UNIVERSITY OF SOUTHAMPTON

FACULTY OF HEALTH SCIENCES

An analysis of hospital-acquired skin damage in neonatal units: "You sometimes feel like they haven't really got any skin"

by

Hannah Liversedge

Thesis for the degree of

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ORCID iD: https://orcid.org/0000-0002-4885-4983

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ABSTRACT

FACULTY OF HEALTH SCIENCES

Nursing

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AN ANALYSIS OF HOSPITAL-ACQUIRED SKIN DAMAGE IN NEONATAL UNITS: "YOU SOMETIMES FEEL LIKE THEY HAVEN'T REALLY GOT ANY SKIN"

by Hannah Louise Liversedge

It is well established that hospitalised neonates are at risk of iatrogenic skin damage. However, published prevalence and incidence rates vary, with the proportion of different types of damage unknown. It is unclear which factors act as barriers to and facilitators of skin care in this population. This motivated the aims of the thesis, which was to identify potential determinants of change related to the prevention of skin damage in neonatal units. In order to achieve this aim a multiphase mixed methods approach was adopted. This included an analysis of nursing staff practice and beliefs using a 19-part survey, a focus group with neonatal nurses, and interviews with lead Tissue Viability Nurses (TVNs). In addition, a prevalence and incidence study of all forms of skin damage on two neonatal intensive care units was conducted.

The free text comments from the survey, the focus group, and the interviews were analysed using a thematic analysis approach informed by the determinants of change outlined in the Implementation of Change Model. This revealed concerns about damage from medical devices and diaper dermatitis. Participants reported that peer-to-peer learning represented their main source of skin education, and that balancing skin care with other clinical needs was challenging. It was also apparent that the unique nature of the neonatal unit acts as a barrier to reporting damage, involving outside specialists, and accurately classifying wounds.

Prevalence data were collected from 54 neonates, 21 of whom presented with some form of skin damage (38.9%). Incidence data were collected from 51 neonates, 36 of whom developed some form of skin damage (70.6%). Of these, 23 neonates developed diaper dermatitis (45.1%), 23 developed damage associated with a medical device (45.1%), and four developed immobility-related pressure ulcers (7.8%). No single device was identified as the primary cause of device-related damage, with 12 of the 21 devices observed during the study noted to be associated with damage. Logistic regression analysis found that lower gestational age at birth was associated with an increased risk of developing both general skin damage and device-related damage. It was not, however, associated with an increased risk of developing diaper dermatitis.

In summary, this thesis has improved our understanding of the issues and complications currently facing hospitalised neonates in relation to skin care. There are a number of clinical implications for these findings. Proposed practice changes include the introduction of skin rounds and 'skin champions', standardised guidelines for when damage should be escalated to TVNs, and training for neonatal nurses on wound assessment and classification. Proposed areas for future research include the development of medical devices that take into consideration the unique requirements of preterm skin. Further qualitative research is needed with healthcare professionals and parents focussing on the role and experiences of the wider care team. In conjunction with the findings of this thesis, these next steps will allow nurses and other professionals to better protect and promote skin health in these most vulnerable of patients.

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DECLARATION OF AUTHORSHIP

I, HANNAH LOUISE LIVERSEDGE,

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.

[title of thesis] .....

.....

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 listed on page xxiv.

Signed: .....

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Definitions and Abbreviations

ANNP: Advanced neonatal nurse practitionerCAPU: Community-acquired pressure ulcer

Cares: Used in this document to refer to “cluster cares”, a nursing process used in neonatal units. May include diaper changes, whole-skin assessment, re-siting temperature and/or oxygenation monitoring, changing mode of CPAP delivery, washing the neonate, and any other nursing intervention which requires direct handling

CGA: Corrected Gestational Age (40/40 is full term)

CQUIN: Commissioning for Quality and Innovation

DD: Diaper dermatitis (used in relation to neonates and children in this thesis)

DTI: Deep Tissue Injury

ELBW: Extremely low birthweight (<1000g)

EPUAP: European Pressure Ulcer Advisory Panel

ER: Evaporation rate

ET tube: Endotracheal tube

GA: Gestational age

HAPU: Hospital-acquired pressure ulcer

HDU: High dependency unit

IAD: Incontinence-associated dermatitis (used in relation to adults in this thesis)

ICM: Implementation of Change Model (Grol *et al.*, 2013)

ITU: Intensive treatment unit

LBW: Low birthweight (<2500g)

HIE: Hypoxic ischaemic encephalopathy

IUGR: Intrauterine growth restriction

MDPRU: Medical device-related pressure ulcer

MHRA: Medicines and Healthcare products Regulatory Authority

MRC: Medical Research Council

NG tube: Nasogastric tube

NICE: National Institute for Health and Clinical Excellence

NICU: Neonatal Intensive Care Unit

NPUAP: National Pressure Ulcer Advisory Panel

NCSC: Neonatal Skin Condition Score

NSRAS: Neonatal Skin Risk Assessment Scale

ODN: Operational Delivery Network

OG tube: Orogastric tube

PICU: Paediatric Intensive Care Unit

PNA: Postnatal age

PPPIA: Pan Pacific Pressure Injury Alliance

PU: Pressure ulcer

PUKAT: Pressure Ulcer Knowledge Assessment Tool

RAS: Risk assessment scale

RDS: Respiratory Distress Syndrome

RM: Registered midwife

RN: Registered nurse

SC: Stratum corneum

SCH: Stratum corneum hydration

TEWL: Transepidermal water loss

TVN: Tissue viability nurse

UK: United Kingdom

US: United States

VLBW: Very low birthweight (<1500g)

WOCN: Wound, ostomy and continence nurse

Publications and conferences

Parts of this research have been previously disseminated as follows:

Publications

Liversedge, H. L., et al. (2018). Survey of neonatal nurses' practices and beliefs in relation to skin health. *Journal of Neonatal Nursing*, 24(2), 86-93

Conferences

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Chapter 1: **Introduction**

1.1 Functions and structure of the skin

The skin is the largest organ of the human body. It acts as both an inside-out barrier, protecting the body from loss of water and other essential components, and an outside-in barrier, protecting the body from external insults (Baroni *et al.*, 2012). This two-way barrier function is implicated in such diverse roles as immunity (Elias, 2007), thermoregulation (Charkoudian, 2003), fluid and electrolyte balance (Rutter, 2003), sensation (Zimmerman, Bai and Ginty, 2014), protection from ultraviolet light (Lai-Cheong and McGrath, 2013), and protection from physical trauma (Baroni *et al.*, 2012). These roles are interrelated, with each contributing to the barrier function of the skin and protecting the internal organs from the external environment.

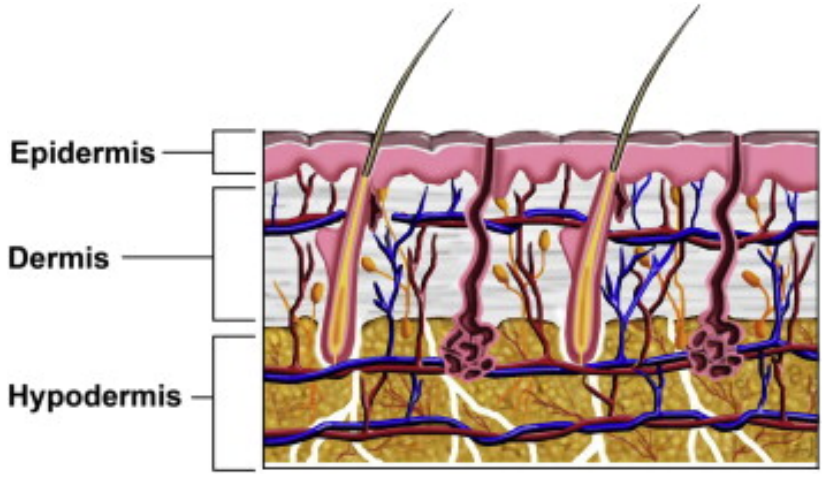

Figure 1.1 Structure of the skin.
Reprinted from (Gao *et al.*, 2013), with permission from Elsevier.

The skin is comprised of the epidermis, dermis, and subcutaneous tissue or hypodermis (Figure 1.1). The epidermis and dermis are both made up of distinct layers. The majority of the barrier functions are attributed to the properties of the epidermis, although the dermo-epidermal junction is of functional importance in maintaining homeostasis, and both dermal and subcutaneous tissue are implicated in thermoregulation and mechanical protection.

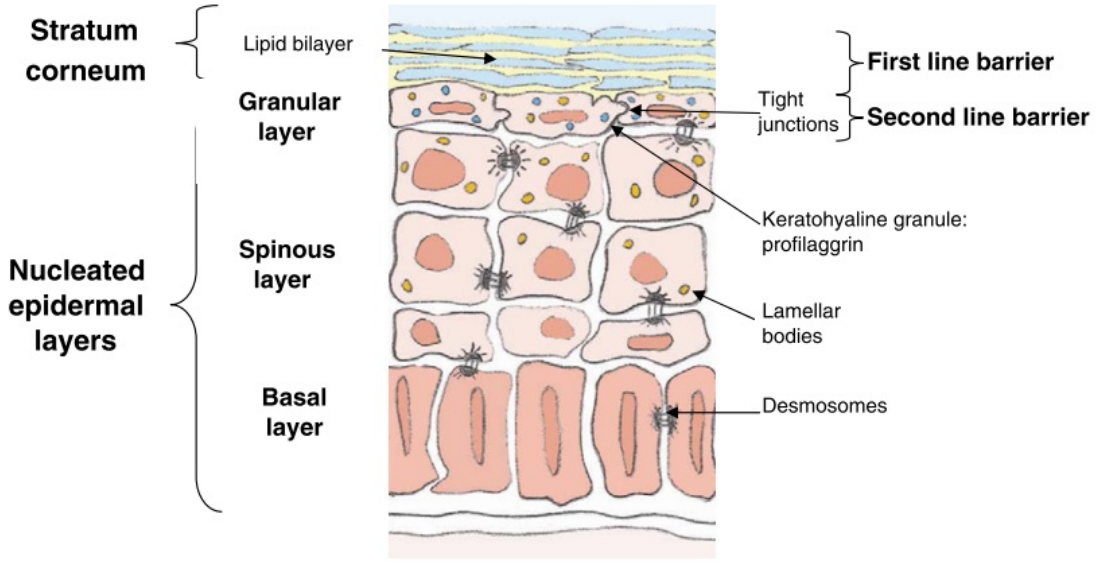

Figure 1.2 Cross-section of the epidermis.
Reprinted from (Baroni *et al.*, 2012), with permission from Elsevier.

1.1.1 Epidermis

The epidermis is primarily composed of keratinocytes (95% of epidermal cells), and can be further subdivided into several strata (see Figure 1.2). In addition to those represented in the figure, the stratum lucidum is present directly below the stratum corneum in thick skin layers; for example, the soles of the feet. It is composed of 3-5 layers of keratinocytes (Bryant and Nix, 2006). The epidermis is frequently referred to as being composed of the stratum corneum (SC) and the viable epidermis (the layers composed of living cells). The basal layer is composed of a single layer of keratinocytes. Daughter cells from this layer undergo differentiation as they progress upwards through the strata of the epidermis, with the terminal stage of keratinocyte differentiation being represented as flattened corneocytes without nuclei in the SC (Lai-Cheong and McGrath, 2013). These corneocytes are held together in an extracellular matrix consisting of a complex lipid mixture. As keratinocytes undergo differentiation, they synthesise the epidermal lipids, along with keratin proteins. In this way, the epidermal tissue is continuously renewed (Baroni *et al.*, 2012). In addition to keratinocytes and corneocytes, there are other specialised cell types in the epidermis (see Table 1.1).

Table 1.1 Epidermal cell types and functions

Cell type	**Function**
Keratinocytes	95% of epidermal cells are keratinocytes in different stages of differentiation (Lai-Cheong and McGrath, 2013)
Corneocytes	Corneocytes are terminally-differentiated anucleated cells that make up the SC and contribute to the barrier integrity (Lai-Cheong and McGrath, 2013)
Merkel cells	Merkel cells provide sensory information to the central nervous system (Hao *et al.*, 2015)
Lymphocytes	Immune function. Involved in specific immune responses (Baroni *et al.*, 2012).
Langerhans cells	Immune function (Baroni *et al.*, 2012).
Melanocytes	Melanocytes synthesise melanin-containing organelles (melanosomes), which are then transferred to basal keratinocytes. (Lai-Cheong and McGrath, 2013).

Many of the barrier functions attributed to the epidermis are localised in the stratum corneum. In addition to providing a physical barrier against invasion by foreign bodies and mechanical trauma, it has an innate immune function, with antimicrobial peptides contained within the lipid matrix (Elias, 2007). These directly kill or inhibit the proliferation of many species of microbe (Baroni *et al.*, 2012). The stratum corneum also acts as a permeability barrier, allowing an appropriate amount of transepidermal water loss (TEWL) and protecting the body from death due to excessive water loss (Madison, 2003). Corneocytes also act as a barrier to electromagnetic radiation (Elias, 2007). Both antimicrobial function and permeability of the epidermis are regulated by the slightly acidic pH of the stratum corneum, or “acid mantle” (Hachem *et al.*, 2003).

Although the stratum corneum provides the body’s outermost barrier, the lower strata of the epidermis also contribute to the protective function. In addition to supplying terminally-differentiated keratinocytes and lipids, the lower strata prevent diffusion of solutes through intercellular spaces, and maintain hydration of the skin. This is accomplished by the desmosomes and tight junctions that seal cells together in the granular layer (Figure 1.2) (Schlueter *et al.*, 2004; Morita, Miyachi and Furuse, 2011). Melanosomes are synthesized by melanocytes and then transferred to basal keratinocytes. The melanin protects the skin from

ultraviolet radiation (Lai-Cheong and McGrath, 2013). The lower strata of the epidermis act as a further barrier against excessive TEWL and invasion of pathogens (Baroni *et al.*, 2012).

1.1.2 Dermo-epidermal junction

The dermo-epidermal junction zone is comprised of the basal layer of epidermal keratinocytes, the dermo-epidermal basement membrane, and the upper (papillary) layer of the dermis (Villone *et al.*, 2008). The basement membrane is made up of the lamina lucida and the lamina densa, and allows molecules to diffuse between the epidermis and dermis (Rocken *et al.*, 2012). The epidermis and dermis are both anchored to the basement membrane. Anchoring filaments connect the hemidesmosomes of the basal keratinocytes to the lamina densa, and anchoring collagen XVII fibrils connect the basement membrane to the papillary dermis (Graham-Brown and Burns, 2007; Leyva-Mendivil *et al.*, 2015).

From term birth to midlife, the dermo-epidermal junction has undulations where the downward projections, or rete ridges, of the epidermis interdigitate with the upward projections, or dermal papillae, of the papillary dermis (Graham-Brown and Burns, 2007). Differences in older adults and neonates are outlined in 1.1.4 and 2.4.2 respectively. These undulations increase the surface contact between the two layers, facilitating the exchange of oxygen, nutrition, and waste products (Ciarletta and Ben Amar, 2012).

1.1.3 Dermis

The dermis is dense connective tissue composed of cellular and extracellular components. The cell types and functions are outlined in Table 1.2. The extracellular matrix (ECM) is composed of collagen, elastin, and proteoglycans (Rocken *et al.*, 2012). Collagen accounts for 70% of the dry weight of the dermis, with the primary collagen types present in the dermis being types I and III, though at least 16 types are present (Rocken *et al.*, 2012). Collagen molecules cross-link with one another, forming a strong and stable network that provides the skin with increased tensile strength and stiffness (Schultz, Ladwig and Wysocki, 2005; Hussain, Limthongkul and Humphreys, 2013). Elastic fibres make up 2-3% of the dry weight of the dermis and are primarily composed of elastin, imparting elasticity and resilience to the skin (Schultz, Ladwig and Wysocki, 2005; Rocken *et al.*, 2012). As with collagen molecules, elastin molecules cross-link with adjacent elastin molecules to form a stable network. Proteoglycans and

glycosaminoglycans (GAGs) form the amorphous gel which surrounds the collagen and elastin fibres (Tracy, Minasian and Caterson, 2016).

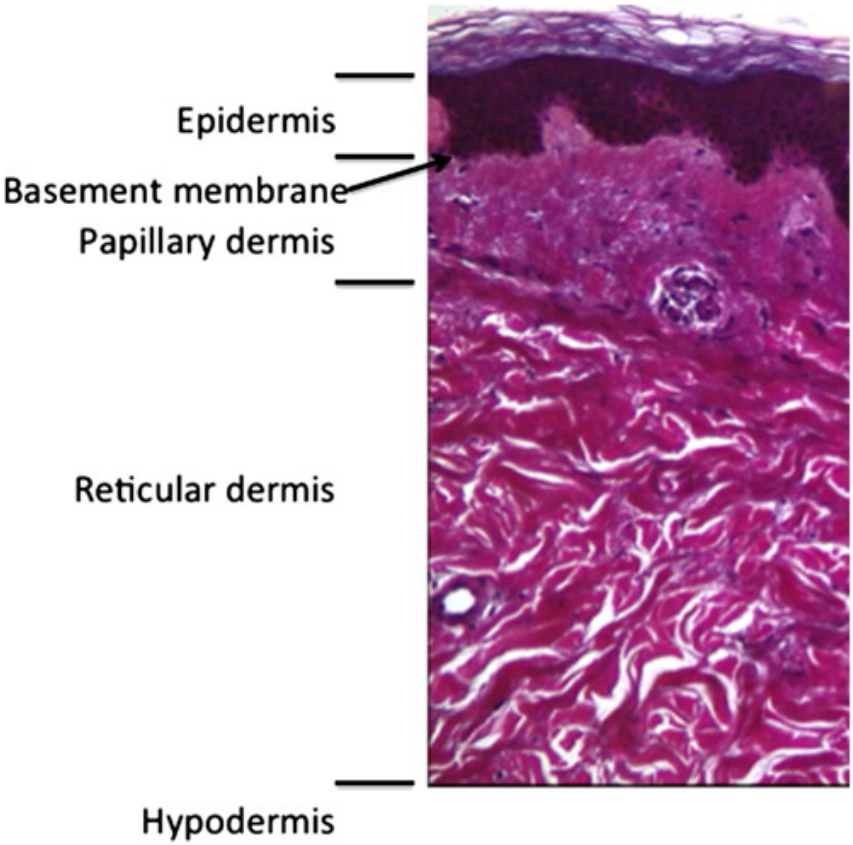

Figure 1.3 Cross-section of the skin showing location of basement membrane and papillary and reticular dermis

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The dermis can be divided into papillary and reticular strata (Figure 1.3). The upper papillary layer comprises approximately 20% of the dermis (Tortora and Derrickson, 2014). The dermal papillae contain capillary loops, with some also containing nerve endings sensitive to heat or touch (Tortora and Derrickson, 2014). The reticular dermis is composed of thicker, denser collagen fibres than the papillary dermis, and contains complete elastic fibres (Rocken *et al.*, 2012; Mikesh *et al.*, 2013).

Table 1.2 Dermal cell types and functions

Cell type	**Function**
Fibroblasts	Synthesise and deposit collagen, elastin, and proteoglycans (Wong, McGrath and Navsaria, 2007) Promote keratinocyte proliferation and release cytokines and growth factor (El-Ghalbzouri *et al.*, 2002) Facilitate re-epithelialisation following wounds (El Ghalbzouri *et al.*, 2004)
Macrophages	Phagocytic immune cells that scavenge foreign substances, including cell debris and damaged tissue (Baroni *et al.*, 2012)
Mast cells	Specialised secretory cells containing granules with contents such as histamine and prostaglandins (Graham-Brown and Burns, 2007)

The dermis is highly vascularised, with cutaneous blood flow contributing significantly to thermoregulation. For example, when the body is subjected to thermal stress, the resulting vasodilation increases the loss of body heat via convection, preventing the internal organs from overheating (Charkoudian, 2003). Sweat glands are also involved in thermoregulation, and these are hosted in the dermis, as are sebaceous glands and hair follicles. The cell types of the dermis and their functions are described in Table 1.2. The subcutaneous fat tissue, below the dermis, protects the internal organs against mechanical trauma, and provides insulation against external extremes of hot and cold (Baroni *et al.*, 2012).

1.1.4 Biomechanical characteristics of the skin

One of the main functions of the skin is to protect the internal organs from mechanical insults, which might arise from a range of loading modalities e.g. tension, compression, shear. The biomechanical characteristics which support this function predominantly arise from the properties exhibited by the dermal structures (Hussain, Limthongkul and Humphreys, 2013), although other layers of the skin have also been implicated providing mechanical integrity of the skin (Agache and Varchon, 2004). As an example, the SC, compromised of keratinised corneocytes, provides a stiff mechanical barrier, but it remains pliable and naturally wrinkled (Agache and Varchon, 2004; Leyva-Mendivil *et al.*, 2015). Additionally, computational modelling has recently indicated that in response to stress, the elasticity of the SC affects not only the strain magnitude within the SC but in the subjacent layers below (Leyva-Mendivil *et al.*, 2015). Rigidity is afforded to the viable epidermis by the keratin structure formed by desmosomes (Figure 1.2) (Agache and Varchon, 2004). The collagen and elastin present in the

dermis confer stiffness and elasticity, respectively (Schultz, Ladwig and Wysocki, 2005). In addition, the ridges present throughout the human are designed to redistribute strain in a more uniform manner (Leyva-Mendivil *et al.*, 2015). The undulations of the dermo-epidermal junction protect the skin from shearing forces (Tortora and Derrickson, 2014).

In relation to skin damage, it is relevant to note that barrier function of the skin is significantly affected by application of mechanical stress, and vice versa. In particular, compromise to the barrier affects the mechanical properties of the skin (Pedersen and Jemec, 2006).

There are significant changes in the mechanical properties of the skin of young neonates through to old age. These changes occur as a result of the structural developments with age (see 1.1.6). Paediatric skin inevitably changes postnatally. In addition, while the crosslinks of dermal collagen typically change with age, the content of dermal elastin drastically reduces, leading to an increased stiffness of elderly skin (Hussain, Limthongkul and Humphreys, 2013).

1.1.5 Note on terminology

Neonates can be described according to birthweight or degree of prematurity. The classifications that will be used for each factor in this document are outlined in Table 1.3 and Table 1.4.

Table 1.3 Birthweight (Bührer and Zimmermann, 2009)

Term	**Birthweight**
Extremely low birthweight (ELBW)	<1000g
Very low birthweight (VLBW)	<1500g
Low birthweight (LBW)	<2500g

Table 1.4 Degree of prematurity (World Health Organization, 2015)

Term	**GA at birth**
Extremely preterm	<28 weeks
Very preterm	28-<32 weeks
Moderate to late preterm	32-<37 weeks

Additionally, throughout this thesis, the term "skin damage" will be defined as any change to the normal structure or function of the skin. This term has been adopted following discussion with neonatal nurses, as unlike "skin breakdown", these clinicians perceive it to refer to colour changes, indentation of the skin, and irritation, as well as broken skin.

1.1.6 Differences in skin structure and function with age

The structure and function of skin as discussed above relates to healthy young or midlife adults. There are some differences in term and preterm neonates and older adults, which will now be discussed.

Although the skin of healthy term neonates is structurally complete, its functional integrity remains incomplete, and the skin continues to thicken over the first years of life (Fluhr *et al.*, 2010). A period of environmental adaptation to a terrestrial as opposed to the intrauterine environment is required (Fluhr *et al.*, 2012). Children aged between 3 and 24 months of age have SC that is, on average, 30% thinner than that of adults, and the other strata of the epidermis are on average 20% thinner (Stamatas *et al.*, 2010).

In addition to differences in thickness, there are some functional differences between the skin of healthy term neonates and that of adults. Term neonates exhibit a skin pH of 6.6-7.5 on day one of life (Yosipovitch *et al.*, 2000; Fluhr *et al.*, 2012). Since SC pH regulates permeability, antimicrobial function, and the rate of barrier repair following injury, the skin barrier cannot be said to be functionally complete in this population. However, the pH decreases over the first 5-6 weeks of life, reaching a value of 5.1, and is stable in older children (Fluhr *et al.*, 2012). This should be compared with the "acid mantle" described in adults, with a skin pH of between 4.5-6.0 (Giusti *et al.*, 2001).

There are rapid changes in TEWL in the hours and days following birth (Hammarlund *et al.*, 1980; Yosipovitch *et al.*, 2000). Immediately following birth, evaporative water loss is extremely high (Hammarlund *et al.*, 1980), but it reduces to a more moderate level by 1 hour of life. Yosipovitch and colleagues found that TEWL was lower in healthy term neonates on day 1 of life than in adults, when measurements were taken between 5 and 10 hours post-birth (Yosipovitch *et al.*, 2000). Other studies have reported average TEWL in healthy term neonates comparable to that of adults (Harpin and Rutter, 1983; Fluhr *et al.*, 2012). Taken together, these data suggest a period of rapid adaptation following birth as the neonate adapts to a cold, dry, gaseous environment. However, the permeability barrier of the skin seems to be competent once this adaptation has occurred (Fluhr, Pfisterer and Gloor, 2000; Fluhr *et al.*, 2012).

In addition to differences between the skin of healthy midlife adults and term neonates, the structure of the skin also changes in older adults. Although the ageing process in skin has been extensively studied, there are still conflicting data regarding the associated structural changes (Waller and Maibach, 2005, 2006). For example, differences between physiologically and photoaged skin and natural variations between individuals make definitive statements problematic, as do inconsistencies in defining “aged” or “older” humans (Waller and Maibach, 2005). Indeed, although there is some evidence that overall lipid content in the SC is decreased by roughly 30% in adults over 50 (Ghadially *et al.*, 1995; Rogers *et al.*, 1996), other studies have shown no age-related difference in lipid content (Cua, Wilhelm and Maibach, 1995). Alternatively, decreased SC lipid in relation to SC protein may be present in older individuals in some anatomical regions, such as the dorsal forearm (Boireau-Adamezyk, Baillet-Guffroy and Stamatas, 2014). Similarly, although it has been generally believed that stratum corneum thickness does not alter with age (Waller and Maibach, 2005), recent research suggests that the stratum corneum increases in thickness in older individuals (Boireau-Adamezyk, Baillet-Guffroy and Stamatas, 2014). The effect of aging on the skin pH also remain unclear (Waller and Maibach, 2005).

Nonetheless, there are some structural differences that have been identified in older skin. First, the dermo-epidermal junction is undulating in nature in young adults, but becomes flatter from the seventh decade onwards (Hull and Warfel, 1983). This may be associated with decreased proliferation of epidermal cells in aged skin (Waller and Maibach, 2005). Functional differences have been consistently described in aged skin. As an example, baseline TEWL has been reported to be consistently decreased in older adults compared with both young and

midlife adults (Ghadially *et al.*, 1995; Waller and Maibach, 2005; Kottner, Lichterfeld and Blume-Peytavi, 2013). The barrier recovery time following epidermal injury is also significantly prolonged in individuals over 80 years of age (Ghadially *et al.*, 1995).

The differences in skin barrier function in preterm neonates, especially the timeline of skin maturation following extremely and very preterm birth, have yet to be fully elucidated. However, it is clear that neonates born extremely prematurely have impaired barrier function compared to term neonates, reflected in an inverse correlation between TEWL and GA at birth (Hammarlund and Sedin, 1979; Harpin and Rutter, 1983; Kalia *et al.*, 1998). This is likely due to structural differences in underdeveloped skin. For example, some areas of the skin are not well-keratinised until approximately 29/40 weeks' gestational age (Hardman *et al.*, 1999). Similarly, dermo-epidermal undulations are not visible until approximately 34/40 (Evans and Rutter, 1986), suggesting that the skin of extremely and very premature neonates is more vulnerable to shearing forces. A summary of differences is also presented in Table 1.5. A more extensive discussion of the literature on development of skin in utero and the resulting differences in barrier function between term and preterm neonates can be found in section 2.3.2.2.

Table 1.5 Structural and functional differences between term, preterm, and adult skin

Skin Characteristic	**Adult**	**Term neonate**	**Preterm neonate**	**Relevance to skin health**
Epidermal thickness	50µm	50µm	27.4µm	↑ TEWL
Cell attachments	Normal	Normal	Fewer	↑ Tendency to blister
Dermis	Normal	↓Collagen and elastic fibres	↓↓Collagen and elastic fibres	↓ Elasticity ↑ Blistering
Eccrine glands	Normal	↓ Activity for 7–10 days	Total anhidrosis	↓Response to thermal stress
Vernix caseosa	NA	Fully developed	Undeveloped or absent	↓ hydration, ↓ bacterial protection
Acid mantle	Normal	Normal	Delayed	↓ antimicrobial processing

Dietel, K., *Morphological and Functional Development of the Skin*, in *Perinatal Physiology*, U. Stave, Editor. 1978, Springer US. p. 761-773.

Sedin, G., et al., *Measurements of transepidermal water loss in newborn infants.* Clinical Perinatology, 1985. **12**(1): p. 79-99.

Ness, M.J., D.M.R. Davis, and W.A. Carey, *Neonatal skin care: a concise review.* International Journal of Dermatology, 2013. **52**(1): p. 14-22.

1.2 Skin damage

In light of the essential functions of the skin, it follows that disease or injury will have deleterious effects on the overall health of any individual. This is particularly true of individuals who are already vulnerable due to ill health, such as hospital inpatients.

1.2.1 Hospital-acquired skin damage in adult patients

Research into hospital-acquired skin damage to date has focused primarily on pressure ulcer (PU) development in the adult population. A PU is defined as localised injury to the skin or tissue as a result of pressure or pressure in combination with shear (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). In addition to pain, development of a PU whilst in hospital is associated with increased length of stay (Graves, Birrell and Whitby, 2005), risk of nosocomial infection, including osteomyelitis and cellulitis (Reunes *et al.*, 2011), and significantly higher overall cost of treatment (Dealey, Posnett and Walker, 2012). In light of these factors, they are regarded as a serious patient safety issue. Additionally, it has recently been estimated to cost £14108 to treat a category IV PU in the UK, representing a significant financial burden to the NHS (Dealey, Posnett and Walker, 2012). They are frequently preventable, though not exclusively (Black *et al.*, 2011). For these reasons, prevention of PUs is now considered a major nurse-sensitive outcome of care quality, frequently incentivised in national policy. For example, in the UK, PUs constitute the highest burden of healthcare-associated harm; therefore guidance for organisations aiming to obtain the Commissioning for Quality and Innovation (CQUIN) payment recommends that providers focus on reducing PU prevalence ((Health and Social Care Information Centre, no date). In addition, “Your skin matters” is one of the High Impact Actions for Nursing and Midwifery (NHS Institute for Innovation and Improvement, 2011).Clinical studies have generally examined adult populations in the community and in hospital (Bergstrom *et al.*, 1987; Waterlow, 1991; Cullum *et al.*, 2001; Moore and Cowman, 2014), with increasing interest in special populations such as ITU or burns patients (Jackson, 1999; Lewis *et al.*, 2012; Coyer, Stotts and Blackman, 2013). Due to previous inconsistencies in PU reporting in the UK (Dealey *et al.*, 2012), it is difficult to determine average PU prevalence or incidence across the country. Approximate values of 21% in 2007 were considerably higher than in other European countries such as Italy and Portugal (Vanderwee *et al.*, 2007).

In addition to PUs, hospital inpatients are at risk of other kinds of skin damage. Incontinence-associated dermatitis (IAD), extravasation injury, peristomal or periwound dermatitis, and chemical burns all occur in this population (Beeckman *et al.*, 2015; Ellanti and Hurson, 2015; Loubani and Green, 2015; Campbell, Coyer and Osborne, 2016). There is also a growing awareness of the risk of medical device-related pressure ulcers in both hospital and community settings (Black *et al.*, 2010). This is discussed in greater detail in 2.5.3.

1.2.2 Skin damage in hospitalised children and neonates

In the last decade, awareness that children and neonates are also at risk of hospital-acquired skin damage has been growing (Baharestani and Ratliff, 2007). In part, this is due to the increasing complexity of neonatal and paediatric intensive care, alongside the increased rate of preterm birth globally (Goldenberg *et al.*, 2008). Neonatal care in particular has led to extremely preterm neonates living into childhood in greater numbers. This has resulted in increased awareness of skin damage, because injuries associated with intensive treatment are becoming more apparent (Fox and Rutter, 1998; Smith and Roy, 2006; Hogeling *et al.*, 2012) (Table 1.6). Iatrogenic skin damage unrelated to devices also occurs in this population (Table 1.7). In addition to the complications of iatrogenic skin damage present in adult patients, the associated cosmetic issues and potential lifelong scarring are an additional concern for this population (Fox and Rutter, 1998; Manning, Gauvreau and Curley, 2015). The skin is not fully developed in extremely preterm or very preterm neonates (Hammarlund and Sedin, 1979; Harpin and Rutter, 1983; Okah *et al.*, 1995; Kalia *et al.*, 1998), and the extent to which this immaturity plays a role in skin damage is not yet known. The functional deficits of preterm neonatal skin are discussed in 2.4.2.

Table 1.6 Device-related skin damage in hospitalised neonates

Device	**Type of damage**	**References**
nCPAP (prongs and mask delivery systems)	Pressure ulcers, septal erosion, unspecified nasal damage	(Robertson *et al.*, 1996; Buettiker *et al.*, 2004; Alsop *et al.*, 2008; Fischer *et al.*, 2010)
nCPAP hats	Forehead necrosis	(Hogeling *et al.*, 2012)
Intravenous and intra-arterial catheters	Extravasation injury, needlemarks	(Fox and Rutter, 1998; Wilkins and Emmerson, 2004)
Oxygen cannulae	Nasal mucosal damage	(Kopelman and Holbert, 2003)
Cooling jackets	Subcutaneous fat necrosis, necrotic skin lesions	(Fumagalli *et al.*, 2011)(Oza *et al.*, 2010)(Demirel *et al.*, 2013)
Transilluminators	Burns	(Keroack, Kotilainen and Griffin, 1996; Perman and Kauls, 2007)
Phototherapy lamps	Burns	(Siegfried, Stone and Madison, 1992)
Adhesive tape	Disruption of barrier function (through epidermal stripping)	(Lund *et al.*, 1997)
ET tubes (oral and nasal)	Pressure ulcers	(Fujioka *et al.*, 2008)
Chest drains	Long-term scarring (initial damage not described)	(Fox and Rutter, 1998)
Warming devices (e.g. heating lamps, water bottles)	Burns	(Simonsen *et al.*, 1995; Möhrenschlager *et al.*, 2003; Rimdeika and Bagdonas, 2005)
Infant abduction prevention systems	Periumbilical skin and soft tissue infection	(Zangwill *et al.*, 2017)

Table 1.7 Skin damage in neonates not associated with devices

Type of damage	**References**
Surgical scars	(Fox and Rutter, 1998)
Diaper dermatitis	(Visscher, Taylor and Narendran, 2013)
Pressure ulcers, especially occipital	(Fox, 2011)

1.4 Content and structure of the literature review

The issue of hospital-acquired skin damage in neonatal units is still being defined. The extent of, factors contributing to, and possible solutions to the problem have yet to be fully elucidated. For this reason, it is not possible to begin a detailed review of the literature with a single question. Instead, a broad overview of many issues associated with hospital-acquired skin damage is required. The literature review will therefore consider several topics related to this issue, based on multiple questions. An example of one search strategy used during the process of the literature review can be seen in Appendix A.

Chapter 2: Literature review

2.1 Clinical motivation

My experiences on a neonatal unit as a student nurse informed my desire to research this topic. Specifically, towards the end of my final placement, I provided care for extremely premature, critically ill twin boys under the supervision of a senior nurse. Shortly after this experience, I returned for a night shift and the senior nurse handing over reported that "both of them have black noses"; that is, both boys had developed skin damage as a result of treatment with nasal continuous positive airway pressure (CPAP). I was struck by the fact that neither my mentor nor I had noticed the early stages of this skin damage, and nurses viewed these injuries as a regrettable but inevitable result of treatment. It was my desire to make skin damage less inevitable in this population that motivated me to undertake this research.

2.2 Historical background of skin care research

Skin care and skin damage have been a priority for physicians and other healthcare staff since at least c.400BC. Hippocrates and his students set aside a chapter of his Corpus to the treatment of several classes of ulcer, including "old ulcers", "bloody ulcers", and "swellings that arise spontaneously in the feet". Recommended treatments ranged from bloodletting to the application of melted goat fat (Hippocrates, 1995). Similarly, Pliny the Elder suggested in c.77AD that "plantain… softened by fire" was ideal for the treatment of ulcers in neonates and the elderly, whereas wagon axle grease could be used for wounds that were otherwise considered untreatable (Pliny the Elder, 1949). It is clear that various forms of skin damage have been recognised and treated as a serious healthcare concern for millennia, including in relation to children and neonates.

Prevention of skin damage, in particular PUs, has been a topic of interest in healthcare research for nearly 200 years, and immobility has been considered the primary contributing factor for the majority of that time. As early as 1832, specialist water beds were being developed for bedbound patients, initially with the intention of treating pre-existing PUs (Arnott, 1832). By 1898, it was generally believed that it was possible to prevent some if not all PUs; in *Notes on Nursing,* Florence Nightingale attributes the development of PUs to immobility and damp blankets, and moreover writes that "a bedsore… is generally the fault of

the nurse" (Nightingale, 1898). Research regarding the prevention of PUs has been pursued by early nurse researchers, including those at the first nursing research centre, opened in 1959 (Norton, McLaren and Exton-Smith, 1975).

2.3 Aetiology

Although the aetiology of PUs has not yet been fully described, there is an increasing body of evidence discussing the various processes involved. When tissues experience mechanical loading in the form of pressure, or pressure in combination with shear, blood vessels are compressed (Gebhardt, 2004; Loerakker, 2007). If this period is prolonged, vessels collapse and perfusion is inhibited, blocking the flow of nutrients to skin and the surrounding tissues, thus creating local ischaemia. Subsequently, the affected tissues have to respire anaerobically due to the lack of oxygen supply (Ceelen, Oomens and Baaijens, 2008). Anaerobic respiration causes accumulation of lactic acid, which lowers intracellular pH and leads to necrosis.

Other mechanisms that have been suggested include reperfusion injury, cell deformation, and impaired lymphatic drainage (Breuls *et al.*, 2003; Loerakker, 2007; Ceelen, Oomens and Baaijens, 2008; Gray, Voegeli and Bader, 2015). Reperfusion injury occurs when ischaemic tissues are offloaded and blood rushes to the area resulting in rapid perfusion. Reperfusion causes cellular oedema, tissue damage, and overproduction of reactive oxygen species triggering a process termed oxidative stress. This may cause the accumulations of unfolded proteins disturbing homeostasis, resulting in cellular stress (Blaisdell, 2002). Studies in a rat model have indicated that the tissue injury worsened with increased numbers of ischaemia-reperfusion cycles compared to one ischaemic insult (Peirce, Skalak and Rodeheaver, 2000), which may be replicated in a clinical environment through turning of patients to relieve pressure.

PUs can be categorised as either superficial or deep tissue injury. The term "Deep Tissue Injury" (DTI) is used to describe an area of persistent, nonblanchable discoloured intact skin (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). In contrast to a category I PU, defined as nonblanchable erythema of intact skin, a DTI originates with deformation of the skeletal muscle and may develop rapidly into a serious open wound (Oomens *et al.*, 2015). Exploration of (DTI) aetiology in a rat model has demonstrated that cell deformation, ischaemia, and reperfusion injury are all implicated, although the importance of each varies

during a period of prolonged loading (Loerakker *et al.*, 2011). Further studies are needed to elucidate the pathophysiology of PU development.

2.4 Skin and barrier function

Much of the work into understanding PU development and risk factors has been based on the conceptual schema developed by Braden and Bergstrom (Braden and Bergstrom, 1987). This contends that the risk of developing a PU is a combination of pressure and shear applied to the skin and tissue tolerance of that pressure. Tissue tolerance is defined as the ability of the skin and soft tissues to tolerate pressure without tissue damage (Coleman *et al.*, 2015), affected by both extrinsic factors such as moisture and intrinsic factors such as decreased nutrition (Bergstrom *et al.*, 1987). The importance of an individual's susceptibility has been highlighted again in a new conceptual framework, which reports that this is comprised of qualities including physiology and repair, and mechanical properties of the tissue (Coleman *et al.*, 2015). Understanding the baseline barrier properties of the skin and soft tissues when unaffected by ill health or other factors is therefore crucial to determining an individual's risk of PU development.

2.4.1 Adults

Transepidermal water loss (TEWL), defined as the amount of water unrelated to sweating lost through the epidermis, is the primary measure used in barrier function studies (Chiou and Blume-Peytavi, 2004). In healthy young and middle-aged adults, defined as 18-64 years, TEWL varies dependent on anatomical site. A recent systematic review found the lowest average TEWL is found in breast skin (2.3 g/m^2/h, 95% CI 1.9-2.7), and the highest average is found in the axilla (44.0 g/m^2/h, 95% CI 39.8-48.2) (Kottner, Lichterfeld and Blume-Peytavi, 2013). TEWL studies are most commonly carried out on the right volar forearm, which has average TEWL ranging from 4.3 g/m^2/h (proximal) to 9.6 g/m^2/h (distal). Indeed, normal TEWL varies across anatomical sites, related to the structure and function of the skin. TEWL appears to decrease in older adults, especially in sites which are not frequently exposed (Boireau-Adamezyk, Baillet-Guffroy and Stamatas, 2014). The reasons for decreased TEWL in older age are not yet fully understood (Kottner, Lichterfeld and Blume-Peytavi, 2013).

Human skin also has an acidic pH or "acid mantle", which has multiple functions (Chan and Mauro, 2011). Firstly, the acid mantle is thought to act as an innate immune element with a

role in antimicrobial defence (Elias, 2007). Additionally, the pH directly regulates barrier permeability (Hachem *et al.*, 2003), with enhanced stratum corneum integrity and rapid barrier recovery found in individuals with lower skin pH (Gunathilake *et al.*, 2009). There is some evidence that skin pH increases in individuals who are over 70 years of age (Waller and Maibach, 2005). Data regarding other aspects of skin structure and function in older people are more conflicting (Waller and Maibach, 2005, 2006), though it is clear that older adults are more at risk from conditions such as atopic dermatitis and that barrier function is slower to recover following insult in older individuals than in young and middle-aged adults (Ghadially *et al.*, 1995).

2.4.2 Neonates

The most preterm neonates to be resuscitated in the UK are those born at 23 weeks' gestation (Drife, 2011). Given the extent to which skin development continues *in utero* past this point (Figure 2.1) neonates born prematurely will necessarily have impaired barrier function and tolerance to external stimuli. In order to understand the risk of skin damage in hospitalised neonates, it is therefore necessary to first characterise the unique qualities of neonatal skin. As with adults, TEWL has been the primary method used to characterise barrier function in neonate. Summaries of studies into TEWL in term and preterm neonates can be found in Table 2.1 and Table 2.2.

2.4.2.1 Term neonates

Hammarlund and colleagues published a series of studies using TEWL over 30 years ago (summaries in Appendix B). Elevated TEWL has been consistently demonstrated in both term and preterm neonates immediately following birth (Hammarlund *et al.*, 1980; Yosipovitch *et al.*, 2000; Visscher, Taylor and Narendran, 2013). However, in term neonates, TEWL appears to stabilise relatively quickly. Hammarlund and colleagues reported mean TEWL of 103 g/m^{2}h immediately following birth, reaching more moderate values by one hour of life (Hammarlund *et al.*, 1980). Similar results were found by Yosipovitch and colleagues, who reported a statistically significant decrease in TEWL between days 1 and 2 of life in term neonates (Yosipovitch *et al.*, 2000). Following a period of adaptation, TEWL in this population appears to be equivalent with that of healthy adults, with values of 5.3-8.1 g/m^{2}h reported (Hammarlund *et al.*, 1977; Hammarlund and Sedin, 1979; Fluhr *et al.*, 2012).

The processes that facilitate this apparent change in barrier permeability are not clearly defined, although Yosipovitch and colleages suggest that it may be due to lipid residue from the vernix caseosa (2000), the fatty layer covering the foetus during the final trimester (Hoath *et al.,* 2006). The role of vernix, including effects of retention after birth, is still being investigated and is outside the scope of this review (Youssef, Wickett and Hoath, 2001; Visscher *et al.*, 2005; Tansirikongkol *et al.*, 2007; Tansirikongkol, Visscher and Wickett, 2007). Others have suggested that high TEWL in the first day of life represents a period of 'drying out' after being in the intrauterine environment (Hammarlund *et al.,* 1980, Fluhr *et al.,* 2010).

2.4.2.2 Preterm neonates

In the series of studies by Hammarlund and colleagues, relationships between various factors and TEWL were investigated using the open chamber method TEWL probe, including gestational age (Hammarlund and Sedin, 1979), activity and body temperature (Hammarlund *et al.*, 1979), and size for GA (Hammarlund and Sedin, 1980). The primary finding from this body of work is that TEWL is significantly elevated in preterm neonates with an inverse correlation between TEWL and GA at birth, suggesting significantly impaired barrier function in the most preterm neonates. These findings have been confirmed by later studies (Harpin and Rutter, 1983; Kalia *et al.*, 1998). Elevated TEWL in preterm neonates is likely to be due to the structural immaturities compared with adults (see 1.1 and 2.4.1 for a review of adult skin structure and function).

The translation of these results to current practice is limited, especially those from early studies. For example, Hammarlund and Sedin (1979) classify neonates as either very preterm (≤30 weeks' GA) or preterm (31-35 weeks GA), with the latter group considered to represent significantly improved overall outcomes over the former. 30 weeks has since been suggested as the GA at which the barrier has functional maturity (Kalia *et al.,* 1998). The results from these more mature neonates may therefore have confounded the results from the extremely preterm neonates of 25 weeks' GA. Additionally, the studies examining preterm neonates do not provide information about the use of drugs and mechanical ventilation (Hammarlund and Sedin, 1979, 1982), which may influence TEWL values (Kalia *et al.*, 1998).

The impact of studies in the 1970s-80s is further limited due to the limited use of humidification in the incubators (Harpin and Rutter, 1983). Humidity has a significant effect on maintenance of core temperature, and its use is now widespread (Sinclair *et al.,* 2009). The rate of skin barrier maturation is affected by relative humidity (RH), with improved barrier

function achieved more rapidly at lower levels of RH (Ågren, Sjörs and Sedin, 2006). Additionally, elasticity of the stratum corneum tends to decrease with increased RH (Leyva-Mendivil *et al.*, 2015). However, use of humidification is also used in minimising evaporative losses through TEWL (Sinclair, Crisp and Sinn, 2009). Healthcare professionals have to balance the need for neonates to maintain a stable core temperature with the developmental benefits of a drier environment. Consequently there is currently no consensus governing the use of humidity in preterm neonates (Sinclair, Crisp and Sinn, 2009).

A longitudinal study by Kalia and colleagues highlighted the prolonged period of barrier maturation in extremely preterm neonates (Kalia *et al.*, 1998). One neonate born at 23 weeks' GA took up to 9 weeks to demonstrate functional barrier maturity. This clearly contradicts a previous study, which indicated that a period of two weeks to attain functional maturity was sufficient, regardless of GA (Harpin and Rutter, 1983). A number of factors unrelated to GA were also highlighted. Indeed the twins included in the study demonstrated different maturation rates, as did the triplets. The authors suggest a number of factors that could have contributed to this, including nutrition type or the use of dexamethasone for respiratory complications.

Although the majority of studies examining skin barrier function in this population have utilised TEWL, other forms of measurement have also been used including capacitance, impedance, and percutaneous absorption (Harpin and Rutter, 1983; Okah *et al.*, 1995; Kalia *et al.*, 1998). These have confirmed impaired barrier function in extremely and moderately preterm neonates, although the timeline of maturation remains unclear. Further longitudinal studies utilising TEWL and other methods are required in order to clarify this (Fluhr *et al.*, 2010).

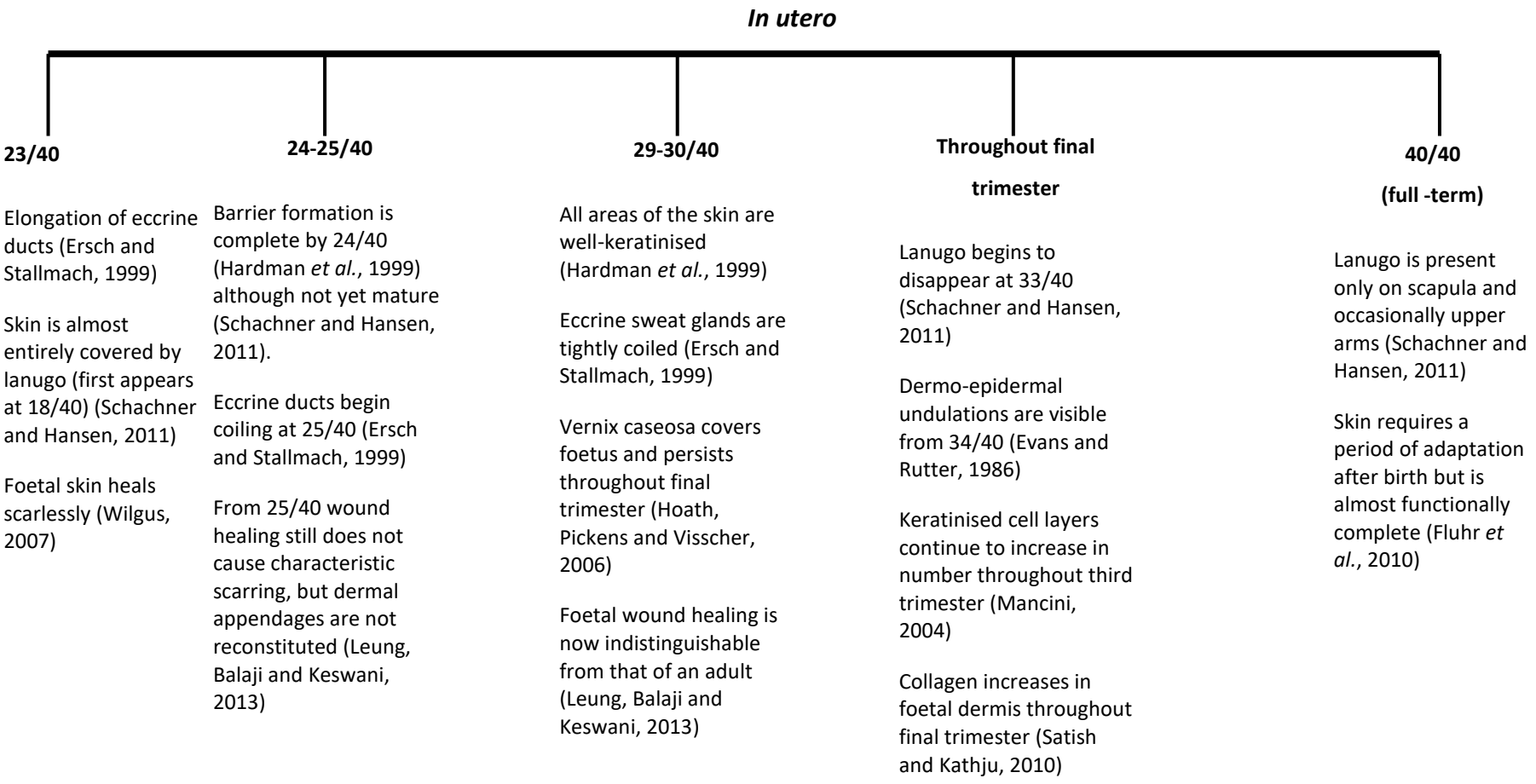


Figure 2.1 Timeline of skin development in utero

Table 2.1 TEWL in term neonates

Reference	**Summary**	**Findings**
Hammarlund, K., Nilsson, G.E., Öberg, P. Å., and Sedin, G. (1977)	Description of TEWL measurement device and calculations Evaporation rate (from which TEWL was calculated) measured on 28 healthy term neonates at varying ambient humidities and anatomical sites	Mean TEWL in healthy term neonates of 8.1 g/m^{2}h at 50% ambient humidity
Hammarlund, K., Nilsson, G. E., Öberg, P. Å., and Sedin, G. (1980)	ER, ambient temperature, body temperature and skin temperature measured in 21 healthy term neonates regularly for 2 hours postnatally: from 1st minute of life in 10 term neonates born vaginally; from 30th minute of life in 11 born by Caesarean section Heat exchange calculated from these data	Water loss immediately after birth high in vaginal delivery series (103 g/m^{2}h), had decreased to approx. 30 g/m^{2}h by 0.5 hours in both series Series 1 reached more moderate water losses by 1h of life, series 2 by 2h Heat loss also decreased over first hour of life, but was 3 times higher in the delivery room than in incubators
Hammarlund, K., Sedin, G., and Strömberg (1982)	ER measured in 34 neonates repeatedly over first 4-5 weeks of life: 7 were born at 25-27 weeks' GA, 13 at 28-30 weeks, and the remaining 14 were term. All	Mean TEWL for term neonates was 3.8 g/m^{2}h on the first day of life; this did not change until 2 weeks of age, when it increased to 4.7 g/m^{2}h

	neonates were appropriate weights for gestational age (AGA). TEWL calculated.	
Yosipovitch *et al.* (2000)	TEWL measured on days 1 and 2 of life in 44 healthy term neonates across different body regions: abdomen, back, forehead, forearm, inguinal region, palms, and soles. Measurements also taken in 20 healthy adults as control.	TEWL significantly higher on day 1 in soles, palms and forearms than on day 2 TEWL significantly higher in palms, forearms and inguinal region than other anatomical regions TEWL significantly higher in term neonates on day 1 than in adult controls
Fluhr *et al.* (2012)	TEWL measured in 108 subjects from 6 age groups, including 18 healthy term neonates aged 1-15 days and 18 healthy adults aged 20-35 years.	No statistically significant difference in TEWL between term neonates and adults. Mean TEWL <10 g/m^2h in both age groups

Table 2.2 TEWL in preterm neonates

Reference	**Summary**	**Findings**
Hammarlund, K., and Sedin, G. (1979)	Evaporation rate measured in 12 neonates of 25-30 weeks' GA, 10 neonates of 32-35 weeks' gestation, and 10 term neonates	Neonates of 25-30 weeks' GA had a mean evaporation rate of 44 g/m^{2}h Neonates of 32-35 weeks' GA had a mean evaporation rate of 6.2 g/m^{2}h Term neonates had a mean evaporation rate of 3.5g/m^{2}h Exponential relationship between TEWL and GA
Hammarlund, K., Sedin, G., and Strömberg (1982)	ER measured in 34 neonates repeatedly over first 4-5 weeks of life: 7 were born at 25-27 weeks' GA, 13 at 28-30 weeks, and the remaining 14 were term neonates. All were AGA. TEWL calculated.	Mean TEWL in neonates 25-27 weeks' GA was 45.4 g/m^{2}h, decreasing to 8.9 g/m^{2}h after 4-5 weeks Mean TEWL in neonates 28-30 weeks' GA was 18.6 g/m^{2}h, decreasing to 11.3 after 5 days and 5.9 g/m^{2}h after 4-5 weeks.
Hammarlund, K., Sedin, G., and Strömberg (1983)	ER measured regularly in 68 term and preterm AGA neonates and 33 SGA term and preterm neonates. Measurements made on first day of life and then on days 1, 3, 5, 7, 14, 21 and 28 days in most subjects. TEWL calculated from ER.	AGA preterm neonates had higher TEWL on day of birth than SGA preterm neonates of corresponding GA. AGA neonates had stable TEWL for first 2 weeks of life, whereas TEWL rose in SGA neonates In both AGA and SGA neonates, there was a strong correlation between lower GA and higher TEWL at birth
Harpin, V. A., and Rutter, N. (1983)	TEWL measured in 70 neonates of 25-41 weeks' GA using	Slightly elevated losses in neonates of 33-36 weeks' GA compared to term neonates, resolving within the first week Highest losses in very preterm neonates, resolving by 2 weeks—highest value 65 g/m^{2}h

	evaporimetry, with focus on postnatal age	
Kalia, Y. N., Nonato, L. B., Lund, C. H., and Guy, R. H. (1998)	TEWL measured regularly in 10 preterm neonates born at gestational ages 23-32 weeks, including one set of twins and one of triplets	Extremely preterm neonates took up to 9 weeks to develop functionally mature barrier Differences in maturation rates between twins/triplets, suggesting factors other than GA Neonates born at 30-32 weeks' GA had normal values from first day of measurement

2.4.2.3 Acidification

In contrast with the 'acid mantle' found in healthy adult skin (see 1.1.1 and 2.4.1), term and preterm neonates have a skin pH that is neutral or close to neutral at birth (Green, Carol and Behrendt, 1968; Hoeger and Enzmann, 2002; Fluhr *et al.*, 2012). However, the timeline of acidification and the role of prematurity are still unclear. Yosipovitch and colleages (2000) reported that in healthy term neonates, pH drops significantly by day 2 of life, but is still significantly higher than in adult controls. Later work has shown a decrease between 3 and 30 days' PNA in healthy term neonates, although measurements were not taken in between these dates, making it impossible to determine how quickly the pH decreased (Hoeger and Enzmann, 2002). In work by Fluhr and colleagues, term neonates had a mean pH of 6.0 (2012); however, since neonates of 1-15 days old were grouped together, no new information is provided about the timeline of acidification. Visscher and colleagues found that pH decreased significantly between days 1 and 10 of life in term and preterm neonates (Visscher, Taylor and Narendran, 2013). Although data were gathered daily, the results are only presented for days 1 and 10, so the timeline is again uncertain. No differences between different body regions are present immediately after birth (Yosipovitch *et al.,* 2000).

Research currently available suggests that the pattern of skin acidification in preterm neonates closely mirrors that of term neonates (Green, Carol and Behrendt, 1968; Fox, Nelson and Wareham, 1998). However, the most preterm neonates included in the first of these two studies were <34 weeks' gestation, limiting application to current practice (Green, Carol and Behrendt, 1968). In the second study, though it is more recent, the mean GA of included neonates is 29.3 weeks (Fox, Nelson and Wareham, 1998). Given that other aspects of barrier maturation such as TEWL appear to take longer than previously thought, especially in extremely preterm neonates (Kalia *et al.,* 1998), it is reasonable to suggest this may be reflected in acidification. At present, data on this subject are lacking.

2.5 Prevalence and incidence of hospital-acquired skin damage

2.5.1 Definitions

Point prevalence is defined as the number of new cases of a disease, in this case skin damage, at a specified point in time. Incidence is defined as the number of new cases over a set period of time (Centers for Disease Control and Prevention (CDC), 2012).

2.5.2 Adults

Studies exploring prevalence and incidence of hospital-acquired skin damage in the adult population have focussed primarily on PUs. Reported PU prevalence and incidence figures for the adult inpatient population vary significantly between countries and clinical specialities, though it has been recognised as an international problem (Halfens *et al.*, 2013). Examples of this can be seen in Table 2.3, which contains summaries of recent papers exploring reported figures. Reported prevalence ranges from 3.22% in Nigeria to 54% in Norway. Some of this may be due to differences in demographics. For example, the participants in the Nigerian hospital were younger, with a mean age of affected patients of 47.0, compared to a modal age bracket of 70-99 in Norwegian patients. Methodological differences are also likely to contribute to these discrepancies, such as exclusion of category I ulcers in the Nigerian study.

In light of the intrinsic and extrinsic factors that contribute to an individual's tissue tolerance, different clinical populations will necessarily have differing levels of PU risk. Studies have frequently demonstrated higher PU prevalence rates in critical care environments than on general wards, for example (Shahin, Dassen and Halfens, 2008; Akbari Sari *et al.*, 2014). This is unsurprising, given that patient acuity is much higher in this environment. It is more difficult to turn critically ill patients without destabilising their clinical condition, patients are more likely to be hypotensive, and use of sedatives or general anaesthesia is more widespread. PU prevalence between 4% and 49% has been reported in ITUs, and incidence between 3.8% to 12.4% (Shahin, Dassen and Halfens, 2008).

2.5.3 Device-related skin damage in adults

Interest in device-related skin damage, especially medical device-related pressure ulcers (MDPRUs), has been increasing in recent years (Coyer, Stotts and Blackman, 2013). Up to

34.5% of all hospital-acquired PUs are associated with medical device use (Black *et al.*, 2010). This is unsurprising, given that any soft tissue that is loaded for a prolonged period of time is at risk of developing a PU. Additionally, medical devices are frequently used in environments such as ITUs, where intrinsic factors such as hypotension and poor perfusion are likely to negatively affect tissue tolerance. MDPRU prevalence of 3.1% has been reported in ITUs in Australia and the United States (Coyer, Stotts and Blackman, 2013).

Cases of MDPRUs have been associated with a wide range of interventional devices (Sleilati *et al.*, 2008; Mulhall and Jindal, 2013; Yamashita *et al.*, 2014; Kim *et al.*, 2015), and, as with immobility-related PUs, complications include pain, increased risk of infection, and long-term scarring. For example, one patient developed a category IV PU on her nasal bridge from a ventilation mask that required surgical correction (Sleilati *et al.*, 2008). Additionally, there have been reports of patients suffering life-threatening rectal haemorrhage associated with pressure ulceration due to faecal management systems (Sparks *et al.*, 2010; Reynolds and van Haren, 2012; Mulhall and Jindal, 2013).

Table 2.3 Prevalence and incidence studies in adult inpatient populations published between 2010 and 2015

Authors	**Location**	**Sample**	**Methodology**	**Key findings**
(James *et al.*, 2010)	Wales (all orthopaedic units in country, n=12; 25% of community hospital beds).	1196 inpatients ≥ 18 years of age 581 in orthopaedic wards 615 in community hospitals	2x point prevalence studies conducted over short periods of time (<2 weeks each)	**13.9%** prevalence in orthopaedic wards **26.7%** prevalence in community hospitals
(da Silva Cardoso *et al.*, 2010)	Brazil (one hospital)	376 patients on day 1 340 patients on day 2	2x point prevalence studies conducted on single days (June 16th, October 2nd 2004)	**11.4%** prevalence day 1 **10.3%** prevalence day 2 **32.7%** average prevalence in ITU **47%** of ulcers Grade II
(Tubaishat, Anthony and Saleh, 2011)	Jordan (one university hospital, one general hospital)	302 inpatients ≥ 18 years of age 175 in university hospital 127 in general hospital Maternity, day care, and emergency care environments excluded	1 point prevalence study conducted	**12%** prevalence rate **29%** prevalence rate in critical care **44%** of ulcers Grade I **17%** of patients at risk received adequate prevention
(Kelleher, Moorer and Makic, 2012)	United States, one 17-bedded surgical ITU	180 patients ≥18 years of age included in total	Quarterly prevalence studies carried out over 36 months Focused on HAPUs	Average prevalence **10.6%** Highest **27.1%** Lowest **0%** (for 3 months consecutively) Prevalence higher at times of unusually high acuity
(Gunningberg, Stotts and Idvall, 2011)	Sweden (five hospitals)	1192 inpatients ≥18 years of age 52.2% female Mean age 67.8 years	1 day point prevalence study with focus on distinguishing between CAPUs and HAPUS	**11.6%** prevalence rate of HAPU **3.3%** CAPU Total prevalence of **14.9%**

		Maternity, psychiatric, day care and hospice units excluded		
(Gunningberg, Hommel, *et al.*, 2013)	Hospitals and nursing homes in Sweden	35053 patients in total 16466 in hospitals 18592 in nursing homes	Point prevalence study Data collected on a single day at each setting Data collected over the course of one week in total	**16.6%** prevalence in hospitals **14.5%** in nursing homes
(Adegoke *et al.*, 2013)	Nigeria (six hospitals)	1211 patients ≥ 16 years of age	Point prevalence study Data collected on a single day at each setting Grade I ulcers not included	**3.22%** prevalence overall Prevalence at individual units ranging from **0%**-**6.9%**
(Alja'afreh and Mosleh, 2013)	Jordan (one hospital)	190 patients in 2 wards	Point prevalence study Data collected over 5 days Incidence study Data collected over 4 weeks	**24%** prevalence **27%** cumulative incidence over 4 weeks
(Fu Shaw *et al.*, 2014)	Taiwan (one teaching hospital)	297 inpatients Admitted to hospital for surgical procedure	Incidence immediately following procedure Incidence 30 minutes after procedure Collected over a 2-week period	**9.8%** incidence immediately following procedure **5.1%** incidence 30 minutes after procedure
(Moore *et al.*, 2015)	Ireland (one hospital) Norway (one hospital)	180 inpatients ≥ 18 years of age 59 in Norwegian site 121 in Irish site	1 day point prevalence study with data collected over a single day at each setting	**54%** prevalence in Norwegian site, 69% of which were Grade I **12%** prevalence at Irish site, 50% of which were Grade II

2.5.4 Children

Although PUs have historically been thought of as a care problem exclusive to the adult population, in recent years there has been an increase in awareness that hospitalised children are also at risk (Baharestani and Ratliff, 2007). A systematic review found prevalence estimates for a general paediatric population from 2-28%, with incidence of roughly 7% in the general paediatric population and 26% in the PICU (Kottner, Wilborn and Dassen, 2010). More recently, Schindler and colleagues found an overall PU incidence of 10.2% in a PICU environment (Schindler *et al.*, 2011). A more recent study found that 50% of PU development in children is associated with the use of interventional medical devices (Schlüer, 2017), and one study found that 90.9% of all PUs in paediatric inpatients occurred in critically ill children (Habiballah and Tubaishat, 2016).

2.5.5 Neonates

It is difficult to determine average PU prevalence and incidence in the NICU for several reasons. Firstly, neonates may be classed with general paediatric patients in studies for reasons of sample size (Schlüer *et al.*, 2009), rather than research being carried out specifically in the neonatal population. Reports of skin damage in neonates tend to be in the form of case reports, largely related to individual devices or therapies (see examples in Table 2.4). One small-scale study of 32 hospitalised neonates found that 19% developed skin damage of some kind during a three-month period (Huffines and Logsdon, 1997); however, the results were being reported along with a new risk assessment scale for use in that population, and selection criteria were unclear. The lack of robust inclusion and exclusion criteria, along with the small sample size, makes it difficult to determine the extent to which these figures are affected by recruitment bias. More recently, Fujii and colleagues found a cumulative incidence of 16% over 11 months in NICUs in Japan (Fujii *et al.*, 2010), and Visscher and Taylor reported an incidence rate of 1.5 PUs per 1000 patient days (Visscher and Taylor, 2014). Prevalence of 31.2% has recently been reported in a NICU in Australia, with 16.8% of these being category III or IV PUs (August *et al.*, 2014).

MDPRUs form a high percentage of all PUs reported in neonatal environments, with over 90% of PUs in preterm neonates being associated with devices (Visscher and Taylor, 2014). Nasal continuous positive airway pressure devices, or CPAP, are frequently reported as causing

issues in this population (Robertson *et al.*, 1996; Yong, Chen and Boo, 2005; Alsop *et al.*, 2008). Other forms of skin damage associated with devices have also been reported in neonatal environments (see Table 1.5)..

Due to the pivotal developmental stage during which patients are treated on the neonatal unit, neonates who experience skin injury in this environment may suffer serious consequences even long after they have been discharged. For example, nasal airway obstruction in childhood requiring surgical correction has been reported as an unusual complication of both CPAP and nasogastric feeding tubes (Smith and Roy, 2006). Long-term cosmetic scarring has also been reported in association with hospital-acquired skin damage (Fox and Rutter, 1998).

2.6 Assessment

2.6.1 Definitions

Sensitivity is defined as the proportion of true positives identified by a particular risk assessment scale (RAS); that is, the number of patients identified as being at risk of a PU who go on to develop one. Specificity is defined as the proportion of true negatives identified by a particular RAS (Altman and Bland, 1994). Use of these terms is complicated in any clinical study looking at PU prevention, as use of prevention measures may be effective in preventing patients at high risk from developing a PU. A given scale may therefore appear to have lower specificity, because it would be unethical to withhold PU prevention from a patient to see if PU development does occur. Nonetheless, these terms are useful in understanding the strengths and weaknesses of given tools when compared with one another and with clinical judgement.

2.6.2 Risk assessment

Early research focused on preventative methods and identification of those at risk. Norton and colleagues developed and tested a risk assessment scale (RAS), the Norton scale, for hospitalised older people (Norton, McLaren and Exton-Smith, 1975). Since the publication of this scale, other researchers have built upon the work conducted and further RAS have been developed, most notably the Waterlow (Waterlow, 1991) and Braden (Bergstrom *et al.*, 1987) scales. These, along with the Norton scale, are the most commonly-used RAS in the UK (Pancorbo-Hidalgo *et al.*, 2006). These three scales differ in format and scoring system, but they include similar categories of risk for pressure breakdown. Table 2.4 highlights the way in which RAS have become more specific as understanding of the risk factors for and aetiology of PUs has developed.

Comparisons of the three most common scales have yielded contradictory results. Balzer and colleagues compared the Norton, Waterlow and Braden scales, finding that Waterlow had the highest sensitivity and Norton was the most specific (Balzer *et al.*, 2007). Schoonhoven and colleagues also compared them, with a focus on clinical effectiveness, and found that none of the three satisfactorily predicted skin breakdown (Schoonhoven *et al.*, 2002). In contrast, a systematic review of studies concluded that both the Braden and Norton scales predict risk more accurately than nurses' clinical judgement (Pancorbo-Hidalgo *et al.*, 2006). However, the review found no evidence that routine use of RAS decreased incidence of PUs. More recently,

a randomised controlled trial of the Waterlow scale against a new, unvalidated scale, as well as against nurses' clinical judgement, found no significant difference in incidence between the three groups (Webster *et al.*, 2011).

In light of this conflicting evidence, it has been argued, that RAS could be used in combination with robust objective biomarkers (Bronneberg *et al.*, 2007; Cornelissen *et al.*, 2009; Anthony *et al.*, 2011), that it is worth favouring sensitivity over specificity, in order to minimise the chances of a patient developing a PU (Balzer *et al.*, 2007), and that new research should be carried out in order to develop RAS that are based on data rather than expert opinion (Schoonhoven *et al.*, 2002). It has also been suggested that the use of RAS is an ineffective use of resources that could be better spent on regular assessment of the skin and specific preventative measures (Schoonhoven *et al.*, 2002). A Cochrane systematic review concluded that there is currently no evidence that use of risk assessment scales decreases incidence of PUs (Moore and Cowman, 2014).

Table 2.4 Comparison of categories in Norton, Waterlow and Braden scales

	Nutrition	**Sensory perception**	**Age**	**Activity**	**Mobility**	**Moisture**	**Sex**	**Weight**	**Friction**	**General condition**
Norton Scale (Norton *et al.,* 1975)	No	No	No	Yes	Yes	Yes (incontinence)	No	No	No	Yes
Waterlow Scale (Waterlow, 1991)	Yes	No	Yes	No[1]	Yes	Yes (incontinence)	Yes	Yes	No[1]	No
Braden Scale (Bergstrom *et al.,* 1987)	Yes	Yes	No	Yes	Yes	Yes (all moisture)	No	No	Yes	No

[1]Although the Waterlow scale does not contain separate categories for *friction* and *activity*, much of the language used in the *mobility* category (such as 'restless' and 'fidgety') implies consideration of these factors.

2.6.2.1 Paediatric and neonatal tools

Although the subject of RAS receives extensive attention in adult nursing research, the use of RAS has come about more recently in children, and is still not routine in most paediatric healthcare settings in the UK. The Braden Q, the first scale designed for use in the paediatric population, was adapted from the adult Braden scale (Quigley and Curley, 1996). However, there are limitations to its use. It is designed for use in children between 3 weeks and 8 years old (Noonan, Quigley and Curley, 2011), therefore excluding a large part of the paediatric population. The minimum age of 3 weeks was chosen because it was believed that, regardless of gestational age, skin has maturity equivalent to that of a term neonate by 3 weeks of age. However, this is unlikely to be the case for extremely preterm neonates (see 2.4.2 for a discussion of this), making it inappropriate for use in the neonatal unit. Additionally, the authors of the Braden Q have expressly stated that it is not appropriate for assessing the risk of device-related damage (Noonan, Quigley and Curley, 2011), calling into question its utility in environments such as PICUs and NICUs, where a significant proportion of paediatric skin damage occurs. The Glamorgan scale, developed more recently (Willock, Baharestani and Anthony, 2009), does include an item for "equipment/objects/hard surfaces pressing against the skin", and weights this highly as a risk factor. A comparison of both the Braden Q and Glamorgan scales, along with the Garvin scale, found that the Glamorgan scale had the highest predictive ability of the three (Anthony, Willock and Baharestani, 2010). However, the authors suggested that assessing mobility alone may prove as useful in predicting and therefore minimising the risk of skin breakdown as utilising a more complex RAS.

The only RAS designed for use in neonatal units is the Neonatal Skin Risk Assessment Scale (NSRAS) (Huffines and Logsdon, 1997). This was also adapted from the Braden Scale based on expert opinion. The tool was tested in the population it was designed for and found to have 83% sensitivity and 81% specificity, but has not been externally validated. Additionally, the tool has not been updated since it was published and the cot types it refers to are not consistent with those currently used in neonatal practice (Schumacher, Askew and Otten, 2013). Since use of humidified incubators significantly affects neonatal skin maturation (Ågren, Sjörs and Sedin, 2006), this is an important consideration. It may be that the rapid pace of practice changes in the NICU environment prevents the development of a comprehensive RAS.

A three-step pressure ulcer trigger tool has been suggested for use in this environment instead, to screen for neonates requiring further assessment (Schumacher, Askew and Otten, 2013). This included three trigger questions, for recognising developmentally-inappropriate immobility, developmentally-inappropriate sensory problems, and inadequate perfusion with tissue breakdown. If a neonate triggered on any of these three points, he or she was referred to the

wound/ostomy and continence nurse (WOCN) for further assessment by means of the Braden Q. Although no trigger for device presence is included in the tool, the authors recommended that any unit adopting the screening tool includes one. The intention of the tool was to introduce screening for PU risk without relying on a long and complex scale. Introduction of the tool did not make a difference to PU prevalence, which was already low at 0-1% per quarter, and did not reduce referrals to the WOC nursing team. This tool has not yet been evaluated in NICUs with a higher PU prevalence. Most recently, August and colleagues reported the development of a new tool (NIPIRA) for combined risk and skin assessment in neonates, as the Modified Braden Q was not felt to be sensitive to injuries that were occurring in their unit (August *et al.*, 2014). However, the process of development and the full tool have not yet been reported.

A recent systematic review on the validation and clinical impact of RAS in paediatric and neonatal populations found that the overall quality of reporting on this issue was poor, and that there is currently no "gold standard" for use in this population (Kottner *et al.*, 2013). Most recently, investigation of the Glamorgan scale and the Visual Analogue Scale found that, though they had good inter-rater reliability, neither scale provided information that was useful to nursing staff when planning PU preventative care (Kottner, Kenzler and Wilborn, 2014). This suggests that routine use of RAS may not be of clinical value in a low risk environment such as a general paediatric ward. To date, there has been no study looking at the clinical utility of RAS in the high risk NICU environment.

2.6.3 Skin assessment

Regular skin assessment is recommended as part of PU prevention and management (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). If an individual's skin is assessed regularly, early signs of damage can be recognised and managed appropriately. Additionally, the correct classification of PUs assists clinicians in choosing the appropriate treatment. International guidelines regarding the classification of existing PUs have been released and can be found in

Table 2.5 (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). These have been widely adopted in clinical practice in the UK and Europe (Mackintosh, Gwilliam and Williams, 2014). Regular skin assessment, when combined with other interventions including staff education and formalised risk assessment, had a positive effect on patient outcomes in a hospital in the US (Young *et al.*, 2010).

The Neonatal Skin Condition Score (NSCS) has been proposed for use in NICUs and well-baby units (known as postnatal wards in the UK), in order to standardise daily assessment of skin health (Lund, 2004). The NSCS scores skin from 1-3 on dryness, erythema, and existing breakdown, with

a total score of 3 being perfect and a total score of 9 being worst. When evaluated, the NSCS had moderate intra- and interrater reliability (68.7-85.4% and 65.9-89% respectively). The clinical effectiveness of this tool has not been evaluated since then, so it is not known whether it contributes helpfully to care planning and delivery.

There has been relatively little discussion about the classification of PUs and other skin damage in preterm neonates, where the thinness of the skin and relative lack of subcutaneous fat may complicate assessment. Recent research has reported PUs of categories I-IV occurring in the neonatal population (August *et al.*, 2014), although these categories have not yet been widely adopted in neonatal practice in the UK (Thames Valley Neonatal Quality Care Group, 2012). Given that neonates are clearly subject to severe PUs in some environments, further research and expert consensus is required regarding standardisation of the assessment process.

Table 2.5 EPUAP/NPUAP pressure ulcer categories (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014)

Category	**Description**
I	Non-blanching erythema of a localised area, usually over a bony prominence
II	Partial thickness skin loss, presenting as a shallow ulcer with a red pink wound bed. No slough or bruising. May also present as an intact or ruptured serum-filled blister.
III	Full thickness skin loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. If slough is present, it does not obscure depth of tissue loss. May include tunnelling or undermining.
IV	Full thickness tissue loss with exposed bone, muscle, or tendon. Slough or eschar may be present. Often includes undermining or tunnelling.
Unstageable	Full thickness tissue loss where wound bed is obscured by slough or eschar. Depth cannot be determined until enough slough/eschar is removed to expose the base of the wound.
Suspected deep tissue injury (DTI)	Purple or maroon localised area of discoloured intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.

2.7 Prevention of skin damage

The intention of regular risk assessment and skin assessment is that care planning is targeted to an individual's needs. Unless preventative practices are put in place as a result of perceived risk, the process does not contribute positively to quality of care.

2.7.1 Repositioning and pressure relief

Regular repositioning of individuals who are at risk of PU development is an integral part of prevention. The theoretical underpinning for this intervention is the understanding that PUs develop when skin and soft tissues experience prolonged loading, and therefore removing or minimising the pressure placed on a particular area will allow tissue recovery to occur and prevent necrosis (Manorama *et al.*, 2010). Repositioning strategies are recommended in all national and international guidelines related to the prevention of PUs (National Institute for Health and Clinical Excellence (NICE), 2014; NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014).

Several factors affect the recommended frequency of repositioning. For example, a trial of a 2-hourly repositioning schedule in an adult ITU found no associated decrease in PU development compared to the 4-hourly standard of care. In addition to this, it was associated with a significant increase in nursing workload, along with device-related adverse events, such as unplanned extubation (Manzano *et al.*, 2014). Additionally, haemodynamically unstable patients may not tolerate regular repositioning (Benoit and Watts, 2007). This is true for many critically ill neonates. Neonates admitted with Respiratory Distress Syndrome (RDS) have significantly better oxygenation when nursed prone than when nursed supine (Eghbalian, 2014). Local guidance for neonatal units recommends regular repositioning of neonates for pressure relief where possible, but recognises that this must be balanced with the neonates' need for sleep and possible clinical instability (Thames Valley Neonatal Quality Care Group, 2012). No evidence is available at present regarding repositioning of neonates specifically for pressure relief, though an incidence study in a PICU found that repositioning 2-4 hourly was associated with a lower risk of PU development (Schindler *et al.*, 2011).

2.7.2 Specialist support surfaces

In addition to RAS and skin assessment, use of specialist support surfaces has been a focus of research into PU prevention. This generally takes the form of specialist mattresses or mattress overlays (McInnes *et al.*, 2015), as well as design of wheelchairs and hospital bedside chairs (Ferguson-Pell *et al.*, 2015). These are often used in conjunction with repositioning schedules,

especially in hospital (Manzano *et al.*, 2014). In some areas, especially areas where repositioning of patients is complicated by multiple medical devices or haemodynamic instability, alternating pressure or continuous low pressure mattresses are widely used (Masterson and Younger, 2014). Alternating pressure mattresses are comprised of cells that inflate and deflate in sequence, helping to relieve pressure in different anatomical regions for a short time (Manzano *et al.*, 2013).

A recent Cochrane review of support surfaces found that the use of higher-specification foam mattresses reduces the incidence of PU development in people at risk compared to standard hospital mattresses (McInnes *et al.*, 2015). Medical-grade sheepskin overlays were also found to be associated with a decrease in PU development. However, the review also found that there is currently relatively little evidence to inform the selection of alternating pressure or continuous low pressure mattresses, and that the methodological quality of several of the included studies was limited.

The use of pressure-relieving mattresses or support surfaces in neonatal environments has not been formally evaluated. However, guidance from the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) in the US recommends the use of sheepskin and gel mattresses (Lund, Osborne, *et al.*, 2001). Local policy in Wessex and Thames Valley advises that no formal evaluation of pressure-relieving surfaces for neonates has been made, but that these may be of use in the 'at risk' neonate (Thames Valley Neonatal Quality Care Group, 2012).

2.7.3 Prevention of device-related ulcers

In some circumstances, MDPRUs are unavoidable due to the fact that the associated devices are necessary to preserve life (Black *et al.*, 2011). However, there is increasing awareness of the problem, and successful quality improvement projects have been reported in relation to specific devices. For example, following identification of a number of tracheostomy-related PUs in a paediatric transitional care unit, where the majority of children are on long term invasive or non-invasive ventilation, a team in the US implemented a PU prevention bundle (Boesch *et al.*, 2012). This included staff education on RAS and skin assessment, parent education, use of a barrier dressing between the tracheostomy ties and the skin, and implementation of risk and skin assessment into nursing practice. Additionally, clinicians worked with a device company to develop a new tracheostomy device that did not impinge on the skin. Following implementation of this bundle, tracheostomy-related PU occurrence fell from 8.1% to 0.3%.

Fujioka and colleagues report five cases of upper lip PUs in intubated preterm neonates, all of which caused scarring (Fujioka *et al.*, 2008). This was believed to be due to shearing forces on the skin of the upper lip, caused by the adhesive tape used to secure the ET tube folding and pulling

the skin over a prolonged period of time. In light of this, a new method of ET tube fixation was developed so that the skin was no longer being deformed in this way, device contact with the skin and mucosa was minimised, and assessment of the skin was easier. Although the sample size was small and the authors did not report prevalence figures of these PUs prior to the intervention, they report that there were no further cases of this type of PU in the subsequent year.

There is a growing body of evidence suggesting that the use of prophylactic dressings to prevent MDPRUs, especially in ITU patients (Clark *et al.*, 2014). For example, both hydrocolloid and film dressings have been shown to be associated with a significant decrease in facial PUs for patients receiving non-invasive ventilation (Weng, 2008). The use of these and similar products has not yet been systematically evaluated in neonates.

2.8 Health professionals' attitudes, knowledge, and decision-making

2.8.1 General nurses

Nurses represent the majority of qualified healthcare professionals employed by the NHS, and are assisted in their duties by support staff such as nursing auxiliaries (NHS Confederation, 2015). As such, they are responsible for the co-ordination and delivery of frontline care in environments ranging from care homes to intensive care units, including the prevention and management of skin damage. Recent international guidelines recommend nurse-led quality improvement programmes as a tool to the prevention and management of PUs (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). In light of this, it is essential to have an insight into the attitudes, knowledge and decision-making of nursing staff (qualified and otherwise) regarding skin integrity, as this will necessarily have an impact on their practices (Lamb and Sevdalis, 2011).

The majority of studies exploring nursing attitudes and knowledge on the subject of PU prevention and management have focused on general and older adult nursing environments. Given the importance of these subjects in relation to PU prevention, tools have recently been developed to standardise assessment of nursing knowledge and attitudes. Firstly, the Pressure Ulcer Knowledge Assessment Tool (PUKAT) was developed to assess nursing knowledge and has been found to be valid for this purpose (Beeckman, Schoonhoven and Defloor, 2008). In recent studies including those using the PUKAT, nursing knowledge has been found to be generally inadequate (Beeckman, Schoonhoven and Defloor, 2008; Demarré *et al.*, 2012; Gunningberg, Mårtensson, *et al.*, 2013). In contrast, Källman and Suserud found generally good knowledge of PU treatment and management (Källman and Suserud, 2009). In the majority of studies, nurses' knowledge of classification and wound assessment was not sufficient (Beeckman *et al.*, 2011;

Demarré *et al.*, 2012). An intervention which included training for nursing staff was associated with an improvement in nursing knowledge, even for staff who did not undertake the training themselves (Sving *et al.*, 2014).

There have been relatively few studies regarding registered nurses' (RNs) attitudes towards PU prevention (Waugh, 2014). Studies generally report a positive attitude of RNs towards prevention (Beeckman *et al.*, 2011; Demarré *et al.*, 2012), though it has been suggested that PU prevention is given a low priority compared to other areas of care, with prevention is delegated to students or healthcare assistants (Moore and Price, 2004; Samuriwo, 2010b; Sving *et al.*, 2012). However, participants often report that they give PU prevention a higher priority than their colleagues or staff in other areas of healthcare do (Athlin *et al.*, 2010; Samuriwo, 2010b). This may be because nurses are reluctant to acknowledge gaps in their own practice, or because nurses who take part in these studies are generally self-selecting and do have a higher degree of interest in PU prevention and management. Regardless of the reason, nursing attitude has been found to be significantly correlated with adequate PU preventative measures on a ward, while nursing knowledge is not (Beeckman *et al.*, 2011; Demarré *et al.*, 2012). Nursing knowledge of PUs and nursing attitude towards PU prevention are not always correlated. Indeed, a recent study of undergraduate nursing students in Ireland found an inverse relationship between knowledge and attitude (Cullen Gill and Moore, 2013).

2.8.2 Tissue viability nurses

Tissue viability nurses (TVNs) are nurses whose role is to provide specialist advice on various aspects of wound care, including PU prevention, management of existing wounds, and staff education (Pagnamenta, 2014). A similar role, Wound Ostomy and Continence Nurse (WOCN) exists in the US, though the roles differ in terms of training and scope (Cutting *et al.*, 2006). In the UK, TVNs work in both hospital and community settings. Although TVNs and WOCNs have been active in carrying out research into PU prevention and other aspects of skin health, there is a lack of information related to their own perceptions of issues related to skin care. Beeckman and colleagues found that TVNs had significantly better PU knowledge than staff nurses, and significantly more positive attitudes towards PU prevention (Beeckman *et al.*, 2011).

Although some specialist children's hospitals in the UK have their own TVN teams (Kipps, 2014), the majority of trusts rely on general TVNs to provide advice to paediatric and neonatal nurses. Creation of a neonatal WOCN position has been reported at one hospital in the US, though the effect that this has had on neonatal tissue viability has not been reported (Kaufman, 2007). At present, there are no studies exploring TVNs' perceptions of neonatal skin care or their role in this

environment. A search on Embase and MEDLINE on 24/4/17 returned only one result for TVNs or WOCNs in relation to infants. This concerned the use of a negative pressure wound treatment system on a complex wound in a 4-month old baby with complications from surgery (Bookout, McCord and McLane, 2004). A further search on CINAHL found seven papers, of which none related to the question. There were no studies concerning neonates or neonatal skin care.

2.8.3 Paediatric and neonatal nurses

There is a dearth of research exploring the knowledge and attitudes of paediatric and neonatal nurses in relation to skin health and skin care. As previously identified (see section 2.3), children and neonates, especially premature neonates, have significant physiological differences from adults in terms of their skin. Drake and colleagues (2012) surveyed paediatric nurses in the US working in specialities outside PICU (Drake *et al.*, 2012). They found that, although nurses had good generalised knowledge of PU prevention, they struggled to individualise care planning for their patients in this area. This is in keeping with similar studies conducted with adult nurses. There were no studies of this subject identified among nurses trained and working in the UK, where paediatric nurses receive very limited training on skin integrity.

More recently, Mohamed and colleagues (2014) conducted a survey of neonatal nurses working in Malaysia on the topic of skin care. This study found that found that, regardless of experience, 80.5% of participants felt that they did not have good knowledge of neonatal skin. The authors suggested that this may be due to difficulties translating theoretical or academic knowledge into clinical practice, as a post-qualification course did not increase participants' confidence. Nurses with the qualification did score more highly on some questions related to aspects of their practice. For example, nurses who had a Neonatal Nursing Certificate (NNC) were more likely to answer questions about skin care for neonates on nasal CPAP correctly, though nurses from all backgrounds had adequate knowledge of pulse oximeters and peripheral cannulae. The authors did not report whether nurses with the NNC were more likely to provide care for neonates receiving CPAP, something that might account for this discrepancy.

An interesting finding from this study was that nurses with <5 years' experience acquired knowledge differently from those with >5 years' experience (Mohamed, Newton and Lau, 2014). Less experienced staff relied solely on advice from senior nurses and head nurses, whereas more experienced staff did their own research online and in books, as well as discussing problems with both medical and nursing colleagues. It is possible that this reflects the process described by Samuriwo (2010a) discussed in section 2.7.1, wherein nurses are more likely to seek out additional information once they have seen a "worst ever" PU. Little is known about knowledge acquisition in relation to PU prevention and other aspects of skin care, and future research on this subject might assist lecturers and clinical educators in devising educational tools that address this need.

The study did not attempt to measure nurses' attitudes towards skin care in relation to other aspects of a busy workload, so it is not known how this compares to attitudes reported in studies

of adult nurses, or how it relates to participants' knowledge or experience. Equally, nurses' perceptions of risk and frequency of damage were not reported. It is also not known how well these findings translate into NICU settings in other countries, where practices and content of neonatal nurse education may differ. Nonetheless, the findings of this study indicate a troubling lack of confidence among the participants regarding their knowledge of preterm skin.

2.8.4 ITU nurses

Though there is very limited information available on the knowledge and attitudes of paediatric and neonatal nurses to the prevention and management of skin breakdown, there are some studies looking at these issues with ITU nurses. Due to the high patient acuity, extensive use of technology, and prevalence of MDPRUs in this environment, these studies may provide some insight into issues faced by neonatal nurses.

Tweed and Tweed developed a tool for assessing the PU knowledge of intensive care nurses in New Zealand (Tweed and Tweed, 2008). They reported that knowledge was initially good (with a mean score of 84%), improved briefly to 89% after an educational programme, and had returned to baseline 20 weeks later. The content of the assessment tool is not reported, so it is difficult to compare these results to those of other studies. However, it does suggest that nurses scored highly on this tool that was directly tailored to their patient load and clinical environment. A more recent study in Iran utilised an adapted version of the Pressure Ulcer Knowledge Test (Pieper and Mott, 1995), though it is unclear which items were altered or omitted (Iranmanesh, Rafiei and Foroogh Ameri, 2011). They reported that participants' knowledge was generally insufficient, although the highest scores were obtained for the PU prevention section. Finally, Strand and Lindgren have investigated nursing attitudes and knowledge in four ICUs in Sweden (Strand and Lindgren, 2010). They found that nurses who had received education in anaesthesia or critical care had significantly more positive attitudes towards PU prevention. In keeping with studies among general nurses, only 46.8% of nurses were able to correctly classify PUs according to international guidelines. RNs had significantly better knowledge of risk factors than enrolled nurses (ENs). No overall mean score is provided for knowledge. Without the same tools being used in the studies, it is difficult to draw conclusions from their findings; however, it appears that nursing PU knowledge varies between ITUs and may be an area of concern in some environments.

To date, no studies have been identified in ITU environments that triangulate assessment of nursing knowledge and attitudes with actual practices. Further research in this specialism would provide useful insight into the challenges and unique factors at work in PU prevention and management in this environment.

2.9 Questions arising from the literature review

Much of the evidence available to inform prevention of hospital-acquired skin breakdown in neonates is adapted from research in adults or older children. The review of the literature suggests that clinical factors, staff attitudes and knowledge, available resources, and assessment practices are all implicated in the risk of the development of skin damage. These factors have been primarily drawn from research carried out in other practice settings, and it is likely that there will be some factors specifically associated with the neonatal unit that have hitherto been overlooked. The lack of studies exploring the opinions of neonatal nursing staff, in particular, makes it difficult to identify what the barriers to and facilitators of change are in this context. Additionally, despite a recent increase in the number of studies exploring the prevalence and incidence of PUs in the neonatal unit, estimated figures continue to vary and do not take into consideration other forms of skin damage. There are therefore some questions that clearly emerge from the literature review.

- To what extent is skin damage an issue in neonatal units?
- What are the barriers to and facilitators of the prevention of skin damage in this population?
- How do nursing staff involved in the delivery of neonatal skin care understand and experience this issue?

A programme of research designed to address these questions was therefore developed. The aims, objectives, and studies involved are described in detail in Chapter 3. Chapters 4 and 5 present the individual studies and findings, and Chapter 6 contains discussion and contextualisation of the findings, and some proposals for future work.

Chapter 3: **Methods**

3.1 Aims

The aims of this research were derived from the questions raised at the end of the literature review. The primary aims and related research questions were:

a) To understand the scope of the problem of skin damage in neonatal units
    - Research question: To what extent is skin damage an issue in neonatal units?
b) Identify potential determinants of change related to the prevention of skin damage in neonatal units
    - Research question: What are the barriers to and facilitators of the prevention of skin damage in this population?
    - Research question: How do neonatal nursing staff understand and experience this issue?

Barriers and facilitators are termed "determinants" in this research project due to the use of the Implementation of Change Model (ICM) (Grol *et al.*, 2013), discussed in more detail below.

In order to achieve these aims a series of studies was undertaken with the following objectives aligned to the global aims of the project:

a) Assess nursing staff perceptions regarding neonatal skin care and its priority on practice
b) Establish the prevalence and incidence of skin damage on neonatal units
c) Examine the barriers and facilitators to the prevention of skin damage in neonatal units
d) Collate the information to establish determinants of change relating to skin damage prevention for neonates.

Together, these studies form the basis for an analysis of the issue of skin damage in neonatal units, with a view to understanding the context in which any future change would take place. This analysis will result in the proposal of recommendations for future practice and clinical research.

3.2 Use of an implementation framework

The impetus for this programme of research, as with the majority of nursing studies, is ultimately to improve patient care. As demonstrated in the literature review, the issue of skin care and skin damage in any healthcare environment is complex. Staff knowledge and attitudes, patient acuity, and available resources are all relevant considerations when trying to reduce the incidence of skin damage. Just as skin damage is a complex issue, neonatal units are a uniquely complex care setting. It is therefore likely that any changes to care would require the use of a complex intervention, i.e. one with multiple interacting components (Craig *et al.*, 2008).

It is widely acknowledged that the introduction of change is difficult. Indeed, it is claimed that approximately 60% of planned change fails, although this figure is not specific to healthcare (Burnes, 2004). The MRC Framework for development and evaluation of complex interventions in healthcare (Craig et al 2008) suggests that neglecting the early stages in intervention development, i.e. clearly defining the problem and understanding current clinical needs, will ultimately lead to limited interventions that are less likely to be implemented successfully. In contrast, focussing on the eventual implementation from the beginning will ultimately assist in identifying and developing interventions that are likely to meet the needs of a given care environment or problem. Therefore, using an implementation framework to inform and structure the project was considered to be an important factor in this research. The ideal framework would provide the basis to establish the current unmet needs in clinical practice, thus informing the recommendations for future interventions. This would increase the likelihood that factors relevant to the implementation of interventions will be considered, and that any recommendations for interventions would result from an in-depth understanding of barriers and facilitators of change in this context. Following the consideration of several frameworks, the Implementation of Change Model (ICM) was selected for the reasons outlined below.

The Grol and Wensing Implementation of Change Model (ICM) recommends a baseline understanding of current practice prior to implementing any change (Grol, Wensing, Eccles, & Davis, 2013). In particular, it recommends that there is a rigorous analysis of potential barriers to and facilitators of change, termed “determinants”, in a given environment. The ICM specifically addresses practical and clinical aspects of intervention development. Most usefully for the current research project, it provides clear guidance regarding factors involved in an analysis of the clinical context and suggests appropriate methodologies with which to accomplish this.

A further advantage of the ICM is its similarity to the nursing process, making it appropriate for use in the context of this project. The nursing process has many formats, although it is typically taught as a five-stage process: assessment, diagnosis, planning, implementation, and evaluation

(Wilkinson, 2007). This reflects the stages outlined by Grol and Wensing in the ICM (2013a). In essence, this project is engaging with the first stage of the nursing process, assessment, with secondary analyses informing both the diagnosis and planning processes. Due to the ubiquity of the nursing process in nursing education and care, most RNs understand these stages and therefore the ICM is appropriate for discussing with them.

The ICM recommends engaging with key stakeholders early in the process and provides guidelines on who these are and how to accomplish this. In relation to neonatal skin care, to date, there have been very few attempts to engage with neonatal nursing staff on the subject. Given that these individuals are integral to the provision of skin care, it is important to understand their perspective at an early stage. Surveys and focus groups are recommended as possible methods for accomplishing this, and accordingly both have been used in the research (see 3.3.2 for more details on how the involvement of clinicians has influenced the project).

Routinely collected data are suggested as an alternative or additional source of information about a clinical problem. However, this information source was not used in the study. This was due to the known differences in reporting between individuals and units, which became more apparent early in our discussions with senior neonatal nursing staff and in the survey. The questionable quality and consistency of reporting was therefore the primary reason for omitting this data (Wensing, Bosch and Grol, 2013b). Instead, a structured prevalence and incidence study was conducted as part of the analysis. This enabled a structured and reliable assessment of skin damage on multiple neonatal units to describe the scale of the issue, providing robust data on which to base our future recommendations.

As identified by Grol and colleagues, a modified sequence of the steps may be necessary to meet a particular clinical situation (Grol et al., 2013), which was the case in this project. In particular, the ICM is predicated on the basis that clear standards for practice exist and are not being met. Step 1 of the model is “Development of proposal for change”, with a view to improving performance to meet these pre-existing care standards. Given the lack of evidence highlighted in the literature review, there is currently no best practice standard for neonatal skin care, although some local guidelines exist (Thames Valley Neonatal Quality Care Group, 2012). It is therefore impossible to begin with a proposal for change aimed at improving care in relation to a specific policy or guideline, as the evidence underpinning any guideline is inherently sparse. However, steps 2 and 3 of the ICM provided useful guidance for analysis of the target group and analysis of the current situation.

In addition to informing the methodology and content of studies that were conducted, the ICM was also instrumental in the analysis of the qualitative data (discussed in greater depth in 3.7.2).

In brief, the determinants of change outlined in the ICM informed the analysis of all qualitative data in the project (Wensing, Bosch and Grol, 2013a). For the survey data, following an initial process of open coding, the codes generated were mapped onto the determinants of change. For the focus group and interview data, the determinants of change informed the analysis of the data, although the data were not "fitted" into the model (see 3.7.2 for a more in-depth discussion of this). Given that proposals for practice change were an intended outcome for this project, the use of the ICM ensured that the critical determinants of change were embedded in the process of data analysis. The ICM has thus been instrumental in the overall structure of the PhD project, as well as the analysis and interpretation of the findings.

3.3 Structure of project

In keeping with the recommendations made in the ICM, this research project has two main components: an analysis of the target group, in this case neonatal nursing staff; and an analysis of the current care situation. The structure of the project is depicted in Figure 3.1.

A multiphase mixed methods approach was adopted to achieve the overall aims of the project. This approach is defined as "several mixed methods projects, in some cases including mixed methods convergent or sequential approaches, while in others including only quantitative or qualitative studies in a longitudinal approach with a focus on a common objective for the multiple projects" (Creswell, 2014). This approach was deemed most relevant due to the dearth of skin health research in neonates (Chapter 2), which has resulted in the phenomenon being poorly defined (Borglin, 2015). The methodologies used for individual studies are described and justified in Chapters 4 and 5. An outline of each study can be found in sections 3.5-3.7, demonstrating their interrelated nature and alignment to the research aims.

In the project, a sequential series of studies (Figure 3.1) were conducted to achieve the overarching aims (Section 3.1). To review briefly, following initial conversations with lead nurses and an extensive literature review, the survey was developed and disseminated, with subsequent analysis of both quantitative and qualitative data. The findings of the survey informed the development of all subsequent studies. This included the piloting and implementation of the prevalence and incidence study. Data derived from this study enabled the researcher to refine the questions for semi-structured interviews and focus groups, with the combined knowledge of the survey results and detailed information regarding the scale and nature of skin damage in neonates. The interviews were conducted after the conclusion of the prevalence and incidence study, and the focus group was the last study conducted for this project.

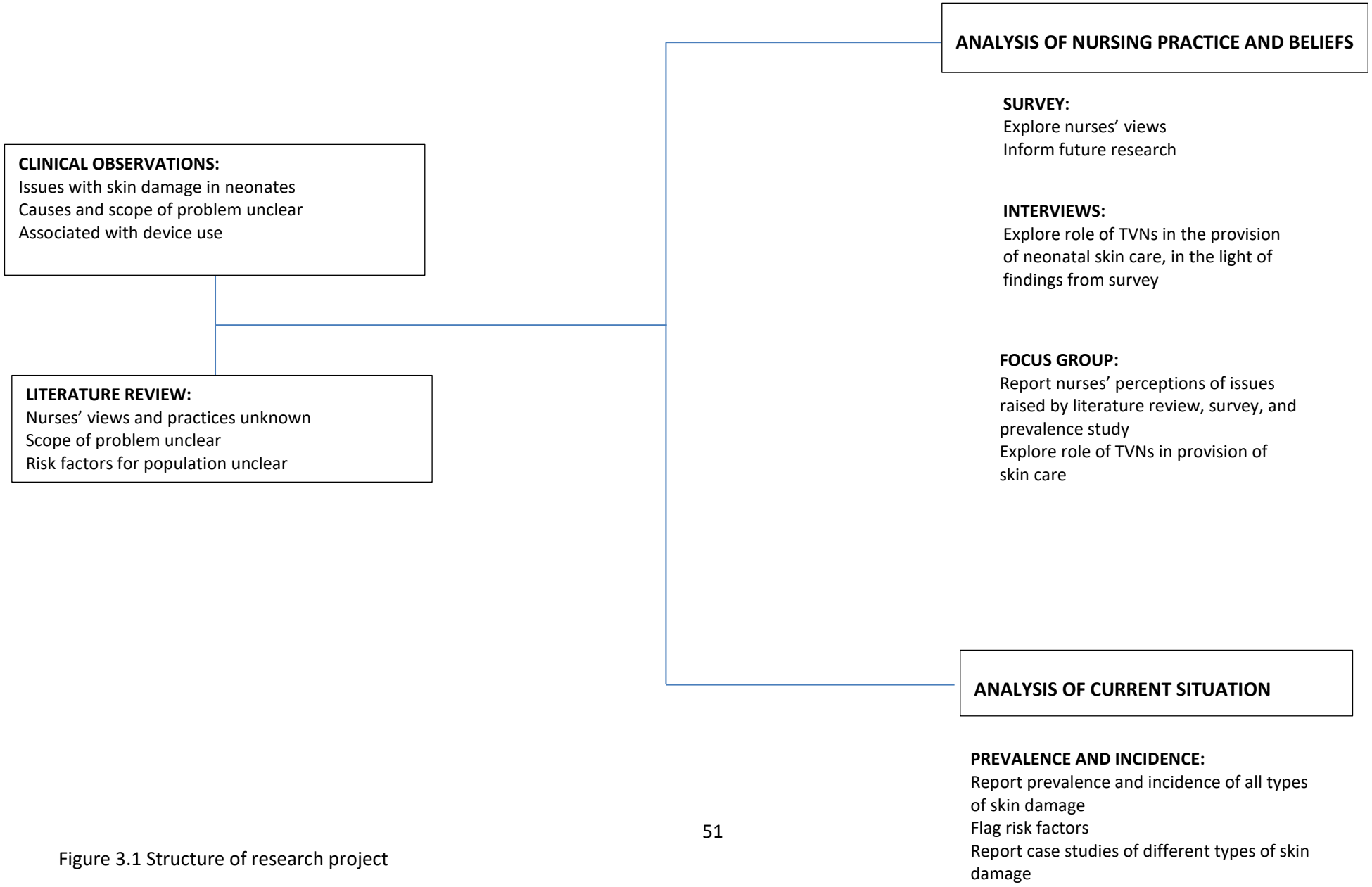


Figure 3.1 Structure of research project

3.4 Involvement of clinicians in informing research design

This programme of research has been carried out largely as a clinical academic project where the researcher was embedded in practice as a staff nurse. The dual experience of working clinically while conducting research has been invaluable in understanding potential issues associated with implementing change in a clinical environment. For example, research conducted without regular input from clinicians runs the risk of being theoretically sound but unworkable in a setting with the constraints and complexities inherent to day-to-day practice. A disconnect between theory and practice has been identified in many areas of nursing, from the management of delirium in critically ill adults to therapeutic holding for children undergoing invasive procedures (Glynn and Corry, 2015; Page and Mcdonnell, 2015). This can also be seen in PU prevention in adult care environments: although we have a good understanding of what causes PUs to develop and know that they are frequently preventable, incidence remains high in many healthcare settings (see sections 2.4 and 2.6 of the literature review).

Although historically the gap between theory and practice was left with nurse educators to resolve (Landers, 2000; Allan, 2011), this issue can also be addressed by regularly involving clinicians in research design. If nurses are intrinsically involved, it is more likely that any recommendation arising from the study will consider the specific needs of that clinical environment. Therefore, throughout the research project presented in this thesis, there was regular recruitment of and consultation with clinicians. In addition to being involved as participants, clinicians have helped shape the direction of the research project, provided valuable feedback on draft protocols and study templates, and contributed to our understanding of some of the study findings. The steps taken to ensure clinicians were involved in the research, especially neonatal nurses and nursery nurses, are outlined below.

First, early contact was made with the nurse lead for education within the Wessex and Thames Valley Operational Delivery Network (ODN). This is a network of neonatal units in the south of England. The ODN comprises of 14 units, providing long-term intensive care for extremely sick and premature neonates. This allowed regular contact with the senior nursing leadership team across all neonatal units in the network. The research project was presented to the Network and senior clinicians provided feedback on study scope and design. They highlighted issues related to skin damage that we had not previously considered. In addition, they reported a lack of education, which was subsequently included as a topic area included in the survey. The involvement of staff nurses and nursery nurses was also considered essential. Nurses and nursery nurses were

involved in the design and content of the survey tool (see Chapter 4 for more details), and the findings of the survey were integral to the design of the other studies.

Awareness of the research project was raised through presentations at study days and for nurses undertaking the neonatal preceptorship programme. Although this was in part a dissemination strategy, these conversations also contributed beneficially to the structure and content of the research project. For example, during the development of the protocol for the prevalence and incidence study, the findings of the survey were presented at a Band 6 study day. The discussion after the presentation was helpful in identifying specific concerns of these staff members, as well as some logistical issues about how best to carry out data collection. Specific aspects of the prevalence and incidence study were additionally discussed with the senior nursing leadership team prior to the submission of the protocol and these discussions informed the design of the data collection proforma. This was also reviewed by neonatologists from three Level 3 units.

Lastly, the findings of the survey and plans for the prevalence and incidence study were presented at the UK Tissue Viability Society conference in 2016, while awaiting ethical approval for the latter. The audience generally included TVNs and following the presentation, attendees had a productive discussion about engaging with the neonatal unit. In conjunction with the findings of the survey, this highlighted the importance of TVNs in neonatal skin health, something that had previously been overlooked.

3.5 Methods

3.5.1 Survey

The survey formed part of the analysis of the target group, namely nursing staff (section 3.1). Specifically, it had the following objectives:

1) To explore the beliefs and practices of frontline neonatal nursing staff regarding skin damage, with specific reference to the following:

a) Current practices of assessing and promoting skin health

b) Prioritisation of skin care

c) Barriers to providing adequate skin assessment and treatment

d) Factors which place neonates at increased risk of skin damage

2. To identify staff concerns, related to skin damage, which have not yet been raised in the academic or professional literature

3. To inform the design and content of a future study looking at the prevalence and incidence of skin damage in neonatal units

3.5.1.1 Choice of survey methodology

Table 3.1 provides a critique of the methods considered. Following discussion among the research team and with senior clinical staff from the target group, it was decided to adopt survey methodology, based on a number of key factors. First, this approach is particularly appropriate for exploring and reporting the prevalence of behaviour within communities, including groups of colleagues (Daly and Burke, 2000), thus matching the study objectives. Surveys are recommended in the ICM as a useful tool for exploring a range of determinants with a number of stakeholders (Wensing, Bosch and Grol, 2013b), in this case the nursing staff. In addition, the use of a survey as opposed to alternative methodologies, such as focus groups or semi-structured interviews, allowed a range of participants within a wide geographical area to be approached.

Surveys can be designed to be completed within 15-20 minutes, minimising the time burden on the participants. Indeed, if a more time-intensive method was introduced, recruitment to the study may have been limited and an additional burden to clinicians and healthcare providers

would have been imposed. Although participation in research is voluntary and therefore the group is necessarily self-selecting, it was felt that staff from a greater variety of roles would respond via the survey.

The anonymity of survey research was another advantage considered. Registered nurses are required by their professional code to ensure they always have the skills and knowledge needed to carry out their roles (Nursing and Midwifery Council, 2015). Neonatal nurses in particular have to meet the key skills framework, which includes a knowledge of various aspects of skin care (Royal College of Nursing, 2012). The anonymous survey method allows for greater honesty in reporting gaps in knowledge than might have been possible in interviews or focus groups (Polit and Beck, 2012).

Table 3.1 Advantages and disadvantages of methods considered for data collection

Method	**Advantages**	**Disadvantages**
Interviews	• Possible to collect in-depth rich data on a few topics (Silverman, 2010) • Patterns from early interviews can be used to inform schedule in later interviews, in order to explore findings (Silverman, 2010)	• Difficult to discuss a broad range of topics, as would be helpful for an initial exploration (Flick, 2009) • Not suited to the combination of qualitative and quantitative questions • Participants may be reluctant to disclose gaps in knowledge during a face-to-face interview with another nurse • Constraints do not allow for participants from all or most units in the region • Participants would have to be released from clinical practice to participate
Focus groups	• Could give indication of how team dynamics affect knowledge and practices of staff (Grol *et al.*, 2013; Krueger and Casey, 2015) • Patterns and topics from early focus groups can be used to inform topic guide for later focus groups (Litosseliti, 2003) • Possible to collect rich data on a few topics (Silverman, 2010). Useful for collecting data from a diversity of participants	• No opportunity for quantitative questions to represent how widespread particular practices or beliefs are (Silverman, 2010) • Participants could be unwilling to discuss concerns or lack of confidence related to their own practice with colleagues (Krueger and Casey, 2015) • Possible issues with interpretation of questions, as participants are not able to request clarification if they don't understand
Surveys	• Allows for participants from a large number of units and a variety of clinical roles • Allows for both quantitative and qualitative questions • Useful for giving a broad overview of how nurses perceive several aspects of this subject • Appropriate for exploring and reporting the prevalence of behaviours within communities (Daly and Burke, 2000) • Can be completed in a short period, increasing recruitment	• Published response rates vary (Fan and Yan, 2010) • Responses cannot easily be explored further in follow-up questions or through subsequent data collection • Possibility of misinterpretation of questions, as participants cannot request clarification • Depending on how the survey is distributed, participants from different demographics may not have equal chance to participate, meaning that the sample may not be representative (Salant and Dillman, 1994)
Delphi technique	• Would allow for participants who are geographically distant from one another and from the researcher to participate (Hasson, Keeney and McKenna, 2000) • Allows for collaboration among participants without compromising their anonymity (Diamond *et al.*, 2014)	• Intention of reaching consensus does not fit with the research aims, which relate to exploring and describing current practice. • Delphi technique requires the use of a panel of experts (Hasson, Keeney and McKenna, 2000). Given the established lack of evidence in this field, it would be difficult to determine whose expertise should be sought.

3.5.1.2 Decision to develop a new survey

It is generally considered preferable to adopt a previously-validated questionnaire tool or scale (Streiner, Norman and Cairney, 2015). Validated tools exist to assess nurses' knowledge and skills in the area of PU prevention (Beeckman *et al.*, 2010) and studies which have used these are discussed in Section 2.7. However, these are designed to investigate nurses working with an adult population. They therefore include questions addressing obesity and skin damage while sitting, which is clearly not appropriate for neonates. The neonatal nursing workforce is composed of staff from a variety of clinical backgrounds. Midwives, paediatric nurses, and general nurses are all involved in delivering care, as well as support workers with varying degrees of training and seniority. A tool focused on the knowledge of registered general nurses working with adults to prevent pressure ulcers would not be appropriate for neonatal clinicians. In addition, researcher engagement with neonatal nurses highlighted that registrants with different clinical backgrounds used skin care terminology differently. It was therefore necessary to develop a new tool using terminology that would be recognised by all staff.

Similarly, the use of a questionnaire focused exclusively on PUs would not have been appropriate for this specialist environment. Indeed, discussion with senior neonatal nurses prior to the design of the study suggested that, as well as pressure-related damage, they were concerned about the issues of cannula extravasation, nappy rash, and non-specified damage from medical devices. In addition, assessing the skin care knowledge of neonatal nursing staff in any formalised manner would prove difficult. The evidence currently available is sparse, and, even when available, often not applicable for neonates born extremely prematurely (Lund, Kuller, *et al.*, 2001).

In light of these considerations, a new survey was designed specifically for neonatal nurses. Items for the questionnaire were identified following a combination of processes to ensure face validity (Rattray and Jones, 2007). These processes are detailed in Chapter 4 (see section 4.2).

3.5.1.3 Design considerations

There are some disadvantages associated with survey methodology. Therefore, during the design of the survey, steps were taken to ensure that these were minimised. Salant and Dillman (1994) describe the cornerstones of survey research as coverage, sampling, response, and measurement (Salant and Dillman, 1994). The processes of survey design and testing to address these issues as far as possible are detailed in Chapter 4.

3.5.1.4 Planned sample and recruitment strategy

In addition to the considerations involved in constructing the survey, the sample of the survey was also important. In order to maximise the generalisability of the results, it was important to address the risk of over- or under-coverage error, in which not all units in the population being investigated are equally represented in the sampling frame (Vannette and Krosnick, 2018). In this instance, following discussion with the lead nurses from across the network, the decision was made to invite all nurses and nursery nurses working in clinical roles across the ODN to participate. Although a sampling frame was not necessary in this instance, other steps were taken in order to minimise the risk of coverage error, chiefly related to distribution of the study. These steps are reported in detail in Chapter 4.

Approximately 800 staff were employed in nursing and support worker roles across the ODN at the time of survey distribution. An estimation of staff numbers by unit type is indicated in Table 3.2**Error! Reference source not found.**. Although not all units responded, an answer was received from all three types of unit, and this information was extrapolated to estimate staff numbers for units which did not respond within the timeframe. Based on previously published response rates, a response rate of 10-15% was anticipated, i.e. 80-120 participants.

Table 3.2 Staff numbers by unit type

Category of unit	Estimate of total nursing staff
Level 1 units	270
Level 2 units	192
Level 3 units *(of which medical)* *(of which medical-surgical)*	338 *(88)* *(250)*

3.5.2 Focus group

One limitation of the use of surveys, identified in Table 3.1**Error! Reference source not found.**, is the fact that further detail and context of participants' answers cannot be obtained through follow-up questioning, as is possible in focus groups and interviews. Some findings of the survey (sections 4.6 and 4.7) warranted further exploration in order to provide context. In order to address this, a focus group with neonatal nurses and two interviews with TVNs were carried out to discuss some of the themes in more detail. The focus group related primarily to research aim b). It was designed to

explore determinants of change that had been identified in the survey and the literature review, as well as identifying any that had previously not been identified.

3.5.2.1 Choice of focus group methodology

Focus groups are a useful method for exploring shared culture and concepts, including among groups known to each other, such as colleagues. They allow for communication between participants in addition to comments made by individuals (Kitzinger, 1994a). Additionally they are one of the methods recommended in the ICM for identifying the determinants of change in healthcare (Grol *et al.*, 2013). The survey highlighted that interactions between nursing staff, such as peer-to-peer education, form part of routine practice on the neonatal unit. A focus group was considered an appropriate method with which to explore these interactions in more depth, as these are suited to collecting rich data on a few topics (Silverman, 2010).

One limitation of focus groups is participants' potential unwillingness to disclose gaps in knowledge to other people, especially other RNs. The anonymity of the survey ameliorated this. However, during presentation of the survey findings at study days and other ODN events, attendees were keen to discuss areas of their own practice. In particular, attendees of a band 6 study day participated in an impromptu discussion on what they perceived to be some of the flaws of skin care in their unit and individual practices. This suggested that participants in a focus group could also engage in similar discussion and critique of their own practice.

3.5.2.2 Planned sample

It was anticipated that two focus groups of four to eight participants would be carried out, with participants recruited from two Level 3 neonatal units. This sample size was selected with the intention of reaching data saturation, defined as continuing to collect data until no new information emerges in order to ensure that the researcher develops as comprehensive an understanding of the phenomenon being investigated as possible (Morse, 1994). In order to reach saturation and ensure that data are of optimal quality, an appropriate sample who are most likely to have knowledge of the research topic should be selected (Morse *et al.*, 2002). In this study, the group most likely to have knowledge of the determinants of change related to skin damage on the neonatal unit were neonatal nurses and nursery nurses. Details regarding recruitment are reported in Chapter 4.

3.5.3 Interviews

3.5.3.1 Choice of interview methodology

The interviews related primarily to research aim b). This study was designed to explore determinants of change that had been identified in the survey and the literature review, as well as identifying any that had previously not been identified. Individual interviews are useful for obtaining insight into the views of healthcare professionals on a particular topic (Wensing, Bosch and Grol, 2013b), in this instance skin and wound care on the neonatal unit.

One unexpected finding of the survey (see Chapter 4 for a more detailed report of the survey findings) was participants' mixed views on the contribution of Trust tissue viability teams. There is no published literature on the subject of TVNs' views or involvement with neonatal care. In order to explore this further, two interviews were conducted with lead TVNs, one from each of the Trusts involved in the prevalence and incidence study.

TVNs were not included in the focus groups for three reasons. Firstly, they are not involved in providing day-to-day care in the environment of the neonatal unit. It is therefore unlikely that they would have been able to contribute to aspects of the discussion related to neonatal nurses' normal practice, e.g. peer-to-peer education. Additionally, the presence of a perceived expert in the group might have discouraged other participants from fully voicing their opinions (Litosseliti, 2003). Lastly, there is a risk that someone with specialist knowledge may overshadow the rest of the data during either data collection or analysis (Bernard, 2012). It was therefore more appropriate to collect data from TVNs in the form of interviews.

3.5.3.2 Planned sample

For the interviews, we planned to approach the lead TVNs from both trusts participating in the prevalence and incidence study initially, and depending on who else was responsible for the neonatal unit in their TVN teams, ask them to approach or suggest other members in their team regarding the study. This approach to sampling was chosen as the lack of clarity around TVNs' responsibilities for the neonatal units in question made it difficult to determine which members of staff would have relevant experience other than the leads. The lead TVNs were the most likely staff members to have this information and therefore they were asked at the end of their interviews if any other TVN team members had been involved in working with the neonatal unit.

As with the planned focus groups, the sample was planned with the intention of reaching data saturation.

3.5.4 Prevalence and incidence

The prevalence and incidence study related primarily to aim a) within the global aims of the project. It had the following specific objectives:

a) Report point prevalence of all forms of skin damage across three neonatal units

b) Report incidence rate of all forms of skin damage across two neonatal units

c) Categorise skin damage according to type and severity

d) Report associations between potential risk factors and development of skin damage in the neonatal intensive care setting

e) Report case studies to demonstrate the types of skin damage that may occur in this population

3.5.4.1 Methods

The study consisted of:

a) A cross-sectional point prevalence study;

b) A prospective cohort incidence study.

As identified in the literature review, previously reported figures for PU prevalence and incidence in neonatal units varied significantly and did not account for other forms of skin damage. The study was designed to contribute further information about the extent of the issue by identifying factors associated with increased risk of skin damage. Additionally, direct observation allows for the potential identification of unanticipated determinants of change (Wensing et al., 2013). Due to the relative lack of research in this area, it is probable that there will be factors affecting care that have not been identified in the literature review. This forms an essential part of the overall analysis. As far as possible, these unidentified factors were considered in the study design through conversations with clinicians or as a result of the survey findings. For example, although nasal CPAP and peripheral cannulae have been previously identified as causes of skin damage in neonatal units, it was evident from the survey that many other types of devices were a cause of concern to clinicians and therefore all devices were documented. The prevalence and incidence study also provided a baseline from

which to measure any future implemented changes. Clearly describing the current situation is a key step in identifying any future targets.

Error! Reference source not found. Table 3.3 details previous studies which have focussed on the prevalence and incidence of skin damage in neonates, with cumulative incidence ranging from 3.22% to 16.0% reported. In addition to PUs, the findings of the survey indicate that other forms of skin damage are of concern in this environment, especially diaper dermatitis and cannula extravasation. These reported skin damage figures may therefore be an underestimation of the issues typically observed in practice.

The role of the prevalence and incidence study within the wider research project is indicated in Figure 3.1. It will contribute to the overall analysis of the target group and setting, as described in the ICM (Grol *et al.*, 2013). If there are particular clinical concerns, such as gestational age, or specific medical devices being associated with a high rate of damage, it will highlight these as challenges in this particular setting. Once these challenges have been identified, they can be prioritised and addressed. By recruiting through multiple centres we also aim to capture potential regional differences in skin damage and provide scope for more generalised findings within this population. Additionally, by illuminating the current prevalence and incidence of skin damage in the target setting, it will provide a baseline figure from which future goals can be met and progress towards these goals can be measured. By identifying risk factors specific to this population, this study will also identify the extent to which these act as barriers to change that should be considered in the design and implementation of any future intervention. Specific design considerations for the prevalence and incidence study, such as the development of the proforma, are reported in Chapter 5.

Table 3.3 Studies reporting prevalence and incidence of skin damage in hospitalised neonates

Study	**Methods**	**Findings**
Ligi, I *et al* (2008) 'Iatrogenic events in admitted neonates: a prospective cohort study', *Lancet,* **371**(9610): 401-10	Included all adverse events occurring in a Level 3 unit in France over 8 months Incidents reported primarily by staff members; data reviewed by a researcher twice a week	267 iatrogenic events in 116 patients, including 94 "cutaneous events" 95% of cutaneous events were minor 34% of cutaneous events were considered preventable Cutaneous events were most commonly occurring iatrogenic injury for duration of study
Fujii, K. *et al* (2010) 'Incidence and risk factors of pressure ulcers in seven neonatal intensive care units in Japan', *International Wound Journal,* **7**(5): 323-8	Daily skin examination of 81 neonates in 7 units in Japan over 11 months Skin examinations carried out by nursing staff	Cumulative PU incidence of 16.0% over 11 months in 81 patients 50% of PUs (n=7) associated with nasal respiratory support Skin texture and endotracheal intubation found to be risk factors for PU development All PUs category I (n=3, 24.4%) or II (n=11, 78.6%)
Fischer, C. *et al.* (2010) 'Nasal trauma due to continuous positive airway pressure in neonates', *Archives of Disease in Childhood: Fetal and neonatal edition,* **96**(6): F447-51	Incidence of nasal trauma in all neonates receiving CPAP over 5 years in a Level 3 unit in Switzerland	42.5% of neonates receiving CPAP developed some form of nasal trauma (420/989) 88.3% of injuries were classified as persistent erythema without ulceration 0.7% of trauma became necrotic and 2 neonates had long-term scarring Incidence and severity of trauma inversely correlated with gestational age and birth weight
August, D. *et al.* (2014) 'Pressure injuries to the skin in a neonatal unit: Fact or fiction', *Journal of Neonatal Nursing,* **20**(3): 129-37	Prevalence of PUs and epithelial stripping injuries reported in 3-monthly audits over 2 years in a single unit in Australia, plus any reports of injury in between audits	Prevalence rate of 31.2% (77/247) 32% of affected neonates had more than one wound (25/77) All categories of PU reported, including IV Most common risk factor was presence of a medical device 24% of PUs associated with intravenous cannulae, 17.8% associated with CPAP, 16.8% associated with pulse oximeters
Nist, MD *et al.* (2016) 'Skin rounds: a quality improvement project to enhance skin care in the neonatal unit', *Advances in Neonatal Care,* **16**, S33-41	Prevalence and incidence data reported as part of a quality improvement project to standardise reporting and assessment of skin damage, especially PUs Data collected weekly for 4 years and 5 months	PUs represented 11.8% of all prevalent skin damage reported, though point prevalence unclear due to number of patients not being reported Incidence rate 0.49 per 1000 patient days at start of study (excluding stage I PUs), 3.9 per 1000 patient days at end of study (including stage I PUs) 86.8% of new PUs noted were associated with devices 9025 assessments carried out though unclear if each of these represents a new patient Stage I PUs represented 29.8% of all new PUs

3.5.4.2 Planned sample

All neonates admitted over the course of the study were eligible for inclusion, with the exception of:

- Neonates with dermatological conditions or congenital wounds
- Neonates receiving cooling therapy on the day of the point prevalence study (due to inability to turn or assess these patients)

Neonates with existing skin damage due to birth trauma sustained before admission to the unit (e.g. ventouse delivery) were eligible for inclusion in both studies.

It was initially estimated that approximately 110 neonates would be recruited to the prevalence study, and approximately 200 to the incidence study. These estimates were based on previous monthly admissions figures from each unit. It was anticipated that the majority of admitted neonates would be eligible and that the parental consent rate for the incidence study would be high. In order to provide prevalence and incidence figures that were as accurate as possible, it was anticipated that the parents of all eligible neonates would be approached, therefore getting as close as possible to investigating the whole population of these units.

Details regarding recruitment and consent are reported in section 5.1.5.

3.6 Ethical considerations

Ethical approval was sought for all aspects of the research project.

3.6.1 Survey

For the survey, ethical approval was sought internally from the University of Southampton's internal review board via ERGO (ID 9305). Participants were informed on the front page of the survey that, by entering the questionnaire tool and filling out the survey, they confirmed that they had read the participant information sheet and their consent was implied.

Participation was completely anonymous. There was a minimal risk that some participants could make themselves identifiable through their demographic information. Participants were

informed of this in the participant information sheet. No information about individual participants was disclosed outside the research team at any time. Paper responses to the survey were stored appropriately in a locked cabinet in a university office requiring swipe ID access outside office hours. Electronic responses were stored on a password-protected university computer and a password-protected university laptop. Anonymised survey results have been presented at conferences and meetings, in addition to publication in a peer-reviewed journal (see page xv for details).

3.6.2 Focus group and interviews

As the focus group and interviews required access to NHS premises in order to recruit NHS staff, ethical approval was sought from the University (ERGO-FOHS-25367) as well as the Health Research Authority (HRA). Capacity and capability were confirmed by the R&D department at the participating trusts. All data were kept confidential and managed in accordance with the Data Protection Act 2018. Data are stored on in the Faculty of Health Sciences research data drive. Informed consent was sought and obtained from all participants. Hard copies of transcripts and consent forms were stored in the University's research archive and managed in accordance with their data protection policy.

3.6.3 Prevalence and incidence study

This study was submitted for full review by the research ethics committee (REC) and local NHS R&D approval through IRAS (IRAS 187655, Faculty of Health Sciences Ethics via ERGO 19405, REC 16/SW/0022). The study was reviewed at a meeting of the Exeter REC in February 2016. Amendments to the documentation were made in response to their comments. Final approval was granted on 12/04/2016. However, subsequent changes to the ethical approval system resulted in an additional application to the HRA.

Confirmation of local R&D approval at Units 1 and 2 were received in July 2016. A third unit was initially involved in the study with full support from clinical and research staff at the site, but R&D opted not to provide confirmation of capacity, so regrettably this unit could not be included in data collection. Details of changes and all written correspondence with the REC, HRA, and local R&D departments can be found in Appendix T. The timeline of approvals processes can be found in Appendix U.

3.6.3.1 Consenting nursing staff

The rationale given for seeking informed consent from nursing staff related to the NMC Code (Nursing and Midwifery Council, 2015), which stipulates that RNs are bound to report unsafe practice. As the lead researcher (HL) was an RN, the REC argued that nurses should be able to opt out from patients in their care being observed, despite the fact that nursing practice itself was not being assessed. This unusual request was contested during the ethics application process. However, ethical approval was contingent upon agreement. Subsequently, consent was obtained from 87 nursing staff at Unit 1 and ~160 at Unit 2. A small minority of staff refused consent in Unit 1.

3.7 Analysis

3.7.1 Quantitative data

3.7.1.1 Survey

The quantitative data from the survey were analysed primarily using descriptive statistics (mode, percentage), with one question analysed by rank sum. Normal distribution cannot be assumed as the data were predominantly ordinal or nominal. For this reason the non-parametric descriptors were used. Additionally, the free text comments for some questions were treated quantitatively where appropriate, e.g. when identifying which areas of the body were most commonly identified by participants as being at risk of skin damage.

3.7.1.2 Prevalence and incidence study

Percentages, mean, mode, and other descriptive statistics were used to characterise patient demographics. These were also used to report the proportion of categories of skin damage. The categories specifically reported were diaper dermatitis, immobility-related PUs, and device-related damage. Where photographs of damage were obtained during the study, these were reported as case studies in addition to the damage being included in the calculation of incidence.

Point prevalence was calculated using the number of patients with any type of skin damage as a proportion of the total under survey. The mean and mode of number of wounds per neonate with a wound were also reported. Specific prevalence rates were determined separately for

immobility-related PUs, medical device-related damage, and diaper dermatitis. Incidence rate per patient day was calculated using the number of neonates who developed any wound during the study period, as opposed to the number of wounds developed. Cumulative incidence was additionally calculated. Detailed reporting of decisions that were made about how wounds were counted can be found in Chapter 5.

Following advice from the faculty statistician, a binomial logistic regression was performed to ascertain the effects of gestational age at birth and birthweight on development of any skin damage. Binomial logistic regression is appropriate for studies investigating the relationship between a set of predictor variables and a dichotomous outcome (Hosmer, Lemeshow and Sturdivant, 2013), in this case "development of skin damage (yes or no)".

3.7.2 Qualitative data

3.7.2.1 Survey

The qualitative data from the survey, generated from comment boxes and free text responses, were analysed initially using a thematic analysis approach. This approach was chosen as it lends itself particularly well to applied health research, and it is intended that the findings of this research project will be applied in developing future interventions (Braun and Clarke, 2014). Thematic analysis is suited to studies where there are specific research questions or objectives, perhaps related to a particular theory (Braun and Clarke, 2006). As can be seen in the research objectives for this study (section 3.5.1), the survey was intended to address particular aspects of clinical practice in relation to the determinants of change laid out in the ICM. The analysis was therefore carried out specifically to address these aspects. Although this provides a less rich overall description of the data, it produces a more in-depth understanding of these aspects (Braun and Clarke, 2006).

The analysis began with open coding, carried out by hand as recommended by Saldana (2013) for first-time qualitative researchers, with particular reference to small-scale qualitative studies. Once codes had been generated, these codes were mapped onto the determinants of change from the ICM (Grol *et al.*, 2013). The mapping exercise was carried out by the student with support from two experienced qualitative researchers and was as follows. The codes generated from the first stage of analysis were printed out. The determinants with individual factors were written onto flipchart paper, and, with regular reference to the description of

these factors provided in the ICM (Grol *et al.*, 2013), the codes were reviewed to see which determinant they related to.

Although the determinants were used to inform the analysis and the codes were mapped onto these following the first stage of analysis, framework analysis was not used. Framework analysis has been described as best suited to the management of large data sets where obtaining a primarily descriptive overview of the data is the goal, and further that it is not suited to studies that must remain open to the unexpected (Gale *et al.*, 2013). In this instance, although the determinants from the ICM were used to inform the analysis, it was possible that other factors would be identified by participants that did not fit organically into this framework. Framework analysis was therefore not an appropriate approach for the aims of this study.

3.7.2.2 Focus group and interviews

The focus group and interviews were also analysed using a thematic analysis approach for the reasons outlined above. The determinants of change identified in the ICM were used to inform analysis of the barriers and facilitators of change.

The data from both focus groups and interviews were transcribed, and coded separately by two members of the research team (HL and LS). Examples of transcripts and the coding process can be seen in Appendix N and Appendix O. The data were analysed initially using systematic reading, familiarization and open coding (Krueger and Casey, 2015). We avoided prematurely "fitting" the data into the ICM (Grol *et al.*, 2013) to remain open to data that do not fit. Disagreements about coding were resolved by consensus and reference to the determinants of change. These codes were then organized into categories and themes by the student, itself a process requiring interpretation (Braun and Clarke, 2006). These themes were discussed with a member of the research team (LS).

3.7.2.3 Trustworthiness and reflexivity

While planning the qualitative elements of this research, steps to enhance the trustworthiness of the research were considered. Credibility, dependability, transferability, and confirmability have been identified by Lincoln and Guba (1985) as criteria on which to base the trustworthiness of qualitative research. In order to address these issues, a number of steps were taken.

Firstly, member checking was used during the focus group and interviews to reduce the risk of miscommunication between participants and the research team and establish trustworthiness (Williams and Morrow, 2009). Member checking was particularly important in the focus group because it had already been identified that participants from different backgrounds did not interpret certain words and phrases in the same way as one other or the research team. As a skin health research student, I assigned specific meanings to terms such as "pressure ulcer". Although there are recognised definitions for these terms, I was aware that not all of my participants would necessarily share this understanding. Conversely, because of my lack of neonatal nursing experience, I was conscious that neonatal nurses used language and terms to which I did not assign the same meaning, and there was therefore a risk of misinterpretation. In addition to member checking during the focus group and interviews, the preliminary findings from the survey were discussed with groups of nurses from the ODN during the process of analysis, since the anonymous nature of the survey precluded in-person member checking with participants (Cohen and Crabtree, 2008). Field notes were also kept on practical and logistical aspects of data collection, as these could affect the content of participants' responses (Beck, 1993).

Triangulation was also used in order to enhance the credibility and confirmation of this research. It was intended that methodological, data, and investigator triangulation would all be used in this research project: methodological triangulation in the use of both focus group and interview approaches to data collection; data triangulation in the sense of having participants from different groups (unregistered care staff, neonatal nurses, and TVNs); and investigator triangulation in the sense of having more than one researcher involved in the process of analysis (Farmer *et al.*, 2006). As identified above, skin damage in neonatal units is a complex problem, and the use of triangulation allows for a more comprehensive and multidimensional understanding thereof.

Reflexivity was also considered in the planning, conducting, and analysing of this project. Reflexivity, defined as continual critical self-evaluation of the effect that a researcher has on the process of producing data (Berger, 2015), is an essential tool in minimising or acknowledging bias in the course of qualitative research. A transcript or comment from participants may have multiple interpretations, and therefore due to the involvement of the researcher in creating and analysing the data, there will always be an element of interpretation in the coding and organisation of the data (Graneheim and Lundman, 2004). In order to enhance the trustworthiness of this research, it was therefore important to acknowledge

biases, research priorities, and any other underlying preconceptions, along with the steps taken to address these in the analysis. In addition, the "distance" between the researcher and the participant may affect both the data collected and the way it is analysed (Beck, 1993; Mays and Pope, 2000).

I was the sole data collector during this study, and it was therefore important for me to consider my position and underlying biases for the reasons above. I am a registered children's nurse but not a neonatal nurse. Further, I had trained at one of the trusts where I collected data, and had worked as a staff nurse at the other. This placed me in the position of having shared experiences with participants, but not being from the same specialism. I was not an "insider", as I had never worked as a neonatal nurse, and participants were aware of this. However, I was also less of an "outsider" than a layperson would have been, or even a healthcare professional with a different registration. In addition to this, I had also spoken about my research at study days and meetings hosted by the ODN and some participants may have associated me with these events. Although the survey was anonymous, this may have informed the information that participants disclosed. In the focus group, this was much more apparent, as participants and I were face-to-face.

In addition to being aware of the potential impact I was having on the information that the participants were sharing, it was also important that I remained aware of my own biases and took steps to minimise the impact these had on my analysis. For the majority of this research project, I was embedded in practice on general paediatric wards rather than in an intensive care environment. While I was working clinically, I was working among generalist paediatric nurses and therefore my perspective was influenced by this environment and these colleagues. On the wards where I worked during this time, neonatal nurses tended to be regarded as highly skilled, but isolationist and unwilling to engage with staff from other clinical teams. It was important for me to remain aware of these views throughout the research project and to be alert to the likelihood that these or other underlying preconceptions would colour my analysis and interpretation of the findings. A specific example of how these views were identified and addressed during analysis can be found in Chapter 4.

Lastly, throughout the process, I kept notes on the decisions I made and aspects of the study that I felt could be improved in future, in accordance with the recommendation that qualitative – and indeed quantitative – researchers engage with 'ongoing… self-appraisal' (Koch *et al.*, 1998). This allowed for regular examination of the extent to which I was impacting

or influencing the data being collected. Examples of how these notes were utilised can be seen in section 4.8.

3.7.3 Integration of qualitative and quantitative results

Throughout the overall research project, the qualitative and quantitative results were connected, rather than merged or embedded, as is appropriate for a multiphase mixed methods design (Creswell, 2014). For instance, in the case of the survey, this means that analysis of the free text responses was informed by the quantitative data, and the quantitative findings were interpreted in light of the qualitative findings. Findings from all studies within the project were connected and interpreted in order to inform the discussion and proposals for future practice and research that are made in Chapter 6.

Chapter 4: A mixed methods analysis of nursing practice and beliefs

The analysis of nursing practice and beliefs took the form of a survey, followed by a focus group and two interviews. The survey component of this analysis was published in 2018 (Appendix G), as **Liversedge, H. L., et al. (2018). Survey of neonatal nurses' practices and beliefs in relation to skin health. *Journal of Neonatal Nursing*, 24(2), 86-93.**

4.1 Survey

A critique of the methodology and relevant ethical approvals for the survey are described in Chapter 3 (see section 3.5.1). This section will focus on the development of the survey, its subsequent dissemination, and finally the results.

4.1.1 Survey design

Items for the questionnaire were identified following a combination of processes to ensure face validity (Rattray and Jones, 2007). This process is depicted in Figure 4.1.

In order to meet the stated research objectives (3.5.1), it was necessary to first clarify which constructs the survey was intended to measure (de Leeuw, Hox and Dillman, 2008). Streiner and colleagues (2015) outline five sources from which new items for a questionnaire or scale can be derived. These are:

1. patients or subjects
2. clinical observation
3. theory
4. expert opinion
5. research

Additionally, questionnaire development may be informed by items included in previous scales (Streiner, Norman and Cairney, 2015). These sources were suggested primarily in relation to health measurement scales rather than staff surveys. However, they informed the development of the survey used in this study. For example, neonatal nurses (potential

research subjects) were involved in decisions about content from an early stage, engaging in several review processes to inform the type questions and descriptors used within the survey.

The generation of themes was an iterative process, and the literature and expert opinion were reviewed regularly throughout the process. For example, the “perceptions of device-related damage” theme was derived from several sources. This is represented in Figure 4.2, and was similar for all the themes that were eventually included. Some early areas for consideration were incorporated into broader themes. For example, “Perceptions of device-related damage” was incorporated into “perception of incidence/risk”. Some questions addressed more than one research objective. This included the following question “How often do you assess the skin of patients in your care?” which was primarily intended to address the research objective related to current practices. However, it was also anticipated that answers to this question would be useful in the design of a future study looking at the prevalence and incidence of skin damage.

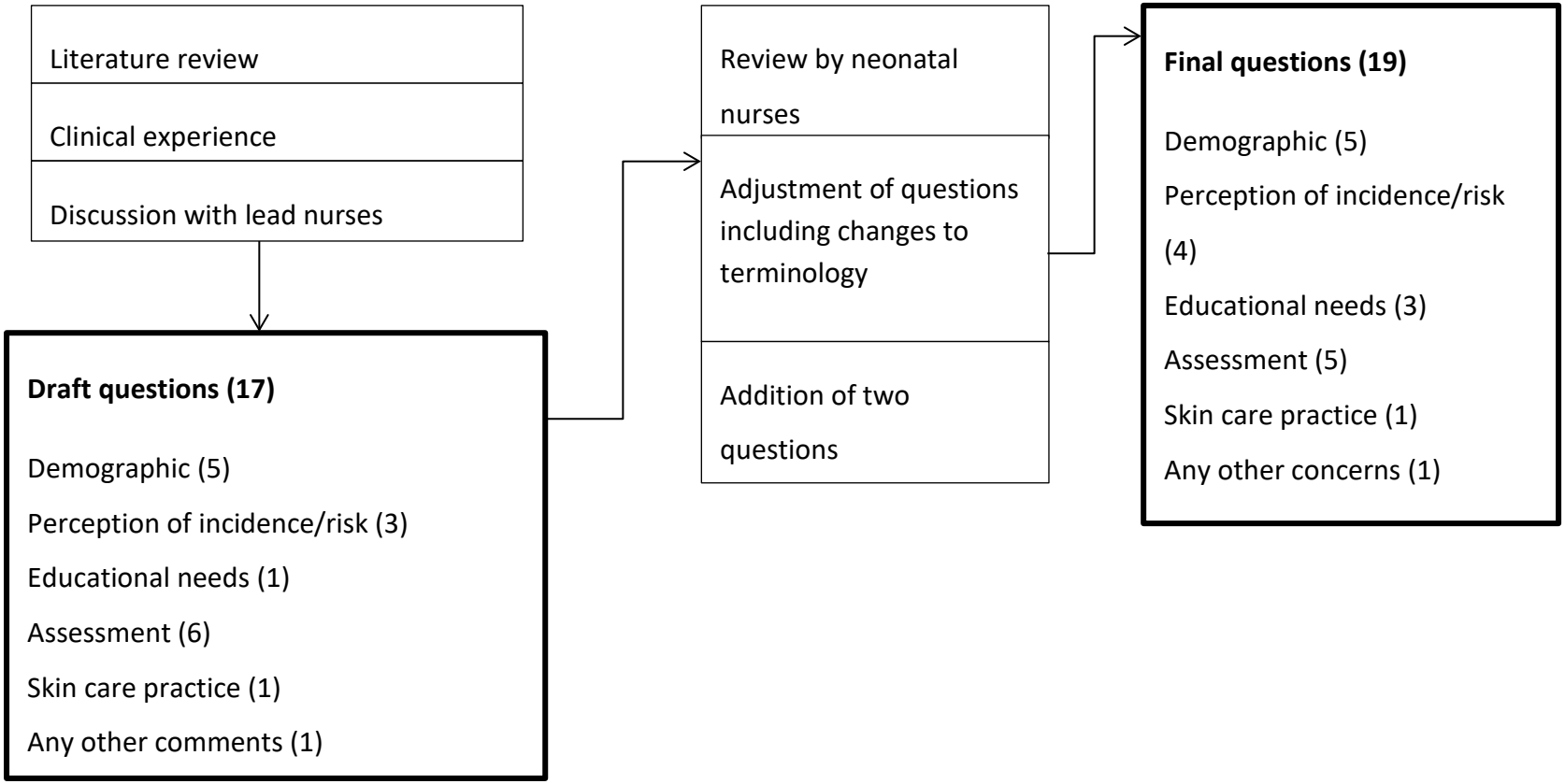


Figure 4.1 Survey development process

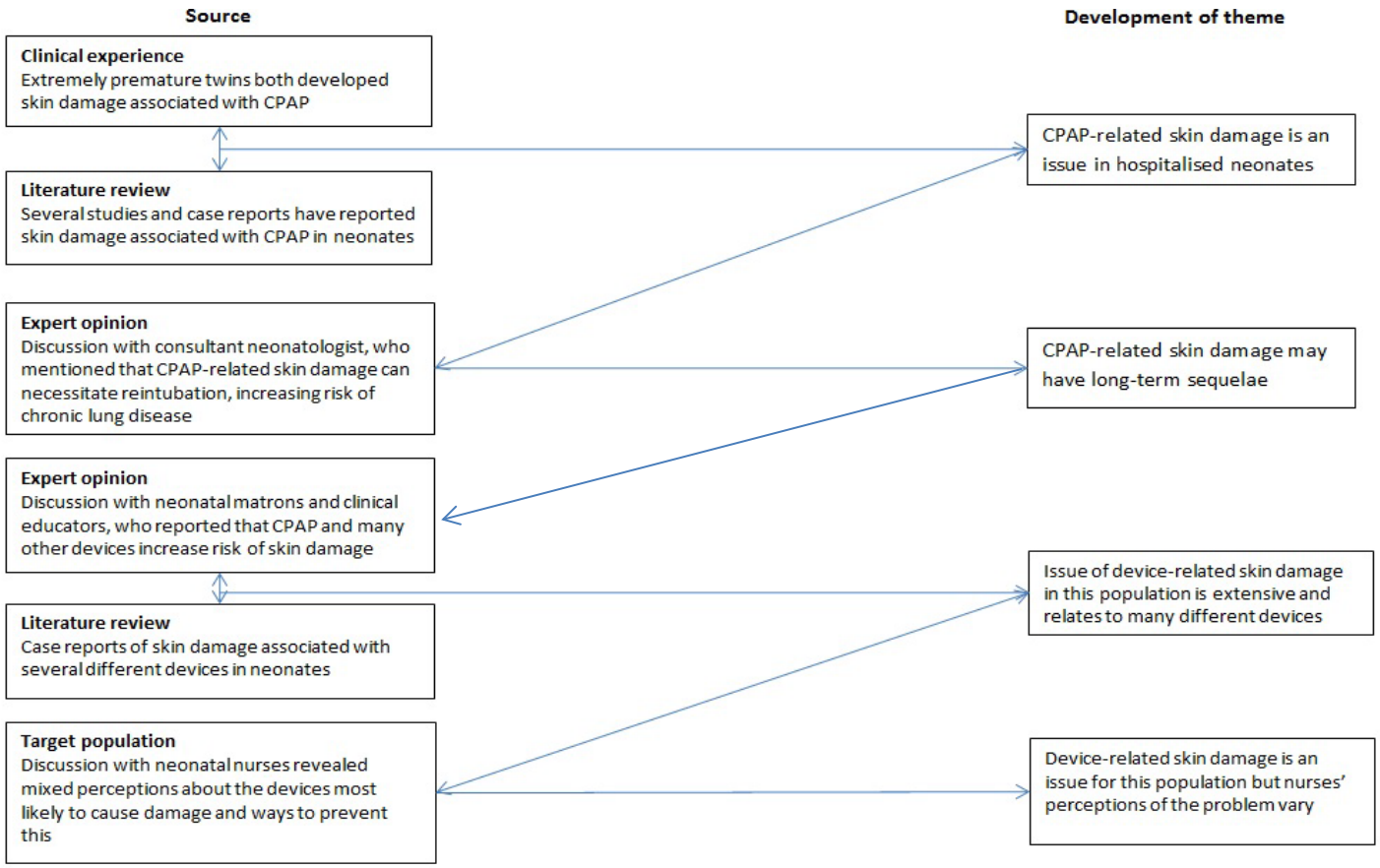


Figure 4.2 Development process for "perceptions of device-related damage" theme
Arrows indicate how regular review of various sources changed content of theme over time.

4.1.1.1 Coverage

Online distribution was initially selected as the most appropriate distribution method to reach the target population, following discussion with lead nurses from the contributing units. However, use of online surveys can cause coverage issues. For example, use of outdated or inaccurate email lists may cause over-coverage. It may also lead to under-coverage, if some participants do not have access to email or do not use the function regularly. In the present case, internal email lists were used, compiled and maintained by the Trusts. This minimised the risk of an invitation being sent to a nurse's personal email address. Similarly, nursing staff at participating units are required to access their emails regularly in order to receive information about study days and other work-related updates. All staff were therefore likely to be familiar with the use of email.

Under coverage error can also be caused by browser incompatibility. Participants would be filling out the survey on hospital computers at their units, and therefore the survey was tested on computers at two of the hospital sites (Portsmouth Hospitals NHS Trust and University Hospitals Southampton NHS Foundation Trust). This exercise revealed that there were no browser or computer incompatibility issues. A computerised survey tool (www.limesurvey.org) was used as the mechanism for delivering the survey. This tool was chosen as it allowed for a potentially high response rate, and was easy to use. Examples of questions in the Limesurvey format are provided in Appendix C.

4.1.1.2 Sampling

The second cornerstone of survey research is sampling. Sampling frames are generally used to reach a finite population within the target group, as whole populations are generally too large to be surveyed (Lehtonen and Pahkinen, 2004). However, in the present instance, the entire population was invited to participate. It was therefore not necessary to develop a sampling frame. This group therefore represents the whole target population of ODN neonatal nurses and support workers. Level 1, 2, and 3 units were all represented within this network, which have a mix of staffing experience, expertise, and patient acuity.

Open inclusion criteria were used, as any member of nursing staff who regularly provided direct patient care was eligible for the study. This decision was made on the basis of the diversity of care delivered on neonatal units within the ODN. For instance, a critically ill, extremely premature neonate who may be intubated for several weeks, and a full-term

neonate who requires temporary blood sugar monitoring for two days both fall within the remit of “neonatal care”. Staff providing care for the former are unlikely to have the same experience of skin damage as staff looking after the latter. In order to account for this in the analysis, details of the participant demographics were collated, for example the type of unit they were currently practicing in.

4.1.1.3 Response

Although the study was originally designed with the intention of reaching the whole population, consideration still needs to be given to response rate, as this may affect the representativeness of the findings (Lynn, 2008). Survey response rates can be extremely varied, with reported values between 10-69% (Baruch and Holtom, 2008). In order to optimise response rates in this study, neonatal nursing staff had input into the development of the tool and the topics covered, meaning that the salience was high for potential participants from this population.

Lynn (2008) suggests two approaches to dealing with non-response. The first is to minimise the non-response rate. The steps taken to address the low response rate are detailed in Section **Error! Reference source not found.**. The second method suggested is to adjust statistically for nonresponse error, such as by stratifying the data after collection and weighting responses from different subgroups (Tourangeau and Plewes, 2013). In our study, inferential statistics were not conducted, as the aim of the study was not to compare sub-groups of individuals, rather gain an understanding of trends across practice. No statistical adjustments were made for non-response error, and generalisations were not made about the whole population of neonatal nurses based on the responses of those who participated. Trends in the data were observed using sub-categories according to the nurse experience, qualification and type of unit they practiced in.

4.1.1.4 Measurement

The final cornerstone of survey research is ensuring that the questions accurately measure the intended constructs, as defined above (de Leeuw, Hox and Dillman, 2008). For example, factors such as the reading level of participants and the use of technical language may inhibit the consistency with which participants interpret questions (Fowler and Cosenza, 2008). In order to improve the reliability of the study, all participants should be able to understand and answer the questions in an equivalent way. In this instance, all potential participants were

nurses or nursery nurses working in the NHS, professionally required to present with a high level of reading comprehension. However, the use of specific language related to skin health required further consideration.

The group of RNs and nursery nurses who reviewed the draft items for content also provided feedback on specific vocabulary choices. For example, the use of the phrase “skin damage” was chosen over “skin breakdown”, as it became apparent that “skin breakdown” could be interpreted as broken skin or open wounds. Given that the questionnaire was intended to cover situations such as colour change and indentation to intact skin, as well as broken skin, the term “skin damage” was selected. This term was understood by participants to cover a broader range of injuries and clinical situations. The term was also clarified in the participant information sheet as follows:

*“**Skin damage** is used throughout the survey to refer to deterioration in a patient’s skin health. This may mean changes in colour where the skin remains intact, or instances where the surface of the skin has been broken”.*

In addition, it was necessary to designate the time frame to which some of the questions referred (Fowler and Cosenza, 2008). The question “How often do you see skin damage in your practice?”, for example, could be interpreted and answered in a variety of ways. This was addressed by providing multiple-choice responses to questions of this nature. The available responses were also considered carefully. For example, a series of responses such as “frequently, occasionally, seldom, never” is vague and depends on the interpretation of the participants. The survey therefore clearly differentiated between “daily”, “weekly”, “once or twice a month” etc. to minimise the risk of inaccuracy. For five of the multiple-choice questions, participants were provided with comment boxes to elaborate or clarify their answers. This was useful for questions where participants from different units might use different terminology, such as for assessment tools, and helped to further reduce the risk of misinterpreting the answers. A mixture of multiple-choice, open-ended and ranking questions was also used to provide the basis for accurate and consistent reporting from the proposed sample.

4.1.1.5 Layout and question order

Consideration was also given to the order of the questions in the tool (de Leeuw, Hox and Dillman, 2008). A funnelling approach was used starting with initial questions concerning

general demographic information and gradually more specific questions were introduced throughout the tool. Questions were predominantly grouped by theme, in order to facilitate natural flow of the survey. One exception to this was Q17, a specific question about risk associated with medical devices. It was not included with other questions regarding perception of risk, as it could have coached participants to consider these devices when responding to these questions (Polit and Beck, 2012). The full questionnaire tool is detailed in Appendix D.

One of the objectives of this study was to begin identifying determinants of change in relation to neonatal practice. For this reason, both open and closed questions were necessary. In particular, the qualitative findings facilitated the interpretation of some aspects of the quantitative data, providing the scope for greater depth of analysis. For example, Q10, "Have you had any training in skin care since you started working with neonates?" clearly identifies the presence or absence of skin care education among neonatal nurses. However, it is not possible to extrapolate nurses' perceptions of the content and quality of this training, and their understanding of how education influences practice from a binary yes/no response. The rich qualitative data generated by the open-ended questions was much more appropriate for this.

In addition, it was likely that participants would have comments and concerns that were not anticipated in the literature review, due to the relative paucity of research on the topic. Open questions provide an opportunity for these issues to be identified, addressing research Objective 2. In particular, Q19 was left open for "any other comments", in addition to several other open text boxes for participants to voice their thoughts. Identification of previously unknown determinants of change is considered an important aspect of problem analysis (Wensing, Bosch and Grol, 2013a).

4.1.2 Pilot testing

Following development of the survey, it was pilot tested in order to ensure that there were no logistical difficulties associated with its completion. Two PhD students (not RNs), two registered adult nurses, and four registered paediatric nurses outside the target population were included in the pilot. Students were asked to comment on the functionality, formatting, and ease of use. Following their feedback, the font size was increased, but no other changes were made. RNs were asked to complete the tool as if they were part of the target population,

and comment on the structure and format. The response was positive and no changes were made following this feedback. It took the RNs on average 15 minutes to complete the survey.

4.1.2.1 Alterations to recruitment

Initial uptake proved to be poor in comparison with previously published response rates (21 responses after 3 months). It was not clear whether this was due to lead nurses not sending the survey out to staff, or because staff were unwilling to complete an online survey. For this reason, further emails were sent to the lead nurses asking them to confirm that they had distributed the survey to staff. The majority of lead nurses did not respond. Thus recruitment was amended with permission from faculty ethics, and 100 paper copies of the survey were sent to all three level 3 units within the ODN, with pre-addressed envelopes in which participants could return completed copies. Additionally, posters were put up in these three units advertising the survey. This prompted an increase in online responses, as well as some paper copies being returned through the post. An ethics amendment was sought and granted for these recruitment changes (ID 12482).

Level 3 units were targeted for two reasons:

i) All three units had one or more members of staff who were willing to act as champions for the study and promote it to members of staff. These were clinical educators or research nurses.

ii) Although it was desirable that all units were represented in the results, Level 3 units provide care for a greater percentage of critically ill and extremely premature neonates, for a longer duration of time. Members of staff working in this environment are therefore more likely to have informed views on medical device use in relation to skin management.

The online survey tool remained open for one year in total, although all responses were received within the first five months. Paper copies were sent out after three months of online recruitment, and 13 were returned within two months of this date (i.e. five months into the study), in addition to a further 22 online responses, giving a total of 56. No further paper or online copies of the survey were completed after this date. Attempts were made to raise the response rate by contacting research nurses and clinical educators from these three units to

confirm survey distribution. These staff were prompted three times via email but this did not raise response rate any further.

4.2 Quantitative results

4.2.1 Demographics of respondents

The response rate was estimated to be =7% if all surveys were distributed and the estimate of nursing staff was correct. A breakdown of participants by subgroup can be seen in Figure 4.3. Further demographic details can be seen in Table 4.1. Participants were predominantly RNs in senior roles, with 44 participants working as senior staff nurses or above (78.6%). The majority of participants care for HDU and/or ITU patients at least some of the time (n=50, 89.3%).

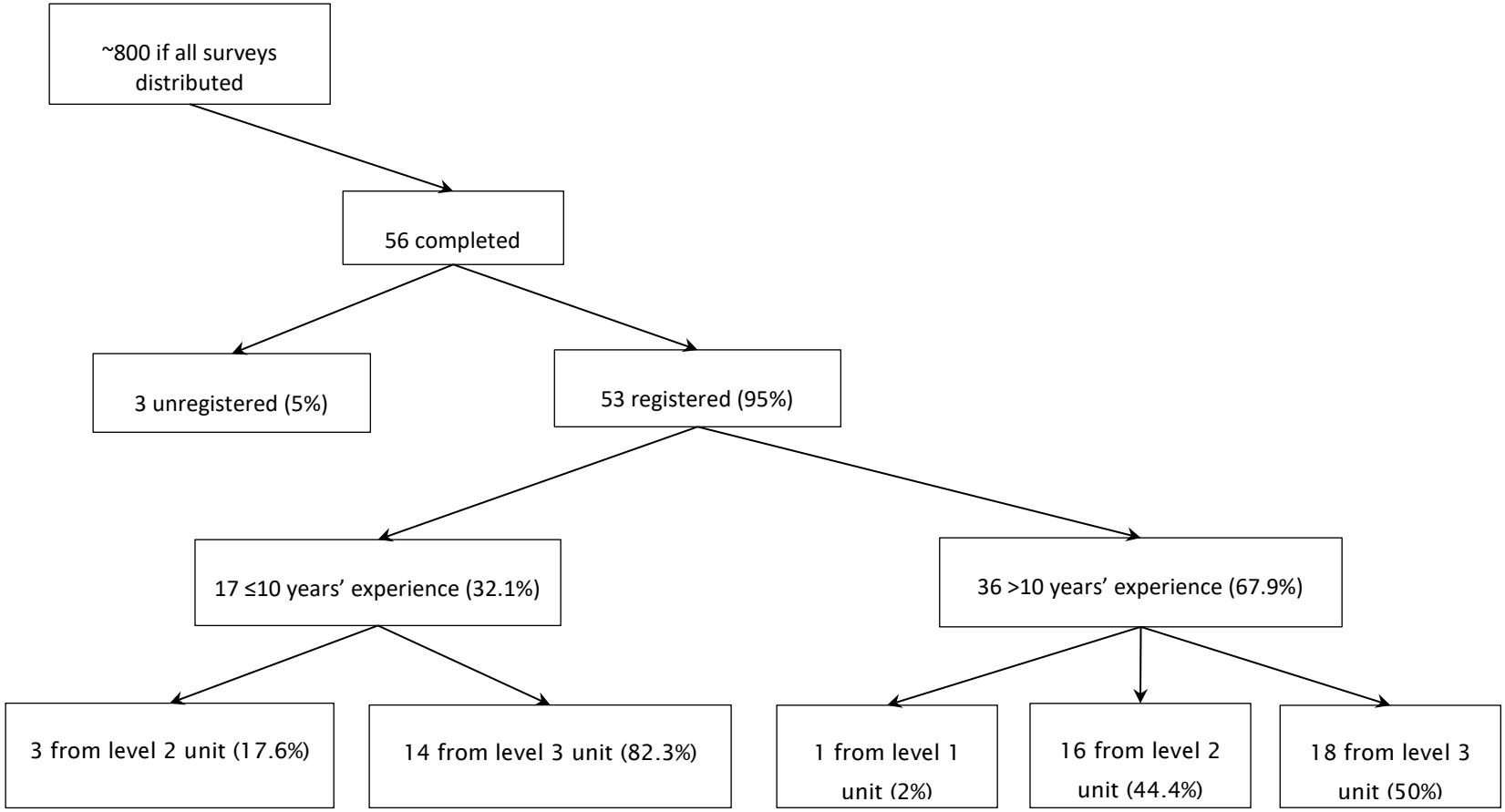


Figure 4.3 Demographics by subgroup[1]

[1]Unit type for one participant with >10 years' experience is omitted due to lack of clarity on paper response.

Table 4.1 Demographics

		Band 2		Band 4		Junior SN		Senior SN		Sister		Senior sister		Clinical educator		Nurse specialist		ANNP[1]	
		n	*% of total*	*N*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*
Professional registration	None	1	*1.8*	2	*3.6*														
	RN (Child)					5	*8.9*	5	*8.9*	7	*12.5*	2	*3.6*	2	*3.6*	2	*3.6*	0	*0.0*
	RN (Adult)					4	*7.1*	4	*7.1*	4	*7.1*	5	*8.9*	2	*3.6*	0	*0.0*	0	*0.0*
	RN (Child) + RN (Adult)					0	*0.0*	1	*1.8*	1	*1.8*	3	*5.4*	1	*1.8*	0	*0.0*	1	*1.8*
	RN (Adult) +RM					0	*0.0*	0	*0.0*	2	*3.6*	1	*1.8*	0	*0.0*	0	*0.0*	1	*1.8*
Years qualified	<1 year					2	*3.6*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*
	1-2 years					1	*1.8*	1	*1.8*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*
	3-5 years					4	*7.1*	3	*5.4*	1	*1.8*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*
	6-10 years					0	*0.0*	2	*3.6*	2	*3.6*	0	*0.0*	1	*1.8*	0	*0.0*	0	*0.0*
	11-20 years					1	*1.8*	1	*1.8*	5	*8.9*	2	*3.6*	2	*3.6*	2	*3.6*	0	*0.0*
	21+ years					1	*1.8*	3	*5.4*	6	*10.7*	9	*16.1*	2	*3.6*	0	*0.0*	2	*3.6*
Type of unit[2]	Level 1	0	*0.0*	0	*0.0*	0	*0.0*	1	*1.8*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*	0	*0.0*
	Level 2	0	*0.0*	2	*3.6*	2	*3.6*	2	*3.6*	6	*10.7*	6	*10.7*	1	*1.8*	0	*0.0*	2	*3.6*
	Level 3 (medical-surgical)	1	*1.8*	0	*0.0*	2	*3.6*	4	*7.1*	5	*8.9*	3	*5.4*	3	*5.4*	2	*3.6*	0	*0.0*
	Level 3 (medical)	0	*0.0*	0	*0.0*	5	*8.9*	2	*3.6*	3	*5.4*	2	*3.6*	1	*1.8*	0	*0.0*	0	*0.0*

[1]Advanced neonatal nurse practitioner
[2]Answer from one senior staff nurse was omitted from this category due to unclear response

4.2.2 Perception of incidence and risk

The first question theme related to “perception of incidence and risk”. This encompassed Q6-8 and Q17 (see Appendix D for question order).

The majority of participants rated the risk of skin damage in their patients as “high” (n=20, 35.7%), with a further 13 rating it as “extremely high” (23.2%). No participant selected the option for “no risk” (Table 4.2). Equally, when asked about the frequency of skin damage in practice, all participants responded that they had seen skin damage (Table 4.3). However, there were some apparent inconsistencies between participants’ perceptions of risk and frequency of damage. For example, two participants rated their participants as being at slight risk of skin breakdown yet reported that they see it daily in practice (Figure 4.4).

The majority of senior staff nurses (8/10; 80%) and 9/14 (64.3%) of sisters felt that their patients were at high or extremely high risk of skin breakdown, in comparison to 4/9 (44.4%) junior staff nurses and 0% of unregistered staff (Table 4.2). However, this trend was not reflected among senior sisters, who were most likely to rate their patients as being at moderate (4/11, 36.4%) or high (4/11, 36.4%) risk of skin damage. Among the small number of participants with specialist or extended roles (ANNP, clinical educator, and nurse specialist), all rated their patients as being at high or extremely high risk of skin damage, except for one ANNP who ranked their patients as being at slight risk.

Junior staff additionally reported seeing skin damage less frequently. For instance, 9/14 (64.3%) of sisters reported seeing skin damage daily or weekly, compared to only 1/9 (11.1%) of junior staff nurses. However, two sisters (14.3%) reported seeing skin damage less than once a year. Staff in specialist or extended roles reported seeing skin damage less frequently than staff nurses and sisters, with answers ranging from “less than once a year” to “once or twice a month”.

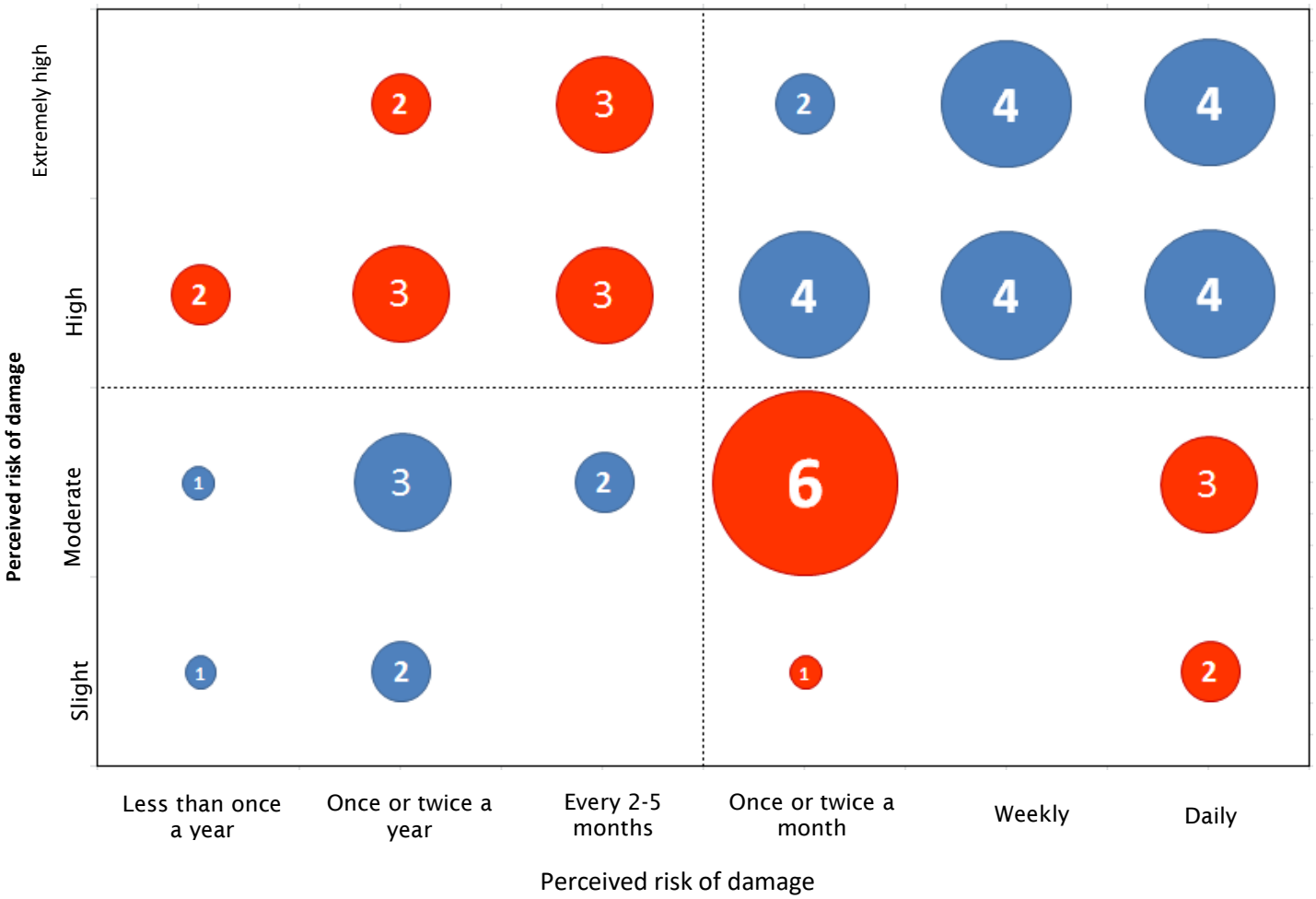


Figure 4.4 Perception of incidence compared to perception of risk among survey participants

Table 4.2 How great do you think the risk of skin damage is in the patients you normally look after?

	Slight		**Moderate**		**High**		**Extremely high**	
	N	*% of total*	*N*	*% of total*	*n*	*% of total*	*N*	*% of total*
Band 2-4	1	*1.8*	2	*3.6*	0	*0*	0	*0*
Staff Nurse	2	*3.6*	5	*8.9*	6	*10.7*	6	*10.7*
Sister/senior sister	2	*3.6*	8	*14.2*	11	*19.6*	4	*7.2*
Educator/ specialist/ANNP	1	*1.8*	2	*3.6*	3	*5.4*	3	*5.4*
Totals	**6**	***10.7%***	**17**	***30.3%***	**20**	***35.7%***	**13**	***23.2%***

Table 4.3 How often do you observe skin damage in practice?

	Less than once a year		**Once or twice a year**		**Every 2-5 months**		**Once or twice a month**		**Weekly**		**Daily**	
	n	*% of total*	*N*	*% of total*	*n*	*% of total*	*N*	*% of total*	*n*	*% of total*	*n*	*% of total*
Band 2-4	1	*1.8*	0	*0*	0	*0*	1	*1.8*	0	*0*	1	*1.8*
Staff nurse	0	*0*	5	*8.9*	2	*3.6*	5	*9.2*	2	*3.6*	4	*7.2*
Sister/senior sister	2	*3.6*	4	*7.2*	4	*7.2*	3	*5.4*	4	*7.2*	8	*14.3*
Educator/ specialist/ANNP	1	*1.8*	1	*1.8*	3	*5.4*	4	*7.2*	0	*0*	0	*0*
Totals	**4**	***7.1%***	**10**	***17.9%***	**9**	***16.1%***	**13**	***23.2%***	**6**	***10.7%***	**13**	***23.2%***

The free text comments provided in response to Q8, “Please list common locations for skin damage”, are summarised in Figure 4.5. The three most common locations given are “nappy area”, “foot/heel”, and “nose”, each reported by at least 20 participants. The context of these comments suggests that causes of damage in these locations are primarily diaper dermatitis, heel prick blood tests, and pressure from respiratory devices, respectively. However, all regions of the body were mentioned by at least one participant, and one participant expressly wrote that “every part of the body” is at risk.

Although the question asked for locations, many participants listed causes instead of/in addition to locations (e.g. “extreme prematurity” or “pressure from devices”), and these comments are presented in Table 4.4. Several participants mentioned specific medical devices. For example, 19 participants (33.9%) identified damage from IV devices in some form or another. Some of these comments referred to extravasation or infiltration injuries, whereas others noted that neonates are at risk of needlemarks. CPAP and ECG leads were also identified by several participants as potential causes of skin damage. The spread of locations for damage reported by participants corroborates this.

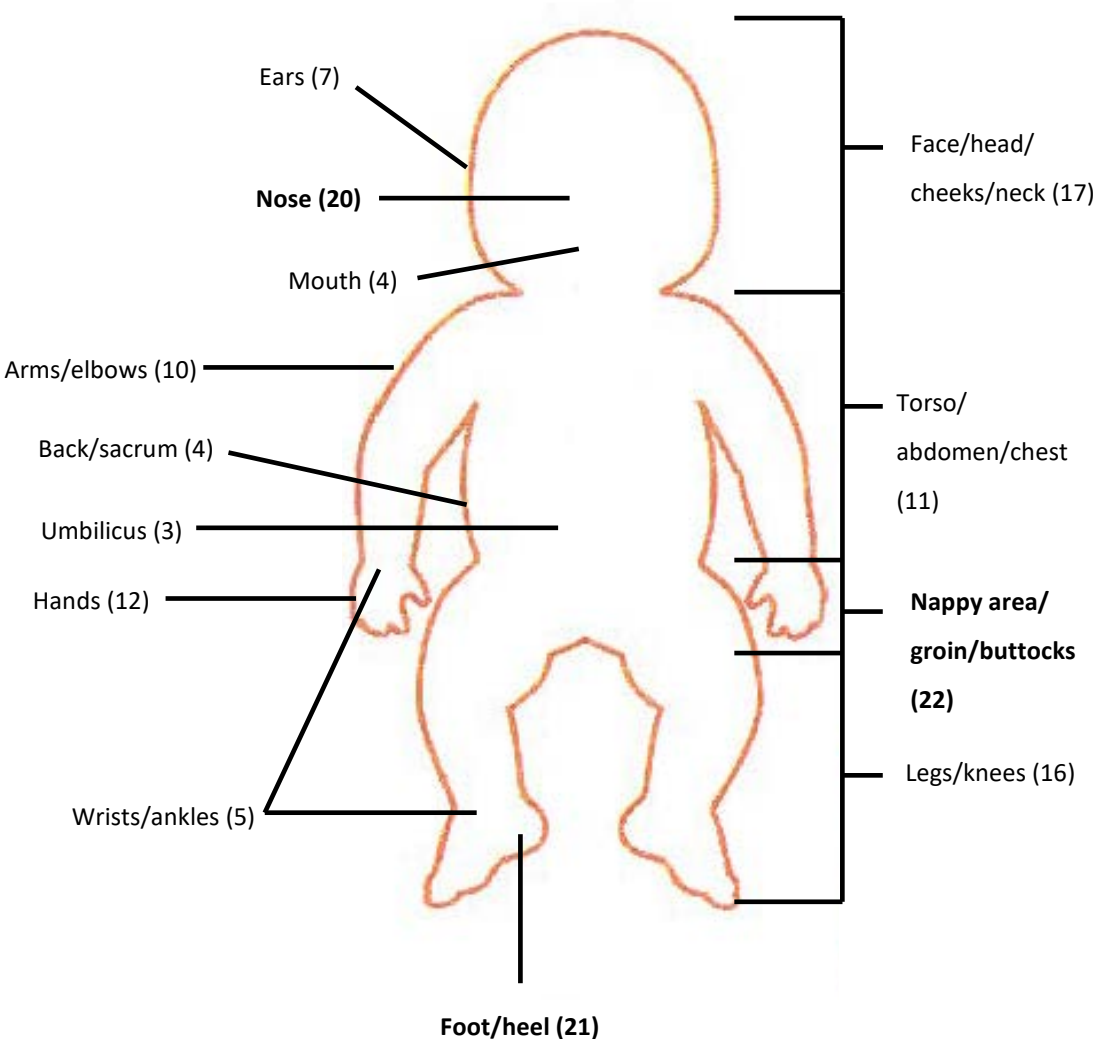


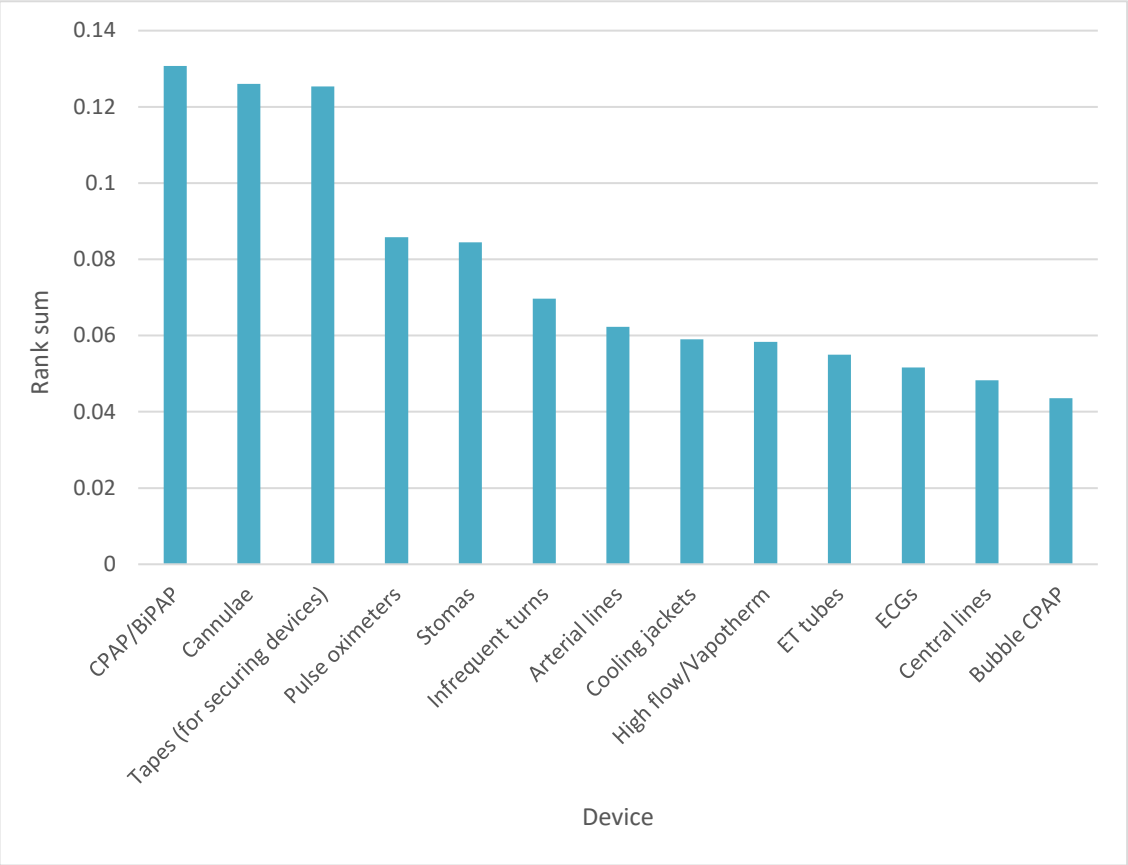
Figure 4.5 Common locations for damage

Table 4.4 Comments from Q7 that did not specify a location.

Comments	***N***
Damage from IV access	19
Damage from named device (e.g. CPAP, ECG leads)	15
Adhesives/dressings/tapes	7
Stoma/ileostomy/colostomy	5
Damage from unnamed device	2
Damage from delivery	2
Excoriation (unspecified)	2
Bony prominences	1
Extreme prematurity	1
Every part of body	1

In Q17, participants were asked to rank possible causes of skin damage according to the risk associated, primarily medical devices. Infrequent turning was also one of the options ranked as this can lead to immobility-related PUs. CPAP/BiPAP, cannulae, and adhesive tape were the three devices most commonly cited as having a high associated risk of skin damage (Figure 4.6). This reflects the comments made in relation to location of damage (Figure 4.5), with a large proportion of injuries occurring on the face/head area.

Figure 4.6 Perceived risk of device-related damage



4.2.3 **Educational needs**

The second question theme was “educational needs”, encompassing Q9-11. Q9 was a free response question and the findings are presented with other qualitative data (section 4.3). Responses to Q10 and 11 are described in Table 4.5.

Table 4.5 Skin care education and awareness of policies

Role	Skin care education						Awareness of policies[1]			
	Yes (informal)		Yes (formal)		None		Yes		No	
	n	*% of total*	n	*% of total*	n	*% of total*	n	*% of total*	n	*% of total*
Band 2-4	2	*3.6*	0	*0*	1	*1.8*	1	*1.8*	2	*3.6*
Staff nurse	10	*17.9*	1	*1.8*	8	*14.3*	9	*16.1*	9	*16.1*
Sister/senior sister	17	*30.4*	5	*8.9*	3	*5.4*	16	*28.6*	9	*16.1*
Educator/specialist/ANNP	8	*14.3*	0	*0*	1	*1.8*	5	*8.9*	4	*7.1*
Totals	**37**	***66.1%***	**6**	***10.7%***	**13**	***23.2%***	**31**	***55.4%***	**24**	***42.9%***

[1]One participant did not answer this question

Only six participants reported receiving any formal skin care training since they started working with neonates (10.7%). In particular, no clinical educator had received formal skin care training, despite the fact that they are responsible for training other staff. One participant who identified himself or herself as “tissue viability link nurse” in a subsequent free text response had received no training at all. No junior staff nurse had received formal skin care training, although this is reportedly part of the induction programme. The majority of staff reported receiving bedside training from their colleagues and peers (n=37, 66.1%).

The type of training and other free comments recorded in response to Q10 can be seen in

Table 4.6. The three most common types of training included the ENB 405 (a postgraduate certificate in neonatal nursing), observation of/talking to other nurses, and involvement in developing guidelines on the subject.

Table 4.6 Type of training

Type of training	**N**	**%**
ENB 405/neonatal modules	3	5.6%
Observing and talking to other nurses	3	5.6%
Involvement in guideline development	3	5.6%
Local training	2	3.8%
Involvement in benchmarking	2	3.8%
Advice from tissue viability nurse	2	3.8%
Comment relates to lack of education	2	3.8%
Personal research	1	1.8%
Use of guidelines	1	1.8%
Theme of the week (staff handover)	1	1.8%
Can't remember	1	1.8%

When asked about skin care policies related to their practice, 31 participants stated that they were aware of these (55.4%). Of those who went on to identify a policy in the comment box (n=26), 10 referred to regional guidelines from the ODN, including guidelines on CPAP and positioning. Seven referred to local Trust or unit guidelines. One participant referred to "AWOH", likely the guidelines released in 2001 by the American Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) (Lund, Osborne, *et al.*, 2001). Of interest, 3/5 clinical educators and 7/14 sisters surveyed stated that they were not aware of any policies relating to skin care in neonates.

4.2.4 Assessment

The third theme related to assessment and encompasses questions Q12-16. Data regarding Q12, "How frequently do you assess the skin of patients in your care?" is presented in Table 4.7. The majority of participants reported that they carried out skin assessments with nappy changes or cares (62.5%, n=35), though the frequency of these differs between participants. The term "cares" was used in keeping with language used by staff working in the ODN at the time of the survey to refer to clustered episodes of care delivery, when many interventions that require handling of the neonate are delivered together in order to minimise disturbance to clinically unstable patients. A further 15 reported that they carried out skin assessment more often than this (26.8%). Only two participants reported that they carried out skin assessments "only when necessary", both of whom were in junior roles.

Table 4.7 Frequency of assessment

Role	Only when necessary		Once per shift		Twice per shift		With nappy changes or cares		More often	
	N	***% of total***	***n***	***% of total***	***n***	***% of total***	***n***	***% of total***	***n***	***% of total***
Band 2-4	1	*1.8*	0	*0.0*	0	*0.0*	2	*3.6*	0	*0.0*
Staff nurse	1	*1.8*	0	*0.0*	0	*0.0*	12	*21.4*	6	*10.7*
Sister/senior sister	0	*0.0*	1	*1.8*	0	*0.0*	17	*30.4*	7	*12.5*
Educator/ specialist/ ANNP	0	*0.0*	2	*3.6*	1	*1.8*	4	*7.2*	2	*3.6*
Total	**2**	***3.6***	**3**	***5.4***	**1**	***1.8***	**35**	***62.5***	**15**	***26.8***

Upon examining the free text responses regarding skin assessment, it was apparent that current practice may not include a top-to-toe assessment. The three comments made most frequently in response to this question were "depends on condition of baby or GA" (n=12, 21.4%), "cannula sites checked hourly when infusion is running (n=11, 19.6%), and "4-6 hourly with cares" (n=7, 12.5%). Contradictions between participants were apparent in some of these responses. For example, two participants stated that it is necessary to assess the nose hourly when a patient is on CPAP or high flow, while two others stated that this should occur every two hours. In addition, three participants stated that skin assessment occurs less frequently in ITU patients than HDU due to instability, whereas one participant stated it occurs more in this sub-population.

When asked about the criteria used for assessment of skin health the most common response was colour changes, selected by 55 of participants (98.2%, Table 4.8). Further comment was provided by five participants, of whom one appeared to refer to the NSRAS tool for assessing risk, as the categories he or she listed match those in that tool (Huffines and Logsdon, 1997). Other participants referred to the gestation of the neonate or the presence of a device. This was a multiple-response question, and given that many participants ticked all or most of the responses, it is possible that these participants just ticked all the options that seemed reasonable.

Table 4.8 Criteria used for assessment

Role	Guidance from the hospital/unit		Colour changes		Moisture/ dryness		Signs of damage		External pressure e.g. devices		Other	
	n	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*	*n*	*% of total*
Band 2-4	1	*1.8*	3	*5.4*	3	*3.6*	3	*5.4*	2	*3.6*	1	*1.8*
Staff nurse	8	*14.3*	19	*33.9*	18	*32.1*	19	*33.9*	16	*28.6*	1	*1.8*
Sister or senior sister	11	*19.6*	24	*42.9*	23	*41.1*	23	*41.1*	21	*37.5*	2	*3.6*
Educator, specialist, or ANNP	2	*3.6*	9	*16.1*	9	*16.1*	9	*16.1*	8	*14.3*	1	*1.8*
Total	**22**	***39.3%***	**55**	***98.2%***	**52**	***92.9%***	**54**	***96.4%***	**47**	***83.9%***	**5**	***8.9%***

Q14 and Q15 concerned the subject of risk assessment for skin damage (**Error! Reference source not found.**). On analysis, it appears that the minority of participants (n=13, 23.2%) routinely use RAS in practice. However, none of the participants who commented named a RAS, instead listing scales for assessing existing damage e.g. "sore bottom flowchart". Participants predominantly felt that a risk assessment tool designed for neonates would be helpful (n=50, 89.3%).

Table 4.9 Risk assessment scales

Question	Yes		No	
	N	*% of total*	*n*	*% of total*
Do you use a risk assessment tool to help you identify the risk of skin damage?	13	*23.2*	46	*76.8%*
Do you think a risk assessment tool designed for use in neonates would be helpful?	50	*89.3*	6	*10.7*

When asked about grading or assessing skin damage, 41 respondents reported using descriptors in the medical notes rather than any standardised reporting system (73.2%). Of those who reported using hospital scales in either this or the previous question, only two are mentioned by name: the VIP score and the NESS score. VIP (Visual Infusion Phlebitis) is a tool for assessing signs of infusion phlebitis around the site of an intravenous device and as such is appropriate for this purpose, albeit it was designed for use in adults. The NESS score is used by at least one unit within the ODN to assess cannula sites (Hill, 2013). It is not clear what "NESS" stands for in this context or whether the NESS score has been validated. Two participants stated that medical photographs would be included along with a description in the notes. However, it is was not evident if this applied for all skin damage or only severe cases.

4.3 Qualitative findings

The qualitative data were analysed as described in section 3.7.2.1. This process was informed by the determinants of change from the ICM, which are presented in Table 4.10. Some individual factors are not included in the analysis, as they were not mentioned by the participants. For example, no comments were made in relation to "financial incentives and disincentives". Additionally, the determinant "Social, political and legal factors" was not represented in the data. In this instance, no codes were identified that did not match the ICM, although the determinant

"incentives and resources" presented differently in these data than described in the ICM. It is therefore termed "availability and suitability of resources".

Table 4.10 Determinants of change

Determinant	**Factors comprising determinant**
Individual health professional factors	• Knowledge and skills • Cognitions (including attitudes) • Professional routines and characteristics
Patient factors	No specific factors listed
Professional interactions	• Team processes • Communication and influence • Capacity for organisational change • Organisational structure • Capable leadership and organisational culture
Incentives and resources	• Availability of necessary resources • Financial incentives and disincentives
Social, political and legal factors	• Legislation • Health professions

The findings from the qualitative analysis are summarised in Table 4.11, which presents barriers and facilitators of skin health grouped according to determinant. In general, the survey participants considered the prevention of skin damage to be important to their practice and part of their professional role. They described steps taken to improve their own skin care knowledge, including peer-to-peer education and staff development projects. In addition, they described skills used to individualise skin care based on GA at birth, presence of specific devices, and other clinical factors. However, their efforts to prevent skin damage were in some instances hampered by inadequate resources, especially those related to medical devices. Additionally, participants reported difficulties in managing competing clinical needs, especially when caring for sick and unstable neonates. One or two key quotes for each code are presented in this table. For a more comprehensive list of participant quotes in relation to these codes and factors, please see Appendix F.

Determinant	Factor	Key codes	Example
Individual health professionals factors	Knowledge and skills	Lack of knowledge	P40: “Often not recognised by staff as an issue, lack of knowledge on how to promote skin health”
		Lack of evidence	P4. “No [I don’t feel about to protect and promote skin health] little evidence on best practice”
		Knowledge of device care	P21. “Change probe sites Ensure cannulas are appropriately strapped and observed. Ensure CPAP and ET tubes are not too tight”
		Knowledge of correct procedures	P13. “Aware of correct technique when blood sampling from heel prick, to prevent bruising”
		Awareness of risk factors	P15. I feel our unit pay particular attention to this area due to the prematurity of our babies where skin tissue damage can be a high risk.”
	Cognitions including attitudes	Care prioritisation	P34: “Sometimes [maintaining skin health] is not the priority (unstable baby, minimal handling, heavy workload, time pressures).”
		Guidelines and protocols	P47: “Nurses preferring their choice [for barrier creams]—rather than using protocol/guidelines regarding nappy area, as we do have a guideline for this.” P8. “Yes [I feel able to protect and promote skin health] we have comprehension skin and wound care guidelines”
		Perceived as important	P30. “I think this is an important topic”
		Positive towards education	P40. “Would like to help create staff education package/protocol”
	Professional routines and characteristics	Assessment	P38. “I would also assess at the beginning and end of each shift too.”
		Repositioning	P30. “Repositioning infants 6 hourly as tolerated”
		Staff-led change	P38. “Our unit still advocates using olive oil… whereas I know sunflower oil is known to be better for their skin. I am in the process of trying to implement this change.”

Professional interactions	Capable leadership and organisational culture	Training	P36: "…there is little training given on the topic [of skin health]" P22. "Skin care training is offered to new staff"
	Organisational structure	Use of experts	P22: "When there are concerns with skin there is no specialist to call, although the tissue viability nurse is called, they often do not have the expertise in neonates" P23. "Link nurses for skin care and tissue viability teams to enable a pathway/guideline to be written"
	Team processes	Working with parents	P13. "Parent co-operation in observing skin from day to day and informing staff"
		Peer education	P40. "Try to inform peers, raise awareness of skin health"
Availability and suitability of resources	n/a	Recent improvements	P34. "Our skin care practices are improving with access to improved equipment and facilities"
		Guidelines and protocols	P48. "There is information available on unit regarding correct positioning for heel prick samples" P30: "More education, guidelines/protocols…would be beneficial for nurses working in neonatal intensive care units"
		Prophylactic treatments	P23. "Use of silk sheets, Cavilon and other barrier products"
		Assessment tools	P19: "No score system for damage from sats probes or NGT's etc"
Patient factors	n/a	Parent behaviour	P13. "Co-operation with parents on consistent observation of skin"
		Patient characteristics	P32. "We have measures in place to help protect skin and promote skin health, however, they are not always sufficient if the baby is very unwell and/or premature"

Table 4.11 Barriers to and facilitators of skin care grouped according to the determinants of change

4.3.1 Individual health professional factors

4.3.1.1 Knowledge and skills

The comments made by participants in relation to knowledge and skills indicate that these may be both barriers to and facilitators of change. Some participants expressed concern or a lack of confidence in their own knowledge and skills, which in some instances they linked to a lack of either training or evidence. Participants who expressed reservations about their own knowledge included senior staff.

In contrast, many participants felt that they did have the required knowledge and skills to provide adequate skin care. In order to demonstrate this, participants referenced particular knowledge and skills they felt they had developed during their neonatal nursing career. For example, some participants referred to minimising the use of adhesive tapes, or regular observation of skin or devices. Others talked about the need to tailor care for individual neonates, such as the use of silk sheets for extremely premature neonates.

4.3.1.2 Professional routines and characteristics

There was no indication from the comments that professional routines or characteristics act as a barrier to change in this environment. Participants spoke positively of routines embedded in practice, reporting those that contributed to the prevention of skin damage. Although participants reported different practices for skin observation (see 4.2.4), many referred to observation and assessment as an important routine. The reported professional routines also included specific practices associated with medical devices, and handovers at the beginning and ending of each shift.

In terms of professional characteristics, some participants refer to trying to educate peers, participating in staff development programmes on skin care, or even making unit-wide changes to standardise practice based on the best available evidence. This was reported by both staff nurses and clinical educators. Grol and colleagues (2013) suggest that changing professional routines is often difficult, but the participants in this particular study appear keen to change unhelpful or outdated practices. None of the unregistered participants made comments to this effect.

4.3.1.3 Cognitions including attitudes

Overall, participants in this study appeared to have a positive attitude towards skin care, with one participant stating expressly that '*this is part of the neonatal nurses' role'* and another stating that '*this is an important topic*'.

In particular, many participants reported that education on this subject is important. However, individual protocols or guidelines may not receive such a positive response from staff. One senior sister specifically referred to the unit's nappy care protocol as an example of a guideline that was not always followed by staff. Additionally, one participant described the challenges associated with nursing workload and other clinical issues taking priority over skin care, particularly when a neonate is unstable.

4.3.2 Professional interactions

4.3.2.1 Team processes

Participants spoke positively about the value of teamwork and the role of various members of the team, with no indication that team processes act as a barrier to change in this environment. Some participants mentioned the importance of co-operating or collaborating with parents as part of the team.

In addition to formalised education in the form of the ENB405 or staff induction, some participants reported peer-to-peer learning from colleagues, including senior staff. One participant who had been qualified for 11-20 years and was in a relatively senior position (Band 6) commented that they would go to more senior staff for advice. In terms of teamwork between units, some participants referred positively to the use of the Wessex and Thames Valley ODN guidelines for subjects such as humidification and skin integrity.

4.3.2.2 Capacity for organisational change

Only one participant made a comment on this topic, which relates to the resources available to individual units or organisations. This participant worked on a level 2 unit and suggested that different units may have different educational needs.

4.3.2.3 Capable leadership and organisational culture

From participants' comments, there seem to be several aspects of unit leadership and culture that were facilitators of change. One participant highlighted that there is a strong emphasis on their

level 3 unit toward anticipating and preventing problems related to skin damage, referring to this as *'team effort'*, which seems from context to relate to the team's collective prioritisation of prevention rather than their interactions with one another. Another participant noted that they felt their unit (also a level 3), paid particular attention to the problem due to the high number of premature babies in their care. Other comments also suggest that these organisations had a culture promoting skin health and prevention of damage, such as the use of "Theme of the Week" at staff handover to share information about skin health. Additionally, some participants reported involvement in staff development projects that included or focussed on skin health, suggesting that these units viewed skin care as a priority for improvement.

However, comments on the availability and quality of training on this subject appeared to vary between individuals and organisations. Some participants reported that training had improved the way they delivered skin care, while others felt that the available training was limited or indeed reported that they had received no formal training, suggesting that skin care was an educational priority for some but not all units involved. Two participants commented that new staff received training on skin health as part of their induction, though one went on to say that this was based on experience and anecdote. One participant commented that more training should be made available to staff. These comments were made by staff in a variety of clinical roles working in both level 2 and level 3 units.

4.3.2.4 Organisational structure

The role of specialised workers, especially tissue viability nurses (TVNs), was positively referred to by several participants, one of whom reported that their unit worked closely with the Trust's TVN team. However, some participants felt that their Trust's TVNs did not have the required skills to work with neonates and that in cases of skin damage there was no expert to call. All the comments about TVN involvement, both positive and negative, came from participants in level 3 units. Plastic surgeons and dermatologists were also cited by one participant as specialised workers available to help protect and promote skin health.

4.3.3 Availability and suitability of resources

The availability of resources was one of the topics referred to most frequently by participants. Resources mentioned by participants included devices, barrier products, assessment tools, and evidence. Some participants commented positively about the resources available to them.

However, more frequently, participants expressed concerns that these resources are not ideal for their purposes. Nasal oxygen prongs and adhesive tape were mentioned by multiple participants as causal factors in skin damage. Some referred to modifying particular devices in order to minimise their effect on skin.

Some participants commented that guidelines were a useful resource for protecting and promoting skin health, whereas others commented that they would value assessment tools or greater availability of protocols. One area where further resources in the form of guidelines would be useful relates to the use of barrier products, especially oils, e.g. sunflower oil and coconut oil. Two participants identified that olive oil is no longer recommended, although other participants referred to using it. Lastly, some participants commented that there was a general lack of evidence underpinning this area of practice, with one participant highlighting the lack of clarity on the pH of premature skin making it difficult to select creams for nappy rash.

4.3.4 Patient factors

Parent behaviour, especially the importance of educating parents, was identified as a factor in skin care by some participants. For example, one participant reported discouraging parents from using wipes and lotions. Additionally, clinical condition was mentioned by some participants in relation to its impact on skin care, with one stating that the measures used to protect skin health are not always sufficient for very unwell babies. The specific challenges associated with caring for premature skin were raised by several participants, either directly or with reference to adjustments to care that would be made to accommodate premature skin.

4.4 Focus group

A justification for the use of a focus group and critique of the methodology is presented in Chapter 3 (see 3.5.2.1 and Table 3.1).

4.4.1 Topic guide

A topic guide was developed to ensure participants received the necessary information about the study and practicalities, as well as to provide some topics for discussion (Appendix I). The topics for discussion were developed from the survey findings and literature review, with a view to addressing the determinants of change outlined by Grol and colleagues (2013). **Error! Reference source not found.** shows examples of questions designed to address specific determinants. The

majority of the factors comprising these determinants are directly addressed (Grol *et al.*, 2013), though some have been omitted. For example, the factor *financial incentives and disincentives,* associated with the determinant *incentives and resources,* was not directly addressed. This is because individual staff nurses are not involved in the financial decisions of a neonatal unit. However, it was possible that information about these topics would be revealed in the discussion.

Some questions were intended to specifically address aspects of the survey findings, rather than particular determinants of change. For example, questions related to barrier creams and oils were informed by survey results suggesting confusion among participants related to their use (see section **Error! Reference source not found.**).

Table 4.12 Examples of questions to address specific determinants of change

Determinant	**Factors**	**Questions**
Individual health professional factors	Knowledge and skills	How would you define skin damage?
	Cognitions (including attitudes)	To what extent is skin care a priority, in relation to other areas of care?
	Professional routines and characteristics	How does regular observation of the skin affect your practice?
Professional interactions	Team processes	If you had a skin care concern, who would you speak to first?

4.4.2 Recruitment and sample

Recruitment for the focus groups was conducted at two level 3 neonatal units (Table 4.13). Recruitment posters and participant information sheets were placed in the staff room at the sites. One nurse contacted the research team immediately expressing interest in the study as a result of these activities. Following this, the researcher went into morning handovers every day for a week at Unit 2 to promote the study, as well as spending some time on the unit speaking to nurses about the study. In total, five nurses, associate practitioners, and nursery nurses expressed interest.

Table 4.13 Units at which recruitment occurred

	Capacity for surgery	**Number of cots**
Unit 1	No	27, including 14 intensive care
Unit 2	Yes	36 initially, including 20 intensive care/high dependency. 8 new intensive care/high dependency cots were added during the study.

Following these recruitment activities, an email was sent to all those who had asked to be contacted containing potential data collection dates, which they were asked to rank in order of preference. The date that was preferable to the majority of potential participants was selected. Nursing staff of any band working on the unit were eligible for participation in the study provided that their role was primarily direct patient care.

Following this, a focus group was held with nursing staff working at Unit 2. It was comprised of two staff nurses. A light lunch was provided to participants and they received a CPD certificate for taking part.

4.4.3 Findings

Overall, the participants in this focus group appeared to place a high importance on skin health and the prevention of damage, and reflected on aspects of care that could be improved. They discussed aspects of their practice and normal working environment that facilitate this, as well as factors which act as barriers. Although it seems that staff were aware and actively involved in skin health in their unit, their comments indicate that this is not always done in a systematic or consistent way. It was evident that nursing staff feel responsible for minimising the risk of damage. Key codes and quotes are presented in Table 4.14, and reported in more detail below. In addition to findings related to the determinants of change, two categories that did not relate directly to individual determinants emerged from the analysis, “education” and “skin damage causing distress”.

Table 4.14 Key codes and quotes from the focus group

Determinant	Category	Key codes	Examples
Individual health professional factors	Knowledge and skills	Device care	P1 "It's very miniscule but I've changed the way that I… cut the tape that you put on the high flow."
		Confident in knowledge	P1 "I'd probably feel more comfortable talking about skin integrity than maybe anything else actually… it's something that you're constantly mindful of so I would feel comfortable"
		Competing demands	P2: "It's just getting that balance… it's quite difficult trying to marry up he needs his bum done but he's just had the cannula put in"
		Selection of topical products	P2 "not to my knowledge there's not a guideline [for selecting nappy rash creams]… sometimes we've been using honey which I quite like"
	Awareness of risk	Frequency of damage	P2 "every day you'd see some sort of skin damage to be quite honest" P1 "[I see damage] most shifts really"
		Complications of damage	P1: "if you're not mindful of your skin and checking your lines and things and then you obviously lose your line then you've lost your fluids … it can lead to loads of other things" P2: "if the nose break downs that's it a lot of them do get reintubated back onto the ventilator to let the nose heal"
	Professional routines	Documentation	P1 "making sure people know you need to be documenting what you've actually done and how it looked… in my personal experience it's not been done consistently but then it's not necessarily easy to find"
		Reporting incidents	P2: "Incident forms tend to get more for like if there's extravasations or for the hole in the CPAP one, that's when we tend more to fill in but for… you know little sore bits or little red bits we tend to mostly in the nursing notes" P1: "I think I usually do [report skin damage] I didn't always used to do this but actually because of something that happened… with a baby with an arterial line"
Professional interactions	Team processes	Peer teaching	P1: "someone showed me the other day about… a new way to cut the foams for the ET tubes" P1: "if someone's struggling you just well everyone asks questions all the time don't they constantly"

		Parental involvement	P1 “teach them how to clean in between [neck rolls] because that gets so sore… it’s giving them little things they can do so they don’t feel like they can’t do anything at all
		Doctors’ involvement	P1 “if you’re working with someone from the medical team and they’re… just like taking dressings off without using apeel… I just go and get the apeel like you forgot this”
		Courage to challenge	P1: “Just challenging and also to have taking the negative connotation away from challenging it doesn’t have to be a negative thing because ultimately you need to do the best for the baby” P1 “When I was newly qualified I don’t think I would have felt very comfortable if you’re taking a handover from a more senior nurse and they’ve done it a certain way”
Other	Education	“Always room for improvement”	P2 “we’re quite good in promoting the education but I think we could just do… that little bit extra sometimes” P2 “more education… for everybody across the board”
		Existing processes	P1 “one minute wonder boards by the gas machines… you have to wait anyway while you’re there so it’s quite good” P2 “they’ll get a little trolley and they’ll just take people out, have you got five minutes?”
	Skin damage causing distress	“We take it to heart”	P1 “I know I don’t just speak for myself but we take it to heart when something does happen like something really bad” P2 “[on finding a wound that other staff had missed] it wasn’t that bad but it was getting that way… it was a little bit oozy but I felt really bad, I went home felt really bad about that”

4.4.3.1 Individual health professional factors

4.4.3.1.1 Knowledge and skills

As with the survey, participants made references to specific medical devices and the associated risk of damage. These comments focussed on ways to protect the skin from devices, ranging from placing foam under cannula hubs to a different way of cutting tape to secure oxygen cannulae. One participant referred to the importance of finding the right size device for any individual neonates, particularly with reference to CPAP prongs, masks, and hats.

Difficulties associated with securing medical devices were reported, with one participant referring to a new tape that had been unsuccessfully trialled for securing nasogastric (NG) tubes. She explained that a tape needs to be '*sticky but not too sticky',* and that in this instance, it was softer but did not secure the tubes tightly enough.

The inconsistent practice and guidance surrounding the use of topical products was followed up in more depth in the focus group. One participant reported that she was not aware of a guideline for the selection of diaper dermatitis creams. Selection of creams for treating dermatitis seemed to be up to nurses' or parents' preference, though one participant referred to consulting the surgical nurse in severe cases. The process of choosing whether to use topical products, and then the correct product for each neonate when they are used, seemed to be on a trial and error basis.

One skill that participants referred to throughout the focus group was the importance of balancing different clinical needs. The participants identified that, although they considered skin health important, other demands also had to be taken into consideration. One example given was that of maintaining a good seal on CPAP to ensure effectiveness but not pulling it so tight that it damages the skin. Another example was providing care for oedematous neonates with chest drains, who need to be nursed supine but also need to be tilted to manage their skin.

4.4.3.1.2 Awareness of risk

All participants stated that they see skin damage in neonates on most shifts. They perceived their patients to be at high risk of skin damage due to number of interventions and skin fragility. One participant stated that it is difficult to know which neonates are most at risk, with no clear relationship between neonates' health status and the incidence of skin damage. For example, she identified that plasters and tape will have no impact on skin for some neonates while for others they cause problems.

When asked how they would define skin damage, participants gave a definition that included marked intact skin as well as broken skin. They referred to both short- and longer-term consequences of skin damage, including pain and being unable to administer fluids due to extravasation.

4.4.3.1.3 Professional routines

Participants also discussed reporting and escalation. This expands on non-specific comments about "benchmarking" made in the survey. They referred to filling out incident forms for some skin damage, particularly extravasations or open wounds caused by medical devices. One participant stated that she had come to realise that incident forms are not negative, though they can have a negative association, but instead are about sharing learning. Additionally, in one situation, there was a problem with a particular brand of device, and with the support of the unit technicians these were collected and sent back to the manufacturer. However, skin damage at a lower severity did not seem to trigger a reporting process. One participant said that '*for little sore bits or little red bits'* these would tend to be documented in the nursing notes, but would not be escalated further. Neither participant had ever called the trust TVNs, but one had worked with the unit's surgical nurses on cases of extravasation and severe diaper dermatitis. She said that the surgical nurse would only be called for bad skin damage, which she defined as '*if it's really red looks really really angry'.* Neither were aware of any formalised process regarding escalation, though one stated that she would report it if it had been missed by another member of staff.

4.4.3.2 Team processes

Survey results referred to a culture of *'team effort'* in preventing skin damage, which was also reflected in the focus group. In particular, they referred to learning from other staff as well as sharing information themselves. Although this did not appear to be carried out systematically, the comments nonetheless suggest that there is a culture of asking questions and sharing good practice. One participant stated that '*everyone asks questions all the time*'. This seems to facilitate the type of peer-to-peer learning highlighted in the survey. Another example included help with a ventilated neonate, in that one participant had been shown a new way to cut ET tube foams. In addition to collaboration between nursing staff, parents and doctors emerged as having a role to play. Parental involvement in skin care was brought up by all participants, who reported teaching parents about skin care. For example, one participant said she had taught parents how to clean neonates' necks '*because that gets so sore'.* Participants mentioned that in some cases, parents'

wishes conflicted with the neonate's clinical needs: wishing to bathe them while their skin was still fragile, for example.

Participants felt that doctors mostly left skin care up to the nursing staff unless it was severe, although they would ask doctors to speak to parents about skin for further reassurance. Participants reported reminding doctors to bear skin health in mind while carrying out procedures, for example using Apeel when removing dressings and minimising the use of tape on cannulas.

Another aspect of unit culture to which participants referred was the importance of questioning other staff members about their practice. They referred to the necessity of courage and confidence in order to challenge other members of staff, and reported encouraging junior staff to '*ask questions… to challenge me even though I'm teaching them',* and '*have the confidence to speak up*'. Participants spoke about the importance of asking questions if unsure, as there are potentially serious consequences for a neonate if a device is wrongly applied. However, one participant acknowledged that when she was newly qualified she would have felt uncomfortable challenging a more senior nurse.

4.4.3.3 Education

Despite the informal peer-to-peer learning identified in the survey and repeated by participants in the focus group, they expressed a desire for more education on skin care to be made available for staff at all levels of seniority. This seemed to be connected to learning from incidents in order to ensure that mistakes were not repeated. At present, most skin care education on the unit is given through developmental care training, which also comprises information about sleeping positions, swaddling, etc. Participants reported that this contained relatively little skin care information.

Participants made reference to educational processes that are already in place on the unit and suggested that these could be leveraged to share skin care practices more consistently. One participant described people '*go[ing] round with the trolley'.* This involves staff being taken out of the clinical rooms for a short period of time in order to talk with a facilitator about a topic. One other participant referred to a board displaying information.

4.4.3.4 Skin damage causing distress

Both participants reflected on instances where they had been involved in the care of a neonate who developed skin damage. They referred to feeling guilt and distress as a result, both individually and collectively, using phrases such as '*we take it to heart'*. With respect to a neonate

who developed an open wound secondary to CPAP, one participant stated *'as a unit it was quite disheartening because we'd played a part in that'.*

This was not limited to serious incidents. One participant described an occasion when she removed a probe without using Apeel inadvertently causing pain, while the other stated that she had recently looked after a neonate who lost two arterial lines in one night and worried that she had not checked the dressings properly. These feelings prompted the participants to examine their practice and see what they could have done differently.

4.5 Tissue Viability Nurse interviews

A justification for the use of a focus group and critique of the methodology is presented in Chapter 3 (see 3.5.3.1 and Table 3.1).

4.5.1 Topic guide

A topic guide was developed for the interviews in order to ensure that they addressed relevant areas of the determinants of change (Appendix M). Examples of interview questions related to the determinants of change can be seen in Table 4.15. This was also developed in light of the literature review and the findings of the survey. In the second interview, topics brought up at the first interview were raised in addition to the original topic guide. For example, the first interviewee mentioned the difficulties associated with assessing a neonatal wound comparative to one on an adult. Though this was not in the original topic guide, the second interviewee was asked about this as well.

Table 4.15 Examples of interview questions related to the determinants of change

Determinant	**Factors**	**Questions**
Individual health professional factors	Knowledge and skills	How would you find information about neonatal skin care?
Professional interactions	Team processes	Can you tell me about anything that makes it easier to work with the neonatal team on issues of tissue viability?

4.5.2 Recruitment and sample

Lead TVNs from each of the trusts that participated in the prevalence and incidence study were approached via email to ask whether they would be willing to be interviewed for the study. The voluntary nature of participation was emphasised both in the emails and in the PIS, which was

attached to the emails (Appendix K). Both TVNs had previously expressed interest in the findings of the incidence study and were keen to participate.

Of the two participants, one had approximately ten years' experience working as a neonatal nurse and further experience working with children in general practice (this participant is represented below as P1), while the other had had no paediatric experience since her nurse training and no experience with neonates (P2).

4.5.3 **Findings**

Participants in both interviews recognised the unique nature of neonatal care and the expertise of neonatal nurses in caring for this population. One of the participants had developed a good working relationship with the neonatal unit, while the other felt that the specialist nature of the unit acted as a barrier to her involvement. Both participants referred to issues around assessment, reporting, and escalation of skin damage, as well as a degree of normalisation that occurs because of the high risk nature of the environment. Both participants were additionally aware of the difficulties posed by the use of medical devices and the fragility of premature skin. Key quotes and codes are presented in Table 4.16, and reported in more detail below. These are grouped primarily according to the determinants of change, although other factors such as reporting also emerged from the analysis. For example, although "reporting and escalation" was related to "professional routines" in the focus group, here it emerged as an important category in its own right, made up of multiple codes.

Table 4.16 Key codes and quotes from the interviews

Determinant	Category	Key codes	Example
Individual health professional factors	Awareness of risk factors	"They haven't really got any skin"	P2 "especially the really early ones [are at risk] because sometimes you know you sometimes feel like they haven't really got any skin it's so fragile" P2 "in fact it's worse in many case because with neonates because their skin isn't developed as much it breaks down much quicker and to a much larger depth"
		All devices are a risk	P2 "I think all devices will place neonates at risk… any tubing that's going to touch the skin is going to put them at risk because their skin isn't completely protected"
		Competing priorities	P2 "…the devices are there for a reason and they have to be used, so I… truly understand that sometimes skin integrity has to take… second place" P1 "In that situation you're thinking you know they might end up with a bit of keloid scarring but actually if I if I keep going in there they're not actually going to be alive for that to be a problem"
	Experiences accessing the unit	Alien environment	P2 "I mean the ones I've seen have usually been in an incubator they've got lots of things going on… because it's an alien environment I'm always much more timid" P1 "if you're outside of the neonatal unit it's quite a scary place … they're so small aren't they and they're so covered with monitors and things… I think that most people leave the neonatal unit alone"
		Interacting with parents	P2 "I don't ever speak to parents without the neonatal um staff with me. I wouldn't go on and speak to any parents, because um questions that come back you need someone with neonatal experience"
	Knowledge and skills	Classification difficulties	P2 "how can you say it's just superficial skin loss if they haven't got a full thickness of skin?"
		Knowledge of neonatal staff	P1 "I would say that the neonatal unit don't really associate any wounds with pressure so we very rarely get called to pressure ulcers… in fact you'd think that they didn't have any"

Organisational culture	Perceptions of unit culture	Normalisation	P1 “it’s seen very much as a normal process of what happens to that baby – you’ve got a medical device you get a wound” P2 “I’ve heard neonatal nurses in the past say well they’re going to get skin damage so I think that’s a culture… if it happens it’s going to happen and there’s not a lot really you can do to prevent it”
		“Used to dealing with it themselves”	P1 “Neonatal nurses are just so used to managing it… I think it’s just part and parcel of what’s happening to them and they’re used to dealing with it themselves” P2 “I think they feel that they are the experts in the neonatal, so that they feel that they can manage… usually specialists… are specifically adult… they’re not paediatric or neonatal trained”
Professional interactions	Collaboration	Doctors’ involvement	P1 “nurses just don’t seem to think that they can just go and do a Datix. It’s like you’ve got to go and get the doctor’s opinion and permission to do it”
		Working with a specialist unit	P2 “sometimes with all areas that are very specialist, it’s very difficult to get outside people or to allow outside people to come in with an opinion, and often that’s seen as somebody interfering” P1 “because of I don’t want to say politics but kind of like the beliefs within the unit of the lack of need to have any outside input into their babies’ wounds, we haven’t been utilised as much”
Other	Reporting	Reporting associated with blame	P1 “you kind of get that feeling sometimes with the neonatal unit probably because they’re not used to Datixing things about skin is that maybe there it’s a blame thing whereas it’s not it’s about like learning”
		Wounds not always reported	P1 “They’re so used to babies having skin damage that it’s just part and parcel of what they do so the whole reporting of it or bringing in the tissue viability nurse, they’re like well we just get on with it” P2 “they don’t also… like to get involved in the pressure ulcer reporting and things, so at the moment we haven’t got um the neonatal unit don’t report that they have any babies with pressure damage”
		Importance of reporting	P1 “we’re never going to get anything changed with the medical devices are we if we don’t report them”

	Education and evidence	Lack of literature	P1 “I’m certainly not expecting a result to come up on Cochrane”
		Education – TVNs	P1 “I’ll have gone to the odd bit… at EWMA and WoundUK and if there’s been a paediatric one then I’ll have you know got on it… so it’s kind of snippets really of grabbing what you can”
		Education – neonatal nurses	P1 “a whole neonatal paediatric study day… you’d be talking about your risk assessment because we don’t have one here… thinking about the different types of wounds or skin breakdown that you get in both neonatal and paeds”
		Lack of peer support	P2 “we have a network of tissue viability nurses… huge national network that we can go to ask questions which I know neonatal do too, but as far as I’m aware there aren’t any neonatal tissue viability nurses”

4.5.3.1 Individual health professional factors

In terms of TVNs' knowledge and confidence, unfamiliarity with the unit was seen to be a factor. The neonatal unit was seen as *'a scary place'* and '*an alien environment'*, due to the high number of interventions, the incubators, and the small size of the patients. One of the participants, who had previous neonatal experience (P1), felt that this could lead to hesitance among external teams to become involved. Despite her experience, she commented that she would no longer even feel safe turning a premature neonate, though she felt confident overall in that environment. This issue appeared to be exacerbated for the other participant (P2), who did not have any neonatal experience. However, she reported that in circumstances where she did attend the neonatal unit, the nursing staff were happy to facilitate while she looked at the wound. Confidence when interacting with parents was also linked by both participants to experience.

In addition to confidence and experience, specific issues related to skills were raised by participants, including the assessment and classification of neonatal wounds. They reported that this is especially difficult with premature neonates due to the immaturity and fragility of their skin, as well as the specific complications associated with classifying device-related skin damage. Distinguishing between category I and II PUs was felt to be particularly challenging, due to the fact that some premature neonates do not have a full thickness of skin.

Both participants demonstrated awareness and knowledge of risk factors related to premature neonates. They perceived neonates to be at a very high risk of skin damage due to the prematurity of their skin and the number of interventions and medical devices required to keep them alive. One participant reported that she had become aware of the risk after the first time she was called to see a category IV in a neonate associated with a device, which had been upsetting and had stuck with her. Both participants additionally commented that with some critically ill neonates, competing priorities mean that skin care may not be the top priority because medical devices or minimal handling are necessary for survival. However, one participant commented that there could be steps taken to protect the skin, including devices used in older children to protect the ears from pressure during oxygen therapy.

4.5.3.2 Organisational culture

Both participants perceived skin damage to have been somewhat normalised on the neonatal unit, due to the high rate at which it occurs and the association with medical devices. They felt that nurses saw it as an inevitable factor in medical treatment, and linked this to a lack of

reporting and escalation (presented in more detail in 4.6.2.4). One participant believed normalisation contributed to a feeling that there was nothing that could be done to prevent skin damage.

As a result, both participants found that the neonatal unit did not always feel the need to involve outside help. One unit had specialist nurses that dealt with skin damage themselves, meaning that the TVNs were not involved in care. The specialist nature of neonatal care was also raised, with one participant commenting that the neonatal nurses felt that they could manage the skin and did not require outside input. A reported advantage of the specialist nature of the unit was that, when outside help was called in, the staff '*know so much about the babies*', making things much easier.

4.5.3.3 Professional interactions

Despite the fact that the unit culture acted as a barrier to TVN involvement, both participants had experience of building a good working relationship with a specialist unit. P1 had been developing her involvement with the neonatal unit since she entered her post two years previously, while P2 had developed a similar relationship with the paediatric intensive care unit (PICU), which had previously not been utilising TVNs. In both instances, developing the collaboration had taken several years but had resulted in positive change. They found that they were called to more instances of skin damage and that their input was more valued than it had previously been. In the former case, the improved relationship was as a result of P1's existing contacts on the neonatal unit and her previous experience; in the latter, the catalyst was a serious wound to which the TVNs were called. Both participants referred to working with senior nurses on the unit, and raising the profile of the TVN team as a result.

Despite initial progress, both participants desired further involvement in neonatal care. This was partly a result of the prevalence and incidence study (see Chapter 5), of which both participants were aware and commented upon. They wanted to be called to more wounds, in order to help with classification and offer support with dressings. One participant referred to the importance of having '*another pair of eyes… from a different perspective'* when assessing and managing wounds.

One unexpected finding of the study was related to the involvement of doctors. P1 reported that nurses perceived the decision to report skin damage as being down to the doctors rather than nursing staff. This participant additionally reported that doctors and a nurse practitioner had been cautious when she asked them to prescribe honey dressings, and she had gone through a series of steps in order to reassure them that the dressing was safe for use. The process she described

involved getting in an industry representative to talk about the dressing, as well as using it on a particular wound, which showed a good effect.

4.5.3.4 Reporting

As a consequence of a perceived lack of awareness of PUs among neonatal nurses, as well as the tendency for neonatal nurses to '*just get on with it',* both felt that not all wounds were reported. Although both sites have trust-wide procedures for systematically reporting and investigating damage, the neonatal units reported little to no damage. One participant specifically stated that, at her trust, the policy was to report all PUs and investigate those at category II or above. However, the neonatal unit had returned weekly audits reporting no pressure damage for the past two year. This is contrary to the survey results indicating a high frequency of damage.

One participant felt that the lack of reporting was a feature of the normalisation of skin damage on the neonatal unit. She additionally felt that filling out an incident report ("Datix") in relation to skin damage was associated with blame or guilt. This was echoed by the other participant, who reported that '*they feel that if they call it pressure damage it means that they've caused it*'. This attitude was reported to be in contrast to adult ITU and paediatric intensive care unit (PICU) environments, who regularly reported skin damage. Both participants stressed the importance of reporting for making future improvements or learning from incidents.

4.5.3.5 Education and evidence

Both participants found it hard to keep themselves up-to-date on paediatric and neonatal skin due to the sparse amount of training and education available. Although they made individual attempts to maintain their skills, e.g. by attending meetings or talks on neonatal skin, neither had had any formal training on the subject. One participant referred to this as '*snippets really of grabbing what you can'*. P2 suggested that there should be training for any adult nurses going into neonatal environments, due to the differences in neonatal skin.

The lack of peer support in relation to neonatal skin was also a concern for the participants. TVNs and neonatal nurses both have professional networks from which they obtain support, but they identified a lack of available help specifically related to neonatal skin. The consequences of this, such as the difficulty in obtaining a second opinion on a particular wound and more generally guidelines on classification and causes of neonatal wounds, were described. One participant additionally referred to the lack of available literature.

Both participants felt that education on skin for neonatal nurses would be beneficial. Suggestions for topics included information on neonatal skin assessment, and management of different types of skin damage. PUs and diaper dermatitis were specifically mentioned. P1 additionally suggested that there could be joint study days run with neonatal and paediatric nurses in order to offer both specialties a degree of peer support that is currently lacking.

4.6 Reflexivity and trustworthiness

The importance and role of reflexivity in this research project has been identified in section 3.7.2.3, along with some of my underlying preconceptions about the research topics. As a check to these underlying preconceptions, I discussed my coding and theme development with my supervisors throughout. A pertinent example of the importance of this arose during the coding of the interview transcripts. The second participant used the phrase “they like to keep things in house” and variations thereof in her interview. To me, this phrase sounded as though it was intended to describe the specialist nature of neonatal nursing and a tendency to rely on their own experts. This was a subject that was raised by the other TVN and even, to some extent, in the focus group. I had therefore intended to use it as a key quote when describing this idea. However, upon discussion with one of my supervisors, she felt that it had negative connotations that I had overlooked, specifically a feeling of being intentionally excluded. This did not reflect the overall tone of either this participant’s comments or those of the other interviewee, and I therefore chose a different key quote to use when describing this idea. In hindsight, my own underlying experiences and biases had coloured my understanding of this quote and led me to assign a particular interpretation to it. Speaking to a different member of the research team exposed this bias and allowed a more truthful interpretation of the data.

The field notes I kept during the data collection process were also used to engage with ongoing self-appraisal. For example, in the first interview I conducted, the participant raised the topic of the prevalence and incidence study and some preliminary findings she had seen. I was faced with the unanticipated challenge of managing this subject without leading the participant to simply echo my own views. I made a note of this afterwards, in order to enable me to prepare more fully for this situation if it arose again. The second participant also raised the subject, although she was not aware that I had conducted the prevalence and incidence study, and I was better able to ask for her views on this topic without leading her.

4.7 Discussion

This phase of the study was designed to establish the barriers and facilitators to skin care in the neonatal population. In addition, questions were raised regarding the factors which increase the relative risk of skin damage, for example the use of medical devices. The survey was successfully distributed across 16 centres in the South of England, although a poor response rate was observed over a 12 month period. There was a range of responders, who had varying clinical roles and experiences. A focus group with neonatal staff nurses and two interviews with lead TVNs were also carried out. Despite this variance in sample population, key commonalities were identified across the survey, focus group, and interviews, namely:

- Medical devices pose a significant risk of skin damage in neonates
- Education for staff is limited, often relying on peer feedback
- Limited use of guidelines or protocols to manage skin health
- Competing clinical demands may make it difficult to prioritise skin health
- Highly specialist nature of the unit can act as a barrier to the involvement of TVNs

The determinants of change identified across all three studies will now be discussed, along with other issues identified that do not directly map to the determinants laid out in the ICM.

4.7.1 Individual health professional factors

4.7.1.1 Knowledge, skills, and attitudes

There is some evidence in the findings from the survey that participants confused the concept of risk assessment (associated with prevention) and skin health/wound assessment (associated with treatment). This may indicate that some participants are not intervening to prevent skin damage, instead reacting when it occurs. Similarly, the TVNs did not feel they were generally contacted unless skin damage had already occurred. This confusion regarding risk assessment is in contrast to findings of studies involving adult nurses using the PUKAT (Beeckman, Schoonhoven and Defloor, 2008), where risk assessment is generally one of the higher-scoring areas (Demarré *et al.*, 2012; Gunningberg, Mårtensson, *et al.*, 2013). The ideas of risk assessment and skin assessment are also conflated in the neonatal PU trigger tool suggested by Schumacher and colleagues (Schumacher, Askew and Otten, 2013), which is used for identifying both risk and presence of skin damage.

The present study did not attempt to assess nurses' knowledge on skin health. However, some participants expressed a lack of confidence in their own knowledge or skills. Similarly, in their survey of neonatal nurses in a NICU in Malaysia, Mohamed and colleagues (2014) found that, regardless of experience or specialist qualification, 80.5% of participants felt that they did not have good knowledge of neonatal skin. The authors suggested that this may be due to difficulties translating theoretical or academic knowledge into clinical practice. One notable finding from the survey, which may reflect this difficulty, is the discrepancy between participants' responses to Q6 and Q7, which enquired about perceived risk and perceived frequency of skin damage respectively. Some discrepancies may be explained by participants' individual job roles. For example, one practice educator reported that their patients were at extremely high risk of skin damage, but reported seeing it "every 2-5 months". This may reflect the participant's decreased level of patient contact leading them to have less contact with skin damage overall. However, instances where participants responded that they believed their patients to be at slight risk, yet reported that they saw it every day in practice, are harder to explain. The numerous discrepancies between participants' responses to these two questions suggest that what they understand to be theoretically true about skin damage does not correspond with what they see in practice.

An alternative explanation for this lack of knowledge and subsequent lack of confidence may relate to the sparse evidence base on this subject, as identified by some of the participants in the survey. Conversely, one participant in the focus group stated that she felt more confident when discussing skin health than any other aspect of practice. To date, there have been no other studies exploring neonatal nurses' perceptions of their own skin health knowledge.

Regarding attitudes, participants in both the survey and focus group stated positively that they consider the prevention of skin damage to be an important part of their role. It was also apparent throughout that skin care is unlikely to be the first priority for an unstable patient. Participants in the focus group identified a number of situations in which there are competing clinical demands that they believed made skin damage difficult to avoid, such as heelprick blood tests. Indeed, despite their inherent focus on skin health, even the TVNs identified that in this environment it may not always be possible to prioritise this over other clinical concerns. This has also been revealed in studies of adult ITU nurses (Strand and Lindgren, 2010). Even when nurses have positive attitudes towards PU prevention, lack of time or staff may impede translation of these attitudes into consistent behaviour (Moore and Price, 2004). Despite these potential barriers, attitudes towards PU prevention among nurses have been shown to be significantly correlated with compliance to guidelines (Beeckman *et al.*, 2011; Demarré *et al.*, 2012). In this study, RNs made unprompted statements about the importance of protecting skin health such as *"it is part*

of the neonatal nurse's role". Additionally, some participants mentioned carrying out independent reading on the subject or being involved in the development of skin care/developmental care protocols. These findings are in line with those of Strand and Lindgren (Strand and Lindgren, 2010), who found that nurses who had specialist critical care education had significantly more positive attitudes towards PU prevention than those who did not.

4.7.1.2 Professional routines and characteristics

The importance of regular skin assessment as a professional routine was stressed by several participants. Although many referred to this as a routine part of practice in the survey comments, it appears that these routines vary. For example, 21 different assessment practices were reported dependent on personal preference, condition of neonate, and other criteria. No cohesive system for assessing all skin damage in neonates was identified and two participants commented that a standardised system would be helpful. It was clear from language used by participants in the focus group, such as describing a particular MDPRU as a *'hole*', that participants continue to struggle with skin assessment.

To this end, the Neonatal Skin Condition Score (NSCS) has been trialled in the US, but has not been adopted in the UK (Lund, 2004). Even among adult nurses where classification guidelines exist (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014), "classification and observation" has previously been reported as a gap in nurses' knowledge of PU prevention (Kelly and Isted, 2011; Demarré *et al.*, 2012; Gunningberg, Mårtensson, *et al.*, 2013). In a neonatal environment, classification is complicated further by factors such as minimal subcutaneous fat deposits (Ness, Davis and Carey, 2013). The TVNs made reference to the immaturity of premature skin and the associated difficulties in determining whether a wound is superficial. International standards for classifying incontinence-associated dermatitis in adults have recently been proposed (Beeckman *et al.*, 2015). However, these guidelines are designed for adult patients and may not be appropriate for classifying diaper dermatitis in neonates.

Another routine reported by several participants was repositioning. Repositioning patients to redistribute pressure is an established aspect of PU prevention in adults, although data on the optimal regimen are still lacking (Gillespie *et al.*, 2014). Regular repositioning as tolerated is also recommended as a preventative practice by the ODN skin integrity guideline (Thames Valley Neonatal Quality Care Group, 2012) and some participants in this study identified it as an important part of skin care. However, as with device care, nurses working with the critically ill patient are faced with a complex problem. Increased frequency of repositioning in adult ITU

patients was associated with an increased number of unplanned extubations (Manzano *et al.*, 2014). In adult units, specialist turning beds may be used for pressure relief (Cullen Gill, 2015). However, equivalent technologies are not widely available for use in neonates. Equally, neonates admitted with respiratory distress syndrome (RDS), a common diagnosis for this population, have significantly better oxygenation when nursed prone (Eghbalian, 2014). Neonates who are too fragile to be turned for frequent assessment, as identified by participants in this study, are unlikely to tolerate regular repositioning. Indeed, one participant identified that the act of turning a neonate may itself cause damage to very fragile skin.

In addition to repositioning patients, regular repositioning of pulse oximeters was identified by participants in our study and that of Mohamed and colleagues as minimising the risk of associated skin damage(Mohamed, Newton and Lau, 2014). Alternating between mask and nasal prongs for CPAP was also reported by some participants as a factor in preventing skin damage, although participants in the focus group reported that some neonates would not tolerate this rotation. The effectiveness of these professional routines has not been widely explored, whether in the adult or neonatal population. One study has shown reduced nasal damage in neonates using a rotating mask/prongs system compared to continuous use of either interface (Newnham *et al.*, 2013). Issues associated with medical devices are discussed in more detail in 4.7.5.1**Error! Reference source not found.**.

4.7.2 Professional interactions

4.7.2.1 Team processes

The qualitative findings from this study suggest that teamwork is an important facilitator of good practice in relation to skin health. This topic has not been extensively explored in previous research. However, a survey of Swedish RNs and nursing assistants found that 33% of respondents identified good teamwork as a facilitator of pressure ulcer prevention (Källman and Suserud, 2009). In the present study, participants highlighted the role of peer-to-peer education. This is reflected and expanded upon in the qualitative findings of the survey and in the focus group, where participants reported seeking advice from more experienced colleagues if they had questions. Although participants across the survey, focus group, and interviews reported that more systematic skin education would be beneficial for neonatal nurses, it seems that peer-to-peer education acts as a positive facilitator of change in this environment.

There is limited research looking at the role of teamwork and peer education in relation to PU prevention. One study by Kelleher and colleagues (2012) in a surgical ICU introduced nurse-led rounding as a strategy to decrease PU prevalence. This intervention included opportunities for nurses to discuss patients' risk of damage with their peers, and develop care plans as part of a team (Kelleher, Moorer and Makic, 2012). The introduction of these rounds was associated with a decrease in PU prevalence during quarterly audits, as well as a significant increase in the number of preventative interventions carried out by staff. These figures are based on small samples of roughly 15 patients per audit. However, the increase in preventative activities suggests that the rounds did raise awareness among nursing staff. The success of this programme, along with the emphasis placed by participants on peer education in the present study, suggests that development of future interventions for this population may be more successful if they harness the education processes already in place. For example, the teaching board referenced by participants in the focus group could be used to share the kind of minor changes to practice they reported sharing informally with their colleagues. Peer education was also used to good effect in a quality improvement project in two Australian residential care homes (Price *et al.*, 2017).

In addition to teamwork between nurses, some participants referred to the role of parents as caregivers within the team. This was also reflected in the interviews with the TVNs, in which participants discussed the importance of updating parents and asking for their perspectives. It has been hypothesised that better partnership between parents and nursing staff in the neonatal unit, leading to earlier involvement of parents in caregiving, may ultimately lead to better neurodevelopmental outcomes for neonates due to improved attachment (D'Agata and McGrath, 2016). Skin care has not been specifically explored in relation to this. However, it is clear that parents are involved in providing skin care on the unit, and therefore need to be considered in any intervention designed to improve skin care practice.

4.7.2.2 Culture and organisational structure

In terms of organisational culture, some survey participants commented that they felt their unit had a strong team focus on the prevention of skin breakdown, whereas others felt that their colleagues were not aware of the issue. Although all units within the ODN operate according to the same protocols and guidelines, one area where there seems to be discrepancy between units is that of education. Some participants commented positively that they find education available on the unit to be a useful tool in skin care, whereas others expressed reservations regarding the availability and quality of education. In addition to the lack of formal skin care training identified, several participants cited lack education as a barrier to promoting skin health in their patients,

and some participants including clinical educators were unaware of the ODN skin integrity policy (Thames Valley Neonatal Quality Care Group, 2012). Equally, TVNs reported that their own education on paediatric and neonatal skin was largely self-directed by attending talks at conferences or meetings . This contrasts with findings among adult nurses in both general and intensive care environments, where staff do not perceive education as a barrier even when it is sparse or unavailable (Moore and Price, 2004; Strand and Lindgren, 2010).

One of the most interesting findings from Mohamed and colleagues' study was that nurses with <5 years' experience acquired knowledge differently from those with >5 years' experience (Mohamed, Newton and Lau, 2014). Less experienced staff relied solely on advice from senior nurses and head nurses, whereas more experienced staff did their own research online and in books. In a study of student nurses' and nurses' attitudes towards PU prevention, Samuriwo (2010) found that education did not become meaningful to staff until they had witnessed a "worst ever" PU. Following this experience, participants in his study reported that they proactively sought out information about PUs. The topic of knowledge acquisition was explored in the focus group, which highlighted the peer-to-peer education discussed above. Additionally, survey participants mentioned participating in the development of guidelines or protocols. This suggests that, on these units, a role for clinical nursing staff in identifying and driving opportunities for change has been established. This contrasts with suggestions that nursing reluctance to change and a tendency to cling to outdated practices is a barrier to implementing evidence-based practice, even in ITU environments (Soh *et al.*, 2013).

Some participants in the survey and both of the TVNs identified the lack of evidence on which to base practice. Given that post-registration education on this topic has been reported as more valuable than pre-registration (Samuriwo, 2010a), and that a general lack of formal education on skin health has been identified among paediatric nurses (Drake *et al.*, 2012), this is an area that warrants attention.

In addition to education, the availability and use of specialists appears to vary between units. This was apparent in the findings from the survey and interviews. Although children's hospitals such as Great Ormond Street have teams of specialist TVNs (Kipps, 2014), it is unclear how those in general hospitals adapt to working in environments with unique requirements such as the neonatal unit. Our interviews with TVNs found that the highly specialist nature of the Level 3 neonatal unit acted as both an inside-out and an outside-in barrier to TVN involvement in the neonatal unit. In addition to acting as a barrier to neonatal staff calling TVNs, the unique nature of the neonatal unit also appeared to act as a barrier to TVNs accessing the unit. Both participants

identified the unit as an alien environment due to the vulnerability of the patients and the high number of interventions. Indeed, both participants said they would feel hesitant to turn or even touch a neonate without a nurse there due to concerns about dislodging a piece of equipment or causing deterioration. TVNs have successfully worked with specialist adult areas such as ITUs to reduce PU incidence (Cullen Gill, 2015). In the US, WOCN were additionally involved in the successful introduction of weekly skin rounds on a NICU (Nist *et al.*, 2016). This suggests that the role of TVNs on the neonatal unit warrants further attention and consideration.

4.7.3 Incentives and resources

There is no information in the findings from any of the studies that relates to the use of incentives or penalties. Processes such as reporting and investigation were considered in the focus group and interviews. Participants in the focus group were not aware of guidelines on the reporting of skin damage, and although incidents were reported on some occasions, this seemed to be based on the judgement of the nurse. The TVNs perceived that PUs were underreported, which is in keeping with the findings of Nist and colleagues (2016), who found that neonatal nurses underreported PUs when not supported by specialists. Learning from incidents was shared, but there is no indication of these data being used to incentivise or penalise units.

4.7.4 Patient factors

The functional and structural immaturity of neonatal skin, especially in extremely preterm neonates, has been discussed at length in 2.4.2. Participants across survey, focus group, and interviews identified gestational age as a factor associated with increased risk of breakdown, reporting various ways in which they would modify their practice when caring for very and extremely premature neonates. No questions were asked with the intention of assessing participants' knowledge of neonatal anatomy and physiology, as this was not one of the research aims, although one of the TVNs interviewed expressed a desire for more training on neonates. In the survey of Malaysian neonatal nurses mentioned above, the researchers included questions on TEWL (Mohamed, Newton and Lau, 2014). They found that although nursing staff knew how to manage TEWL in their patients, they did not know what caused it. No other study to date has explored neonatal nurses' knowledge of postnatal development of premature skin.

4.7.5 Other issues

4.7.5.1 Medical device-related damage

The issue of device-related damage is reflected throughout the findings. In particular, the three devices ranked by survey participants as most likely to cause skin damage (CPAP, peripheral cannulae, and medical tape) were also frequently referred to by participants throughout the free-text comments and in the focus group. It is clear that participants view the availability of appropriate resources, especially medical devices, as an important factor in promoting skin health in their patients. Participants in the focus group specifically raised the issue that sizing of devices for neonates does not always take into account the range of sizes a neonate may need during their stay. For example, one participant reported that there had previously been a cannula splint available in a smaller size that was no longer available, making it more difficult to secure cannulae.

The locations for skin damage reported by participants in the survey corroborate comments by participants in all studies about the issue of device-related damage. It is likely that most of the skin damage occurring on the face, head, and nose, will be medical device-related. The same is likely to be true of damage occurring on the hands, which may be associated with the use of peripheral cannulae and other lines, whereas damage to the feet and heels is likely to be caused by heel prick blood tests. Reports of skin damage in the nappy area is likely to be a form of diaper dermatitis. The sacrum and knees are more likely to represent “traditional” immobility-related PUs.

The importance of devices and device care in relation to skin health in neonates has been established for some time, with nasal CPAP known to be a frequent cause of iatrogenic injury (Kopelman and Holbert, 2003; Buettiker *et al.*, 2004; Hogeling *et al.*, 2012; Collins *et al.*, 2014). Indeed a recent study associated 90% of PUs in neonates with medical device use (Visscher and Taylor, 2014). In particular, CPAP was mentioned frequently throughout data collection, and survey participants ranked as one of the three devices most likely to cause damage. This is in keeping with studies that have highlighted nasal trauma as a result of CPAP use in this population (Yong, Chen and Boo, 2005). The incidence has been shown to be greater in extremely preterm and very preterm neonates (Fischer *et al.*, 2010). Extravasation has also been reported in the literature in this population, with reported prevalence of severe extravasation injury 2.4%. Extremely preterm neonates are significantly more likely to develop skin necrosis following an extravasation injury (Kostogloudis *et al.*, 2015).

Although no study has previously explored the views and practices of neonatal nurses in relation to general device care, a study of neonatal nurses in Malaysia asked specifically about pulse oximetry, CPAP, and IV sites (Mohamed, Newton and Lau, 2014). The results of that study suggest that nursing staff of all levels of experience had adequate knowledge regarding the care of pulse oximeters and IV cannulae, but only 15.4% of junior staff nurses had adequate knowledge regarding the care of neonates on CPAP. The findings of our study confirm that neonatal nursing staff are aware of the risks associated with these and other devices, but struggle to minimise this risk. Attempts to minimise the damage associated with CPAP in this population through use of specialised dressings have not been successful to date (Collins *et al.*, 2014). Indeed, modifications for devices to preserve skin health were mentioned by some survey participants. Other such device modifications have been reported in this population, specifically CPAP modification, again for reasons of preserving skin integrity while maintaining functionality of the device (Carlisle *et al.*, 2010). However, they are faced with a difficult dilemma. Staff working with critically ill patients, regardless of patient age, have to balance the need to maintain device function while preserving skin health. In our findings, this was reflected in comments regarding the difficulty of maintaining a good CPAP seal while protecting the nose and cheeks from pressure damage, or keeping a line in place without overusing tape. The NPUAP committee were unable to reach a consensus regarding whether the proper use of medical devices overrides protecting the skin (Black *et al.*, 2011). This issue is particularly complex in ITU and NICU environments, where the devices causing complications may be life-saving (Coyer, Stotts and Blackman, 2013). If a device does cause a PU, that device is no longer functional and alternative therapy may be required. For example, a neonate who experiences skin breakdown from CPAP may require reintubation (Furdon, 2003). Prolonged ventilator support increases the risk of chronic lung disease in the long term (Shah *et al.*, 2012).

Adhesive tape was also cited by survey participants as one of the three most common causes of skin damage, and one participant in the focus group commented on the difficulty of finding tape that is adhesive enough to keep a device in place without being so adhesive as to cause damage itself. At present there is relatively little published research into securing devices in hospitalised neonates. Removal of adhesive tape, even when not associated with a medical device, has been shown to compromise the barrier function of neonatal skin (Lund *et al.*, 1997). In extremely premature neonates, the dermo-epidermal junction is weakened by its lack of undulations, meaning that removal of adhesive tape or dressings risks removal of the entire epidermis (Fox, 2011). In healthy adults, it has been demonstrated that repeated applications of some adhesive dressing products caused increased TEWL over baseline when compared to other products

(Dykes, 2007). At present, there is no evidence of a similar nature to guide NICUs when making purchasing decisions.

4.7.5.2 Barrier creams and oils

Participants in the survey expressed confusion in relation to which barrier products and creams should be used, or whether this intervention was appropriate at all. When the survey was carried out, the routine use of topical ointments and creams was not recommended in neonatal units due to increased risk of coagulase negative staphylococcal infection (Conner, Soll and Edwards, 2003). However, a more recent Cochrane review on the subject found no evidence that emollient therapy increased the risk of death in neonates, suggesting that emollient therapy for skin health in these patients may be worth exploring (Cleminson and McGuire, 2016).

At present, the evidence regarding routine use of emollients in the NICU, particularly oils, is unclear. Topical applications of coconut oil have recently been shown to reduce TEWL and improve general skin condition over standard care in very and moderately preterm neonates in NICUs in India and Pakistan (Nangia *et al.*, 2015; Salam, Darmstadt and Bhutta, 2015). Olive oil, referred to by several participants in the survey, has been shown to damage barrier function in healthy adults (Danby *et al.*, 2013). Sunflower oil, also mentioned by survey participants, had no effect on barrier function in the same study. Further research into this area is required to determine how best to use emollients in this population, if at all.

With regard to creams for managing diaper dermatitis, it is unclear what guides selection. Although focus group, survey, and interview participants all made reference to guidelines on this subject, the focus group participants' comments suggest that this is largely down to the preference of parents and nursing staff. There does not appear to be clear guidance on which creams or products should be used, or when this is necessary. The creams mentioned in the focus group and survey were Medihoney, Sudocrem, DermaS, Bepanthen, and Metanium. Inconsistencies in the use of barrier products and creams for the management of diaper dermatitis have been noted in other neonatal units (Ratliff and Dixon, 2007; Malik *et al.*, 2017a), and at present there is no clear standard for management of diaper dermatitis in this environment.

4.7.6 Limitations

4.7.6.1 Survey

There are some limitations inherent to the use of a survey, as identified in 3.5.1. This study cannot be considered representative of all neonatal nursing staff. The sample was self-selecting, suggesting a degree of interest in skin care (Coughlan, Cronin and Ryan, 2009). There was also a high degree of seniority and experience among participants, with only three unregistered staff participating and relatively few junior staff nurses (n=9). Since demographic information for staff across the network is not available, it is impossible to make any comprehensive statement about how representative the sample is (Salant and Dillman, 1994). Additionally, some senior staff had previously attended presentations and discussions directly associated with this research. They may therefore have drawn on information presented at those times, rather than their general knowledge and understanding. In addition, the study was conducted exclusively in NHS units in the south of England, limiting generalisability although, as identified in the discussion, some of the findings correspond well to research carried out among neonatal nurses in Malaysia (Mohamed, Newton and Lau, 2014)

As it was not initially anticipated that the survey would be distributed in paper form, the questionnaire was designed for online use. Although there are a number of similarities between optimum layouts for web-based and paper surveys (Blair, Czaja and Blair, 2013), the ranking question (17, see Appendix D) became less easy to use when printed out. There were some errors by participants when filling this question out on paper e.g. ticking devices rather than ranking them, meaning that the data could not be used. In addition, some participants did not answer questions when filling out the paper copy that had been marked as “mandatory”. This led to some missing data. In total, six data sets had missing or unusable variables (10.7%). The data from all questions that these participants completed were included for analysis. In this instance, since inferential statistical tests were not used to analyse the data (De Leeuw, 2001), no attempt was made to estimate or impute the missing data. In future research, it would be beneficial to consider the survey tool in different formats prior to dissemination, as format and layout can have an effect in terms of minimising both nonresponse and missing data (Fan and Yan, 2010).

The survey design process took into consideration several potential sources of inaccuracy and efforts were made to ensure that the language was accessible to all staff, since confusing or poorly-worded questions could lead to measurement error (Fan and Yan, 2010). In hindsight, it would have been beneficial to carry out individual item analysis and to have pilot tested the tool

more extensively before conducting the full study (Rattray and Jones, 2007). Having terms defined on the front page of the survey would have kept them at the forefront of participants' minds. It is also clear from the responses that some participants did not differentiate between risk assessment and skin assessment tools, affecting the validity of the responses to questions about RAS. The neonatal nurses with whom the items were discussed prior to finalisation of the questions did not identify this as a problem and appeared to differentiate successfully between the two concepts. However, these nurses were all either senior staff or worked on a Level 3 unit. Given that staff with different levels of seniority and clinical experience are likely to have different levels of knowledge about skin health (Gunningberg, Mårtensson, *et al.*, 2013), it would have been beneficial to have included junior staff from Level 1 and 2 units in this discussion.

The issues associated with nonresponse could have been addressed sooner and more thoroughly. Given that the response rate improved somewhat following distribution of paper copies to three units, it would potentially have minimised the degree of nonresponse if paper copies had been distributed to all units, or if face-to-face contact had been established with potential participants in order to more clearly convey the goals and potential clinical utility of the study (Hox and De Leeuw, 1994; Barriball, 1999). In this instance, not all units responded to communications regarding the distribution of the questionnaire. The decision to focus on Level 3 units was primarily due to the presence of clinical educators who had expressed interest in the study and were willing to help with promoting it. However, it is possible that asking for further assistance from the staff who work centrally with the network would have proven effective in other units.

4.7.6.2 Focus group

There are some limitations inherent to the use of focus groups, some of which are outlined in Table 3.1 and section 3.5.2. Firstly, recruiting busy healthcare professionals to groups is acknowledged to be challenging (Wensing, Bosch and Grol, 2013b). In this instance, though the research team had permission from the matron to invite staff working clinically to participate on the day, staffing levels would not allow for nurses to leave the unit for an hour. The two nurses who did participate came in in their own time, suggesting an interest in skin health and skin damage, and a willingness to explore and critique current practice, that may not be representative across all staff on that unit (Robinson, 2014).

Given that a sample size of at least four had been anticipated, this initially appeared to be a limitation of the group. However, as the group progressed and especially as analysis was carried out, it became apparent that there were certain strengths to the small sample size. The ability to

observe and analyse participant interactions is a strength of focus group methodology (Kitzinger, 1994b), and one of the key areas of interest in this focus group was the peer-to-peer education identified in the survey. During the focus group, the interactions between the two participants provided a clear example of this. One participant paused in the middle of a comment to demonstrate to the other a new way of cutting foams for ET tubes, for instance. These interactions provided invaluable context to the participants' comments, as well as to data from the interviews and survey, that would have been lacking in a larger group. However, team processes that could exist between participants with a greater diversity of clinical roles were not identified in this small focus group, despite the fact that this was likely to be a factor in the unit as a whole (Wensing, Bosch and Grol, 2013a).

Ideally, it would have been helpful to repeat the focus group with more participants in order to reach saturation, as had been intended (Morse, 1994). This was not possible within the time and resource constraints of a doctoral research project. However, questions about the trustworthiness of the data given the small sample size are partly addressed by the analysis of these data in the context of data from the survey and the interviews. Although some unexpected findings arose primarily from this focus group, the majority of the findings are corroborated and strengthened by findings from the other studies (Carter *et al.*, 2014). The themes that arose only from this focus group require further exploration with a wider variety of participants, especially nurses from other units, unregistered care staff, and other professionals. This is particularly the case for observations related to unit culture and other professionals, which is reflected in the suggestions for future research (section 6.6). Although these findings need to be treated with a greater degree of caution in terms of transferability, they still provide useful insight into the barriers and facilitators of good skin care when considered alongside other findings from the studies.

4.7.6.3 Interviews

Only two TVNs were interviewed for this study, and the interviews cannot be considered representative of all TVNs who work in trusts with Level 3 neonatal units. However, the two TVNs interviewed were the leads for their respective teams, and were therefore the most likely to be called to the neonatal unit, meaning that they had the required experience and expertise to comment on the topics under discussion (Wensing, Bosch and Grol, 2013b). Additionally, the two TVNs had vastly different levels of experience with neonates, and were therefore able to give very different perspectives on the issue of neonatal skin health.

Both the interviews were conducted in working areas, and during P1's interview there was another member of staff working in the room. It is possible that this affected the answers this participant gave, as some participants may be reluctant to share their thoughts in the presence of other people (Krueger and Casey, 2015). However, prior to commencing the interview, the participant confirmed that she was happy for the interview to go ahead despite the presence of her colleague. Indeed, following the interview, the participant asked her colleague if she had anything to add, and the second member of staff raised two additional points. The interview locations had been chosen to fit around the TVNs' busy schedules and ensure that they felt comfortable (Ritchie and Lewis, 2003), and the alternative would have been to cancel the interviews altogether.

Both participants had seen preliminary results of the prevalence and incidence study (Chapter 5) and referred to these in their interviews, though only P1 was aware of the connection between the two studies. There is a risk that this biased the findings of the study, as these participants may have been simply expressing what they had recently heard. Since the lead TVNs were the most likely to be aware of local skin health research, this was unavoidable. The only alternative would have been to interview other members of the TVN team instead, who would not have been appropriate for the study due to limited involvement with the neonatal units.

In both interviews, the interviewer made no comment about the findings of the prevalence and incidence study, allowing the participant to steer this aspect of the discussion by highlighting the aspects of the study that they found most interesting, before moving onto other topics. This decision was made to minimise the extent to which the researcher's own views and experienced shaped the responses given by participants (Berger, 2015). In addition, both participants mentioned historical instances of neonatal skin damage that they had witnessed prior to the beginning of the prevalence and incidence study, suggesting that they were both aware of this as an ongoing problem and were not merely repeating what they had recently heard.

4.8 Summary

The participants in these studies represent a highly motivated and skilled group of staff, primarily registered nurses, in a wide range of clinical positions. Their responses demonstrate interest in this area, an eagerness to change and improve their practice, and a desire to know more about the subject of neonatal skin care. The complex nature of delivering skin care in the neonatal intensive care unit is reflected in the findings. Professional routines, including regular assessment and repositioning, form the basis of standard skin care on the unit. Nurses use their own

knowledge and that of those around them to deliver individualised preventative care. In particular, participants viewed peer education as a valuable source of learning, as well as an aspect of their own role. However, barriers to care include a lack of consistency in evidence and education, limited resources, and clinical pressures such as workload and acuity. The highly specialist nature of the neonatal unit acts as a further barrier, by complicating the relationship between the neonatal unit and the tissue viability team.

The identification of these barriers to and facilitators of change should influence the development and implementation of any future interventions. For example, any intervention involving an education component would benefit from making use of peer-to-peer education in order to disseminate information. The willingness of participants in these studies to learn from their peers, question their own practice and that of others, and be involved in practice change suggests that the informal educational processes already in place would facilitate this. Similarly, although the relationship between the TVNs and the neonatal unit is currently limited due to the organisational and individual factors identified above, a future intervention could address this proactively. For example, TVNs and neonatal nurses could be involved in the development of guidelines for the classification and reporting of skin damage in this environment. In addition to drawing on the expertise of both groups, this would allow for the development of more substantial links between the unit and the TVN team, gradually increasing the unit's awareness of the TVNs as well as increasing TVN confidence in this environment.

However, although there are interventions that could be developed and implemented based on this analysis of nursing practice and beliefs, further research is required. The paucity of published research on the subject of neonatal skin care and skin health, in terms of both basic and clinical science, was identified by participants as an issue in all three studies. Even when literature is available, it is often inconsistent. Participants were aware of this as an issue, and were keen to be involved in implementing changes. Methodologically robust research into all areas of neonatal skin care and skin health is needed in order to inform practice, thus minimising the risks posed by mechanical trauma and pressure on preterm skin. The findings of the prevalence and incidence (Chapter 5) will be integrated with the findings of the survey, focus group, and interviews in order to make more robust recommendations for possible interventions (Chapter 6).

Chapter 5: Prevalence and incidence study

As identified in Chapter 3, a key aspect of the analysis is reporting and analysing the scope of the current problem. Although the findings of the survey provided some early indication of the determinants of change in relation to the subject area, the scale of the problem remained unclear. The literature review**Error! Reference source not found.** details previous studies which have focussed on the prevalence and incidence of skin damage in neonates, with cumulative incidence ranging from 3.22% to 16.0% reported. The findings of the survey additionally indicate that other forms of skin damage are of concern in this environment, especially nappy rash and cannula extravasation. Given that a clear baseline and established metrics with which to evaluate success are both key to the implementation of change, a prevalence and incidence study was designed firstly to identify the scale of the problem and secondly to identify risk factors associated with skin breakdown in this environment. The role of this study within the wider research project is indicated in Figure 5.1.

5.1 Aims

1. Determine the prevalence and incidence of skin damage in hospitalised neonates

2. Identify factors that are associated with increased risk of skin damage in hospitalised neonates

5.2 Detailed objectives

1. Report point prevalence of all forms of skin damage across three neonatal units

2. Report incidence rate of all forms of skin damage across two neonatal units

3. Categorise skin damage according to type and severity

4. Report associations between potential risk factors and development of skin damage in the neonatal intensive care setting

5. Report case studies to demonstrate the types of skin damage that may occur in this population

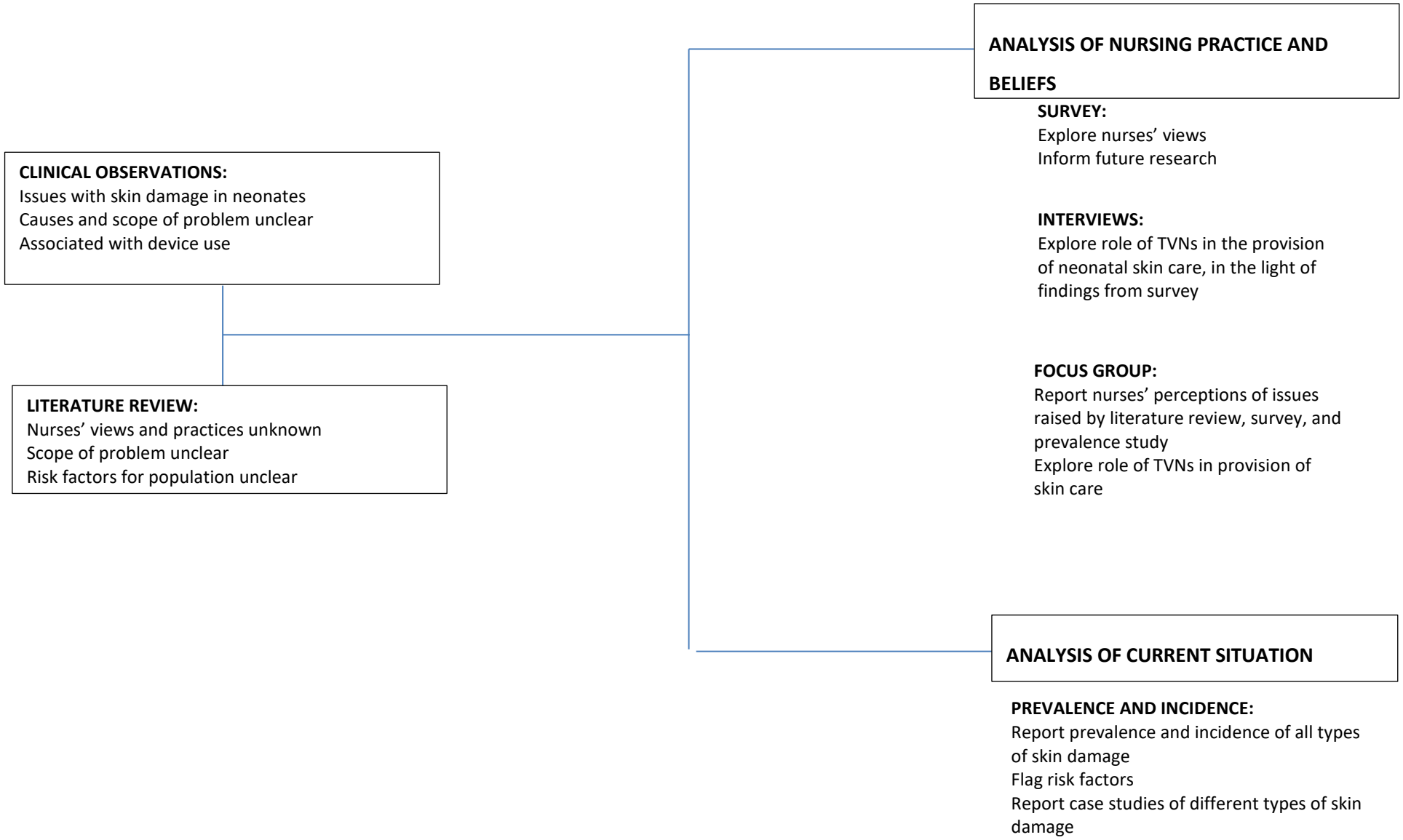


Figure 5.1 Role of prevalence and incidence study within wider research project

5.3 Use of survey results

The survey findings informed the design of the study in several ways (Table 5.1). For example, it was apparent that medical devices were perceived to be the primary cause of skin damage in this population. Detailed information about the number and purpose of all devices was therefore recorded for all patients enrolled on the study.

Table 5.1 Findings of survey and associated influence on study design

Finding	**Influence on study design**
Diaper dermatitis is a widespread problem and a high clinical priority for staff	Data was collected on presence and severity of diaper dermatitis in addition to other forms of skin damage
Devices are a frequent cause of skin damage. Management of this is not standardised across units.	Detailed information about device type, brand, size, and method of fixing was recorded where available Information about number and purpose of all devices was recorded for all patients enrolled
Confusion between participants regarding the use of skin treatments, such as oils	Use of any kind of oil, cream, ointment, barrier film, or other skin treatment was recorded during data collection where available
Frequency of skin assessment depends on the clinical stability of the patient	The appropriate time to observe skin assessment was agreed at the start of every shift following discussion with nursing staff on the unit
Frequency of skin assessment may be affected by the presence of specific devices such as CPAP	Frequency of skin assessment will be recorded during data collection

Table 5.2 Characteristics and rationale of the risk factors included in the proforma

Item	**Risk factor measured**	**Rationale**
Gestational age (GA) at birth; birthweight	Degree of prematurity	Lower gestational age at birth has been associated with less effective barrier function (Kalia *et al.*, 1998).
Corrected gestational age (CGA)	Degree of prematurity	This indicates the degree of barrier development since birth.
Gender	Gender	Retained from minimum data set. It is not known whether gender is a risk factor for skin damage in neonates.
Nutrition	Nutrition	Poor nutrition is associated with increased risk and severity of PU development in older adults (Iizaka *et al.*, 2010). This relationship has not been explored in neonates. Nutrition will be measured by recording the type(s) of nutrition and method of feeding.
(If damage is present) Associated with device?	Medical device	Up to 50% of PUs in neonates are caused by medical devices (Ness, Davis and Carey, 2013)
Previous cooling?	Therapeutic hypothermia	It was not possible to assess neonates while they are receiving therapeutic hypothermia (cooling) due to inability to inspect skin. However, subcutaneous fat necrosis associated with cooling has been reported (Oza *et al.*, 2010), so noting previous use is relevant.
Oscillated? [Use of High Frequency Oscillation Ventilation]	Friction and/or shear forces	High frequency oscillation ventilation (HFOV) is a form of ventilation used for some critically ill neonates, who cannot be turned. Accordingly they are at increased risk of friction and/or shear as HFOV effectively subjects the neonate to micromotion.
Care group	Clinical condition	This item has been retained from the minimum data set. It served as an indicator of the neonate clinical condition.
Primary diagnosis	Diagnosis; clinical condition	It is not known how common diagnoses other than prematurity, including intrauterine growth restriction (IUGR) and hypoxic ischaemic encephalopathy (HIE), affect tissue tolerance.

Microclimate	Moisture, temperature	Humidified incubators have been associated with slower barrier maturation in preterm neonates (Sinclair, Crisp and Sinn, 2009). Additionally, they may cause a neonate to have excess moisture on their skin, which can affect tissue tolerance.
Presence of (list of devices)	Type of medical device	Recording the presence, brand and setting of a device, regardless of whether it is associated with a PU, was intended to provide insight into which devices are associated with the greatest risk of damage.
Frequency of cares	Moisture (possibility of being left in wet diaper); immobility	Replacement for prevention item. This will indicated roughly how often a neonate's diaper is changed, and how often a neonate is being turned or repositioned.
Frequency of skin assessment if different	Infrequent assessment	The presence of particular devices may trigger more frequent skin assessment (4.1.4).
Damage present (all that apply)	N/A	Damage represented a study outcome.
Steroid use	Steroid use	Steroid use may be associated with slower barrier maturation in preterm neonates (Kalia *et al.*, 1998).
Presence and severity of diaper dermatitis	N/A	This represented a study outcome. Neonates in the neonatal unit are at risk of diaper dermatitis (Visscher, Taylor and Narendran, 2013).
Presence and severity of chemical burns	N/A	This represented a study outcome as identified by clinicians.

5.4 Sample

Both the point prevalence study and the incidence study took place at two NICUs in the south of England. One provides care for both medical and surgical patients, and one provides care for medical patients only (Table 5.3**Error! Reference source not found.**). Both are situated within the same clinical network and work to the same clinical guidelines, including in relation to skin care (Thames Valley Neonatal Quality Care Group, 2012). The incidence study ran as a prospective cohort study over three months at Unit 1 and three months at Unit 2, with a seven week overlap during which data were collected at both sites.

Original estimated recruitment figures given in section 3.5.4.2 were devised prior to unexpected requests from the REC and the withdrawal of Unit 3 from the study.

Table 5.3 Participating units

	Capacity for surgery	**Number of cots**
Unit 1	No	27, including 14 intensive care
Unit 2	Yes	36 initially, including 20 intensive care/high dependency. 8 new intensive care/high dependency cots were added during the study.

5.5 Recruitment

For the prevalence study, an opt-out model of consent was utilised for parents, as the study was entirely observational and no identifying information was held on record. Posters were displayed in the units displaying information about the study (Appendix P), and parents were able to opt out if they did not wish their baby to be included, though none did. For the incidence study, informed written consent was sought from parents and confirmed once a week while the study was in progress. Nursing staff informed the researcher if a patient was ineligible for the study, to prevent the research team from screening patient information prior to consent being obtained. At Unit 1, the lead research consultant assisted with obtaining informed consent from parents. At Unit 2,

the researcher carried out the majority of recruitment, with assistance from a medical research fellow at the outset of the study.

Consent was sought from the parents of neonates included in the incidence study by the lead researcher, with assistance from the lead research consultant at Unit 1 and some assistance from a medical research fellow at Unit 2. The research consultant and research fellow were members of the clinical team and were therefore aware of which neonates were eligible for inclusion of the study. The researcher was not familiar with patients or parents, and therefore discussed patients with the nurse in charge or research nurse prior to approaching any parents. In addition to ensuring that any patient whose parents were approached met the eligibility criteria, this ensured that parents were not approached at an inappropriate time; for example, if a parent had just received unexpected news about their child, they were not approached at that time. This also allowed for any issues around parental capacity to be discussed and resolved prior to approach. The member of the research team would approach parents when they were on the unit, briefly explain the purpose of the study, and give the parents a PIS to read. Parents were given time to read this, and approached the next day to see if they had any questions. Time from approach to consent took between one hour and one month, dependent on parental concerns or questions. The majority of parents who consented did so within two weeks. In the instance where consent took a month, this was due to the parents not being present on the unit on days when the researcher was in. Additional consent was sought for photography.

The parents of 16 neonates declined involvement at Unit 1 and 3 at Unit 2. Parents did not have to give reasons for their desire not to participate, but of those who chose to do so, the most common reason given was that there were already many people involved in their child's care and they did not want to complicate the matter further. It is not known whether these neonates were representative of the general NICU population in terms of gestational age, as patients' notes were not accessed before consent was obtained.

5.6 Procedures

5.6.1 Development of the proforma

The standardised documentation for the point prevalence data collection was based on the NPUAP/EPUAP minimum data set (Vanderwee *et al.*, 2007). However, selected items were adapted to match the specific features of the sub-population. As the Braden scale is neither designed nor validated for use with neonates, these items were replaced with other potential risk

factors specific to the neonatal population (as detailed in **Error! Reference source not found.**). The data collected within the present study may provide information which can contribute to new RAS being developed. The development of a new RAS would be out of the scope of the PhD project, but may be considered in future postdoctoral research.

Several risk factors for skin damage were highlighted in the literature review and survey and informed the development of the proforma.

5.6.2 Wound assessment tools

All wound assessment tools referred to are detailed in Appendix Q.

PUs were categorised and documented according to international guidelines where possible (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). However, distinguishing between categorise III and IV proved difficult, due to the thinness of neonatal skin and minimal subcutaneous fat. Cannula-related injuries were staged according to the Visual Infusion Phlebitis (VIP) score (Infusion Nurses Society, 2011).

Categories for assessing incontinence-associated dermatitis (IAD) have recently been recommended and were adopted (Beeckman *et al.*, 2015). IAD does not have the same aetiology as diaper dermatitis and neonatal skin differs substantially from that of adults (see 2.3). These categories were therefore not ideal for assessing IAD in neonates. However, in the absence of a standardised and validated tool for assessing diaper dermatitis in this population, these categories were adopted. Burns were classified according to degree of injury when this could be determined (Werner, 2012). Any other type of skin injury, e.g. skin irritation, was documented. Cases of skin damage were photographed as permitted by parental consent and clinical condition.

5.6.3 Pilot testing

Prior to data collection, a pilot test was conducted over a two day period in Unit 1. This proved useful in identifying problems with the consent process for nursing staff, which were addressed (see section 5.4.6). Additionally, during the ethical approval process, the units moved from cluster cares to cue-based cares. Cares were no longer likely to be carried out at pre-determined times. This affected the data collection process, as it was no longer practical to arrange a time to observe a neonate based on when the nurse is likely to carry out cares. During the pilot test, the majority of the neonates included in the sample were being cared for in special care or high dependency

cots (n=9/13). The inclusion of neonates from ITU rooms proved problematic, as these neonates tend to receive cue-based cares.

Following discussion with doctors and nurses in Units 1 and 2, it was agreed that the most efficient way to collect these data was for the data collector to shadow the ward round. Any cases of skin damage were recorded while a neonate was being examined by the physician, and other relevant information was gathered from the patient notes or through discussion with nursing or medical staff.

5.6.4 Prevalence study

Eligible neonates were observed by a single data collector (HL) over a two-day period at each unit, and all cases of skin damage were recorded on a standardised proforma (Appendix R). Detailed information about each medical device associated with a given neonate were recorded where possible.

Given the clinical instability of the population, patients in intensive care cots were visually inspected during the ward round, as the whole of the skin was usually exposed during this process. The extent to which any erythema was blanchable was assessed by the doctor or nurse practitioner carrying out the ward round. It was not possible for the researcher to perform any hands-on assessment of skin in intensive care patients due to clinical instability.

For patients in high dependency and special care cots, appropriate times to observe patients were arranged with the nurses providing care for these neonates. Although this was a less efficient way to collect data, it was impossible for one researcher to go on all three ward rounds on a given unit simultaneously, and therefore a pragmatic solution had to be reached.

Assessment of the skin regions affected by the presence of any medical device was a critical aspect of this study. However, the patients most likely to require multiple devices are also generally those who are most clinically unstable. Patient treatment through device use was not compromised at any point, which meant that for some patients these skin regions could not be observed. In these cases, this was noted on the proforma, and any damage that had been noted by staff, obtainable from medical notes or discussion with staff, was documented.

Neonates who are receiving cooling therapy for hypoxic ischemic encephalopathy (HIE) cannot be turned, and the majority of the skin is obscured by the cooling jackets. Thus, neonates receiving this intervention on the day of data collection were excluded from the point prevalence study.

However, previous use of cooling therapy will be noted, as concerns have been expressed in the literature about skin damage associated with cooling (Oza *et al.*, 2010; Demirel *et al.*, 2013).

5.6.5 Incidence study

An amended version of the prevalence data collection proforma was used (Appendix S). During the study, a single observer (HL) attended the unit twice weekly to collect data. As with the point prevalence study, unstable or critically ill neonates were assessed during routine nursing cares or ward round, to avoid disruption of treatment. The optimal time for this was established through discussion with medical and nursing staff at the start of each shift. All new skin damage sustained by any given neonate were documented. Neonates remained enrolled in the study from first data collection until discharge, death, transfer out of the network, or end of the study. Continuation of consent was checked with all parents at least once a week during the study. In one instance, questions were raised about legal parental responsibility during the study and no further data were collected, as continuation of consent could not be confirmed.

Although excluded from the prevalence study, neonates receiving cooling therapy were eligible for the incidence study, as the duration of the study permitted assessment of skin once cooling has been discontinued. However, no neonates who were being actively cooled were recruited to this study.

Patients are often transferred between units in the network for specialist care. In order to ensure that all skin damage was documented without duplication or patients becoming identifiable, a patient's demographic information (gestation at birth, birth weight, primary diagnosis, gender, postcode, NHS number) was recorded in a secure database and assigned a unique identifying number on the day of enrolment. This database was checked at the end of every day during data entry. For patients transferred in and out of a unit multiple times during the three month data collection period, all their data was attached to the same unique identifying number. Recruitment data were uploaded to EDGE and Portfolio in accordance with local requirements.

Over the course of the study, it proved necessary to collect data during both the ward round (as suggested during the pilot study) and nursing cares, dependent on the patient and the clinical staff on duty. It was therefore impossible for a single data collector to observe all neonates on a unit in a single day. However, in comparison to the method used during pilot testing (observing cares whenever possible), which favoured the ease of data collection in special care, this method favoured data collection towards those receiving intensive care. Extremely premature and critically ill neonates were therefore disproportionately represented in the final sample. Since the

literature and the survey findings suggest that these represent those critically at risk of skin damage, inclusion of these neonates was a priority. Care was taken to observe as many neonates from HDU and special care rooms as possible.

5.7 Analysis

An overview of the analytical methods used can be found in Chapter 3 (see section 3.7). Detailed information about decisions related to classification, checking of assumptions, and factors omitted from the regression analysis are presented below.

Analysis was carried out using a combination of SPSS (IBM, USA) and Excel (Microsoft, USA).

Where skin damage developed, resolved, and then redeveloped in the same place, this was counted as separate instances if the area had appeared completely better with no sign of damage. However, if the skin damage improved and then deteriorated, but damage was always apparent, this was counted as one instance of damage. Wounds were characterised as “device-related damage,” “diaper dermatitis”, “immobility PU”, or “other”. Though they were assessed and categorised where appropriate during data collection, due to the difficulties associated with accurate classification in this population (see 5.8.4), for the purpose of analysis they were characterised as “broken skin” or “intact skin”.

Although surgical wounds and needlemarks were noted during the study, these were not included in the point prevalence and incidence numbers unless deterioration of the wound had occurred. These wounds represented intentional breaks in the skin carried out for therapeutic or diagnostic reasons, in contrast to unintentional and unanticipated damage resulting from other aspects of treatment.

When calculating incidence for each category, the most severe wound for each patient was utilised. Incidence rates were also calculated for device-related damage, immobility-related PUs, and diaper dermatitis.

5.7.1 Regression analysis

A binomial logistic regression was performed to ascertain the effects of gestational age at birth and birthweight on development of any skin damage. GA at birth was treated as a continuous variable, rather than classifying neonates as “term” or “premature” as has been done in previous studies (Visscher and Taylor, 2014), due to the immaturity of the barrier in extremely preterm

neonates when compared to moderate to late preterms (Kalia *et al.*, 1998). Prior to carrying out the logistic regression analysis, a Box-Tidwell (1962) procedure was carried out to determine if the continuous independent variables were linearly related to the logit of the dependent variable. A Bonferroni correction was applied based on the advice of Tabachnick and Fidell (2014), resulting in statistical significance being accepted if $p<0.01$. Based on this, none of the variables in the equation were statistically significant and therefore all were linearly related to the logit of the dependent variable. This test was repeated for the dependent variables "development of diaper dermatitis" and "development of any device-related damage". Again, all the variables were linearly related to the logit of the dependent variable in both cases. We therefore proceeded with the regression analyses as planned. There were no outliers detected in the analysis.

This was carried out in SPSS (IBM, USA), with the dependent variables "development of skin damage", "development of any diaper dermatitis", and "development of device-related damage" analysed separately (all coded as dichotomous variables: yes or no). Nagelkerke R^2 was calculated in order to determine the extent to which variation is explained by the models. Hosmer and Lemeshow goodness-of-fit was also calculated.

5.7.2 Factors omitted from the regression analysis

Some of the potential risk factors on which data were collected during this study were not included in the regression analysis. This was for one of two reasons. Firstly, for some items, the risk factor applied to few or no neonates. Only two neonates received HFOV during the study, for example, and no neonates had been treated with therapeutic hypothermia. This was also a consideration for humidification. In terms of the use of steroids, steroid use proved difficult to document during the study as it was not recorded in a consistent place on patient drug charts. Though efforts were made to retrieve the missing data from computerised records at the end of the study, it was impossible to determine from these records whether steroid treatment had begun before or after the first instance of skin damage. The steroid use data were therefore considered unreliable and not included in the analysis. Equally, during the time spent gaining ethical approval for the study, both units moved away from "cluster cares" to "cue-based cares", which are not carried out at set intervals. Recording set frequency of cares and frequency of assessment was therefore not possible.

5.8 Results

5.8.1 Demographics

In total, prevalence data were collected from 54 neonates. The demographic breakdown of participants enrolled on the study (GA) at birth can be seen in **Error! Reference source not found.**. Included in the prevalence figures were 21 neonates whose parents consented to their inclusion in the incidence study but who were transferred or discharged following only one data collection point, and whose data could therefore not be included in the incidence study. Birthweight data were unavailable for two neonates in this group. The mean birthweight for the remainder of the neonates was 1644g to the nearest gram, with a range of 500-4000g. The range of GA at birth was 23+2 to 40+6. The most common GA group was moderate to late preterm, and the most common birthweight group was ELBW. 28 of the neonates were male (51.9%).

Incidence data were collected from 51 neonates. The demographic breakdown of participants enrolled in the study can be seen in **Error! Reference source not found.**. The mean GA at birth was 30 weeks, with a range of 23+2 to 40. The mean birthweight was 1354g to the nearest gram, with a range of 538-3850g. The most common GA group was very preterm, and the most common birthweight group was ELBW. 24 of the neonates were male (47.1%).

Table 5.4 Prevalence demographics

	Birthweight*				GA at birth				Gender	
	ELBW	VLBW	LBW	Normal	Extremely preterm	Very preterm	Moderate to late preterm	Term	M	F
Unit 1	8	6	7	5	5	6	12	3	11	16
Unit 2	11	4	5	6	12	3	7	5	17	10
Totals	**19**	**10**	**12**	**11**	**17**	**9**	**19**	**8**	**28**	**26**

*Birthweight data were unavailable for two neonates.

Table 5.5 Incidence demographics

	Birthweight				Gestational age at birth				Gender	
	ELBW	VLBW	LBW	Normal weight	Extremely preterm	Very preterm	Moderate to late preterm	Term	M	F
Unit 1	13	12	5	0	7	19	4	0	12	18
Unit 2	8	3	6	4	6	4	9	2	12	9
Totals	**21**	**15**	**11**	**4**	**13**	**23**	**13**	**2**	**24**	**27**

The most common diagnosis for neonates enrolled on the incidence study was complications of prematurity (37/51). 14 neonates had other or additional diagnoses, including twin-to-twin transfusion (2), congenital diaphragmatic hernia (2), oesophageal atresia (1), jaundice (1), HIE (1), and chromosomal abnormalities (2).

5.8.1.1 Ineligible neonates

The most common reason for ineligibility was parents who did not speak English (15 neonates). Other neonates were excluded because of concerns around parental capacity and ability to provide informed consent (2), inability to access the room because of barrier nursing (2), congenital wounds (7), and neonate receiving palliative care (1). The parents of some neonates were not approached based on clinical advice, and these neonates were in some instances transferred out of the unit or onto comfort care before their parents were subsequently approached.

5.8.2 Prevalence

Some form of skin damage was observed in 21 of the 54 neonates included in the prevalence study (38.9%). Of these, four had broken skin (7.4% of enrolled neonates). Prevalence of diaper dermatitis, device-related damage, immobility PUs, other skin damage, and total damage is presented in **Error! Reference source not found.**. One neonate had a wound from an arterial line insertion, reported by the nurse, which could not be assessed due to tape on the area. It has therefore been included in the prevalence figure, but not the figure for broken skin. There were 31 instances of skin damage during the study, of which 16 were associated with medical device use, seven were diaper dermatitis, and four were immobility-related PUs. The remaining instances comprised delivery trauma (3) and non-blanching erythema where the cause was unclear (1).

Nasogastric/orogastric tubes were associated with two instances of damage in the prevalence study, in both cases indentation on neonates who were lying prone. Peripheral cannulae were also associated with two instances of damage: one irritation/erythema from contact with a cannula splint, and the other an extravasation injury. All other devices implicated were associated with only one (**Error! Reference source not found.**).

Table 5.6 Prevalence of skin damage by birthweight, degree of prematurity, and gender

	Birthweight								Degree of prematurity								Gender			
	ELBW	%	VLBW	%	LBW	%	Normal weight	%	Extremely preterm	%	Very		Moderate to late preterm	%	Term	%	Female	%	Male	%
DD*	1	5.26	2	50	1	12.5	2	28.57	2	11.76	1	11.11	3	15	1	12.5	4	15.38	3	11.11
Device-related damage	5	26.32	0	0	2	25	7	100.00	3	17.65	2	22.22	4	20	5	62.5	6	23.08	8	29.63
Immobility PU	1	5.26	0	0	1	12.5	1	14.29	1	5.88	1	11.11	0	0	1	12.5	2	7.69	1	3.70
Any damage	6	31.58	2	50	4	50	8	114.29	5	29.41	4	44.44	7	35	5	62.5	11	42.31	10	37.04

*One neonate developed DD whose birthweight was not available

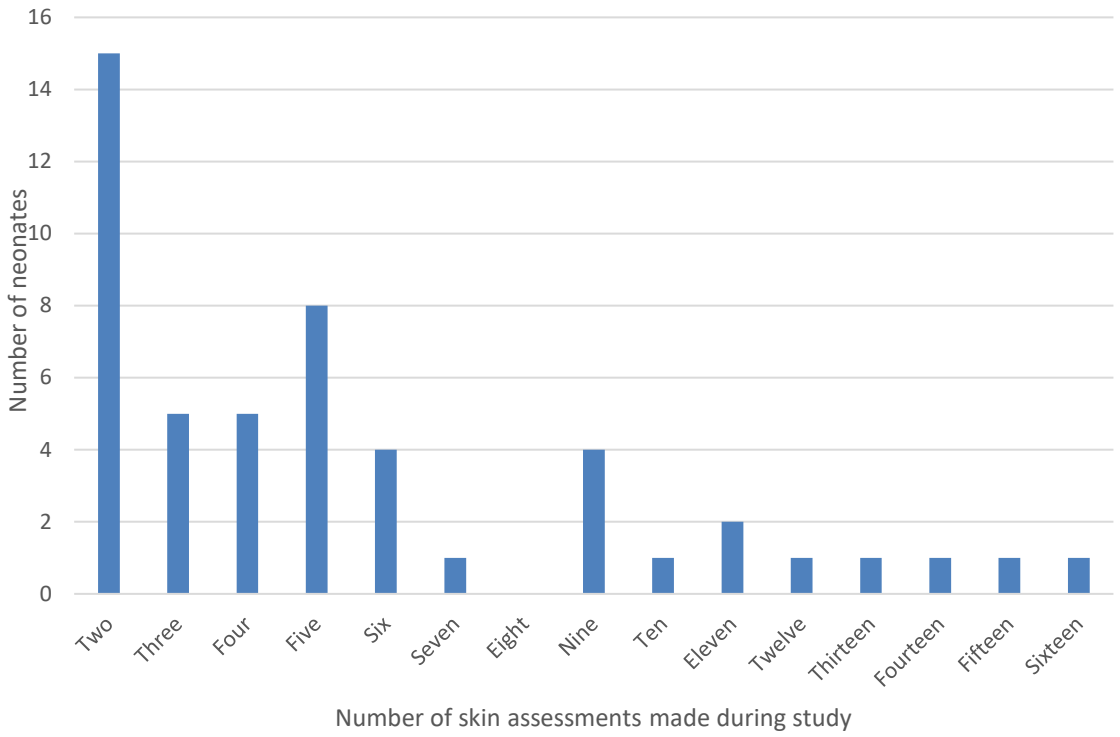
Table 5.7 Prevalence data - damage associated with devices

Device	**Number of neonates with device in situ**	**Instances of damage associated with device**
NGT/OGT	43	2
ECG leads	25	1
Pulse oximeter	20	1
Cannulae	18	2
Long line	13	0
Cord clamp	11	1
Apnoea monitor	9	1
High flow oxygen	9	1
Low flow oxygen	8	0
ET tube	5	1
CPAP/BiPAP	3	0
Arterial line	2	2
UVC/UAC	2	0
Phototherapy	1	0
Trilogy BiPAP	1	0
Stoma	1	0

5.8.3 **Incidence**

Though skin damage at enrolment was not a study outcome, it is worth noting that 15 neonates had skin damage at enrolment, ranging from birth trauma to a chemical burn. These instances were not included in the incidence calculation, although neonates with pre-existing skin damage were nonetheless eligible.

Over the course of the incidence study, 274 assessments were made. Neonates were assessed between two and 16 times (**Error! Reference source not found.**). The mode number of assessments was two and the median was five.



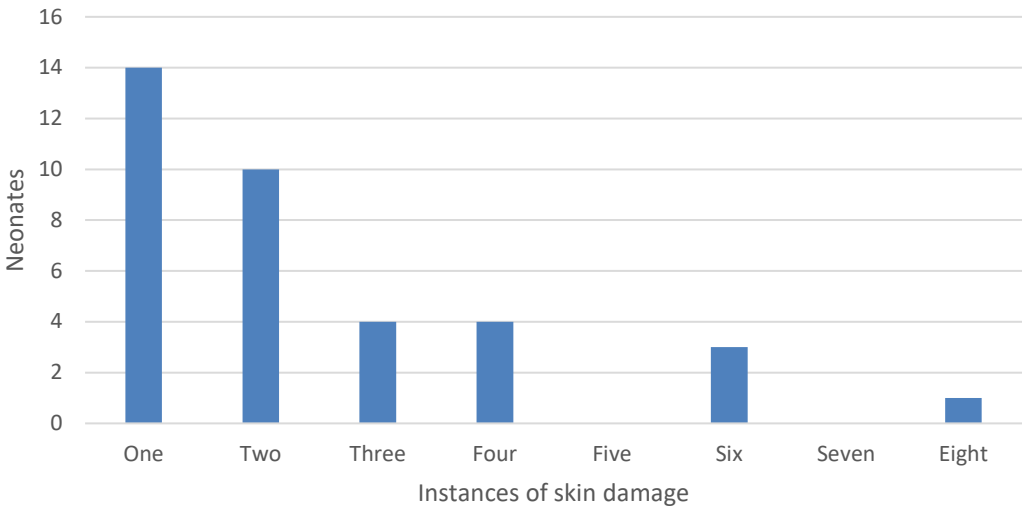
This figure shows the overall number of skin assessments made as part of the study per neonate, i.e. 15 neonates were observed twice each as part of the incidence study.

Figure 5.2 Number of skin assessments per neonate enrolled on the study

In total, 36/51 of enrolled neonates developed some form of new skin damage during the study (70.6%). This represents an incidence rate of 30.13 affected neonates per 1000 patient days. The mean length of stay at the first point where damage was observed was 37.9 days. Four neonates developed immobility-related PUs (7.8%), 23 developed damage associated with a medical device (45.1%), and 23 developed diaper dermatitis (45.1%). Over the course of the study, 88 instances of skin damage developed in 36 patients, of which 13.6% (12/88) involved some form of break in the skin. There were 42 instances of skin damage associated with a medical device (47.7%). The category “skin damage associated with a medical device” refers to any damage where the history or appearance of the wound suggests that a medical device was implicated, including PUs, skin irritation, and indentation without erythema. These findings are presented stratified by gender, birthweight, and degree of prematurity at birth in **Error! Reference source not found.**.

Table 5.8 Incidence of skin damage by birthweight, degree of prematurity, and gender

	Birthweight								Degree of prematurity								Gender			
	ELBW	%	VLBW	%	LBW	%	Normal	%	Extremely preterm	%	Very preterm	%	Moderate to late preterm	%	Term	%	M	%	F	%
Developed device-related damage	11	52.4	8	53.3	3	27.3	1	25	10	76.9	8	36.4	3	23.1	1	50	9	37.5	14	51.9
Developed DD	8	38.1	10	66.7	4	36.4	1	25	5	38.5	12	54.5	4	30.8	1	50	10	41.2	13	48.1
Developed immobility PU	2	9.5	1	6.7	1	9.1	0	0	1	7.7	2	9.1	0	0	0	0	1	4.2	3	11.1
Developed any skin damage	17	81	12	80	6	54.5	1	25	13	100	15	68.2	6	46.2	1	50	16	66.7	20	74.1



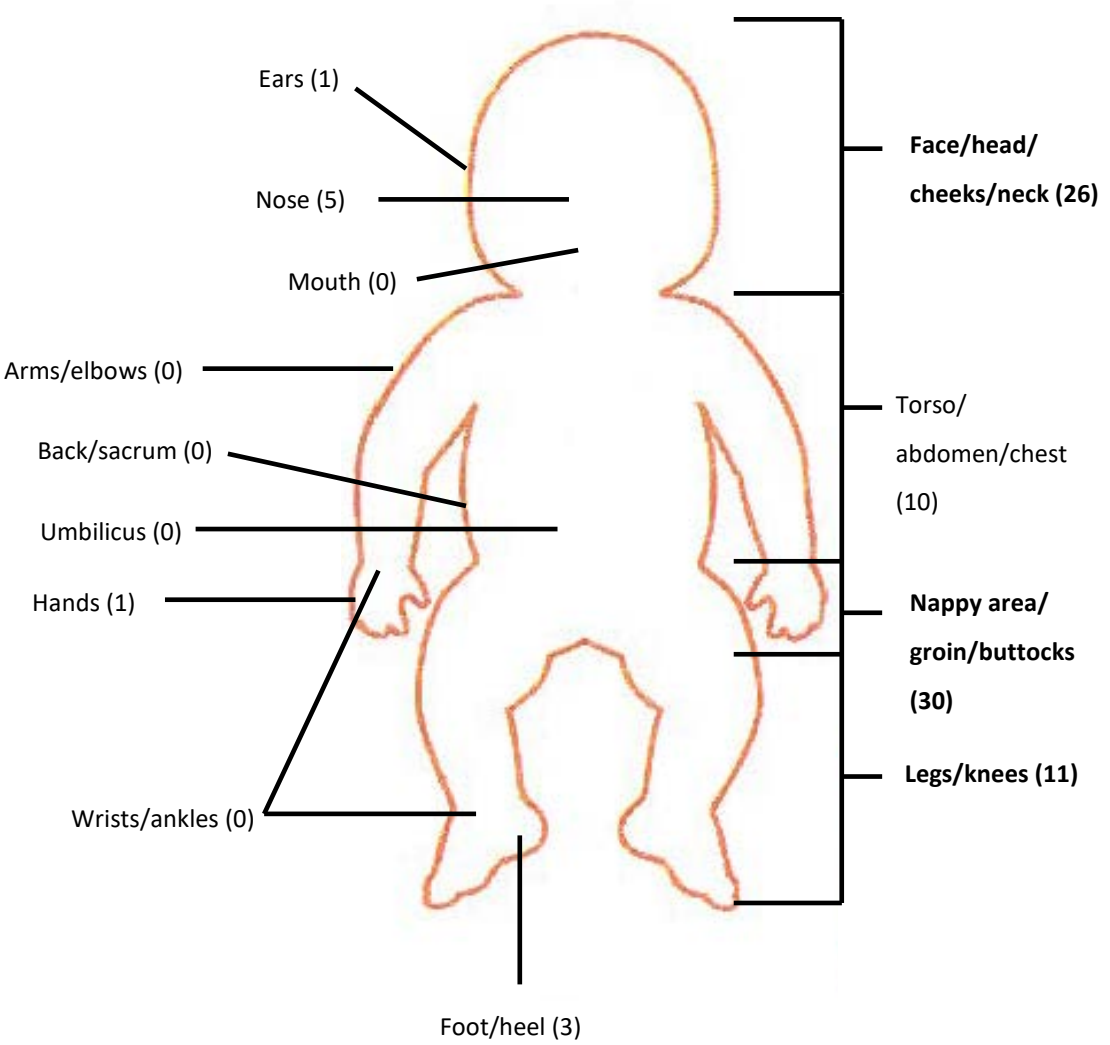
The *x* axis shows number of instances of skin damage, and the *y* axis shows the number of neonates who were observed to have that many instances of skin damage over the course of the study, i.e. 14 neonates sustained once instance of skin damage each. Neonates who sustained no skin damage are not represented in this figure.

Figure 5.3 Number of instances of skin damage per patient with skin damage

Over half of enrolled neonates who developed skin damage experienced multiple instances of damage (22/36, 61.1%). One neonate developed eight instances of damage over the course of the study, including two with broken skin, though the majority of these resolved quickly.

5.8.3.1 Locations of damage

The most common location for skin damage that occurred during the incidence study was the buttocks/genitals (**Error! Reference source not found.**). The majority of this skin damage was diaper dermatitis, though device-related PUs were also developed in this area, and one neonate developed a wound of unknown cause consistent with a burn. The second most common location was the face, including irritation from dressings and tape, PUs from medical devices, and scratches of unknown cause (possibly due to neonates with cannulae in their hands rubbing their faces). Nasal damage, which was primarily caused by CPAP, was counted separately to other facial damage as this was a particular concern for participants in the survey. However, in this study, damage to the nose represented only 5 of the 88 instances of skin damage developed.



The three most common areas in which new skin damage was observed during the incidence study are **bolded.** Damage in similar areas (e.g. legs/knees) is grouped together for ease of reading.

Figure 5.4 Locations of new skin damage during the study

5.8.3.2 Degree of prematurity

Neonates who developed multiple instances of skin damage tended to be more premature, though one term neonate developed four instances of skin damage during the study, including one occurrence of broken skin. This neonate had multiple complications, including trisomy 21 and oesophageal atresia, and required surgery during the study period. All 13 of the extremely premature neonates enrolled on the study developed some form of skin damage, including one who was already corrected to term at the start of the study. Of the extremely premature neonates, 5 developed broken skin (38.5%), compared to 3/22 very premature neonates (13.6%). No moderate to late preterm neonates developed broken skin.

Extremely preterm neonates were additionally the most likely to develop multiple instances of skin damage, with 9/13 extremely preterm neonates developing more than one (69.2%), compared to 9/22 very preterm neonates and 2/13 moderate to late preterm neonates (40.9 percent and 15.4% respectively). Ten extremely premature neonates developed some form of damage related to medical devices (76.9%). The neonate who developed the highest number of new skin damage was born at 26 weeks' gestational age, and had a corrected gestational age of 31+2 at the start of the study. Very premature neonates had the highest rates of diaper dermatitis (12/22, 54.5%), even when compared to extremely premature neonates.

5.8.3.3 Gender

Female neonates developed all forms of skin damage more frequently than male neonates (see **Error! Reference source not found.**), despite the fact that slightly fewer female patients were extremely preterm (5 compared to 8 male). Female patients were also more likely to develop multiple instances of skin damage (13/27 compared to 9/24). This may be an artefact of the small sample size. Twice as many female neonates were enrolled at Unit 1 than at Unit 2, where slightly more skin damage occurred (72.4% of enrolled neonates compared to 68.2% of enrolled neonates).

5.8.3.4 Medical device use

In total, there were 261 devices observed on 51 neonates (**Error! Reference source not found.**). All neonates enrolled on this study had at least one device *in situ* at some point during the study. The most commonly-used device was a nasogastric/orogastric tube (47/51, 92.2%), followed by pulse oximeters (45/51, 88.2%). The mode number of devices used for a neonate over the course of the study was five, with a maximum of 10 (see **Error! Reference source not found.**).

Table 5.9 Type and number of devices observed during incidence study

Name of device	Number of neonates with device in situ during study
NG tube/OG tube	47
Pulse oximeter	45
ECG leads	28
Cannula	23
Long line	19
High flow oxygen	17
Apnoea monitor	17
Low flow oxygen	16
ET tube	7
CPAP/BiPAP	6
Temperature sensor	4
Phototherapy	3
Umbilical arterial catheter/umbilical venous catheter (UAC/UVC)	2
Cord clamp	2
Nasojejunal tube	2
Arterial line	2
Stoma	1
Cerebral functioning analysing monitor (CFAM)	1
Gastrostomy	1
Chest drain	1
Replogle tube	1

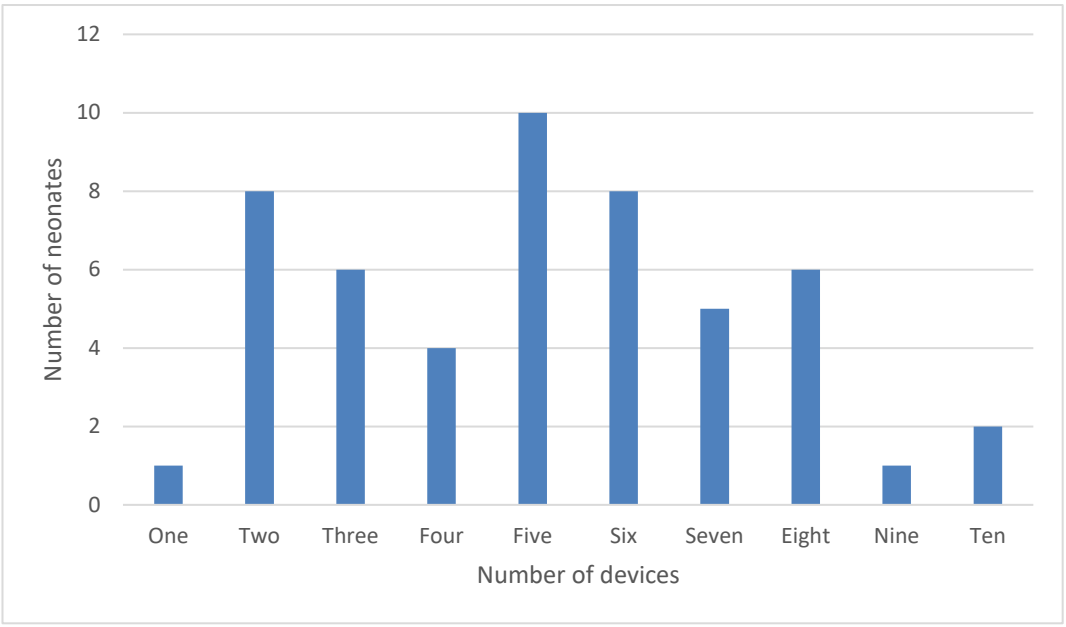
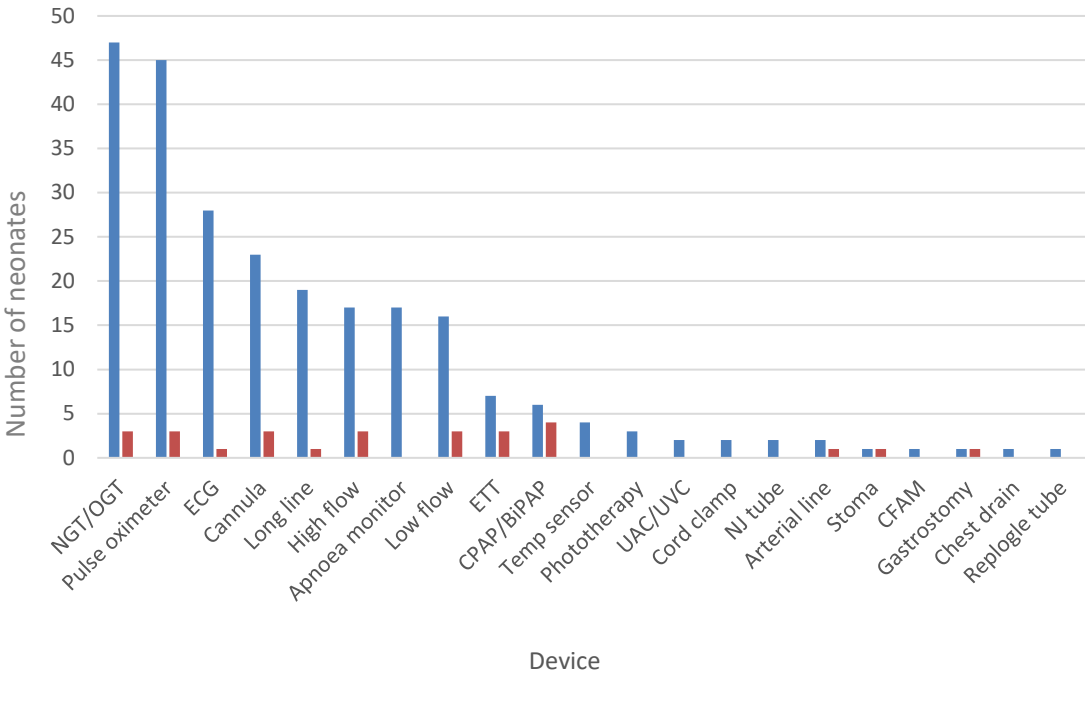


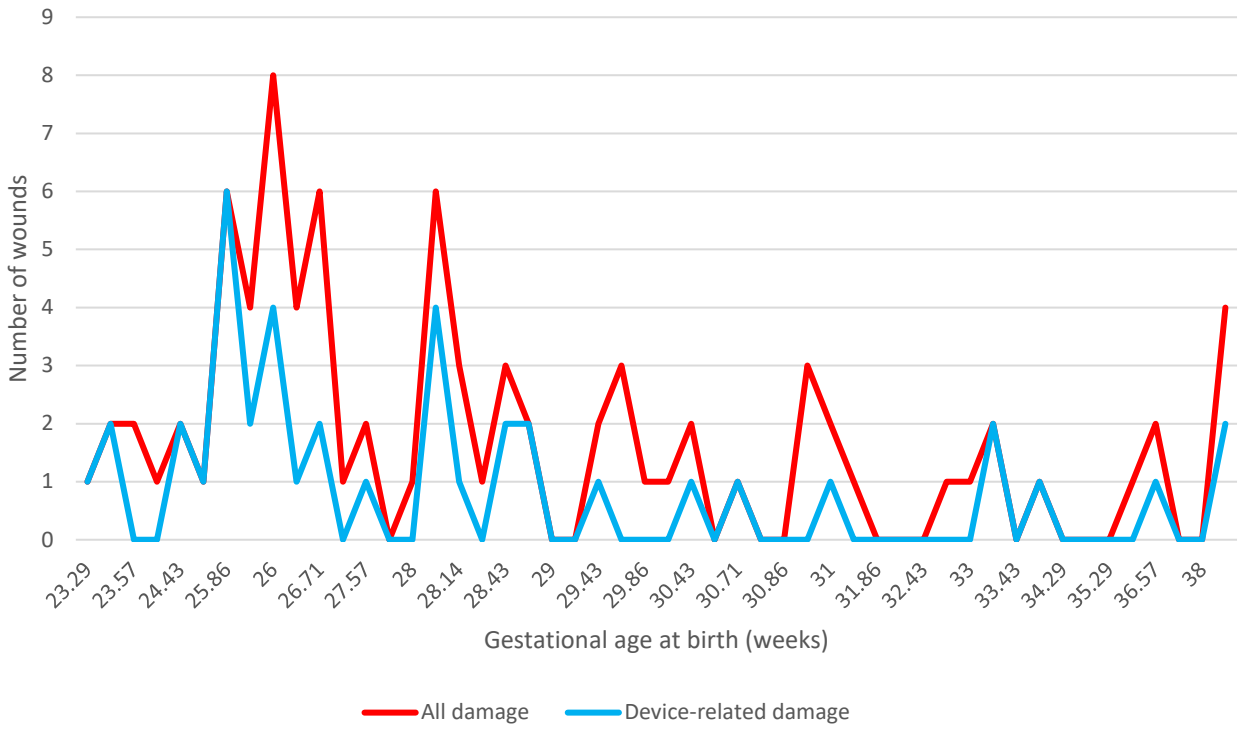
Figure 5.5 Number of devices used per neonate over course of incidence study



This figure shows the number of neonates who developed damage associated with a given device in comparison to the overall number of neonates using the device over the course of the study. For example, three neonates developed skin damage associated with the use of an NG tube out of the 47 neonates observed to have the device in situ over the course of the study.

Figure 5.6 Number of devices and number of neonates who developed damage associated with device

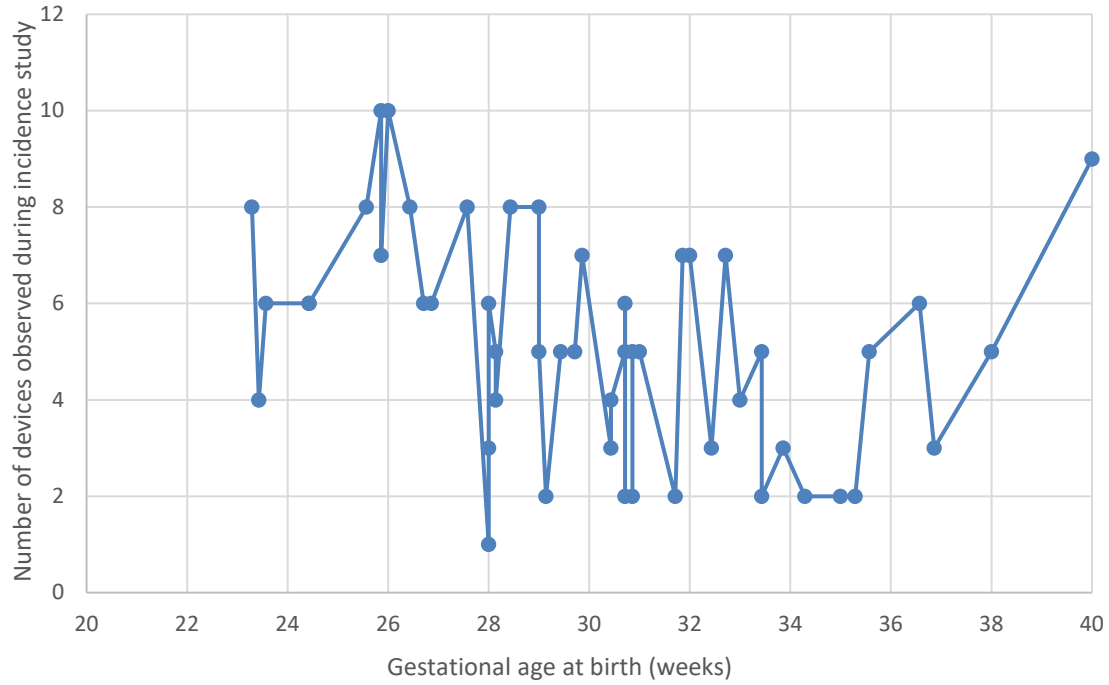
The device most frequently associated with damage was CPAP/BiPAP, with 4/6 neonates who required CPAP developing damage as a result of its use during the study. Damage from dressings or tape securing devices, and damage from diapers that was not dermatitis (e.g. category I PUs from the line of the nappy), were also counted in “device-related damage”, though these are not represented in the figure above as presence of a diaper/medical tape was not specifically noted unless there was damage associated with them. Of the five devices that were used on only one neonate, two had associated skin damage: a gastrostomy, and a stoma. Neonates born at earlier gestational ages tended to have a higher proportion of their wounds from medical devices than those born closer to term (**Error! Reference source not found.**).



This figure shows the proportion of all device-related skin damage in relation to all skin damage observed during the study, organised according to GA at birth, i.e. one neonate born at term (40 weeks) sustained four instances of skin damage during the study, of which two were related to devices.

Figure 5.7 Proportion of all damage related to devices, by gestational age at birth

Of the 51 enrolled neonates, 50 had at least two devices *in situ* over the course of the study, irrespective of gestational age at birth. There was no apparent relationship between GA at birth and number of medical devices (**Error! Reference source not found.**).



The *x* axis shows the GA at birth of an individual neonate enrolled on the study in weeks. The y axis shows the number of devices observed to be in situ on that neonate over the course of the study. For example, one neonate born at 28 weeks' GA had 6 devices in situ over the course of the study, while another neonate born at that GA had only one.

Figure 5.8 Number of devices observed in situ by gestational age

5.8.3.5 Associations

Both p-values and confidence intervals (CIs) are reported in the tables below, as generated by SPSS. However, following discussion with the faculty statistician, the decision was made to focus primarily on the CIs for these values when interpreting the findings. This was due in part to the smaller than expected sample size. Basing a decision about the clinical relevance of the findings exclusively on p-values, especially when the sample size is small, may not be appropriate. Small samples are less likely to generate statistically significant results, irrespective of the clinical relevance of the findings (du Prel et al., 2009). In addition, CIs indicate the direction of any effect and are more useful in clinical decision making (Akobeng, 2008), as they indicate the precision of the odds ratio for each variable (Berben, Sereika and Engberg, 2012).

The logistic regression model comprised of GA at birth and birthweight predicted development of any skin damage accurately 74.5% of the time, compared to 70.6% in the constant. It had a sensitivity of 91.7% and a specificity of 33.3%. The Nagelkerke R^2 value was 0.223, suggesting that 22.3% of the variance in the data was explained by the model.

Table 5.10 Variables in the equation – development of any skin damage

Variables in the Equation

		B	S.E.	Wald	Df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	Gestational age at birth	-.208	.163	1.623	1	.203	.812	.590	1.118
	Birthweight	.000	.001	.134	1	.714	1.000	.998	1.001
	Constant	7.692	4.178	3.390	1	.066	2191.283		

a. Variable(s) entered on step 1: Gestational age at birth, Birthweight.

GA at birth is given in weeks. Birthweight is given in grams.

The column Sig. shows statistical significance, although as identified above CI is the focus of this analysis due to its clinical usefulness with a small sample size. The column Exp(B) shows the change in the odds for each unit increase in the variable. For example, for each week's increase in GA at birth, the odds of developing any skin damage decrease by 0.812. Upper and Lower show the upper and lower bounds of the CI.

GA at birth was found to affect the odds of developing skin damage, although birthweight did not (see Table 5.10**Error! Reference source not found.**). This may be due to correlation between the two factors. For every week's increase in GA at birth, the odds of developing skin damage decreased by 0.812 (95% CI 0.590 to 1.118). This corresponds to the finding that extremely preterm neonates were the most likely to develop skin damage in the incidence study.

When the logistic regression analysis was carried out for diaper dermatitis, neither GA at birth not birthweight was found to affect the odds of developing this form of skin damage (**Error! Reference source not found.**). Indeed, the model slightly decreased accuracy of prediction over the constant (54.9% to 52.9%). However, GA at birth was found to affect the odds of developing device-related damage (**Error! Reference source not found.**). The Nagelkerke R^2 for this model, comprised of GA at birth and birthweight, was 0.120, suggesting that 12% of the variance in the data was explained by the model. For every week's increase in GA at birth, the odds of developing skin breakdown decreased by 0.842 (95% CI 0.636 – 1.115).

Table 5.11 Variables in the equation - development of diaper dermatitis

Variables in the Equation

		B	S.E.	Wald	Df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	Gestational age at birth	.080	.137	.340	1	.560	1.083	.828	1.417
	Birthweight	-.001	.001	.583	1	.445	.999	.998	1.001
	Constant	-1.786	3.290	.295	1	.587	.168		

a. Variable(s) entered on step 1: Gestational age at birth, Birthweight.

GA at birth is given in weeks. Birthweight is given in grams.

The column Sig. shows statistical significance, although as identified above CI is the focus of this analysis due to its clinical usefulness with a small sample size. The column Exp(B) shows the change in the odds for each time the independent variable increases by one unit. Neither birthweight not GA contributed to the model in this instance. Upper and Lower show the upper and lower bounds of the CI.

Table 5.12 Variables in the equation - any device-related damage

Variables in the Equation

		B	S.E.	Wald	Df	Sig.	Exp(B)	95% C.I.for EXP(B) Lower	Upper
Step 1[a]	Gestational age at birth	-.172	.143	1.437	1	.231	.842	.636	1.115
	Birthweight	.000	.001	.000	1	.999	1.000	.998	1.002
	Constant	4.944	3.487	2.010	1	.156	140.385		

a. Variable(s) entered on step 1: Gestational age at birth, Birthweight.

GA at birth is given in weeks. Birthweight is given in grams.

The column Sig. shows statistical significance, although as identified above CI is the focus of this analysis due to its clinical usefulness with a small sample size. The column Exp(B) shows the change in the odds for each time the independent variable increases by one unit, i.e. for every week's increase in GA at birth, the odds of developing device-related skin damage decrease by 0.842. Upper and Lower show the upper and lower bounds of the CI.

5.8.4 Difficulties with classification

Although much of the skin damage observed during this study was attributable to particular causes and could be easily identified as irritation, erythema, pressure damage etc., there were difficulties in assessing and classifying the wounds in some instances. For example, in a wound reported to have developed due to a peripheral cannula, it was unclear from both the medical notes and direct observation whether this was due to extravasation of the cannula or a pressure ulcer developing below the cannula hub. Though the damage was visually more consistent with

that of a pressure ulcer and the wound has therefore been classified accordingly, the lack of consistent guidance on classification of skin damage in premature neonates made judgements like this challenging. Similarly, a wound that developed on the buttock of a neonate was classified by hospital staff as diaper dermatitis. However, the shape and appearance of the wound (**Error! Reference source not found.**), along with the fact that it did not resolve with treatment for diaper dermatitis, is more consistent with that of a second-degree burn. The presumed cause for this is a saturation probe cable that was caught in the nappy. A burn from a shorting saturation probe cable was reported in a neonate many years ago, though in that instance she was extremely premature (Sobel, 1992).

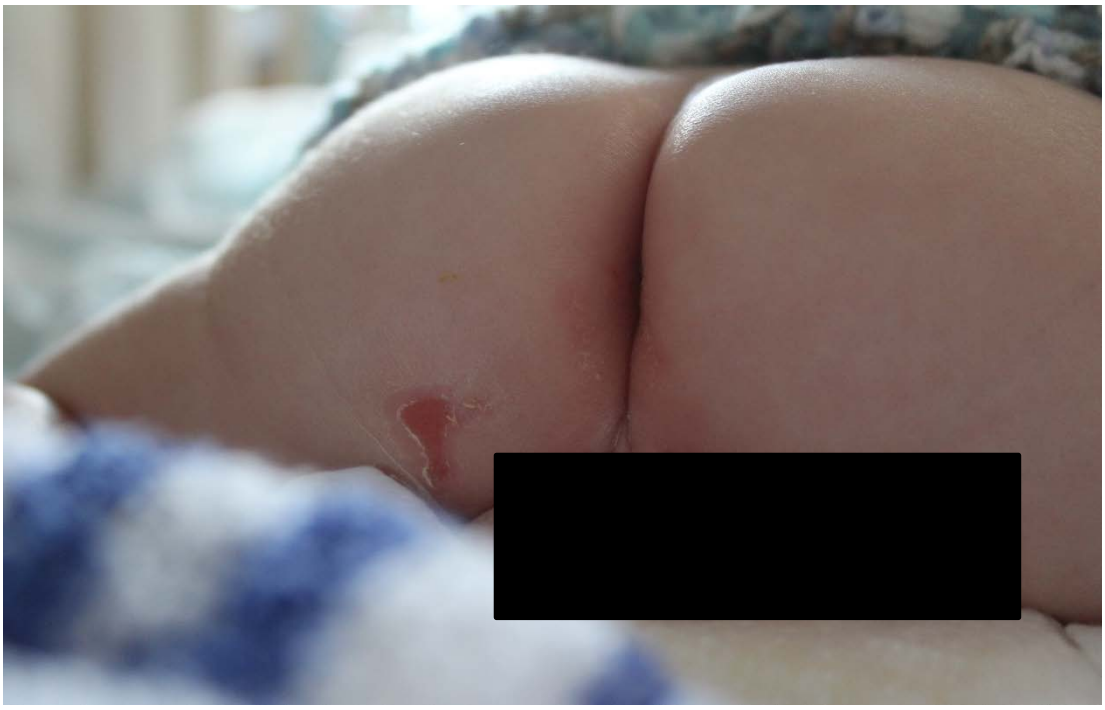


Figure 5.9 Cause unclear but fits with possible second-degree burn from saturation probe cable

Lastly, some pressure ulcers developed in areas that could not be easily assessed. For example, a PU developed on the upper lip of a neonate as a result of an ET tube and was identified when he was extubated (**Error! Reference source not found.**). However, because the neonate was still unstable and the PU was directly beneath his high flow prongs, the area could not be easily assessed. This was complicated further by the fact that this neonate had been born at 26 weeks' gestational age and was now 33 weeks' corrected gestational age, therefore still had very thin and fragile skin. The PU could be either a category I or II PU but this is difficult to determine. For these reasons, wounds were classified as "broken skin" or "intact skin" rather than attempting to categorise them. Equally, because it was often impossible to reliably determine whether a wound associated with a device was caused by pressure, moisture, irritation, or some combination

thereof, wounds were classified as “device-related damage”, “diaper dermatitis”, “immobility-related PU” or “other”.

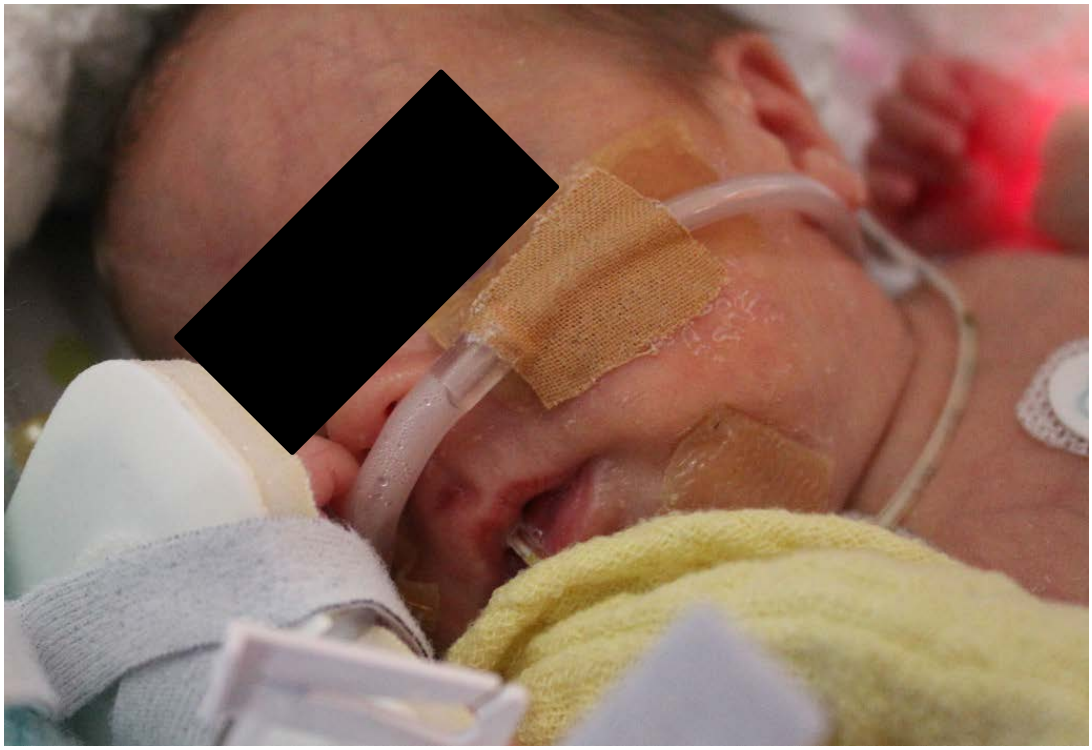


Figure 5.10 PU above upper lip from previous ET tube

5.8.5 **Case studies**

Although not all participants’ parents consented to photography, this was possible with some neonates. As more serious wounds were more likely to develop under life-saving medical devices, it was not always possible to photograph these. Similarly, the neonate with the most serious wounds was too unstable to be held in place for photographs of the affected areas. However, photographs that were obtained and that have not been reproduced above are presented and discussed below.

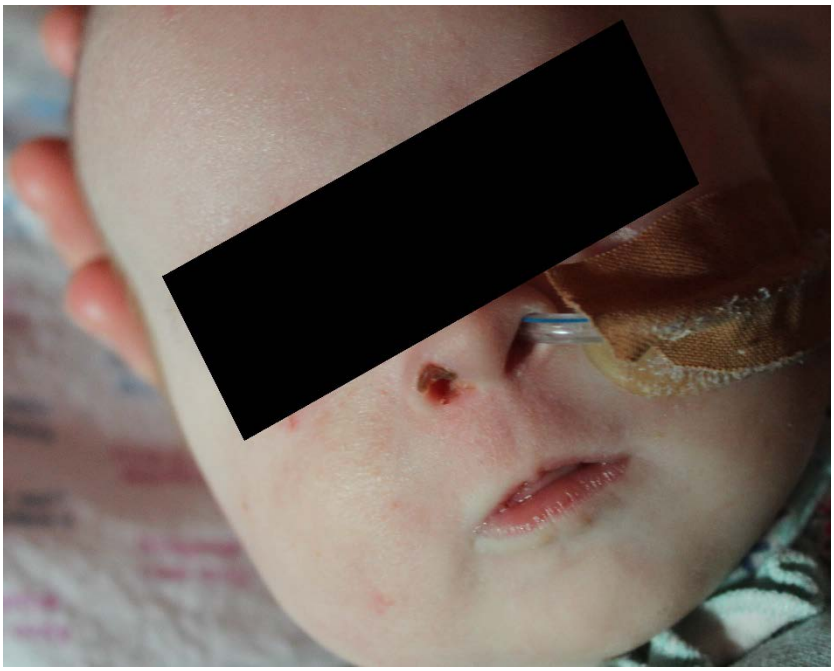


Figure 5.11 PU on nose from previous nasal ET tube

Error! Reference source not found. shows a nasal PU that developed as a result of a nasal ET tube. In this instance, the neonate who developed the PU was off the unit at the time of the injury, having undergone surgery and recovered in the trust's paediatric ITU. The extent of the wound when it first occurred is therefore not known, as the neonate did not return immediately to the unit. It was challenging for nursing staff to manage this particular wound, as the neonate in question had a replogle tube (pictured) *in situ.* This essential interventional device, which prevents neonates with oesophageal atresia from aspirating on their salivary secretions, was originally rotated between nostrils every few days in order to minimise pressure on one nostril. However, once the PU occurred, nursing staff had to decide between aggravating a pre-existing wound by continuing to switch sides, or leaving the replogle tube in one nostril for a longer period of time and potentially causing another wound. In the photograph, the nostril with the replogle tube in situ can be seen already pulling at the skin and soft tissues. The nurses chose to resite the replogle tube. It was therefore not possible to take follow-up photographs of the wound as at the next two data collection points it was obscured by the replogle tube.

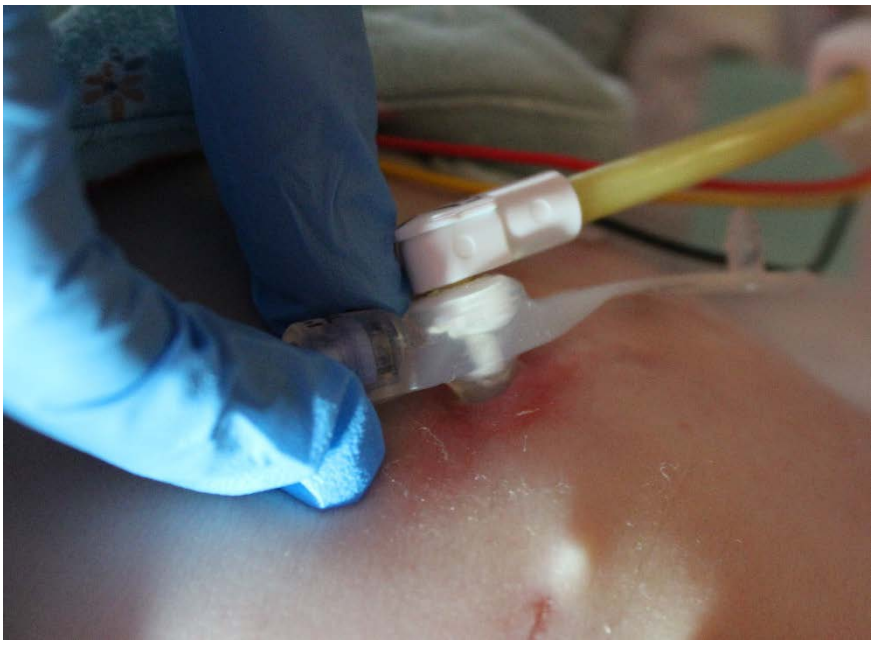


Figure 5.12 Skin damage from gastrostomy

Error! Reference source not found. shows another instance of skin damage on the same neonate as in **Error! Reference source not found.**, this time as a result of gastrostomy use. After this photograph was taken, nursing staff padded the area with a foam dressing and gauze to prevent the device impinging on the skin. The damage initially resolved, but had recurred 18 days later at the last data collection point. Though it is clear that this wound resulted from the gastrostomy, the specific aetiology is less clear. It may be caused by pressure or friction from the gastrostomy, moisture around the wound site, a reaction to the plastic, or most likely a combination of factors.

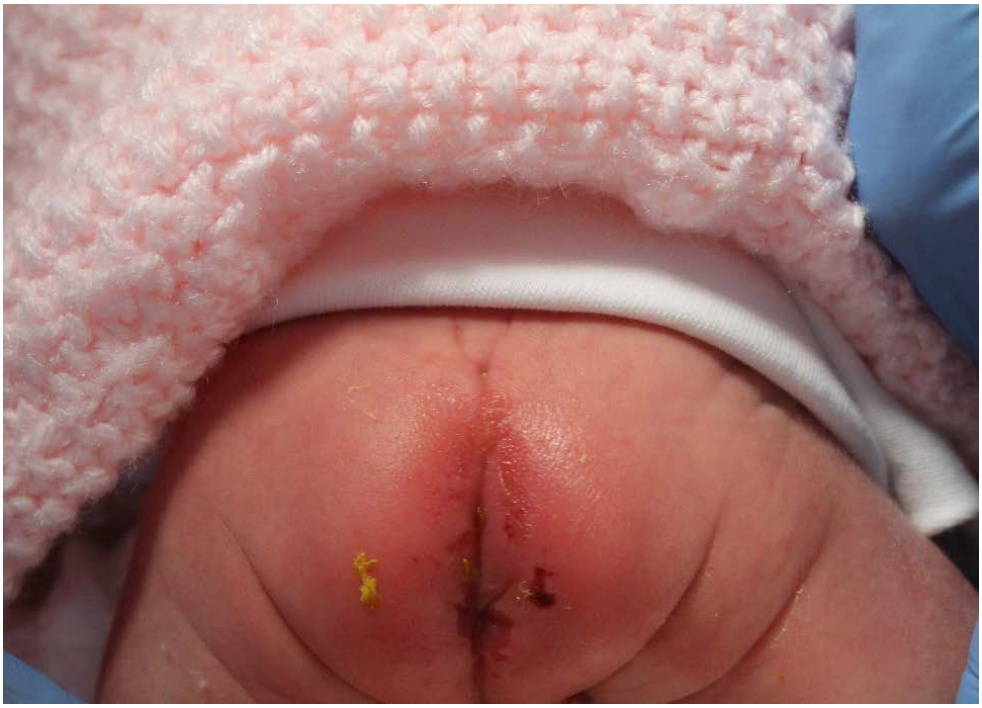


Figure 5.13 Broken skin from diaper dermatitis

The neonate in **Error! Reference source not found.** already had broken skin in the perianal area when she was enrolled on the study. Initially this resolved after she was nursed exposed (prone and without a nappy) but it recurred and continued to deteriorate. Medihoney cream, DermaS sticks, and being nursed exposed overnight were all attempted as management strategies. When this was ineffective, she was transferred from expressed breast milk to a dairy-free formula, and the diaper dermatitis resolved within four days. This neonate was discharged several weeks after her twin brother due to a variety of complications, including though not limited to this instance of skin damage.

5.9 Discussion

5.9.1 Prevalence and incidence of damage

Given the high incidence found during the study, it is surprising that the prevalence figure is not higher (70.6% and 38.9% respectively). It is likely that the differences are due to three factors. Firstly, it was noted during the incidence study that, though the rate of damage was high, it was generally superficial and resolved quickly. Secondly, the mean GA at birth for the incidence study was lower than for the prevalence study, due to the relatively well term babies who were observed only once and who were discharged too quickly to be included in the incidence study. The neonates included in the prevalence study are therefore likely to be more representative of the unit population as a whole. Given the increased incidence of skin damage that was noted among extremely premature and very premature babies in the incidence study, it stands to reason that a group with a lower mean GA at birth would have a higher rate of skin damage. Lastly, five of the extremely preterm babies included in the prevalence study already had a corrected GA equivalent to term. The effect of GA at birth on prevalence and incidence is discussed in more detail in section **Error! Reference source not found.**.

In addition to the difference between the prevalence and incidence figures, the amount of damage observed in this study is higher than that found in other studies within this population. As identified in **Error! Reference source not found.**, a range of prevalence and incidence figures have previously been reported, with Visscher and colleagues (2014) reporting an incidence of PUs of 3.22%. This is likely due to the fact that we used a broader definition of skin damage and did not focus on PU development. Additionally, in that study, data were only collected once every two weeks. In our study, data were collected twice a week where possible, and therefore category I PUs and other superficial skin damage were therefore more likely to be picked up before they were resolved. This may account for the relatively low proportion of broken skin found in our study comparative to theirs, which found that 65% of PUs observed were category II.

5.9.2 Types of skin damage

This was the first prevalence and incidence study that set out to report all forms of skin damage in the neonatal unit, ranging from irritation caused by adhesive dressings to chemical burns and pressure ulcers. Although a wide range of types of skin damage have previously been reported in the neonatal unit (Newnham *et al.*, 2013), usually in the form of case studies, this was the first study to attempt to understand the prevalence and incidence of different forms of skin damage in this environment. Previous studies have looked at both PU development and diaper dermatitis in this environment (Visscher, Taylor and Narendran, 2013; August *et al.*, 2014; Visscher and Taylor, 2014), as well as damage associated with specific devices.

The incidence study found an equal incidence of device-related damage and diaper dermatitis. Although the diaper dermatitis was generally superficial, in some cases extensive breakdown occurred, causing pain and delaying discharge. In a study looking at all wounds on the neonatal unit that required active wound management, diaper dermatitis was the most common (Meszes *et al.*, 2016). No studies have been identified that report incidence of diaper dermatitis in neonatal intensive care units, though an incidence of 28% in term neonates without Neonatal Abstinence Syndrome (NAS) and 86% in those with NAS has been reported (Malik *et al.*, 2017b). However, the researchers in that study identified that diaper dermatitis was only documented correctly 23% of the time, so it is possible that the rate was in fact higher. Term neonates, those with trisomy 21, and those with congenital diaphragmatic hernia have been reported to be at increased risk of diaper dermatitis (Visscher, Taylor and Narendran, 2013). In contrast, very premature neonates developed the highest rates of diaper dermatitis in the present study. Only one neonate with trisomy 21 and two with congenital diaphragmatic hernias were enrolled on this study, and therefore the sample size was insufficient to explore these risk factors.

It has been previously suggested that immobility-related PUs tend to occur on the occiput in neonates due to their comparatively large heads (Fox, 2011). However, all of the immobility-related PUs in the prevalence and incidence study occurred on the knees of babies who were positioned prone, in keeping with the findings of August and colleagues (2014) who also did not identify the occiput as a region at risk of PU development.

5.9.3 Damage associated with specific devices

The device associated with the most damage in the incidence study was CPAP. This is in keeping with previous studies suggesting that CPAP is a frequent cause of skin damage in the neonatal unit (De Paoli *et al.*, 2008; Squires and Hyndman, 2008; Jatana *et al.*, 2010; Filippi *et al.*, 2012), and the data from the survey and focus group, which suggest that nurses continue to perceive use of

CPAP as a significant risk to skin health. Partly in response to this, there has been a recent study looking at the use of humidified high flow as respiratory therapy immediately following extubation (Collins *et al.*, 2013, 2014). These found that the rates of skin damage were lower with humidified high flow than CPAP and that respirator outcomes were not clinically worse. Indeed, relatively few neonates in the present study were receiving respiratory support via CPAP. It is also worth noting that three neonates in the prevalence study were being treated with CPAP, none of whom had skin damage on the day of data collection, though of course these neonates were not followed up.

Despite the low rates of CPAP use, there were many other devices implicated in the development of skin damage across the two studies. Devices as seemingly mundane as apnoea monitors and cord clamps were associated with skin damage in the prevalence study, while neonates in both the prevalence and incidence studies developed damage as a result of Duoderm use, intended to preserve the skin. The variety of devices found to be associated with skin damage corresponds to previous findings that devices ranging from phototherapy lamps to infant abduction prevention systems have been associated with damage in neonates (Siegfried, Stone and Madison, 1992; Zangwill *et al.*, 2017). It is also in keeping with comments made by the participants in the focus group and interviews that any device poses a potential risk to neonatal skin health. No one device could be identified as the primary cause of damage in this study.

5.9.4 **Degree of prematurity**

With regard to the effect of birthweight and GA at birth on the risk of developing skin damage, there was a strong contrast between the prevalence and incidence data. In the former, extremely premature neonates were the least likely of all gestational groups to develop skin damage; in the latter, the most likely. Neonates who were classified as “moderate to late preterm” in our incidence study developed the fewest cases of skin damage, and the regression analysis of the incidence data suggested that lower gestational age was associated with increased risk of skin damage. Previous studies of specific types of skin damage in neonatal environments have found that, for immobility-related PUs and diaper dermatitis, term neonates are in fact at greater risk than those born prematurely, while device-related PUs are more common in those of a lower gestational age at birth (Visscher, Taylor and Narendran, 2013; Visscher and Taylor, 2014).

This difference may reflect the type of skin damage most likely to be suffered by extremely preterm neonates. Irritation, indentation, and PUs from devices were noted to be frequent in the incidence study, and most common in extremely preterm neonates. This corresponds to the findings of Visscher et al (2014). However, this type of damage was not noted to be as widespread

in the prevalence study. Device-related damage, though it occurred frequently in the incidence study, was also generally superficial and resolved quickly. It follows that less short-term superficial injury was observed at a single point in time than over a period of several months.

Specifically with regard to the findings of the incidence study, these suggest that neonates who are extremely premature at birth are at increased risk of skin damage in an intensive care environment, even when compared to very premature neonates. Though Visscher and colleagues (2014) found that premature neonates had a lower rate of PU development than term neonates, this may be because the neonates in that study were stratified as premature (<37 weeks' gestational age at birth) or term (≥37 weeks' gestational age at birth), rather than being stratified by degree of prematurity. The moderate to late preterm neonates, who developed the least damage in our study, would therefore have been classed alongside the extremely preterm and very preterm neonates. The low number of term neonates enrolled on our study (n=2) means that we cannot compare term neonates to all preterm neonates (n=49) in order to determine how their findings correspond to our findings.

While the present study corresponds to these studies in finding that extremely preterm neonates were at the greatest risk of device-related damage, they also suggest that the relationship between degree of prematurity and risk of different types of skin damage may be more complex than originally thought. In our study, because neonates were more narrowly stratified based on gestational age, it has emerged that neonates in different gestational groups developed types of skin damage at different rates. For example, the regression analysis carried out with diaper dermatitis as the outcome suggested that GA at birth was not a risk factor for this type of skin damage.

It is likely that the increased risk of extremely preterm neonates observed in the incidence study is due to a combination of factors, especially the prematurity of the skin and the potentially prolonged time spent in intensive care environments, as they require time to grow and develop in addition to time for treatment. However, in the incidence study, there was not a linear relationship between gestational age at birth and number of devices *in situ* during the study, suggesting that increased exposure to devices was not a factor in the high rate of device-related damage in this group. Future research into skin damage in this environment may benefit from stratifying neonates according to degree of prematurity to account for the differences in skin maturity at birth, and to understand this relationship further.

5.9.5 Determinants of change

Although the focus of this study was on understanding the scale of the problem, with regard to patient risk factors and amount of skin damage occurring, there were aspects that illuminated some of the issues raised by participants in the survey, focus group, and interviews. These are outlined below.

5.9.5.1 Conflicting priorities

This study has highlighted the challenges associated with preventing skin damage in premature and sick neonates. For example, though in the survey participants referred to minimising the use of tape as far as possible, and indeed Hypafix tape and an unspecified brown tape were found to have caused skin damage in this study, it is also a necessity to secure life-sustaining devices. The neonate portrayed in **Error! Reference source not found.**, for instance, had recently been extubated at the time of the photograph and still required respiratory support. Although the beginning of a reaction to the tape securing the high flow can be seen in the picture, leaving the device unsecured was not a viable option. Even resources intended to preserve the skin can cause problems: Duoderm dressings were associated with irritation and inflammation in three neonates.

Previous studies have looked at ways of addressing device-related damage in this population, such as using different types of dressing to secure CPAP or extubating neonates directly onto humidified high flow oxygen (Collins *et al.*, 2014). Though the relatively low rates of CPAP use in this study are likely to reflect this change in practice, there remains an issue of many medical devices being fundamentally not designed for neonatal skin. Humidified high flow may cause less damage than CPAP, but it was nonetheless associated with damage in both the prevalence and incidence studies.

5.9.5.2 Classification

As identified in Section 5.2.4, classification of some wounds proved difficult. This concern was also raised during the interviews with TVNs. Difficulties with classification of wounds, especially distinguishing between sacral PUs and incontinence-associated dermatitis in adults, have been widely reported (Beeckman *et al.*, 2011; Gunningberg, Mårtensson, *et al.*, 2013). Indeed, the Global IAD Expert Panel have released specific guidance on differentiating between category II PUs and IAD (Beeckman *et al.*, 2015). In neonates, especially premature neonates, these difficulties are compounded by a relative absence of subcutaneous fat and the thinness and fragility of the epidermis (see 2.4.2 for a review of neonatal barrier function). Even where the type of damage could be determined, it was often impossible to categorise or stage the wound. In the present study, difficulties surrounding classification were resolved by classifying all wounds as

"broken skin" or "intact skin". However, given the implications of both type and category of skin damage for effective treatment, as well as accurate reporting, more research is required into an alternative classification system that takes into consideration the unique patient needs and clinical environment of neonatal care.

Additionally, there is the further issue of "indentation", occurring as a result of a medical device, sometimes without erythema. In our study, this was most commonly associated with CPAP and high flow oxygen, though it was present with a number of other devices as well. Using the definition of a pressure ulcer as localised damage to the skin and soft tissues as a result of pressure, or pressure in combination with shear (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014), it seems that indentation of the skin and soft tissues from a medical device is necessarily a form of pressure ulcer. Similar indentation marks have recently been reported as a consequence of C-spine collars in adult trauma patients who were immobilised in the ED (Ham *et al.*, 2016). However, there is currently no classification for this type of ulcer, nor is it mentioned in the new "medical device related pressure injury" category recently introduced by the NPUAP (NPUAP, 2016).

5.9.6 **Limitations**

In hindsight, this was an ambitious project to attempt with just one data collector. Although the original plan was for the study to run first at one site and then subsequently at the second, this was not possible due to the delays outlined in section 3.6.3, and data were collected concurrently at the two sites. This meant that the data collector could not be on site every day but was travelling between the two, which had an impact on recruitment. During the study, we did apply for some additional funding for research nurse support, but this did not come through until after the study had finished. If we were to run the study again, it would be beneficial to have more staff involved from the outset. For example, if data collectors could have followed both the special care and ITU ward rounds in each environment, this would have facilitated both data collection and recruitment, as recruitment could then be carried out after the ward round had finished.

The ambivalence towards the study from some senior nurses at Unit 1 also caused ongoing difficulties. Though these were ameliorated with the intervention of the matron, there were still some logistical issues that could not be resolved. For example, the researcher was occasionally asked to stop shadowing the ward round by senior nursing staff for reasons of confidentiality or because they were perceived to be in the way. In order to deal with this challenge, more data was collected from neonates during routine nursing cares than during ward round, as this allowed for a greater degree of liaison between researcher and nurse. However, again, in some cases nursing

staff had to change the neonate earlier than planned for clinical or workload reasons, meaning that these neonates were sometimes missed.

As with all clinical studies, there were some challenges that arose unpredictably. For example, at Unit 2, one of the four main rooms on the unit was closed off for two weeks to contain an infection. After discussions with senior nursing staff on the unit, the decision was made not to collect data in that room while the outbreak lasted due to the risk of carrying it elsewhere on the unit, even if hand hygiene was adhered to. Some enrolled neonates therefore have a two-week period where no data was collected from them. Equally, one neonate who had extensive skin damage at the start of the study went through periods of being extremely unstable, during which he was managed with absolutely minimal handling even during ward round. This meant that he could not be moved for assessment.

The REC requirement to consent all nursing staff was one of the most significant limiting factors in this study. Due to staff turnover, the nature of shift work, the nurses who declined to consent, and the use of agency staff, it was impossible to consent all members of the nursing team. To some extent, this was managed by delaying the start of data collection until recruitment of nursing staff had taken place on both units. However, though this lessened the impact, it did not solve the problem. All neonates therefore had days where data could not be collected from them due to unavailability of consented nursing staff. In some cases, this was addressed by parents who were extremely positive about the study offering to change and turn the neonate themselves if the nurse was not willing to do this while being observed. However, for very premature or fragile neonates, this was not an appropriate solution.

There were some limitations associated with specific measures. For example, the measure “length of stay at first new damage” reflects the point at which new damage was first observed in this study. However, many neonates had been on the unit for several weeks when they were enrolled on the study. For example, one neonate born at 23+4 weeks first had skin damage recorded at the age of 137 days. However, she had been on the unit for 91 days when she was enrolled on the study. It is possible that she had developed skin damage on one or more occasions prior to the first time it was observed in this study. Some neonates had also transferred in from other units and would have therefore been exposed to multiple care environments. This measure, calculated from date of birth until the date skin damage was first recorded in the study, can be said to be an accurate measure of how long a neonate would have been exposed to some form of care environment at the time when the damage in question was first observed. However, it is unlikely to be a true measure of how long it was before a neonate first experienced hospital-acquired skin damage.

Due to the smaller than anticipated sample size, the confidence intervals for the logistic regression analyses are large and the findings must therefore be treated with caution. For example, only two term neonates were enrolled on the incidence study, one of whom had multiple complex conditions. Similarly, the decision to omit the unreliable steroid use data and the low numbers of enrolled neonates receiving HFOV or humidification means that these factors could not be included in the regression analysis (see 5.7.2), meaning that their influence on the development of skin damage could not be determined. However, this is the first study to look at degree of prematurity as a risk factor for all forms of skin damage in the neonatal unit, and therefore still makes an important contribution to the understanding of this issue.

Chapter 6: Discussion and future work

6.1 Summary of aims and objectives

This doctoral research project was composed of two main components: an analysis of nursing practice and beliefs in relation to neonatal skin care, and an analysis of the current situation with a view to understanding the scope of the problem. This was in order to accomplish the following aims:

a) To understand the scope of the problem of skin damage in neonatal units
b) Identify potential determinants of change related to the prevention of skin damage in neonatal units

The different stages of the projects had different objectives. These are summarised below.

6.1.1 Objectives of survey, focus group, and interviews

1) To explore the beliefs and practices of frontline neonatal nursing staff regarding skin damage, with specific reference to the following:

a) Current practices regarding the assessment and promotion of skin health

b) Prioritisation of skin care

c) Barriers to providing adequate skin assessment and treatment

d) Factors which place neonates at increased risk of skin breakdown

e) Role of the TVN team in neonatal skin care

2. To identify staff concerns, related to skin damage, which have not yet been raised in the academic or professional literature

3. To inform the design and content of a future study looking at the prevalence and incidence of skin damage in neonatal units

6.1.2 Objectives of prevalence and incidence study

1. Report point prevalence of all forms of skin damage across two neonatal units

2. Report incidence rate of all forms of skin damage across two neonatal units

3. Categorise skin damage according to type and severity

4. Report any associations between a number of potential risk factors and development of skin damage in the neonatal intensive care setting

6.2 Summary of key findings

This research has identified a number of potential determinants of change in this environment. Factors that emerged from the research as potential barriers to the protection and promotion of skin health on the neonatal unit are presented in .

6.2.1 Analysis of nursing practice and beliefs

The survey, and the follow-up data collection in the form of a focus group and two interviews, found that nursing staff working with neonates believed that skin damage occurs frequently in neonates, who are at high risk because of their fragile skin and the amount of care required in order to treat them. Twenty-six percent of survey participants reported that they see skin damage on every shift, a statement echoed by the participants in the focus group. The participants in all aspects of this analysis reported that they thought skin care and the prevention of damage was an important part of their job, though neonatal nurses reported that competing clinical demands and the high acuity of their patients meant that this could not always be their top priority.

The educational needs of neonatal nurses were highlighted in this analysis. Though both the survey and the focus group suggested that there is a culture on the neonatal unit of passing on practice from one member of staff to another, including advice related to skin care, this was not always done in a systematic way. This is reflected in the fact that only six of the survey respondents had received formal skin care training since they started working with neonates. Participants in the focus group reported that they would value more education on this subject for themselves and for their colleagues.

Additionally, the highly specialist nature of neonatal care and the unusual environment in which it takes place can act as a barrier to external teams such as the TVN team. This barrier appears to

function both inside-out and outside-in: neonatal nurses are used to managing their patients' wounds and do not consider contacting the TVNs, who are unlikely to have experience or knowledge of neonatal skin; and TVNs who are unfamiliar with the population are hesitant to involve themselves in the care taking place on the unit. There also appears to be a degree of normalisation of skin damage on the neonatal unit. These issues, in turn, leads to a lack of reporting and escalation of wounds, which may prevent learning from being shared.

Lastly, the vulnerability of this population to damage from medical devices was underscored in the findings across this aspect of the project. Neonatal nurses reported a number of strategies used to minimise the risk of skin damage from device use, including modification of devices, rotation of sites, careful securing of devices, and minimal use of adhesive products. However, despite these strategies, they reported that damage still occurred. In some cases, this was exacerbated by inadequacies in the resources available to them. For example, some devices did not have a sufficient range of sizes to accommodate all the patients in their care.

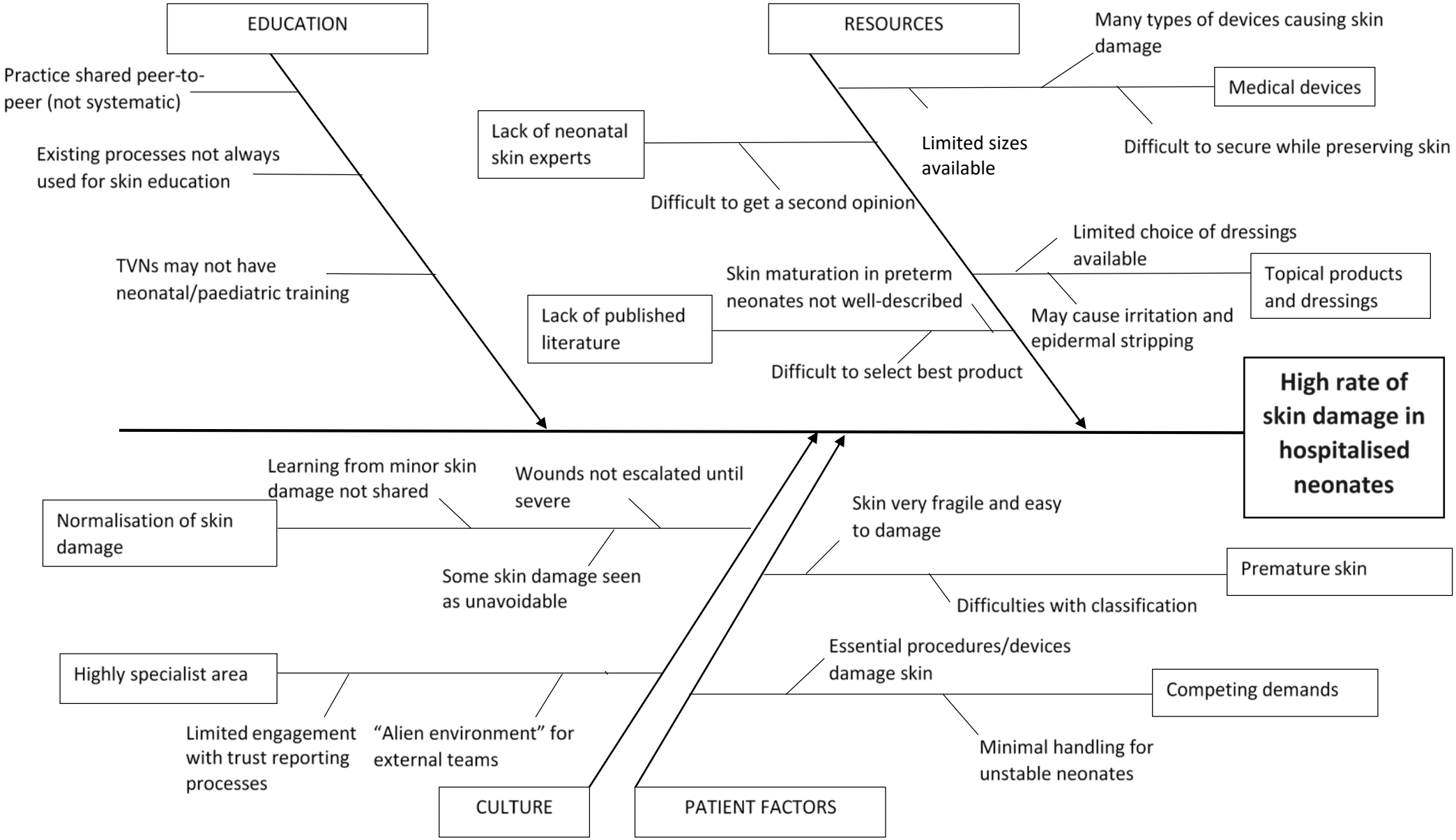
6.2.2 Prevalence and incidence study

This study found high overall rates of both prevalence and incidence of skin damage in this population. Both the prevalence and incidence studies found that diaper dermatitis was the most commonly-occurring type of damage, closely followed by device-related damage. Nasogastric/orogastric tubes were most common causes of device-related damage in the prevalence study, while CPAP was the device most commonly the cause of damage in the incidence study. However, many different devices were found to be associated with some sort of skin damage across the two studies.

The incidence study additionally found that extremely preterm neonates developed skin damage at a higher rate than neonates in any other gestational group. This finding was not mirrored in the prevalence study, which found that term neonates had the highest rate of damage. Both studies found a higher rate of skin damage in female neonates than in male.

The logistic regression analysis found that lower gestational age at birth was associated with increased risk of developing any skin damage and increased risk of device-related damage. Gestational age at birth was not associated with the risk of developing diaper dermatitis, and birthweight was not associated with any of these outcomes.

Figure 6.1 Fishbone diagram showing key barriers to the prevention of skin damage on the neonatal unit



6.3 Discussion of the findings across the project

The key findings of this research project will be set in the context of the literature and the determinants of change (Wensing, Bosch and Grol, 2013a). In keeping with the principles of the ICM, factors identified as facilitators in this environment can be used to help overcome some of the barriers (Grol and Wensing, 2013). Barriers are depicted in Figure 6.1, which demonstrates the interactions between different factors and the way in which these contribute to a high rate of skin damage in hospitalised neonates. Both barriers and facilitators are discussed below, and suggestions for future practice that harness the facilitators in order to address some of the barriers are discussed in section 6.6.

6.3.1 Individual health professional factors

Individual health professional factors, which in the ICM include *knowledge and skills, cognitions including attitudes,* and *professional routines and characteristics* (Wensing, Bosch and Grol, 2013a)*,* were found during the research project to be largely facilitative of skin health in neonatal units.

6.3.1.1 Knowledge and skills

The determinant *knowledge and skills,* classed in *individual health professional factors* by Wensing and colleagues (2014), encompasses factors such as professional knowledge, decision-making, information seeking, and insight into own practice. In this research project, confidence and experience also emerged as key factors in individuals' knowledge and skills.

By comparing the findings of the survey and the findings of the prevalence and incidence study, it can be seen that participants generally had good knowledge of and insight into the scope of the problem of iatrogenic skin damage. Many of the concerns raised by participants in the survey were found to be accurate. For example, comparing the figures showing perceived location of at-risk areas from the former, and locations of actual new damage during the latter, there is some overlap (Figure 6.2). Although damage to the face generally was more common in the incidence study, and damage to the nose less common, it is likely that this reflects a wider practice change to use CPAP less frequently. Humidified high flow oxygen is now used more frequently than at the time of the survey. Although it causes less nasal trauma than CPAP (Collins *et al.*, 2014), it can cause damage to the cheeks. Similarly, participants in the survey identified the foot/heel as an area particularly prone to skin damage, which was not reflected in the findings of the prevalence and incidence study. This is probably due to the fact that damage from heelpricks and

needlemarks was not counted in the incidence figures, unless the wounds had started to deteriorate.

Participants' concern about diaper dermatitis is borne out by the findings of the prevalence and incidence study that diaper dermatitis was the most commonly occurring form of skin damage in this population, as well as by a recent report suggesting that diaper dermatitis is the form of skin damage that most commonly requires active wound management in the neonatal unit (Meszes *et al.*, 2016). The fact that these and other concerns raised by survey and focus group participants were borne out in the prevalence and incidence study suggests a fairly good understanding on the part of the neonatal nurses into the causes of skin damage on the unit.

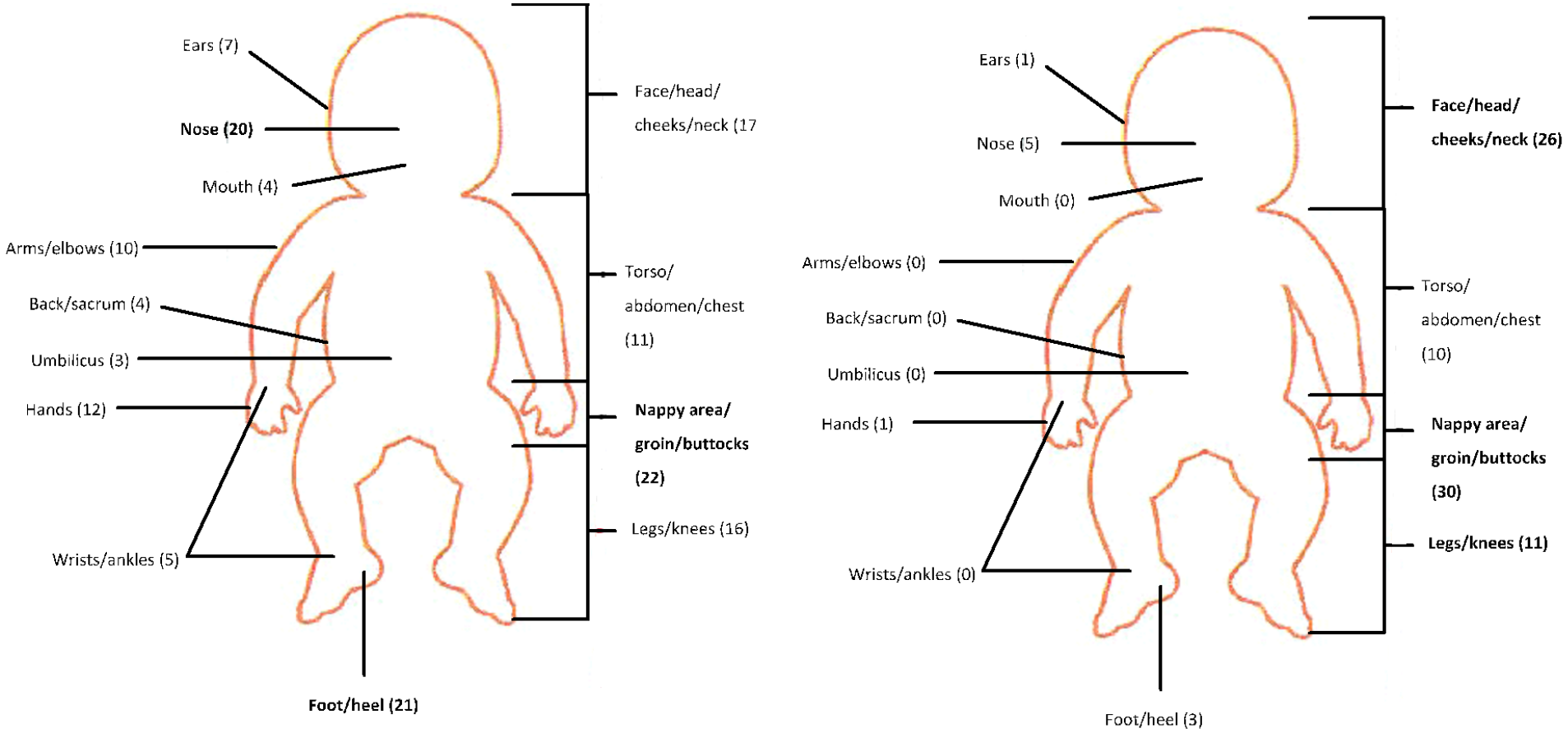


Figure 6.2 Frequent locations of skin damage as identified by survey participants (left) and observed in the incidence study (right)

As a consequence of their awareness of the causes of skin damage, nurses in the neonatal unit have developed a set of practices and skills designed to minimise the risk. These cannot be assessed against an existing evidence base in the same way that adult nurses' knowledge of PU prevention can (Beeckman, Schoonhoven and Defloor, 2008), due to lack of previously published research on the subject. Preventative practices include regular rotation of specific devices, judicious use of tape, modifying or padding devices where possible, and using the minimum amount of pressure necessary to achieve efficacy for devices such as CPAP. However, despite these practices, skin damage continues to occur, suggesting that other factors are involved.

Research among adult nurses has found that, even when nurses have theoretically adequate knowledge of PU prevention, they do not demonstrate a reflective approach to this area of their practice and therefore may not be using their knowledge (Athlin *et al.*, 2010). In contrast, the participants in the focus group and some of the participants in the survey identified gaps in their own skin knowledge. Participants in the focus group in particular reported times when they had made mistakes and demonstrated a reflective attitude towards learning, as well as a belief that they would always be learning. This suggests that these participants are willing to integrate new knowledge into their skin care practice, something that it has previously been suggested neonatal nurses struggle with (Mohamed, Newton and Lau, 2014).

Despite the generally good insight into the problem and into their own behaviour demonstrated by participants in both the survey and the focus group, there did appear to be gaps in neonatal nurses' knowledge. It was reported by the TVNs who participated in this research that neonatal nurses do not often associated wounds with pressure and therefore may misidentify PUs and other wounds, leading to a lack of escalation (see 7.3.5.5 for further discussion of reporting and escalation).

6.3.1.2 Cognitions including attitudes

Nursing staff who participated in this research generally spoke of the prevention of skin damage as an important part of their role, despite a number of competing clinical demands. (see 6.3.3). Although it has previously been suggested that busy RNs may see PU prevention as a task to be delegated to students or healthcare support staff (Sving *et al.*, 2012), this was not reflected in our findings. Indeed, participants in the focus group expressed distress at the fact that neonates in their care experienced skin damage, and stated that it was their responsibility to prevent it wherever possible. This is noteworthy because nurses' efforts to prevent skin damage can be linked to the value they place on it (Samuriwo, 2010b).

Surprisingly, participants did not only place value on preventing serious skin damage, but also recalled instances where they had caused fairly minor damage, as having caused sensations of guilt or distress. Previously it has been suggested that nurses have to encounter a "worst ever" pressure ulcer in order for them to place a high value on PU prevention (Samuriwo, 2010a), but participants in the focus group and in the survey referred to the importance of preventing relatively superficial damage as often or more often than preventing severe damage.

6.3.1.3 Professional routines

Professional routines such as regular skin assessment and sharing information at handover emerged from the analysis of nursing practice and beliefs as tools to prevent skin damage. Regularly assessing the skin of patients at risk of PU development, especially skin underneath medical devices, is a recommended measure to reduce the risk of skin damage (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014). However, 21 different assessment routines were described by participants in the survey based on preference, condition of the neonate, presence of particular devices, and various other criteria. Equally, one participant in the focus group reported that during handover she and the receiving nurse would look at the neonate together, in order to ensure that no skin damage had been missed. Systematic checks at handover have been suggested as a tool to minimise the number of critical incidents occurring in NICU and PICU (Frey *et al.*, 2000). Similarly, after a standardised handover process including information about skin was introduced in an adult ITU, nurses were significantly more likely to perform tasks such as checking of pressure areas (Malekzadeh *et al.*, 2013). However, routines such as these are more effective when they are carried out universally rather than according to personal preference, as appears to be the case here. Although professional routines do not appear to be detrimental to skin care in this environment, it is possible that standardising these would increase their effectiveness.

6.3.1.4 Confidence and experience

The importance of confidence and experience emerged from both the focus group and the interviews. Experience in any given clinical speciality has been linked to better clinical decision-making in general and in relation to pressure ulcer prevention (Banning, 2007; Moore, 2010). In this instance, participants in the focus group linked willingness to challenge and question other members of staff to becoming more experienced themselves. This confidence allowed them to learn from other staff members without feeling self-conscious, as well as promoting patient safety by feeling able to challenge bad practice (Garon, 2012).

6.3.2 Culture of the neonatal unit

6.3.2.1 Peer-to-peer education

Peer-to-peer education was reported by participants in both the survey and the focus group to be the primary means by which they develop their skin care knowledge and skills. The chief advantage of this system is that it appears to encourage a culture on the unit wherein staff continue to learn daily and are aware of their own education needs. Given the lack of evidence and difficulties cited by TVNs in obtaining neonatal skin training, it is unsurprising that neonatal nurses are relying on word of mouth to learn from one another and update their practice. However, this also means that information is not always shared systematically across the unit, and certainly not across the ODN. Though peer education has been used to good effect in previous efforts to decrease PU prevalence (Kelleher, Moorer and Makic, 2012; Price *et al.*, 2017), this is generally in the form of skin champions or other semi-formal role in which the peer educator has had some form of training. The present system means that there is a risk bad practice will be shared as easily as good, in addition to the probability that not all members of staff will be made aware of new practices.

6.3.2.2 Normalisation

High prevalence and incidence rates of skin damage were observed during this research project, much of which was associated with the use of essential medical devices. This corresponds to what was expected based on the findings of the survey, as well as other studies in this population (Visscher and Taylor, 2014; Nist *et al.*, 2016). Both TVNs interviewed for this research believed that the high rate of skin damage that occurs on the neonatal unit, as well as the fact that such a high proportion is associated with medical device use, contributes to a degree of normalisation of skin damage on the unit. This normalisation, in turn, was thought to lead neonatal nurses to believe that nothing could be done to prevent damage. Given that nurses' attitudes towards PU prevention have been shown to be correlated with preventative behaviours while knowledge is not (Beeckman *et al.*, 2011; Demarré *et al.*, 2012), and indeed one study showed an inverse relationship between knowledge and attitude (Cullen Gill and Moore, 2013), it may be that the knowledge demonstrated by neonatal nurses is not being used in practice. Normalisation of damage due to high rates thereof would, in this way, be contributing to even higher rates of damage.

The TVNs' perception that this normalisation had contributed to a feeling of inevitability was not entirely borne out by the focus group, however. Although participants in the focus group did comment that some forms of skin damage were unavoidable, they described a number of steps

taken to minimise the risk of skin damage to neonates. Nurses' practices were not directly observed during this study, so it is impossible to determine whether individuals were carrying out the preventative steps they reported. However, it was noted throughout the incidence study on Unit 2 that preventative measures such as foams for ET tubes, reported by nurses in the focus group, were in use.

6.3.2.3 Highly specialised area

The neonatal unit is a unique and highly specialised area, with extremely vulnerable patients, a high acuity of care, and a number of interventions and therapies being carried out at any one time. This appeared to act as both an inside-out and an outside-in barrier to the involvement of TVNs on the unit. Because neonatal nurses were so used to managing the risk of skin damage in their patients, they rarely contacted the TVN team. Conversely, the unusual environment and high number of interventions being carried out were reported to make the neonatal unit difficult to access. Indeed even the TVN with neonatal experience reported that she would no longer feel comfortable turning or handling a premature neonate. No other studies have been identified exploring the experience of non-paediatric specialist teams when working with neonatal units or other specialist paediatric environments.

6.3.3 Patient factors

6.3.3.1 Fragility of neonatal skin

The vulnerability of neonatal skin, especially in those born extremely prematurely, was highlighted throughout the entire research project. Effects of premature skin noted during the project included device unsuitability, vulnerability to chemical burns, difficulties in assessment and classification, lack of appropriate dressings and topical products, and complications with handling and repositioning. This is reflected in the fact that all the extremely preterm neonates enrolled in the incidence study developed at least one instance of skin damage. These issues have been noted previously, particularly the increased vulnerability to various types of skin damage (Newnham *et al.*, 2013). Neonatal health professionals use a variety of strategies to manage the clinical consequences of being born with an immature barrier, such as humidification (Sinclair, Crisp and Sinn, 2009; South Central Network Quality Care Group, 2012). Despite these strategies, however, the fragility and immaturity of the skin remains one of the most difficult challenges facing neonatal nurses when trying to prevent skin damage.

6.3.3.2 Competing demands

Throughout the analysis of nursing practice and beliefs, especially the focus group and interviews, the competing demands and difficulty of prioritisation in this environment was apparent. Nursing staff working with critically ill neonates have to balance skin care with a range of pressing clinical needs, deciding what is most important at any given time and how best to achieve this. Interventions ranging from insertion of peripheral cannulae and heelprick blood tests to the use of respiratory support were all cited by participants as particularly difficult to balance with the maintenance of good skin health. Difficulties have previously been reported in providing skin care to critically ill adult patients in intensive care environments (Strand and Lindgren, 2010), even without the addition challenges posed by the fragility of premature skin. This is further underscored by the high proportion of device-related damage found both in our incidence study and in others conducted in this population (Visscher and Taylor, 2014; Nist *et al.*, 2016).

6.3.4 Incentives and resources

6.3.4.1 Issues with devices and dressings

Prior to commencing this research project, it was already clear from a review of the literature that medical devices were frequently implicated in neonatal skin damage (Newnham *et al.*, 2013). Findings from across all involved studies confirmed this, with participants in the analysis of nursing practice and beliefs expressing concern about many devices and the methods of securing these such as tape. Device-related damage additionally contributed to the overall high rates of damage in the prevalence and incidence study. Indeed damage was not limited to devices such as respiratory support used primarily on unwell neonates, but was also observed in relation to devices such as apnoea monitors, which are used primarily on neonates who are well enough not to require more extensive monitoring. Even Duoderm, used as a prophylactic barrier between nasal oxygen or NG tubes and the skin, caused irritation in some neonates.

Participants raised particular concerns about the limited sizing of some devices, as well as the difficulty of maintaining clinical efficacy without placing excessive pressure on the skin and soft tissues. Although more consistent education could help with this, it is clear that some devices used regularly in the neonatal unit would benefit from being redesigned with neonatal anatomy and physiology in mind. This has been previously noted, especially with regard to nasal CPAP and to a lesser extent other respiratory support (Fujioka *et al.*, 2008; Carlisle *et al.*, 2010; Collins *et al.*, 2014). Indeed clinicians have reported fashioning makeshift oral CPAP out of an ET tube in an attempt to reduce the amount of pressure applied to the nose and cheeks (Carlisle *et al.*, 2010).

6.3.4.2 Risk assessment tools

RAS related to PU development or other skin damage are not used in either of the two units where prevalence and incidence data were collected, nor did participants in the focus group use them. Though one participant appeared to refer to the NSRAS in the survey, overall participants in the study seemed to conflate risk assessment and skin assessment, suggesting that routine use of RAS is not commonplace in units across the network. Although a second risk assessment tool is currently in development for this population (Vance *et al.*, 2015), it is unclear whether this would be of benefit to the units studied in this analysis. The clinical utility of RAS for preventing PU development has been called into question in recent years (Webster *et al.*, 2011). Additionally, participants in the survey and focus group were already aware of the increased risk posed by factors such as extreme prematurity, and already taking steps to minimise the risk to these neonates. It may be that a simpler screening tool, such as a revised version of the neonatal pressure ulcer trigger tool (Schumacher, Askew and Otten, 2013), would be of use. Alternatively, it may be of more benefit to devote the staff time and resources that could be spent on risk assessment on increased frequency of skin assessment, and reacting to superficial damage before it has a chance to escalate.

6.3.4.3 Skin assessment

In contrast to RAS, a need for coherent guidelines on skin and wound assessment is clear throughout the findings of all the studies in this project. The Neonatal Skin Condition Score (NSCS) is intended to be used for skin assessment in hospitalised neonates, and has subscales for dryness, erythema, and breakdown. It has been shown to have good interrater reliability (Lund and Osborne, 2004). Although it is not designed to assess individual wounds and therefore would not resolve the classification difficulties found in this project, it is possible that daily skin assessments using a tool such as the NSCS would prompt neonatal nursing staff to escalate any damage that does occur more quickly.

Differences in the perspectives of neonatal nurses and TVNs with regard to assessment and classification were apparent during the first phase of the data collection. One participant in the focus group referred to a particular wound as a '*hole'* on the nose, but went on to describe the CPAP that caused it in detail, as well as the skin care difficulties associated with that device. In contrast, a TVN referring to a similar wound described it as a '*grade IV pressure ulcer'*, also on the nose, but simply reported that it had been caused by a '*tube'*. It is apparent that, in order to address the difficulties associated with assessing, classifying, and identifying causes of skin damage in this population, the perspective of both neonatal specialists and tissue viability specialists would be beneficial. This has previously been identified in the neonatal unit, where

involvement of WOCN in weekly skin rounds and staff education improved the consistency and quality of skin assessment and reporting of PUs (Nist *et al.*, 2016).

Accurate classification of wounds is essential for treatment, and, in the trusts in which the majority of this research took place, it is also linked to reporting and investigation. Although studies of skin damage in neonates have often used international guidance for the staging of PUs to report severity of wounds (August *et al.*, 2014; Visscher and Taylor, 2014; Nist *et al.*, 2016), the incidence study found that this was challenging for neonates who had been born very or extremely preterm and therefore still had fragile thin skin. Additionally, indentation marks, bruising, and other atypical manifestations of pressure damage further complicated this issue. Research is required into the validity of the NPUAP/EPUAP staging system for wounds in this population, as well as into classification of indentation marks and other skin damage such as irritation and moisture lesions.

6.3.4.4 Reporting processes

In adult inpatient environments, the reporting of PU development in particular is considered strategically important in order to allow trusts to make informed decisions about issues such as resource allocation. Reporting skin damage is additionally an important aspect of education. Although some element of reporting and escalation appeared to be happening within the unit, this was not always in accordance with trust processes, and often did not occur unless damage was severe. Differences in the way that TVNs and neonatal nurses think about reporting were apparent in the focus group and interviews. In the focus group, incident reports were considered another aspect of professional routine and were raised in the context of documentation, whereas TVNs considered reporting and escalation to be essential in analysing skin damage and preventing future incidents. The TVNs additionally linked a lack of reporting to the normalisation of skin damage on the unit (see section 6.3.2.2). Classification and reporting of skin damage in the neonatal unit is a complex issue that has been gaining more attention in recent years (Nist *et al.*, 2016).

Only one participant in all of these studies referred to the MHRA, a TVN with a specific interest in medical devices and vulnerable skin. In the focus group with neonatal nurses, the participants were not aware of the MHRA or of reporting processes around medical device-related damage. Though it is clear from the findings of that focus group that there are some processes in place to deal with recurrent issues associated with particular devices, this seems to be carried out on a fairly ad hoc basis, and standardised processes for reporting medical device-related damage are not in place. Although participants in that study had access to two technicians who are based on the unit, most neonatal units do not have this resource and would not be able to easily obtain

advice from specialists in this area. In their study of paediatric tracheostomy-related PUs in a long-term ventilation unit, Boesch and colleagues found that manufacturers redesigning their devices was a key factor in reducing the incidence (Boesch *et al.*, 2012). As identified in the interviews, substantial improvement of medical devices by manufacturers is not likely to be improved without systematic reporting of device-related skin damage by clinicians.

6.4 Limitations of the research project

Within the scope of the doctoral research project, it is impossible to consider every aspect of the issue. For example, though neonatal nurses are a key provider of skin care in this population, parents are also likely to provide skin care to neonates in hospital. In the focus group and interviews, other professionals were also mentioned as important to processes such as reporting and prescribing, namely technicians and doctors. Data were not collected on these professionals' views during the research project, although three consultant neonatologists reviewed the protocol for the prevalence and incidence study. In order to develop a more comprehensive understanding of the issues raised in this project, further research with other professional groups would be beneficial, which is addressed in section 6.6.3.

Other than the interviews with the lead TVNs, all the studies in this project struggled to recruit. This is a recognised problem in healthcare research, with less than 31% of RCTs reaching their recruitment targets, for example (McDonald *et al.*, 2006). For future studies, it would be beneficial to allocate more time and resources to recruitment from the start. For example, had resources been available, it would have improved recruitment on the incidence study to have had the responsibilities for recruitment and data collection separated out to different members of staff in order to allow more time for both. Additionally, although the response of parents to the incidence study was generally positive, use of Patient and Public Involvement early in future research projects could benefit recruitment by suggesting the best possible methods by which to do this (Brett *et al.*, 2014). The limitations of the small sample sizes and the effect this has had on data collection and analysis are outlined in sections 4.7.6 and 5.9.6, particularly with regard to the focus group, where it was not possible to reach saturation.

There were also delays to the prevalence and incidence study, focus group, and interviews due to ethical approval difficulties that unavoidably affected data collection. These delays and their effects on data collection and analysis have been outlined in sections 4.7.6 and 5.9.6. Although it was initially believed that a generous time period was being allocated for governance processes for each study, this proved not to be the case. It is to be hoped that the changes that have

recently been made by the HRA and local R&D departments will go some way to addressing these problems for future research.

6.5 Novel contributions of this research

This research project has made several novel contributions to the body of knowledge on skin health and skin damage in neonatal units. Firstly, it represents the first analysis of the determinants of change in the neonatal unit regarding skin care practice. In particular, it reports the beliefs, assessments, and interventions of key stakeholders in the process, namely neonatal nurses and TVNs. The finding that the highly specialist nature of neonatal care acts as both an outside-in and an inside-out barrier to the involvement of TVNs, as well as an obstacle in engaging with reporting processes, has not previously been reported. Additionally, this study has reported neonatal nurses' and TVNs' perceptions of the risks to skin health in this environment, as well as the strategies currently utilised to manage this. Indeed the vast majority of staff perceived skin damage as a frequent and challenging issue.

This PhD thesis also reports the first prevalence and incidence study of neonatal skin damage to include all forms of skin damage rather than focussing on MDPRUs, immobility PUs, or diaper dermatitis. It has therefore been the first study to report the proportions of these types of damage in this population. The incidence study, in particular, is the first study of skin damage in this population to have treated GA at birth as a continuous rather than a dichotomous variable, and therefore possible nuances in the risks posed to neonates of different gestational ages were identified.

6.6 Future work

6.6.1 Characteristics of previously-successful interventions in relation to skin health

Although hospital-acquired skin damage, especially PU development, continues to be an issue in many clinical settings (see section 2.5), some teams have seen a measure of success with interventions to reduce prevalence. Three interventions in particular are summarised in **Error! Reference source not found.**. This table does not present an exhaustive list of all successful interventions that have been reported in the literature. Rather, it presents three approaches that have been successful, and the three interventions selected demonstrate the evolution of interventions in this field. Interventions to prevent PU development have become gradually more complex over time, as more is understood about the field. Though these projects and studies have been carried out in a variety of clinical settings and with a range of interventions, they have some

characteristics in common. Firstly, all three combined several different components. Staff knowledge and attitudes, available resources, and time available to commit to prevention activities are all implicated. Issues of interventional medical devices, factors intrinsic to individual patients, and priorities in a given clinical area are also relevant.

Table 6.1 Summaries of three successful skin-related interventions

Reference	**Clinical context**	**Breakdown of intervention(s)**	**Findings**
Boesch *et al.* (2012) 'Prevention of tracheostomy-related pressure ulcers in children', *Pediatrics,* **129**(3): e792-7	Paediatric long-term ventilation unit with 18 beds, operating as a step-down from ITU and to facilitate transition of children requiring long-term ventilation at home	• Instigated due to a higher than expected rate of tracheostomy-related PUs • Based on "Plan-Do-Study-Act" model (Langley *et al.*, 2009), with intention of trialling and adapting several small interventions and combining them into a bundle • Key drivers for intervention developed following literature review and previous analysis of issue • Education of all nursing staff on issues associated with PU risk • Parent education by staff • Regular monitoring and evaluating of PU occurrences during study, including changes to intervention • Changes to assessment and documentation by nursing staff • Alterations to existing device care (e.g. inserting Mepilex dressing between tracheostomy tube and skin) • Redesign of device through partnership with industry, with specific focus on reducing pressure at the neck and sternum	Tracheostomy-related PUs decreased from 8.1% prior to intervention to 0.3% at the end of the implementation period
Visscher *et al.* (2013) 'A quality-improvement collaborative project to reduce pressure ulcers in PICUs', *Pediatrics,* **131**:e1950	One 42-bed PICU and one 53-bed NICU	• Use of Plan-Do-Study-Act cycles • Formation of multidisciplinary quality improvement team • Analysis prior to implementation: collecting data once every two weeks on all inpatients, with a focus on severity and aetiology of PUs • Using a risk assessment scale • Four hourly repositioning • Moisture management • Head-to-toe assessment • Staff and parent education	PU incidence in PICU fell from 14.3/1000 patient days prior to interventions to 3.7/1000 patient days subsequently PU incidence remained low in NICU at 0.9/1000 patient days

		• Use of specialist mattresses and staff training in use of positioning aids • Changes to assessment with a view to developing systematic process for identifying "abnormal" skin features such as blistering, nonblanching erythema • Development and training of "skin champions" • Twice weekly skin rounds • Development of skin and wound care plans	
Price *et al.* (2017) 'Education and process change to improve skin health in a residential aged care facility', *International Wound Journal,* (epub ahead of print)	Two residential care homes for older people with a total of 261 residents	• Four distinct phases • Phase 1: Fortnightly prevalence studies and assessment of participants' knowledge • Phase 2: Implementation of an intervention comprised of several components. This included resident involvement and education, face-to-face group education, e-learning, nurse practitioner support, one-on-one training sessions, bedside reviews with senior staff, and workshops. • Phase 3: repetition of data collection from Phase 1 • Phase 4: analysis and evaluation of the results	PU prevalence decreased from 12.5% to 6.8% (p=0.01). Staff reported skin damage at an earlier stage. Altered use of skill mix—e.g. unregistered staff spending more time on fundamental care, and RNs spending more time on the prioritisation of care, such as carrying out risk assessment.

All three interventions began with an analysis of the problem. This is essential for the success of any intervention, as outlined in section 3.2, and two of the three studies listed above specifically reported this as a stage in their research (Visscher *et al.*, 2013; Price *et al.*, 2017). Two of the studies additionally report the identification of key drivers for the intervention, prior to implementation, as a part of the planning or pre-work stage (Boesch *et al.*, 2012; Visscher *et al.*, 2013). However, two of the three studies used a rapid Plan-Do-Study-Act cycle and the other did not report following a particular implementation model. Therefore, despite the identification of key drivers, no study reports specifically identifying barriers to and facilitators of practice change prior to implementation of the intervention, although observing and dealing with obstacles is inherent to the iterative change process described by all three.

By conducting a thorough analysis of the clinical, cultural, and individual issues associated with skin damage in this environment prior to selecting or designing an innovation, we have avoided some of the issues noted in the studies listed above, which had to regularly identify problems throughout implementation due to the rapid Plan-Do-Study-Act process used. Our thorough analysis has allowed us to anticipate some of these issues. For example, Boesch and colleagues (2012) identified key drivers from the literature and from data looking reduction of all PUs. They did not see a significant reduction in PUs until the tracheostomy tubes in use were redesigned through collaboration with industry and the new devices were available. This issue was specific to that clinical environment, a paediatric long-term ventilation unit where tracheostomies were used extensively. Similarly, Visscher and colleagues (2013) did not involve junior nursing staff in the design of the intervention or carry out an analysis of the target group prior to beginning their quality improvement project, and therefore did not introduce new educational interventions until the quality improvement project had already been running for ten months. Our evaluation has been carried out in much more depth. It has therefore identified some of the key barriers to and causes of skin damage specific to neonates and the neonatal unit environment, prior to the commencement of any change. Additionally, by using the determinants of change to inform the analysis, factors that are likely to facilitate change and routines into which interventions can be integrated were identified. This has allowed for the proposal of interventions most likely to address the unique issues that affect this population, as well as being sustainable and workable in this complex environment.

Another hallmark of all three studies was that frontline clinical staff were involved in designing, improving, evaluating, or leading the implementation of change. This involvement varied in scope and nature, from the development of a multidisciplinary team with responsibility for the study (Boesch *et al.*, 2012), to all willing participants filling out reflective diaries throughout the process

of change (Price *et al.*, 2017). However, despite these differences, it is clear that, especially in the two most recent studies, there were regular attempts to engage clinical staff as active participants of change (Visscher *et al.*, 2013; Price *et al.*, 2017). Staff were not being asked to deliver an intervention into which they had no input.

As identified in section 3.4, it has also been important in this research to involve clinicians, especially nursing staff, at all stages throughout this process. Lead nurses have been involved in the design of the research project from the beginning, and nursing staff from many roles have been involved as participants. The interventions proposed below are therefore truly reflective of the issues and challenges faced by these members of staff when dealing with the complex issue of neonatal skin. As far as possible, they make use of existing processes, relationships, and expertise rather than imposing new external structures on clinicians that risk being unacceptable to these clinicians or unworkable in the neonatal unit environment. Accordingly, these proposals for practice change are more likely to be adopted and integrated into practice in the longer term rather than resulting in temporary or superficial change.

6.6.2 Clinical practice

6.6.2.1 Education

The existing teaching processes in place at Unit 2 would be an ideal starting point for increasing the consistency of skin care education in this environment through a number of small changes, in keeping with the recommendation in the ICM that changes are more likely to be maintained if they are integrated into existing routines (Grol *et al.*, 2013). For example, advice on how to appropriately secure various devices could be displayed on the 'one minute wonder' board referenced by participants in the focus group. This would improve consistency of practice between staff rather than relying on word of mouth to share new practices.

Equally, given the strong emphasis on peer education as a facilitator of change in this environment, the use of 'skin champions' with a responsibility of keeping their colleagues up-to-date while being regularly updated themselves, could be beneficial, as it has been in other environments (Price *et al.*, 2017). This would be distinct from the surgical nurse role mentioned by participants in the focus group, as it would not be a nurse specialist role and the emphasis would be on prevention rather than managing existing wounds. In this context, the term 'champion' is being used to describe a member of staff internal to the unit with an interest in skin care, who would be involved at all stages when introducing both minor and substantial practice changes (Thompson, Estabrooks and Degner, 2006). It is suggested in the ICM that interventions are more likely to be acceptable if they are presented by someone regarded by the target group as a

member of that group rather than an outsider (Grol *et al.*, 2013). Given the importance of in-house expertise on the neonatal unit identified in the research project, it is reasonable to believe that this effect would be magnified in this environment. The role would be ongoing and would not be limited to a particular intervention or innovation.

In terms of more formalised education, this would benefit from including a variety of content. Based on the needs identified in this research, study days could include teaching on neonatal anatomy and physiology, wound assessment, and reporting processes. For example, it would benefit neonatal nurses to know about the weaker dermo-epidermal junction in premature neonates (Fox, 2011), as they would then understand why it is important to remove adhesive products carefully. Similarly, information on skin maturation *in utero* and following premature birth could be included in preceptorship. In keeping with the recommendations of the ICM, any formalised education should be based on a needs assessment, and should evolve over time in keeping with these needs (Grol *et al.*, 2013). Our research project has identified current educational priorities for neonatal nurses on the subject of skin health, but these will change as the treatments and therapies used in this environment change.

Changes to nursing education are already in progress at one of the two participating units, partly as a result of the high rate of skin damage found during this research project. Skin care education is being made statutory for nurses at this unit, with the possibility of this subject being included in preceptorship for new staff as well. The results of the research will be disseminated to clinical educators to support the development of new education packages that reflect the complex nature of the issue.

6.6.2.2 Reporting and interprofessional working

Previously successful attempts to reduce healthcare-acquired skin damage have included the involvement of staff from a variety of professional backgrounds. Increased co-ordination of care between different professionals is also one of the recommended strategies for introducing change on an organisational level in the ICM (Grol *et al.*, 2013), suggesting that this may be a suitable way to address some of the barriers related to organisational culture identified in this project. Although the majority of the research has been carried out among registered and unregistered neonatal nursing staff, other professional groups have been identified as important, especially collaboration between neonatal nurses and tissue viability nurses. One of the quality improvement projects identified in **Error! Reference source not found.**, carried out by Price and colleagues (2017), found that the involvement of a nurse practitioner to advise and educate staff nurses was essential to improvement.

The different perspectives and complementary skills of neonatal nursing staff and trust TVNs were highlighted during the focus group and interviews. In order to improve reporting and investigation of skin damage with reference to factors such as medical devices, it would be beneficial for neonatal nurses to have more involvement with TVNs. Although it is likely that resources would not allow for the weekly joint skin rounds used by Nist and colleagues (2016), it is possible that introducing weekly skin rounds by designated members of the neonatal nursing team, with training, support, and advice from TVNs, would have a similar effect on consistency of reporting and classification. It would additionally be beneficial for neonatal staff to have guidelines on when skin damage should be escalated to the TVN team.

As identified by participants in the interviews, the investigation of skin damage is essential for learning from incidents. However, due to the unique nature of the neonatal unit and the difficulties with classification in this environment, it is unlikely that an investigation process designed for adult wards would be of use. Instead, TVNs and neonatal nursing staff should work together to determine what reporting, escalation, and investigation processes should look like in this environment. This makes use of both skill sets in order to find something that is clinically useful for this patient group, and will facilitate shared learning.

6.6.3 Clinically-focussed research

Although there are some practice changes that can be introduced and monitored as a result of the findings in this series of studies, it is clear that more research is required in order to further elucidate this issue.

6.6.3.1 Other professionals

Other professionals directly or indirectly involved with neonatal skin care were identified during the analysis of nursing practice and beliefs, specifically technicians and doctors. Further qualitative research with these professionals would be of benefit to better understand their role in the provision of skin care and especially in reporting processes. Given that the two TVNs interviewed for this project had profoundly different relationships experiences with their local neonatal units, it would also be beneficial to interview TVNs from other sites in order to develop a more complete picture of this aspect of a TVN's role. Similarly, it would be helpful to carry out further qualitative research with neonatal nurses from other units to explore the findings of this project in other contexts.

Additionally, very few unregistered nursing staff were involved in this research project, despite efforts to recruit them. More research that specifically focusses on nursery nurses and healthcare

support workers should be conducted in order to understand challenges that these members of staff may face in delivering skin care. For example, it is likely that these members of staff are involved in preparing families for discharge, which may include teaching parents to care for a neonate discharged with a medical device *in situ*. These issues and others could best be explored in research specifically targeted to this staff group.

6.6.3.2 Skin and wound assessment

Though skin assessment occurs frequently on the neonatal unit, no standardised tool is currently used in the sites studied. The findings of this research suggest that nursing staff would find a standardised tool helpful. The NSCS has been suggested for this purpose (Lund and Osborne, 2004), and has been used to assess the skin of term and preterm neonates for research purposes (Garcia Bartels *et al.*, 2012; Newnam *et al.*, 2015). The NSCS has moderate interrater reliability, including among ELBW neonates (Lund and Osborne, 2004), and by attempting to assess skin dryness and erythema it addresses some of the issues raised in this study. However, at present, it is not clear whether it would be useful for routine clinical assessment, or whether there should be a particular score at which escalation of care should take place. It would be beneficial to explore this initially with neonatal nursing staff and TVNs, to determine whether they would find it helpful in identifying skin damage early and noting any deterioration. Subsequent research could include a trial of daily skin assessments with the NSCS looking at whether this led to skin concerns being escalated more quickly.

In addition to assessing general skin health, there is also a lack of clarity related to the assessment of individual wounds in this population. Although international pressure ulcer classification guidelines have been used in previous studies in this population, these are designed for use in adults and older children and the descriptions of the stages are therefore not written with the anatomy and physiology of premature neonates in mind. Research should therefore be conducted order to determine the validity and reliability of PU classification guidelines and other wound assessment tools in this population, particularly with a view to interrater reliability. If these tools are found to be unsuitable for the population, new tools should be developed in order to assist with classification, escalation, and management of neonatal wounds.

6.6.3.3 Topical products and dressings

The selection of topical products such as emollients and barrier creams remains largely driven by nurse and parent preference. This is due primarily to the lack of evidence available to inform the process. Clinical trials should be carried out looking at the efficacy of these different products in the neonatal unit, in order to develop a robust guideline for managing instances of diaper dermatitis and dry skin.

In the sites studied for this research, Duoderm was the dressing most frequently used as a preventative barrier between medical devices and skin, as well as on the knees of babies positioned prone. However, it was noted during the incidence study and focus group that Duoderm was sometimes associated with irritation and epidermal stripping when removed. Other

dressings have been used prophylactically under devices, including soft silicone foam dressings (Clark *et al.*, 2014). A trial comparing a soft silicone foam dressing to Duoderm in this setting would be beneficial to determine whether this would be associated with less irritation and trauma upon removal.

6.6.3.4 Medical devices

Although there are a number of practice changes proposed above that are likely to make a positive difference to skin care practice on the neonatal unit, the primary issue remains that many devices are fundamentally not suited to neonatal skin in general, and premature skin in particular. There is a clear role for industry in developing devices with softer interfaces that nonetheless provide the necessary support and treatment. Greater variability in sizing would also be of benefit for neonates, who may grow from 500g to 3kg during their stay in the neonatal unit. It would additionally be beneficial for industry to involve clinicians in the process of designing or refining medical devices.

Neonatal nurses demonstrated a clear understanding of the difficulties associated with device use in this research. However, it is also essential for device-related damage to be reported to the Medicines and Healthcare products Regulatory Authority (MHRA) in order to facilitate this change. This will incentivise industry to consider the unique anatomy and physiology of neonates, and the complexities of the clinical environment in which they receive care, when designing and redesigning devices. Awareness of the MHRA and guidance on whose responsibility it is to report device-related damage would therefore be vital considerations of any education package or reporting guidelines developed in response to this research.

6.7 Summary

The neonates being cared for in a NICU represent some of the most vulnerable patients in any healthcare environment. Their developmental immaturity, clinical instability, and requirement for multiple interventions contribute to a very high risk of iatrogenic events, including skin damage. This is reflected throughout the findings of this research project. During a prevalence and incidence study, high rates of skin damage were observed, with diaper dermatitis and medical device-related skin damage the most common forms of injury. Despite the high value placed on prevention of damage by nursing staff, the vulnerability of premature skin and inadequacy of many devices for this population make it extremely challenging to protect these patients from damage.

As a first response to this research project, steps to be taken clinically should include standardisation of skin care education for neonatal nurses, and engaging with trust reporting processes to allow learning from incidents to be shared. Longer-term practice changes could include the introduction of weekly skin rounds and training of skin champions. Priorities for future research have also emerged, including the design of devices and products that truly take into consideration the unique nature of neonatal anatomy and physiology.

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Appendices

Appendix A Example search strategy

24/9/2015 – Prevalence and incidence of hospital-acquired skin damage

CINAHL plus via Ebscohost

1. prevalence OR incidence OR frequency	237201
2. hospital-acquired OR healthcare-acquired OR iatrogenic OR healthcare associated OR hospital-associated	8624
3. pressure ulcer OR decubitus OR sore OR bedsore OR bed sore OR pressure injury OR pressure sore OR pressure damage OR hapu	13257
4. skin breakdown OR skin damage OR wound	34311
5. diaper dermatitis OR incontinence-associated dermatitis OR moisture lesion	212
6. skin tears	134
7. epidermal stripping OR skin stripping	39
8. S3 OR S4 OR S5 OR S6 OR S7	46466
9. S1 AND S2 AND S8	220
10. Limit S9 to English language	212

Read after review of abstract 18

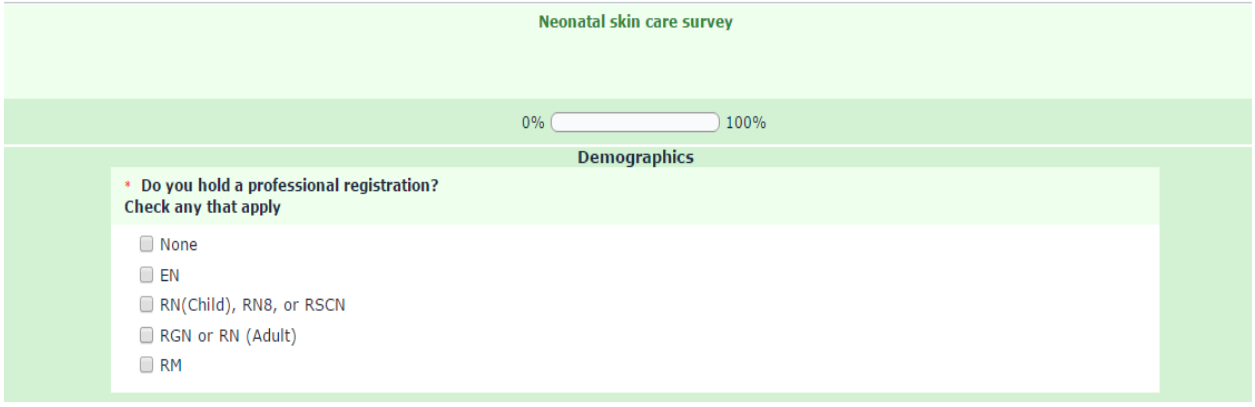
Appendix B Summary of the *Transepidermal Water Loss* series of studies by Hammarlund and colleagues 1977-1983

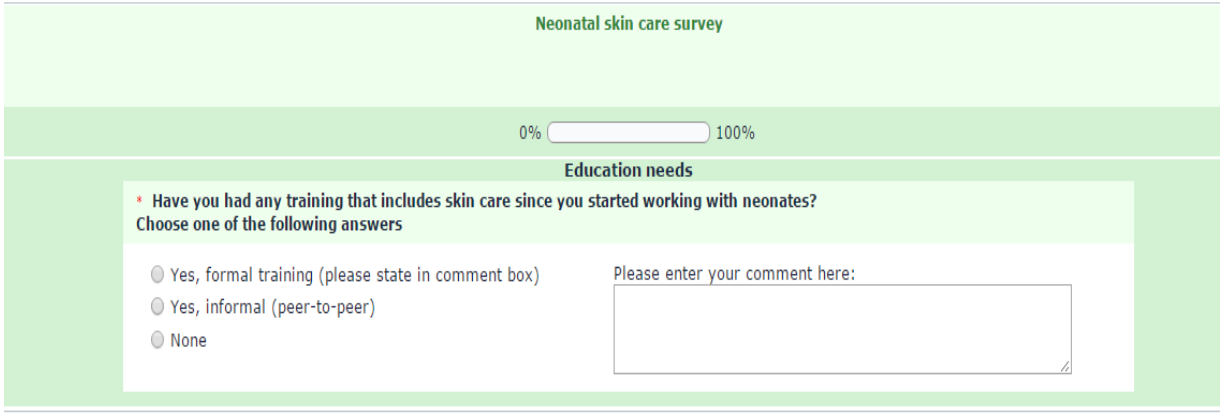
	Summary	**Results**	**Conclusions**
Hammarlund, K., Nilsson, G.E., Öberg, P. Å., and Sedin, G. (1977) 'Transepidermal water loss in newborn infants. **I**. Relation to ambient humidity and site of measurement and estimation of total transepidermal water loss', *Acta Pædiatrica Scandinavica,* **66**(5): 553-62	Description of TEWL measurement device and calculations Evaporation rate (from which TEWL was calculated) measured on 28 healthy term neonates at varying ambient humidities and anatomical sites	Mean TEWL in healthy term newborns of 8.1 g/m^{2}h at 50% ambient humidity	Provided guidelines on the new method of TEWL measurement Ambient humidity and TEWL varies depending on anatomical site
Hammarlund, K., Nilsson, G. E., Öberg, P. Å., and Sedin, G. (1979) 'Transepidermal water loss in newborn infants. **II**. Relation to activity and body temperature', *Acta Pædiatrica Scandinavica,* **68**(3): 371-6	Evaporation rate measured in 10 healthy term neonates at rest and during activity (crying) Evaporation rate measured in 9 healthy term neonates during a rise in body temperature (through use of humidified incubators)	Mean TEWL before activity 5.3 g/m^{2}h Mean TEWL during activity 6.4 g/m^{2}h Mean TEWL after activity 3.9 g/m^{2}h TEWL rose nearly 80% at body temperature of 37.2˚C	TEWL increases with activity (37% higher) TEWL increases significantly with a body temperature of >37.1˚C
Hammarlund, K., and Sedin, G. (1979) 'Transepidermal water loss in newborn infants. **III**. Relation to gestational age', *Acta Pædiatrica Scandinavica,* **68**(6): 795-801	Evaporation rate measured in 12 neonates of 25-30 weeks' GA, 10 neonates of 32-35 weeks' gestation, and 10 term neonates	Neonates of 25-30 weeks' GA had a mean evaporation rate of 44 g/m^{2}h Neonates of 32-25 weeks' GA had a mean evaporation rate of 6.2 g/m^{2}h Term neonates had a mean evaporation rate of 3.5g/m^{2}h (Calculated TEWL means not given for this study)	TEWL 15 times higher in neonates of 25-30 weeks' GA than in term neonates Exponential relationship between TEWL and GA
Hammarlund, K., and Sedin, G. (1980) 'Transepidermal water loss in newborn infants. **IV**. Small for gestational age infants', *Acta Pædiatrica Scandinavica,* **69**(3): 377-83	Evaporation rate measured in 25 small for gestational age (SGA) neonates of 30-40 weeks' GA. TEWL estimated from this value and compared with pre-existing data from appropriate for gestational age (AGA) neonates. Evaporation rate was also measured for these neonates at different relative humidities.	Mean estimated TEWL for term SGA neonates was 2.8 g/m^{h}h, compared with 5.3 g/m^{2}h for term AGA neonates. This trend is continued in moderately preterm neonates. Two SGA neonates were found to absorb water from the environment (negative TEWL)	Term SGA neonates have a significantly lower TEWL than AGA neonates. Reaction to changes in ambient humidity same in both groups.
Hammarlund, K., Nilsson, G. E., Öberg, P. Å., and Sedin, G. (1980) 'Transepidermal water loss in newborn infants. **V**. Evaporation from the skin and heat exchange	ER, ambient temperature, body temperature and skin temperature measured in 21 healthy term neonates regularly for 2 hours postnatally: from 1st minute of life in	Water loss immediately after birth high in vaginal delivery series (103 g/m^{2}h), had decreased to approx. 30 g/m^{2}h by 0.5 hours in both series	Evaporative water loss & associated heat loss very high in first minutes of life, decreasing to a

during the first hours of life', *Acta Pædiatrica Scandinavica,* **69**(3): 385-92	10 neonates born vaginally; from 30th minute of life in 11 born by Caesarean section Heat exchange calculated from these data	Series 1 reached more moderate water losses by 1h of life, series 2 by 2h Heat loss also decreased over first hour of life, but was 3 times higher in the delivery room than in incubators	moderate level by 1 hour of life Significantly more heat lost via radiation in the delivery room than in the incubator
Hammarlund, K., and Sedin, G. (1982) 'Transepidermal water loss in newborn infants. **VI**. Heat exchange with the environment in relation to gestational age', *Acta Pædiatrica Scandinavica,* **71**(2): 191-6	ER measured at varying ambient humidities on 41 neonates between 25-39 weeks' GA TEWL calculated from ER for 52 neonates between 25-39 weeks' GA Skin temperature, body temperature, ambient temperature and incubator wall temperature measured in all cases Heat exchange calculated from these data	TEWL and evaporative heat loss demonstrated similar relationships with GA: lower GA associated with greater degree of evaporative heat loss Neonates born <28 weeks' GA required high temperatures or high humidity to maintain normal body temperature	In very preterm neonates, a high ambient humidity or a high ambient temperature are required in order to maintain temperature. Preterm neonates lose a greater proportion of heat through evaporative loss than term neonates.
Hammarlund, K., Sedin, G., and Strömberg (1982) 'Transepidermal water loss in newborn infants. VII. Relation to post-natal age in very pre-term and full-term appropriate for gestational age infants', *Acta Pædiatrica Scandinavica,* **71**(3): 369-74	ER measured in 34 neonates repeatedly over first 4-5 weeks of life: 7 were born at 25-27 weeks' GA, 13 at 28-30 weeks, and the remaining 14 were term. All neonates were AGA. TEWL calculated.	Mean TEWL in neonates 25-27 weeks' GA was 45.4 g/m^{2}h, decreasing to 18.3 after 5 days and 8.9 g/m^{2}h after 4-5 weeks Mean TEWL in neonates 28-30 weeks' GA was 18.6 g/m^{2}h, decreasing to 11.3 after 5 days and 5.9 g/m^{2}h after 4-5 weeks. Mean TEWL for term neonates was 3.8 g/m^{2}h on the first day of life; this did not change until 2 weeks of age, when it increased to 4.7 g/m^{2}h	TEWL decreases in preterm neonates after birth, and is still more than twice as much as that of healthy term neonates by 4-5 weeks of life In term neonates, TEWL is stable for the first two weeks of life, and increases in the following two weeks. It is possible that this may be due to postnatal changes in metabolism.
Hammarlund, K., Sedin, G., and Strömberg (1983) 'Transepidermal water loss in newborn infants. VIII. Relation to gestational age and post-natal age in appropriate and small for gestational age infants', *Acta Pædiatrica Scandinavica,* **72**(5): 721-8	ER measured regularly in 68 term and preterm AGA neonates and 33 term and preterm SGA neonates. Measurements made on first day of life and then on days 1, 3, 5, 7, 14, 21 and 28 days in most subjects. TEWL calculated from ER.	AGA neonates had higher TEWL on day of birth than SGA neonates of corresponding GA. Term AGA neonates had stable TEWL for first 2 weeks of life, whereas TEWL rose in SGA term neonates In both AGA and SGA neonates, there was a strong correlation between lower GA and higher TEWL at birth	Exponential relationship between GA and TEWL in the first 4 weeks of life, reflected in both AGA and SGA neonates Very preterm AGA neonates may lose more water through TEWL than urine in first days of life Postnatal period of drop in TEWL less prolonged in SGA preterm neonates

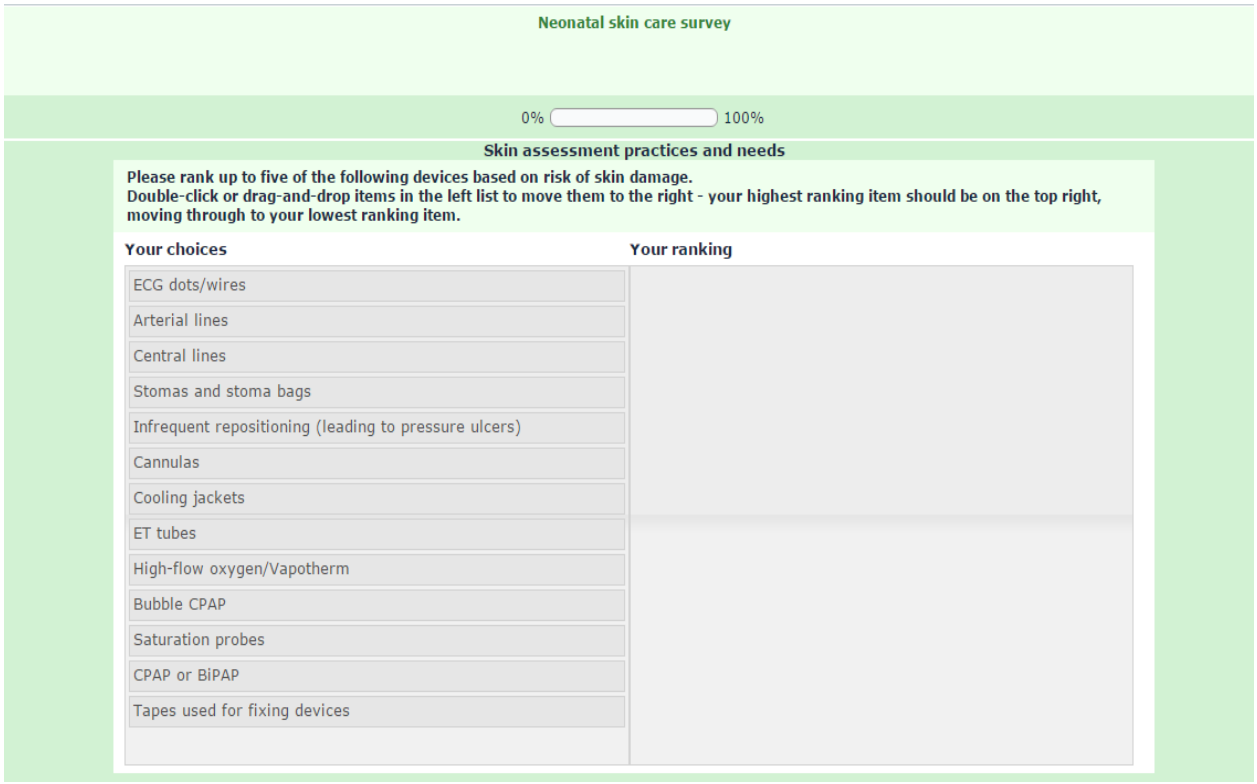
Strömberg, B., Hammarlund, K., Öberg, P. Å., and Sedin, G. (1983a) 'Transepidermal water loss in newborn infants. IX. The relationship between skin blood flow and evaporation rate in fullterm infants nursed in a warm environment', *Acta Pædiatrica Scandinavica,* **72**(5): 729-33	ER and skin blood flow were measured in 15 healthy term neonates born by Caesarean section The neonates' body temperatures were slowly rising over course of measurements due to being nursed in a warm environment	Skin blood flow increased as body temperature steadily rose ER initially decreased, then increased between 37.0˚C and 37.2˚C. At 37.1˚C it increased rapidly as the neonates began to sweat	Increases in skin blood flow do not appear to affect evaporative water loss in the body temperature range 36.6-37.1˚C in healthy term neonates
Strömberg, B., Öberg, P. Å., and Sedin, G. (1983b) 'Transepidermal water loss in newborn infants. X. Effects of central cold-stimulation on evaporation rate and skin blood flow', *Acta Pædiatrica Scandinavica,* **72**(5): 735-9	ER and skin blood flow were measured in 17 healthy term neonates delivered by Caesarean section The neonates' body temperatures were raised until sweating occurred or until 37.5 ˚C was reached, at which point cold 10% glucose was administered orally	ER decreased in 9 minutes to the baseline values in the sweating neonates. Blood flow decreased in 3 minutes to baseline values. Cold glucose feeding did not significantly alter either variable in neonates who were not visibly sweating	Not all neonates sweat at a rectal temperature >37.1 ˚C Central cold-stimulation results in vasoconstriction and inhibited sweating in neonates who have started to sweat

Appendix C Examples of questions in the Limesurvey format





Appendix C



Neonatal skin care survey

0% 100%

Skin assessment practices and needs

Please rank up to five of the following devices based on risk of skin damage.
Double-click or drag-and-drop items in the left list to move them to the right - your highest ranking item should be on the top right, moving through to your lowest ranking item.

Your choices	Your ranking
ECG dots/wires	
Arterial lines	
Central lines	
Stomas and stoma bags	
Infrequent repositioning (leading to pressure ulcers)	
Cannulas	
Cooling jackets	
ET tubes	
High-flow oxygen/Vapotherm	
Bubble CPAP	
Saturation probes	
CPAP or BiPAP	
Tapes used for fixing devices	

Appendix D Content of survey tool

Neonatal skin care

Thank you for agreeing to participate in this survey about skin care. By proceeding with the survey, you indicate that you have read the participant information sheet and agree to take part.

This survey will store a cookie on your computer. This will not store your responses and is only used to prevent repeat entries.

There are 19 questions in this survey.

1. Do you hold a professional registration? *

Please choose all that apply:

☐ None
☐ EN/Level 2 registered nurse
☐ RN(Child), RN8, or RSCN
☐ RGN or RN(Adult)
☐ RM

2. If so, how many years ago did you qualify?

Please choose only one of the following:

Less than one

1-2

3-5

6-10

11-20

21+

3. What is your current role? *

Please choose only one of the following:

- Band 2 clinical staff
- Band 3 clinical staff
- Band 4 clinical staff
- Staff nurse without neonatal modules (405 or equivalent)
- Staff nurse with neonatal modules (405 or equivalent)
- Sister/charge nurse
- Senior sister/senior charge nurse
- Clinical educator
- Nurse specialist
- Advanced neonatal nurse practitioner
- Other

4. What type of unit do you work at? *

Please choose only one of the following:

- Level 1 centre
- Level 2 centre
- Level 3 centre (medical-surgical)
- Level 3 centre (medical)

5. What type of patients do you normally look after?

Please choose all that apply:

- [ ] Intensive care
- [ ] High care
- [ ] Special care
- [ ] Transitional care
- [ ] Community/hospital at home

6. How great do you think the risk of skin damage is in the patients you normally look after? *

Please choose only one of the following:

- No risk
- Slight risk
- Moderate risk
- High risk
- Extremely high risk

7. How often do you observe skin damage in practice?

Please choose only one of the following:

- ○ Never
- ○ Less than once a year
- ○ Once or twice a year
- ○ Every 2-5 months
- ○ Once or twice a month
- ○ Weekly
- ○ Daily

8. Please list common locations for skin damage separated by a comma.

Please write your answer here: _____

9. Do you feel able to protect and promote skin health in your patients? Please give details.

Please write your answer here:

_____

_____

_____

10. Have you had any training that includes skin care since you started working with neonates? *

Please choose only one of the following:

- ○ Yes, formal training (please state in comment box)
- ○ Yes, informal (peer-to-peer)
- ○ None

Make a comment on your choice here:_____

11. Are you aware of any local, regional or national policies relating to skin care in neonates? *

Please choose only one of the following:

○ Yes (please specify in comment box)
○ No

Make a comment on your choice here:_____

12. How often do you assess the skin of patients in your care? (N.B. Not including patients with dermatological conditions). Please use the box for further comment if you wish. *

Please choose only one of the following:

○ Only when necessary
○ Once per shift
○ Twice per shift (e.g. beginning and end)
○ During nappy changes/cares (please specify how often this is)
○ More often

Make a comment on your choice here:_____

13. What criteria do you use to assess skin health? Please select all that apply.

Please choose all that apply:

☐ Guidance from the hospital/unit
☐ Colour changes
☐ Moisture/dryness
☐ Signs of breakdown
☐ External pressure e.g. devices

14. Do you use a risk assessment tool to help you identify the risk of skin damage? *

Please choose only one of the following:

○ Yes (please specify)
○ No

Make a comment on your choice here:_____

15. Do you think a risk assessment tool designed specifically for use in neonates would be helpful? *

Please choose only one of the following:

- ○ Yes
- ○ No

16. Do you grade or stage instances of skin damage? Please use the box to provide further information if you wish. *

Please choose only one of the following:

- ○ Yes, using a scale provided by the hospital
- ○ Yes, using traditional pressure ulcer staging
- ○ No, but I describe them in the medical notes
- ○ No, I have never seen skin damage in neonates

Make a comment on your choice here:_____

17. Please rank up to 5 of the following devices based on the associated risk of skin damage.

Please select between 0 and 5 answers, with 5 being the highest ranking.

CPAP or BiPAP

Bubble CPAP

High-flow oxygen/Vapotherm

ET tubes

ECG dots/wires

Saturation probes

Tapes used for fixing devices

Infrequent repositioning (leading to pressure ulcers)

Stomas and stoma bags

Cannulas

Arterial lines

Central lines

Cooling jackets

18. What steps do you take in your practice to minimise the risk of skin damage? Please list any you feel are relevant, separated with commas.

Please write your answer here:

_____

19. Do you have any other concerns or comments on the topic of skin care that you would like to mention?

Please write your answer here:

_____

_____

_____

Thank you again for your time!

Appendix E Participant information sheet (survey)

Participant Information Sheet

Study Title: Survey of nursing attitudes towards skin health in neonatal care

Researcher: Hannah Liversedge **Ethics number**: ERGO-FoHS-9305

Please read this information carefully before deciding to take part in this research. If you are happy to participate, please continue to the survey.

What is the research about?

You are being invited to participate in a survey of neonatal nursing staff on the subject of skin health. The intention of the research is to understand how nurses currently assess and care for skin in the neonatal unit, as well as identifying any areas where clinical staff believe more research is needed.

The survey is the first in a series of studies for a doctoral research project on the topic of neonatal skin health, and will lead to a doctoral thesis. It is being organised by researchers at the University of Southampton and funded by Portsmouth Hospitals Trust.

Why have I been chosen?

All registered and unregistered clinical nursing staff in the Wessex and Thames Valley Neonatal Networks are being invited to take part. Participation is entirely voluntary. You do not have to complete the survey if you would prefer not to. Managerial staff at your unit will not know whether or not you have chosen to take part.

What will happen to me if I take part?

If you decide to take part, you will be asked to complete the survey for which you have been emailed the link. The survey consists of 19 questions and will take approximately 10-15 minutes to complete, depending on factors such as connection speed. Some questions are core questions, which must be completed if you decide to participate. These are indicated by a red asterisk.

Appendix E

Definition of terms:

Skin damage is used throughout the survey to refer to deterioration in a patient's skin health. This may mean changes in colour where the skin remains intact, or instances where the surface of the skin has been broken.

Skin care is used to refer both to the maintenance of healthy skin and also to the treating and protecting of skin which has been damaged.

Are there any benefits in my taking part?

The survey is a preliminary study to identify areas that are currently under-researched. Although the survey may not be of direct benefit to you, it is hoped that it will lead to practice developments to minimise the risk of skin breakdown for neonates who are hospitalised.

Are there any risks involved?

Although your participation is confidential and your answers will be anonymous, it is possible that some participants may be identifiable through the information they provide about their job role and the unit in which they work. However, this risk is minimal as only very general information is gathered.

Will my participation be confidential?

Data will be managed in accordance with the Data Protection Act 1998. Answers are submitted anonymously and will be stored on a password-protected computer. Only the research student and supervisors of this study will have access to the data. The research team will not have access to your email address or other identifying information. Although the results may be published in a journal, this would not include any identifying information. Participating in the survey will place a cookie on your user account on this computer. This will not store any personal data and is designed to prevent repeat submissions of the survey.

In the event of unsafe practice being disclosed within the survey, your participation will remain anonymous and the research team will not know who has disclosed the practice. However, an email highlighting the issue will be sent from the researcher to the network's clinical educator, who in turn will contact the network's lead nurses and ask them to make their staff aware of the fact that this is unsafe practice.

What happens if I change my mind?

You can withdraw from the survey by closing the survey window. None of your answers are stored until you click 'submit'. Since the research team will not know who has submitted which answers, it will be impossible for your answers to be identified and deleted after submission.

What happens if something goes wrong?

In the unlikely case of concern or complaint, please contact:

Dr Martina Prude

Head of Research Governance

(02380 595058, mad4@soton.ac.uk)

Where can I get more information?

Contact Hannah Liversedge on hll1g09@soton.ac.uk or 02380 777222 extn 5345 for further details.

Appendix F Survey quote tables

Determinant	Factor	Key codes	Example
Individual health professionals factors	Knowledge and skills	Lack of knowledge	P40: "Often not recognised by staff as an issue, lack of knowledge on how to promote skin health" "I feel I would benefit from more info/training as a newly qualified nurse" "Often not recognised by staff as an issue, lack of knowledge on how to promote skin health"
		Lack of evidence	P4. "No [I don't feel about to protect and promote skin health] little evidence on best practice"
	Cognitions including attitudes	Care prioritisation	P34: "Sometimes [maintaining skin health] is not the priority (unstable baby, minimal handling, heavy workload, time pressures)."
		Guidelines and protocols	P47: "Nurses preferring their choice [for barrier creams]—rather than using protocol/guidelines regarding nappy area, as we do have a guideline for this." "…would like to help create staff education package/protocol"
Professional interactions	Capacity for organisational change	Differences between units	P12: "As I work in a level 2 unit I need further knowledge how to protect skin especially in the small preterm babies"
	Capable leadership and organisational culture	Training	P36: "…there is little training given on the topic [of skin health]"
	Organisational structure	Use of experts	P22: "When there are concerns with skin there is no specialist to call, although the tissue viability nurse is called, they often do not have the expertise in neonates"
Incentives and resources	Availability of necessary resources	Lack of evidence	P30: "Unsure about the use of olive oil - used to use it regularly but now have been informed that it is not advisable but I haven't seen any evidence to back this up"
		Guidelines and protocols	P30: "More education, guidelines/protocols…would be beneficial for nurses working in neonatal intensive care units"

		Assessment tools	P19: “No score system for damage from sats probes or NGT's etc”
Patient factors	n/a	Patient characteristics	P32. “We have measures in place to help protect skin and promote skin health, however, they are not always sufficient if the baby is very unwell and/or premature”

Determinant	Factor	Key codes	Example
Individual health professionals factors	Knowledge and skills	Knowledge of device care	"Change probe sites Ensure cannulas are appropriately strapped and observed. Ensure CPAP and ET tubes are not too tight" P7 "Pressure care of devices such as CPAP" P34 "Releasing pressure e.g. nasal prongs" P36 "Reducing temperature for transcutaneous co2 monitoring in extremely premature infants" we cut the plaster sticky off of the saturation probe and use a foam wrap to secure probes in place to minimise the risk of ripping skin when removing saturation probes from feet
		Knowledge of correct procedures	"Aware of correct technique when blood sampling from heel prick, to prevent bruising" "Good hygiene behind ears, regular observation of 'at risk' areas, avoiding the placement of sticky tape directly to skin, good use of humidification in the incubator, use of silk sheets..."
		Awareness of risk factors	I feel our unit pay particular attention to this area due to the prematurity of our babies where skin tissue damage can be a high risk." We are aware of risks and monitoring and evaluate skin health on a daily basis. "Aware of risk of pressure wounds depending on CPAP use, Phototherapy masks, positioning of baby"
	Professional routines and characteristics	Assessment	"I would also assess at the beginning and end of each shift too." "Good routine for reviewing sites of cannulas" "Regular, sometimes hourly, observation of vulnerable areas" "Daily routines of observing skin during care for babies" "Daily observations alongside skin integrity charts" P47. "Observations hourly of nasal septum/cannulade used if sore. Observations at position change/nappy changes"

		Repositioning	P30. “Repositioning infants 6 hourly as tolerated” P4. “Regular repositioning where possible” P35. “regular assessment and repositioning of babies and probes” P43. “Reposition baby” P44. “Regular position changes, ensuring the baby is not lying on anything, regular equipment repositioning”
		Staff-led change	P38. “Our unit still advocates using olive oil on the babies skin, whereas I know sunflower oil is known to be better for their skin. I am in the process of trying to implement this change.” “…would like to help create staff education package/protocol” “Developmental care study”
		Other routines	“Change of bedding daily”
	Cognitions including attitudes	Perceived as important	P30. “I think this is an important topic”
		Positive towards education	P40. “Would like to help create staff education package/protocol” “Should be included in formal training so everyone is aware of the dangers of the neonate on skin damage & how to avoid this & promote this area of concern.”
Professional interactions	Team processes	Working with parents	P13. “Parent co-operation in observing skin from day to day and informing staff” It is important for staff to be up to date with their knowledge and to give parents consistent information.
		Peer education	P40. “Try to inform peers, raise awareness of skin health” “I have some knowledge but also have access to more senior staff who have more knowledge” “I picked up skin training through observing and talking to other nurses”

		Use of guidelines	P8. “Yes [I feel able to protect and promote skin health] we have comprehension skin and wound care guidelines” *“Yes [I feel able to protect and promote skin health in my patients], we have a variety of interventions and use the network guideline”.* South Central Neonatal Guideline
	Capable leadership and organisational culture	New staff training	P22. “Skin care training is offered to new staff”
		Culture of prevention	P43. “Yes there is quite a lot of team effort in promoting good skin care, there is also a big focus on prevention and problem anticipating.”
		Staff development	P36. “Developed nappy care guideline as part of band 6 development programme”
	Organisational structure	Making use of experts	P23. “Link nurses for skin care and tissue viability teams to enable a pathway/guideline to be written” Advice received from Trust tissue viability nurse on occasions when there have been concerns about an extremely premature neonate's skin and how best to care for it. We work closely with the tissue viability team.
Incentives and resources	Availability of necessary resources	Recent improvements	P34. “Our skin care practices are improving with access to improved equipment and facilities”
		Guidelines and protocols	P48. “There is information available on unit regarding correct positioning for heel prick samples”
		Prophylactic treatments	P23. “Use of silk sheets, Cavilon and other barrier products”
Patient factors	n/a	Parent behaviour	P13. “Co-operation with parents on consistent observation of skin” *“Parent co-operation in observing skin from day to day”*

Appendix G Publication in the Journal of Neonatal Nursing

Liversedge, H. L., Bader, D. L., Schoonhoven, L., and Worsley, P. R. (2018) 'Survey of neonatal nurses' practices and beliefs in relation to skin health', *Journal of Neonatal Nursing,* **24**(2): 86-93 https://doi.org/10.1016/j.jnn.2017.07.007

Published April 2018.

Abstract

Despite the reported high prevalence of skin damage in neonatal units, little is known regarding assessment and management of neonatal skin.

A questionnaire was designed addressing beliefs and practices of participants. This was distributed to neonatal nurses across southern England.

In total 56 responses were returned (7% response rate). Incidence of damage was perceived to be high, with 26% of participants reporting that this occurred daily. Skin damage was frequently associated with medical devices, including nasal continuous positive airway pressure, medical tape, and peripheral cannulas. Staff education emerged as a key theme in promoting skin health. However, only 10% of participants had received skin care training. Participants highlighted concerns about the lack of previous research in this area.

The results confirm the vulnerability of neonatal skin to medical devices, with participants citing these as the primary cause of damage. Additionally, skin care is constrained by lack of training and resources.

Keywords

Skin damage

Neonates

Medical devices

Nursing attitudes

Nursing practice

Skin care

Introduction

Hospitalised neonates, especially those who are premature, are at risk of skin breakdown, with reported pressure ulcer (PU) prevalence of 23–31.2% in neonatal intensive care (Baharestani and Ratliff, 2007, Fujii et al., 2010, August et al., 2014). Neonatal care has led to extremely preterm neonates living into childhood in greater numbers, thus injuries associated with this kind of intensive treatment are becoming more apparent (Fox and Rutter, 1998, Smith and Roy, 2006, Hogeling et al., 2012). The structural integrity of the skin has not been fully established in extremely preterm or very preterm neonates (Hammarlund and Sedin, 1979, Harpin and Rutter, 1983, Okah et al., 1995, Kalia et al., 1998). Indeed, in neonates born at 24 weeks' gestation, the stratum corneum is only one or two cell layers thick, dermal elastic fibres are sparse in distribution (Visscher and Narendran, 2014), and the characteristic features of the dermal–epidermal junction are poorly developed (Tortora and Derrickson, 2014). In addition, neonates, including those born at term, have a neutral skin pH, in contrast to the “acid mantle” of older children and adults (Ali and Yosipovitch, 2013, Visscher and Narendran, 2014). Each of these factors contribute to abnormal skin physiology in the neonate, including increased transepidermal water loss (TEWL), invasion of micro-organisms, and absorption of potential toxins from topical products (Rutter, 2003). Although the development of skin following premature birth has not yet been fully elucidated, there is some indication that it may take up to nine weeks for extremely premature neonates to develop a functional barrier maturity (Kalia et al., 1998). The extent to which this affects the risk of breakdown is still to be clarified.

In premature neonates, over 90% of PUs are associated with interventional medical devices (Visscher and Taylor, 2014). Other forms of iatrogenic skin damage have also been reported in this population, including diaper dermatitis, skin tears, and burns (Visscher et al., 2009, Sardesai et al., 2011). Although skin care has been recognised as a key aspect of neonatal nursing (Furdon, 2003), there is a paucity of evidence with which to inform practice, and skin care is primarily based on clinical expertise. Indeed national and international guidelines on the prevention and treatment of PUs do not provide much information related to this specialist group (Health and Social Care Information Centre,, NHS Institute for Innovation and Improvement, 2011, NPUAP, 2014) Accordingly, it is essential to explore nurses' perceptions of these issues in order to understand current practice. Although studies exploring adult nurses' perceptions of pressure ulcer prevention have been performed in association with general and critical care settings (Strand and Lindgren, 2010, Gunningberg et al., 2013), very few

studies have involved the highly specialised neonatal care environment. One exception to this involving a questionnaire of neonatal nurses in Malaysia reported gaps in participants' theoretical and practical knowledge of preterm neonates' skin (Mohamed et al., 2014). However, this questionnaire did not focus on nurses' perceptions of incidence and risk, and specific prevention practices were not reported.

Although validated tools exist to assess nurses' knowledge and skills in the area of PU prevention (Beeckman et al., 2010b, Beeckman et al., 2010a), these are focused on general nurses caring for adults. Thus these tools are not suitable for direct translation to the present study for several reasons:

i) the neonatal nursing workforce is made up of staff from a variety of clinical backgrounds (midwives, paediatric nurses, and general nurses)

ii) skin damage in neonates often appears to be related to medical device use, which is not addressed by existing tools

iii) prevention of PUs in neonates is fundamentally different in neonates than in adults due to the immaturity of the skin (Visscher and Narendran, 2014)

iv) current evidence on skin care in neonates is limited (Lund et al., 2001).

This provides the motivation for the present study which has been designed to explore issues related to skin health with neonatal nurses, in order to determine the current state of skin care practice and define the factors that are perceived to increase risk of skin breakdown in this vulnerable patient group.

Methods

Survey methodology was used in the form of a 19-part questionnaire tool.

Development of tool

Items for the new questionnaire were developed following a combination of processes to ensure face validity (Rattray and Jones, 2007). Draft items were generated from a literature review, the researcher's own experience as a paediatric nurse, and discussion with the lead nurses from a regional neonatal network in the south of England. This draft tool then underwent a process of review by registered nurses (RNs) and nursing assistants from neonatal intensive care units within the network (Fig. 1). During this process, changes in wording were adopted in order to ensure that the questions measured the topics we intended to measure (de Leeuw et al., 2008). The questionnaire was pilot tested with 6 RNs with either adult or paediatric qualifications, which is reflective of the

neonatal nursing workforce in the UK. During this process they were asked to comment on the functionality, formatting, and ease of use of the online tool. Following their feedback, the font size was increased, but no other changes were made. It took the RNs on average 15 min to complete the questionnaire.

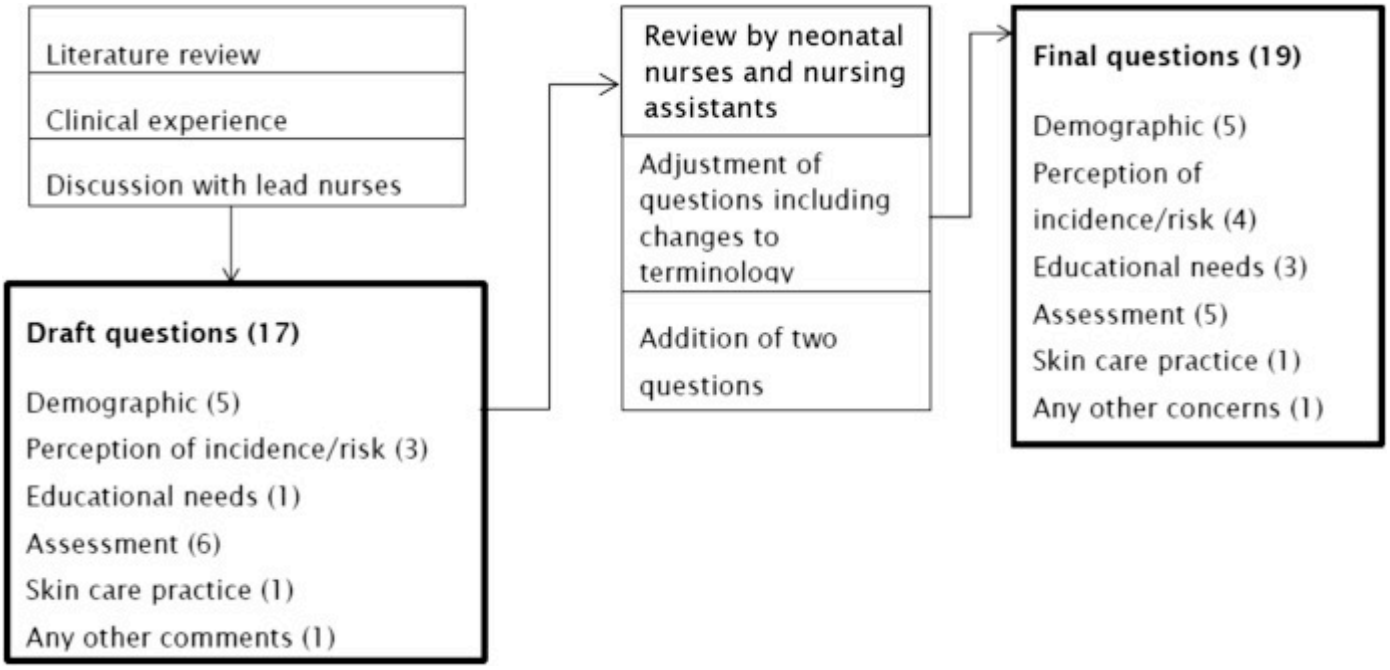


Fig. 1. Development process of questionnaire.

The questionnaire utilises both open and closed questions. The majority of questions are multiple-choice in nature, with between two and eleven possible responses depending on the question. Ranking and free-text questions are also used. Initial questions concern general demographic information, with more specific questions gradually introduced throughout the questionnaire (Table 1).

Table 1. Themes of questionnaire tool.

Theme	Question number(s)	Source(s) of theme
Demographic	1–5	Factors such as experience may have an impact on knowledge and practice (Samuwiro and Dowding, 2014)
Perception of incidence/risk	6–8, 17	A wide range of values for prevalence and incidence of skin damage have been reported for this population (Baharestani and Ratliff, 2007, August et al., 2014). Although not an objective measure, it will be useful to know how nursing staff perceive the problem. Perception of risk may affect personal effectiveness in preventing damage (Beeckman et al., 2010b)
Educational needs	9–11	Personal competence/confidence to prevent pressure ulcers was adapted from the APuP tool (Beeckman et al., 2010b) Anecdotal reports suggest that skin care education is lacking in neonatal and paediatric environments.
Assessment	12–16	Assessment practices were not standardised between different NICUs. This was the concern most commonly raised by neonatal nursing staff throughout the questionnaire development process (see Fig. 1). Classification and observation is also one of the key themes included in a validated adult pressure ulcer knowledge assessment tool (Beeckman et al., 2010a).
Skin care practice	18	The nursing pilot group indicated that prophylactic skin care was important in practice and should therefore be included in the questionnaire.
Any other comments	19	Item was included to allow participants to raise any concerns that had not been covered elsewhere.

Sample

Recruitment

The study recruited RNs and nursing assistants from the South of England working in three levels of neonatal unit:

1.

Special Care Baby Unit (SCBU): for babies who need monitoring of vital signs, supplemental oxygen, tube feeding, phototherapy or convalescence from other care.

2.

Local Neonatal Unit (LNU): for babies needing short-term intensive care with respiratory support, including continuous positive airway pressure(CPAP)

3.

Neonatal Intensive Care Unit (NICU): for babies who are born at <28 weeks, need respiratory support including ventilation, who weigh <1000 g, and/or need significant CPAP support. These babies may also require surgery or other intensive treatment.

Lead nurses from a total of 16 units agreed to disseminate the questionnaire to a staff of approximately 800. Paper copies were also issued to the three NICUs. Recruitment took place from July to December 2014.

Participants were given an information sheet. Implied consent was taken on completion of the questionnaire. All participant data were anonymised.

Analysis

Quantitative data

Quantitative data were analysed using descriptive statistics (mean, mode, percentage). For one question, participants were asked to rank multiple medical devices according to associated risk of skin damage. Responses to this question were analysed by calculating the rank sum based on the top five devices selected by the participants.

Qualitative data

Qualitative data generated in the comment boxes accompanying some multiple-choice questions, as well as in open-ended questions about nurses' opinions and practices, were analysed using content analysis (Saldaña, 2013). A codebook was

developed in the process of analysis due to the lack of previous research in this area (Gibbs, 2007). Data were coded descriptively, recoded, and then organised into categories and subsequently into themes (Saldaña, 2013). These themes were then used to identify any new areas of interest or concern that have not yet been reported in the literature, in addition to providing general information about beliefs and practices of nursing staff (Greene et al., 1989).

Following this process, the data, codes, and emerging categories were triangulated with an experienced qualitative researcher (LS) to minimise bias.

Results

Demographics

In total, 56 responses were received, equivalent to a response rate of 7%. A breakdown of participants by subgroup, indicated in Fig. 2, reveal responses predominantly from RNs in senior roles, with 44 participants working as senior staff nurses or above. The majority of participants cared for HDU and/or ITU patients as part or all of their caseload (n = 50).

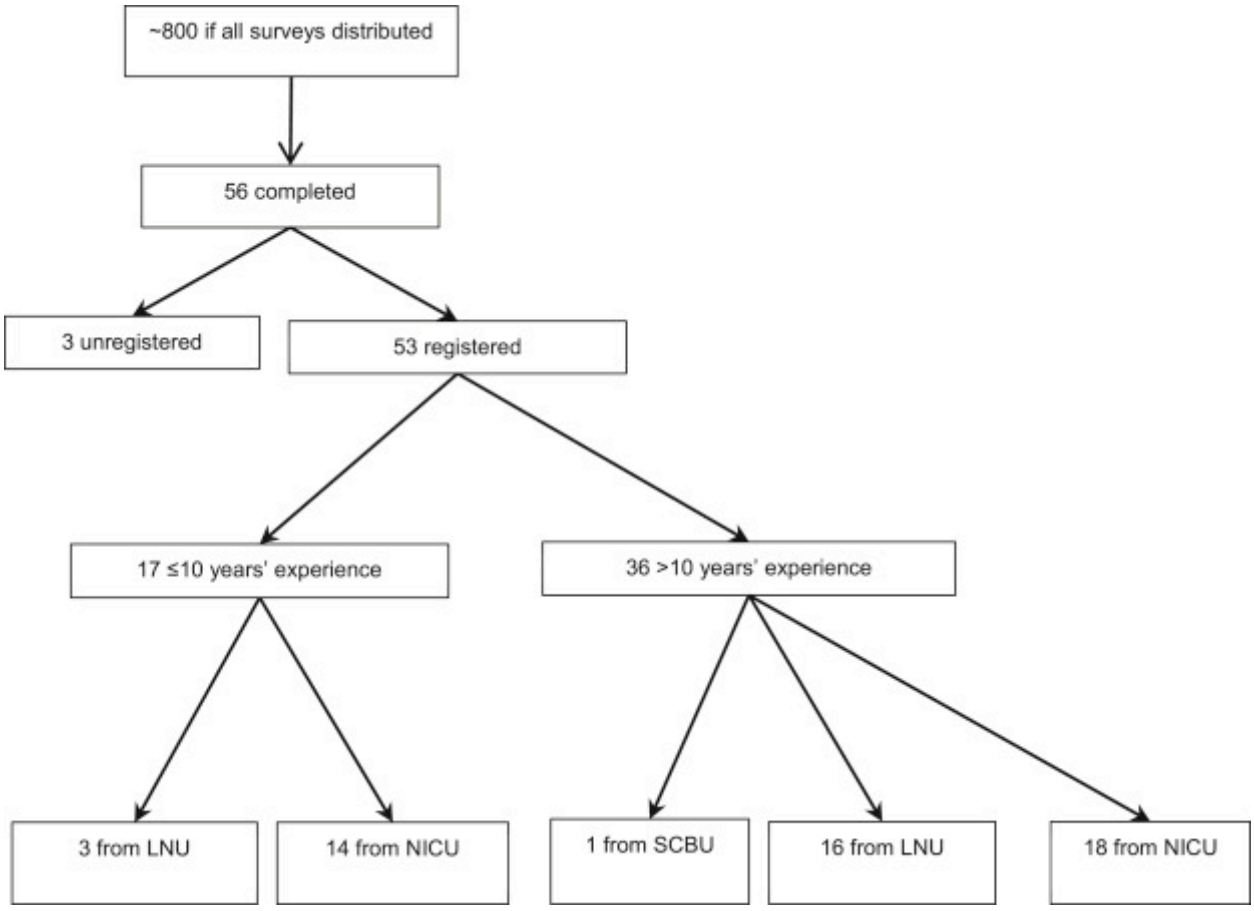


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Fig. 2. Demographics by subgroup.

In total, six data sets had missing or unusable variables. The data from all completed questions were included for analysis.

Perception of incidence and risk

The majority of participants rated the risk of skin damage in their patients as “high” (n = 20) or “extremely high” (n = 13). No participant selected the option for “no risk”. Equally, when asked about the frequency of skin damage, no participant responded that they had never seen skin damage in neonates. However, there are some apparent inconsistencies. For example, two participants rated their patients as being at slight risk of skin breakdown and yet reported that they observed skin damage every day in practice (Fig. 3). The majority of participants reported that they observed skin damage at least 1–2 times per month (n = 30).

Fig. 3. Perception of incidence of skin damage vs. perception of risk for skin damage.

Participants were asked to list locations in which skin damage commonly occurs. The most common sites were the nose, the foot/heel, and the groin/buttocks, as indicated in Fig. 4. Fig. 4 also includes comments which did not directly specify a location; for example, damage from IV access.

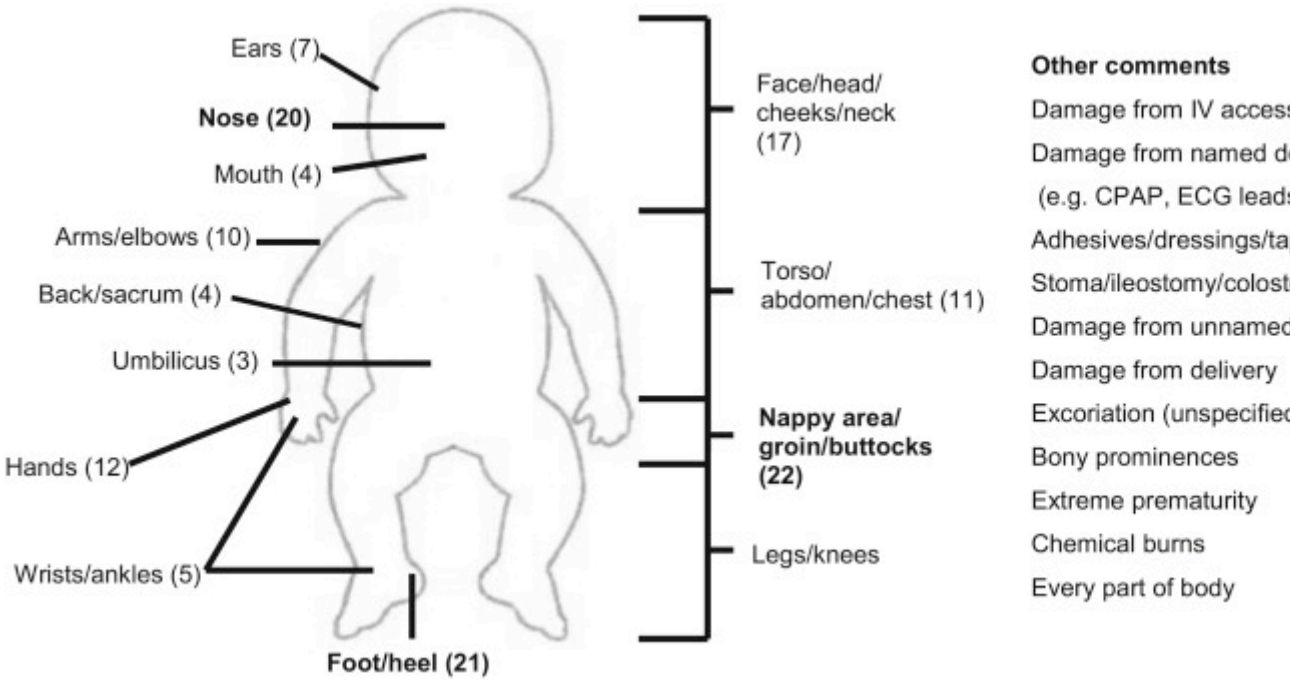

Fig. 4. Common locations for damage.

Subsequently, participants were asked to rank medical devices according to associated risk of skin breakdown. CPAP, peripheral cannulae, and medical tape were all ranked equally, as most likely to cause skin damage, with pulse oximeters the next highest. This generally matches the comments related to location.

Educational needs

Only 6 participants had received formal skin care training since they started working with neonates. No clinical educator had received formal skin care training, and one participant, who self-identified as “tissue viability link nurse”, had received neither formal skin care training nor bedside training. Junior staff nurses did not report formal skin care training, although this was reported to be part of their induction. By contrast, the majority of participants had received bedside training from their peers (n = 37).

Assessment

The majority of participants reported that they carried out skin assessments with nappy changes or cares (n = 35). “Cares” are defined as clustered episodes of care delivery, when many interventions that require handling of the neonate are delivered together in order to minimise disturbance. From the additional comments provided, it is clear that this differs between participants and between patients. A further 15 of the participants reported that they carried out skin assessment more

often than this. Two participants reported that they carried out skin assessment "only when necessary".

An examination of the additional comments reveals that reports of "skin assessment" may not constitute full body assessment. Participants commonly reported that "it depends on condition of baby/gestational age" (n = 12), "cannula sites checked hourly when infusion is running" (n = 11), and "4–6 hourly with cares" (n = 7). Contradictions are apparent in some of these responses. For example, two participants state that the nose must be assessed hourly when a patient is on CPAP, while two suggest that this should occur every 2 h. In total, 21 different assessment practices were reported by the participants.

When asked about grading or assessing skin damage, 41 participants reported describing them "in words" in the medical notes as opposed to using a standardised system of reporting. Both of the standardised tools referred to by participants in this section relate to assessment of peripheral cannulae, the Visual Infusion Phlebitis (VIP) score (Infusion Nurses Society, 2011) and the Neonatal Extravasation Score (NESS) (Edwards, 2015).

Qualitative data

Two themes emerged from the analysis of the free text comments; namely, clinical factors and cultural factors. These factors intersect with one another at several points and both have an impact on patient care.

Clinical factors

Participants' comments included information about specific clinical aspects of care delivery. These comments address four categories: individualisation of care, medical devices, use of barrier products, and resources, as described in Table 2.

Table 2. Clinical factors impacting skin care.

Category	Code	Quotes
Individualisation of care	*Gestation*	"I promote and protect skin health by using silk sheets on extremely low birth weight babies where possible" P25, Q9
		"…reducing temperature for transcutaneous co2 monitoring in extremely premature infants" P36, Q18
		"Humidification for preterms less than 28 weeks' gestation" P46, Q11

Category	Code	Quotes
	Clinical condition Other	"[On assessment frequency] If it is a really sick baby once or twice during a 12 hour shift + they cannot tolerate being handled" P51, Q12
		"[On assessment frequency] Several times per shift, mostly during nappy changes/cares, but also more often especially for babies exposed in an incubator" P13, Q12
		"Paying special attention to pressure areas or areas where lines or cannulas are inserted" P51, Q9
		"Hourly observation of IV sites, nappy areas with cares, nasal septum every couple of hours when on CPAP/High Flow" P20, Q12
Medical devices	*CPAP*	"Make sure CPAP etc is not too tight on baby's face" P21, Q18
		"Correct size for CPAP hats" P13, Q18
		"Aware of risk of pressure wounds depending on CPAP use" P13, Q9
	Adhesive tape/dressings	"[Locations for skin damage] dressing/tape removal" P50, Q8
		"Use minimal amounts of tape" P21, Q9
	Peripheral cannulae and lines	"Good routine for observing site of cannulas" P13, Q9
		"Ensure cannulas are appropriately strapped and observed" P21, Q9
		"Make sure not lying on lines" P29, Q18
	Oxygen nasal prongs	"Careful positioning of prongs and checking the nasal septum for any signs of breakdown" P53, Q18
		"Nasal Prong Cannulas are not always well designed." P22, Q9
	ECG monitoring	"No ECG leads for very premature babies" P24, Q18
	Endotracheal tubes	"…positioning ETT so it is not 'pulling' on the skin or gum" P22, Q18
		"Ensure… ET tubes are not too tight" P21, Q9
	Pulse oximeters	"Feet [are a common location for skin damage] from oxygen saturation stuck with plasters to skin" P14, Q8

Category	Code	Quotes
		"Some of the products…we use could be better such as saturation probes (which are sticky)" P22, Q9
		"We re-site saturation probes every nappy change" P14, Q18
Barrier products	*Oils*	"Use effective oils, like coconut oil, according to latest study" P13, Q9
		"Our unit still advocates using olive oil on the babies' skin, whereas I know sunflower oil is known to be better for their skin" P38, Q9
		"Olive oil for dry cracked skin" P21, Q9
	Prophylactic dressings	"Using Duoderm on areas at risk i.e. knees if laying on front for long period" P42, Q9
		"Use Duoderm as a base for the positioning of [nasogastric] tubes" P14, Q9
		"Cannulaide dressing for CPAP" P23, Q18
	Barrier creams	Some units have policies to guide use of barrier creams, but nurses may prefer their own choices over those included in the policy
		Barrier creams used prophylactically by some participants and only on red or broken skin by others
Lack of resources	*Education*	"Skin care training is offered to new staff. This is based on experience and anecdotal history" P22, Q10
		"As I work in a level 2 unit [LNU] I need further knowledge how to protect skin especially in the small preterm babies" P12, Q9
	Evidence	"Little evidence on best practice" P4, Q9
		"Products to use can be a bit of a trial and error." P22, Q19

Quotes are presented in participants' own words. Misspellings have been corrected for ease of reading.

Cultural factors

For the purposes of this analysis, a description of organisational culture was used (Kaufman and McCaughan, 2013). This encompasses factors such as rituals (including ward rounds and patient handovers), teamwork, communication, and

values/behaviour. The categories within this theme are “team effort”, “role of evidence”, and “unit routines”. Summaries of categories and key codes are indicated in Table 3.

Table 3. Categories and key codes from ‘cultural factors’ theme.

Category	Code	Quotes
Team effort	*Sharing of knowledge*	“I have some knowledge but also have access to more senior staff who have more knowledge” **P28, Q9** “…there is quite a lot of team effort in promoting good skin care” **P43, Q9**
	Parental involvement	“Parent co-operation in observing skin from day to day and informing staff” **P13, Q9**
	Staff communication	“Daily observations alongside… identifying each shift handover” **P15, Q9** “Would be helpful to have a grading system, easy for handover's too” **P45, Q16**
	Use of experts	“Can seek advice from dermatology specialist if necessary” **P6, Q9** “…there is no specialist to call, although the tissue viability nurse is called, they often do not have the expertise in neonates” **P22, Q9**
Role of evidence	*Use of evidence*	“Occasionally read research articles relating to skin care” **P3, Q10** “…some care plans (nappy care) that are more evidence based” **P22, Q10**
	Nurse as expert	“In some extremely premature babies the skin is at much higher risk an the expert neonatal care is crucial” **P22, Q9** “It is part of the neonatal nurses role” **P21, Q9**
Unit routines	*Policies and guidelines*	“Nursing guidelines for Skin Integrity are available” **P5, Q10**
	Routine practices	“Tissue breakdown can happen very quickly, so vital checking is a must” **P45, Q19** “Repositioning infant's 6 hourly as tolerated” **P30, Q18**

Quotes are presented in participants' own words. Misspellings have been corrected for ease of reading.

Discussion

This study comprised a 19-part questionnaire, distributed to neonatal nursing staff covering a network in the south of England. The aims were to explore current practice in assessing skin integrity, nurses' perceptions of factors that increase risk of skin breakdown, and the extent to which nurses view prevention of skin

breakdown as a priority. The results showed inconsistencies in practice, particularly in relation to skin assessment. Indeed participants expressed concern about the lack of evidence available and limited education on the subject. These findings also highlighted the complications associated with interventional medical devices in this vulnerable population.

Research from the United States suggests that over one third of hospital-acquired PUs in adults can be associated with medical devices (Black et al., 2010). The importance of devices in relation to skin health in neonates has also been well established (Kopelman and Holbert, 2003, Buettiker et al., 2004, Hogeling et al., 2012, Collins et al., 2014). Indeed a recent study found 90% of PUs in neonates were associated with medical devices (Visscher and Taylor, 2014). In the present study, participants highlighted this as a critical causal issue. CPAP was mentioned frequently throughout the responses and ranked as one of the three devices most likely to cause damage. This finding is similar to that which highlights nasal trauma resulting from CPAP use (Yong et al., 2005), particularly in extremely preterm and very preterm neonates (Fischer et al., 2010). Extremely preterm neonates are also significantly more likely to develop
skin necrosis following extravasation (Kostogloudis et al., 2015).

A survey of a comparable group of neonatal nurses in Malaysia by Mohamed et al. (2014) sought to explore participants' skin care practices and their perceptions of their own knowledge. Although that study did not seek to explore nurses' perceptions of device-related damage, questions related to pulse oximeters, CPAP, and peripheral cannulae were included. The results suggested that nursing staff of all levels of experience had adequate knowledge of pulse oximeters and IV cannulae, but only 15.4% of junior staff nurses demonstrated adequate knowledge regarding the care of neonates on CPAP. Comparisons between the two studies, however, is limited due to differences in both format and content of the questions, with the previous study utilising a series of true/false questions as opposed to a scale or open-ended questions as in the present study. There are nonetheless clear similarities. The findings of our study confirm that neonatal nursing staff are aware of the risks associated with these and other devices, but struggle to manage this due to resource limitations. Staff working with critically ill patients have to balance the need to maintain functionality of the device, while preserving the health of vulnerable skin. It is notable that an NPUAP committee were unable to reach a consensus regarding whether the proper use of medical devices overrides protecting the skin (Black et al., 2011). This issue is particularly complex in critical care environments, where the devices causing complications may be lifesaving.

One finding of the current study was that type and frequency of skin assessment varied between respondents. Indeed 21 different assessment practices were reported, with participants citing personal preference, condition of neonate, and other influencing factors. No single system for skin assessment was identified. To this end, the Neonatal Skin Condition Score has been trialled in the US, but has not been adopted in the UK (Lund, 2004). “Classification and observation” has previously been reported as a gap in adult nurses' knowledge (Demarré et al., 2012, Gunningberg et al., 2013). In one study in the UK, nurses correctly classified 56% of PUs, increasing to 62% following intensive training (Kelly and Isted, 2011). In a neonatal environment, classification is complicated further by factors such as minimal subcutaneous fat deposits (Ness et al., 2013). International standards for classifying incontinence-associated dermatitisin adults have been proposed (Beeckman et al., 2015), but these may not prove appropriate for classifying diaper dermatitis in neonates.

Participants in the current study identified gestational age as a factor associated with increased risk of skin breakdown. No questions were asked with the intention of assessing participants' knowledge of neonatal anatomy and physiology, as this did not represent one of the aims of the study. In the survey of Malaysian nurses, questions related to TEWL suggested that the nursing staff managed TEWL in their patients, without knowing what it represented in physiological terms (Mohamed et al., 2014). No other study to date has explored neonatal nurses' knowledge of postnatal development of the skin. This is likely to be relevant to skin care in this population, as the underdeveloped skin barrier in extremely premature neonates increases the vulnerability of the skin to breakdown (Visscher and Narendran, 2014).

Participants expressed reservations regarding the availability and quality of skin care education. Several respondents also cited lack of education or gaps in education as barriers to promoting skin health in their patients. This contrasts with findings among adult nurses in both general and intensive careenvironments, where staff do not perceive lack of education as a barrier to practice (Moore and Price, 2004, Strand and Lindgren, 2010). Some participants in the present study linked lack of education to diminished confidence in this area, a finding also reported previously (Mohamed et al., 2014). However, it is clear from the present findings that participants are motivated to improve their own practice and that of

others. This contrasts with suggestions that nurses' reluctance to change is a barrier to implementing evidence-based practice, even in ITU environments (Soh et al., 2013).

There were some limitations associated with the method and sample. The response rate was low at 7% related to 800 potential participants. This limits the generalisability of the results. The sample was self-selecting, suggesting a degree of interest in skin care that may not be mirrored across all staff. Participants were predominantly senior staff, with only three unregistered staff participating and few junior staff nurses (n = 9). This may mean that in the majority of the neonatal nursing workforce, the level of awareness and knowledge demonstrated may be lower than that demonstrated by participants. There were also some errors by participants when filling out the paper version of the questionnaire (e.g. ticking devices rather than ranking them, meaning that the data could not be used). Additionally, some participants did not answer questions when filling out the paper copy that had been marked as “mandatory”. These limitations restrict the generalisability of the results to other populations, and may not reflect the whole of the neonatal nursing population even in these units surveyed.

Despite these limitations, this is a useful first step in understanding nurses' perspectives on the issues associated with providing skin care to this highly vulnerable population. Given the demographics of the participants, the findings of this study are likely to represent the part of the neonatal workforce with the most skin care experience. Although a previous questionnaire has looked at neonatal nurses' knowledge of skin care (Mohamed et al., 2014), this is the first to explore nurses’ perceptions of barriers and opportunities unique to this population. Given that neonatal nurses are experts in their patient group, it is essential to consider their perspectives and views as research continues into this area.

In light of this, the study has implications for clinical practice as well as future research. First, although some participants in this study received skin care training during induction, this is not consistent across all participating units. Given previously reported concerns around confidence (Mohamed et al., 2014), it is likely that this is a common issue for nurses working with premature or critically ill neonates. This can only be addressed with further clinically-focussed studies, as the problem is associated with lack of evidence. However, increasing the availability of skin care training could lead to increased consistency of practice. Additionally, the study highlights the complex clinical issues surrounding the use of interventional medical devices. Although these devices are often essential and life-

saving, this study draws attention to devices that may require frequent observation while in situ in order to minimise the risk of skin damage.

Conclusion

The participants in this study represent a skilled group of staff, primarily RNs, in a range of clinical positions. Their responses demonstrate enthusiasm for improving practice and learning more about neonatal skin. The collective experience and knowledge of the team is used to deliver individualised preventative care, monitor skin health, and to respond rapidly to the onset of skin damage. However, discrepancies in the responses are indicative of gaps in evidence and education. Several participants mention actively seeking out new research in this area with the intention of improving practice. The paucity of published research on neonatal skin health makes this difficult. Research into all areas of neonatal skin integrity is required to inform practice, thus minimising the risks posed to preterm skin by intensive treatment. The reporting structures for skin damage in neonates should also be considered, as at present these are predominantly adapted from those designed for adults and may not be appropriate for this population. A role for industry is also indicated in developing devices tailored to the specific needs of preterm neonates, preferably in partnership with clinicians including nurses.

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Supporting statements

Conflict of interest: There is no conflict of interest to declare.

Ethical approval: Ethical approval was granted by the University of Southampton institutional ethics committee (ERGO-FoHS-9305).

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Appendix H Consent form (focus groups)

CONSENT FORM

Study title: Focus groups to explore neonatal nurses' current perceptions in relation to skin care and skin damage

Researchers: Professor Dan Bader, Professor Lisette Schoonhoven, Dr Peter Worsley and Miss Hannah Liversedge

Ethics number:

Please initial the box(es) if you agree with the statement(s):

. I have read and understood the information sheet (14/7/2017, Version 4) and have had the opportunity to ask questions about the study. ☐

2. I agree to participate in the study and that my research data may be recorded for the purpose of the study ☐

3. I understand that my participation is voluntary and I may withdraw at any time without ☐

4. I agree to the use of audio recording devices, with the possibility of anonymised verbatim quotes when the results are published ☐

5. I have had the opportunity to ask questions and have received ☐

Data Protection

I understand that this consent form will be stored in a locked cabinet in accordance with the Data Protection Act.

Name of participant……

Signature of participant……

Name of researcher……

Signature of researcher……

Date……

Appendix I Participant information sheet (focus groups)

Participant Information Sheet

Study Title: Exploring neonatal nurses' current perceptions and experiences of neonatal skin integrity

Researchers: Professor Dan Bader, Professor Lisette Schoonhoven, Dr Peter Worsley and Ms Hannah Liversedge

Ethics number: ERGO 25367

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

Some babies admitted to neonatal units experience skin damage as an unintended consequence of their hospital care. Although this often heals completely, it can be very painful, increases their risk of infection, and may prolong their hospital stay. At present, most of what we know about skin care and skin damage is based on research conducted with adult patients. Neonatal nurses are experts in their specialist patient group, and we want to understand how they currently experience issues around skin care and skin damage.

I am a registered children's nurse, and I work for Portsmouth Hospitals NHS Trust. This study is part of my PhD project which I am conducting at the University of Southampton. The aim of the study is to explore and understand:

a) The experiences and practices of nursing staff who provide care for neonates in relation to skin health

b) Any barriers to and facilitators of the provision of skin care for hospitalised neonates

Why have I been chosen?

All registered nurses, registered midwives, and nursery practitioners on the neonatal unit, who provide direct patient care as part of their role, are being offered the opportunity to take part.

What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form in duplicate. The focus group will be organised at a time convenient to you and your colleagues. Each group will consist of between 4 and 8 participants, who are likely to be known to you. We intend to conduct two focus groups.

During the focus group, you will be asked to discuss some topics that have been developed from the responses to a survey of neonatal nurses in the Wessex and Thames Valley region, collaboration with senior

nurses, and the early findings of the ongoing prevalence and incidence study. These may include: any experiences you have had looking after babies who have developed skin breakdown, what helps or hinders you when you are providing skin care, the involvement of parents in skin care, and your personal opinions about what causes skin breakdown in babies. Two members of the research team will be present. One will act as a moderator, whose job is to encourage and facilitate discussion and ensure that everyone who wishes to contribute has the opportunity to do so. The other will be in the role of assistant moderator, which involves organising seating, refreshments, and making some notes on what participants are saying.

The focus group will be audio recorded to allow for later review and analysis, and will last no longer than an hour.

Are there any benefits in taking part?

If you would like one, you will receive a certificate stating that you took part in the focus group and the topics discussed, which can be counted towards CPD hours. Light refreshments will also be provided.

The findings of the research may be used to inform future innovations or research, as well as teaching for staff within the Wessex and Thames Valley Neonatal Network.

Are there any risks involved?

There are no direct risks involved in taking part of the study. Some participants may find recalling previous experiences related to neonatal skin care and skin damage distressing. If this is the case you will be free to leave the focus group at any point.

Will my participation be confidential?

This research will be conducted in accordance with the Data Protection Act and the data storage policy of the University of Southampton. If you agree to participate, you will be asked to sign a consent form. This will be stored in a locked cabinet in a University office. As it is likely that you will know the other participants in the focus group, each participant will be asked to adhere to a set of ground rules prior to the discussion. One such rule will be that confidentiality of discussion points is maintained within the group and not discussed outside of this setting. All audio recordings will be password protected and held on a password protected computer. Any notes made will also be stored securely. In order to maintain a linked anonymity all participants will be coded, rather than using names with all reported data being linked only to this code. During the process of this research focus group discussion data will only be shared amongst the research team (named above). Anonymised study data will be stored for a minimum of 10 years in accordance with the data storage policy of the University of Southampton. Personal contact information will not be retained after data collection is complete.

Once analysis is completed, an anonymised report of the findings will be presented to the unit and to the education team at Wessex and Thames Valley Neonatal Network. These results will also be written up, published, and presented at conferences and study days with anonymity maintained.

What happens if I change my mind?

You can change your mind at any stage throughout the study. This will not affect your legal rights. If you decide to leave the study early, and you do not want your data to be used, you can inform the moderator or assistant moderator.

What happens if something goes wrong?

If you have a concern or a complaint about this study you should contact the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: rgoinfo@soton.ac.uk).

If you remain unhappy and wish to complain formally the Research Governance Office can provide you with details of the University of Southampton Complaints Procedure.

Where can I get more information?

If you wish to participate, or if you have more questions after we have discussed this information, or at any point during the study, you can talk to me when I am on the unit, or contact me by email/telephone. If you decide that you wish to participate, please let me know within three days of reading the information sheet in person or on the number below:

Hannah Liversedge: hll1g09@soton.ac.uk
02380 777222 extension 5345

Thank you for taking the time to read this information sheet.

Appendix J Topic guide (focus groups)

Focus group-Neonatal nurses and nursery practitioners

1. **Introduction**

"Thank you for taking the time to attend this focus group. This meeting will be recorded for research purposes."

Introductions

"It would be good to start with some introductions in case we don't all know each other."

- Moderator introduction
- Participant introduction: name, role, number of years working with neonates

"Does everybody agree to the use of first names during the group?"

Introduction to topic and aim of group

"This group is part of a larger study with the ultimate aim of improving skin care for hospitalised neonates and minimising their risk of developing skin damage. In the past decade or so, we have become more aware of the fact that neonates who are hospitalised immediately after birth may experience many kinds of skin damage. A lot of the guidelines that have been issued to try and prevent this are based on research conducted with adults, which causes problems when trying to implement them in the neonatal environment. We are interested in exploring what neonatal nursing staff currently do in practice in order to protect and promote skin health, as well as anything that makes it easier or more difficult to prevent skin damage in your patients. It's okay to talk about any experiences in this neonatal unit or any previous experiences working with neonates in other environments. You might be aware of some questionnaires that were previously sent out on the subject of skin health, and will hopefully know about the prevalence and incidence study currently taking place on the unit. The results from these two studies will form the basis of our discussion today.

The aims of this study are, firstly, to explore the experiences and practices of nursing staff who provide skin care for neonates, and secondly, to identify and understand barriers to and facilitators of skin health in the neonatal unit.

We will also be conducting a second focus group with other nursing staff on the unit, as well as carrying out some interviews with members of the tissue viability team here in the trust. This combination of methods will allow us to gain a greater understanding of topics related to skin care and skin damage in the neonatal unit."

Role of moderator

"I invite you to speak your mind on any issues that you feel affect skin care and skin damage in the neonatal unit. We are interested in your own experiences and it is expected that there will be differences of opinion. There are no right or wrong answers, and I would invite you to give your opinion freely.

This meeting is being recorded to ensure that we do not miss any of your comments and to assist with the analysis afterwards. Your name will not be included in the analysis or reporting of the data.

During the discussion, please speak one at a time and allow everyone who wishes to speak to do so. If necessary, I will remind you of this during the group.

I will take notes throughout to support the recordings. These will also be included in the analysis. Towards the end, I might also ask some questions based on these notes to make sure I understand your comments.

Before we start, does anyone have any questions?"

2. **Focus group discussion**
    - **Perceived risk of skin damage**
        - How would you define 'skin damage' on the neonatal unit?
        - How often do you see skin damage on the unit?
        - Which babies are most at risk of skin damage?
        - What is the worst instance of skin damage you've seen in neonates? (What do you think caused it?)
    - **Education**
        - Have you had any training specifically related to skin care? What was it like?
        - What do you feel like you have learnt from other staff?
        - How do you feel about teaching parents and/or junior staff about skin care?
    - **Expertise**
        - Are TVNs ever called?
        - What would make you call the TVN team?
        - What is your experience of working with TVNs like?
        - Other specialists e.g. surgeons—are they involved in skin care? How?
    - **Device use**
        - Which devices do you think increase risk of skin damage/are associated with lots of damage?
        - How is skin under these devices protected?
        - CPAP and NG tubes in particular—do these cause issues?
        - What's the right balance between using the device properly and protecting the skin—how is this managed?
    - **Prioritisation**
        - How is a need for skin care/assessment balanced with other needs?
        - What makes it difficult to protect and promote skin health?
        - Is skin care as important as other areas of care?
    - **Skin care products**
        - Do you use any skin care products in your regular practice?
        - If so—how do you choose which to use?
        - Guidance on this subject sufficient?
    - **Preferred practice**
        - What would help facilitate better practice in this area?
        - Anything related to skin care you'd like to know more about?

10 minutes before end—begin drawing to a close, inform participants of the amount of time left.

- Is there anything we haven't discussed yet that you feel is important?

3. **End of group**
    - Thank participants for taking part
    - Draw some preliminary conclusions—do participants agree?
    - Any additions, clarifications, further comments on conclusions?
    - Offer of summary results at later stage

Appendix K Participant information sheet (interviews)

Participant Information Sheet

Study Title: Exploring tissue viability nurses' current perceptions and experiences of neonatal skin integrity

Researchers: Professor Dan Bader, Professor Lisette Schoonhoven, Dr Peter Worsley and Ms Hannah Liversedge

Ethics number: ERGO 25367

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

Some babies admitted to neonatal units experience skin damage as an unintended consequence of their hospital care. Although this often heals completely, it can be very painful, increases their risk of infection, and may prolong their hospital stay. At present, most of what we know about skin care and skin damage is based on research conducted with adult patients. Very little is known about the role of tissue viability nurses in providing skin and wound care for neonates.

I am a registered children's nurse. This study is part of my PhD project which I am conducting at the University of Southampton. The aim of the study is to explore and understand:

a) The experiences and practices of tissue viability nurses in relation to providing care for neonates

b) Any barriers to and facilitators of the provision of skin care for hospitalised neonates

Why have I been chosen?

Tissue viability nurses from this Trust are being invited to take part because the hospital has a neonatal intensive care unit.

What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form in duplicate. The interview will be organised at a time convenient to you.

During the interview, you will be asked to discuss some topics that have been developed from the responses to a survey of neonatal nurses in the Wessex and Thames Valley region, collaboration with senior nurses, a literature review, and the early findings of an ongoing prevalence and incidence study. These may include: your experiences of working with neonatal nurses or nursery nurses to provide skin care, what

helps or hinders you if you are called to the neonatal unit, and your personal opinions about what causes skin breakdown in babies. Your interview will be with a member of the research team.

The interview will be audio recorded to allow for later review and analysis, and will last no longer than an hour.

Are there any benefits in taking part?

If you would like one, you will receive a certificate stating that you took part in the interview and the topics discussed, which can be counted towards CPD hours.

The findings of the research may be used to inform future innovations or research, as well as teaching for staff within the Wessex and Thames Valley Neonatal Network.

Are there any risks involved?

There are no direct risks involved in taking part of the study. Some participants may find recalling previous experiences related to neonatal skin care and skin damage distressing. If this is the case you will be free to leave the interview at any point.

Will my participation be confidential?

This research will be conducted in accordance with the Data Protection Act and the data storage policy of the University of Southampton. If you agree to participate, you will be asked to sign a consent form. This will be stored in a locked cabinet in a University office. All audio recordings will be password protected and held on a password protected computer. Any notes made will also be stored securely. In order to maintain a linked anonymity all participants will be coded, rather than using names, with all reported data being linked only to this code. During the process of this research, raw data will only be shared within the research team (named above). Anonymised study data will be stored for a minimum of 10 years in accordance with the data storage policy of the University of Southampton. Personal contact information will not be retained after data collection is complete.

Once analysis is completed, an anonymised report of the findings will be presented to the unit and to the education team at Wessex and Thames Valley Neonatal Network. These results will also be written up, published, and presented at conferences and study days with anonymity maintained.

What happens if I change my mind?

You can change your mind at any stage throughout the study. This will not affect your legal rights. If you decide to withdraw early from the interview, and you do not want your responses to be used, you can inform the interviewer.

What happens if something goes wrong?

If you have a concern or a complaint about this study you should contact the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: rgoinfo@soton.ac.uk).

If you remain unhappy and wish to complain formally the Research Governance Office can provide you with details of the University of Southampton Complaints Procedure.

Where can I get more information?

If you have more questions after we have discussed this information, or at any point during the study, you can contact me by email/telephone. If you decide that you wish to participate, please let me know within three days of reading the information sheet in person or on the number below:

Hannah Liversedge: hll1g09@soton.ac.uk
02380 777222 extension 5345

Thank you for taking the time to read this information sheet.

Appendix L Consent form (interviews)

CONSENT FORM

Study title: Interviews to explore tissue viability nurses' perceptions and experiences of neonatal skin care

Researchers: Professor Dan Bader, Professor Lisette Schoonhoven, Dr Peter Worsley and Miss Hannah Liversedge

Ethics number:

Please initial the box(es) if you agree with the statement(s):

1. I have read and understood the information sheet (14/7/2017, Version 3) and have had the opportunity to ask questions about the study. ☐

2. I agree to participate in the study and that my research data may be recorded for the purpose of the study ☐

3. I understand that my participation is voluntary and I may withdraw at any time without ☐

4. I agree to the use of audio recording devices, with the possibility of anonymised verbatim quotes when the results are published ☐

5. I have had the opportunity to ask questions and have received ☐

Data Protection

I understand that this consent form will be stored in a locked cabinet in accordance with the Data Protection Act.

Name of participant……

Signature of participant……

Name of researcher……

Signature of researcher……

Date……

Appendix M Topic guide (interviews)

Opening remarks

Thank you for taking part in this interview.

It is part of a larger study with the ultimate aim of improving skin care for hospitalised neonates and minimising their risk of developing skin damage. In the past decade or so, we have become more aware of the fact that neonates who are hospitalised immediately after birth may experience many kinds of skin damage. A lot of the guidelines that have been issued to try and prevent this are based on research conducted with adults, which causes problems when trying to implement them in the neonatal environment. We are interested in understanding current practice in relation to neonatal skin care, in order to inform future research and innovation. We are also interested in any experiences you have had working with neonates in your current role as Tissue Viability Nurse.

The aims of this study are, firstly, to explore the experiences and practices of staff who are involved in providing skin care to neonates, and secondly, to identify and understand barriers to and facilitators of skin health in the neonatal unit.

This interview will be recorded for research purposes. The recording and content of the interview will be kept confidential. When the results are written up, they will be anonymised and you will not be identifiable.

Main interview-topics to discuss

Opening question: Can you tell me about any experiences you have had working with the neonatal team on issues of tissue viability?

- **Knowledge and skills**
    - Perceptions of skin damage (frequency/severity) in neonatal unit
    - Risk of skin damage in neonates compared to adults
    - Causes of skin damage in neonates
        - What factors do you think affect a hospitalised baby's skin integrity?
    - Sources of information about neonatal skin care
        - How would you find information about neonatal skin care?
    - Any training on neonatal skin
    - Anything that would be useful/helpful in practice in relation to neonatal skin care
        - Can you tell me about any training you've had regarding neonatal skin or tissue viability issues?
- **Cognitions**
    - Confidence/competence relating to neonatal skin compared to rest of workload

        - How confident do you feel when you get called into the neonatal unit, compared to your day-to-day work?
    - Evidence base for neonatal skin care—adequacy/quality
    - Priority of skin care in relation to other aspects e.g. device use
- **Team processes**
    - Role of TVNs in relation to neonates
    - Frequency of TVNs attending neonatal unit
        - To what extent are neonates part of your role as TVN, in comparison with the rest of your workload?
    - Is best use made of your expertise?
    - Communication with neonatal team
        - Can you tell me about anything that makes it easier to work with the neonatal team on issues of tissue viability?
        - Can you tell me about anything that makes it difficult to work with neonates?
    - Interacting with parents

Closing comments

We are nearly at the end of the interview.

Is there anything else related to the subject of neonatal tissue viability that you would like to talk about?

Thank you very much for your time and contributions to the study.

This audio recording will be transcribed and analysed, along with transcripts from other interviews and focus groups. The transcript and recording will be stored securely on a password-protected university computer. A copy of the findings of this study will be made available to

Appendix N Interview transcripts

Participant 1 - 7/10/17

[Consent process explained off-tape, and consent form signed. HL explains that the interview is about to start; switches on microphone].

P1: I can't stop drinking my tea though.

HL: [laughter] That's fine. Okay, we are now recording, just so you know. Before we start the interview, I just want to read you a statement about the research just so you – I know you read the Participant Information Sheet again this morning, but just so you know what we're doing.

P1: Okay.

HL: [opening statement]

HL: So just as we get started, can you tell me about any experiences you've had working with the neonatal team on issues of tissue viability?

P1: Well, I did previously work with neonates, so [indistinct] their skin was part of my day really and I and I left that about um I don't know maybe [pause] 20 years ago now, but I did that 10 13 years and then since I've been in this role which I've been in for two and a half years, crikey, um, it's usually me if we get a referral that goes up to tissue viab- up to the neonatal unit.

HL: Mm. Okay. You said you, just to check you said you worked with neonates for about ten years-

P1: Yeah

HL: and that was about twenty years ago.

P1: Yeah

HL: Okay. Thank you. Um, er, so in your experience both previously as a neonatal nurse and now as a tissue viability nurse, in your opinion, er, do you, do you perceive neonates to be at risk of skin damage?

P1: Yes. Yeah I mean especially the really early ones because sometimes you know you sometimes feel like they haven't really got any skin it's so fragile.

HL: Do you think that, um er, how do you think that the risk factors in neonates er compare to the risk factors in adults for skin damage?

P1: Um, say that again?

HL: So, obviously – or firstly maybe I should ask how great a part of your workload do neonates make up in comparison to adults?

P1: A really really tiny proportion, yeah.

HL: And, er, obviously, if most of your work is with adults, um how great er or how do you think the different risk factors for skin damage compare in neonates to with adults?

P1: I think the neonates have got just as big a risk um as the adults, but I don't think it's, not as high profile, but er neonatal nurses are just so used to managing it that I don't if they always think of it as particularly, like with the word risk I think it's just part and parcel of what's happening to them and they're used to dealing with it themselves [pause] but for me they're hugely at risk you've got to turn them and just that particular movement can be so abrasive that their skin breaks down.

HL: Okay thank you. Um what factors in particular do think might affect a neonate's tissue viability?

P1: Do you mean [pause] their skin or do you mean like external?

HL: Either

P1: Okay, I mean I think having worked there and obviously still having some contact that if you're outside of the neonatal unit it's quite a scary place to go and they're so small aren't they and they're so covered with monitors and things that you can be really hesitant anybody to to get in there and they don't really understand neonates, and so I think that most people leave the neonatal unit alone. I don't just mean tissue viability, I kind of like mean generally really, and therefore I think neonatal nurses, and a lot of them are children's nurses, the whole kind of pressure ulcer thing doesn't really affect them. They're so used to babies having skin damage that it's just part and parcel of what they do so the whole reporting of it or bringing in the tissue viability nurse, they're like well we just get on with it. So I think that I think that's quite an issue, so to get in there and to make change, is can be quite challenging.

HL: Yeah, okay. Thank you. Um er and in terms of if you were called into the neonatal unit or if you were still working there as a neonatal nurse, um, what particular things do you think would place a neonate at increased risk of skin damage?

P1: Um what apart from the fact that they're usually preterm and if they are term then they're sick so those two factors place them at more risk. Um I think it's around the whole – it is around

medical devices, because obviously even with adults we're not designed to have tubes and things but their skin's so fragile that um I think people talk about pressure from the medical device but I, well I never hear really hear people talk about is the fact that underneath that medical device babies are often really mobile and some medical devices don't fit firmly to the skin so it's, I think to myself it's not really going to be a pressure ulcer because I can actually get my little finger in between that, but the baby moves around so much that you get like a trauma and a friction from that medical device. Um and it's really hard to know how to protect them from that because anything that you put on that skin such as a dressing when you take it off, you think well I'm going to cause more damage so I'm better off leaving them, so I think medical devices um and we don't, you know, we don't always have air mattresses and things because they're usually quite mobile.

HL: Okay. Thank you. Er – I know you've got um previous experience working with neonates, but if you were um called into a situation and you wanted to find some extra information about it, where would you look?

P1: Do you mean extra information about that wound looking in the medical notes, or extra information so I'd go off and do a literature search?

HL: Yeah, something like a literature search.

P1: Well if I look at something and I think blimey then I would do the same thing as I'd do with adults and then I'd get online and I'm doing a search – um – because I'm not in neonates any more it's harder for me to have that um get a peer opinion something like that. I'll often phone or try and get hold of because he's always a good person to run things past.

HL: Okay, thank you. And how if you were looking for um you mentioned literature search, how do you think you would find the um evidence base for neonatal tissue viability in comparison to adults?

P1: I would probably think well that's no use whatsoever because there's nothing there um so I wouldn't I don't think I'd get many hits. I'm certainly not expecting a result to come up on Cochrane.

HL: Okay, thank you. In your current role, have you had any training on neonatal or paediatric skin?

P1: Um [pause] not hugely but I'll have gone to the odd bit um uh sort of like at EWMA and WoundUK and if there's been a paediatric one then I'll have you know got on it and even going to the medical devices talk the other day from I found that really interesting just kind of like a bit of

a reminder really about the depth of skin and how it could go on you know and develop this permanent scar damage, so it's kind of snippets really of grabbing what you can.

HL: Thank you very much. Um er is there anything else that you think could training that you could have that you would find helpful? Does that question make sense?

P1: Um [pause] I don't know about training, I think it would it's always helpful to sit with a roomful of people who deal with this to actually start thinking about kind of like the political side really, and you know when do you call something a pressure ulcer when don't you, because I don't believe that everything from a medical device is a pressure ulcer. But how you know what what do they call and and how do they make that decision so you can kind of throw ideas and bounce ideas off each other really to try to because it's just such a difficult area.

HL: Out of curiosity, when you are called into the neonatal unit is it normally for a pressure ulcer or are there a variety of different skin concerns?

P1: They don't, I would say that the neonatal unit don't really associate any wounds with pressure so we very rarely get called to pressure ulcers um in fact you'd think that they didn't have any but I know that your report is telling me different. So that's something that you know we need to address. It would usually, it's usually moisture damage and they're worried about managing that.

HL: Okay, thankyou. That's really helpful to know. Um er in terms of when you are, you've you've slightly alluded to this already, but compared to the rest of your workload, when you are called to the neonatal unit, how confident do you feel in that particular environment?

P1: Yeah, okay actually. Probably because I did it before. I mean, not confident any more in I wouldn't feel safe even turning a baby over whereas you know used to flip them around like there was no tomorrow, but I don't feel unconfident in looking at the skin and you know the whole environment doesn't freak me.

HL: Okay, thank you. Um and in an environment such as a neonatal intensive care unit, how, this is a maybe a difficult question but how great a priority do you think skin care should take in relation to the rest of the baby's care?

P1: Well [pause] having worked there for a long time I know that actually keeping them alive sometimes is actually your greatest priority and um some babies you can't you know absolutely minimal handling because otherwise their sats will be in their boots. So when you're thinking in that situation you're thinking you know they might end up with a bit of keloid scarring but actually if I if I keep going in there they're not actually going to be alive for that to be a problem. But [pause] it's very painful you know and it's very distressing and it can give real long-term problems

so it's certainly way up there with importance but I think keeping them you know alive sometimes means that you can't get in there as often as you like.

HL: Sure. Thank you. Um how working in this trust in your role as a tissue viability how do you see your role working with the neonatal team?

P1: Um I think that it's really important that they that we work together and and I think they're much aware of tissue viability than say they were a couple of years ago in regard to thinking that they've got to get our input say in care plans um [pause] you know when they're trying to devise a new care plan when they're thinking of a pathway for you know looking after skin and they know that they can't you know in a way order what they want because they're thinking about formulary and they can't just take things off reps, so they're very aware of that um and [pause] they're coming I think they probably know that I'm going to be in touch with them shortly to be in touch with them about pressure ulcers so I think they've got more of an awareness of it.

HL: Um what do you think has facilitated that over the past couple of years?

P1: Um probably because we're quite a proactive tissue viability team so the three of us are well known throughout the trust and we haven't been scared to get into there, into paediatrics and formulary and and and getting up on the neonatal unit really.

HL: Thank you. Um er would you like to be more involved in that – or if you were to describe ideally how the neonatal unit would use you and your expertise, what would you like that to look like?

P1: I think I would like to be called to more cases of wound damage which I think will happen when we start challenging them about the slide that put up.

HL: Do you find that at the moment they call you only when a serious wound has already occurred or when they are or is it more preventative there's a baby they're/particularly concerned about.

P1: /Both actually you know we've I've taken a referral where they've just been worried it was like a 23 weeker and the skin was just so fragiule that they were just saying is there anything else we can do again there's so little we can do isn't there? So both really.

HL: Okay. So is that what you would like to be called in both preventative and/when there's already-

P1: Yeah why wait, I would always prefer that with adults to you know if our workload wasn't so horrific we would promote more really.

HL: Um and how often would you say at the moment that you're called to the neonatal unit?

P1: I don't know. If I said once a month I'd be exaggerating.

HL: Okay. Thank you. Um er and when you first came here, do you feel that the best use was being made of your expertise?

P1: With the neonatal unit?

HL: Yeah.

P1: Um yeah probably because I've still got friends up on the neonatal unit so they immediately know that I was in post so they yeah.

HL: Okay, thank you. Um and so do you think that has improved over the time that you've been here or not changed very much?

P1: I think an awareness of the service has improved. I think that because of the [pause] because of I don't want to say politics but kind of like the beliefs within the unit of the lack of need to have any outside input into their babies' wounds, we haven't been utilised as much

HL: Okay. Could you expand a little bit on that?

P1: You know that if you get a wound you would then get an report it as a serious learning event and so you'd try to get any learning out of a wound, so I don't think that all wounds are reported because it's seen very much as a normal process of what happens to that baby – you've got a medical device you get a wound – so it's not always reported as a pressure ulcer we're not always we're not always called um and that's the kind of ethos of the trust, of of that unit and so it's quite difficult to get that challenged and changed so sometimes you might say something, you might say that needs a we used to call them Datix, oh that needs a Datix, oh no and you're like what why and so it's kind of getting that change which is going to be my next challenge.

HL: I'm curious to know how you find that compares to very high care environments in adults like ITU where again that's lots of/medical devices

P1:/They Datix everything.

HL: Okay.

P1: And they call us for everything.

HL: Do you think I know there are specific prescribed standards in adult units around reporting, do you find that really do you find that helpful when you're going into adult units compared to paediatric or neonatal units?

P1: I think the difference is that in adults it's just accepted that's what you do, the nurses make that decision and do it, whereas in neonates it's nurses just don't seem to think that they can just go and do a Datix. It's like you've got to go and get the doctor's opinion and permission to do it. Which is not not like it is in adults.

HL: Yeah, um er and do you think that um more reporting or things like that would be more helpful?

P1: I think so because then um hopefully we can learn from them, and we're never going to get anything changed with the medical devices are we if we don't report them. So that's like another thing that I've added to my job list is to remember both with adults as well that every time we get a pressure ulcer from a medical device I must report it to the medical device [pause] thingy. [laughter]

HL: Okay, thank you. Um er and in terms of when you are you've already slightly alluded to this, but when you are working with neonatal team, in terms of your communication with them, is there anything that makes it harder or easier to talk to them?

P1: Um no they're always kind of really pleased to see us because I think if they call us cause they leave so much without calling us that the times that they do call us they're really pleased to see us and um they really want to do everything that we've suggested.

HL: Yeah. Okay, thank you. Um I know that there are tissue viability link nurses on that unit. Have you had much contact with them?

P1: Yeah. [pause] so um they'll be the ones that tend to contact us the most or are [indistinct] so I know them all, um invited them to the day the other day and I was really pleased that three of them turned up. So yeah I'd say that they were all keen and yeah.

HL: Thank you. Can you just describe for me typically what happens when they make a referral to you?

P1: Um what they'll do is we've got an online referral so they just go online, fill it in, and send it to us, press submit it comes through we pick them up every morning and throughout the day. Um we would try and do the neonatal unit first if we've got one because then we're not taking bugs from the adults wards onto the neonatal unit same for paeds and maty, um and then we go and

see the patients. Yeah. Sometimes it will be something that we'll think ooh you know we're going to follow this up and so we'll see them more than once and other times we won't and other times I might look at it and think I don't need to see that patient and I'll just phone the neonatal unit up and say you know I think that what you're doing is fine.

HL: Lovely, thank you. Um and again I know you've got previous experience working on the neonatal unit. Have you ever been asked to work with parents to talk to them about their child's condition?

P1: With the skin?

HL: With the skin.

P1: Um [pause] I don't think I've ever been called in when they're not there but I've often spoken to parents if if they're present because I always think you know it's your baby so they should know what it is that I'm doing and thinking really.

HL: And how have you found that, how have you felt and how has that been received?

P1: Yeah – um yeah. Fine. I think I worked in general practice for a long time so I was always used to talking to parents about their children on lots of different topics so I don't – I'm completely fine about it and yeah the parents are always fine as well I think if you just explain the background and the reason why something's happening and what you're trying to do to prevent it and what the possible outcomes could be, and you try and give them basically everything that you know then they're usually quite happy. If you give them a plan as well.

HL: Yeah, thank you. At the towards the start of the interview you mentioned that er as you've been trying to make some changes in the neonatal unit you've encountered a little bit of resistance or found that difficult. Could you expand on that a little bit?

P1: Well I think that [pause] some people and this is across the trust is that they can think that putting something into Datix or reporting an incident is something to do with blame rather than learning and I, you kind of get that feeling sometimes with the neonatal unit probably because they're not used to Datixing things about skin is that maybe there it's a blame thing whereas it's not it's about like learning um so I don't know whether that's where the kind of culture had come comes from because that's certainly not the belief of the senior nurse there but this is something that I'm going to be investigating further.

HL: Thank you. Is there anything that based on those experiences you think could er would help that would make that easier?

P1: Um probably some more education but I think that that's something that I've had conversation with about the nurse that leads on sort of Datix reporting and you know we're going to have to work on that together and try to get to the root of what's going on and why these things aren't being reported.

HL: Um again if you could ideally design what would you like um the skin health education for neonatal nurses to look like?

P1: Um [pause] well I think it would be great wouldn't it say in an ideal world if you could like you know get loads of nurses off there for the day and and to do like a whole neonatal paediatric study day so you know you'd be talking about your risk assessment because we don't have one here um about the you know thinking about the different types of wounds or skin breakdown that you get in both neonatal and paeds. Nappies you know to stop the nappy rash we put on all sorts of things just whole day of you know good old-fashioned study day on lots of different topics that would be nice and then um probably some regular inhouse sessions I think it's good sometimes to get the neonates and the paediatrics staff mixed in it gives them the neonatal staff access to someone else as well apart from each other, and to have like a monthly session really but it would probably need to be by someone who's got a better understanding of paediatric skin health than me cause I don't know if I'd have time to keep myself current on all those things, but I'd probably be able to find access to somebody to do that.

HL: Okay, that's really helpful, thank you. We're nearly towards the end of the interview, is there anything else related to the subject of neonatal tissue viability that you would like to talk about or raise?

P1: Um [pause] I don't think so. I think one of the challenges really is dressings because there's not really any good concrete evidence with what you can dress the wounds with because obviously who's going to do it on a neonate, um so that can be quite difficult, and then if you do want to prescribe something the doctors are all quite nervous about it, you have to really convince them that the dressing's alright.

HL: I'm curious to know how you go about doing that, first how you choose which dressing you want to use, and then how you convince the doctors to um co-operate.

P1: I think honey is a nice safe dressing and lots of um neonatal units use it, um I've had some talks on it at EWMA so what I did was I got the honey rep to come in and she brought some you know documented evidence up for them and then I used it on a baby that had a kind of like a nasty old umbilical wound I think they must have had an umbilical catheter in and it was amazing, and so they've seen it both in practice and in theory, um.

HL: Do you think that's made a difference?

P1: Yeah, so they will use they will use um you know the docs will use the honey now, and I've changed over the barrier cream for them and again I just had to go armed and they're just worried that they're going to you know they're going to be sued sometimes you know I don't blame them it's a very contentious issue, isn't it?

HL: Yeah

P1: So that's stuff I usually have to do.

HL: Okay, thank you, that's helpful. And how do you um find so that's a little bit about doctors how do you find nurses react when you bring in new products?

P1: Um the nurses are usually they're just quite excited to have something apart from the senior neonatal nurse practitioner who obviously would be prescribing it as well and signing and writing it up, and naturally worried about their NMC registration so she needs the same reassurance if not more than the doctors.

HL: That's really interesting. I hadn't thought about that, thank you. Um is there anything else you would like to mention?

P1: I don't think so, but if I think of anything I'll email you.

HL: Thank you. Thank you so much for your time and for taking time out of your lunch break to talk to me I really appreciate it, um this audio recording will be transcribed and analysed along with transcripts form other interviews and I'm hoping to do focus groups with the neonatal nurses too. The transcript and recording will be stored securely on a password-protected university computer. A copy of the findings of the study will be made available to you if you wish. This is the 6th of October 2017.

P1: Lovely

[End of recording]

Participant 2

Consent process completed prior to recording.

HL: [opening statement]

HL: So just as we get started, um have you had any sort of specific experiences working with neonates in relation to tissue viability?

P2: Um I have in the fact that um we as a tissue viability team we cover everybody within the trust so we'll see anybody um so I have been called over to look at um different skin issues in the past not frequently um but yes I have been over and seen um neonates. I'm not children trained though I'm adult trained as are most tissue viability nurses.

HL: Yes, of course. Um are there any particular experiences that particularly stick in your mind?

P2: There probably the the the most was we had in this hospital we had um a neonate who developed a grade IV pressure ulcer to the septum of the nose from um a tube. This is probably going back about ten years so it was when I first started within the team um and that was the first time that I'd really clicked that that babies and neonates and and and um you know children that young, because I'd always been adult-focussed, could get skin damage the same as adults and in fact it's worse in many cases because with neonates because their skin isn't developed as much it breaks down much quicker and to a much larger depth so yep.

HL: Mm. How did you when you had that first experience er how did you find that in relation to the rest of your workload?

P2: Very strange. It was very it was very upsetting because you I wasn't used to seeing little babies so and being adult-trained I'd done a um a placement with children but not really never been near a neonate unit so the unit itself is very um high-tech in in a in a way that when you're not trained in that area so and I think going over to see something that small was was quite a was quite an experience for me and that that little that little baby still sticks in sticks in in my mind.

HL: Thank you. Um er so you've alluded to the fact that you think neonates are at risk of skin damage, um how great do you think the risk of skin damage is in babies who are hospitalised in the neonatal unit?

P2: I think they're at just as a high risk as anybody that is hospitalised so when anyone's hospitalised we do things to them. They're hospitalised for a reason so they're acutely unwell, there's something going on, and also they've also got the um issues that their skin hasn't completely formed they've been born preterm so everything isn't working as it should.

HL: Yeah, thank you. Um er what how do you think the factors that place a neonate at risk of skin damage in in your opinion compare to those that place an adult at risk of skin damage?

P2: Neonates probably are more at risk in in in in my in my opinion and I'm not an expert but in my opinion I would say they were more device-related, because they're so small and they're so unwell they've got an awful lot of um interventions going on, so I would imagine that they're they're at higher risk of breaking down from devices rather than just with adults it's more to do with the fact that they're sedentary and they're not moved or they're not moving, whereas children tend to move a little bit more. Um so I think it's probably more device.

HL: Thank you. Um again are there any particular devices that you've noticed you've mentioned one already that kind of er you think place neonates especially at risk?

P2: I think all devices will place neonates at risk, I think even from the like ECG pads, or or any any tubing that's going to touch the skin is going to put them at risk because their skin isn't completely protected, but I think NG tubes, the intubation tubes, anything that's happening on their face especially or near their little nose etcetera is going to cause issues.

HL: Okay, thank you. Um and if you were um called into a situation on the tissue viability – oh the tissue viability unit, the neonatal unit – and you wanted er some more information about that particular type of skin damage, where would you look for information about skin damage in neonates?

P2: I'd probably just look on some of the um wound care sites so there's um some information on the European Wound Management site, the world health um management site, but to be honest um there isn't a lot of information out there so when I first saw um the little neonate that I was my first experience, I looked up a lot of um tried to find information and there isn't an awful lot out there on skin damage specifically in neonates.

HL: Um and how easy do you think it would be to kind of get a second opinion or a peer opinion with er neonatal skin damage in comparison to adult skin damage?

P2: Much more difficult.

HL: Mm/ okay.

P2:/Much more difficult cause I don't think neonates are I think sometimes the other issue I think I have from going over is that neonates is such a speciality and the the nurses and people that work with neonates are so very skilled in neonates that they tend to um in-house manage any areas of skin damage so the tissue viability team isn't always called in cause they try to manage

things themselves because they have the skills with neonates so they just tend to just be a speciality that deals with themselves.

HL: Um that's really helpful thank you. Um er have you had any training since you started working as a tissue viability nurse on neonatal skin?

P2: Nope.

HL: Um do you think there is anything that would be helpful for you to have in relation to neonatal skin training or other otherwise?

P2: Absolutely I think that for for neonates and for children there should be some specific training for for um adult nurses that are going into these things it's it's really difficult in um a situation where you haven't got those honed skills. I've got wound care skills and I know how a wound heals but having to learn about neonate skin and things it's a lot of it is just self-directed learning and then also you're you're not 100% sure you're picking up everything, all wounds are are very similar in their aetiology and and how we're going to manage them, but neonate skin is so different that I think it would be really useful. And of course children and neonates in the whole are in a in a have a a black hole when any of the patients go home, so there are no tissue viability nurses in the community that cover children, which is real issue.

HL: Mm. So do you think a neonate going home after being hospitalised here would be potentially still at risk of skin damage?

P2: Absolutely. I think they are and also how manage who monitors them? Who with wound care knowledge or skin knowledge monitors them? So I presume neonates would be monitored the same with midwives or not midwife with a midwife or health visitor? With very few skills in wound care.

HL: Yeah, that's really helpful thank you. Um er one of the things I wanted to ask was how easy do you find it to stage er or grade a pressure ulcer that's happening on a neonates?

P2: [laugh] Again, very very difficult. With the more difficult I think with the superficial skin er grades, so grades I or II, skin often in neonates from my very little experience is often quite red anyway in some areas they often have discolouration, er but and grade IIs how can you say it's just superficial skin loss if they haven't got a full thickness of skin of their skin still developing? That's very difficult. I think when you get to seeing something that's fully necrotic um or er you know or has fully developed and you can see that the tissue's devitalised that's much easier because you know you've lost that tissue but for the more superficial ones I think it's much more difficult.

HL: Mm. And does that then affect how easy it is to manage that particular wound?

P2: Absolutely. Plus the fact that a lot of the things that we have in the the form of dressings and interactive dressings can't be used on under twos, let alone tested on neonatal skin so there you know you've got a real problem with how you treat those wounds you've got to think of it in a totally different way because you can't use a lot of the products you would use in the in an adult population you can't use in children and neonates definitely not.

HL: Okay, thank you. Um er so oh the other thing I wanted to ask was um something I've heard from a few other people I've spoken to, how easy do you find it to determine the cause of a particular piece like piece of skin damage, whether it's a pressure ulcer or whether it's something else in a neonate?

P2: It's really difficult, very very difficult. So what I tend to do is um speak to the staff that are looking after the neonate cause as a tissue viability nurse you go in and you see them at one particular point, you don't see what's happened previously, so quite often what we'll do is gain information from parents because they'll they're usually the best judge of what's going on um and the the the nurses and also the doctors because sometimes it can be rubbing or trauma or so to to to distinguish whether it's pressure or something else is extremely difficult especially when you only seeing them at one point.

HL: Um I'm curious to know how you find er going onto the neonatal unit and talking to the staff there compared to other places that you go.

P2: I think um it's very different. I think in the adult population the the um nurses are used to us, and are are are expecting help, I think even in paediatrics they like our help, I think in neonatals I'm not saying they don't like the help but what they do they like to keep things in house, that's how it feels so as a as a specialty they like to do things themselves, and they like to manage things themselves and um they don't also um like to get involved in the pressure ulcer reporting and things, so at the moment we haven't got um the neonatal unit don't report that they have any babies with pressure damage, although there has been a piece of research happened in Southampton recently that shows that they have got pressure damage, but they don't see it as pressure damage, so I think it's very difficult to when you go on the unit when you go on the unit everybody is very friendly, but they don't really see the point of us being there.

HL: Um do you think that is the case with them more generally reaching out to other specialties so other specialist nurses? I know you will have only had experience as a tissue viability nurse but/is that the feeling that you get?

P2: /Yes, I think so, yeah. And I think because that with from the meetings I've had with them, I think that's how they feel the so I think they feel that they are the experts in the neonatal, so that they feel that they can manage the the neonatal better than the other specialties that usually specialists a specialist teams are specifically adult or you know they're not paediatric or neonatal trained.

HL: Um is there anything that um you've encountered that makes it particularly easy to work with them or particularly difficult?

P2: I think um particularly easy is the fact that they are very willing and they know so much about the babies so when you go over, it's you know when you speak to the nurse looking after that baby you get every detail of what's happening medically or clinically with with the little one so that's really really easy makes life so much easier you don't get that in adults um quite often, so you get that I think the difficulty going over is they the the fact that their knowledge of the neonatal staff in pressure ulcers they don't understand the implication of pressure ulcers, and I don't think they understand the implications for in the bigger strategic picture of reporting so I don't think that they feel that is important, their focus is on making sure that the the little one's okay so the the pressure ulcer thing is is quite difficult.

HL: So I know that in the trust for adults there are sort of mandatory reporting for skin damage I know that probably doesn't always happen, but for some grades of skin damage is that right?

P2: There's mandatory reporting in all areas.

HL: That's what I was going to ask, so it does [indistinct] apply to them.

P2: Yes. And neonatal the neonatal unit return a weekly audit on pressure ulcers to say whether they've had any um any baby within that previous week with any pressure damage should be returned on the weekly return.

HL: Is that only above a particular grade?

P2: Nope. That's everything, so that's grades I II III and IV.

HL: Thank you that's very helpful to know. Um er the other thing I wanted to ask about your experiences of actually going onto the neonatal unit, um have you ever been asked to talk to parents about or you've mentioned that you did talk to parents about the skin, how do you find that? Obviously you're not a child children's nurse.

P2: Absolutely. I mean I I find that now I'm more experienced I find that a bit easier but I don't ever speak to parents without the neonatal um staff with me. I wouldn't go on and speak to any

parents, because um questions that come back you need someone with neonatal experience to to to answer any specific questions. I'm quite happy to explain about the breakdown in the skin it's because of whatever, but er and also ask them what how they've seen the wound develop, so I can I'm quite happy asking questions, but I'm a little bit more nervous about telling them things. Also because um you don't know because I don't know neonates I don't know the prognosis of the little neonate so I don't know what's happening in the bigger picture so I wouldn't want to say anything to parents about this could, you know, this might heal in a month's time or something I would be more happy doing that with an adult than I would with a child because I don't know what's going on.

HL: That was going to be one of my other questions actually. Um er how confident do you feel generally when you're talking when you're working with neonates compared to working with adults?

P2: I'm much more confident with adults not and much less confident with neonates. I think because it's a it's an alien environment, I mean the ones I've seen have been usually have been in an incubator they've got lots of things going on it's quite I don't like touching even sometimes and er you know because you don't want to dislodge anything and you don't want to make anything worse or move anything or [indistinct] so because it's an alien environment I'm always more more timid and I would always expect the nurse to be with me say and asking her can I touch there where can I do and you know just to make sure I know.

HL: Yeah. And when they um when they do call you are they happy to facilitate you and be kind of with you while you're talking to the parents and things like that?

P2: Absolutely I've never had a never had a problem where they don't didn't want to interact in fact they usually get two or three people to come over and have a look at the same time so yep no they've always been brilliant when I've gone over.

HL: That's that's good to hear.

P2: Yeah they've always been great.

HL: Er [pause] in er any high care environment whether it is neonates or ITU or anything like that, um how great a priority do you think skin care takes like how should it be prioritised in relation to the other care. So for example if there's a device that's causing problems, how important do you think the skin care is in relation to the rest of the care?

P2: I suppose it's a difficult question for a tissue viability nurse [laughter]!

HL: [laughter] That's why I'm asking you, I want lots of different people's/ opinions!

P2: /Yes, so for my opinion yes, skin care is of utmost importance, because um you know your skin's your largest your largest organ in your body of the body, if you get a break of skin integrity you've got a risk of infection coming in, so for me the skin and the maintaining of a good skin integrity is absolutely paramount because if you can gain re regain that it's all, everything else will work around it. With devices obviously the devices are there for a reason and they have to be used, so I I I truly understand that sometimes skin integrity has to take a second second place however what we want to do and what I would expect is they're going to look at protecting the skin integrity even with a device, so using different pieces of equipment or something to to reduce it so with adults for example we use, and in children sometimes, we use um a tape to go over the ears to stop the um oxygen masks from causing pressure damage and things like that so there are things you can put in so again I think skin integrity is so important because if they've got a device on, and you break down their skin integrity, that device is then going to hurt them so you're going to cause more pain you're going to put cause more risk of them non complying with the device because it hurts so keeping the skin integrity is is essential.

HL: So you've introduced a few things like that in adult and paediatric environments. Have you ever tried to introduce a change like that in the neonatal environment?

P2: No.

HL: How do you think you would find it if you did?

P2: I don't think that they the neonatals would be particularly um [noise of colleague entering] sorry Sarah I don't think that the environment would be very conducive, to somebody else coming in and suggesting a change.

HL: Um can you expand on that a little bit?

P2: So for example if I've been into neonatals before and we've discussed dressings and when we were changing the formulary I spent a long time with the um with a lot of the neonatal nurses discussing their specific needs for within the formulary, and they felt that they knew their skin much better, they used specific products, and weren't really very happy to to change so I think with their with their knowledge and their expertise I think that that maybe that somebody else coming in that they know has an adult background they don't seem to be as willing to take things on board um as as other adult areas do.

HL: Is there anything that you think could in in um in an ideal world how would you improve that or how would you change that?

P2: In an ideal world if I could if if if you know you could work with them in neonates, um if you could do a course I mean a course in neonatal skin or ti you know issues or pressure ulcers, would be amazing, you know if I could do something like that, then I would feel more confident discussing things so I could go in and and with a bit more confidence, so at the moment I would go in with confidence in pressure ulcer knowledge, but with no confidence with neonatal knowledge so um that's when you hit a barrier because um if somebody doesn't really want to listen about pressure ulcers then you don't know enough about neonates, you can't sort of use a good argument or a positive argument to say well this would really work.

HL: Um that's helpful thank you. Um you mentioned earlier that the neonatal team don't really seem to see anything as pressure damage, why when do they call you then?

P2: To be honest they call us when there is an area that has broken down and it's not healing, so if they're getting into problems with an area that's not broken down and not healing then they call us. The referrals from neonates very few.

HL: Yeah. How often roughly would you say they call you?

P2: Maybe [pause] once every six months, if that.

HL: Okay.

P2: So not not frequent at all. When I first came into the job then we were called very frequently there was a lot of referrals, however they got they had a team um over there a senior team in our neonatal unit who tended to be the ones that manage the skin issues so they sort of took over and sort of um manage things unless they get stuck.

HL: So they have like tissue viability links?

P2: I don't know I don't think they have links but they have a senior team so I think they have a surgical practitioner so I think she does a lot of the skin care and I think they sort of do it as a senior team they manage any area of skin damage that occurs on the unit they would manage um from with with that higher level of neonatal experience and it's only if they get into a difficult where they're not quite sure what to do then they would come to us.

HL: Okay. And you haven't particular who tends to call you when somebody does call you?

P2: One of the nurses will just call one of the nurses on the ward.

HL: So it's not somebody from a specific team or anything like that?

P2: No. And we have had a couple of instances where we have been called and when we phone back to find out more and to arrange to go over we're told oh you don't need to come because so and so's back in she's seeing the wound.

HL: Okay. Um if would you like to be more proactively involved?

P2: Absolutely. I would love to be love to be more involved because um as I say recently at a meeting I found out that there's been a study in the neonates which I wasn't aware of which found that our neonates are having some pressure damage however for the last year two years neonates have returned their weekly pressure ulcer form every week with no pressure damage on it so that's why I've I would like to get in to establish what's what's happening to see if there are any things that we can do that are very simply to um be able to change things because we have a network of tissue viability nurses have a huge national network that we can go to ask questions which I know neonatal do to but as far as I'm aware there aren't any neonatal tissue viability nurses.

HL: Okay. I'm not aware of any either.

P2: No.

HL: Um er so if you could kind of describe what you would ideally like your role to look like on the tissue viability not the tissue viability unit/I keep saying that/

P2: /I know what you mean!/

HL: /what would you like your role to look like?

P2: I would like to be there as a supportive role I would like to be called in to check um when there is a pressure ulcer the same as we do with adults um check on the grading so that there's another pair of eyes from looking at it from a different perspective so literally as a supportive role to help with the neonates so obviously I don't know more than them and I would never feel that that that a specialist role is a very um it's a very unique role anyway because you are not an expert in the different areas you go you are you have more knowledge in one singular place which you can bring as a different set of experience to a unit that's obviously very specialised. So we would do the same with ITU so we have an extremely good relationship with ITU we have an extremely good relationship with PICU so our paediatric intensive care call us constantly so I would say we have at least two or three referrals a week from PICU um we we're for all ages of children so if they've had any areas with there when there's been a pressure ulcer or they've got an area that's just a little bit sore they will call us to go and check and advise and make sure

they're doing the dressings correctly. So that's the sort of relationship I'd really like with the neonatal unit as well.

HL: Okay, lovely, thank you. I am curious to know whether you've had any or particular interactions with the neonatal doctors when you've been over there?

P2: No.

HL: No. Okay, well don't worry about that question then.

P2: No, no no interactions with them really.

HL: Um er I think that's almost all of my questions let me just check my notes. Um oh um going going back to the fact that the neonatal nurses don't really see anything as pressure ulcers, have they ever called you for other types of skin damage like severe nappy rash or anything like that?

P2: Not severe nappy rash, no but they have um I think with the severe nappy rash that was um we did when we did the formulary we did manage to put in a protocol for dealing with that so they know what products to step up to.

HL: Okay.

P2: So I think that's the reason we don't get more nappy rash we've had a few surgical incisions that um there's been a little bit of breakdown on a surgical incision so we've gone and seen things like that but again as I say that that it's very far in and between ten years ago there was quite a lot and it's sort of petered off and I don't think that any of my team have been I think probably um just one of my team as well as myself have been to neonates in the past year.

HL: Okay. Okay. That's helpful thank you and the last question I think um er neonatal nurses I've heard from lots of people might not view skin damage in the same way that tissue viability nurses do, er do you think there any particular causes of that?

P2: I think it's probably just the culture I think that the culture of the neonatal unit is very different from what I understand so from what I can understand their main um aim is to just clinically get the baby through and dev you know keep them going, and I think that skin is not viewed as skin damage is viewed as a as a what's the word just a consequence so it's not viewed in the same way and you know because they're so small the skin hasn't formed I've heard neonatal nurses in the past say well they're going to get skin damage so I think that's a culture that they don't believe that it you know that that it's going to happen if it happens it's going to happen and there's not a lot really you can do to prevent it.

HL: Okay. And you've talked about what your ideal er what training you would like, is there any training you would like neonatal nurses to have about skin, how would you like that to look in an ideal world?

P2: In an ideal world I'd like them to have very similar to us so actually having um a breakdown of what neonatal skin exactly what the damage can what damage can be caused and also about pressure damage and the risks of pressure damage and how they should should should manage it and looking for ways to prevent it so I think that they should definitely have that. I know that they couldn't have the pressure pressure ulcer education that we have probably isn't that we have for adults isn't isn't right for neonatal nurses I think they would just find that useless to them because it's totally different, but I think they should have some knowledge of neonatal skin knowledge that pressure ulcers do occur would be really useful and what to do about it but also of grading as well.

HL: Yeah, okay. Okay that's all really helpful, thank you so much.

P2: No, that's fine.

HL: We're towards the end of the interview, is there anything else on the subject that you would like to bring up? Um a lot of the time what happens is I turn the tape recorder off and then the per the other person says I didn't think this was relevant but, so if you have any random asides I would love to hear them.

P2: I think um neonatals is just such a very very special very very niche specialty that I think um it's sometimes with all areas that are very specialist it's very difficult to get outside people or to allow outside people to come in with an opinion and often that's seen as somebody interfering in the in the area so I think it is all about culture and building relationships and and having an understanding of what specialist nurses can do and I think that would be a really useful thing to bring out is that you know is tissue viability nurses aren't there to say you're doing this wrong or you've made a pressure ulcer they're there to say okay what can we do to help and I think sometimes we're not outside um outside teams aren't viewed like that in the neonatals I think it's very similar in the intensive care units but it's much it's been much easier for us to go into the neon into the other intensive care units within the trust and work with them so PICU we've really really worked well with them and it's it's amazing I'd love to be able to do the same with neonates but we don't seem to get the same reaction.

HL: Is there um the good relationship with PICU, was that already in place when you started working here?

P2: No.

HL: How did you develop that?

P2: We developed that because they had again they had a nasty wound so they they called us we went to review it we worked with the staff to help them you understand how to do dressings and things and then again the culture changed so they started to understand what we were about and that we weren't coming in to um you know tell them that you've done this wrong you've got to do it like this but to work with them and to help them so I think that by doing that and by working with the senior team who then start thinking okay actually you're really useful to come in, I think that's how we've we've worked and it's taken a few years to build up but we have a really really good relationship and I think that would be possible with neonates, but we'd need a almost a bit of a culture shift to understand why we were going in.

HL: Okay. That's that's extremely helpful thank you. Um and the last thing just on that the other specialist areas that might feel that the tissue viability nurse is coming in to say "this is wrong", do you think that kind of blame is still associated with skin damage in the neonatal unit in your experience there?

P2: I think it probably is I think if they I think from what I've heard I think if they they feel that if they call it pressure damage it means that they've caused it.

HL: Okay

P2: And they feel that that's you know that that's then viewed as being you've you've done something to harm this baby and this isn't the way we look at pressure damage We just.

HL: So I know that's how adult nurses used to often feel about skin damage, do you think that has shifted among general nurses?

P2: [pause] Mostly. I don't I don't think all of them view it like that but the majority do so I think there has been a shift now to say towards prevention so I think there's lots of people that when a pressure ulcer occurs they're really upset and they want to know why it's occurred now instead of thinking okay we're blamed they're trying to think well why's this happened, so I think there's been a shift generally. Some areas are slower than others to come on with that but there has been a shift where I think that's where pressure ulcers have been given such a high priority and thes they've been so difficult I I was a tissue viability on my tissue viability nurse on my own so I was the only tissue viability nurse for the trust until um five years ago and then over the last five years with the increase of pressure ulcers I now have a team of six.

HL: That's really good.

P2: With lots of work the reason for that.

HL: Yeah, of course.

P2: Is the pressure ulcers. So there's been an awful lot of education an awful lot of staff education on pressure ulcers within the adult population so I think we need that in the neonates and the paediatrics.

HL: You just mentioned that there's been much more focus on finding out why skin damage has happened, so er is there an investigation process for adults when there's serious skin damage occurs in hospital?

P2: Yes.

HL: Has anything similar ever happened with neonates as far as you're aware?

P2: No. But I think that's because they're not reporting so if they were reporting then there would be so the process is not doesn't rule the process is there for all paediatrics and for everyone in the hospital but it would so the the process is is is set off when a ward reports so when a ward reports damage we go and see the damage we then do the investigation once we've validated that it is pressure damage.

HL: Is that tied like it is in some trusts to a specific grade?

P2: Yes, IIs IIIs and IVs.

HL: Do you think the difficulty around grading in neonates would make that more difficult or would they need to have a slightly different process?

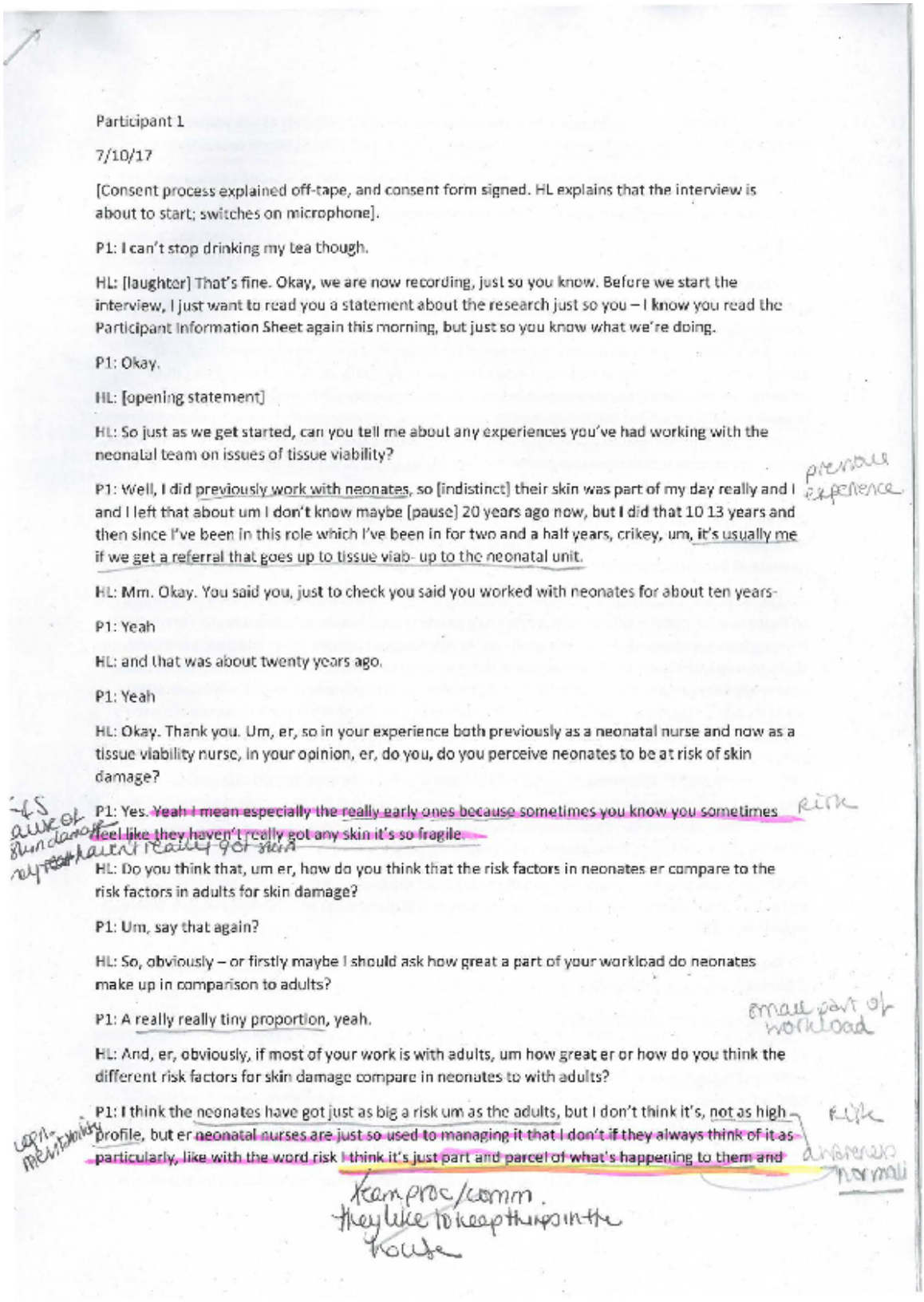
P2: They'd have to have a slightly different process I think there'd be a different process and I think it would be um a different investigation people need would need to be in from a different thing because with neonates a lot of the time they can't take devices off there are an and a lot of them I would imagine are device-related if they get any damage it would be device-related so the investigation process would be very easy but it would because it would be device-related so you know normally what's happened, but um I think there would have to be a separate because of the difficulties with grading so I think it would be unless it was a completely obvious high grade I think the investigation would bring out what the damage was and again the investigation isn't there it's part of our reporting process to the commissioners but it's about learning and it's about saying okay this has happened was there anything we could have done differently and the likelihood is

there wasn't in neonates however you never know that there there those little tiny things that we could have done differently are the learning we want to get in.

HL: Okay that's all amazingly helpful, thank you for giving up some of your morning. Is there anything else you would like to talk about?

P2: Nope.

Appendix O Coding on interview transcript



Participant 1

7/10/17

[Consent process explained off-tape, and consent form signed. HL explains that the interview is about to start; switches on microphone].

P1: I can't stop drinking my tea though.

HL: [laughter] That's fine. Okay, we are now recording, just so you know. Before we start the interview, I just want to read you a statement about the research just so you – I know you read the Participant Information Sheet again this morning, but just so you know what we're doing.

P1: Okay.

HL: [opening statement]

HL: So just as we get started, can you tell me about any experiences you've had working with the neonatal team on issues of tissue viability?

P1: Well, I did previously work with neonates, so [indistinct] their skin was part of my day really and I and I left that about um I don't know maybe [pause] 20 years ago now, but I did that 10 13 years and then since I've been in this role which I've been in for two and a half years, crikey, um, it's usually me if we get a referral that goes up to tissue viab- up to the neonatal unit.

HL: Mm. Okay. You said you, just to check you said you worked with neonates for about ten years-

P1: Yeah

HL: and that was about twenty years ago.

P1: Yeah

HL: Okay. Thank you. Um, er, so in your experience both previously as a neonatal nurse and now as a tissue viability nurse, in your opinion, er, do you, do you perceive neonates to be at risk of skin damage?

P1: Yes. Yeah I mean especially the really early ones because sometimes you know you sometimes feel like they haven't really got any skin it's so fragile.

HL: Do you think that, um er, how do you think that the risk factors in neonates er compare to the risk factors in adults for skin damage?

P1: Um, say that again?

HL: So, obviously – or firstly maybe I should ask how great a part of your workload do neonates make up in comparison to adults?

P1: A really really tiny proportion, yeah.

HL: And, er, obviously, if most of your work is with adults, um how great er or how do you think the different risk factors for skin damage compare in neonates to with adults?

P1: I think the neonates have got just as big a risk um as the adults, but I don't think it's, not as high profile, but er neonatal nurses are just so used to managing it that I don't if they always think of it as particularly, like with the word risk I think it's just part and parcel of what's happening to them and

Appendix O

they're used to dealing with it themselves [pause] but for me they're hugely at risk you've got to turn them and just that particular movement can be so abrasive that their skin breaks down.

HL: Okay thank you. Um what factors in particular do think might affect a neonate's tissue viability?

P1: Do you mean [pause] their skin or do you mean like external?

HL: Either

P1: Okay, I mean I think having worked there and obviously still having some contact that if you're outside of the neonatal unit it's quite a scary place to go and they're so small aren't they and they're so covered with monitors and things that you can be really hesitant anybody to to get in there and they don't really understand neonates, and so I think that most people leave the neonatal unit alone. I don't just mean tissue viability, I kind of like mean generally really, and therefore I think neonatal nurses, and a lot of them are children's nurses, the whole kind of pressure ulcer thing doesn't really affect them. They're so used to babies having skin damage that it's just part and parcel of what they do so the whole reporting of it or bringing in the tissue viability nurse, they're like well we just get on with it. So I think that I think that's quite an issue, so to get in there and to make change, is can be quite challenging.

HL: Yeah, okay. Thank you. Um er and in terms of if you were called into the neonatal unit or if you were still working there as a neonatal nurse, um, what particular things do you think would place a neonate at increased risk of skin damage?

P1: Um what apart from the fact that they're usually preterm and if they are term then they're sick so those two factors place them at more risk. Um I think it's around the whole – it is around medical devices, because obviously even with adults we're not designed to have tubes and things but their skin's so fragile that um I think people talk about pressure from the medical device but I, well I never hear really hear people talk about is the fact that underneath that medical device babies are often really mobile and some medical devices don't fit firmly to the skin so it's, I think to myself it's not really going to be a pressure ulcer because I can actually get my little finger in between that, but the baby moves around so much that you get like a trauma and a friction from that medical device. Um and it's really hard to know how to protect them from that because anything that you put on that skin such as a dressing when you take it off, you think well I'm going to cause more damage so I'm better off leaving them, so I think medical devices um and we don't, you know, we don't always have air mattresses and things because they're usually quite mobile.

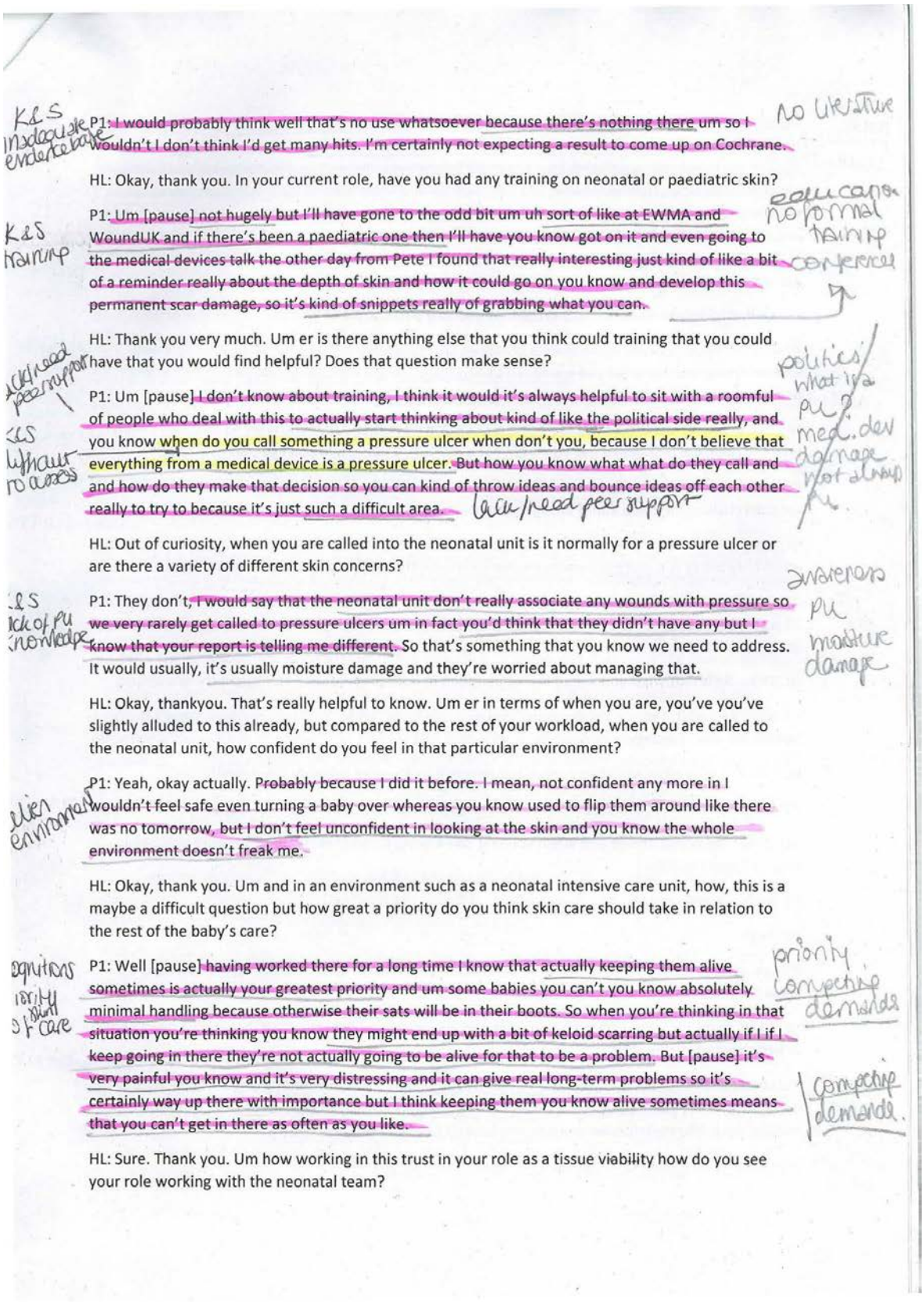
HL: Okay. Thank you. Er – I know you've got um previous experience working with neonates, but if you were um called into a situation and you wanted to find some extra information about it, where would you look?

P1: Do you mean extra information about that wound looking in the medical notes, or extra information so I'd go off and do a literature search?

HL: Yeah, something like a literature search.

P1: Well if I look at something and I think blimey then I would do the same thing as I'd do with adults and then I'd get online and I'm doing a search – um – because I'm not in neonates any more it's harder for me to have that um get a eg opinion something like hatti'll often phone – or try and get hold of – because he' always a good person to run things past.

HL: Okay, thank you. And how if you were looking for um you mentioned literature search, how do you think you would find the um evidence base for neonatal tissue viability in comparison to adults?



P1: I would probably think well that's no use whatsoever because there's nothing there um so I wouldn't I don't think I'd get many hits. I'm certainly not expecting a result to come up on Cochrane.

HL: Okay, thank you. In your current role, have you had any training on neonatal or paediatric skin?

P1: Um [pause] not hugely but I'll have gone to the odd bit um uh sort of like at EWMA and WoundUK and if there's been a paediatric one then I'll have you know got on it and even going to the medical devices talk the other day from Pete I found that really interesting just kind of like a bit of a reminder really about the depth of skin and how it could go on you know and develop this permanent scar damage, so it's kind of snippets really of grabbing what you can.

HL: Thank you very much. Um er is there anything else that you think could training that you could have that you would find helpful? Does that question make sense?

P1: Um [pause] I don't know about training, I think it would it's always helpful to sit with a roomful of people who deal with this to actually start thinking about kind of like the political side really, and you know when do you call something a pressure ulcer when don't you, because I don't believe that everything from a medical device is a pressure ulcer. But how you know what what do they call and and how do they make that decision so you can kind of throw ideas and bounce ideas off each other really to try to because it's just such a difficult area.

HL: Out of curiosity, when you are called into the neonatal unit is it normally for a pressure ulcer or are there a variety of different skin concerns?

P1: They don't, I would say that the neonatal unit don't really associate any wounds with pressure so we very rarely get called to pressure ulcers um in fact you'd think that they didn't have any but I know that your report is telling me different. So that's something that you know we need to address. It would usually, it's usually moisture damage and they're worried about managing that.

HL: Okay, thankyou. That's really helpful to know. Um er in terms of when you are, you've you've slightly alluded to this already, but compared to the rest of your workload, when you are called to the neonatal unit, how confident do you feel in that particular environment?

P1: Yeah, okay actually. Probably because I did it before. I mean, not confident any more in I wouldn't feel safe even turning a baby over whereas you know used to flip them around like there was no tomorrow, but I don't feel unconfident in looking at the skin and you know the whole environment doesn't freak me.

HL: Okay, thank you. Um and in an environment such as a neonatal intensive care unit, how, this is a maybe a difficult question but how great a priority do you think skin care should take in relation to the rest of the baby's care?

P1: Well [pause] having worked there for a long time I know that actually keeping them alive sometimes is actually your greatest priority and um some babies you can't you know absolutely minimal handling because otherwise their sats will be in their boots. So when you're thinking in that situation you're thinking you know they might end up with a bit of keloid scarring but actually if I if I keep going in there they're not actually going to be alive for that to be a problem. But [pause] it's very painful you know and it's very distressing and it can give real long-term problems so it's certainly way up there with importance but I think keeping them you know alive sometimes means that you can't get in there as often as you like.

HL: Sure. Thank you. Um how working in this trust in your role as a tissue viability how do you see your role working with the neonatal team?

P1: Um I think that it's really important that they that we work together and and I think they're much aware of tissue viability than say they were a couple of years ago in regard to thinking that they've got to get our input say in care plans um [pause] you know when they're trying to devise a new care plan when they're thinking of a pathway for you know looking after skin and they know that they can't you know in a way order what they want because they're thinking about formulary and they can't just take things off reps, so they're very aware of that um and [pause] they're coming I think they probably know that I'm going to be in touch with them shortly to be in touch with them about pressure ulcers so I think they've got more of an awareness of it.

HL: Um what do you think has facilitated that over the past couple of years?

P1: Um probably because we're quite a proactive tissue viability team so the three of us are well known throughout the trust and we haven't been scared to get into there, into paediatrics and formulary and and and getting up on the neonatal unit really.

HL: Thank you. Um er would you like to be more involved in that – or if you were to describe ideally how the neonatal unit would use you and your expertise, what would you like that to look like?

P1: I think I would like to be called to more cases of wound damage which I think will happen when we start challenging them about the slide that put up.

HL: Do you find that at the moment they call you only when a serious wound has already occurred or when they are or is it more preventative there's a baby they're/particularly concerned about.

P1: /Both actually you knoww e've I've taken a referral where they've just been worried it was like a 23 weeker and the skin was just so fragiule that they were just saying is there anything else we can do againt here's so little we can do isn't there? So both really.

HL: Okay. So is that what you would like to be called in both preventative and/when there's already-

P1: Yeah why wait, I would always prefer that with adults to you know if our workload wasn't so horrific we would promote more really.

HL: Um and how often would you say at the moment that you're called to the neonatal unit?

P1: I don't know. If I said once a month I'd be exaggerating.

HL: Okay. Thank you. Um er and when you first came here, do you feel that the best use was being made of your expertise?

P1: With the neonatal unit?

HL: Yeah.

P1: Um yeah probably because I've still got friends up on the neonatal unit so they immediately know that I was in post so they yeah.

HL: Okay, thank you. Um and so do you think that has improved over the time that you've been here or not changed very much?

P1: I think an awareness of the service has improved. I think that because of the [pause] because of I don't want to say politics but kind of like the beliefs within the unit of the lack of need to have any outside input into their babies' wounds, we haven't been utilised as much

HL: Okay. Could you expand a little bit on that?

P1: You know that if you get a wound you would then get an report it as a serious learning event and so you'd try to get any learning out of a wound, so I don't think that all wounds are reported because it's seen very much as a normal process of what happens to that baby – you've got a medical device you get a wound – so it's not always reported as a pressure ulcer we're not always we're not always called um and that's the kind of ethos of the trust, of of that unit and so it's quite difficult to get that challenged and changed so sometimes you might say something, you might say that needs a we used to call them Datix, oh that needs a Datix, oh no and you're like what why and so it's kind of getting that change which is going to be my next challenge.

HL: I'm curious to know how you find that compares to very high care environments in adults like ITU where again that's lots of/medical devices

P1:/They Datix everything.

HL: Okay.

P1: And they call us for everything.

HL: Do you think I know there are specific prescribed standards in adult units around reporting, do you find that really do you find that helpful when you're going into adult units compared to paediatric or neonatal units?

P1: I think the difference is that in adults it's just accepted that's what you do, the nurses make that decision and do it, whereas in neonates it's nurses just don't seem to think that they can just go and do a Datix. It's like you've got to go and get the doctor's opinion and permission to do it. Which is not not like it is in adults.

HL: Yeah, um er and do you think that um more reporting or things like that would be more helpful?

P1: I think so because then um hopefully we can learn from them, and we're never going to get anything changed with the medical devices are we if we don't report them. So that's like another thing that I've added to my job list is to remember both with adults as well that every time we get a pressure ulcer from a medical device I must report it to the medical device [pause] thingy. [laughter]

HL: Okay, thank you. Um er and in terms of when you are you've already slightly alluded to this, but when you are working with neonatal team, in terms of your communication with them, is there anything that makes it harder or easier to talk to them?

P1: Um no they're always kind of really pleased to see us because I think if they call us cause they leave so much without calling us that the times that they do call us they're really pleased to see us and um they really want to do everything that we've suggested.

HL: Yeah. Okay, thank you. Um I know that there are tissue viability link nurses on that unit. Have you had much contact with them?

P1: Yeah. [pause] so um they'll be the ones that tend to contact us the most or are [indistinct] so I know them all, um invited them to the day the other day and I was really pleased that three of them turned up. So yeah I'd say that they were all keen and yeah.

HL: Thank you. Can you just describe for me typically what happens when they make a referral to you?

P1: Um what they'll do is we've got an online referral so they just go online, fill it in, and send it to us, press submit it comes through we pick them up every morning and throughout the day. Um we

would try and do the neonatal unit first if we've got one because then we're not taking bugs from the adults wards onto the neonatal unit same for paeds and maty, um and then we go and see the patients. Yeah. Sometimes it will be something that we'll think ooh you know we're going to follow this up and so we'll see them more than once and other times we won't and other times I might look at it and think I don't need to see that patient and I'll just phone the neonatal unit up and say you know I think that what you're doing is fine.

HL: Lovely, thank you. Um and again I know you've got previous experience working on the neonatal unit. Have you ever been asked to work with parents to talk to them about their child's condition?

P1: With the skin?

HL: With the skin.

P1: Um [pause] I don't think I've ever been called in when they're not there but I've often spoken to parents if if they're present because I always think you know it's your baby so they should know what it is that I'm doing and thinking really.

HL: And how have you found that, how have you felt and how has that been received?

P1: Yeah – um yeah. Fine. I think I worked in general practice for a long time so I was always used to talking to parents about their children on lots of different topics so I don't – I'm completely fine about it and yeah the parents are always fine as well I think if you just explain the background and the reason why something's happening and what you're trying to do to prevent it and what the possible outcomes could be, and you try and give them basically everything that you know then they're usually quite happy. If you give them a plan as well.

HL: Yeah, thank you. At the towards the start of the interview you mentioned that er as you've been trying to make some changes in the neonatal unit you've encountered a little bit of resistance or found that difficult. Could you expand on that a little bit?

P1: Well I think that [pause] some people and this is across the trust is that they can think that putting something into Datix or reporting an incident is something to do with blame rather than learning and I, you kind of get that feeling sometimes with the neonatal unit probably because they're not used to Datixing things about skin is that maybe there it's a blame thing whereas it's not it's about like learning um so I don't know whether that's where the kind of culture had come comes from because that's certainly not the belief of the senior nurse there but this is something that I'm going to be investigating further.

HL: Thank you. Is there anything that based on those experiences you think could er would help that would make that easier?

P1: Um probably some more education but I think that that's something that I've had conversation with about the nurse that leads on sort of Datix reporting and you know we're going to have to work on that together and try to get to the root of what's going on and why these things aren't being reported.

HL: Um again if you could ideally design what would you like um the skin health education for neonatal nurses to look like?

P1: Um [pause] well I think it would be great wouldn't it say in an ideal world if you could like you know get loads of nurses off there for the day and and to do like a whole neonatal paediatric study day so you know you'd be talking about your risk assessment because we don't have one here um

about the you know thinking about the different types of wounds or skin breakdown that you get in both neonatal and paeds. Nappies you know to stop the nappy rash we put on all sorts of things just whole day of you know good old-fashioned study day on lots of different topics that would be nice and then um probably some regular inhouse sessions I think it's good sometimes to get the neonates and the paediatrics staff mixed in it gives them the neonatal staff access to someone else as well apart from each other, and to have like a monthly session really but it would probably need to be by someone who's got a better understanding of paediatric skin health than me cause I don't know if I'd have time to keep myself current on all those things, but I'd probably be able to find access to somebody to do that.

HL: Okay, that's really helpful, thank you. We're nearly towards the end of the interview, is there anything else related to the subject of neonatal tissue viability that you would like to talk about or raise?

P1: Um [pause] I don't think so. I think one of the challenges really is dressings because there's not really any good concrete evidence with what you can dress the wounds with because obviously who's going to do it on a neonate, um so that can be quite difficult, and then if you do want to prescribe something the doctors are all quite nervous about it, you have to really convince them that the dressing's alright.

HL: I'm curious to know how you go about doing that, first how you choose which dressing you want to use, and then how you convince the doctors to um co-operate.

P1: I think honey is a nice safe dressing and lots of um neonatal units use it, um I've had some talks on it at EWMA so what I did was I got the honey rep to come in and she brought some you know documented evidence up for them and then I used it on a baby that had a kind of like a nasty old umbilical wound I think they must have had an umbilical catheter in and it was amazing, and so they've seen it both in practice and in theory, um.

HL: Do you think that's made a difference?

P1: Yeah, so they will use they will use um you know the docs will use the honey now, and I've changed over the barrier cream for them and again I just had to go armed and they're just worried that they're going to you know they're going to be sued sometimes you know I don't blame them it's a very contentious issue, isn't it?

HL: Yeah

P1: So that's stuff I usually have to do.

HL: Okay, thank you, that's helpful. And how do you um find so that's a little bit about doctors how do you find nurses react when you bring in new products?

P1: Um the nurses are usually they're just quite excited to have something apart from the senior neonatal nurse practitioner who obviously would be prescribing it as well and signing and writing it up, and naturally worried about their NMC registration so she needs the same reassurance if not more than the doctors.

HL: That's really interesting. I hadn't thought about that, thank you. Um is there anything else you would like to mention?

P1: I don't think so, but if I think of anything I'll email you.

Appendix P Parent information poster (prevalence and incidence)

Version 1
3/12/2015

Ethics number: IRAS 187655

UNIVERSITY OF Southampton

Neonatal skin care research

Study Title:
Point prevalence and incidence of skin damage in neonatal intensive care units

What the study involves:

Your baby's skin will be observed during the routine cares provided by the healthcare professionals on the unit. The study will not influence the treatment of your child in any way.

What is being measured:

The health of your baby's skin will be documented and if an injury is present, the cause will be documented, for example nappy rash. Your baby will not be identifiable through the information collected.

Do I have to take part?

This is a completely voluntary study, if you do not want your child to take part please inform one of the clinical staff.

For more information contact Hannah Liversedge, PhD student, Faculty of Health Sciences, e-mail: hll1g09@soton.ac.uk

Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Survey hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk
Skin Care Study hll1g09@soton.ac.uk

Appendix Q Wound assessment tools

Staging of PUs per international guidelines (NPUAP, EPUAP and Pan Pacific Pressure Injury Alliance, 2014)

Category	**Type of damage**
1	Skin intact; non-blanching erythema
2	Partial thickness skin loss
3	Full-thickness skin loss (no exposed bone, muscle or tendon)
4	Full-thickness skin loss (exposed or directly palpable bone, muscle or tendon)
Unstageable	Full-thickness skin loss where depth of injury is obscured by slough or eschar
Suspected Deep Tissue Injury	Localised area of purple or maroon discolouration (skin intact) or blood-filled blister associated with pressure, or pressure in combination with shear.

Staging of IAD (Beeckman *et al.*, 2015)

Severity of IAD	**Signs**
1-Red* but skin intact (mild)	Erythema +/oedema
2-Red* with skin breakdown (moderate-severe)	As category 1 +/- vesicles +/- denudation +/- skin infection

Classification of burns (Werner, 2012)

Classification of burn	**Histology and appearance**
1st degree	Epidermis No blisters, painful
Superficial 2nd degree or superficial partial thickness	Epidermis and superficial dermis Blisters, very painful
Deep 2nd degree or deep partial thickness	Epidermis and deep dermis, sweat glands and hair follicles Blisters, very painful
3rd degree	Entire epidermis and dermis charred, pale, leathery; no pain
4th degree	Entire epidermis and dermis as well as bone, fat and/or muscle

Appendix Q

Visual Infusion Phlebitis (Infusion Nurses Society, 2011)

Visual Infusion Phlebitis Score	**Signs**
0	IV site appears healthy
1	Slight pain near IV site or slight redness near IV site
2	Two of the following are evident: -Pain at IV site -Redness -Swelling
3	All of the following are evident: -Pain along path of cannula -Redness around site -Swelling
4	All of the following are evident and extensive: -Pain along path of cannula -Redness around site -Swelling -Palpable venous cord
5	All of the following are evident and extensive: -Pain along path of cannula -Redness around site -Swelling -Palpable venous cord -Pyrexia

Appendix R Data collection proforma (prevalence)

NHS NUMBER: **IRAS** 187655

HOSPITAL

Gestational age at birth:

_____

Corrected gestational age:

_____

Birth weight:

_____

Expected length of stay:

_____

Gender:

☐ **Male**

Nutrition:

☐ **TPN**

☐ **PN & enteral EBM**

☐ **Enteral EBM**

☐ **Enteral formula** _____

☐ **Exclusively breastfed**

☐ **Mixed feeds** _____

☐ **Formula only** _____

Damage present (all that apply):

☐ **None**

☐ **Non-blanchable erythema**

☐ **Blister**

☐ **Broken skin**

☐ **Visible fat/muscle/cartilage**

Associated with device?

☐ **No**

☐ **Yes** _____

Previous cooling?

☐ **No**

☐ **Yes (duration)** _____

Oscillated?

☐ **No**

☐ **Yes**

☐ **Previous (duration)**_____

Care group:

☐ **ITU** ☐ **SCBU**

☐ **HDU** ☐ **TC**

Primary diagnosis:

☐ **Prematurity**

☐ **IUGR**

☐ **HIE**

☐ **Other** _____

Environment/moisture:

☐ **Radiant warmer**

☐ **Humidified incubator __%**

☐ **Cot**

☐ **Other** _____

Presence and severity of diaper dermatitis:

☐ **None**

☐ **Yes** _____

Any preventative measures:

_____

Presence of:

☐ **CPAP/BiPAP**

☐ **ET tube**

☐ **NG/OG tube**

☐ **UVC/UAC**

☐ **Peripheral cannula(e) (If yes, #_____)**

☐ **Stoma**

☐ **Cooling**

☐ **High-flow**

☐ **Vapotherm**

☐ **Urinary catheter**

☐ **Other device** _____

Frequency of cares:

☐ **More often**

☐ **4 hourly**

☐ **6 hourly**

☐ **8 hourly**

☐ **Less often** ___

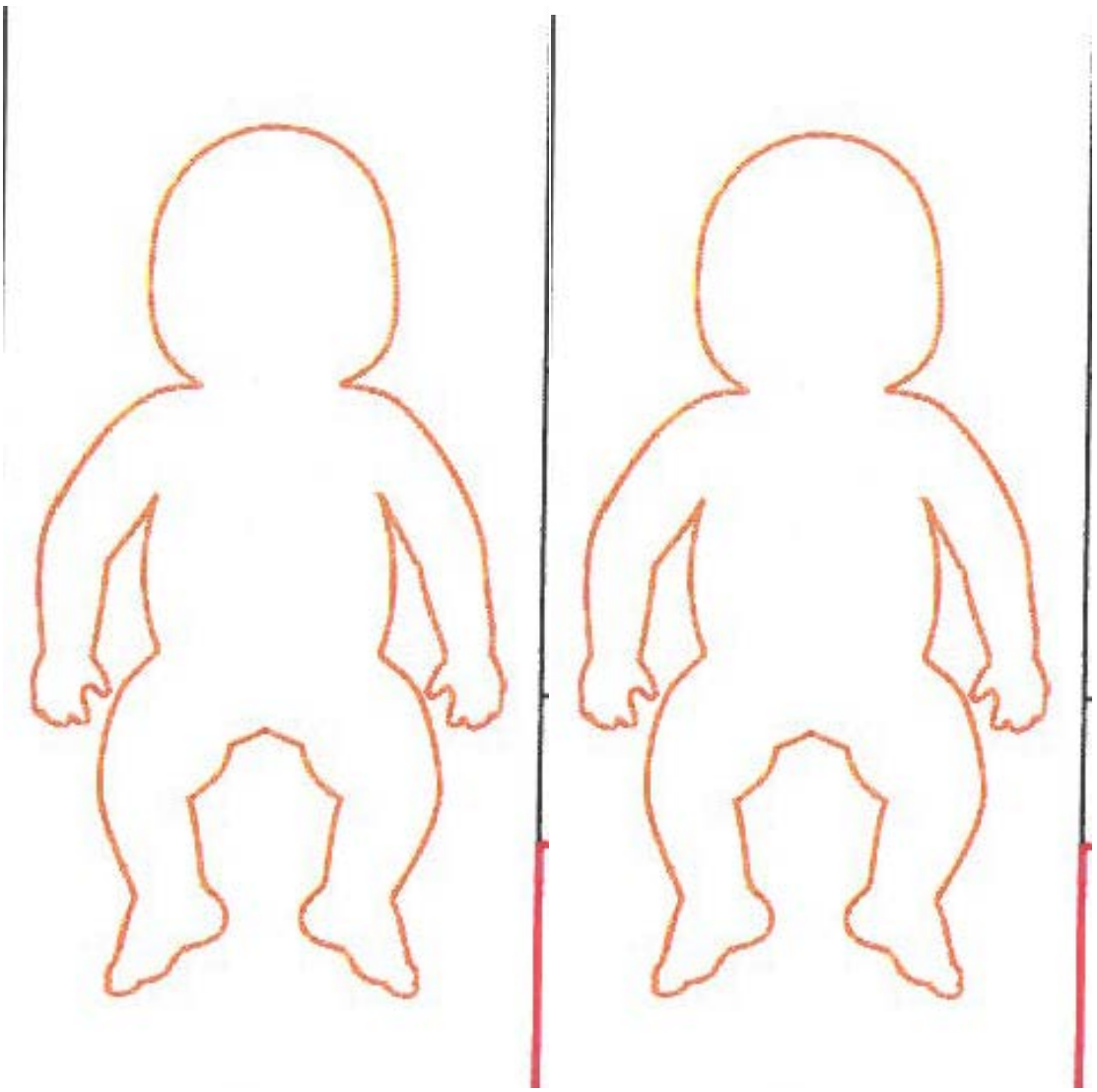
Frequency of skin assessment if different:

_____

Appendix R

FRONT

BACK



Appendix S Data collection proforma (incidence)

VERSION 1 **25/2/16** **IRAS** 187655

Corrected gestational age:

_____

Expected length of stay:

_____

_

_____

Nutrition:
☐ **TPN**
☐ **PN & enteral EBM**
☐ **Enteral EBM**
☐ **Enteral formula _____**
☐ **Exclusively breastfed**
☐ **Mixed feeds _____**
☐ **Formula only _____**

Damage present (all that apply):
☐ **None**
☐ **Non-blanchable erythema**
☐ **Blister**
☐ **Broken skin**
☐ **Visible fat/muscle/cartilage**

Associated with device?
☐ **No**
☐ **Yes _____**

Previous cooling?
☐ **No**
☐ **Yes (duration) _____**

Oscillated?
☐ **No**
☐ **Yes**
☐ **Previous (duration)_____**

Care group:
☐ **ITU** ☐ **SCBU**
☐ **HDU** ☐ **TC**

Primary diagnosis:
☐ **Prematurity**
☐ **IUGR**
☐ **HIE**
☐ **Other _____**

Environment/moisture:
☐ **Radiant warmer**
☐ **Humidified incubator __%**
☐ **Cot**
☐ **Other _____**

Presence and severity of diaper dermatitis:
☐ **None**
☐ **Yes _____**

Any preventative measures:

_____

Steroid use?
☐ **No**
☐ **Yes (duration) _____**

Presence and severity of chemical burns:

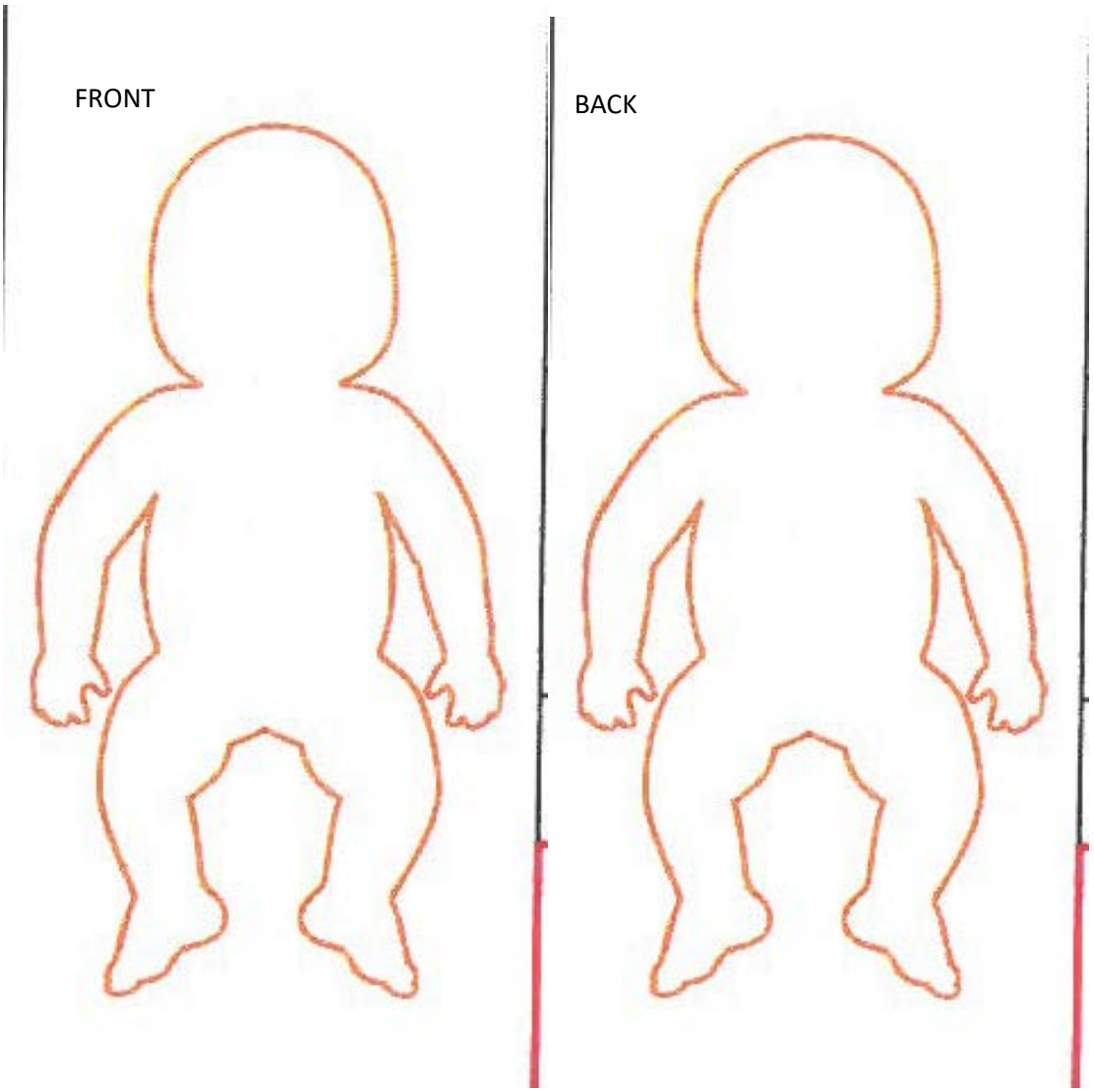
☐ **None**
☐ **Yes_____**

Presence of:
☐ **CPAP/BiPAP**
☐ **ET tube**
☐ **NG/OG tube**
☐ **UVC/UAC**
☐ **Peripheral cannula(e) (If yes, #_____)**
☐ **Stoma**
☐ **Cooling**
☐ **High-flow**
☐ **Vapotherm**
☐ **Urinary catheter**
☐ **Other device _____**

Frequency of cares:
☐ **More often**
☐ **4 hourly**
☐ **6 hourly**
☐ **8 hourly**
☐ **Less often ___**

Frequency of skin assessment if different:
_____

Appendix S



Appendix TCorrespondence with the REC

NHS
Health Research Authority
South West - Exeter Research Ethics Committee
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1335
Fax:0117 342 0445

17 February 2016

Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A, South Academic Block
Southampton General Hospital, Tremona Rd
Southampton
SO16 6YD

Dear Ms Liversedge

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

The Research Ethics Committee reviewed the above application at the meeting held on 04 February 2016. Thank you for attending to discuss the application.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

1. Members wanted to know who would take the photograph/s and requested further details regarding storage; confidentiality; etc.

2. Members queried the thickness of the peripheral cannula to be used, and how long they would have been in place.

3. Members considered you should ascertain/clarify the number of participants needed for this study, or provide justification for not doing so.

4. The Data Collection Proforma should include a date and version number.

5. The applicant should investigate the possibility of a unit-based parental group who could provide feedback on the study.

6. A copy of the insurance certificate covering this research should be provided.

7. It was unclear whether the nurses had given their permission to be observed. Members requested for a participant information sheet and consent form for nurses to be submitted for review and approval.

8. Members agreed that a copy of the lay summary of results should be provided to all mothers. Confirmation that this would be complied with was requested.

9. The Committee requested two separate participant information sheets for the prevalence and observation parts of the study for the purposes of clarity.

10. The participant information sheet (PIS)
    - contained academic language: it should be simplified and shorter sentences used
    - the title should be revised to state "neonates" rather than "neonatal intensive care units"
    - the word "prevalence" should be replaced by a simpler term as the committee did not think this would be clear to the public
    - on page 1, the word "conducted" should be "conducting"
    - a telephone contact number should be provided as not everyone would have access to email (although it was appreciated that the CI would be available on the ward for parent to speak to her).
    - it should be made explicit that the baby would not be handled by the chief investigator
    - it should be clarified that what the nurse did, would be part of routine care and not for the purposes of this study
    - should mention that participants did not have to give a reason for withdrawal
    - there should be a footer stating that one copy would be given to the participant, and one would be retained on file.
    - Clarify which stage of the study the PIS is referring to (i.e. the prevalence or the observation)
    - should thank potential participants for taking the time to read this.
    - include the total number of participants in this study
    - Provide contact details for PALS

11. All PIS should include wording advising that confidentiality would be broken should any disturbing information/observation come to light, and how this would be dealt with.

12. The consent form (CF)
    - Should include wording to the effect that the participant has received a satisfactory answer to their questions.

Please refer to the HRA website for further guidance on composing PIS/CF at:
http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Mrs Naaz Nathoo on 0117 342 1335 in the first instance.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link:
http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 18 March 2016.

Summary of the discussion at the meeting

- **Social or scientific value; scientific design and conduct of the study**

  Members considered the applicant should ascertain/clarify the number of participants needed for this study, or provide justification for not doing so.

  The Committee asked how this study would be undertaken.
  You advised three units would be involved in the point of prevalence study. The intention was to collect data of all forms of skin damage in neonates on one day in each unit. Observation would be undertaken while the nurse was carrying out care of the baby. No photographs would be taken.
  Data would then be collected from two units. Informed consent would be obtained from parents. Upon query, you confirmed you would go to the ward yourself. Whilst the nurses were carrying out routine clinical care, this would be observed.

Members wanted to know the likelihood of discovering non-accidental injury in any baby.
Dr Worsley replied that medical device-related injury did occur but was sometimes unavoidable to support life in intensive care.

Members asked about non-accidental damage by staff or parents.
Members were advised this was unlikely; the applicants had not come across this before. If discovered they would be able to escalate this.
You had worked in a neonatal unit but would not be handling neonates.

It was unclear to members how the researcher would ensure that photographs were not taken of those babies where the mother did not want these to be taken.
Members were advised that data would be link-anonymised and a note of this would be made.

Upon query, you confirmed that no statistical input had been obtained. The application had been seen by the supervisor of the Faculty. You confirmed that the number of participants selected was based on the number likely to be passing through the units.

Members queried why pre-existing dermatological conditions were being excluded.
You advised that (a) these were quite rare; (b) the risk factors for them would be very different; and (c) the way care was delivered would also be different.

Lack of translators was not considered a good enough reason to exclude those who did not have sufficient English. Members asked whether the demographic service by the hospital was comparable.
Miss Liversedge replied Southampton and Portsmouth were reasonably comparable, but it was difficult to say.

- **Recruitment arrangements and access to health information, and fair participant selection**

Members wanted to know why posters were being used instead of gaining consent, as mothers might not actually read the poster.
You replied that all three units undertook research regularly. The poster included information for the parents to contact the chief investigator. This had been done on the advice of the lead consultant as it was considered to be burdensome for mothers.

Upon query, you confirmed that no parents had been consulted.
The Committee stated that most units would have a parental support group who would be able to provide feedback, and it would be advisable to obtain this.

When asked, you confirmed this would be part of her PhD. She informed the Committee that she aimed to finish data collection by the time the PhD ended.

Members asked if you would be able to collect sufficient data.
Members were advised that the project was due to run for 6 months. If you could start by the middle of March, you envisaged being able to collect sufficient data.

Members wanted to know whether there would be 24 different babies or it would be the same baby being observed.
You advised that observation would be carried out over 3 months on each unit. The maximum number of times a baby would be observed was 24, before being transferred or discharged.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Other [Summary CV supervisor (Dan Bader)]	1	08 December 2015
Other [Summary CV for supervisor (Lisette Schoonhoven)]	1	10 December 2015
Other [Confirmation of pre-engagement checks (Southampton)]	1	11 December 2015
Other [Confirmation of pre-engagement checks (Oxford)]	1	11 December 2015
Other [Letter of support (Southampton)]	1	15 October 2015
Other [Letter of support (Portsmouth)]	1	21 September 2015
Other [Letter of support (Oxford)]	1	27 November 2015
Other [Parent information poster]	1	03 December 2015
Participant consent form [Consent form]	1	11 November 2015
Participant information sheet (PIS) [Parent information sheet]	1	11 November 2015
REC Application Form [REC_Form_06012016]		06 January 2016
Referee's report or other scientific critique report [Peer review feedback]	1	21 August 2015
Research protocol or project proposal [Protocol v1]	1	06 June 2015
Summary CV for Chief Investigator (CI) [Hannah Liversedge summary CV]	1	20 August 2015
Summary CV for supervisor (student research) [Peter Worsley summary CV]	1	03 December 2015

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

Appendix T

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

16/SW/0022	Please quote this number on all correspondence

Yours sincerely

pp. Dr Denise Sheehan
Chair

Email: nrescommittee.southwest-exeter@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to: *Diana Galpin, University of Southampton*
Graham Halls, Portsmouth Hospitals NHS Trust

A Research Ethics Committee established by the Health Research Authority

South West - Exeter Research Ethics Committee
Attendance at Committee meeting on 04 February 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Rosamund Bagnald	Retired Store Manager	Yes	
Mrs Isobel Brooks	Retired Social Care Manager	Yes	
Emeritus Professor Malcolm Cowburn	Emeritus Professor of Applied Social Science	Yes	
Dr Nicole Dorey	Consultant Clinical Oncologist	Yes	
Dr. Roy J. Powell	Research Design Consultant	Yes	
Mrs Joan Ramsay	Retired Associate Director of Nursing (Women and Children)	Yes	
Dr Lettie E Rawlins	Junior Doctor	No	
Mr Phil Regan	Minister of Religion	No	
Mrs Carol Richardson	Senior Nurse (Retired)	Yes	
Dr Denise Sheehan	Consultant Oncologist	Yes	
Dr Jo Thompson Coon	Senior Research Fellow in Health Services Research	No	
Dr Chris Vallance	Retired chemist (non-research)	Yes	
Mr Royston Van Tromp	Retired Head Teacher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Naazneen Nathoo	REC Manager
Ms Lisella Wilkinson	Observer - Quality Assurance Coordinator

A Research Ethics Committee established by the Health Research Authority

Appendix T

UNIVERSITY OF Southampton

25th February 2016

Dear Dr Sheehan,

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

Hannah Liversedge (CI), Lisette Schoonhoven, Dan Bader, Peter Worsley.

Thank you for reviewing our study 'Point prevalence and incidence of skin damage in neonatal intensive care units' (IRAS ID: 187655) at your recent meeting on 4/2/2016, and for your subsequent comments. We have provided a response below and trust our changes to the documentation are satisfactory.

1. Members wanted to know who would take the photograph/s and requested further details regarding storage; confidentiality; etc.

Response:

Photographs will be taken by HL on a digital camera used only for this purpose. At the end of every day, the photographs will be downloaded onto a password-protected university laptop or password-protected university desktop computer and stored within this system, linked to the data for that child by use of their anonymous ID. The SD card in the camera will be wiped after photographs are downloaded and they will only be accessed by members of the research team. They may be used in a PhD thesis, in publications, or in staff education. The consent form covers this use, and any identifying features will be obscured prior to publication.

2. Members queried the thickness of the peripheral cannula to be used, and how long they would have been in place.

Response:

With regards to peripheral cannulae, any cannula used will be inserted entirely autonomously by the clinician as part of routine care. This applies to all aspects of cannula insertion including thickness and duration of use. This study is exclusively observational, and no cannulae will be inserted or used as part of the study.

As with other devices, information about the size, brand, and use of device will be recorded on the data collection proforma as part of the study (see Appendix D of the protocol), without influencing practice.

UNIVERSITY OF Southampton

3. Members considered you should ascertain/clarify the number of participants needed for this study, or provide justification for not doing so.

Response:

Given that previous pressure ulcer prevalence and incidence studies in this population are very few in number and sample sizes range from 81-747, it is difficult to determine the sample size needed. The estimated sample size of 250 in our study has been determined from data given by the units on their average number of monthly admissions, taking into consideration neonates not included due to the stated exclusion criteria or lack of parental consent.

The few values on incidence of pressure ulcers from previous studies show that incidence is high (cumulative incidence 16%, incidence rate 1.5 per 1000 patient days). Using 16% as an estimate we would be able to detect 40 patients with a pressure ulcer. As we are not looking at pressure ulcers alone, the number of neonates with skin damage is likely to be higher. Therefore we believe our sample size will provide a representative estimation of skin damage in this population.

4. The Data Collection Proforma should include a date and version number.

Response:

As requested, a date and version number have been added to the data collection proforma. New versions of these documents have been uploaded onto IRAS.

5. The applicant should consider the possibility of a unit-based parental group who could provide feedback on the study.

Reponse:

Within the time and resource constraints of this doctoral study, it will not be possible to conduct any formal PPI. The study is purely observational and will not interfere with routine care in any way. Medical and nursing staff have been involved in the design of the study in order to ensure that it is appropriate for this patient group and environment. We will consider substantial use of PPI for any future studies in paediatric and neonatal environments.

6. A copy of the insurance certificate covering this research should be provided.

Response:

The insurance certificate is attached to this application. Insurance will be activated once ethical approval is given. We have applied for an extension of this insurance until December 2016 through faculty ethics.

7. It was unclear whether the nurses had given their permission to be observed.

In relation to consenting nursing staff, nursing practice is not being assessed in any way and routine practice will not be interrogated. Observations are of patients rather than nursing staff. Data

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regarding the observed health of patients' skin and the factors which affect it will be collected in accordance with the proforma. This will not be tied to members of staff, and the lead nurses and consultants from the 3 units have all given permission for data to be collected on standard care in this way.

Following extensive feedback from senior clinicians, and considering that no information about nursing staff will be recorded, we do not feel it is necessary to obtain individual consent. Members of nursing staff have been involved in designing the study in order to ensure that it does not burden them in any way.

8. Members agreed that a lay summary of the results should be provided to all mothers. Confirmation that this would be complied with was requested.

Response:

We agree that it would appropriate to inform parents of our results. We will collect postal addresses from all parents involved in the study and store these with the completed consent forms. This will allow us to keep them separate from patient information and maintain anonymity. Lay summaries will be posted to parents at the end of the study.

9. The Committee requested two separate participant information sheets for the prevalence and observation part of the study for the purpose of clarity.

Both the prevalence and incidence studies are observational. There are now separate parent information sheets for both studies.

10. The participant information sheet (PIS)

- **contained academic language: it should be simplified and shorter sentences used**
- **the title should be revised to state "neonates" rather than "neonatal intensive care units"**
- **the word "prevalence" should be replaced by a simpler term as the committee did not think this would be clear to the public**
- **on page 1, the word "conducted" should be "conducting"**
- **a telephone contact number should be provided as not everyone would have access to email (although it was appreciated that the CI would be available on the ward for parent to speak to her)**
- **it should be made explicit that the baby would not be handled by the chief investigator**
- **it should be clarified that what the nurse did, would be part of routine care and not for the purposes of this study**
- **should mention that participants did not have to give a reason for withdrawal**
- **there should be a footer stating that one copy would be given to the participant, and one would be retained on file**
- **Clarify which stage of the study the PIS is referring to (i.e. the prevalence or the observation)**

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- **should thank potential participants for taking the time to read this.**
- **include the total number of participants in this study**
- **Provide contact details for PALS**

Response:

The changes you requested have been made. Lay terminology has been used throughout, and the terms "prevalence" and "incidence" have been replaced or explained. The total number of participants included is listed.

The section "What will happen to my child if he or she takes part?" has been rewritten in order to clarify that what the nurse does is part of routine care, and that the CI will not be handling the babies.

A footer has been added to the information sheets explaining that parents will receive a copy to keep, and that a copy will be retained on file.

The PIS concerning the incidence study now lists the title as "Incidence of skin damage in neonates". The PIS concerning the prevalence study lists the title as "Point prevalence of skin damage in neonates". This has been done in order to clarify which stage of the study these PIS are referring to.

A telephone number for the research team has now been added to both PIS, as well as contact details for the PALS service at all participating hospitals. At the end, the participant is thanked for taking the time to read the information sheet.

All changes have been highlighted to answer the above comments.

11. All PIS should include wording advising that confidentiality would be broken should any disturbing information/observation come to light, and how this would be dealt with.

Response:

Both information sheets now contain an explanation that it may be necessary to break anonymity in the event that a child appears to have experienced an unexplained injury, and the steps that would be taken in that case.

12. The consent form (CF) should include wording to the effect that the participant has received a satisfactory answer to their questions.

Response:

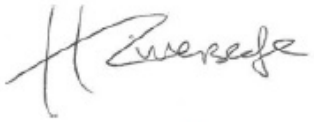
This wording has been added to the consent form.

Appendix T

UNIVERSITY OF Southampton

We do not have the financial resources within this doctoral project to provide translation services for this study, and do not wish to burden NHS translation services provided for clinical use. Regrettably, we will therefore be unable to include children whose parents don't speak English.

Thank you again for your time.



Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A
Southampton General Hospital
Tremona Rd
Southampton
SO16 6YD

NHS
Health Research Authority
South West - Exeter Research Ethics Committee
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT

21 March 2016

Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A, South Academic Block
Southampton General Hospital, Tremona Rd
Southampton
SO16 6YD

Dear Ms Liversedge

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference number:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID	**187655**

Thank you for your revised documents submitted on 9th March 2016, responding to the Committee's request for further information on the above research, and enclosing the following revised documents:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Verification of insurance]	1	30 July 2015
IRAS Checklist XML [Checklist_02032016]		02 March 2016
IRAS Checklist XML [Checklist_09032016]		09 March 2016
Other [Parent information sheet (prevalence)]	1	23 February 2016
Other [Data collection proforma (prevalence)]	1	25 February 2016
Other [Data collection proforma (prevalence)]	1	25 February 2016
Other [Data collection proforma (detailed device documentation)]	1	25 February 2016
Other [Response to review]	1	25 February 2016
Other [Parent information sheet (prevalence)]	2	23 February 2016
Other [Data collection proforma (incidence)]	1	25 February 2016
Participant consent form [Consent form]	1	23 February 2016
Participant consent form [Consent form v2]	2	23 February 2016

Participant information sheet (PIS) [Parent information sheet (incidence)]	1	23 February 2016
Participant information sheet (PIS) [Parent information sheet (incidence)]	2	23 February 2016
Research protocol or project proposal [Protocol v1]	1	06 June 2015
Research protocol or project proposal [Protocol v2]	2	08 March 2016

The further information and revised documentation has been considered on behalf of the Committee by the Chair together with the Vice Chair the REC.

The Committee was satisfied with the responses to:

1..Members wanted to know who would take the photograph/s and requested further details regarding storage; confidentiality; etc.

2. Members queried the thickness of the peripheral cannula to be used, and how long they would have been in place.

3.Members considered you should ascertain/clarify the number of participants needed for this study, or provide justification for not doing so.

4. The Data Collection Proforma should include a date and version number.

5. The applicant should investigate the possibility of a unit-based parental group who could provide feedback on the study.

6. A copy of the insurance certificate covering this research should be provided.

8. Members agreed that a copy of the lay summary of results should be provided to all mothers. Confirmation that this would be complied with was requested.

9. The Committee requested two separate participant information sheets for the prevalence and observation parts of the study for the purposes of clarity.

10. The participant information sheet (PIS)

- contained academic language: it should be simplified and shorter sentences used
- the title should be revised to state "neonates" rather than "neonatal intensive care units"
- the word "prevalence" should be replaced by a simpler term as the committee did not think this would be clear to the public
- on page 1, the word "conducted" should be "conducting"
- a telephone contact number should be provided as not everyone would have access to email (although it was appreciated that the CI would be available on the ward for parent to speak to her).
- it should be made explicit that the baby would not be handled by the chief investigator.
- It should be clarified that what the nurse did, would be part of routine care and not for the purposes of this study

- should mention that participants did not have to give a reason for withdrawal
- there should be a footer stating that one copy would be given to the participant, and one would be retained on file.
- Clarify which stage of the study the PIS is referring to (i.e. the prevalence or the observation)
- should thank potential participants for taking the time to read this.
- include the total number of participants in this study
- Provide contact details for PALS

11. All PIS should include wording advising that confidentiality would be broken should any disturbing information/observation come to light, and how this would be dealt with.

12. The consent form (CF)
    - Should include wording to the effect that the participant has received a satisfactory answer to their questions.

However, the Committee would be grateful for a more complete response on the following points:

1.Members have requested the applicant produces a separate PIS and CF for the nurses. Members have also pointed out that the applicant would be duty bound by her professional code of conduct to report any bad practice aside from this (e.g. poor hand washing, rudeness to parents, unsafe techniques) therefore members have requested nurses must have the option to opt out of being observed.

Any further revised document submitted should be given a revised version number and date.

The 60 day clock for issue of a final ethical opinion on this application will re-start when the Committee has received a response on the outstanding points.

16/SW/0022	**Please quote this number on all correspondence**

Yours sincerely

Frances Race
REC Assistant

Email: nrescommittee.southwest-exeter@nhs.net

Copy to: *Diana Galpin, University of Southampton*

A Research Ethics Committee established by the Health Research Authority

Appendix T

Graham Halls, Portsmouth Hospitals NHS Trust

A Research Ethics Committee established by the Health Research Authority

UNIVERSITY OF Southampton

21st March 2016

Dear Dr Sheehan,

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

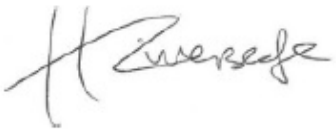
Hannah Liversedge (CI), Lisette Schoonhoven, Dan Bader, Peter Worsley.

Thank you for your response letter dated 21.3.2016 regarding our study detailed above. We have provided a response below and trust that the additional documentation is satisfactory.

1. Members have requested the applicant produces a separate PIS and CF for the nurses. Members have also pointed out that the applicant would be duty bound by her professional code of conduct to report any bad practice aside from this (e.g. poor hand washing, rudeness to parents, unsafe techniques) therefore members have requested nurses must have the option to opt out of being observed.

A separate PIS and CF have been produced for nursing staff, containing wording that makes it clear the research team are duty bound to report bad practice and that nursing staff can opt out of being observed. These are now attached to the application.

Thank you again for your time.



Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A
Southampton General Hospital
Tremona Rd
Southampton
SO16 6YD

UNIVERSITY OF Southampton

23rd March 2016

Dear Dr Sheehan,

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

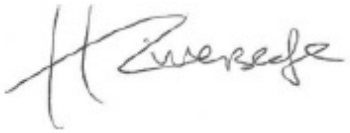
Hannah Liversedge (CI), Lisette Schoonhoven, Dan Bader, Peter Worsley.

Thank you for your feedback forwarded to use by Frances Race on 23/3/2016. We have provided a response below and trust that the changes to the documentation are satisfactory.

1. The PIS needs to mention an independent body for complaints to the parental PIS and they are not included on this PIS. This should be included in the nurses' PIS too.

Details for the Research Governance Office are included on all three PIS. The PIS for parents also have information for PALS. In addition to this, we have now updated the PIS with information about INVOLVE. Upon taking advice from Southampton's R&D department, they informed us that members of staff with a grievance would need to follow normal Trust policy for making a complaint. This information has now been included on the nurses' PIS.

Thank you again for your time.



Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A
Southampton General Hospital
Tremona Rd
Southampton
SO16 6YD

NHS
Health Research Authority
South West - Exeter Research Ethics Committee
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT

Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A, South Academic Block
Southampton General Hospital, Tremona Rd
Southampton
SO16 6YD

Dear Ms Liversedge

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference number:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID	**187655**

Thank you for your letter of 23rd March 2016, responding to the Committee's request for further information on the above research, and enclosing the following revised documents:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Verification of insurance]	1	30 July 2015
IRAS Checklist XML [Checklist_02032016]		02 March 2016
IRAS Checklist XML [Checklist_09032016]		09 March 2016
IRAS Checklist XML [Checklist_21032016]		21 March 2016
IRAS Checklist XML [Checklist_23032016]		23 March 2016
Other [Parent information sheet (prevalence)]	1	23 February 2016
Other [Data collection proforma (prevalence)]	1	25 February 2016
Other [Data collection proforma (prevalence)]	1	25 February 2016
Other [Data collection proforma (detailed device documentation)]	1	25 February 2016
Other [Response to review]	1	25 February 2016
Other [Data collection proforma (incidence)]	1	25 February 2016
Other [Response to letter from REC dated 21.3.16]	1	21 March 2016
Other [Parent information sheet (prevalence)]	3	23 March 2016
Other [Participant information sheet (nurses)]	2	23 March 2016
Other [Consent form (nurses)]	2	23 March 2016

Other [Response to further feedback dated 23.3.16]	1	23 March 2016
Participant consent form [Consent form v2]	3	23 March 2016
Participant information sheet (PIS) [Parent information sheet (incidence)]	3	23 March 2016
REC Application Form [REC_Form_21032016]		21 March 2016
Research protocol or project proposal [Protocol v1]	1	06 June 2015
Research protocol or project proposal [Protocol v2]	2	08 March 2016

The further information and revised documentation has been considered on behalf of the Committee by the Chair and Vice-Chair.

The Committee do not think it is appropriate for the complaints procedure to go through Involve, as stated in the Nurses Participant Information sheet. If a complaint is made by nursing staff against the university research staff it will be as research participants rather than as staff members, and therefore it would be more appropriate for any complaints made by the nursing staff involved in this study to go through PALs, as with parental participants.

Any further revised document submitted should be given a revised version number and date.

The 60 day clock for issue of a final ethical opinion on this application will re-start when the Committee has received a response on the outstanding points.

16/SW/0022	**Please quote this number on all correspondence**

Yours sincerely

Frances Race
REC Assistant

Copy to: *Diana Galpin, University of Southampton*
Graham Halls, Portsmouth Hospitals NHS Trust

A Research Ethics Committee established by the Health Research Authority

UNIVERSITY OF Southampton

4th April 2016

Dear Dr Sheehan,

Study Title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

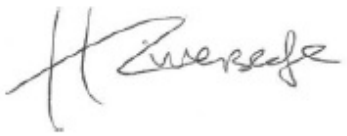
Hannah Liversedge (CI), Lisette Schoonhoven, Dan Bader, Peter Worsley.

Thank you for your letter forwarded to us on 4th April 2016. We have provided a response below and trust that the changes to the documentation are satisfactory.

1. The Committee do not think it is appropriate for the complaints procedure to go through Involve, as stated in the Nurses Participant Information sheet. If a complaint is made by nursing staff against the university research staff it will be as research participants rather than as staff members, and therefore it would be more appropriate for any complaints made by the nursing staff involved in this study to go through PALS, as with parental participants.

We have now updated the nurses' PIS with contact details for PALS at each participating hospital and removed the information about Involve. The dates and version numbers have been updated on the nurses' PIS. The nurses' consent form has also been updated to include the new PIS date and version number.

Thank you again for your time.



Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A
Southampton General Hospital
Tremona Rd
Southampton
SO16 6YD

Appendix T

NHS
Health Research Authority
South West - Exeter Research Ethics Committee
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1335
Fax:0117 342 0445

12 April 2016

Reissued Letter dated 26.4.2016

Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A, South Academic Block
Southampton General Hospital, Tremona Rd
Southampton
SO16 6YD

Dear Ms Liversedge

Study title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

Thank you for your letter of 4 April 2016 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Naazneen Nathoo, nrescommittee.southwest-exeter@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. In the participant information for nurses, the sentence relating to the Trust's normal grievous procedure should be removed.

   A copy of the revised PIS should be lodged with the Ethics office prior to commencement of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Verification of insurance]	1	30 July 2015
IRAS Checklist XML [Checklist_02032016]		02 March 2016
IRAS Checklist XML [Checklist_09032016]		09 March 2016
IRAS Checklist XML [Checklist_21032016]		21 March 2016
IRAS Checklist XML [Checklist_23032016]		23 March 2016
IRAS Checklist XML [Checklist_04042016]		04 April 2016
Other [Summary CV supervisor (Dan Bader)]	1	08 December 2015
Other [Summary CV for supervisor (Lisette Schoonhoven)]	1	10 December 2015
Other [Confirmation of pre-engagement checks (Southampton)]	1	11 December 2015
Other [Confirmation of pre-engagement checks (Oxford)]	1	11 December 2015
Other [Letter of support (Southampton)]	1	15 October 2015
Other [Letter of support (Portsmouth)]	1	21 September 2015
Other [Letter of support (Oxford)]	1	27 November 2015
Other [Parent information poster]	1	03 December 2015
Other [Data collection proforma (prevalence)]	1	25 February 2016
Other [Data collection proforma (detailed device documentation)]	1	25 February 2016

Other [Response to review]	1	25 February 2016
Other [Data collection proforma (incidence)]	1	25 February 2016
Other [Response to letter from REC dated 21.3.16]	1	21 March 2016
Other [Parent information sheet (prevalence)]	3	23 March 2016
Other [Response to further feedback dated 23.3.16]	1	23 March 2016
Other [Participant information sheet (nurses)]***	3	04 April 2016
Other [Consent form (nurses)]	3	04 April 2016
Other [Response to letter from REC dated 4.4.16]	1	04 April 2016
Participant consent form [Consent form v2]	3	23 March 2016
Participant information sheet (PIS) [Parent information sheet (incidence)]	3	23 March 2016
REC Application Form [REC_Form_21032016]		21 March 2016
Referee's report or other scientific critique report [Peer review feedback]	1	21 August 2015
Research protocol or project proposal [Protocol v2]	2	08 March 2016
Summary CV for Chief Investigator (CI) [Hannah Liversedge summary CV]	1	20 August 2015
Summary CV for supervisor (student research) [Peter Worsley summary CV]	1	03 December 2015

***See above

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Appendix T

NHS
Health Research Authority
South West - Exeter Research Ethics Committee
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT
26 April 2016

Ms Hannah L Liversedge
Clinical Academic Doctoral Fellow
University of Southampton and Portsmouth Hospitals NHS Foundation Trust
Faculty of Health Sciences, Level A, South Academic Block
Southampton General Hospital, Tremona Rd
Southampton
SO16 6YD

Dear Ms Liversedge

Study title:	**Point prevalence and incidence of skin damage in neonatal intensive care units**
REC reference:	**16/SW/0022**
Protocol number:	**FOHS-2015-16891**
IRAS project ID:	**187655**

Thank you for your revised documents submitted on 19th April 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 12 April 2016.

Documents received

The documents received were as follows:

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Verification of insurance]	1	30 July 2015
IRAS Checklist XML [Checklist_02032016]		02 March 2016
IRAS Checklist XML [Checklist_09032016]		09 March 2016
IRAS Checklist XML [Checklist_21032016]		21 March 2016
IRAS Checklist XML [Checklist_23032016]		23 March 2016
IRAS Checklist XML [Checklist_04042016]		04 April 2016
IRAS Checklist XML [Checklist_19042016]		19 April 2016
Other [Summary CV supervisor (Dan Bader)]	1	08 December 2015
Other [Summary CV for supervisor (Lisette Schoonhoven)]	1	10 December 2015

A Research Ethics Committee established by the Health Research Authority

Other [Confirmation of pre-engagement checks (Southampton)]	1	11 December 2015
Other [Confirmation of pre-engagement checks (Oxford)]	1	11 December 2015
Other [Letter of support (Southampton)]	1	15 October 2015
Other [Letter of support (Portsmouth)]	1	21 September 2015
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Other [Response to letter from REC dated 21.3.16]	1	21 March 2016
Other [Parent information sheet (prevalence)]	3	23 March 2016
Other [Response to further feedback dated 23.3.16]	1	23 March 2016
Other [Response to letter from REC dated 4.4.16]	1	04 April 2016
Other [Participant information sheet (nurses)]	4	18 April 2016
Other [Consent form (nurses)]	4	18 April 2016
Participant information sheet (PIS) [Parent information sheet (incidence)]	3	23 March 2016
REC Application Form [REC_Form_21032016]		21 March 2016
Referee's report or other scientific critique report [Peer review feedback]	1	21 August 2015
Research protocol or project proposal [Protocol v2]	2	08 March 2016
Summary CV for Chief Investigator (CI) [Hannah Liversedge summary CV]	1	20 August 2015
Summary CV for supervisor (student research) [Peter Worsley summary CV]	1	03 December 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/SW/0022 **Please quote this number on all correspondence**

Yours sincerely

Frances Race
REC Assistant

Copy to: *Diana Galpin, University of Southampton*
Graham Halls, Portsmouth Hospitals NHS Trust

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User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
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HRA Training

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http://www.hra.nhs.uk/hra-training/

16/SW/0022	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Denise Sheehan
Chair

Email:nrescommittee.southwest-exeter@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

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Appendix U Timeline of approvals for prevalence and incidence study