufacturer's name

Appendix I Ethical approval – cognitive pre-test study

A 19 Pre-testing study ethical approval

Approved by Faculty Ethics Committee - ERGO II 60794

ERGOII <ERGOII@soton.ac.uk>
Mon 29/03/2021 14:02
To: Ewa Crunden <E.A.Crunden@soton.ac.uk>

Approved by Faculty Ethics Committee - ERGO II 60794

ERGO II – Ethics and Research Governance Online https://www.ergo2.soton.ac.uk

Submission ID: 60794
Submission Title: Pre-testing of the Minimum Data Set for reporting Medical Device-Related Pressure Ulcers
Submitter Name: Ewa Crunden

Your submission has now been approved by the Faculty Ethics Committee. You can begin your research unless you are still awaiting any other reviews or conditions of your approval.

Comments:

- Thank you for addressing all of the revisions requested. Happy to approve, we wish you well with your Data collection

Click here to view the submission

TId: 23011_Email_to_submitter___Approval_from_Faculty_Ethics_committee__cat_B___C_ Id: 363627

eac1g14@soton.ac.uk coordinator

Appendix J Cognitive interviews topic guide

1. Introductions

2. Introduce MDR MDS (how it was developed – systematic review, qual study, consensus study), highlight that this is not final version.

3. To improve the MDR MDS further so that it can be used in clinical practice, we are looking to improve the design, layout, language, and understanding. We want to make sure that the items are understood in the same way consistently, are clear, easy to find out, and possible to complete during the report completion.

4. Remind the participant there are no right or wrong answers.

5. Explain the 'think aloud technique' – you will be asked to complete the MDR MDS based on a case study. As you complete the form, I would like you to tell me what you are thinking as you are doing it. Regardless of how unimportant it may seem to you. I am interested in everything you have considered during the process of formulating your responses.

6. Remind the participant the interview is audio-recorded, answer any questions and confirm you can proceed with the interview.

7. If necessary, i.e. if the participant fills in the form but gives no verbal feedback, use verbal prompts to promote 'think aloud' technique – ask for explanations. Ask clarifying questions as long as it does not interrupt the flow of the participant. If this may be the case – take notes to go back to the question at the end of the interview. Ask to highlight any areas that the participant want to talk about at the end of the interview.

8. If the participant comments on any items as impossible to complete, reassure them the MDR MDS is in the development stage, there are no right or wrong answers, and that her comments are valuable for the research.

9. Possible prompts:

- Is the MDR MDS easy to understand?
- Is the structure of the form easy to follow?
- Are there any items that are redundant? Why?
- Are there any items missing? What are they and why?
- Is the language and vocabulary used in the form used in clinical practice?
- Overall, how was the MDR MDS to complete?
- Are there any areas that could be further developed?
- What would make the MDR MDS easier to complete?

Appendix K Pre-test focus groups topic guide

Ground rules: everyone will have a chance to speak. There are no right and wrong answers. Everything that is said in the group remains confidential. Participation is voluntary and participants have the right to withdraw at any point.

The researcher then will remind participants that the discussion will be audio-recorded, answer any questions, and ensure everyone is happy to proceed before the focus group starts.

1. Introduction of the researcher and group members by name.

2. Present aims of the session – consider acceptability of using MDR MDS, with special interest in:

- What is good/liked
- What was not good/disliked
- How easy was it to use
- Any areas that were unclear/confusing
- Any issues in clinical practice the nurses can foresee

3. Participants are given case studies and copy of the MDR MDS to complete. – approx. 10mins – but check with everyone before starting discussion.

4. Group discussion about the usability and how the form was found overall. Where there any areas of confusion/ lack of clarity. The researcher to check the MDS forms to see if there are any missing data to discuss reasons.

5. Group discussion about any issues that participants can foresee with using the MDR MDS form in clinical practice.

Appendix L Changes to the draft MDRPU reporting form based on pre-testing cycles

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
1	1	**Medical reason for the device use**	Medical reason for the device use	-	-
2	2	**The number and type of medical devices in situ**	Other devices in situ Yes/ No; Number of devices; Insert location & type	Item deleted. The potential length of the list may be too great to complete since patients in, e.g. critical care, have many devices attached. Additionally, even one MD raises the risk of MDRPU development and compiling a list would have been time-consuming but not necessarily relevant to the current MDRPU being reported.	
3	3	**The prevention used** (e.g. type of prophylactic dressings)	Preventive measures in place	Added a pre-defined list of measures based on MDRPU prevention literature.	-
4	4	**A record of when an MD was first applied**	Date of the first application	-	-
5	5	**A record of the type of securement used**	Type of securement used	Added a list of securement options, informed by academic literature, after feedback indicating that giving options to choose from is the best way to ensure completion. The 'Not applicable' option is available because some MDs, such as anti-embolic stockings, do not require securement. The 'Not applicable' option is available because some MDs, such as anti-embolic stockings, do not require securement.	-
6	6	**How frequently the securement was changed**	Frequency of change	-	-

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
7	7	**Documenting if the MD could be safely repositioned**	MD repositioning safe to patient Yes – date and time last repositioned; No – give details	The 'No' answer changed 'give details' to 'clinical rationale' to clarify the requested details.	- The added word 'rotated' – 'Could the MD be safely repositioned/ rotated'. The rotation might require more minor adjustments but is clinically relevant.
8	8	**A record of device repositioning**			
11	9	**Whether the MD is used as prescribed or 'off label.'**	Yes/no, give details	Included an aide memoir of what 'off license' use means, based on the UK MHRA website. The feedback after interviews was that the term was not understood and the question impossible to answer.	Item removed after feedback, that staff is always assumed to follow manufacturer's guidance, and that staff are trained only on the use of mechanical devices, but not, e.g. dressings. Additionally, even if a device was used incorrectly, this is something that the ensuing investigation would ascertain.
12	10	**Documenting patient communication regarding the MDRPU presence and/or development**	Was the presence/ development of the MDRPU discussed with the patient/ carer? Give details	Added: 'Yes – give details when with whom and what information was given No – give a rationale.'	-
14	11	**The type of MD**	-	-	Changed 'device type' to ' Type of device that caused MDRPU' and listed alphabetically medical devices most common in MDRPU development. Feedback from clinicians indicated this would facilitate quick completion and ensure data were completed.

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
15	12	**The name of the manufacturer or distributor** *	-	-	-
16	13	**The exact name/product** number *	-	Changed to: 'Exact name and/or product number' to indicate that both should be reported ideally.	-
21	14	If the **MD is still in place**	Yes/no	-	- Added 'If yes – is the device still required for patient's care or treatment – Y/N'. Clinicians in the focus group reported this is essential information because sometimes MDs are left but not medically required. (A similar account was received in the qualitative study). If the device is still needed, collecting those data may prompt introducing a different type of MD or preventive measures.
22	15	The **type of material** the MD is made of *	MD material	Removed this item due to feedback showing it would be challenging to ascertain this information. Recording the MD name and manufacturer would cover this information.	
23	16	**The body site**	Presented as a table + aide memoir EPUAP/ NPUAP classification	Changed 'body site' to anatomical location' to reflect the language used in clinical practice. Added 'and L(eft)/ R(ight)/ Front/ Back' to enable clear identification of the MDRPU location. Changed size in mm to length (cm) and width (cm) to reflect current practice.	-
13	17	**Pressure Ulcer category**			
24	18	**Size of the MDRPU**			

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
25	19	**The date and time of the finding** of the MDRPU	Date and time of identification	-	-
26	20	**Including photographs**	Photo attached? Yes/ no	Added 'photo of the device attached Y/N'. We are interested in the MDRPU and the device that caused it. It may be our best opportunity to identify the MD from the photograph if the reporter does not collect data on the device for any reason. Feedback highlighted that when a specialist nurse reviews the MDRPU, the device is no longer in place, so that a photograph would be helpful.	-
28	21	**The environment** (i.e. Ward OR theatre location) in which the MDRPU was first observed	Patient's physical location when MDRPU identified, e.g. ward, operating theatre	-	-
29	22	**The short-term effect** of the MDRPU on patient care	Brief description of the short-term effect on patient care	Added 'planned' patient care to clarify the form's need.	Item removed, feedback stated it is still not clear enough what should be recorded and including narrative extends the time required to complete the record. Hence it is likely this item would be left blank.
31	23	**Patient's age**	Patient's age (choose units) or DOB	-	-
33	24	**Patient's weight**	Specify units	-	- Added units to select from to ease completion. We moved BMI to Weight from 'Nutritional status' after feedback that it fits better with those data.

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
34	25	**Patient's nutritional status**	Low BMI/ high BMI/ poor nutritional intake/ unplanned weight loss/ no issues	-	I changed 'poor nutritional intake' to 'insufficient nutritional intake' – more precise wording. Added 'nil by mouth'.
35	26	**Patient's primary diagnosis**	-	-	-
36	27	Patient's **co-morbidities**	-		It was changed to 'relevant medical conditions/ co-morbidities' for only those conditions that might have impacted MDRPU development to be logged.
37	28	**Pressure Ulcer Risk Assessment score**	Give score and indicate scale used	Added Purpose T categories 'at risk/not at risk' since this risk assessment tool does not use a numerical scale.	Removed the space for numerical value and the choice of RA tools in favour of a list of risk categories. This allows for clarity about the level of risk for the patient and is universal across RASs
38	29	**Skin assessment**	Date and time of the last skin assessment	Added categories to describe skin status on the last skin assessment: vulnerable or no issues.	I added 'under the device' for clarity. The feedback recommended specifying this since this is the body area the report is concerned with. Vulnerable skin status is defined with skin condition categories, where choosing one option would designate skin damage susceptibility.

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
39	30	When **the patient was last repositioned**	Date and time	-	-
40	31	A record of the patient's **skin tone** is necessary	Dark/ light	Added Fitzpatrick scale with six types and colour chart. The feedback received was no clarity on what the descriptors meant; hence a scale has been introduced. The Fitzpatrick scale is straightforward and sensitive enough for the staff to appropriately assess the skin colour.	- Added 'Light' and 'dark' categories as in V1 but referred to the Fitzpatrick scale for assessment. Since the literature refers to the early identification of pressure damage in dark skin, we went back to dichotomous categorisation. Still, we used the Fitzpatrick scale to assign the right skin colour category.
42	32	Recording if the **patient was proned with a medical device in situ**	Yes/ no; give details	-	-
	33	Other comments	It allowed for a narrative to give more context to the MDRPU incident. This was added because there might be circumstances not covered by the form, but equally important and thus needing reporting.	-	-
	34	Patient's NHS number	-	-	-
	35	Patient's Hospital number	-	-	-
	36	Report ID	-	Added 'Datix ID'	Changed to 'Datix/ Ulysses ID' as different systems are used

Item number (Delphi)	#	Item agreed for inclusion in the Delphi study	MDRPU reporting form draft v1 item	Changes after cognitive interviews (cycle 1) (v2 of the form)	Changes after focus groups (cycle 2) (v3)
	37	Date of report	-	-	-
	38	Name of the reporter and position	-	-	-
	39	Signature of the reporter	-	-	-
	40	Addressograph		Some hospitals use printout stickers with patient details. This space was added to facilitate this and omit manual inserting patient's data into the form.	-

Appendix M System Usability Scale questionnaire

Feasibility testing of a Medical Device-Related Pressure Ulcers reporting form – usability assessment questionnaire

Dear Colleague,

You have been using the form to report medical device-related pressure ulcers (MDRPUs) as a part of your practice for at least 4 weeks.

We would like to invite you to give feedback on its usability in practice, which will help to assess the feasibility of use in practice.

The questionnaire is divided into 2 sections:

Part 1 – The usability survey questions

Part 2 - Demographic data

Be reassured your participation is voluntary and your answers are anonymous.

Participant Information Sheet is included with this questionnaire. If you have any questions, please contact Ewa Crunden via email E.A.Crunden@soton.ac.uk

Once completed, please leave in the return box provided in the TVN office.

Thank you very much for your time!

Part 1

Please, think about when you last used the form for reporting an occurrence of a medical device-related pressure ulcer.

Now, read each statement and score it on a scale from 1 (strongly disagree) to 5 (strongly agree). *If you don't know how to respond, simply check box "3".*

		Strongly disagree				Strongly agree
		1	2	3	4	5
1	I think that I would like to use this reporting form frequently.	O	O	O	O	O
2	I found the reporting form unnecessarily complex.	O	O	O	O	O
3	I thought the reporting form was easy to use.	O	O	O	O	O
4	I think I would need the support of an experienced colleague to be able to use this reporting form.	O	O	O	O	O
5	I found the various items in the reporting form were well integrated.	O	O	O	O	O
6	I thought there was too much inconsistency in this reporting form.	O	O	O	O	O
7	I would imagine most people would learn to use this reporting form very quickly.	O	O	O	O	O
8	I found this reporting form awkward to use.	O	O	O	O	O
9	I felt very confident using the reporting form .	O	O	O	O	O
10	I needed to learn a lot of things before I could get going with this reporting form.	O	O	O	O	O

Part 2

Demographic information – please can you complete the form below.

Current role:	
Professional qualifications:	
Years' experience working within tissue viability (since qualifying):	
Years' experience incl. wound assessment and/or reporting:	

Appendix N NHS HRA approval – feasibility study

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mrs Ewa Crunden
AA 60 South Academic Block
Southampton General Hospital (MP11)
Tremona Road
SO16 6YDN/A

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

25 October 2021

Dear Mrs Crunden,

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Feasibility testing of a reporting form for Medical Device-Related Pressure Ulcers (MDRPUs).**
IRAS project ID:	**288116**
Protocol number:	**n/a**
REC reference:	**21/HRA/4099**
Sponsor	**University of Southampton**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **288116**. Please quote this on all correspondence.

Yours sincerely,

Christopher Cole
HRA Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Alison Knight*

Appendix O Feasibilty study focus group topic guide

Ground rules: everyone will have a chance to speak. There are no right and wrong answers. Everything that is said in the group remains confidential. Participation is voluntary and participants have the right to withdraw at any point.

The researcher then will remind participants that the discussion will be audio-recorded, answer any questions, and ensure everyone is happy to proceed before the focus group starts.

1. Introduction of the researcher and group members by name.

2. Present aims of the session – consider the acceptability of using MDRPU reporting from, with a special interest in:

- What is good/liked
- What was not good/disliked
- How easy was it to use
- Any areas that were unclear/confusing/difficult to complete (why? And what can be done about this?)
- Any issues in clinical practice the nurses can foresee

3. Group discussion about the usability and how the form was found overall.

4. Group discussion about any issues that participants can foresee with using the MDRPU reporting form as a part of routine clinical practice.

PROMPTS:

So, you have used the new reporting tool for 3 months, what do you think about it?

Was it easy to use?

How long was it to complete it?

How easy was it to find all the information the report required?

Did the tool help you in your practice?

Do you think it's something you would use? Why?

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