Neonatal skin injuries from mechanical forces: a multicentre, mixed methods study

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Statement of the Contribution of Others

Nature of Assistance	Contribution	Names, Titles
Assistance related to entire thesis		
Intellectual support	Development of research questions Proposal writing Co-developed data collection tools Verified literature searches Data Analysis Statistical support Co-wrote, revised manuscripts Editorial assistance	**Yoga Kandasamy** Primary Advisor, Neonatologist, The Townsville Hospital and Health Service, Adjunct Professor, James Cook University
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Data collection	Interview design	

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Intellectual support	Transcription of interviews and focus groups	Jessie Oldfield

This research was undertaken with assistance and contribution of many groups as well as individuals. Statements of contribution of others towards the publications within this thesis are provided in Introduction Table 1. All other content within chapters were co-developed by the PhD Candidate (DA) with assistance from the advisory team Yoga Kandasamy (YK), Robin Ray (RR) and Karen New (KN). Additionally, I was also fortunate enough to work with a number of experts and clinicians to produce a number of publications and credit for these contributions can be seen in Introduction Table 1. First drafts were constructed by DA with revision with editorial input from YK, RR and KN. Unless stated otherwise, all figures and tables were developed by DA. Additional acknowledgements for individual studies, are recognised in each the pertaining articles and listed here for transparency. Roles of individuals were related to study champions or occasional recruitment or data collection Jytte Tiley, David Brown, Louise McIldowie, Dr Susan Ireland, Judith Benton, Janelle Tangney, Li-An Collie, Lashay Schulz, Juliet Manning, Dr Liza Edmonds, Donna Hovey, Carmen Neumann, Lynne Chapple, and Ms Juliet Manning.

Abstract

Background

Skin injuries are complications that most people associate with the elderly or specific conditions such as diabetes, but not with neonates. However hospitalised neonates are prone to hospital acquired skin injury related to the numerous procedures and devices required to sustain life. Many of these acquired injuries are related to the combination of a medical device and mechanical force, which alters or distorts the integrity of the skin or underlying structures. I hypothesised that several forces contributed towards injuries and set out to examine neonatal skin injuries related to mechanical forces. Additionally, without non-invasive diagnostic or laboratory methods to confirm injury identification and etiology, I also hypothesised that clinical images or wound cameras could assist in injury confirmation.

Aim

To summarise the evidence and explore and determine the epidemiologic factors of neonatal skin injuries from mechanical force (pressure, friction, shear, stripping and tear) through several data sources (literature, documents, clinician experience, period prevalence, clinical images).

Methodology

Considering the multifactorial nature of skin assessment, this research utilised an exploratory sequential mixed methods design; comprising two phases, with each phase conducted over two stages, converged with triangulation. Within this work, eight methods were utilised including two systematic literature reviews, document analysis, semi-structured interviews and focus groups, a feasibility investigation, a case series, a period prevalence study with Classification and Regression Tree (CART) analysis, evaluation of consistency of injury assessment study, culminating in between-methods triangulation. This research was conducted between 2015-18, within two Australian and one New Zealand neonatal unit.

Results

A total of seven publications arose from this research. The first outcome was a visual diagram, using fetal and neonatal scientific evidence, for neonatal skin development and maturation. Key development features from 0 to 40 weeks' gestation were represented within the diagram. Additionally, as part of the background work, skin injury severity and neonatal risk factors were examined and a systematic review was undertaken to characterise the effects of antenatally administered glucocorticoids on skin maturation. A total of 11 studies (six animal and five human) were identified. Antenatally administered glucocorticoids accelerated skin maturation in animal studies, but studies of human fetuses found conflicting results. A systematic review of neonatal injury frequency and risk factors was conducted to identify the frequency, locations and risk factors for neonatal skin injuries from pressure, friction, shear and stripping. Of 1545 papers identified, 76 full texts were examined, 21 studies met the inclusion criteria. Studies identified skin injuries from various etiologies (n=7), pressure (n=4) and then stripping (n=4). The injury frequency ranged from 9.25 to 43.1%, and medical devices, gestational age and weight were identified as the most common risks.

The document analysis, semi-structured interviews and focus groups study demonstrated a culture of transparency and responsibility for skin injuries while indicating a need for education sessions to strengthen understanding of injury etiology and severity. Followed by a feasibility investigation of wound cameras, devices and applications resulted in an iOS application being selected for its point of care reporting and supplementary clinical image collection. To further support clinical image collection, a metric graduated colour tool was developed, which comprised 15 colours, metric dimensions, and offered a discernible reference for clinical images. A publication arose describing the tool's development, with a case series of four neonatal skin injuries using the tool for assessment comparison.

Within the period prevalence study, enrolled neonates (N=501) had a mean birth gestational age of 33.48±4.61 weeks and weight of 2138.81±998.92 grams. Skin injuries were sustained by 206 (41.1%), resulting in 391 injuries to the feet (16.4%, n=64), cheek (12.5%, n=49), and nose (11.3%, n=44). Medical devices were associated with 61.4% (n=240), but 50.0% (n=120) of devices were fixed and could not be repositioned. In a CART Analysis, the strongest predictor of injury was birth gestation ≤30 weeks, followed by length of stay >12 days and birth weight < 1255g. The probability for injury was slightly different when the cohort was split by illness acuity rating, predicting injury based on birth gestational age and length of stay, but also lack of antenatal steroid course.

Two hundred ninety-seven images of neonatal skin injuries were collected during the period prevalence study, with 60 random images assessed by neonatal and adult specialists for consistency of assessment. Overall, results identified assessments were more consistent for colour than severity. Consistency of colour assessment was achieved more often with neonatal specialists (n=50, 85%) than adult specialists (n=41, 73%). Neonatal specialists' consistency for injury staging (n=107, 60%) was higher compared to adult specialists who were uncertain (n=8,16%) and less consistent (n=47, 44%). When comparing specialists as a group, consistency with baseline assessment was significantly different between neonatal and adult specialists for colour (p<0.010) and injury stage (p<0.009). Additionally, neonatal specialists assessed injury elements more confidently than adult specialists reporting 59-60 (98-100%) injuries visible compared to 51-53 (85-93%), respectively.

Four hundred twenty-seven data points were collected from literature, documentation and interviews, focus groups and free text injury assessments. Data convergence revealed numerous terms used to describe neonatal skin injuries with preferences for "*injury*", "*trauma*", or "*redness*". Injuries occur in over 20 anatomical locations, and risks for injuries included hospitalisation and prematurity. Essential medical devices, lack of clinician experience and fragile skin were uniquely associated risks. An incongruency between sources was also identified. Literature and documents emphasised pressure as the only force related to skin injury, whilst clinical data sources identified a number of forces.

Conclusion

This research established that multiple mechanical forces contribute towards neonatal skin injury; neonates are more at risk for injury when compared to other hospitalised populations; and a portion of injuries are not preventable with current care modalities. Furthermore, additional non-modifiable extrinsic and intrinsic risk factors were identified and methods for neonatal injury assessment including clinical images were established.

Despite neonatal clinicians' awareness of injuries, there are limitations for assessing injury etiology and severity. These findings have direct implications for neonatal clinical practice.

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Publications, Presentations and Outputs by the Candidate Relevant to the Thesis

Peer-reviewed publications

2020

August DL, Kandasamy Y, New K, and Ray R. Neonatal skin assessments and injuries: nomenclature, workplace culture, and clinical opinions – method triangulation a qualitative study. *Journal of Clinical Nursing.* 2020;(29;21-22):3986-4006.

August DL, Kandasamy Y, Ray R, Lindsay D and New K. Fresh perspectives on hospital acquired neonatal skin injury prevalence from a multicentre study: length of stay, acuity and incomplete course of antenatal steroids. *Journal of Perinatal and Neonatal Nursing*. (Accepted April).

2019

August DL, van der Vis K, and New K. Conceptualising skin development diagrammatically from foetal and neonatal scientific evidence. *Journal of Neonatal Nursing*. 25(6):311-4.

August DL, Hitchcock I, Tangney J, Ray R, Kandasamy Y, and New K. Graduated colour tape measure: Development and demonstration in a case series of neonatal skin injuries. *Journal of Tissue Viability*. 28(3)133-138.

2018

August DL, New K, Ray R, Kandasamy Y. Frequency, location and risk factors of neonatal skin injuries from mechanical forces of pressure, friction, shear and stripping. A systematic literature review. *Journal of Neonatal Nursing*. 24(4): 173-180.

2017

August DL and Kandasamy Y. The effects of antenatal glucocorticoid exposure on fetal and neonatal skin maturation. *Journal of Perinatal Medicine.*2017. 45(8):969-975.

Conference Presentations (invited*)

2020

Webinar, Australia: Conceptualising skin development diagrammatically from foetal and neonatal scientific evidence. Australian College of Neonatal Nurses Virtual Conference Day; September

2019

*Honolulu, United States: Battle Scars Be Gone: *Neonatal Skin Injury research and the NIPIRA Study*. 2019 Global Neonatal Nurses Institute; October

Auckland, New Zealand: *Neonatal Skin and Pressure Injury Study: Language, Frequency, Emerging Themes*. 21st Council of International Neonatal Nurses (COINN); May

*Gold Coast, Australia: *Quality improvement for neonatal skin integrity*. 21th Congress of Perinatal Society of Australia and New Zealand (PSANZ); March

2018

Launceston, Tasmania: Medical adhesives and removal techniques – producing education resources to reduce neonatal MARSI. Australian College of Neonatal Nurses ACNN; August

Launceston, Tasmania: Colour brings clarity to skin injuries: development and pilot of the metric graduated colour tool. Australian College of Neonatal Nurses ACNN; August

2016

*Dunedin, New Zealand: S*kin Assessment in the Newborn & Skin Injury tools for the Newborn*, Neonatal Nurses College of Aotearoa; October

Vancouver, Canada: *The language of neonatal skin injuries*: Council of International Neonatal Nurses (COINN) August

*Townsville: *Handle with Care- Preserving Newborn Skin Integrity*. 20th Perinatal Society of Australia and New Zealand (PSANZ); May

Townsville: The Role of Digital Imaging and Mobile Camera Application in Neonatal Skin Injury Assessment. 20th Perinatal Society of Australia and New Zealand (PSANZ); May

Other outputs informed by or arising from this research

2021

Moniaci V, Alessi S, August D, Conway-Orgel M, New K, and Bellflower B. Skin physiology and thermal protection. In; Thermoregulation in the Care of Infants Guideline for Practice. Chicago, ILL: National Association of Neonatal Nurses 2021: n/a.

2020

August D, Chapple L, Flint A, Macey J, Ng L, New K. Facilitating neonatal MARSI evidence into practice: Investigating multimedia resources with Australian Neonatal Nurses – A participatory action research project. *Journal of Neonatal Nursing.* 2020. doi: 10.1016/j.jnn.2020.12.001

2018

Brandon D, Hill CM, Heimall L, et al. *Neonatal Skin Care Evidence Based Guideline*. Washington, DC: Association of Women's Health, Obstetric and Neonatal Nurses; 2018 *external reviewers August D and Thape J*.

August DL, Marceau J, Benton J. Neonatal skin and wound care. In: Mannix T, Kain, V, eds. *Neonatal Nursing in Australia and New Zealand: Principles for Practice* Chatswood, NSW: Elsevier; 2018: 359-380.

2016

New investigator award Preliminary exploration of adjunct tools for visual assessment was presented at a scientific forum; and won best at the Perinatal Society of Australia and New Zealand, 2016.

List of Abbreviations

Abbreviation	Name
ACNN	Australian College of Neonatal Nurses
ACSQHC	Australian Commission on Safety and Quality Health Care
ANZNN	Australian & New Zealand Neonatal Network
BW	Birth weight
CART	Classification Trees Analysis
CGA	Corrected gestational age
CPAP	Continuous positive airway pressure
D	Day of age in life, as in Day 1
Dc	Document
ELBW	Extremely low birth weight
Fg	Focus group
GA	Gestational age
g	grams
iOS	Apple Operating System
IV	Intravenous
Int	Interview
IWL	Insensible water loss
LOS	Length of stay
MARSI	Medical adhesive related skin injuries
MGC	Metric graduated colour tool
MP	Ometabolites and myeloperoxidase
mRNA	Messenger ribonucleic acid
NCPAP	Nasal continuous positive airway pressure
NIPIRA study	Neonatal Infant Pressure Injury Risk and Assessment study
NO	Nitric oxide

Abbreviation	Name
NSQHS	National Safety and Quality Health Service (NSQHS) Standards
NPIAP	National Pressure Injury Advisory Panel (after 2017)
NPUAP	National Pressure Ulcer Advisory Panel (prior to 2017)
NSRAS	Neonatal Skin Risk Assessment Scale
PPV	Positive predictive value
PSANZ	Perinatal Society of Australia and New Zealand
QBA	Queensland Bedside Audit
TEWL	Transepidermal water loss
TBARS	Thiobarbituric acid reactive substances
SC	Stratum corneum
SERTA	Townsville Hospital Study Education and Research Trust Account
VLBW	Very low birth weight

Glossary of Terms

Term	Meaning
Acid mantle	A thin film on top of the skin, which forms a chemical barrier to prevent bacteria from multiplying, consisting of oils and amino acids, and measuring a higher pH. which is why it's called an acid mantle.
Brown fat stores	A special type of adipose tissue which helps to maintain heat in cold temperatures (also known as brown adipose tissues).
Bony prominence	An anatomical location where the bone is immediately below the skin, without other intermediate tissue layers, such as the tailbone, elbow or heel.
Classification	Groups of outcomes for healthcare which describe pathophysiologic changes, class and rank complications to facilitate comparison, e.g., class injuries as either pressure injury or skin tear; but may also include ranking of the outcome such as stage two or stage three severity for a pressure injury.
Clinical image	A photo, video recording, or audio recording of a patient’s body
Desquamation	A term used to describe skin peeling, or the normal physiologic process of shedding of the outermost layer of the skin.
Epidermal stripping	A mechanical force injury where a portion of the epidermis is damaged or removed when the strength of the adhesive to the skin is stronger than the epidermal/dermal bond of the skin to itself. Also known as MARSI or epidermal stripping, skin stripping.
Friction	A mechanical force or movement of two surfaces across or against each other creating resistance between surface and skin and/or tissue.
Mechanical force	(Also known as mechanical load) any force that is applied to soft tissue, because of contact with or between the skin and surface.

Term	Meaning
MARSI (Medical adhesive related skin injury)	An overarching term used to describe injuries related to adhesives including epidermal stripping, tension injury, non-allergic contact dermatitis, allergic contact dermatitis, folliculitis, and maceration.
Neonate	A live newborn until the first 28 days of life or until hospital discharge from a neonatal care facility; inclusive of a range of gestational ages from less than 37 to 42 weeks' and greater.
Nomenclature	A collection of language or terms used to define or describe something, which if used commonly, can be an expression of workplace and organisational culture.
Offload/ing	The act or practice of relieving, reduction or distribution of weight or mechanical force (e.g., pressure) from tissue that is compromised or compressed; relief may be short term or longer.
Paediatric	Reference to a human between infancy (from 29 days of age) to early teen years.
Pressure	A mechanical force against the skin or tissue in which the direction of the force is most often perpendicular. This force may contribute to injury depending on the tissue health and mechanical load.
Pressure ulcer	A localised area of soft tissue damaged by pressure, commonly appearing as shallow crater or ulcer.
Pressure injury	A localized injury to the skin or underlying tissue, because of distortion or mechanical force such as pressure or pressure in combination with shear and/or friction.
Preterm	A neonate born before 37 weeks' gestation.
Post-term	A neonate born greater than 42 weeks' gestation.
Risk assessment tools	A set of ranked evidence-based risk factors, traits or symptoms associated with a condition, theoretically identifying individuals most at risk for the complication (also see risk assessment scales)
Scale (Skin Injury Risk Assessment Scale)	A set of ranked risk factors, traits or symptoms associated with skin injuries, to facilitate identifying individuals

Term	Meaning
	most at risk for the complication (also see risk assessment tools)
Shear	A parallel force or load created when there is resistance between the skin and a surface or device, resulting in the outer layers of skin remaining still while deeper layers move with the skeleton, and subsequent injury. Shear forces can also distort of internal tissue and other structures (blood vessels and lymphatic system) between the dermis and fascia, resulting in an injury to tissue and other structures.
Stratification	Building or multiplying of the skin's cellular layers, particularly related to s. Corneum.
Stripping	A peel force related to the removal of a medical product or layers of skin from one another (also see epidermal stripping).
Severity of injury	A generic term to describe the extent of a skin injury most often related to depth but may also refer to surface area.
Staging of injury	A categorisation of a skin injury related to the extent of tissue damage related to the depth rather than surface area. For this PhD the staging of injuries endorsed by the international expert panels of the national pressure injury advisory panel and the pan pacific pressure injury alliance were used.
Skin tear	A traumatic injury caused by mechanical forces, including the removal of adhesives; severity may vary by depth including separation of the epidermis from dermis or separation of both epidermis and dermis (full thickness) but not extending through the subcutaneous layer
Tear	A blunt force which results in separation (tearing); and when referring to skin layers results in the separating of the epidermis from the dermis (partial thickness) or separation of both epidermis and dermis from underlying structures (full thickness).
Term	A neonate born between 38 to 42 weeks' gestation

Dedication

To the neonates and their families; you entrust your lives to us, may we always strive to improve our care. For Ester, Jaxson, Santiago, and their parents for sharing their faces so this problem could be authentic.

Finally, for the numerous friends, family and colleagues who encouraged me not to be afraid of my integrity. Ironically, this individual value, would lead me to search for the elements that compromised the skin integrity of my patients.

Chapter 1 Introduction

Skin injuries are complications that most people associate with the elderly or specific conditions such as diabetes, but not with neonates. Therefore, when in 2010 I started to theorise that neonates might be one of the most at-risk hospitalised populations for skin injuries; it was not surprising this was met with considerable scepticism. I wanted to understand neonatal skin injuries within my daily practice as a neonatal nurse, as the frequency and risk factors reported in the peer reviewed literature conflicted with my clinical observations. Adding to the challenge of conflicting information, was that the Australian Commission on Safety and Quality Health Care directive and a large portion of the peer reviewed literature postulated that all skin injuries were preventable and therefore could be eliminated from clinical practice.[1-3] Yet the injuries I observed in practice were acquired by neonates with under developed skin, and seemingly related to their hospitalisation, particularly from the numerous required procedures, treatments and devices. However, neonatal specific risk factors and the relationship of injury frequency, treatments, and devices for necessary care was inconsistent or missing from the peer reviewed literature. Thus, I believed there was a clear gap in the evidence which could be resolved by an epidemiological investigation into the distribution and determinants of neonatal skin injuries.[4]

Although, there are several etiologies related to skin injury, my research focuses on the epidemiology of neonatal skin injuries related to mechanical force associated with care in specialised neonatal care settings (I.e., Neonatal Intensive and Special Care Units). While I was interested in all skin injuries that occur in relation to mechanical force, I was aware that some injuries occur outside of neonatal care settings. For example, skin injuries related to forceps or vacuum extraction during birth are related to mechanical forces. However, the risk factors and decisions related to the care associated with these injuries occur in the obstetric space. Similarly, some injuries related to adhesives can be attributed to the force of adhesive removal, while other injuries are related to a dermatitis, yet all fall under the larger Medical Adhesive Related Skin Injury (MARSI) category. Thus, due to the differing risk factors, injuries related to birthing or obstetric care and MARSI unrelated to forces while important were excluded from this work.

Overall mechanical force as a cause for injuries appears to have been under represented, making me sceptical of the perception that *all* mechanical force injuries were preventable.[1-3] Generally, mechanical force skin injuries are associated with an external motion or force, which changes skin integrity or underlying tissue structure of the skin such as a skin tear or a pressure injury.[5-7] To provide context to my research, this chapter introduces skin, the nuances between injuries and wounds, the Australian healthcare setting, the neonatal population and provides an overview of the thesis.

1.1 Skin integrity, injuries and wounds

Integrity is the state of being whole and undivided, thus when 'integrity' is utilised to describe human skin, it suggests a soft, elastic, intact and appropriately moist organ.[8] Skin integrity is furthermore an absence of a breakage, trauma, injury or wound.[9] Regardless of the label, an injury or wound are both a break to the structure or function of the integumentary system or underlying structures, and often result in the loss of tissue.[10]

While there are a number of terms used to describe changes to skin integrity, differentiating the etiology between an injury and a wound has become extremely important in healthcare over the last decade.[11] Traditionally differentiating between a skin injury or wound was simply determining the etiology in order to establish appropriate management, treatment and future prevention.[12] However, in the current healthcare model certain changes to skin integrity, such as a skin tear, are seen as a complication of healthcare delivery and have additional consequences for the health care team as well as the patient.[5,13] Consequences for the health care team could include practice changes to prevent injuries, review of individual clinician's actions related to the injury or a possible financial consequence for the facility where the injury was acquired.[13]

Skin injuries are thought to be related to more extrinsic risks, such as mechanical forces or inappropriate removal of a dressing. However, many skin integrity experts argue that prevention of skin injuries is complex and that many injuries can be attributed to mechanical forces in addition to factors such as diabetes, perfusion, moisture or malnutrition,[6,14] but it appears few healthcare facilities have integrated this theory. Comparatively, wounds are more classically considered a result of pathological limitation of the body's capacity to heal and/or related to the primary diagnosis (intrinsic risks) rather than ineffective care.[15] Additionally challenging, is the fact that seminal sources for 'skin integrity' are founded in wound care.[10,16,17] Therefore, the language used in seminal sources and subsequent literature related to injury is potentially based on wound prevention and assessment, and therefore there is some contradiction or overlapping of language used in injury management.

Differentiating the etiology of a skin injury can be challenging, in that injury confirmation for day to day clinical practice is not conducted by diagnostic or laboratory methods, thus confirmation is based on clinical assessment.[16,18] Skin assessment requires a careful and detailed examination of the patients' history and physical examination, including visual and tactile observations.[18] While assessment may sound simplistic, deciphering changes in integrity can be challenging and reliant on clinician knowledge or experience due to the countless ways the skin presents clinically, and most injuries cannot be confirmed with non-invasive methods.[18] For example an intact circular reddened area presents on the face of a neonate near the respiratory support interface, which could fit the descriptions of a pressure injury or a fungal infection. Without sending invasive skin scraping for fungal identification, differentiating between the potential causes could only be completed with examination for raised edges or boarders, quantity of circular areas, how the respiratory support fit, and conducting a blanch test. Similarly, distinguishing between a number of skin injuries which are complications of care can be challenging as they may be related but reported and treated differently; such as mechanical force injury from components of the peripheral cannula or extravasation of the infusate.[10,11] Another example would be two different cases of MARSI[19]; a tension blister is related to the force applied upon adhesive product application compared to epidermal stripping which is related to the force applied during removal of the product. Whilst conceptually different, once the adhesive product is removed it is difficult to establish whether force of application or force of removal contributed to the skin injury.

There are additional challenges when distinguishing between neonatal injuries and wounds which centers around a lack of population specific evidence and the application of wound care foundations to injuries. Prior to 2015, much of the available evidence for neonatal skin injury assessment, prevention and management was borrowed from adult or paediatric evidence and adapted for neonates.[11] This had implications for my research, as I had to draw on the best available evidence, which at times was not population specific or was sourced from foundations of wound care, despite differences between injuries and wounds, and differences in injuries for neonates and those in older populations.

1.2 Skin injury standards

In 2011 the Australian Government introduced the National Safety and Quality Health Service (NSQHS) Standards.[3] Similar to many international accreditation programs, this initiative was introduced to protect healthcare patients from harm, improve the quality and service provision, and hold healthcare facilities accountable for complications acquired during care.[3] Ten key areas were encompassed within the NSQHS Standards developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC), and the eighth standard focused on the prevention and management of pressure injuries.[3] The NSQHS standards prompted many healthcare facilities to develop services to prevent pressure ulcers such as prevalence audits, risk assessment tools, and clinical guidelines for pressure injury/ulcers. Simultaneously, Queensland Health introduced a benchmarking program for quality and safety indicators, known as the Queensland Bedside Audit (QBA), which included capturing the prevalence of hospital acquired complications such as pressure ulcers.[20] Both the NSQHS and QBA were initiated to improve patient outcomes, with a focus was on a single type of skin injury (pressure injuries); despite patients who are at risk of pressure injuries having common risk factors for other types of hospital-acquired skin injures.[14]

National and statewide audits were performed for all hospitalised populations, and a Queensland benchmark for skin injury frequency was established (16%).[14] Yet, this frequency was established using only adult data without evidence or variances for other patient populations such as neonates. To assist in the consistency of audits and benchmarking activities, diagrams and images of all pressure injury severities were included in the NSQHS Standards and QBA guidelines, but yet again all examples provided were of adult patients.[5] Additionally, the NSQHS standards focused on bed surface and immobility related skin injuries; with particular attention to injuries caused over bony prominences.[5] This resulted in resources and equipment or devices for injury prevention, assessment, and management being related to bony prominence or bed surface injuries. The NSQHS standards did not differentiate or include device related mechanical force skin injuries; with the only context for devices related to injury prevention rather than cause.[3] There were additional mixed messages within the NSQHS standards, with audits and risk assessment tools focused on pressure, but included friction and shear within the pressure injury definition. Therefore, despite forces such as friction and shear considered as mechanical forces; [21,22] assessment of injuries related to these forces without pressure were based on clinician discretion. It seemed that in the development of the NSQHS standards, a number of considerations were overlooked which could affect the consistency of data reporting including vulnerable populations such as neonates, medical devices, and less common mechanical forces.

1.3 Forcing a fit - expectations for neonates based on adult epidemiology

The immediate and automatic application of the NSQHS standards into healthcare facilities, created several paradoxes for clinicians working with non-adult patient populations such as neonates. Foremost were the changes to practice and outcome reporting which acknowledged injury risk factors for only certain populations. For example, specific prevention and treatment tasks were detailed for clinicians looking after geriatric patients with considerations for the inherent structural weaknesses related to ageing skin.[21] However, neonatal skin is still maturing and thickening at birth,[23] and neonates are at risk for injury from the numerous procedures and devices when hospitalised. At the time, emerging peer reviewed literature reported mechanical force skin injuries in neonates.[24-26] Comparatively, the NSQHS standards were general with the only specialist group noted as geriatrics[3] therefore focusing on preventative recommendations tools, and devices available for adults. Whereas, an international guidelines the Pan Pacific Clinical Practice Guideline for Prevention and Management of Pressure Injuries[5] mentioned neonates in sections for population specific risk assessment tools, but provided limited preventative measures.[1,27] At the time of standards and guideline publication, two observations neonatal studies were available reporting neonatal skin injuries were as high as 16-42%.[28,29] Yet, this evidence was not included within the guidelines and no specific considerations for population specific risks provided in the standards, therefore neonatal units that participated in audits or reported injury incidence appeared to have unacceptably higher rates of occurrence. Differentiating between adult and neonatal populations was also necessary for assessment of injury severity or staging[5], in particular the appearance of injury depth in an adult compared to a neonate. The NSQHS standards classified severity for mechanical force injuries differently compared to the neonatal literature.[5,28] If severity assessment were inconsistent or unclear, certain stages of neonatal skin injury might be under or overreported and could appear abnormally high in comparison to adult benchmarks.[30] Furthermore, no skin injury or related outcomes were reported within the international collaborative network, the Australian & New Zealand Neonatal Network (ANZNN), which collates and reports neonatal morbidity and mortality core outcomes. Thus, without clear guidance for which severity system to use for neonates, accurate population specific benchmarks were unlikely to be achieved.

1.4 The neonatal population

While neonates were equally deserving of quality standards, the NSQHS standards appeared to marginalise neonatal healthcare outcomes and misrepresent the care required to achieve best practice for this unique population. Sick and preterm neonates are not little adults but a distinct population. Advances in modern science and healthcare have allowed for younger, smaller, and sicker neonates to survive, thus, resulting in an increase in the number of newborns requiring specialised quality neonatal care.[31]

By definition, a neonate is any live birth for the first 28 days of life,[32] and are sub-categorised for selection of age appropriate treatments and outcome comparisons. These categories are based on gestational age such as preterm (born less than 37 weeks) inclusive of extremely preterm (<28 weeks), very preterm (<32 weeks) and moderate- late preterm (born between 32 to 36+6 weeks' gestation); term (38 to 42 weeks' gestation); and post term (born greater than 42 weeks' gestation).[33] Additionally, categories are also based on birth weight including extremely low birth weight (ELBW) born less than 1000 g; or very low birth weight (VLBW), born between 1000 to 1500 g.[33] However, in the context of a hospital neonatal unit, the word 'neonate' is often applied to all newborns requiring specialist neonatal care until discharge, irrespective of the number of days in hospital. Thus, depending on gestational age, or complexity of condition, hospitalisation will be greater than 28 days and occasionally for several months.

Best practice care for hospitalised small, sick, and preterm neonates differs from the care required by well term newborns, paediatric and adult patients. This finite population are particularly vulnerable to complications, and have additional considerations related to the development and maturation of organ structure and function including the skin. Interdisciplinary teams provide numerous interventions to this population including assistance with normal physiological functions such as breathing, temperature regulation, feeding, and infection prevention measures. Thus, most observations and interventions require medical devices, such as an oxygen saturation probe or an endotracheal tube, which are secured to a single interface, *the skin*. Therefore, many required observational and interventional devices will have an impact on skin integrity. The development of an injury or skin breakdown, may mean treatment may be prolonged or difficult to facilitate, further contributing to a neonate's hospitalisation and subsequent morbidities.[34,35]

1.5 From neonatal clinician to PhD candidate

As a nurse, I was aware of my responsibilities to identify, document and communicate all changes to a patient's condition, including skin injuries. However, the documentation and communication around skin injuries appeared subjective, inconsistently handed over, and assessment agreement between colleagues was scarce. During a neonatal assessment, I frequently discovered a nondescript pink or reddened area which differed from the surrounding skin colour. Furthermore, these areas were frequently associated with the alteration or removal of a medical device. While the area was metrically small in proportion to the patient's size, the discolouration appeared substantial. I considered that just because the area could not be confirmed by a diagnostic or laboratory test, such as a blood sample or an x-ray, there was potentially an implication for the neonate. Yet, colleagues stated to me, 'that spot will go away by the end of tomorrow' or 'that's not like a pressure ulcer, that's just a bit of skin gone'. Such comments and a lack of recognition within the NSQHS standards about skin injuries for the vulnerable neonatal population, motivated me to explore further and ask questions.

To further understand skin injuries observed in practice, I consulted with adult skin experts, and to my surprise, several adult experts appeared unconcerned as injured areas appeared metrically small compared to injuries seen in adult patients. During this time I also became part of the Townsville Hospital and Health Services Pressure Ulcer Prevention team and undertook a retrospective prevalence study of neonatal skin injuries to better understand skin injury assessment.[30] These activities reinforced that many of the resources available lacked clarity on injury confirmation or population specific risk factors, at best suggesting that only premature neonates had fragile skin.[36,37] Thus, more questions were generated such as: how prevalent were neonatal skin injuries in other units?, how could injury assessment be confirmed?, and which neonates were most at risk for injury? Furthermore, the findings from the retrospective prevalence study identified that neonatal injuries were related to a combination of etiologies, life sustaining medical devices such as respiratory interfaces (not a bed surface) and rarely occurred over a bony prominence,[24,28,38,39] which contrasted with national and international guidelines.[3,21] As researcher I understood that pressure, friction and shear were forces which acted on skin and thus contribute towards injury; compared to stripping or tear which were considered the injury presentations from mechanical and/or resistive forces.[19,40] However, as a pragmatic clinician these were still similar categorisations at the endpoint of an injury related to hospital care. If mechanical force skin injuries were categorised separately (e.g. pressure injury or skin tear) but concurrently investigated; I could explore the overall risk, prevalence and relationship of these skin injuries for the neonatal population. These questions and conundrums were the catalyst for my PhD journey in which I explored neonatal skin injuries related to any combination of mechanical force(s) regardless of relation to device or surface.

1.6 Aim, research questions, methodology and thesis style

1.6.1 Aim and research questions

The aim of my research was to summarise the evidence, explore and determine the epidemiologic factors of neonatal skin injuries from mechanical force (pressure, friction, shear, stripping and tear), through sources of data (literature, documents, clinician experience, period prevalence and clinical images).

Question 1: What do documents reflect about neonatal skin care, skin injury, assessments, severity, and etiology of skin injures?

Question 2: What are neonatal clinicians' perceptions of assessment, etiology, severity and prevention of neonatal skin injuries?

Question 3: What is the period prevalence and associated risk factors for neonatal skin injury from pressure, friction, shear, stripping and tear?

Question 4: What is the consistency in the assessment of neonatal skin injuries?

Question 5: How are neonatal skin injuries described, defined, identified, and communicated?

1.6.2 Selection of a methodology

When selecting the methodology and design for my research, I was aware that I needed to consider a number of challenges and determine solutions for each of these. Primarily, while neonatal and adult skin inspection and injuries were similar; my clinical experience had demonstrated that skin injury etiology differed. My experience, coupled with knowledge assessment components, prepared me in understanding the variety of skin injury etiologies, and that existing skin injury definitions were likely inconsistent and imperfect for neonatal skin injuries for a number of reasons. The guiding principle for adult skin injury prevention (offloading to alleviate sustained pressure/shear), would not be feasible for most neonatal skin injuries related to mechanical force. Instead, my clinical observations lead me to believe that most neonatal injuries were related to i) a combination of mechanical forces with ii) the application, position or removal medical devices; only some of which could be safely be moved or temporarily disconnected. Moving lifesaving medical devices to visualise underlying skin can be risky, making coordinating confirmation by expert assessors difficult. Therefore, it was important that my data collection methods facilitated and incorporated neonatal clinicians' observations to capture an accurate skin injury frequency.

Secondly, I anticipated that skin injuries might differ between clinical practice settings, so a multicentre study would provide a more accurate data set. As the historical nature of skin injury reporting is punitive, to achieve reliable multicentre enrolment and data collection, clinicians would need to trust me, understand the purpose of the study, and have invested interest in reporting study data. This would require my understanding of unit culture and the mindset related to neonatal skin injuries from each of the neonatal settings in which the study would take place. Furthermore, the nature of skin injury confirmation (visual assessment) and data collection would likely need to include clinical photography. Collecting clinical images would necessitate additional trust and understanding for why this portion of the data was important. Overall, my research would require methods conducive to multiple types of data: qualitative (nomenclature and culture), quantitative (numerical and categorical), and multimedia (clinical images). Each of these considerations led me to propose a mixed methods study design. The strengths of mixed methods research includes the consideration of a particular research question from multiple viewpoints, perspectives, and positions.[41] This methodology would allow me to explore my research questions though both qualitative and quantitative methods, but more importantly maintain a systematic integration of both methods for the purposes of obtaining a fuller picture and deeper understanding of neonatal skin injuries from mechanical forces.[41] The qualitative components of the research would improve my insight of unit culture but also facilitate exploration of concepts that quantitative data cannot express, such as experience of neonatal clinicians instead of just the frequency of the condition.[42-45]

1.6.3 Thesis style

My chosen thesis style was thesis by publication and the following points clarify the variances in syntax, spelling (such as colour vs color) and nomenclature (such as neonate vs baby). This thesis was undertaken in an Australian University, so spelling and grammar have been stylised where possible to the Australian format for the non-published portion of the work. However, this thesis contains a number of papers published in a variety of international peer reviewed journals thus syntax and two versions of spelling may be included to account for published and unpublished work, which is sign posted within chapters for the reader (such as aetiology or etiology; fetus or feotus). The reference list for each original article has been cross-referenced to the thesis reference list for continuity appearing at the end of each manuscript, in the order originally published. However, to provide a consistent way of identifying sources, references for the entire thesis have been combined at the end of the thesis in one complete list. Therefore, the numbers corresponding to the references within the published sections have been renumbered based on the order in which they appear in the thesis. Similarly, tables, images, and figures from publications have been re-numbered to correspond within the chapters in which they are included, rather than the number from the original published work. While data collection within this study occurred sequentially, there were instances when data from one phase was combined with earlier work to demonstrate application within publications. Like most post graduate work, the frameworks, definitions and guidelines refenced during each Phase of the thesis maybe superseded at time of PhD submission. Details related to the version or year of frameworks, definitions and guidelines are provided within each of the relevant methods to help provide historical context for currency at time of data collection (2015-2018).

1.7 Thesis structure

This thesis is comprised of nine chapters. The first four chapters, including this chapter, focus on background content explanation and research methods.

Chapter 2 reviews skin structure function and development through fetus to early infancy and provides an overview of risks for skin injury with considerations for the organs' structure, function, maturation, antenatal treatments, and risks proposed by risk assessment tools. Two publications are included in this chapter: *Conceptualising skin development diagrammatically from foetal and neonatal scientific evidence* [46] and *The effects of antenatal glucocorticoid exposure on fetal and neonatal skin maturation.*[47]

Chapter 3 further explores skin injury assessment, etiology, context of injury severity and frequency and includes the publication*: Frequency, location and risk factors of neonatal skin injuries from mechanical force of pressure, friction, shear and stripping: A systematic literature review.*[48]

Chapter 4 details the methodological approach and the specific methods for each study, including the selection of an exploratory, sequential mixed methods study design for the investigation of mechanical force related neonatal skin injuries.

The remaining five chapters are dedicated to results and implications of the research. Chapter 5 presents analysis of the documents and interview and focus group results for Phase 1. Specifically, the exploration of workplace context, nomenclature (also known as language) and culture of participating neonatal units through documents and clinician experiences with skin injuries.

Chapter 6 reports on the feasibility investigation and development work for adjunct tools for visual assessment, including the feasibility of specialised wound cameras, mobile image applications, and clinical image reference tools to capture skin injuries. This chapter includes the publication: *Graduated colour tape measure: Development and demonstration of this tool in a case series of neonatal skin injuries.*[49]

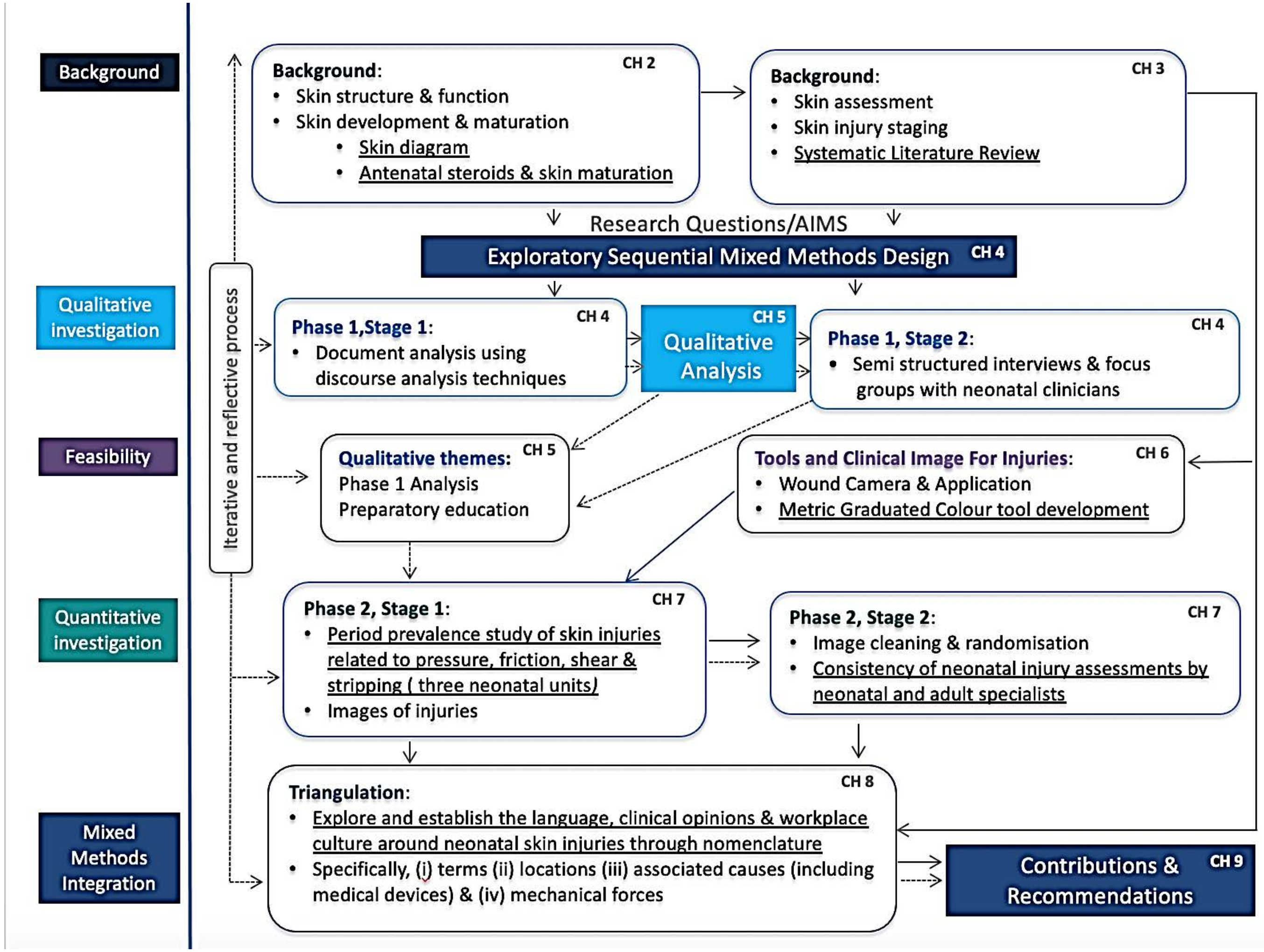
Within Chapter 7 reports on the multicentre period prevalence study and the use of clinical images to capture injuries are reported in the publication: *Fresh perspectives on hospital-acquired neonatal skin injury prevalence from a multicenter study: length of stay, acuity and incomplete course of antenatal steroids.*[50]

A second output from Phase 2 (Stage 2), the use of clinical images, and variances in depth perception and the influence of adult compared to neonatal specialists on assessment findings is reported in the publication: *Evaluation of the consistency of neonatal skin injury assessment using clinical images and the metric and graduated colour tool*. (Under review)

The last of the results reported in Chapter 8 relate to the conceptual understanding of the epidemiology of skin injuries from mechanical force, through an in-depth exploration of nomenclature from all data sources: investigation of terminology, locations, associated risk factors and the related mechanical forces for skin injuries; which were completed through triangulation.[51,52] The publication within this chapter is titled: *Neonatal skin assessments and injuries: nomenclature, workplace culture, and clinical opinions – Method triangulation a qualitative study.*[53]

Concluding this thesis, Chapter 9, presents the implications and recommendations from this work for the clinical setting and future research.

To enhance the readers' navigation, a conceptual map which illustrates the sequence of phases, stages, and summarises methods and analysis (Figure 1.1) is positioned a number of times throughout the thesis to signpost the location of the chapter or section in the overall work.



KEY: Underlined text = published or submitted for review; CH= Chapter

Figure 1.1 Thesis conceptual map.

Chapter 2 Skin Structure, Function, Development, Risks for Injury and Neonatal Implications

In undertaking a thorough review of skin development, structure and function through fetus to infancy, I quickly realised that a good portion of evidence for skin structure and function was best established for adult or mature skin. Thus, to aid understanding and conceptualisation of the differences and deficits of fetal and neonatal skin; adult skin structure, function and development was used as a reference for comparison. This was important as it informed the studies and considerations of whether risk factors differed for neonates compared to adults, and for preterm neonates compared to their term counterparts. In addition, I explored the role of co-morbidities likely to contribute towards injury formation, as well as risks proposed within established neonatal risk assessment tools. This chapter presents the overview of skin structure, function, development and maturation, as well as the established risks for neonatal injury.

2.1 Skin function and tissue structures

Regardless of age, the skin is the organ that forms the interface between the human body and the external world.[54] It is a complex organ with properties for chemical, physical (mechanical) and biological barriers to external elements.[55] Once fully mature the skin will control and contribute towards a number of purposes such as thermoregulation (including the management of transepidermal water loss (TEWL)), barrier function (chemical and mechanical), immunity, sensory reception (pain, touch, temperature), fat storage, ultraviolet (UV) light protection, and facilitation of Vitamin D production.[55]

Mature adult skin consists of three tissue structures: epidermis, dermis and the hypodermis (sometimes called the subcutaneous layer).[55] The outermost layer, the epidermis, includes three sub structures known as the stratum basale, spinosum, granulosum, and corneum (the uppermost layer). Throughout the lifespan the epidermis will repeatedly stratify (build layers) and desquamate (shed layers), thereby replenishing the strength of the outermost covering.[56] Interestingly, in the sole and palm areas, the epidermis contains a fourth layer called the stratum lucidum.[57] The dermis is similar to connective tissue, but importantly contains a rich supply of nerves, blood vessels, lymphatic structures, collagen bundles, macrophages and fibroblasts.[55] The dermis has two layers, the papillary dermis and reticular dermis.[58] Additionally, the area between the epidermis and dermis, known as the dermoepidermial junction or basement membrane, consists of a special extracellular matrix where both epidermal and dermal cells contribute to form a bond between structures. The last layer of the skin, the hypodermis, is often considered only a connective structure. However, this is the location of lipid and fat storage, consisting of adipocytes (fat cells) that are important in injury and wound healing.[59] Together, these structures form a network of cells and tissues that serve the body with an extraordinary number of functions.

2.2 Contrasting neonatal and adult skin structure, function and susceptibility to injury

The structural components of term neonatal skin are different to adult structures, with additional differences for those preterm neonates born ELBW and VLBW.[60] For example, specific structures of the skin such as the periderm only exist during the fetal period, which may still be present when born ELBW.[61-63] Overall preterm and term neonatal skin is thinner than adult skin, with either incomplete or near complete keratinisation/cornification which limits the strength of the skin layers to each other. Additionally, the preterm dermis has fewer structural proteins.[60] Interestingly, the thickness of stratum corneum (SC) at term age (9-10um) is similar to adult skin (9-15um).[64] However, reports of neonatal skin maturity and comparisons to adult skin, are primarily related to the structural maturation of SC, which will thicken as early as nine weeks post birth for those born ELBW and VLBW.[60] The exact age of development and maturation of other important skin structures including the dermoepidermial junction, rete ridges, dermis (including reticular dermis) and hypodermis were unclear when I first commenced this research.

Unlike the knowledge related to the structural development of the s.corneum, determining the age of functional maturation is more difficult. Firstly, while skin comprises of a number of structures and functions, there is a paucity of a single measurement or marker to determine maturity. Secondly, it is uncertain if functional skin maturation is linear, and it is understood that organ maturation would be dependent on the development of all structures and functions. One function particularly deficit when born preterm or term, is the barrier function. The skins capacity to act as a physical barrier against the diffusion of water through the skin (TEWL) or a chemical barrier (acid mantle) to prevent bacteria from multiplying is weaker for all neonates, and even term newborns when compared to adults. While not certain, other skin structures such as reticular dermis boundary or collagen fibres are expected to take longer to develop, than the s.corneum, with exact time points for maturation unknown.[60,64] Furthermore, while some evidence suggests structural completeness of the barrier only takes days for those born near term age,[23,65,66] the functional maturation equivalent to adult counter parts can take weeks for those born preterm.[56,64,67] Some studies suggest the skin will not reach functional maturity until the first or second year of life.[63,68] Therefore, considering the structural limitations of neonatal skin, it is logical that neonatal skin would be more suspectable to injury, and similarly injuries would have additional functional implications for this population. Detailed comparison of skin structures and associated implications dependent on age are presented in Table 2.1, with similar comparison of skin properties and functions presented in Table 2.2. Of note, comparisons within the table are made between preterm, term and adult skin where possible, based on the current available evidence. The word neonate has been used within the table when no indication or specific gestational age group such as preterm or term were provided.

Table 2.1

Skin structure, description, development, and differences for neonates compared to adults.

Structure	Structure description	Neonatal and adult skin structure, limitations and implications
Stratum corneum	Uppermost structure and first line of barrier defence	Stratification starts at 23 weeks' gestation[69] Preterm and term skin has fewer cellular layers compared to adults[64] • Thickness of preterm skin will increase overtime, and thickness accelerates if born prematurely[69] • Fewer layers increase the risk of diffusion of water through TEWL[65,70] Post term neonates have increased cellular desquamation [57] Preterm and term skin has a higher surface pH (more alkaline) compared to adult skin, which delays the formation of the acid mantle [71,72]
Dermoepidermial junction	An undulating structure of peaks and valleys (also known as ret ridge, rete peg or fibrils[73]) Assists in layers' attachment[57,74]	Preterm rete ridges are fewer in number, thinner and smaller than term ridges, decreasing adhesion; term neonates are thought to have fewer ridges than adults[1,75] • Weaker structural connections (rete ridges) increase the susceptibility for separation of layers, shearing trauma, adhesive removal injury, and blistering[7,73,76]
Dermis	Middle structure of connective tissues of structural proteins	Neonatal dermis contains fewer structural proteins, collagen and elastin fibres than adults affecting strength and function [69,77]
Hypodermis	Inner most structure	Neonates have increased proportion of saturated fatty acids compared older counterparts, increasing the risk of hypoxic trauma which can lead to subcutaneous fat necrosis (exact preterm or term proportions uncertain)[18]

Structure	Structure description	Neonatal and adult skin structure, limitations and implications
Vernix caseosa	A cheese like substance is composed of 80% water, 10% protein and 10% lipids[78]; consisting of desquamated skin cells, sebaceous gland secretions and shed lanugo hairs	At 22 weeks' gestation vernix will begin to form, is minimal before 27 weeks and will act as a protective barrier against amniotic fluid for the fetus/neonate[78]
	Only present in utero and on neonatal/newborn skin	Expected to cover skin completely by 35 weeks when intrauterine[78]
		Proteins within vernix contribute to the formation of the stratum corneum[57]

Table Key: TEWL= transepidermal water loss, elements of the table borrowed from[16,23,53,55,70,78-84] [61,65,85]

Table 2.2
Skin property, function and neonatal implications and limitations.

Property	Function in adults	Neonatal implications and limitations
Chemical barrier (acid mantle)	An acid mantle, which prevents bacteria on the skin from multiplying pH less than 5 has bactericidal properties[72]	Term birth term pH usually >6.0 but falls to 4.9 by day four [72] Neonates have delayed formation of the acid mantle[71,72] An increased surface pH (alkaline) is thought to increase the risk of mechanical damage[72]
Physical (mechanical) barrier	Protects against diffusion of water through TEWL Prevents the absorption of chemicals and substances	Term rates of TEWL are initially increased after birth, but normalise during the first week of life[62], thus increasing the risk for heat, fluid and electrolyte loss All gestational groups, TEWL increased after adhesive removal, from a single event in some cases[86] Preterm barrier defence against TEWL may take up to nine weeks or longer[60,62] • 23-27 weeks' gestation-TEWL is approximately 60g-75g/m^2/hr at birth, similar to the rate for adult injured skin[70,87] • 29 weeks- TEWL is 17g/m^2/hr[88] • 34-35 weeks or greater - TEWL is 4-6g/m^2/hr[67] and approaches the rate of adult TEWL soon after birth[70] Preterm skin, especially ELBW, has increased permeability which increases the risk for chemical burns related to procedural cleaning[64,89]

Property	Function in adults	Neonatal implications and limitations
Biological barrier	Dendritic cells within the epidermis (Langerhans cells) ingest foreign substances, activate the immune response and cooperate with T-lymphocytes in the skin to initiate cellular responses against foreign antigens Dermal macrophages form a second immunological response	Timeline of Langerhans cell development and impact for term and preterm birth is unknown Vernix (a unique neonatal element) contains proteins with immunological and antibacterial properties[57] • Contains significant immune modulators which provide a first line of defence against microbial invasion[57] • Presence or absence of vernix plays an important role in term skin hydration[78]
Thermoregulation	Skin thermoreceptors detect temperature changes and feedback to the hypothalamus for the body to increase or decrease heat production Blood flow and the production of sweat adjust to regulate temperature Shivering/vasoconstriction/dilation	Thermoreceptors and regulatory mechanisms are underdeveloped • Thin structural layers • Lack of brown fat stores • Increased TEWL • Large surface area to weight ratio • Unable to produce heat using shivering Term and preterm at risk for hypo and hyperthermia
Touch, pain, and temperature	Multiple receptors contained within skin • Touch (mechanoreceptors and Merkel cells) [90] • Pain (nociceptors)[83,85] • Temperature (thermoreceptors) Between 0.2-5% of epidermal cells are Merkle cells (related to touch reception)[90] Nociceptive responses are a useful measure of central pain processing[82]	• The development of Merkel cell may be as early as 8-11 weeks.[90] • Before 35 weeks sensitivity of flexion reflex to tactile stimulation inconstant, likely related to a lack of differentiation between tactile and noxious cortical activity[82] Other impacts of preterm birth on receptors are uncertain, especially the impact of injured skin on pain and touch reception

2.3 Conceptualising skin development from fetal to term gestation

The information within Table 2.1 and 2.2, was collated from a number of sources, as no single source provided a comprehensive summary of neonatal skin structure and function development. Furthermore, linear representation of changes during different gestational periods were lacking, and I wondered if information could be presented in a more illustrative way to aid clinician conceptualisation and understanding along the continuum of fetal/neonatal skin development. While there were a number of published articles including cross-sectional diagrams on skin development,[91,92] these were focused on adult skin structures or they lacked development detail from fetal to term gestation. Therefore, with a medical student, whom also had a background in communication design, fetal and neonatal skin development and maturation was mapped and subsequently used to produce a visual, linear representation of key development features by gestational week blocks. The diagram and the details of its development were published in the Journal of Neonatal Nursing. *Based on the publisher's specifications the traditional spelling for fetus/fetal ("foetus") was used for this article and the original article's list of references has been cross-referenced to the thesis reference list for continuity.

2.4 Article: Conceptualising skin development diagrammatically from foetal and neonatal scientific evidence

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Background

Skin injury is a problem for at least 40% of the neonatal population, with increasing risk for neonates of decreased gestational age and those who require devices to support medical care.[11] Importantly, changes to skin integrity can affect a neonates' sensory perception (pain), hydration (trans-epidermal water-loss) and morbidity (length of stay) among other considerations.[66] Clinicians' understanding of the skin's physiology, structure, and development informs clinical decisions and is traditionally learned through text sources, accompanied by occasional figures or diagrams. However, the importance of visual models for knowledge acquisition continues to grow, supporting a shift away from text as the primary source of information.[93,94] Examples of visual diagrams that regularly inform clinical practice are the three-dimensional cubes depicting degree of skin damage presented by the National Pressure Ulcer Advisory Panel (NPUAP).[95]

Visual representations of foetal and neonatal skin development from peer-reviewed sources have previously been published as electron/light micrographs, diagrams, figures and illustrations. Ersch, Stallmach [67] represented skin development through schematic histological slides and illustrations, while contemporary models have demonstrated development of the skin through cross-sectional figures.[91] Histological images are biological evidence and therefore a gold standard for identifying cell and tissue development. However, present day ethical and fiscal constraints reduce the possibility of large-scale histological investigations. Of the existing visual examples many were found to have limitations such as: the need for interpretation of electron micrographs and images of histological slides,[67,92,96] the absence of structures such as periderm and vernix[91,92] and missing gestational ages within figures.[91] Using foetal and neonatal scientific evidence we have developed a diagram for skin development from 0 to 40 weeks' gestation.

Diagram development

During PhD research, the opportunity arose for collaboration between a neonatal nurse with a wound specialty, and a medical student with a background in communication design. It was identified there was a need for a diagram that would help clinicians conceptualise skin development from early genesis to term gestation, to improve understanding of the function limitations of underdeveloped skin. Like many organs, the skin has structural and functional weakness at term gestation with further deficiencies noted when born premature. The model proposed in Fox [91] displays development of the organ from four weeks to 28 weeks. While the extremely premature timeframe presents increased skin challenges, all neonates requiring care in neonatal units are at increased risk of skin damage because of mechanical forces from securement of medical devices. Hence, using the lateral markers (time brackets for weeks of development) from Fox's work, we proposed an extended diagram to span from 0-40 weeks' gestation and detailed developmental illustration of essential skin structures and elements.

The literature was reviewed for evidence of the development for each of the following elements and structures: ectoderm, periderm, basal cells, stratum (s.) (basale, spinosum, granulosum, corneum), dermal cells (papillary and reticular layers), dermoepidermial junction (rete ridges), hair follicle, sweat gland, adipose tissue, blood vessels, desmosomes, and vernix. Next gestational periods were populated with skin development milestones from multiple sources such as expert opinion statements, data (tables), diagrams, illustrations, figures, histology, and electron/light micrographs (photomicrographs).[11,23,57,63,67-69,71,77,91,92,96,97] The genesis and development of each element within the diagram (for example: basal layer) was crosschecked against all sources. If there was disagreement between sources, as occurred with the genesis of adipose tissue, the decision was made based on most recent and majority consensus within the literature. The diagram was also designed inline with the stages of organ development: (i) organogenesis- embryonic period (0– 60-plus days) before 8 weeks, (ii) histogenesis - the early foetal period 8 to 20 weeks, and (iii) maturation - the late foetal period (5–9 months) 20 weeks onwards.[57] Adobe Illustrator software was used to produce the diagram.

An evidence-based visualisation for skin development from 0-40 weeks

There is now an expectation that to enhance learning and memory processing, materials, where possible, should be presented in text and graphical formats,[94] giving more focus to the visual than the textual learning style alone. Thus, this skin diagram (Figure 2.1), is presented with a table (Table 2.3) which outlines key development aspects for each lateral marker time period. This style of educational resource is likely to inform students, neonatal clinicians, clinicians for whom English is a second language and those whom infrequently care for neonates. Additionally, Table 2.4 provides details on depth and sub-skin layers for preterm and term infants comparative to adult measurements. These details facilitate contextualising the scale of skin depth demonstrated within the diagram.

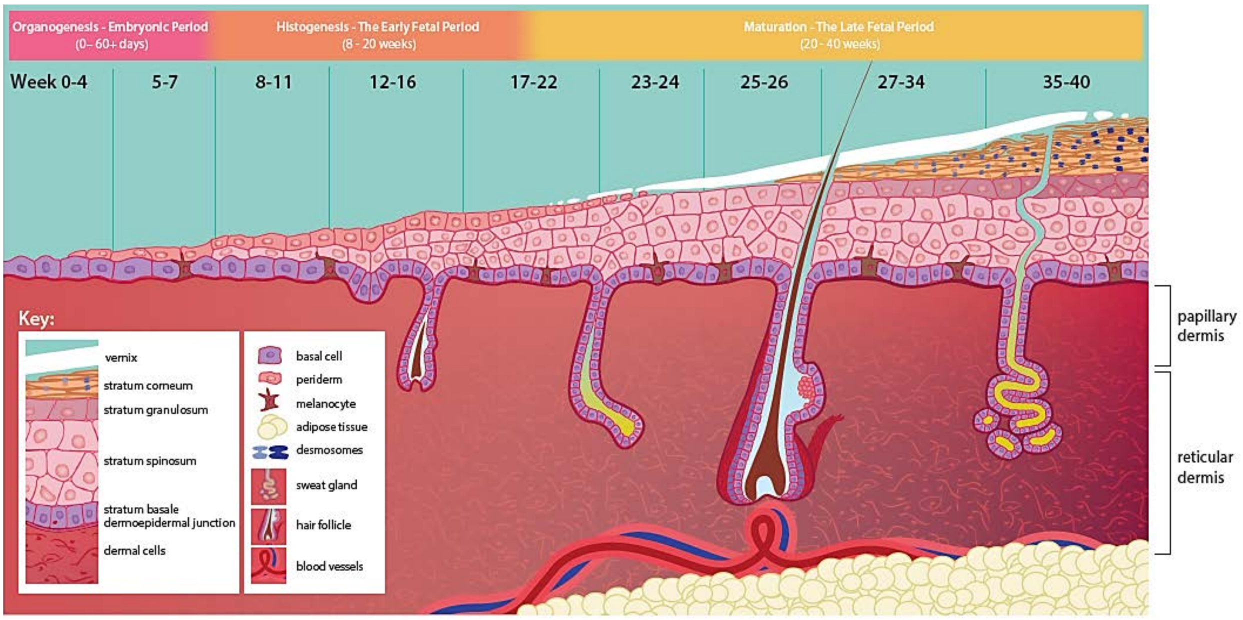

Figure 2.1 Skin development from 0-40 weeks

Table 2.3

Key development features and considerations by weeks.

0-4	**5-7**	**8-11**	**12-16**	**17-22**	**23-24**	**25-26**	**27-34**	**35-40**
Single layer of ectoderm. Periderm and basal layer emerge.	Melanocytes emerge.	Spinous cell layer emerges.	Periderm, basal cells, desmosomes, hair follicles emerge. Two layers of spinosum.	Four-five layers of epidermis. Vernix begins to form.	Epidermal layer begins to proliferate. Periderm deteriorates (finished by 24 weeks), adds to vernix.	Epidermis keratinised (cornified). Multiple layers of stratum corneum.	Vernix and stratum corneum thicken.	Thick vernix covers the skin and then by 40 weeks remains only in the creases.

KEY: (diagram excludes the stratum lucidum) content [11,23,57,69,96]

Table 2.4
Depth of skin and sub-layers for preterm and term neonate's comparative to adults.

Structure	Preterm*	Term	Adult
Skin	0.9mm (900um)	1.2 mm (1200um)	2.1 mm (2100 um)
Epidermis	20-40 um	36-50 um	>50 um
Stratum corneum	4-5 um	9-10 um	9-15 um
	(5-6 cells)	(>15 cells)	(>15 cells)

KEY: mm- millimetre, um- micrometre
*(exact gestation not available); data sources [57,67]

Limitations of sources to inform diagram

This diagram is derived from the available evidence; combining foetal and neonatal skin evidence and therefore makes some assumptions about development after preterm birth. Half of the content originated from foetal skin literature (<22 weeks' gestation), while the remaining weeks of skin development are from a combination of foetal and neonatal sources. This combination of sources has been synthesised to resolve skin development post 22 weeks, with some discrepancies and gaps in the literature. Specifically, this diagram was unable to accurately depict i) the exact number of cell layers in the stratum spinosum after 17 weeks, ii) the variation in skin depth and structure across different anatomical locations as well as iii) when the stratum lucidum development was differentiable from other epidermal layers. Additionally, the stratum lucidum is only present in the soles and palms[57], thus it has not been presented in this diagram. Furthermore, the diagram's lateral makers were divided based on available evidence which has resulted in non-linear segments with some segments representing 2 weeks while others represent 5 weeks. Despite these challenges the authors believe this is the closest representation of overall skin structure and development based on currently available data.

Future research

While histological images are a gold standard; ethical constraints are likely to restrict future large-scale histological studies necessitating other visual representation of scientific knowledge. We acknowledge it will be difficult to research the development of the dermis, comprising of the dermo-epidermal junction (specifically rete ridges,[74] as well as the papillary and reticular dermis. However, there is a specific need to enhance understanding of the junction's role in skin connectivity, to inform the prevention of neonatal medical adhesive related injuries.[48] Lastly, continued research regarding pre and post-natal skin development will likely require non-invasive measurements applied to graphic illustrations to enhance clinician's knowledge of skin development and inform strategies to reduce majority of neonatal skin injuries.

Funding

No funding has been received to undertake this research.

2.5 Extrinsic implications for skin maturation: antenatal steroids

Investigating the development and maturation of fetal-neonatal skin, led me to consider if there were extrinsic factors that may influence skin development and maturation particularly for those born preterm. As skin maturation is interrelated with intrauterine processes, I considered if treatments commonly prescribed during preterm labour could influence skin maturation and susceptibility for injury. This was particularly pertinent, as the standard practice worldwide for a mother in suspected or actual preterm labour, is the administration of antenatal steroids.[98,99]

As reported earlier in this chapter, lipids and proteins are part of skin structure and function and have specific functions within the hypodermis and vernix caseosa such as wound healing and contribution to the natural moistening factor of stratum corneum. Lipids are also a vital structural and functional component within the lungs, and thus antenatal steroids are administered to women expecting a preterm birth.[99] This steroid group, also known as glucocorticoids, specifically accelerate fetal lung maturation including the biosynthesis of phospholipids (a type of lipid) and pulmonary surfactant.[98,99] Considering the action of glucocorticoids, I hypothesised that antenatal steroids could have some effect on skin lipid content and overall maturation.[100] Therefore, I undertook a systematic review of antenatally administered steroids for the effect on skin structure and maturation. Due to the paucity of human studies, animal models were also investigated resulting in the findings published in the Journal of Perinatal Medicine. *Based on the publisher's specifications the North American spelling for fetus/fetal was used for this article and the article's reference list of has been cross-referenced.

2.6 Article: The effects of antenatal glucocorticoid exposure on fetal and neonatal skin maturation

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Abstract

Aims: The use of antenatal glucocorticoids in women with preterm labor has dramatically improved outcomes for premature infants. The most commonly used antenatal glucocorticoids are betamethasone and dexamethasone. Glucocorticoids accelerate fetal lung

growth by several mechanisms, including the maturation of type II pneumocytes enabling surfactant production. Furthermore, the lipids in the lung share similarity with those in the skin. Therefore, antenatal administration of glucocorticoids may have effects on the structure and function of the developing epidermal barrier in fetuses and neonates.
Methods: We performed a systematic review to characterize these effects, identifying 11 studies (six animal and five human studies).

Results: Five out of the six animal studies used a rodent model for investigating the effects of antenatally administered glucocorticoids, while the other used an ovine model. Antenatally administered glucocorticoids accelerated skin maturation in animal studies, but studies of human fetuses found conflicting results. None of the reviewed studies compared the effects of different types of glucocorticoids.

Conclusions: More human studies are needed to fully understand the effects of antenatal steroids. However, as the antenatal use of glucocorticoids in preterm pregnancies has become part of standard clinical practice, it would be unethical to carry out a large randomized controlled trial. We may have to rely on animal models to improve our understanding of the effects of antenatal glucocorticoid exposure on the fetal and neonatal skin maturation.

Introduction

Fifteen million infants are born prematurely each year, a number that is expected to increase.[101] The use of antenatal glucocorticoids in women with preterm labor has dramatically improved outcomes for premature infants.[98] The most commonly used glucocorticoids are Betamethasone and Dexamethasone, administered as an intramuscular injection; their effects last about a week. Antenatal use of this medication is associated with a reduced risk of intraventricular hemorrhage, respiratory distress syndrome (RDS), and perinatal death.[98] Professional bodies, such as the American College of Obstetrics and Gynaecology and the Royal Australia and New Zealand College of Obstetrics and Gynaecology, currently recommend that pregnant women between 24 and 34 weeks of gestation who are at risk of delivering within seven days be given a single course of corticosteroids (either Betamethasone or Dexamethasone).[102]

Corticosteroids accelerate fetal lung growth by several mechanisms, including the maturation of type II pneumocytes and the production of surfactant.[103] Lung lipids share some similarities with the skin. The outer layer of the epidermis is the stratum corneum, and lipid bilayers fill the intercellular spaces between the corneocyte cell plates. The cell layer immediately below the stratum corneum, known as the stratum granulosum, produces this lipid in lamellar bodies in the cytoplasm. The contents of the lamellar bodies are extruded into the intercellular spaces, a process that is similar to the production of pulmonary surfactant.[104] Thus, antenatal administration of glucocorticoids may affect the structure and function of the developing epidermal barrier in fetuses and neonates. We performed a systematic review to characterize such effects.

Methods

We conducted electronic searches in the MEDLINE, Scopus, and ISI Web of Knowledge databases, using the following medical subject headings and terms: *Antenatal Glucocorticoids*, *Antenatal Betamethasone*, *Antenatal Dexamethasone*, and *skin*. Human and animal studies published in the English language through July 1, 2016 were included, with no further restriction on publication date. We then manually searched the reference lists of all eligible articles. Two authors independently assessed the eligibility of each identified study for inclusion according to pre-established criteria and using a specifically designed form. Duplicate publications were excluded. Differences in opinion were resolved through discussion to achieve consensus.

Results

Of a total 11 identified studies, six were animal studies[105-110] and five were human studies.[87,104,111-113]

Animal studies

Table 2.5 summarizes all the animal studies that have been published to date. Five out of six animal studies used a rodent model to investigate the effects of antenatally administered glucocorticoids. The remaining study used an ovine model. In one study, a combination of Dexamethasone and Betamethasone was administered, while Dexamethasone was administered alone in two studies. In the other three studies, Betamethasone alone was administered.

Aszterbaum et al. investigated the relationship between maternal glucocorticoids and maturation of the stratum corneum (SC) in fetal rats.[105] Female rats were injected with Betamethasone (study) or saline (control) on days 16–18, with pups delivered prematurely on day 19. The investigators used transepidermal water loss (TEWL) as a measure of skin maturity, finding that pups that received antenatal Betamethasone had significantly lower TEWL compared to the control group (0.74 ± 0.14 mg/cm^2 per hr vs. 8.16 ± 0.52 mg/cm^2 per hr; $p < 0.001$). Apart from TEWL, the investigators also performed thin-layer chromatography to determine differences in the percentage of lipids in skin biopsy samples and visually assessed the epidermal layers by electron microscopy. Based on these assessments, the results suggest that antenatal Betamethasone also: (a) accelerated maturation of the lamellar body and membrane ultrastructure of the SC; (b) increased total lipid content of the SC twofold; and (c) increased cholesterol and polar ceramide content of the SC three- to sixfold. Based on these findings, the investigators concluded that antenatal glucocorticoids accelerate biochemical, functional, and morphological maturation in fetal rats.

Okah et al. investigated the effects of antenatal steroids on skin hydrophobicity in fetal rats, measuring the peak surface hydration of the skin at birth and the subsequent evaporative drying desorption of amniotic fluid under controlled environmental conditions.[106] Apart from this, the investigators also recorded the capacitance of the skin, which was a proxy indicator of TEWL. Thirty dams were randomly assigned to treatment (intramuscular Betamethasone) and control (normal intramuscular saline) groups on day 17, and pups were delivered prematurely on days 18, 19, and 20 and then assessed. The investigators reported that initial skin-surface hydration at birth was significantly lower in steroid-treated pups than in control pups at gestational ages 19 and 20 days. Baseline skin hydration was significantly lower in steroid-treated pups than in control pups at gestational ages 19 and 20 days. Next, the pups were euthanized, and skin biopsies were assessed by scanning and transmission electron microscopy, which showed the morphologic maturation of the peridermal layer of dorsal skin in the treatment group. The investigators concluded that antenatal exposure of fetal rats to steroids accelerated the maturation of fetal skin function and morphology.

In another study, Agren et al. investigated the effects of antenatal glucocorticoids and postnatal fluid restriction on TEWL and the cellular membrane protein aquaglyceroporin-3 (AQP3), which is involved in water transport.[109] The investigators demonstrated that pups exposed to antenatal Betamethasone had lower TEWL in the neonatal period. Such pups also had increased expression of AQP3 messenger ribonucleic acid (mRNA) in the epidermis. This study suggests that glucocorticosteroids mature fetal skin as demonstrated by lower TEWL, lower surface hydration, lower skin water content, and increased epidermal AQP3 expression in pups exposed to glucocorticosteroids compared to unexposed controls.

The role played by antenatal glucocorticoids and fetal skin in intrauterine hypoxia was investigated by Kaptanoglu et al.[108] In this study, an ischemia/reperfusion (I/R) injury was induced in Sprague-Dawley dams by clamping the outer-ovarian arteries for 30 minutes. The animals were initially randomized into control and study groups (intraperitoneal Dexamethasone) 20 minutes before this induction of hypoxia, and fetal skin samples were harvested for analysis once the clamps were removed. The effects of Dexamethasone on fetal rat skin after intrauterine I/R injury were determined by measuring the concentrations of Thiobarbituric acid reactive substances (TBARS), as an indicator of lipid peroxidation, and nitric oxide (NO) metabolites and myeloperoxidase (MPO), as indicators of leucocyte infiltration into the skin. The fetal skin was also examined histologically after intrauterine I/R injury to assess subcellular changes and the ultra-structural effects resulting from treatment. The investigators found that TBARS, MPO, and NO were significantly lower in pups receiving antenatal Dexamethasone, concluding that Dexamethasone has protective properties on the fetal skin for pups with in-utero I/R injury.

Young et al. investigated the effects of antenatal Betamethasone on the fetal nervous system, noting as an incidental finding that pups born to dams exposed to antenatal Betamethasone and Dexamethasone have dry, flaking skin over their entire bodies, particularly on the back of the neck.[107] However, the investigators did not attempt to determine whether these changes were beneficial or not for the pups.

Stonestreet et al. investigated the effect of antenatal glucocorticoids on the water content of various organs, including the skin, in an ovine model.[110] Antenatal dexamethasone was administered to ewes at three different gestational ages. The fetuses were then surgically delivered and euthanized, and their organs were harvested. The investigators found that skin in the study group, like other non-neural organs, had lower water content, postulating that maternal administration of antenatal glucocorticoids affects water and electrolyte homeostasis in fetal skin.

Table 2.5

Summary of animal studies.

Author (Year)	**Subject**	**Sample size (n)**	**Type of glucocorticoids**	**Findings**
Aszterbaum et al. (1993)[105]	Sprague-Dawley rats	Control = 27 Study = 31	Betamethasone	Pups in the study group had: 1. Reduced transepidermal water loss 2. Accelerated maturation of lamellar body and SC 3. Doubling of SC lipid content 4. Three- to six-fold increase of skin cholesterol and polar ceramide content
Okah et al. (1995)[106]	Sprague-Dawley rats	Control = 15 Study = 15 (Three subgroups)	Betamethasone	In this study group: 1. Skin surface hydration in pups at gestational ages 19- and 20-days' birth was significantly lower in study group 2. Scanning and transmission electron microscopy showed morphologic maturation of the periderm
Agren et al. (2010)[109]	Sprague-Dawley rats	Control = 6 Study = 4	Betamethasone	1. Antenatally administered functional changes in skin of premature pups 2. Increased epidermal AQP3 expression
Kaptanoglu et al. (2013)[108]	Sprague-Dawley rats	Control = 6 Control (with sham operation) = 6	Dexamethasone	1. Study group with antenatal glucocorticoids had less severe skin oedema and skin mitochondrial damage

Author (Year)	Subject	Sample size (n)	Type of glucocorticoids	Findings
		Study group (laparotomy and clamping of bilateral utero-ovarian arteries) = 6 Study group (with dexamethasone)		
Young et al. (2006)[107]	Sprague-Dawley rats (pups)	Study = 15 (betamethasone) Study = 13 (dexamethasone) Control = 12	Betamethasone and dexamethasone	1. The primary objective of this study was to investigate increased seizures threshold and this was demonstrated in both study groups 2. Secondary outcome that involved assessment of physical appearance, which demonstrated altered skin appearance (increased skin flakiness). The significance of this finding is unknown
Stonestreet et al. (2003)[110]	Ovine fetus	60% Gestation (study n = 15; control n = 14) 80% Gestation (study n = 9; control n = 8), 90% Gestation (study n = 12; control n = 10)	Dexamethasone	The objectives are to compare the differences in various neural and non-neural tissues (skin, liver, muscle and kidney) 1. Water content was reduced in non-neural tissues from all the different gestational ages. For neural tissues, differences were observed in the least mature group (60%) 2. Reduction in water content in the skin of fetuses in the study group could be due to increased maturity of fetal skin as a result of exposure to antenatal glucocorticoids

KEY: SC- Stratum corneum, AQP3- Water and glycerol transporting integral membrane protein aquaglyceroporin.

Human studies

Table 2.6 summarizes all the human studies that have been published to date.

Omar et al. investigated the effects of antenatal glucocorticoids on fluid and electrolyte balance in extremely low birth weight infants (ELBW; weight < 1000 g).[111] Infants born to mothers who received one full course of antenatal Dexamethasone (12 mg x 4 doses) or Betamethasone (12 mg x 2 doses) within the 7 days prior to birth were recruited into the study group. Birth-weight- and gestational-age-matched infants born to women who had not received antenatal glucocorticoids were recruited as controls. The investigators compared insensible water loss (IWL) between the two cohorts, calculated as IWL = total fluid intake – (fluid output + weight loss). Infants from both cohorts were administered intravenous fluids (5% dextrose) and regularly monitored for weight and electrolytes over the first seven days of life. The investigators, finding that infants in the treatment group experienced lower IWL, lower incidence of hypernatremia, and earlier diuresis, concluded that antenatal glucocorticoid administration enhances epithelial cell maturation. The numbers of patients recruited in both cohorts were small (seven in each), and no attempts were made to investigate any differences between Dexamethasone and Betamethasone administration.

Dollberg et al. investigated the effects of antenatal glucocorticoid administration on the thermal capabilities of skin in ELBW infants.[87] The investigators measured time-taken skin temperature to reach equilibrium with environmental temperatures. The study reviewed medical records and analyzed data extracted from a computerized thermoregulation system used in a particular hospital's unit. Infants exposed to antenatal glucocorticoids were classified as study subjects, while a group of gestational-age- and weight-matched infants not exposed to antenatal glucocorticoids were recruited as controls. The investigators found that birth weight and gestational age both affect infants' thermal capabilities, while antenatal steroid administration was not associated with maturation of thermal capabilities. In another study, Jain et al. compared barrier function in preterm infants exposed to antenatal corticosteroids to that of a partly historical control group.[104] In this prospective, observational study, 87 infants were recruited into the study group and further divided into subgroups based on gestational age (above and below 30 weeks' gestation). All infants in the study group had received at least one dose of antenatal corticosteroids, with approximately half (43/87, 49.4%) receiving two doses. Because the use of antenatal corticoid steroids is very wide, the investigators recruited some of the infants for their control group from much earlier years (1985/86), an era during which antenatal glucocorticoids were not widely administered. Infants in the control group were birth-weight- and gestational-age-matched with the study group. Using a non-invasive device, an Evaporimeter, the investigators measured TEWL as an indicator of epidermal-barrier function. Measurements were taken within the first 48 hours from birth and corrected for ambient humidity. The investigators detected no differences in TEWL between the study and control groups, concluding that antenatal glucocorticoids have no influence on epidermal maturation.

However, Dimitriou et al. reported the opposite findings.[112] The investigators measured IWL in a cohort of 48 infants exposed to antenatal steroids, demonstrating that these infants had lower IWL (and hence greater skin maturation) compared to birth-weight- and gestational-age-matched infants. In a more recent study by August et al.[113], instead of using TEWL, investigated the effects of antenatal steroids by comparing the prevalence of pressure injuries in neonates with and without antenatal steroid exposure. Using multivariate regression, the investigators found that female neonates exposed to antenatal steroids tend to have fewer neonatal pressure injuries.

Table 2.6
Summary of human studies.

Author (year)	Sample size (n) and gestation	Type of glucocorticoids	Findings and conclusions
Omar et al. (1999)[111]	n = 16 (study) n =1 4 (control) 24–28 Weeks' gestation in both groups	Dexamethasone or betamethasone (7 days before delivery with the last dose given at least 24 h)	**1.** The study group had a significantly lower mean peak serum sodium **2.** Of the control group, 36% developed Na > 150 mmol/L **3**. In conclusion, antenatal glucocorticoid treatment enhances epithelial cell maturation, thus improving the skin barrier function
Dollberg et al. (2000)[87]	n = 21 (study 27.0 ± 2.8 weeks) n = 41 (control group: 26.1 ± 2.1 weeks)	Betamethasone (Two doses prior to birth)	**1**. No significant difference in time to reach skin-air temperature equilibration (proxy indicator of skin maturation) **2.** Skin thermal capability is dependent only on gestational age and birth weight
Jain et al. (2000)[104]	n = 87 (study) n = 50 (control) Gestation < 34 weeks in both groups	Dexamethasone (One or two doses prior to birth)	1. No relationship between corrected transepidermal water loss (a proxy indicator of skin maturation) and antenatal glucocorticoids 2. Antenatal glucocorticoids have no effect on epidermal maturation in preterm infants
Dimitriou et al. (2005)[112]	n = 48 (study) n = 48 (control) Gestation 23–33 weeks in both groups	Dexamethasone (One or two doses/courses) Within 7 days prior to birth)	1. Infants exposed to antenatal glucocorticoids have a lower insensible water loss (an indicator of skin maturation) 2. Antenatal glucocorticoids enhances skin maturation in preterm neonates
August and Kandasamy (2016)[113]	n = 53 (study) n = 88 (control) Gestation 30.3 weeks (IQR 26.3–40.0 weeks)	Dexamethasone (One or two doses prior to birth)	1. Female preterm neonates exposed to antenatal glucocorticoids had a lesser chance of developing pressure injury in the neonatal period (OR = 0.317, 95% [CI 0.105–0.956], P = 0.041) 2. Antenatal glucocorticoids appear to be beneficial in reducing pressure injury prevalence in female neonates

Discussion

Most of the animal studies discussed in this review demonstrated both functional and structural changes in fetuses exposed to antenatal glucocorticoids, while the effect in human fetuses appears to be equivocal. A larger prospective study could help shed more light on the effects of antenatal glucocorticoid steroids; however, as their administration has become routine clinical practice, it would be unethical to deprive women in premature labor of corticosteroids.

The human and animal studies discussed here involved the administration of Dexamethasone, Betamethasone, or a combination of both, and it remains unknown whether different corticosteroids have any different effects. Corticosteroids administered antenatally are metabolized in the placenta by the enzyme 11-b-hydroxylase steroid dehydrogenase-2[114], and approximately 33% and 50% of Betamethasone and Dexamethasone, respectively, will enter fetal circulation.[115] Corticosteroids accelerate fetal lung growth by several mechanisms, including the maturation of type II pneumocytes and the production of surfactant.[103] A systematic review by Khan et al. also showed that antenatally administered corticosteroids reduce birth weight, head circumference, and birth length,[115] apart from their effects on the developing brain,[116] kidney,[117] and cardiovascular system.[118]

Many of the studies reviewed here used TEWL and IWL to determine skin maturity. Skin development begins with a single-cell layer of ectoderm in an embryo, which then develops into two layers of cells (a basal cell layer and a periderm layer). This further develops into three layers, with an intermediate layer added by the third month of embryogenesis. Thin and immature epidermis and dermis are formed by the second trimester. By the end of the second trimester, the periderm sloughs, becoming part of the vernix caseosa.[119] It remains unknown whether corticosteroids have different effects if administered at different gestational ages.

Conclusion

Antenatally administered glucocorticoids accelerated skin maturation in animal models. However, the effect in human fetuses appears to be ambiguous, and none of the studies compared the effects of different types of glucocorticoids. More human studies are needed to fully understand the effects of antenatal steroids. However, since the antenatal use of glucocorticoids in preterm pregnancies has become part of standard clinical practice, it would be ethically problematic to carry out a large randomized controlled trial. We may have to rely on animal models to improve our understanding on the effects of antenatal glucocorticoid exposure on the fetal and neonatal skin maturation.

2.7 Risks for skin injury based on risk assessment tools

Having explored skin development, maturation, and implications for injury, an examination/exploration of neonatal skin injury risk assessment tools for risk factors was required. I envisaged these risk assessment tools would include valid risks which could inform future research, or existing risk factors that might need validation with epidemiologic neonatal studies. Generally, risk assessment tools rank evidence-based risk factors, traits or symptoms associated with skin injuries, theoretically identifying a group of individuals predisposed to injuries despite unknown exact causal factors.[4,88] Skin injury risk assessment tools have been utilised with adult populations as early as the 1960s (Norton)[120] and paediatric populations since the mid-1980's (Braden & Bergstrom)[120]. Therefore, I sought to identify tools recommended for the neonatal population, including validation, source of tool development, and targeting specific neonatal risk factors.

In 2015 at the start of this PhD a search of the peer reviewed literature identified seven neonatal skin risk assessment tools. An additional tool was identified before completion of this research,[88] and subsequently has been included. Only four of the tools were validated,[88,121-123] so to best compare evidence strength the validated tools are presented in Table 2.7 and the unvalidated tools[24,124-126] in Table 2.8. On review it was apparent that none of the tools identified were created applying neonatal epidemiological or injury data and that some risk factors were inappropriate for neonates, such as the ability to ambulate.[121] Four of the eight tools were based on the Braden Risk Assessment for Pressure Injury,[24,121,122,125] developed from adult risk factors, and then subsequently modified for paediatrics including neonates, or neonates alone.[24,121,122,125] The remaining four tools were derived from the peer reviewed literature and/or clinical expertise.[88,123,124,126]

Of the eight tools, only two clearly identified the target population including preterm and term neonates[88,122] and two reported development for neonatal populations but the birth gestation of participants was unclear.[124,126] One tool was developed for a mixed neonatal and infant population,[24] and three were developed for paediatric populations which may have included neonates or infants.[121,123,125] Of interest, six tools were developed before 2006,[24,121-125] likely impacting on the applicability of tools for today's neonates as sick and preterm neonatal populations were proportionally older and heavier, than the current demographics of neonates within first world neonatal settings.[127,128] Continued innovations and improvements to obstetric and neonatal care, are related to a larger proportion of 22-28 week neonates surviving,[129] and these preterm neonates have risks factors for injury which appear under-represented in tools. Most of the validated tools appear antiquated and most likely under representative of current morbidities of hospitalised neonatal populations.

Based on a number of the tools' developed from adults risk tools, it was not surprising that all eight tools include risk factors common to adults: sensory perception, mobility or activity, tissue perfusion and oxygenation.[24,88,121-126] Other risk factors less consistently included in neonatal tools were: nutrition[24,88,121-125], moisture [24,88,121,122,124], perfusion (peripheral perfusion, hypotension, tissue oxygenation),[24,121,123,125,126] and the forces of friction/shear. [24,121,125] Additionally, four of the tools also proposed gestational age as a risk factor, [24,88,122,126] and one specified corrected gestational age.[88] Additional risk factors included in two or less tools were temperature, pyrexia, hypothermia;[123,124] skin integrity (previous history of break to integrity);[123,124] equipment, respiratory support;[88,123] anemia;[123] surgery; [123] blood collection;[88] visual exam initiated[124] and level of care.[124]

Based on this review, several limitations with current risk assessment tools were identified including development from older population data, lack of validation and inclusion of risks reflective of non-neonatal specific considerations. Specifically, mental state[122] and ability to ambulate[121] (such as reposition or offload an area) are both difficult to measure in the neonatal population therefore the level of risk of injury is theoretical. While each of the respective publications accompanying the risk assessment tool reported risks for injury included fetal and neonatal skin development only three tools contained this as a risk factor. The adaptation from adult epidemiologic data may explain the common use of risk factors that reflect adult or paediatric risks, rather than neonatal risks. The most recent assessment tool might prove more effective, but includes few unique risk factors and was validated at a single site within Australia, currently limiting the generalisability of its application.[88] Many of the risk assessment tools were focus only on pressure injuries or unclear about which types of injury they prevented; thus future work should be explicit about the classifications of injuries assessed and prevented. Additionally, forms of mechanical skin injury, such as skin tears, mucosal injuries or epidermal stripping seemed to be forgotten within current risk assessment tools; so further work is needed to identify if existing tools can assist in preventing any additional forms of mechanical force injury. Lastly, none of the risk assessment tools differentiate between modifiable or unmodifiable risks, which is a pillar in consideration for prevention of injury.

While paucity of validated neonatal risk assessment tools may have necessitated modification and adaptation of adult and paediatric risk tools, this does not necessarily translate to evidenced based risks for neonatal skin injury. Thus, with the increasing rate of preterm birth and younger viable neonates there is an urgent need for the identification of neonatal skin injury risk factors from contemporary epidemiological data to inform clinicians and practice.

Table 2.7
Validated neonatal skin risk assessment tools.

Tool	**Participants**	**Tool source**	**Risks**		**Reliability and/or Validity**
Neonatal Skin Risk Assessment Scale (NSRAS) (1997)[122]	Neonates (26-40 weeks) n=32	Braden Scale for Predicting Pressure Sore Risk© (1987)	Physical condition (GA) Mental state Mobility	Activity Nutrition Moisture	Sensitivity – 0.83 Specificity- 0.81 PPV – 0.50 r- 0.89
Braden Q Pediatric Skin Risk Assessment Scale (2003)[121]	Paediatric (21 days-8 years) (N=322, n=90 <1 years)	Braden Scale for Predicting Pressure Sore Risk© (1987)	Mobility Activity (ability to ambulate) Sensory perception	Moisture Friction/shear (ability to move) Nutrition Tissue perfusion and oxygenation	Sensitivity- 0.83 Specificity- 0.58 PPV – 0.15

Tool	Participants	Tool source	Risks		Reliability and/or Validity
Glamorgan Pediatric Pressure Ulcer Risk Assessment Scale (2005)[123]	Pediatric (1 day-7 years) n= 336	Pediatric and adult injury literature, nursing impressions	Difficulty positioning Anaemia Equipment Reduced mobility Prolonged surgery Persistent pyrexia Poor peripheral perfusion Low serum albumin Weight $<10^{th}$ percentage for age	Inadequate nutrition Incontinence inappropriate for age Hypothermia Poor tissue oxygenation Reduced conscious level Weight $>90^{th}$ percentage for age Self-care ability inappropriate for age Hypotension	Sensitivity – 1.0 Specificity- 0.52 r- 0.63 to 1.0
Skin Risk Assessment and Management Tool (SRAMT) (2019) [88]	Neonates n=63, 32.90 weeks (24.0-41.60), (248 assessments)	Peer reviewed literature and clinician experience	Current gestational age Sensory perception Activity/mobility Moisture Respiratory support	Skin integrity Blood Collection Nutrition	Sensitivity- (90.0 (80.5-95.9), 72.86 (60.9-82.8) Specificity- (88.46 (81.7-93.4), 79.23 (71.2-85.8)

KEY: Key: PPV- positive predictive value, GA- Gestational Age, Table adapted from Brandon et al.[66] and Vance et al.[130]

Table 2.8
non-validated neonatal skin risk assessment tools.

Tool	Participants	Tool source	Risks		Reliability and/or Validity
Neonatal/ Infant Braden Q (2004)[24]	Neonate/ Infant (10 days-17 years) n=107	Braden Scale for Predicting Pressure Sore Risk© (1987)	Mobility/activity Sensory perception: responsiveness Gestational age Tissue perfusion and oxygenation	Nutrition Moisture Friction/shear	Not reported
Northampton neonatal skin assessment tool (2004)[124]	Neonate ages not indicated	Working party	Gestation Weight Age Skin integrity Temperature control	Mobility Nutritional status Visual examination Level of care	Not reported
Starkid Skin Scale (2005)[125]	Paediatric, ages and number of neonates not indicated	Braden Scale for Predicting Pressure Sore Risk© (1987)	Mobility/activity Sensory perception Moisture Friction/shear	Nutrition Tissue perfusion and oxygenation	Not reported
Pressure Ulcer Tigger Tool (2013)[126]	Neonate/Infant (24 weeks-Term) n=15	Literature and trigger questions for adults from Institute for Clinical Systems Improvement	Movement extremities or body appropriate for age Response to discomfort appropriate for age	•Adequate tissue perfusion based on formula (mean arterial pressure =gestational age and/or capillary refill <3 seconds)	Not reported

KEY: Key: GA- Gestational Age; Table Adapted from Brandon et al.[66] and Vance et al.[130]

2.8 Summary

By investigating the skin's structure, function and maturation I identified that neonatal skin was thinner, weaker in structure, immature in function; all of which helped me to appreciate that it would be predisposed to injury from external sources.[60] The examination of knowledge on structure helped to appreciate that histological samples were the gold standard for skin depth measurement; but ethical constraints would make this method unapplicable to clinical practice or future research necessitating further understanding for other methods. Additionally, the presence of an injury could impact on morbidity and mortality, alterations to functions such as TEWL, care time and financial burden related to facility acquired injury.[11,131] With these implications in mind, I also considered that neonatal skin injury might differ, especially considering the structural differences of term and preterm skin. The next chapter presents skin assessment, explores the boundaries of 'neonatal skin injury', establishes known skin injury frequency as well as the context of injury severity.

Chapter 3 Skin Injuries: Assessment, Etiology, Severity, Classification and Frequency

Following on from my investigation into skin structure, function and maturation, I next needed to ascertain how to differentiate between skin integrity and injury. The activity of visual examination for determinant of skin health or alterations to integrity occurs during a 'skin assessment' or 'skin inspection'.[12,16] A skin assessment includes a number of visual elements including inspection, noting skin integrity and if an injury noted, evaluation of injury etiology including severity. As discussed previously, establishing the cause or etiology of an injury is particularly important for mechanical force injuries, as they are considered a *preventable* complication within healthcare institutions.[132] In this chapter the five types of mechanical force and related skin injuries are elaborated upon; pressure, friction, shear, stripping and tear. In addition, as injury severity impacts the actions taken by healthcare facilities, a review of injury severity and classification systems is provided. Likewise, neonatal injury frequency and risk factors are further examined.

3.1 Skin injury assessment

A comprehensive skin assessment includes the visual examination as well as tactile elements such as palpation, pain assessment and patient history.[7,16] Patient history is of particular importance as it informs assessment related to etiology and contributing risk factors.[8,12,16] Assessment requires a careful and detailed examination of the cutaneous layer, as differentiating skin abnormalities can be challenging due to the countless ways the skin can express disease.[18] For example scaly skin is very different for an adult than a newborn, which can express both Ichthyosis (inherited condition of abnormal keratinization) or normal post maturity desquamation.[18] Clinical experience and knowledge of specific condition factors is important to help differentiate findings. If an assessor is unexperienced with the neonatal population, intricacies of assessment could change the perception for injury confirmation.[133] Furthermore, due to the nature of neonatal skin structure, particularly thickness, perception of injury severity could differ.

3.1.1 Contrasting neonatal and adult skin assessment

While neonatal and adult skin experts agree there are particular assessment criteria, the components of assessments differ for these two populations, with differences likely related to the uniqueness of the skins' structure.[16,64] Peer-reviewed literature describes adult skin assessment in detail, however there is less information related to neonatal skin assessment, with many details drawn from generic newborn assessments, dermatologic text books and either narrative or descriptive review articles.[12,15,16,64,120,134] Table 3.1 presents available details and descriptions related to skin assessment for adults and neonates.

Table 3.1
Details and descriptions for adult and neonatal skin assessments.

<table>
<tr><th>Adult skin assessment</th><th>Neonatal skin assessment</th></tr>
<tr><td>Inspect the skin noting
Lesions, including breaks
Vascular alterations
Oedema
Colour
Moisture
Dryness
Hygiene
Hair assessment/nail assessment
Palpation for
Moisture
Temperature
Texture
Lesions</td><td>Inspect the skin noting
Lesions
Colours, borders and configuration (shape and size)
Peeling (desquamation)
Breakdown (only injury description noted in standardised skin assessment tool)[135]</td></tr>
<tr><td>Healthy skin tone/colour dependent on melanin content (range)

Ecchymosis (bruising) can be appropriate dependent on age

Abnormal colours include erythema (redness), cyanosis (blue tinge), pallor (pale) or jaundice (yellowing).</td><td>Healthy skin tone/colour will change in first 24-36 hours with adaptation to extra-utero environment;
Fetal circulation demonstrated as acrocyanosis (blue discoloration of hands and feet)

General skin tone may be plethoric (red), jaundiced (yellow), stained brown or yellow (meconium stained), or pale (white/pale-pink if maternal antepartum haemorrhage or general anaesthetic)

Mottling occurs easily, due to transient temperature changes</td></tr>
</table>

Adult skin assessment	Neonatal skin assessment
	Skin may be covered in white cheese like substance (Vernix Caseosa) Ecchymosis unusual, unless related to delivery injury or trauma; petechial rashes equally unusual Skin should be flat, few growths or elevated areas Fine soft hair (lanugo) might cover the body
Desquamation with normal physiologic process of self-renewal or when extra dry (e.g., sunburn) Consideration for lesions • Skin tags • Moles • Scar tissue	Mild and peripheral desquamation common for post-term neonates, or preterm neonates when at 2-3 weeks of life • Other widespread desquamation is unusual Consideration for benign skin lesions • Erythema toxicum • Milia • Sucking blisters • Sebaceous hyperplasia
Consider the following for any lesion (including injuries): • Colour- including border and surrounding skin • Moisture- presence or absence of moisture, colour and consistency will determine if blood or other fluid • Depth- measurement expected for adults • History, condition contributing factors or conditions o Adult- diabetes or chronic vascular insufficiency o Neonate- conditions such as epidermis bullosa or Staphylococcal scalded skin syndrome	
References [12,15,16,64,120,134]	

3.1.2 Preterm and term skin assessment and appearance

Skin appearance is another unique consideration for preterm and term skin assessments compared to adult skin assessment. In addition, there are distinct differences between the appearance of preterm and term neonate's skin. Specifically, preterm skin is described as gelatinous, shinny, appearing wet, and transparent with veins visible. This appearance will change in colour and texture over the course of postnatal life (Image 3.1 author's image). Comparatively, term skin may be covered by a layer of white vernix caseosa, stained yellow from meconium, and/or cracked and dry when post term (Image 3.2, authors own image).[64]

A.

B.

Image 3.1 A. Preterm skin (hours after delivery) B. Post-term skin.

3.2 Skin injury etiology

Determining the etiology is important as it informs if injury prevention was plausible, dictates clinical management and is an essential consideration when determining injury severity related to mechanical forces.[16,134]

3.2.1 Mechanical forces

By definition, a force is a strength or energy between two objects, compared the term mechanical force or load often used to describe an effect on skin or soft tissues.[136] This force can be related to contact with the skin and an external surface, object, medical device or other parts of the body.[136] These forces can also act perpendicular to the skin which is considered a normal force (pressure), or act parallel to the skin considered a shear force (shear or friction).[136] Dependant on the health of the skin tissue, force strength and duration; contact may result in an alteration or distortion to integrity of the skin or underlying integumentary structures ranging from transient erythema to tissue death.[6] Whilst there is an enormous body of international work on the relationship of individual mechanical forces and adult pressure injury formation; similar work for neonates is extremely limited.[136] Thus, the role of the forces on neonatal skin, especially those related to the skin tear and epidermal stripping is not well understood.

Interestingly, the grouping or categorisation of skin injuries related to mechanical force is not always completed in the same way, and injuries can be classified separately despite their common etiology and similar presentation.[14,120] For example, pressure injuries and friction injuries can be categorised separately,[6,21] based on separate prevention strategies, unique visual presentations and impact to skin and other tissues a cellular level. Comparatively, it understood that for adult injuries related to pressure and shear often occur together or from the combination of forces.[6,21] This is supported by the guiding principle of adult pressure injury prevention offloading, in which the sustained pressure/shear from the at risk tissue can minimised and prevent injury. Another example of separate categorisation, is that medical device related injuries can be considered a separate outcome, rather than a similar outcome with different contributing factors (e.g. force alone compared to device and force against the skin).[137] However, for each of these injuries one contributing factor is a single or a combination of mechanical forces against the skin which are involved in the formation of a single injury.[6] My clinical experience led me to consider that the traditional approach of separate categorisation of skin injury complications, actually lead to siloed evaluations where only certain injury presentations were considered a priority.

Comparatively, other pragmatic injury frameworks at the start of this PhD, argued that despite the individual etiologies, any mechanical load or distortion of skin tissue contributes to the frequency of skin injuries.[14] This concept is reflected more commonly in the literature post 2018,[40,136] but was uncommon at the time of this PhD in 2015. Therefore, I used the broader conceptualisation of injury etiology to hypothesise that any skin injury, to any location (boney prominence or not), with or without a device, from a single or multiple force; was a complication to the larger organ system (the skin) and therefore warranted comprehensive investigation rather than the traditional approach. Thus in this PhD I set to explore mechanical force injuries inclusive of five types of force; pressure, friction, shear, stripping and tear. Further definitions and distinctions between these forces and injury presentations are presented in Table 3.2 and graphically illustrated in Image 3.1.

Table 3.2
Mechanical force term, force or action, skin injury formation and description, skin injury outcome.

Force term	Force or action	Injury formation (F) or description (D)	Injury outcome
Pressure	Pressure Shear	F- Force against the skin or tissue in which the direction of the force is most often perpendicular, sustained compression on or against the tissue.[21,136,138] D- Localised damage (change to skin integrity) presenting as a number of stages from an area of focused erythema, superficial/open skin, or focused necrosis.[136]	Pressure injury
Friction	Friction Shear	F-Movement of two surfaces across or against each other, related to deformations or stresses on surface layers, within layers or subcutaneously; creating resistance between skin and surface.[5,21] D- Area of inflammation, abrasion, or a friction blister.[136]	Superficial injury or friction blister
Shear	Shear	F-A parallel load that causes body to slide against resistance between skin and a surface. The outer layers of skin remain still, while deeper layers move with the skeleton; generating distortion of other structures (blood vessels and lymphatic system) between dermis and fascia.[5,21,136] D- see Pressure injury, friction blisters, stripping or tear	Pressure Injury
Stripping	Peel Shear Shearing	F- Separation of the skin (or removal of entire layers/portions of the epidermis) related to the peel or shear force with the removal of medical adhesives. This force maybe distributed across surface of skin as adhesive is lifted. Damage is more likely when the strength of the adhesive is stronger than the epidermal/dermal bond of the skin to itself (within 24 hours of application).[23,40,136,139-145] D-Ranges from non-visible trauma, to superficial or shallow lesions, often irregular in shape, skin appears shinny, can also have open lesions may be accompanied by erythema and blisters [40,143]	Epidermal stripping, MARSI or skin tear
Tear	Blunt Tension Shear/friction	F-Blunt force resulting in separation of skin layers, which can be partial thickness (separation of the epidermis from the dermis) or full thickness (separation of both epidermis and dermis from underlying structures), otherwise described as multidirectional tension/tensile force. They may also be related to handling, equipment or medical adhesives (MARSI), and most frequently seen in [14,40,136,146]	Skin Tear or MARSI

	D-Traumatic area presenting as a number of appearances from no skin loss but linear/flap tear where skin can be repositioned to cover injury bed, to total loss of the skin flap with an entirely exposed bed, bruising and bleeding may be present[40]

MARSI- Medical Adhesive Related Skin Injury

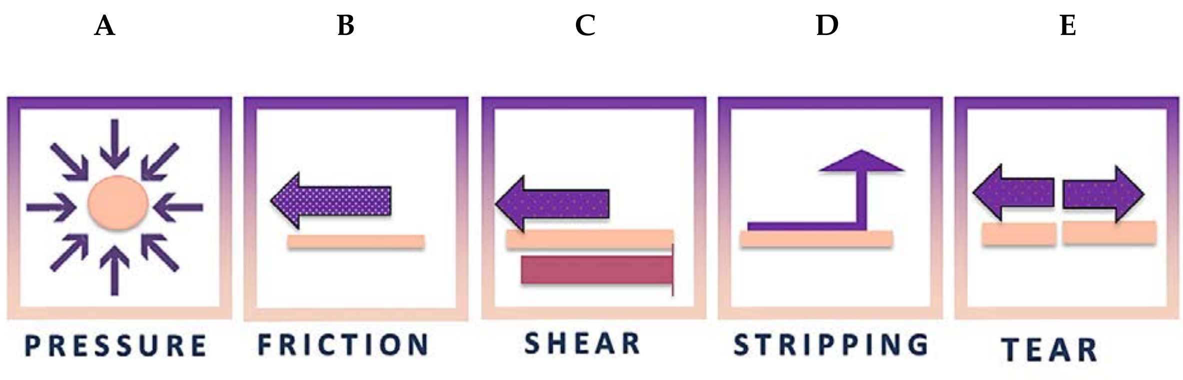

Figure 3.1 Mechanical force type and direction(s) of the applied force.
The peach colour represents the skin and the purple arrow(s) depict the direction of the force (A-pressure, B- friction, C- shear, D- stripping, E-tear).

3.3 Injury severity and classification assessments

Changes to skin integrity may or may not result in tissue loss, therefore determination of injury severity including depth is considered an essential component of assessment.[83] Currently, skin injury severity is determined using visual inspection and use of a classification system.[147] For example after initial identification, a pressure injury is categorised with a uniform classification system which facilitates evaluation of injury progression or improvement at the point of reassessment and informs injury management.[148]

Classification systems comprise of descriptions of pathophysiologic changes, and use of a system can assist in ranking complications to facilitate comparison of outcomes, quality and cost of care.[149] The majority of classification systems have stepped or ordinally ranked groupings, often called stages or grades, but may also contain other types of injury not part of the ranked system such as mucosal injury or suspected deep tissue injury.[120] In another example of the variety of categories in established systems, both a Stage 1 and suspected deep tissue injury will present with intact skin, but suspected deep tissue injures involve more tissue than Stage 1 or Stage 2.[120] Thus, systems are called classifications systems rather than staging systems.[120] The most common classification system for mechanical force injuries is the National Pressure Ulcer Advisory Panel (NPUAP) injury classification system, called the National Pressure Injury Advisory Panel (NPIAP) injury classification system since 2017.[120] Prior to 2017, the NPIAP injury staging system was endorsed for all populations by the European Pressure Ulcer Advisory Panel and the Pan Pacific Pressure Injury Alliance.[5,95] The NPIAP system includes six classifications with four ranked stages, in which severity is determined related to depth and severity of tissue damage rather than surface area. Three stages apply to intact skin (Stage 1, Stage 2, and deep tissue injury) and the remaining three to broken skin or the level of absent tissue (Stage 3, Stage 4, and Unstageable). The NPIAP system was developed and validated for injuries related to pressure, or shear and friction, and was not intended to define injuries related to stripping or tear. Importantly, there was no evidence on the feasibility or psychometric testing of the applicability this system for the neonatal population and associated injuries.

3.3.1 Complexities and inconsistencies comparing neonatal and adult severity

In reviewing the NPIAP classification system, I identified that injury depth was defined differently between the official adult recommended systems (e.g.NPIAP system) and classifications or descriptions reported in neonatal studies. For example, within the NPIAP system, a Stage 2 pressure injury is defined as a "partial thickness loss of dermis presenting as a shallow, open wound with a red-pink wound bed; shiny or dry, shallow ulcer without slough or bruising".[5] Whereas other publications report a Stage 2 injury to the nasal septum (external nasal trauma caused by pressure) in neonates as a "superficial ulcer or erosion, with partial thickness skin loss".[28(p488)] Image 3.2 demonstrates differences between anatomy contrasting a diagram of a Stage 2 injury (image A) and a Stage 2 injury for an adult and a neonate (image B and C respectively). While both injuries have moist injury beds, with shallow or superficial loss there are notable differences in size, marked outer margins and actual depth of these injuries. Interestingly, some tissue viability experts would suggest that the NPIAP system is not designed for nasal injuries at all despite many occurring external to the mucosa. Yet the 2012 the Pan Pacific Clinical Practice Guideline for the Prevention and Management of Pressure Injury only stated exclusion of mucous membranes and included how to stage area of cartridge such as the nose.[5(pg60)] Thus, it became apparent that a review of severity systems for neonatal skin injuries was warranted.

A B C

Image 3.2 Graphical Images of-Stage 2 injury (A), adult heel injury (B), and neonatal nasal septum injury (C). Image sources: A,[95] B,[5] and C (author's image).

3.3.2 Neonatal injury classification and severity systems

An investigation of the peer-reviewed literature on neonatal classification or severity systems was needed to examine possible variances and inconsistences within the research. For this review, I considered a classification system as a group of stages or types of injuries with similar injury etiologies but not within an ordinal rank. Comparably, a severity scale was considered an ordinal stage or rank of injury with clear progression whereas a descriptive type was a grouping of injuries with no recognised relationship between grades, stages, or groups. Of note as this was a broad exploratory review and no exclusions were made, therefore details of anatomical locations reported were provided if available.

A total of 20 studies were identified which investigated neonatal skin injuries using a classification or severity system. An adult pressure injury system was used by five of the studies,[24,29,39,150,151] two studies utilised a modified system,[28,30] and the remaining utilised systems uniquely for the neonatal population.[25,36,86,147,152-160]. Most systems consisted of both categorical and ranked outcomes, including the six classifications from the NPIAP system [24,28-30,39,150,152,161] or sub-groups with the number of groups ranging between 2-6.[25,36,86,147,150,153-160] In ten studies, rational or order of sub-grouping or stages were unclear therefore considered descriptive types.[25,36,86,152-158] Specific findings from studies identified are summarised in Table 3.3. Data within the table is reported as per the publication such that version numbers of tools or systems were provided when available, and as most studies were published prior to 2017, the NPIAP Staging System was often referred to as NPUAP. Additionally, any observations related to topic context are provided in italic text for the readers ease (e.g. modification of a staging system or injury type similar to epidermal stripping but called a different outcome adhesive injury).

When reviewing the scale source, a total of 13 studies used a system previously published,[24,28-30,39,150,152,155,158-161] while seven studies used unique unvalidated systems or source of the categorisation was not avalible.[36,86,147,153,154,156,157] The traditional NPIAP system was used in eight studies,[24,28-30,39,150,152,161] while two studies modified NPIAP for neonatal specific considerations,[28,30] and three studies utilised an ordinal scale but not the NPIAP.[147,159,160] Modifications to severity scales included changes to the number of stages,[28] separation of injuries into those related to a device and those related to pressure over a bony prominence.[39] Five studies additionally provided further classifications for pressure as well as stripping or tear injuries,[24,30,147,150,153] with three investigating only stripping.[36,86,158] The utilisation of unique or modified scales did not seem to be related to geographical region, however, it was noted that classifications based on the NPIAP system were more common in studies within the last 10 years when compared to older studies. Actual injury depth or tissue severity was not measured in any study.

Table 3.3

Characteristics of classification systems, severity scale or descriptive type in studies investigating neonatal skin injuries.

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
Broom et al. (2017)[153] Australia	Prospective longitudinal study with intervention	**Injury investigated**	Skin injury
		Injury defined	No
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Not reported
		Characteristics	SRAMT (skin risk assessment and management tool) Bruises Excoriation Pressure Abrasions Extravasation Epidermal stripping
Nist et al. (2016)[150] USAa	Retrospective, descriptive	**Injury investigated**	Pressure injury, mucosal injury and skin tear (*adhesive related*)
		Injury defined	Yes
		Classification system, severity scale or descriptive type	Classification system
		Injury location	14 anatomical locations including nose
		Characteristics	National Pressure Ulcer Advisory Panel (NPUAP) Staging System 2007, *no stages or severity* for mucosal injuries or skin tear
Chen et al. (2016)[154] Taiwan	Prospective comparison, Trauma pre and post intervention	**Injury investigated**	Nasal trauma
		Injury defined	No
		Classification system, severity scale or descriptive type	Descriptive type

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
		Injury location	Nasal area (*specifics not reported*)
		Characteristics	Nasal trauma • Hyperaemia • Bleeding • Ulceration
Milligan and Goldstein (2016)[152] USA	Prospective comparison Injuries pre/post intervention	**Injury investigated**	Nasal trauma
		Injury defined	Yes
		Classification system, severity scale or descriptive type	Severity Scale
		Injury location	Nasal area (*specifics not reported*)
		Characteristics	Modified Nasal Trauma Scale from Fischer et al. (2010) [28] • Stage 0 • Stage I • Stage II • Stage III
Newnam et al. (2015)[155] USA	Randomized control trial Nasal prongs, mask or rotation	**Injury investigated**	Skin breakdown
		Injury defined:	No
		Classification system, severity scale or descriptive type	Descriptive type
		Injury location	Nasal area (*specifics not reported*)
		Characteristics	Neonatal Skin Condition Scale from Lund et al. (2001) [135] • Dryness • Erythema • Breakdown
Collins et al. (2014)[160]	Randomized control trial	**Injury investigated**	Nasal Trauma
		Injury defined	No

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
Australia	high flow, CPAP ± dressing	**Classification system, severity scale or descriptive type**	Classification System
		Injury location	Nasal area (*specifics not reported*)
		Characteristics	Modified from Kaufman et al. (2007) [162] 0 = normal 1 = pink/red 2 = bleeding/ulcer/scab 3 = skin tear
Visscher et al. (2014)[39] USA	Prospective/ descriptive	**Injury investigated**	Pressure ulcer
		Injury defined	Yes
		Classification system, severity scale or descriptive type	Classification system
		Injury location	14 anatomical locations including nose and nares
		Characteristics	National Pressure Ulcer Advisory Panel (NPUAP) Staging (2007)
August et al. (2014)[30] Australia	Retrospective descriptive cohort	**Injury investigated**	Pressure injury and epidermal stripping
		Injury defined	Yes
		Classification system, severity scale or descriptive type	Classification system
		Injury location	Five anatomical regions reported
		Characteristics	*Modified* NPUAP 2009 classification system, with, skin stripping as separate category
Migoto, de Souza,and Rossetto (2013)[147] Brazil	Prospective/ descriptive observational	**Injury investigated**	11 lesions including pressure ulcer, nasal lesions, adhesive label lesions
		Injury defined	Yes

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
		Classification system, severity scale or descriptive type	Severity scale (nasal) and Descriptive type (adhesive)
		Injury location	Not reported
		Characteristics	*1*-Nasal lesions • Mild with hyperaemia • Moderate with bleeding • Severe with necrosis 2-Adhesive label • Abrasion • Erythema • Ulceration
Visscher et al. (2013)[151] USA	Prospective	**Injury investigated**	Pressure ulcer
		Injury defined	No
		Classification system, severity scale or descriptive type:	Classification system
		Injury location	Not reported
		Characteristics	National Pressure Ulcer Advisory Panel Staging (2007)
Fischer et al. (2010)[28] Switzerland	Observational	**Injury investigated**	Nasal trauma
		Injury defined	Yes, with images
		Classification system, severity scale or descriptive type:	Severity Scale
		Injury location	*Specific locations not reported, but authors noted that isolated internal trauma may have been missed*
		Characteristics	*Modified* US National Pressure Ulcer Advisory Panel (NPUAP) Staging (2007), *3 Stages (Stage 4 absent)*

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
Fujii et al. (2010)[29] Japan	Prospective/ descriptive cohort	**Injury investigated**	Pressure ulcer
		Injury defined	No
		Classification system, severity scale or descriptive type:	Classification system
		Injury location	Six anatomical regions reported
		Characteristics	1. National Pressure Ulcer Advisory Panel Staging (1989) 2. Dubowitz Neonatal Maturation Assessment Scale (1970) *(0 most immature- 4 normal)*
Günlemez et al. (2010)[156] Turkey	Randomised control trial CPAP with silicone gel sheeting and without	**Injury investigated**	Nasal Injuries
		Injury defined	No
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Nasal area (*specifics not reported*)
		Characteristics	• Bleeding • Crusting • Excoriation • Columella necrosis
Jatana et al. (2010)[157] USA	Cross-sectional incidence complications	**Injury investigated**	External nasal trauma
		Injury defined:	No
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Nasal cavity, external and internal (*no frequency*)
		Characteristics	• Normal • Columnar necrosis
Nascimento et al. (2009)[159]	Descriptive cross-sectional	**Injury investigated**	Nasal injury
		Injury defined	Yes

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
Brazil		**Classification system, severity scale or descriptive type:**	Severity scale
		Injury location	Nasal area (*specifics not reported*)
		Characteristics	From Buettiker et al[163] • Mild-reddening around the nasal ostium • Moderate-bleeding either at the septum or nasal ostium • Severe-necrosis either on the septum or nasal ostium
Yong, Chen, and Boo (2005)[25] Malaysia	Randomised control trial (Nasal prongs or mask)	**Injury investigated**	Nasal trauma
		Injury defined	No
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Nasal area, internal and external (*frequency not reported*)
		Characteristics	Presence of trauma • Redness • Bleeding • Crusting • Excoriation • Narrowing of nasal passage
McLane et al. (2004)[24] USA	Cross sectional, prevalence survey	**Injury investigated**	Pressure ulcer and other skin breakdown (skin tear, extravasation abrasion, excoriation, friction, blister)
		Injury defined	Yes

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
		Classification system, severity scale or descriptive type:	Classification system
		Injury location	18 anatomical locations including nasal (*specifics not reported*)
		Characteristics	National Pressure Ulcer Advisory Panel Staging (1998) *Skin tear, tape damage*
Lund et al. (1997)[86] USA	Intervention: comparison of four sites (3 adhesives /1 control)	**Injury investigated**	Adhesive removal (*skin stripping)*
		Injury defined	No
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Back
		Characteristics	Skin irritation Skin stripping
Dollison and Beckstrand (1995)[158] USA	Case control: adhesive comparison	**Injury investigated**	Epidermal stripping
		Injury defined	Yes
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Not reported
		Characteristics	Epidermal stripping categories by Lund et al (1986). [36]
Lund et al. (1986)[36] USA	Intervention: Pectin barrier	**Injury investigated**	Epidermal stripping
		Injury defined:	Yes
		Classification system, severity scale or descriptive type:	Descriptive type
		Injury location	Not reported
		Characteristics	• I- intact, moist • D- dry

Author, Year, Country	Study design	Injury classification systems, severity scales and descriptive types	
			• R- red, intact • E- excoriated, areas

Italic text= not reported by the publication, clarification added to provide subject context

Based on data of publication, National Pressure Ulcer Advisory Panel (NPUAP) Staging System may be reported instead of the current name the National Pressure Injury Advisory Panel (NPIAP) injury classification system

In summary, injury severity was a common assessment consideration for studies investigating neonatal skin injuries but rarely undertaken in the same manner. While classification scales such as the NPIAP (NPUAP) were used to describe neonatal injuries, there were a number of variances within studies. Dates and versions of tools used, were often not reported within methods, with reference lists the only place to identify the year. This could lead to confusion and outdated reporting in future studies if version numbers are not carefully checked. Whilst in recent years (after 2017) specific classification scales have advised that mucosal injuries or adhesive related injuries must be assessed using other tools. However, almost half of the studies in Table 3.3 focused on nasal injuries (n=9) and/or included the nose as an area of injury (n=11). Furthermore, one quarter (n=5) of studies also provided further groupings for stripping or tear injuries suggesting the importance of this type of injury.

Overall, the findings for neonatal classification or severity systems suggest more research is needed to establish what components are natural and/or clinically meaningful for clinicians. Thus, as a part of my future research and planning my studies, I knew it would be important to establish the state of evidence for frequency of mechanical force skin injuries; as well as how and why clinicians classified injuries. Considering the focus on a number of mechanical force injuries, I continued to pursue my investigation of skin injuries from a holistic and pragmatic approach; such that any injury to the skin related to a mechanical force regardless of the name or location of the outcome would be of interest.

3.4 State of the evidence for neonatal skin injuries from mechanical forces

Having established an understanding for the boundaries of skin assessment, mechanical forces and injury severity; I undertook a systematic literature review to establish the frequency of neonatal skin injury related to mechanical forces, as well as the anatomical locations of occurrence and related risk factors.[48] The review was published in 2018[48] in the Journal of Neonatal Nursing and included publications up to August 2017. Of note, while the inclusion/exclusion criteria for this study has not changed, a request for clarification for the results has occurred since publication. In the results, it is noted that one study reported internal/external nasal injuries (with only external reported in this review). This exclusion is related to the method of assessment, in that internal injuries for [157] were assessed by endoscope, not visual assessment and therefore not included. The publication uses the spelling of multicenter rather than multicentre, and the original article's list of references has been cross-referenced to the thesis reference list for continuity.

3.5 Article: Frequency, location and risk factors of neonatal skin injuries from mechanical forces of pressure, friction, shear and stripping: A systematic literature review

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Abstract

Introduction: Recognition of neonatal skin injuries from mechanical forces and their risk factors are limited and vague. *Aim*: To identify frequency, locations and risk factors for neonatal skin injuries from pressure, friction, shear and/or stripping. *Methods*: Joanna Briggs Institute Systematic Review process was used to search and review articles from Ovid (MEDLINE), CINAHL, Scopus databases and Cochrane Library published from 1990 to 2017. *Results*: Of the 1545 papers originally identified, 76 full text articles were examined, 21 studies met the inclusion criteria. Studies were more likely to identify skin injuries from various etiologies (n=7), pressure (n=4) and stripping (n=4). Prevalence of neonatal skin injury ranged from 9.25 to 43.1%. Risk factors included medical devices, gestational age and weight. *Conclusion*: Neonatal skin injuries from mechanical forces occur more frequently and differ in location from adults. Future studies need to identify modifiable risk factors and use consistent skin injury classifications applicable to neonates.

Introduction

Premature or sick neonates survive the neonatal period based on the assistance of multidisciplinary care and devices therefore are at risk for skin injuries. Historically research in this area has been limited but it is increasing and recent work suggests that risk factors for neonatal skin injury are decreased gestational age and medical devices.[164,165] However, neonatal skin has many structural differences compared to paediatric and adult populations including fragility, depth (between 0.9 and 1.2 mm thick compared to 2.1 mm in healthy adult skin) and weaker connections in the epidermal-dermal junction[64]; therefore potential for skin injury is high.[165] These differences present distinctive challenges for injury prevention but may also suggest additional etiologies for injury development; compared to paediatric and adult populations.

Skin injuries from pressure, friction or shear are most often classified as pressure injures, defined as "a localised damage to skin and underlying tissue over a bony prominence or related to a medical device".[95] Whilst the terminology of injury is focused on direct pressure, elements of shear and friction may also be involved and it is uncertain which forces work in isolation to form injuries. Additionally, epidermal stripping is an injury related to the force of adhesive removal with the bond between the adhesive and skin stronger than the layers of skin to each other.[37] Epidermal stripping injuries, also known as medical adhesive related skin injuries (MARSI), are suggested to occur frequently in the neonatal population.[143]

Skin injuries from pressure, friction, shear and stripping; are reported to be common for hospitalised adults and paediatric patients with well understood locations and risks; but less is known for the neonatal population.[165] Thus, the aim of this review is to explore frequency, locations and risk factors of neonatal skin injuries from these four mechanical forces, pressure, friction, shear and stripping.

Methods

Search string

A three-phase search-strategy was conducted guided by the Joanna Brigs Institute Systematic Review process.[166] Initial searches in Ovid (MEDLINE), CINAHL, Scopus and Cochrane Library databases were conducted to identify search terms (MeSH terms or subject headings) from the following: skin injury, pressure injury, pressure ulcer, epidermal stripping, skin stripping, skin tear, iatrogenic skin injury. Following which, keyword searches were also conducted and search strings were generated based on results (see Figure 3.2). Searches in Ovid (MEDLINE), CINAHL, Scopus and Cochrane Library databases were restricted only by publication date (1990 current 2017). Articles identified were imported into reference library, combined and searched for duplicates. Once duplicates were removed, the titles and abstracts were reviewed using the inclusion and exclusion criteria.

(A) infant* OR newborn* OR neonat* (MeSH term or subject heading)

(1) “skin trauma” OR “skin breakdown” OR “skin break”
(2) “skin injury" OR “skin injuries”

Following searched with skin OR dermis OR epidermis (not always associated with skin)
“pressure injury” OR “pressure injuries” **+1 , +2**
erythem* **+1, +2**
friction **+1, +2**

(3) "skin stripping" OR "skin tear" OR "epidermal stripping" OR "medical adhesive-related skin injury"

(4) "bed sore" OR "bed sores" OR bedsore* OR "decubitus ulcer" OR "decubitus ulcers" OR "pressure sore" OR "pressure sores" OR "pressure ulcer" OR "pressure ulcers" OR "deep tissue injury"

(5) "skin shearing" OR "skin-shearing" OR "shear force"

Figure 3.2 Search string details.

Study inclusion criteria

- Neonatal population (up to 44 weeks CGA or until discharge from a Neonatal unit)
- Human studies, published in English
- Definition or identification of skin injuries from pressure, friction, shear and/or stripping was determined based on the paper's own identification of the condition
- Observational (descriptive) and experimental studies for skin injuries from pressure, friction, shear and/or stripping
- Frequency of skin injury expressed as incidence or prevalence and/or locations of injury and/or risk factors for injury

Study exclusion criteria

- Case studies; case series; conference papers, posters or abstracts; reviews; periodicals; letters to the editor; textbooks; or thesis papers
- Skin injury identified as: surgical wound, dermatitis, venous/ capillary punctures, burns (thermal or chemical), infection, birth/delivery complications, extravasation, skin diseases or dermatologic conditions (including epidermis bullosa, granuloma, erythema toxicum), congenital anomalies, birthmarks (port wine stain),
- Fetal injury, in vitro studies

Full text articles were retrieved for remaining studies and reference lists searched for additional articles. Full texts were scanned for inclusion and exclusion criteria and grouped into include, exclude by two authors (DA, KN) independently with reasons for exclusion documented. If agreement was not reached articles were reviewed by a third author (YK).

Data Extraction

Authors then independently used a data extraction spreadsheet for included studies. The spreadsheet included: author(s), title, frequency (incidence or prevalence), anatomical location, and risk factors.

Results

The combined libraries identified 1536 articles, with 1021 remaining after duplicates removed and nine other articles were retrieved from other sources (references) (Fig. 3.3).

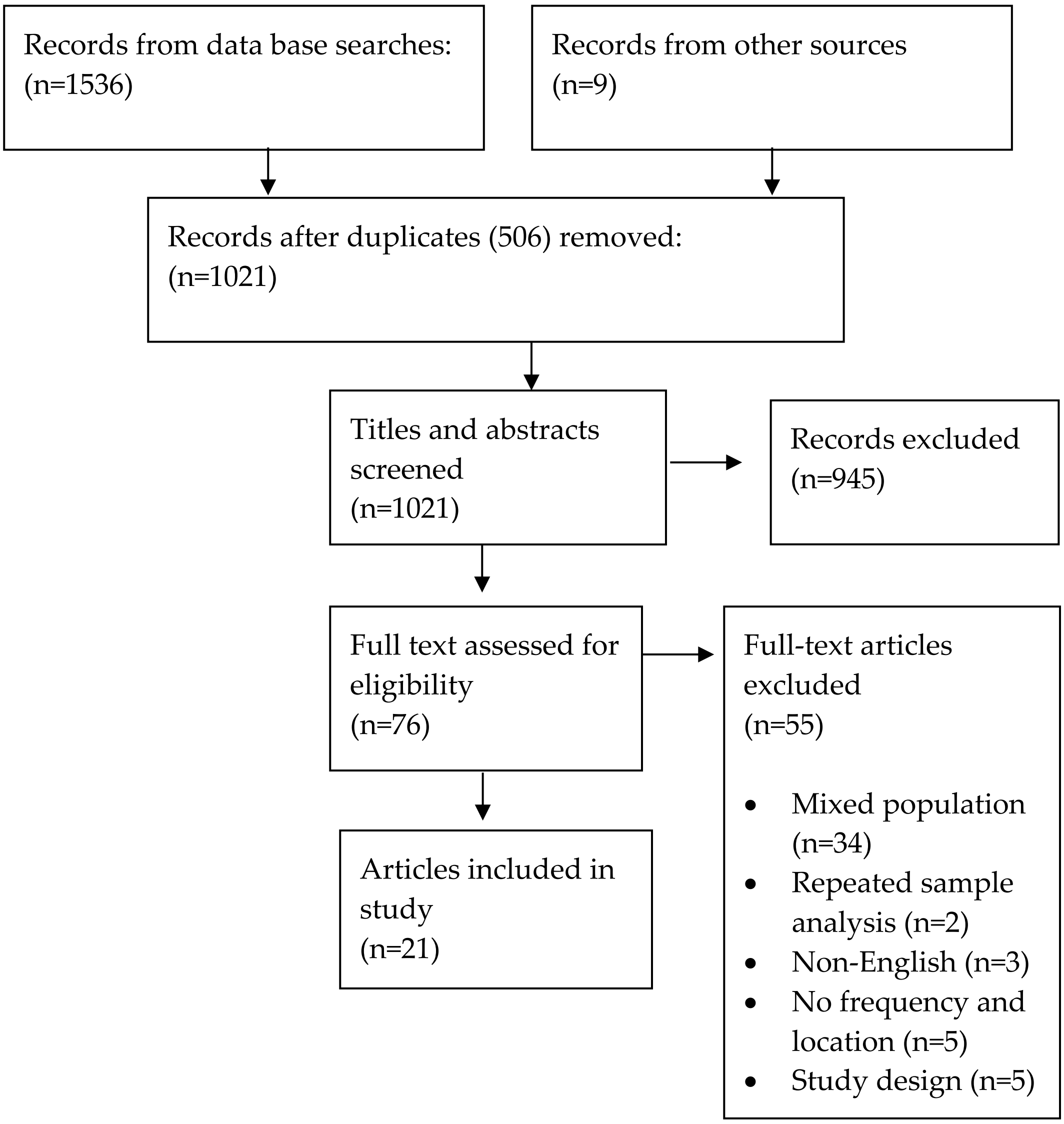

Figure 3.3 Selection process of articles.

Next, titles and abstracts of a further 945 articles were excluded based on not meeting inclusion criteria. The full-text for 76 articles were reviewed. Studies conducted in paediatric intensive care units, with neonates identified in demographics but without subgroup analysis were also excluded from this study (n=34). Other reasons for exclusion included:

repeated sample for sub-analysis (n=2), articles not available in English (n=3), product evaluation (n=5), skin injury frequency not provided (n =5) and discussion papers and/or case studies (n=6). A total of 55 studies were excluded with reasons documented resulting in 21 studies for review (see Tables 3.4 and 3.5).

Table 3.4

Study characteristics: non-specific locations.

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Location	Risk factors
Csoma et al. (2016)[167] Hungary	Prospective cross-sectional	460	BW 2236.86 g (965.53, 540-5470) GA 33.8wks (4.4, 22-41)	**Overall skin disorders** 83/460 (18%) **Epidermal stripping** 11/103 (10.7%) **Pressure ulcer** 9/103 (8.7%)	No data*	No data*
Meszes et al. (2016) Hungary	Retrospective, descriptive	211	BW 2353.6 g (±981) GA 34.5wks (4.3, 23 e41)	**Wounds requiring management** 32/211 (15.2%) **Epidermal Stripping** 7/35 (20%) **Pressure ulcer** 5/35 (14.3%)	Epidermal stripping Umbilicus (3) Cheeks (3) Nipple (1) Foot (1) Pressure ulcers Occipital region (4) Nasal orifice (1)	Low GA & low BW predisposed epidermal stripping (71.4%) (5/7)
Nist et al. (2016)[150] USA	Retrospective, descriptive	9025 *assessments* 3765 *injuries*	NICU	**Pressure ulcer** 0.49 per 1000 days to 4.9 per 1000 days (n=406 OR 446 pressure ulcers) **Erythema** 40.4% **Skin tears** 11.4% **Abrasion** 1.6%	No data	Device related 86.8% of pressure ulcers; Respiratory device related 60.1% pressure ulcers (78.8% related to CPAP); Positioning, immobility, other medical devices;

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Location	Risk factors
				Pressure ulcers 11.8%		Skin tear related to adhesive & epidermal stripping
August et al. (2014)[30] Australia	Retrospective descriptive cohort	247	BW 1155 g (620, 445-2678) GA 28wks (4.1, 22-41)	**Overall** 77/246 (31.2%) **Epidermal Stripping** 16/107 (14.9%) **Pressure Injury** 91/107 (85)%	Upper limbs (27) Lower limbs (32) Abdomen (10) Head region (38), including nose	Medical devices (68.2%) 24/107 intravenous catheter, 18/107 oxygen temperature probes, 19/107 continuous positive airway devices Unknown (31.8%) 34/107 <37 wks
Visscher and Taylor (2014)[39] USA	Prospective descriptive cohort	741	*Injury group* BW 2143 g (SEM 202) GA 33.1wks (SEM 0.9) *Uninjured group* BW 2340 g (SEM 49) GA 34.3wks (SEM 0.2)	**Overall** 1.5 pressure ulcers per 1000 patient days 39/49 medical devices 10/49 conventional	Toe/foot/heal Face/earlobe/chin Neck Nares Chest Head (back of) Knuckle Buttocks	(90%) medical devices LOS, younger GA, lower BW ($p<0.05$) >37 wks (71.4%) medical devices (20.4%) conventional pressure
Migoto et al. (2013)[147] Brazil	Prospective descriptive	40	BW (535-3444 g) GA (23-41wks)	**Overall skin lesions** 16% incidence, 58% prevalence (n=195 lesions) 0/195 pressure ulcers 19/195 (9.8%) adhesive lesions 10/195 (5.1%) nasal lesions	No data*	*Non-medical agents:* 36/195 (18.4%) including adhesive labels, prongs, oximetry monitoring, surgical procedures *Unknown causes:* 77/195 (39.5%)

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Location	Risk factors
Visscher et al. (2013)[151] USA	Prospective	741 461 during 280 after	*During* BW 3.90 kg (1.4) GA 34.4 wks (4.5) *After* BW 2.60 g (1.0) GA 34.0wks (4.6)	**Pressure ulcer** 0.9/1000 ulcers/patient days 18/461 (3.9%) during 31/280 (11%) after	No data	*Medical devices* 61% during intervention 90% after intervention pulse oximeter, extracorporeal membrane, oxygenation cannulas
Fujii et al. (2010)[29] Japan	Multicentre, prospective descriptive cohort	81	BW 1745 g (478-4122) GA 32.5wks (24-41)	**Pressure ulcer** 13/81 (16%)	Nose (n=7) Labrum (n =2) Dorsum, foot (n=2) Back (n=1) Occiput (n=1) Leg (n=1)	*Univariate analysis:* BW, skin texture, incubator temperature, incubator humidity, support surface, limited number of position changes, endotracheal intubation Multivariate analysis: Skin texture score (p=0.012), intubation (p=0.047)
Ligi et al. (2010)[35] France	Prospective comparison	1033 388 *pre* 645 *post*	*pre* BW 1890g [1280-750] GA 34wks [30-39] *post* BW 2080g [1400 - 3050] GA 35wks [31-39]	**Overall cutaneous events** 24% pre, 20% post 89/388 (22.9%) pre 124/645 (19.2%) post *(Excluding antiseptic, ocular and thermoregulation events)*	Nose No other data	*Decrease with incidence reporting system:* Cutaneous events (p=0.14) CPAP nasal necrosis (p=0.063)

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Location	Risk factors
Schluer et al. (2012)[168] Switzerland	Multicentre, cross-sectional, point prevalence	109	No data	**Pressure ulcer** 47/109 (43%)	No data	No data*
Huffines and Logsdon (1997)[122] USA	Descriptive	32	GA 30.33wks (3.99, 26-40) *breakdown* W 1488 g (528.98, 937 -2390) *No breakdown* W 2030g (703.64, 825 -3565)	**Skin breakdown** 6/32 (18.8%)	No data	Lower birth GA breakdown group 29.4 wks (±2.6) compared to birth GA no breakdown 33.9 (±3.8) Lower weight with breakdown 1488 g (±529 g) compared to no breakdown 2030g (±704 g)
Waterlow (1997)[169] UK	Multicentre prospective descriptive	54	No data	**Pressure sore** 6/54 (9.25%)	No data*	No data

KEY: BW- birth weight, W- weight, g- grams, kg- kilograms, GA- gestational age, wks- weeks (refers to GA), CPAP- continuous positive airway pressure, NCPAP- nasal CPAP, LOS- length of stay, SEM- standard error of the mean, IQR- interquartile range, OR- odds ratio, CI- Confidence Interval, p- p value, SD- standard deviation.

* Combined data for other injury types or age groups; demographics expressed as provided by authors: mean (SD, range), mean (range) or median [IQR, range].

Table 3.5
Study characteristics: facial respiratory interfaces.

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Risk Factors
Chen et al. (2016)[154] Taiwan	Prospective comparison, Trauma pre and post intervention	118, 31 *pre* 82 *post*	*Trauma* GA 29.7wks (4.3), BW 1449.3 g (776) *No trauma* GA 33.1wks (4.5), BW 2058.7wks (880.4)	14/31 (45.2%) *pre* 16/82 (19.6%) *post*	Trauma with NCPAP days (13.1 ± 7.1) Trauma recovery quicker larger infants (4.6 ± 3.1 vs. 2.1 ± 1.0 days) Logistic regression Duration of NCPAP use (OR: 1.08, 95% CI: 1.01-1.15, p Z 0.04) Lack of structured nursing protocol (OR 0.09, 95% CI: 0.01-0.77, p Z 0.03)
Milligan and Goldstein (2016)[152] USA	Prospective comparison Injuries pre/post intervention	112 75 *pre* 37 *post*	GA 226.72 days (32.99) BW 1930.34 (1033.46)	**Nasal injury** 33/112 (29.5%) 26/75 (34.7%) *retrospective* 7/37 (18.9%) *prospective*	Time and models of support not significant
Newnam et al. (2015)[155] USA	Randomised control trial Nasal prongs, mask or rotation	78 21 *prongs* 35 *mask* 22 *both*	BW range 500-1500 g	**Overall breakdown** 24.2% 85.3% *septum* 29.9% *bridge* (26.6% forehead)	Regression analysis Current mean post menstrual age ($p < 0.006$) Number of days on CPAP ($p < 0.001$) Erythema and excoriation less frequent in rotation group
Collins et al. (2014)[160] Australia	Randomised control trial	132 67 *high flow* 65 *CPAP*	No data	**Nasal trauma** NCPAP 13/65 (20%)	No data

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Risk Factors
	high flow, CPAP ± dressing				
Fischer et al. (2010)[28] Switzerland	Prospective, observation	989	GA 34wks (4) BW 2142 g (840)	**Overall trauma** 420/989 (42.5%) 30.6 cases/1000 days of CPAP	Born < 32 weeks (OR 2.48, 95% CI 1.59-3.86) Born < 1500 g (OR 2.28, 95% CI 1.43 to 3.64) Nasal CPAP >5 days (OR 5.36, 95% CI 3.82 to 7.52) LOS >14 days (OR 1.67, 95% CI 1.22 to 2.28)
Günlemez et al. (2010)[156] Turkey	Randomised control trial CPAP with silicone gel sheeting and without	179 87 *control* 97 *sheeting*	*Sheeting* GA 32.2wks (3.3) BW 1776 g (715) *No Sheeting* GA 32.1wks (3) BW 1752 g (689)	**Overall injury** 17/179 (9.5%) 4/179 (4.3%) *sheeting* 13/ 179 (14.9%) *no sheeting*	Duration CPAP treatment; Injury 19.6 (±10.6 days) without injury 4 (±3.3 days) Risk for injury comparing sheeting to no sheeting (OR: 3.43; 95% CI: 1.1-10.1; $p < 0.05$) Lower birth weight and gestational age ($P < 0.001$)
Jatana et al. (2010)[157] USA	Cross-sectional incidence complications	100 91 NCPAP 9 Cannula	*NCPAP no- complication* GA 28.2wks BW 1221 g *NCPAP complications* GA 27wks BW 1010	**Overall complications:** 12/ 91 (13.2%) 5/91 (5.5%) external necrosis NCPAP	After 10-25 days of exposure to nasal CPAP

Author	Study design	Sample size	Sample demographics	Injury frequency (Prevalence/incidence)	Risk Factors
Nascimento et al. (2009)[159] Brazil	Descriptive cross-sectional	146	GA<37wks 123 newborns	**Overall nasal injury** 147/ 147 (100%) 117/147 (79.6%) mild 29/147 (19.7%) moderate 1/147 (0.7%) severe	Use of prongs for more than 2 days
Yong et al. (2005)[25] Malaysia	Randomised control trial *nasal prongs or mask CPAP*	189	*Mask* GA 28.7wks (2.3) BW 1085 g (232) *Prong* BW 29.7wks (2.5) BW 1185 g (288)	**Overall trauma** 29-35% 12/41 (29%) *mask* 17/48 (35%) *prong*	Length of time on CPAP (adjusted OR1.04; 95% Cl 1.01-1.07) p=0.003 Gestational age & use of prong/mask not significant

KEY: BW- birth weight, W- weight, g- grams, kg- kilograms, GA- gestational age, wks- weeks (refers to GA), CPAP- continuous positive airway pressure, NCPAP- nasal CPAP, LOS- length of stay, SEM- standard error of the mean, IQR- interquartile range, OR- odds ratio, CI- Confidence Interval, p- p value, SD- standard deviation.

* Combined data for other injury types or age groups; demographics expressed as provided by authors: mean (SD, range), mean (range) or median [IQR, range].

Results of this review include studies from a variety of geographical settings and a combination of observational (n=15)[28-30,35,39,122,131,147,150,157,159,161,167-169] or interventional studies (n=6).[25,154-156,160] Additionally, results reflect that previously neonatal skin injury from pressure, friction, shear and stripping were reported primarily as a group of various etiologies (n=7) [30,35,122,131,147,150,167] while pressure related injuries have been the focus of four studies[39,161,168] and a further four studies identified epidermal stripping.[30,131,150,167] Of note, friction was identified in relation to adhesive labels[147]; but otherwise friction and shear were always identified in combination with pressure.

Frequency

Frequency of injury was reported by prevalence and ranged from 9.25 to 43.1% for skin injuries of all anatomical locations.[29,30,122,168,169] A further three studies reported that the incidence of neonatal skin injuries ranged between 0.49 and 1.5 pressure ulcers per 1000 days.[39,150,161] Five studies focused on skin injury related to respiratory interfaces (such as nasal CPAP) and found between 20 and 100% of neonates developed skin injury.[25,28,155,159,160] The frequency of injury from remaining studies, included injuries excluded from our criteria (burns or surgical wounds)[35,131,147,157,167] or frequency reported as a range (pre/post intervention or case-control).[152,154,156] Additionally, five studies identified that a single neonate may suffer multiple injuries such as finding 107 injuries among 77 injured patients.[29,30,39,147,167]

Anatomical locations

Injuries to head, face or nasal region were the most common (n =9), especially when related to respiratory interfaces (see Table 3.5).[25,28,152,154-157,159,160] Of those, two studies described more specific areas of the face[155] and one indicated a difference between internal/external nasal injuries (with only external reported in this review).[157] The remaining studies (n=12) reported injuries from various anatomical regions and four provided details on specific locations (see Table 3.4).[29,30,39,131] Both the nasal region and lower limbs were identified to have injuries by all four studies.[29,30,39,131] Similarly, the chest/abdomen region [30,39,131] and back of the head were identified by three studies [29,39,131]; while locations like the upper limbs,[30,39] face,[39,131] neck,[39] buttocks,[39] or back[29] being identified by two or fewer of the studies.

Risk factors

Gestational age, birth weight and medical devices were the risk factors most commonly identified for neonatal skin injuries in this review. Duration of medical devices, length of stay and risks from individual devices (respiratory interface types, adhesives and saturation probes) were also identified as contributing the causes but less frequently. Risks identified in single studies included current mean postmenstrual age,[155] conventional injuries (surface injuries),[39] absence of skin injury reporting system,[35] absence CPAP protocol [154] and absence of protective sheeting.[156] Skin injury was also related to the duration of a device (respiratory interfaces) in seven studies, with time to injury varying between 2 days[159] and 19.6 days.[156] In contrast, one study found birth weight statistically insignificant [29] and another found both weight and gestational age were insignificant.[25] Tables 3.4 and 3.5 provide statistical measurements for risk factors and a breakdown of risk factors per study can also be seen in Table 3.6 (except for studies where risk factors were calculated for combined age groups).

Table 3.6
Risk factors related to skin injury.

Author	Risk Factor						
	Gestation	**Weight**	**Length of stay**	**Medical devices**	**Duration device**	**Specific devices**	**Other**
Meszes et al. (2016)	+	Birth +				P A	
Nist et al. (2016)						P A **N**	immobile/position
August et al. (2014)						P A **N**	conventional pressure
Visscher and Taylor (2014)	+	Birth+	+	+			
Thais Migoto et al. (2013)				+		P A **N**	
Visscher et al. (2013)				+		P	
Fujii et al. (2010)	+						intubation/skin score
Ligi et al. (2010)							pre intervention
Huffines and Logsdon (1997)	+	+					
Nasal interface studies							
Chen et al. (2016)		Birth +			+		pre intervention
Milligan and Goldstein (2016)							pre intervention
Newnam et al. (2015)		+			+		post menstrual age
Fischer et al. (2010)	Birth+	Birth +	+		+		
Günlemez et al. (2010)	+	Birth +			+		no intervention
Jatana et al. (2010)					+		
Nascimento et al. (2009)					+		
Yong et al. (2005)					+		

KEY: P -saturation probe, A –adhesive, **N** -respiratory devices

Discussion

The aim of this review was to explore frequency, locations and risk factors of neonatal skin injuries from four mechanical forces, pressure, friction, shear and stripping. These results highlight the broad methodologies utilised by studies, injury outcomes and risk factors for neonatal skin injuries. The differing methodologies used by the 21 studies made the comparison, analysis and/or interpretation of data difficult. For example, summarizing data was challenging when injury outcomes were grouped within an overall skin condition score, producing a frequency that may be misinterpreted.[152,160] Overall, studies either 1) investigated skin injuries in traditional adult methodologies (pressure injuries[95] separate to epidermal stripping[143]); or 2) investigated all skin injuries regardless of etiology. Studies more commonly investigated a combination of skin injuries, which may support the theory that neonatal skin injuries from various forces maybe uniquely related due to the physiologic components of immature skin.

The severity of the injury appears to influence the reporting of injuries with one study only reporting data on injuries requiring wound management but stated that other injuries occurred to neonates studied.[131] While another reported septal necrosis, which would suggest only late or severe forms of injury were identified.[157] While not the aim of this review, it was noted that staging and classification reporting were also inconsistent ranging from: mild, moderate and severe [155]; Stage 1, 2, or 3 [28]; or validated adult injury systems such as National Pressure Ulcer Advisory Panel.[29,39] The variety of descriptions for severity or classifications may have influenced frequency rates, especially if only moderate or severe injuries were represented. In order to get a true understanding of neonatal skin injury frequency and severity a consensus on skin injury definitions and/or measurement is needed. While the face and nasal regions were the anatomical regions of most interest, minimal detail was provided for particular nasal areas such as collum, septum, bridge, rinum, tip.[26] Furthermore, identifying the anatomical region at most risk was also difficult as location of injuries was not reported in many studies, or studies combined injury types such as burns, extravasations and injuries related to pressure, friction, shear and stripping. Areas of soft tissue (nose or abdomen) were identified to have a higher frequency of injury rather than areas over bony prominences (tailbone, elbow or heel), which is distinctly different from studies in the adult population. The occiput (back of the head) was the only bony area identified in neonates studied.

Studies indicated that neonates with medical devices and adhesives are highly susceptible to injury. This finding is paradoxical, as hospitalised neonates will consistently require these interventions to receive life sustaining treatments and care. Comparatively, the frequency of adult skin injury appears to be less, with facility acquired pressure injuries between 7 and 14%[170] and medical device injuries less than 30%.[171,172] Many of the studies found that greater than 70% of neonatal skin injury cases were device associated[30,39,150] implying that the injuries were facility acquired. These results may place a burden of responsibility on neonatal nurses and clinicians to 'prevent' injuries without evidence to facilitate prevention and management, as hospitals and health care organizations expect skin injuries to be a 'never event'. Birth weight, along with gestational age, was found to have a strong association with risk for injury, adding to the burden of prevention as they are non-modifiable risk factors. Future investigations need to provide insight into possible modifiable risk factors of skin injury management. Lastly, neonates acquiring multiple skin injuries related to mechanical forces, require closer investigation as they may be key to identifying intrinsic physiologic risks rather than complication of care provision such as specific medical device.

Strengths and limitations

The main strength of this review is the unique focus on skin injuries from multiple mechanical forces (pressure, friction, shear and stripping). This study highlights the gap in evidence related to risk factors and types of skin injuries that occur in neonates, which is important to collect before practice improvements and prevention strategies can be defined and implemented. This study is a first step in identifying the need for harmonised reporting of neonatal skin injury risk factors, locations and severity. A limitation of this review is that the methodological quality of each individual study was not appraised to determine the extent to which the study addressed the possibility of bias in design, conduct or analysis. Additionally, identifying frequency for epidermal stripping may have been limited, as two studies related to medical adhesives were excluded based on reported outcomes focusing on product evaluation rather the effect on the skin.[158,173]

Conclusion

Results of this review suggest that frequency of neonatal skin injury is higher than in the adult population, with all neonatal injuries acquired during hospital care. Locations of skin injury occur in areas of soft tissue, are mostly related to the medical devices required to provide care, which contrasts with injuries common in the adult population. Injury severity in terms of stages and classifications need to be well defined and applicable to neonatal physiology in order to accurately represent frequency rates. Implications for future practice and research include multicentre studies to investigate neonatal skin injuries with refined injury inclusion/exclusion criteria, in-depth understanding of injury severity, and thorough investigation of condition at the time of injury. Such studies would assist in identifying modifiable risks and facilitate the prevention of neonatal skin injuries from pressure, friction, shear and stripping.

Acknowledgements

Stephen Anderson, liaison librarian for College of Medicine and Dentistry at James Cook University for guidance in search strings. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

3.5.1 Systematic literature search update

By 2019, I had noted several new publications in this area and therefore undertook an update of the literature to confirm the current state of the evidence. The original search methodology was applied, but with filters limiting publications between August 2017 and February 2019. A total of ten papers were identified and based on screening of title and abstract, six were excluded due to study design.[174-179] On reviewing the full texts, two papers were excluded as injury frequency was not reported[180,181], leaving two papers meeting the inclusion criteria; one investigated multiple etiologies of skin injury[153] and the other adhesive tape injury (epidermal stripping)[182] (Table 3.7).

Table 3.7

Included studies from updated search.

Author	Study Design	Sample size	Sample Demographics	Injury Frequency	Locations	Risk Factors
Broom et al. (2017)[153] Australia	Prospective longitudinal study with intervention	60 *pre*, 30 *post*	34.1 weeks (30.6-38.8); 2.18 kg (1.35-2.98) *pre* 35 weeks (31-39), 2.52 kg (1.63-3.39) *post*	n=54 (61.7%) *pre* n=14 (40.0%) *post*	No data	Pre only (data unclear for post population) Medical devices: intravenous, blood collection and CPAP equipment (46%) Routine skin care: dry skin, excoriated buttock, positioning (39%)

Author	Study Design	Sample size	Sample Demographics	Injury Frequency	Locations	Risk Factors
Habiballah (2017)[182] Jordan	Cross sectional, period prevalence	169	8.32 days (SD 8.87) 3-56); 36.27 wks (SD 3.19) 27-42 wks	26.6% (n=45)	Face, arms, chest, feet, back, buttocks, multisite	*Device associated with injury:* Endotracheal tube fixation tape (24%, n=11/45); IV cannulae (11%, n=10) Nasogastric tube fixation tape 18% (n=8) Electrode adhesive caused 16% (n=7) Oxygen probes 4% (n=2) Diaper fixation tapes 4% (n=2) *Increased prevalence with:* Older age (which equals to longer LOS) ($p<0.001$) Respiratory disorder ($p<0.003$) Preterm ($p<0.007$) Underweight ($p<0.001$) Mechanical ventilation > than four days ($p<0.034$)

KEY: BW- birth weight, g- grams, kg- kilograms, GA- gestational age, wks- weeks (refers to GA), CPAP- continuous positive airway pressure, NCPAP- nasal CPAP, LOS- length of stay, SEM- standard error of the mean, IQR- interquartile range, OR- odds ratio, CI- Confidence Interval, p- p value, SD- standard deviation

3.6 Summary

Initial investigations, as demonstrated in the preceding chapters, highlighted that visual inspection, injury etiology classification and severity were important elements in injury assessment. In addition, five mechanical forces contribute towards skin injury, supported by the findings of the systematic literature review, that mechanical force skin injuries were more frequent for neonates (9.35-43.1%)[48] than adults (6-16.6%)[8] and anatomical locations of injury differed from adults.[48] Categorisation of injury severity seemed heterogeneous, and without further exploration into neonatal injury severity and injury assessment; reporting could be affected by scale selection. Another area of reporting inconsistently was that of nasal injuries, as adult guidelines or investigations often separated nasal injuries, distinguishing them as mucosal membrane injuries. However, my clinical background informed me that respiratory interfaces resulted in injuries to a number of internal locations (nasal passages) and external locations (forehead, ears, and bridge of nose). Thus moving forward, reporting this data in a comprehensive manner was important in this early phase of the exploratory research. The next step would include investigation to provide context and understanding of current skin injury assessment practices was needed before epidemiological investigations could be undertaken. Each of these had an influence in the development of the PhD research including determining: i) the definition and boundaries for mechanical force related skin injury; ii) injury bed colour, size and severity of neonatal skin tissue; iii) context of neonatal clinicians who assess an injury; iv) consistency of injury severity and re-assessment criteria; and v) affirmation of neonatal specific risk factors from epidemiologic data.

Chapter 4 Methodology

The multifactorial nature of skin assessment as previously described indicated that a variety of methods would be needed to conduct this research. Skin injury assessments required qualitative data, such as the description of an injury bed, and quantitative data in the form of prevalence. Furthermore, clinicians undertaking injury assessment can encounter complexities such as the unique organ structure and variations for injury assessment as described in Chapter 3. Therefore, a single methodology would be inadequate to explore the epidemiology of neonatal skin injuries and a range of data collection strategies were needed to facilitate investigation from multiple viewpoints. These included the elements of skin injury identification, variances in clinician assessments, and additional data sources to demonstrate that skin injury investigation was more intricate than a single method or source of data. Additionally, at the time of methodology selection there was growing interest in visual data within multi-method studies,[183,184] prompting an opportunity to add an emerging data collection tool previously unutilised for neonatal skin injuries, by way of injury/wound photography. Theoretically, visual data such as clinical images could objectively capture real time skin injury appearance, overcoming challenges of the variance in classification systems or subjective descriptions from multiple assessors. Therefore, combining multiple perspectives of investigation through qualitative, quantitative, and multimedia data suited a mixed methods design.[41,44,185] This chapter describes the considerations for selecting an exploratory, sequential mixed methods study design for the exploration and investigation of neonatal skin injuries.

4.1 An exploratory, sequential mixed methods study design

Mixed methods research embodies a pragmatic approach to enquiry, founded in the ideology that reality exists in a natural state, a physical state, and also a psychological and social realism; which could be subjective to experience, expressed through the nomenclature and culture of healthcare.[185] A mixed methods design was particularly appropriate as it integrated qualitative data such as social and cultural contexts of skin injury including staff opinions, or culture related to neonatal skin injuries;[44] with the quantitative data such as injury prevalence and measurements of actual injuries. Additionally this design provides a research method appropriate for capturing complex, multilevel process system factors, as well as the causality of skin injury.[185-187] Similarly, a mixed methods enquiry is not simply the collection of multiple types of data; but that sequence, priority and integration of each enquiry are of equal importance.[183,185,187] The outcomes of the systematic literature review revealed that the state of knowledge for neonatal skin injury was mostly based on quantitative data,[48] with limited qualitative data[130,175,188] but no mixed methods. Furthermore, local practices and clinician impressions at each site needed to be explored to identify issues that might impact on collection. Therefore, it was clear that the sequence of this research should begin with qualitative exploration. An exploratory sequential mixed methods design, enabled interview and focus group data to be collected with participants at the study sites in preparation for investigating skin injury prevalence through quantitative enquiry.[186,187,189] A sequential design in particular, allowed for review of data at multiple time points in an ongoing iterative analysis,[52] enabling a deeper analysis; particularly within Phase 1 and the between-methods triangulation of all data in the later stages of the research.[41,43,51,52,185] Triangulation of data from multiple phases improves the capacity for findings to be translatable for clinical practice. The overarching mixed-methods exploratory sequential design is outlined in Figure 4.1.

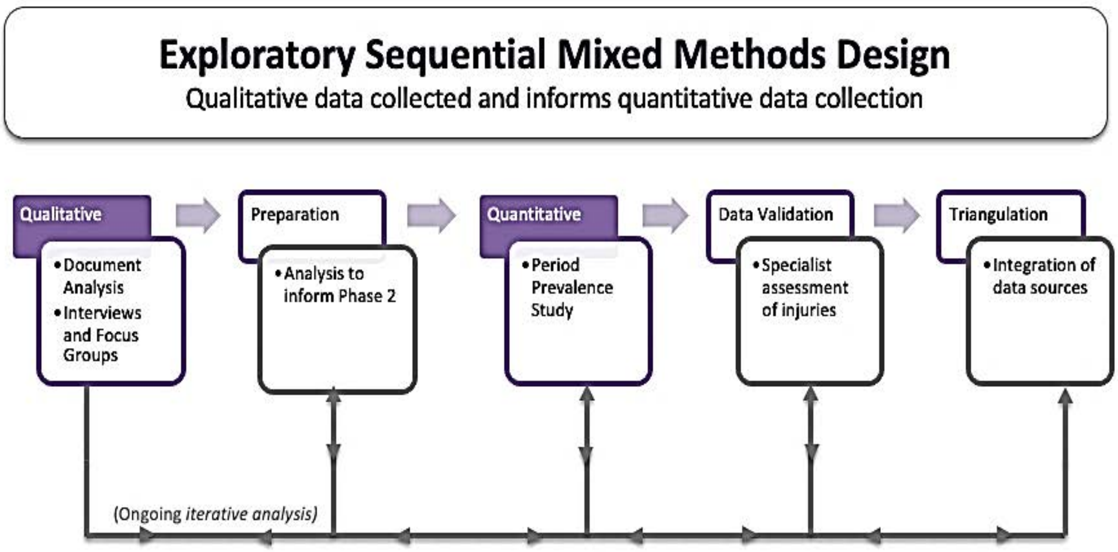

Figure 4.1 Exploratory sequential mixed methods design flow chart.

4.1.1 Reflective practices

A part of a strong mixed methods design is reflexive practice which can improve rigor and increase the trustworthiness of the results.[43,190,191] The first reflexive practice employed, was the identification of factors such as experiences or assumptions of the research team that might affect the research outcomes, for example my previous life and clinical experience.[43,190,191] These potentially could inform the lens I brought to this research. As a female, American-Australian, in the middle of my life, I value science, integrity and honesty. As a health care worker, I believe we have a duty to provide neonates and their families the best care and evaluate the quality of care provided. I also believe that pragmatic research results in quality evidence that is translatable to bedside care. Another reflexive activity undertaken was to keep a reflective journal to protect confirmability of the data throughout the research.[29,192] This journal included personal thoughts and field notes, which provided a systemised and trackable record for early codes and then themes arising from the qualitative data.[192] As an additional step, my advisory team and I worked together to cross check interpretations to avoid assumptions.

These reflexive practices helped me to account for challenges and considerations that might have arisen related to insider/outsider perspective (emic/etic)[193]; as I represented both a neonatal nurse and researcher.[193] For example, at times I would be able to empathise with clinicians as I provided care in similar circumstances. Yet, in other circumstances I was an outsider now scrutinising and evaluating their actions. For additional clarity, reflexive practices that pertain to the conduction of specific research phases are reported within the respective sections of Chapters 5 and 8.

4.2 A multicentre study

Considering the number of ways skin injury outcomes were reported in the peer reviewed literature, it seemed likely that interpretation of skin injury could impact assessment and reporting parameters. Another potential influence on skin injury assessments were written sources such as local guidelines and government documents, and the structures and systems used to report injury events. Each of these might contribute towards variations of injury assessment, prevalence, and perceived associated risks. In turn these impressions were likely to impact on clinical reporting and knowledge translation initiatives[180,188]; but more importantly could be valuable data sources. It was apparent that to gain a more comprehensive view and potentially strengthen the generalisability of the outcomes of my research and for translation into practice, data collection needed to be undertaken at multiple sites. A multicentre study allowed for the strengths of a large sample size, within an achievable timeframe, and the possibility of external validity.[45] In addition, investigation through multiple data types such as documents, clinicians' impressions, injury prevalence, and injury images provides a broader exploration of the epidemiology of neonatal skin injuries. The specific considerations for site selection were also important, as neonatal units based in the same health district or geographic region are likely to have similar practices. Therefore, site selection included neonatal units providing a tertiary level of service delivery, located in different health districts and geographically regions.

4.3 Research phases and stages

The research plan (as presented in Figure 4.2) included two phases, with each phase conducted over two stages, followed by between-methods data triangulation. An overview and justification for each research phase and stages are outlined in further detail below., while methods and materials are reported with the results in Chapters 5 to 8 respectively.

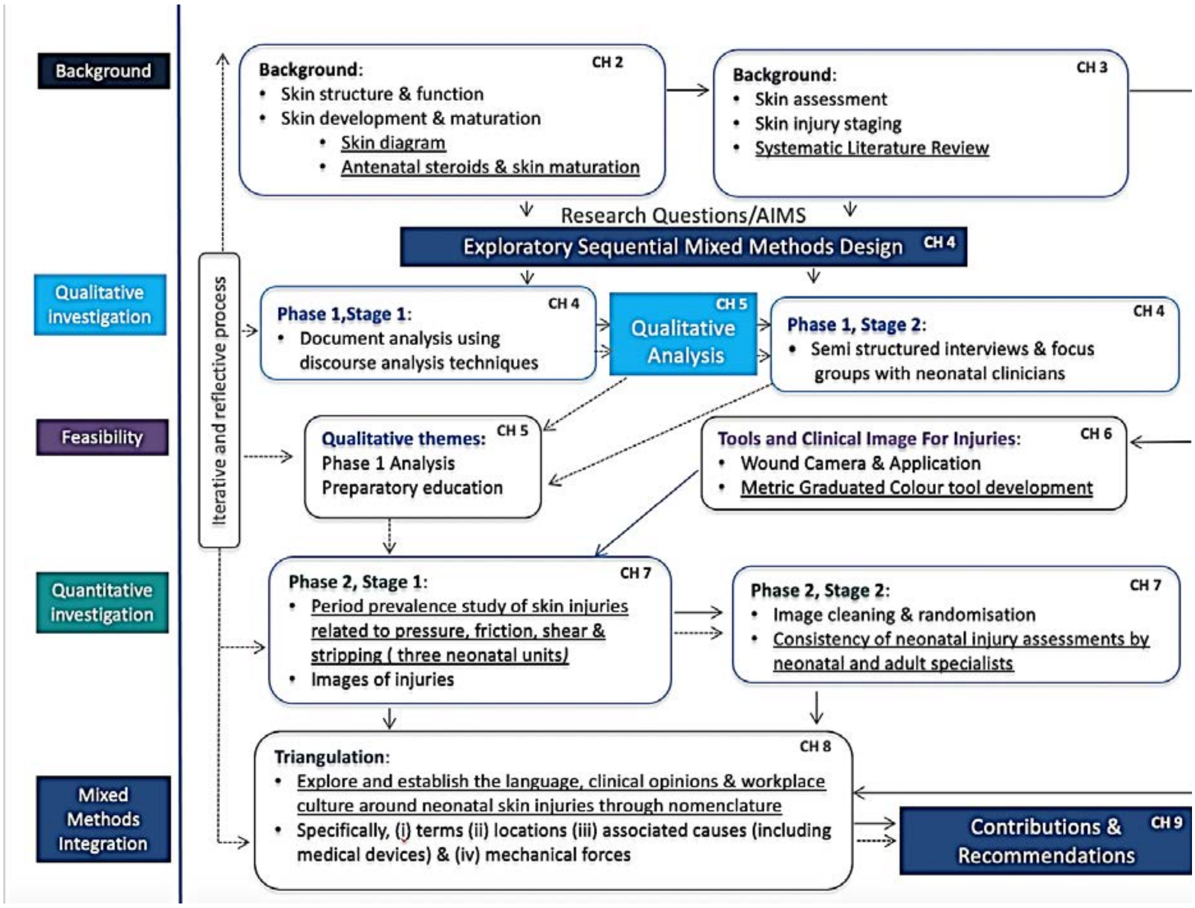

Figure 4.2 Thesis conceptual map.
(Key: Underlined text = published or submitted for review; CH= Chapter).

4.3.1 Phase 1 (Stages 1 and 2): document analysis, interviews and focus groups

Phase 1 applied qualitative methods to explore workplace nomenclature and culture through analysis of documents, individual interviews and focus groups. At this stage, it became evident that historical injury knowledge and awareness from neonatal clinicians was relevant therefore a review of the literature related to clinician experience of skin injuries was undertaken. The results of that review added depth to the range of data captured in this Phase, including unexpected nomenclature. Injury assessment was comprised of descriptive nomenclature influenced by workplace impressions and clinicians' experiences which shaped injury reporting and perceived risk factors. Collection of the quantitative data was critical, as it established a shared understanding of terms and assessment criteria to improve the validity of the data collected in Phase 2. (Stage 1) specifically, the investigation of neonatal skin care documents at each study site provided insights into reporting culture and descriptive nomenclature.[51] Analysis of the documents was performed to inform questions for Stage 2; semi-structured interviews and focus groups. The document analysis also helped to identify gaps and differences between documents, national guidelines and clinical practice. After which, interviews and focus groups with neonatal nurses, nursing managers, neonatologists, registrars, and nurse practitioners were conducted. Interviews and focus groups enabled clinicians to use their own words to describe practice and the factors influencing injury assessment. Data elicited nomenclature, culture, and group perceptions related to neonatal skin injury risk factors.[44,187]

4.3.2 Analysis and preparatory education

Analysis of the data collected in Phase 1 established the common ground for skin injury nomenclature in each of the sites, as well as identifying major themes and educational needs, which informed the preparatory education and procedures required for Phase 2.

The findings from Phase 1, demonstrated the need to provide visual examples of skin injuries with the use of uniform language. These were incorporated into the education sessions which also included an overview of the research, further information on assessment aids, injury severity or stages, eligibility, consent and collection of study data using the wound camera/application. The locally provided education sessions strengthened the applicability of the prevalence study within each setting, provided opportunity for local endorsement[187,189], and enabled data collection in Phase 2 to be rigorous and valid.

4.3.3 Evaluation and testing clinical images and tools for neonatal skin injury assessment

The challenges of neonatal skill assessment described in Chapter 3, together with the limitations of visual assessment reported in adult studies[17,194,195] might have been overcome by using two trained skin injury assessors to verify assessment and severity.[196] However, there was a paucity of trained neonatal skin specialists at the time this research was undertaken and an expectation of a high skin injury prevalence. Consequently, it would have been difficult for initial assessment of study injuries to be undertaken by two trained assessors. Therefore, to overcome this potential limitation in the period prevalence study (Phase 2), an evaluation and testing of the applicability of clinical images and related wound cameras was undertaken. Concurrently, the team developed and designed a single use metric and colour tool to use with clinical photography known as the Metric Graduated

Colour (MGC) tool [49]. This tool served as a standardized reference similar to colour-rendition or 'ColourChecker' charts for any clinical images collected. This work was conducted before Phase 2, (Stage 2) and included assessment of the use of clinical images at the time of initial assessment[197] as a tool for specialist assessment of injury type and severity at a later time Phase 2, (Stage 2). Chapter 6 describes the investigation of available devices and tools to measure, assess and capture images of neonatal skin injuries. This chapter also describes the development of education and resources for Phase 2 data collection.

4.3.4 Phase 2 (Stage 1): period prevalence study

In designing the prevalence study, several issues identified in the systematic literature review[48] (Chapter 3), were taken into consideration. Firstly, skin injury frequency was reported as either prevalence (period and point) or incidence, making it difficult to establish an overall frequency. Secondly, a number of studies (n=5) reported that an individual neonate can acquire more than one injury over a short time period.[29,30,39,147,167] As incidence is considered the number of cases of a condition or disease and focuses on the new instances;[198] only the initial or first injury is reported, and therefore the number of actual injuries is likely to be under-reported. Given the NSQHS Standards use of prevalence for reporting skin injury frequency, used/referred to by clinicians, it seemed reasonable that clinicians were more likely to identify with prevalence than incidence, reinforcing the decision to undertake a prevalence study. Therefore, Phase 2 (Stage 1) was comprised of a multicentre period prevalence study informed by previous research[30,39,157] and additional strengths such as clinician engagement and education, reporting of all anatomical locations (rather than a single site), use of clinical images to capture an injury, and the subsequent verification of the injury by another clinician or specialist. Variables such as gestational age, birth weight, medical devices and cot humidification[48] considered for the data collection tools were informed by the outcomes of a review of risk factors (Chapter 2) and the systemic review (Chapter 3). Other risk factors specific to neonates were considered such as time from birth to injury, birth mode, antenatal steroids, acuity, type of medical and devices' capacity to be offloaded from the skin without compromise to the treatment.[5] Additionally, to reflect culture of NSQHS reporting at the time of the study, risk factors were also grouped into direct (extrinsic/modifiable) and indirect (intrinsic/non-modifiable) risks.[6,188] The results are reported in Chapter 7.

4.3.5 Phase 2, (Stage 2): wound and skin specialist assessment

This stage involved using the clinical images collected in Phase 2, (Stage 1), to investigate variances for injury assessment and the influence of clinical background on assessment. Specifically, comparison of assessment consistency for neonatal skin injury etiology and skin colour, injury size, injury colour and injury severity were undertaken by invited neonatal and adult specialists using the MGC tool. Considering my background in neonatology and training in wound care, I assessed the same images as the invited specialists as the baseline for evaluation. These results are reported in Chapter 7.

4.3.6 Between-methods triangulation

Between-methods triangulation[41,52] was used to assimilate and integrate a number of data sources (Literature review, Phase 1, (Stage 1 and 2); and Phase 2 (Stage 2) and study results to establish a new perspective on the phenomena of neonatal skin injuries. More specifically triangulation of nomenclature from four data sources, founded on inductive reasoning, enabled the development of a generalised conceptual understanding of the epidemiology of skin injuries from mechanical force as well as the nomenclature used to communicate neonatal skin injury. Triangulation provided a more detailed picture and deeper understanding[51,52] of this hospital acquired complication; thus offering new insights to inform practice change in neonatal skin care.[41] Results from triangulation are reported in Chapter 8.

4.4 Additional methodological considerations

4.4.1 Ethical considerations

The National Statement of Ethical Conduct in Human Research identifies four key values that should be considered when designing and undertaking research: research merit and integrity, beneficence, justice and respect.[199] While ethical considerations are required for all study participants, there are additional considerations for unique populations including neonates. I considered both the key values and population specific requirements while planning and conducting my research. The national statement specifies that research involving children can be particularly challenging when trying to achieve new knowledge without placing the participant in unnecessary harm.[199] For example, feasibility investigations and education sessions were undertaken to trial and test image data collection without compromising vulnerable neonates with excess handling and care interruption. The selected study design also limited the burden and time required for handling the neonates by care providers, and parents in order to justify undertaking the research. Informed consent from a parent of participating neonates ensured respect of parental choices. Investigating clinician experience prior to data collection established, limited disruption to clinical care and delays in data collection. Lastly, this research contributes to justice through a further understanding of the consequences of necessary medical interventions applied to all born ELBW or VLBW despite attentive care. Ethical review and approvals were granted from the participating hospitals and universities (HREC/13/QTHS/212) TTHS, (HREC/16/QRBW/30) RBWH; (H16/099) Otago and SHDH and James Cook University (H6400) (Appendix 1,2,3 and 4).

Chapter 5 Phase 1 – Qualitative Components

With the possibility of diverse workplace cultures and work practices across the three sites, an exploration and preparatory education phase was undertaken to promote local engagement and enhance data collection. This chapter begins with a synopsis of the literature relevant to clinician's experience of neonatal skin injuries as a background to the workplace context, language and culture of participating neonatal facilities (Phase 1, (Stage 1) and 2 see Figure 5.1). Results from the document analysis, semi-structured interviews and focus groups are presented. Only the analysis and results which directly informed subsequent stages are found in this chapter with collective outcomes are reported within a published manuscript as a part of Chapter 8.

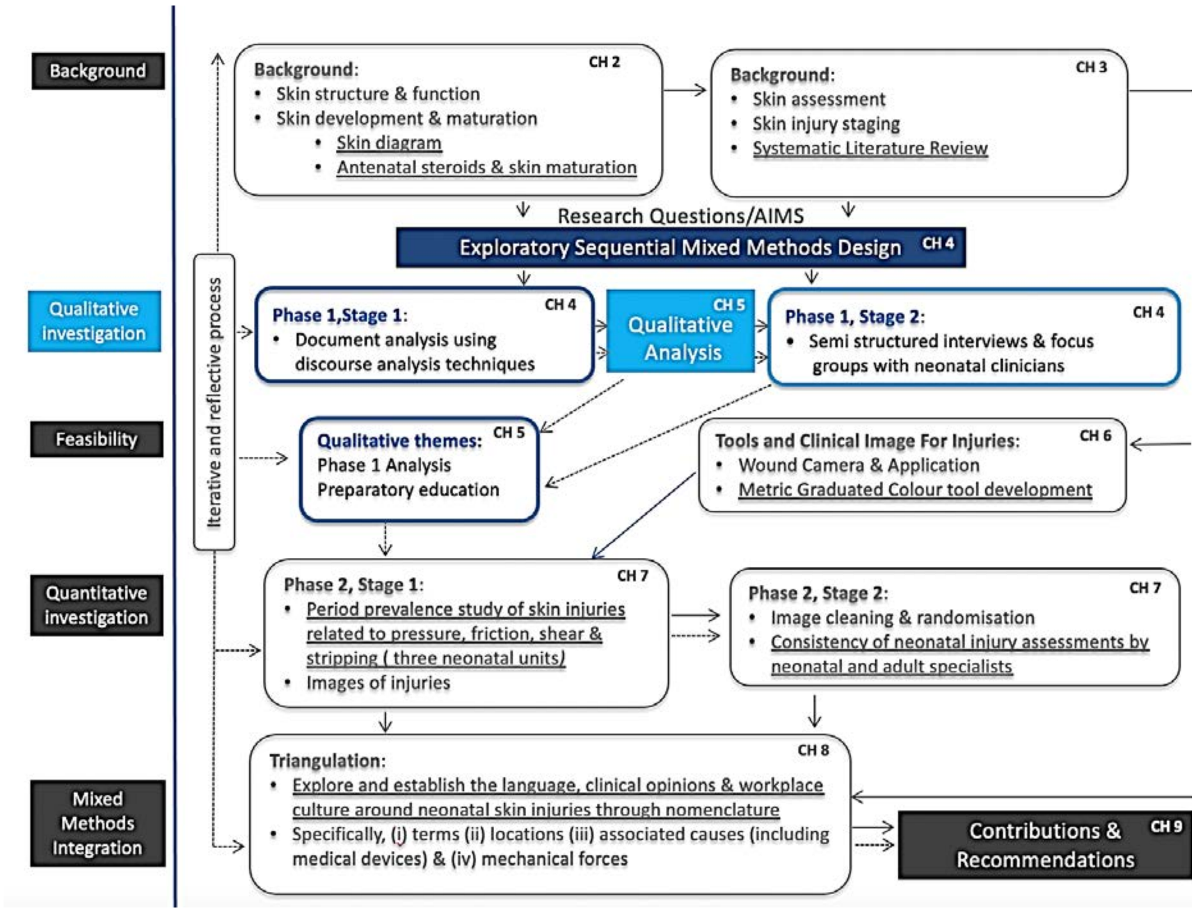

Figure 5.1 Thesis conceptual map with Chapter 5 content highlighted.
(Key: <u>Underlined text</u> = published or submitted for review; CH= Chapter).

5.1 Clinicians' experiences with skin injures: a literature synopsis

The titles and abstracts of studies included in the literature review (Chapter 3) were searched again for relevance to clinician experience involving neonatal skin injuries. Only four studies were identified, three utilised quantitative methods[38,130,200] and one utilised qualitative methods.[188]

Of the four studies, two had surveyed neonatal nurses. Maguire et al. (1999)[38] surveyed American neonatal units, requesting completion by a neonatal nurses with at least 2 years NICU experience. Responses were received from 45% (n=215) of units. The reported overall skin injury rate for ELBW neonates was 21% (n=not reported) and that injuries most likely occurred during the first 10 days of a neonates' life. Only 4% (n=not reported) of nurses reported they did not think neonatal skin injury occurred at all and 25% (n=not reported) reported that injury measurement was subjective and formal systems for reporting were absent.[38] In response to four colour photographs of ELBW skin injury, less than 25% (n=42) of nurses were able to identify the correct description or severity of injury. The second survey investigated Malaysian neonatal nurses (n=41) perceptions and knowledge of preterm infants skin.[200] Interestingly, most of the nurses disagreed that they had strong knowledge of preterm infants skin (80.5 %), despite having neonatal credentials and more than half with five or more years of neonatal experience (n=28, 68%).[200] Length of neonatal experience and specialised neonatal certificate were not found to be predictive of correct responses to knowledge questions. Investigators recommended the development of specific neonatal skin care education.[200]

The two remaining studies utilised clinical opinion to gain knowledge of skin injuries. A Delphi study was conducted among neonatal and wound care nurses within the United States.[130] Two rounds of Delphi evaluation concluded that there were nine risks for neonatal skin injury: medical devices, adhesives, postmenstrual age (birth weight), activity, co-morbidities, skin integrity (tolerance) moisture (chemicals) and nutrition.[130] These results were used to develop a skin risk assessment tool, but at the time of this thesis submission, evaluation of the tool validation was unpublished. Clinical opinion was also reported within survey responses from Irish neonatal nurses (or n=56), as part of an action research cycle for a skin injury risk assessment tool implementation.[188] Nurses reported that the implementation of the tool had improved skin assessment, skincare practices and awareness of injuries, as well as improving accountability for documentation injuries.[188] While, nurses identified that further improvements to skin care practices were needed, they suggested advancements to treatment delivery would also be needed to achieve the necessary improvements to skin care. Additionally, it was suggested that improving skin care was challenging as the prioritisation of skin care was often overcome by competing interests for other intensive care needs[188] (such as ventilation).

Despite the geographical spread of these studies, findings were primarily comparable with the conclusions established in Chapters 2 and 3 and those in the systematic literature review.[48] Specifically, nurses participating in the studies were aware that neonates acquired skin injury, those born ELBW or preterm were at increased risk, and medical devices or adhesives were additional risk factors for injury. [38,130,188,200] However, a number of insights were identified which were explored in my research in Phase 1, (Stage 2). Firstly, the subjective assessment of injuries, and secondly the experience of both neonatal nurses and medical clinicians. While topic of skin injury has been explored with clinicians, none of the four studies specifically addressed mechanical forces as a cause of injury etiology with more of a focus on risk factors. Therefore, this phase explored workplace culture, clinician experience, assessment including severity, risk factors, and documentation or reporting for injury with the intent to identify the mechanical forces related to etiology.

5.2 Phase 1, (Stage 2) document analysis

Using document analysis to investigate workplace documents such as procedures[51], delivered a novel source of data which had not been utilised in previous studies. In addition, reviewing of each site's documents identified unique and common workplace practices and culture as well as insight into the local framework for neonatal skin injury assessment and reporting.

5.2.1 Particulars of site selection and participating neonatal units

Proposed study sites were chosen based on service capacity to provide equivalent tertiary level of service, within separate health districts and located in distinct geographic regions. Sites were also matched to levels of patient acuity for assurance of patient illness level as a possible confounder of injury. Five neonatal units were approached and after consultation three sites confirmed participation. The participating sites provided complex care, ventilation, retrieval services, long-term nutritional support, with family-centered care models, and interdisciplinary developmental care follow-up. Despite similar services, unit size varied with cot capacity ranging between 16 cots to 70 cots, thus staffing numbers differed. Two of the neonatal units were in Queensland, Australia; one in a metropolitan area and the other in a regional area. The third site was a regional metropolitan unit, located in New Zealand. Of note, neonatal nurse practitioners were a part of the clinical workforce at all study sites. Like many neonatal units across Australia and New Zealand, individuals working in the role of the nurse practitioner are a part of the medical roster, acting as an advanced registrar or fellow and therefore can be considered medical clinicians or part of the medical team.

5.2.2 Reflexivity for document analysis

Reflexive practices were important for this portion of the PhD, and while using these practices it became apparent that the influence of my employment in one of the participating units should be considered as a risk. As an employee at one of the three sites, the insider-perception of the unit culture at my workplace might have been overlooked, as opposed to an outsider perspective for the remaining two sites.[190,193] Therefore, to mitigate risk for bias, the initial analysis of each source was conducted by myself (DA) and then reviewed by one of the advisory team (RR or KN). Data, analyses, and saturation were further discussed with the entire team during monthly meetings, during both data collection and analysis. The practice of reflective journaling also assisted me to separate out insights from opinions, which might have been generated by insider or outsider lenses.

5.2.3 Data collection and analysis

To initiate data collection for the document analysis, an informational letter was provided to each site, requesting documents which included a summary of the method and lists of relevant examples. Relevant sources included local documents, government documents, or structures and systems for skin injury reporting. Data collection and analysis occurred over a staggered 26 months (2015-2017). Documents were not restricted to those applicable to neonates alone, both those to which the site and neonatal clinicians used for reference which could have included adult or hospital wide resources. Upon receipt of document sets, sites were assigned a letter (Site A, B or C), and documents were designated a number resulting in a unique code for each document (for example Site B Dc12). Characteristics for each document were also collected, such as document name, purpose, source of production, date of creation and review date.

A combination of content and thematic analysis was applied at various stages of the document analysis. Content analysis was used to extract data concerning language, statements, processes or recommendations related to skin injury prevention assessment, identification, practice, reporting, or management. Multiple levels analysis were completed within this document analysis, including a combination of content and thematic analysis.[51] Content analysis specifically descriptive and selective coding was used.[51,201,202] Data included terms, statements, processes or recommendations related to skin injury prevention assessment, identification, practice, reporting, or management. The source of local language used to communicate skin injuries in each site was also noted, as in descriptive or terms consistent with literature or documents .[51] The 2011 National Safety and Quality Healthcare Service (NSQHS) standards criteria related to pressure injury prevention (8.1-8.10), were selected as a framework for data collection,[3] which was the only Australasian framework at the time of method development (2015). Of note, this analysis was completed between 2015-2017 and since 2017, frameworks were developed and published for skin tears (2018)[40] and MARSI (2020),[19] thus they are included within this work. Criteria from the NSQHS standards were particularly relevant as they are used to audit health procedures, practices and documentation for national benchmarking and accreditation, yet it should be noted that they are focused on pressure injuries. Of note, four of the criteria were excluded (sections 8.5, 8.6.2, 8.6.3 and 8.7) as they were deemed to be outside the scope of this study or evidence related to the standard was lacking. For example, criteria (8.5) reported that risk factors for pressure injuries should be identified using an agreed screening tool for all presenting patients, but risk assessment tools for contemporary neonatal populations were unavailable. Data were entered into an Excel Spreadsheet v14.7, 2011.

To further understand workplace culture as represented by the documents, an examination of discourses (language, text, and other features of communication) was conducted using discourse analysis.[203,204] Discourses were used to compare local culture (from documents) to the expectations within of the NSQHS standards.[3] Discourses included opinions, emotions, feelings, perceptions and workplace cultures.[203,204] Examples of the discources are included in this chapter and in futher detailed in Chapter 8.

Commonalities in nomenclature and understanding of skin injuries, were analysed using deductive content analysis[201]. Terms, location of injury, associated risks and injury etiology were extracted from documents using the following parameters:

- Terms or language were considered as a single word or phrase;
- Location was considered as an anatomical location/region;
- An associated risk was considered as medical devices or co-morbidities; and
- Etiology was considered a primary cause of injury; with mechanical force classified as any movement against or sustained to the tissue and underlying structures.

5.2.4 Results

A combination of electronic and paper-based documents totalling 59 items were received from all three sites. The types of documents included skin care or skin assessment related policies, procedures, guidelines, educational tools, and documentation forms. The sites also provided information on injury reporting structures, with two sites utilising electronic reporting structures and the other site used a paper-based reporting structure. Hospital wide policies were provided by two sites, both of which were focused on adult pressure injury prevention. None of the sites provided a comprehensive document which outlined a definition, assessment procedure and associated risks for neonatal skin injury. Two sites had ELBW guidelines comprised of sections describing specific skin care practices, while the third site had a dedicated screening and assessment tool for neonatal skin injuries and a complementing guideline in draft. The dedicated screening and assessment tool from the third site, incorporated multiple sections for skin assessment findings ([skin] colour, peri skin etc) within the generic observation document, while the second site had a document including sections for skin or wound assessment findings (wound description, peri skin etc). However, both of these documents were considered optional for each neonate, and the collection and use were left to the discretion of individual clinicians. For those documents that were required, an area for descriptive observations titled by a single header with room for free text descriptions existed (e.g., skin assessment or physical assessment). With the exception of a single international guideline, all other documents were produced locally.

5.2.4.1 Nomenclature and expectations from National Safety and Quality Healthcare Service standards

The nomenclature within the 2011 NSQHS standards proposed that evidence, prevention strategies and tools existed which could assist clinicians to prevent, identify, monitor and manage any kind of pressure injury in any hospitalised population. This expectation was demonstrated within statements such as "Policies, procedures and protocols are consistent with best practices" (NSQHS 8.1) and "Equipment and devices are available to effectively implement prevention strategies for patients at risk and plans for the management of patients with pressure injuries" (NSQHS 8.4). Comparatively, documents from the three sites acknowledged skin injury but contained far less detail in relation to prevention monitoring and managing injuries. Content from the included criteria within the NSQHS standards and individual site context and culture from the site documents are presented in Table 5.1, along with the characteristics of site documents. Of note, when NSQHS standards criteria were similar or overlapping they were reported together in the table in order to reduce repetition. Within Table 5.1 direct quotes (both single and multiple words) are displayed in italics rather than placed in double quotation marks, and inferences or impressions from discourse analysis are presented in blue coloured font for visual clarity. Additionally, inferred practices or considerations created by comparison of NSQHS standards criteria with site documentation are presented in brown coloured font.

Table 5.1

Comparison of 2011 NSQHS standards criteria with site documents and corresponding inferred practices or considerations.

2011 NSQHS Standards Criteria	**Site A**	**Site B**	**Site C**	**Results of comparison**
Policies, procedures and protocols are consistent with best practice (8.1)	23 documents • 6 observations/assessments • 14 guidelines • 2 parent information sheets • 1 policy (adult) • 0 other Guidelines all reviewed within date, reviewed in 4-year cycles. 3 met components of best practice guidelines. Definitions for terms provided within hospital wide policies for adult pressure injury prevention.	19 documents • 10 observations/assessments • 7 guidelines • 0 parent information sheets • 0 policies • 2 other- reports The guidelines with the most skin injury content were past review date, other documents within date, documents reviewed in 3–4-year cycles.	17 documents • 6 observations/assessments • 8 guidelines • 0 parent information sheets • 1 policy (adult) • 2 other- reports Guidelines all within review date, reviewed every three years. 5 guidelines specifically reference current literature including Pan Pacific[5], met components of best practice guidelines. Definitions for terms provided within hospital wide policies for adult pressure injury prevention.	Evidence for best practice exists, is available and transparent for all patient populations. Assumes that neonatal skin injuries from mechanical force are the same as those acquired by adults.

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
Reporting systems and risk assessment frameworks are used to identify, investigate and take action to reduce the frequency and severity of injuries (8.2)	Single header prompt *Skin*, under *Head-to-toe assessment* for nursing staff as well as multiple anatomical sites prompts for each shift including *septum (*also described in section (ii) Locations). Single header prompt *Skin,* for medical staff on admission and discharge documents. Numerous daily assessments of skin for nursing staff, suggesting one discipline more responsible or expected to monitor. The overall number of areas for documentation, suggest skin assessment a priority element of care. *Small baby* [< 31 weeks and 1200g] *guideline*, 5 of 7 pages address skin care and injury prevention includes request for photo collection to monitor damage progress. Particular document and length of detail suggest clear intention to monitor damage and track healing of injuries, with particular concern for risk of injury for those of low BW and GA.	Documents for nursing and medical staff included single header prompt *skin* for assessment findings. Medical within particular documents associated with admission and discharge *examination of newborn* and *infant exam*, often completed near discharge compared to daily field for nurses. The specific section for nares assessment, suggests this is a location of high risk for injury. Within the ELWB guideline, two of 53 pages address skin trauma and prevention. Specific instructions within this guideline suggests higher risk for injury for those born low BW and GA. Incident reporting documents *skin problems: ear ischemia, skin damage* from *adhesive* A or B, *burn, damage from temp probe* as well as *abrasion to philtrum, septum*, or *bruising from bonnet*. Incident reporting paper	Nursing and medical documents included single header prompt *skin assessment* (medical only on discharge, nursing daily). Additional prompts on nursing assessment for *nares.* The specific prompt for nares, suggests this is a location of high risk for injury. Hospital policy for reporting available and extensive (meets best practice guidelines), other local documents reference this policy. Reporting done electronically at facility level; unit specific data/reports available (not currently utilized). Neonatal specific data has been incorporated into reporting system, such as anatomical location have been added applicable to neonate (e.g., septum, fingers). Evidence of collaboration between facility and unit to record injuries accurately, by amending reporting system-	Reporting and documentation of injuries are expected at all levels of healthcare; local unit [site] and facility level. If a unit is only reporting at unit level, how does that impact on frequency reported when other units include injuries in facility reports? How can comparisons for care be made? How does the unit's frequency of injury impact on the facility's overall injury frequency?

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
	Hospital wide incident and management policy, no neonatal specific content. Hospital wide electronic reporting will be initiated soon, no neonatal specific content. Standard practice to photograph and include in medical record some skin injuries (e.g., extravasation) which are also provided to national accident compensation program.	format separate from patient documents, handwritten. Report summaries reviewed at unit level adverse event meetings. No clear indication how injuries reported or benchmarked at facility level. Lack documentation areas suggest, clinicians could regularly document in generic sections such as progress note, or only document injuries as an 'incident'; which suggests a level of seriousness and may deter them from reporting less severe injuries.	suggest specific risks or needs of the neonatal population. Unit specific reports from facility wide audits produced for unit staff. Reports produced by a working party and part of nursing professional development portfolio. Why is the report generated by a working party? What if that working party disbands? How will clinicians learn about injuries? How will they be reported to the facility? Neonatal skin injury assessment and reporting guideline (in draft).	

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
Clinical data used tomonitor and investigate frequency and severity of pressure injury and undertake quality improvement activities (8.2 and 8.3)	All instances of skin breakdown (injury) are swabbed and sent for culture. Prevalence of skin breakdown and instances of positive bacterial growth reviewed at infection control meetings, every four weeks (infection control meeting minutes provided). No other skin related audits or outcomes in minutes. No clear indication of if or how this is feedback to bedside clinicians. Severity or staging not identifiable in any of the documents. Staging present in hospital wide online reporting system (not currently used by neonatal unit).	Skin injury reported within comprehensive incident document with other complications such as medication error. A summary of skin injury incidents is reviewed once a month by medical and nursing management. No clear indication if feedback to bedside clinicians. Records provided for two recent facility-wide skin injury audits; unit did not participate in audit. Severity or staging not identifiable in any of the documents.	Regular audits completed, reported locally and to the facility. Injuries are reviewed on a patient-by-patient basis. Unit specific reports generated by working party undertaking quality improvement activities. Cumulative reports emailed and posted quarterly in staff common areas (examples of reports provided). The unit generated reports, are separate to what is reported at hospital level. Local reports have more detail regarding cause, specific population to reporting system. Why are different details required? Is this evidence of an increased surveillance, or uniqueness of patient population? Guidelines, reports and observations documents include information of severity in stages, as well as height and width. Stages	*Pressure* is the mechanical force mentioned in the standard's criteria. Therefore, pressure must be most important hospital acquired injury. What about the frequency of injuries related to other mechanical forces such as friction or stripping? Pressure injury severity (staging) is the same across all populations (infers no consideration of tissue depth or anatomical location).

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
			clearly defined (Stages 1-4, Suspected deep tissue injury and Unstageable) with an evidence based reference.[3] Draft educational resources include descriptive terms for stages, such as *epithelialization* and *pink* for a *Stage 1* injury, plus example images and diagrams.	
Prevention plans for all patients at risk of a pressure injury Equipment and devices are available to effectively implement prevention strategies for patients at risk and plans for the management of patients with pressure injuries (8.4)	Neonatal Skin Condition Score (NSCS) recommended within guidelines but no location for score within observation and assessment documents, no guidance for actions or treatment if high score occurs. Multiple guidelines specify, individual high-risk treatments, interventions or procedures that increase risk for injury (e.g., *inspect site once per shift for signs of infiltration (redness, swelling, oozing, pus, oedema*), or (*correct size hat, prongs; interface, ensure correct positioning of prongs and mask tubing maintained*, or *observe face, septum, surrounding soft tissue*). Some guidelines specified treatment for injury. Suggests awareness of risk	No risk assessment scale, score, or tool. Documents identify specific high-risk treatments or procedures related to injury (e.g., *nasal interface*, *temperature probe* or adhesives) and treatment actions for corresponding treatments (e.g., *check size*, frequency of site change and remove carefully). Some guidelines had specific instruction for caution and injury prevention; removal of micropore and Comfeel® from abdomen must be removed by neonatal nursing staff before [theatre staff remove] to prevent rapid removal. Set of cautions suggests injuries have been previously monitored	Unvalidated neonatal risk assessment tool in use, pilot evaluation underway. Documents provide specific care for high-risk treatments or procedures related to injury and treatment actions (e.g., nasal interface or peripheral cannula); but not called prevention plans. Practice implications and actions for smaller gestational age and birth weight within many documents. Specific information suggests this group is at additional risk for injury within the population.	Criteria does not consider age-appropriate differences, especially in relation to screening or risk tools tool. NSQHS standards would suggest the only way to determine an *at-risk* patient is by a score attained from risk assessment tools and assumes that risks assessment tools are valid and available for all populations.

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
	for injuries and importance of assessment, but lack of clarity on prevent and management plans. The specific skin-care guidelines for smaller gestational age and birth weight (born less 31 weeks or 1200 grams), suggests this group is at additional risk for injury within the population. Hospital wide policy stated use of the Braden Q tool for risk assessment in neonates, but not in use currently. Hospital wide policy not correlating with best practice, Braden Q is not an appropriate tool for age, paediatric tool. Two sets of assessment tools provided (NSCS and Braden Q), but no place to document scores and lack of guidance to how to alter practice once completed. Multiple documents specify examples of preferred equipment or processes; inferring change has	and there is a specialty specific knowledge, neonatal compared to others. Hourly prompts for assessment findings for specific devices (*prong* and *hat*), could be suggestive of risk; but requires inherit knowledge.	Hourly prompts for assessment findings for specific devices (*nares*, *probe* [saturation], and *site* [probe]), could be suggestive of risk; but requires inherit knowledge.	

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
	been monitored. For example, prevention inferred by interventions recommended; *only use this adhesive* or *only use decontamination agent A; not B*.			
Comprehensive skin inspections (assessment) (8.6)	Single header prompt Skin, under Head-to-toe assessment, rather than unique documents. Additional assessment areas in daily nursing document: septum, prongs, mask; skin colour, bruising/rash, oedema; wound, perineum/buttocks; skin folds, neck, axilla, and ears (documentation each shift). The specific areas for skin assessment suggest these areas are high risk for injury or abnormal assessment.	Single header prompt *skin* on nursing observation document. Abnormal skin observations could be documented sections: *stoma care plan/wound care plan*, or *complications*. Headings differ between intensive care and nursery.	Single header prompt *skin* under *Physical assessment* within nursing documentation each shift. *Assessment* as provided in these documents may allow for a variety of findings.	*Inspection* as suggested by NSQHS is an aggressive search; compared to *assessment* which could be construed as optional or passive.
Manage and treatment (8.8)	Treatment plan for one specific type skin injury (extravasation specific to neonates). Neonatal specific best practice references. Space for documentation of assessments free text; this could require initiative from staff to report and describe.	Single header prompt on a single document "wound care plan" within nursing care plan. Small amount of space to document plan, may suggest management plans are completed in progress notes or by other interdisciplinary team members.	Dressing chart available, no references or guideline to determine if alights with best practice. Space for documentation of assessments free text; this could require initiative from staff to report and describe.	Clear and evidence-based management and treatment options are available for all skin/pressure injuries.

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
	Pain relief mentioned in *small baby guideline*, in relation to management of skin complications.			
Communicate with consumers regarding skin injury risks and frequencies (8.9-10)	Informational brochure for parents related to "very small baby", describes that neonates have immature skin and includes information specific to bacterial skin colonization. Available in parent common areas with other consumer information. Besides brochures, there may be another method which injuries, risk factors and management plans are discussed with parents (who are the consumers in this population), but unclear.	No information for parents or families on skin care or injuries. Risk factors and management plans may be discussed with parents (who are the consumers in this population), but unclear.	Parent brochure provided as part of document set for neonatal skin injuries, but not in clinical areas or parent areas. Besides brochures, there may be another method which injuries, risk factors and management plans are discussed with parents (who are the consumers in this population), but unclear.	There is an expectation to supply appropriate information with patients and families. Open disclosure expected, as well as discussion of management plans with patients, but no management plans obvious. Do parents require a different method of information sharing related to skin injuries?

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
Overall Impressions	Skin assessment is a component of essential care, skin health plays a role in the healthcare delivery. It is possible to attain a skin injury while hospitalized. Skin integrity is considered important by disciplines including larger organization, medical and nursing. Importance evident in documents related to breakdown, nappy dermatitis, extravasation and bacterial surveillance. Reference to tools such as NSCS and Braden suggest awareness, but also; lack of consistency and poor implementation of scores and necessary actions. Reference to some mechanical forces, but severity/ stages, and description of skin injury absent. However, focus is not specific to skin injury from mechanical forces. Skin injury inferred but not described (outside hospital wide guideline); many instructions on how to prevent injury but little	Skin assessment is part of care delivered but regarded as adverse events rather than an element of assessment finding or part of standardized documentation. Skin injury is a serious event. But risks are related to treatments, procedures or anatomical locations. Injury prevention may also be related to specialty specific knowledge (neonatal nurses only allowed to remove adhesive). Mechanical forces, severity/ stages, and description of skin injury absent.	Neonates obtain pressure injuries and skin injuries. Conducting skin assessments is a component of essential healthcare delivery of neonate Nomenclature and definition for skin injury inconsistent (i.e., trauma, ulcer, & still for recently published documents, or absent in others. Some individual documents reflect partnerships between facility and organizational structure for interdisciplinary prevention, manage and injury identification (such as facility audit documents and reporting system). However, lack of partnership evident in content often directed at nursing staff actions or precautions, with little mention of other interdisciplinary roles.	Best practice is available and transparent for all patient populations. Neonatal skin injuries are the same as those acquired by adults. Pressure is most important force that creates skin injuries and injury severity (staging) is the same across all populations.

2011 NSQHS Standards Criteria	Site A	Site B	Site C	Results of comparison
	describing injury; descriptive terms such as erythema. Severity/staging absent.		Unvalidated risk assessment tool suggests current tools insufficient or unfit for use.	

KEY: Table legend: *Italic font* - direct quotes (both single and multiple words), blue font- Inferences or impressions, brown font- comparison between documents and NSQHS standards from discourse analysis, NSQHS- National Safety and Quality Health Service**,** ELWB- extremely low birth weight.

- Terms or language

No single term or set of nomenclature for neonatal skin injuries or severities was identified. While there were similarities between sites, consistency of terminology even within each the sites were absent. Instead, a wide range of terms (n=17) related to skin injuries were identified within documents across all three sites. The term "pressure +/-ulcer" occurred most often (n=19), followed by "epidermal stripping" (n=10), followed by "skin breakdown" (n=9) and "nasal pressure ulcers" (n=5). An additional 13 terms were used at least once such as trauma, wound, integrity (loss of), tear, blanching, excoriation, damage, abrasion, bruising, narrowing, ischemia, redness, and erythema.

- Locations

All three sites had a reference to the assessment of the nasal area or equipment placed in that location, suggesting specific risk to injury for the nose (see Table 5.1). However, no document specifically stated or listed anatomical locations at risk for injury. At risk locations could only be assumed from the assessments of a particular location or under/near a specific treatment, procedure, or device such as adhesive removal or respiratory interface application. For example: "It is important to have correct size hat, prongs or interface and ensure correct positioning of prongs/mask to avoid damage" (Site A) or "Nares, septum, head, ears must be assessed with each care time for pressure injuries or trauma and recorded on the physiological observation chart" (Site C).

- Associated risk factors

Within documents from all three sites special assessments, care instructions and cautions were evident for neonates of low gestational age and/or birthweight. For example, "All gestational groups are at risks for skin breakdown…. with particular risk for ELBW" (Site C, document 14). Two sites had unique guidelines for low gestational age and/or birthweight with particular attention to procedures related to injury prevention (Table 5.2). While not overtly stated, both nasal CPAP application and adhesive removal had assessment or associated instructions at all three sites, inferring particular risk for these procedures and practices. "Remove [specific adhesive] with removal wipes…to prevent skin trauma due to hurried removal…"(Site B). Of interest, as documents were focused on individual procedures, few referenced literature related to incidence or risks of neonatal skin injuries from epidemiological studies.

- Etiology-mechanical forces

Reference to mechanical forces or injury etiology were most related to the injury description rather than injury formation: "[areas] must be assessed with each care time for pressure injuries or trauma and recorded on the physiological observation chart" (Site C). Contents from another document suggested that the guideline could "assist staff to minimise epidermal stripping" (Site A). In the entire document sets, only four forces were identified; pressure and stripping occurred the most frequently, whilst friction and shear were rarely mentioned.

5.2.5 Themes from deductive content analysis

A total of five preliminary themes associated with skin injury were identified from the content analysis of terms, locations, risks, and expectations set by the NSQHS standards: skin injury descriptors, skin injury etiology, skin injuries assessment and indicators of risks and skin injury accountability. Table 5.2 presents the themes from the deductive content analysis.

5.2.5.1 Skin injury descriptions

The first theme identified, skin injuries are described not defined, arose from the search for common nomenclature. None of the sites used consistent terms, definitions, or descriptions of skin injuries through documents sets; and only a single hospital wide (adult) policy defined injuries. Many of the observation or assessment documents were 'free text', rather than prescriptive about assessment location or severity. Injuries were described based on location "nose" (Site A); but most often described in relation to device specific damage or prompts included on observational documents such as "adhesive A" or "B, "temperature probe" (Site A), "hat" (Site B) or "probe" (Site C).

Table 5.2
Themes from deductive content analysis.

Themes	Codes	Quotations (document source)
Skin injury descriptors	Skin break/problem Location specific injuries	*"Skin break"* (Site document) "*Skin problems*" (Site document) "*Ear ischemia*" (Site document) "*Breakdown"*; or "*Nappy dermatitis*"; or "*Extravasation*" (Site document)
Skin injury-etiology	Device specific injury Procedure specific injury	"*Skin damage from adhesive A*" or "*adhesive B*" (Site document) "*Damage from temperature probe*" (Site document) "*Check* [locations] *regularly to prevent trauma*" (Site document) *"Pressure"* (site document) and additional etiologies ("*burn"*) (Site document)
Skin injury assessment and indications of risk	Regular assessment of particular anatomical locations Release force (pressure) Screening tools	"*Nose/septum*" or "*Wound*" or "*Skin folds*" (Site document) *"Prong/hat"* (Site document) "*Nares*" and "*Probe re-site*" (Site document) "*Monitor bacterial surveillance of skin to prevent*" [complications] (Site document) "*Skin Assessment*" or "*Physical Assessment*" [single header prompts for free text descriptions] (Site documents) "*Action taken to reduce frequency and severity pressure injuries*" (NSQHS) "*An agreed tool to screen for pressure injury risk is used by the clinical workforce to identify patients at risk*" (NSQHS)

Themes	Codes	Quotations (document source)
Skin injury accountability	Assessment on admission Shared responsibility Reporting Communication [families /consumers] Lacking	[skin injury] "*Present on admission (yes/no)*" (Site document) "*Action is taken to maximize the proportion of patients who are screened for injury on admission*" (NSQHS) "*Skin assessment" [Medical admission and discharge checks]* (Site document) "*Incidence is reported throughout the organization*" (NSQHS) Online adverse event reporting system [skin injury or pressure injury] (Site document) "*Prevalence of skin injury*" [neonatal data included in hospital wide report] (Site document) "*Prevalence of skin injury*" [neonatal data missing, hospital wide report] (Site document) "*Skin surveillance for parents: …your baby is undergoing weekly testing... surveillance to detect colonisation of a particular specifies of bacteria*" Parental/consumer information skin care (Site document) "*Communicating with patients and careers: Patients and carers are informed of the risks, prevention strategies and management of pressure injuries*." (NSQHS)

KEY: Table legend: CPAP-Continuous positive airway pressure, NSQHS- National Safety and Quality Health Service

5.2.5.2 Skin injury etiology

Injury etiology and descriptions and were often integrated. Terms suggesting etiology were most often related to specific devices with an occasional description inferring a physiological process or etiology: "ear ischemia" (Site B). In comparison nomenclature within the NSQHS standards suggested only an interest in pressure injuries, but the variety of language in site documents indicates that skin injuries from any etiology are important: "check [locations] regularly to prevent trauma" (Site C) or "skin damage, damage or abrasion" (Site B). "Pressure" (Site A, B and C) was mentioned infrequently but as a descriptor of outcome as well as other etiologies ("burn") (Site B).

5.2.5.3 Skin injury accountability

Documents from all three sites provided evidence of skin injury awareness culture but the processes for reporting varied. At Site C auditing was conducted quarterly and reported to unit and facility levels. Comparatively, Site B reported monthly at a local level while Site A provided reports without predetermined time intervals, but neonatal specific data was absent.

A culture of transparency and responsibility for skin injuries was evident within documents from all sites such as detailed areas for assessment or reporting structures. This was the responsibility of nursing staff, as nursing assessment of areas were expected daily or during each shift, while medical assessments only focused on admission and discharge. At Sites A and B skin injuries were discussed regularly at unit interdisciplinary meetings, while at Site C skin injuries were only reported. Additionally, injuries were reported at various levels of facility or unit, suggesting there were different cultures of accountability ranging from direct reporting to the larger hospital system (Site C), sub-reports to the facility but reports were screened (Site A), through to reporting at unit level (Site B). The expectations of reporting at the facility level were unclear within the NSQHS standards and documents, thus it was difficult to determine if each facility was meeting the expected benchmark. Another benchmark difficult to identify, was communication with consumers related to risks, prevention strategies and management of injuries. It is likely that clinicians delivered ad-hoc verbal parental education, but interesting to note the specific written educational material at one site was on bacterial surveillance (two versions) but not skin injury.

Another element of responsibility identified within the documents from one site and NSQHS standards was related to the facility or unit where an injury was acquired and demonstrated by the assessment of "present on admission" (Site C). Nomenclature within the standards related to facility-acquired skin injury, inferred that the unit where an injury was acquired was responsible for the injury and care provided, rather than consideration of risk factors.

5.2.6 Implications for Phase 1, (Stage 2)

Reflection on aforementioned themes, together with the literature reviews (Chapters 2 and 3), provided the framework for developing a total of eleven semi-structured questions, with accompanying prompts, used in either interviews or focus groups (Appendix 5). Firstly, questions were developed to explore neonatal clinician's opinions of injury definition and elements considered during assessment such as *What does a skin injury look like? What would you document in your assessment? What words would you use to describe an injury?"*. Responses to these questions further informed the definition of mechanical force injury used in the period prevalence study. Similar to the multimedia method first used in Maguire (1999)[38], five images of neonatal skin injuries were provided during interviews and focus groups to encourage descriptions, discussion and provide assessment context. Images were A1 in size and comprised of deidentified images of a Stage 1 in knees, epidermal stripping to face, deep tissue injury to finger, Stage 1 a single knee, Stage 2 nose. Other semi-structured questions were developed to establish anatomical locations for injury observed in their clinical practice, considering contrast in locations identified in literature and documents. Also, clinicians' impressions of the role of GA, BW and medical devices as well insights for other risk factors were explored.

5.3 Phase 1, (Stage 2) interviews and focus groups

Data concerning clinicians' opinions, knowledge, perceptions and experiences about neonatal skin injuries, were collected through face-to-face semi-structured interviews and focus groups.[44,187,205,206] Establishing clinician application of nomenclature, injury reporting practices and familiarity with risk factors was important background for the prevalence study.

5.3.1 Reflexivity statement

While the advisory team comprised an appropriate mix of clinicians, academics whom had experience in appropriate methods; I was an employee at one of the sites where the interviews and focus groups took place. Therefore, to avoid potential bias at my site of employment, interviews and focus groups were facilitated by an external team member and experienced interviewer (EM). I conducted the interviews and focus groups for the remaining two sites.

5.3.2 Recruitment

Purposive sampling was used to recruit participants who were able to provide the necessary specific data. Signs were displayed in common staff areas and neonatal nurses, nursing managers, neonatologists, registrars, and nurse practitioners received an email invitation to participate that included participant information sheets and consent forms. Nursing and medical students, assistants in nursing, and non-clinical staff were excluded given the probable limited experience assessing skin injuries. Advertisements were displayed in the neonatal areas and no exclusion was provided for interdisciplinary team members; in that if any site could have included a tissue viability specialist as a key staff member. To minimise the potential for supervisors to influence responses, senior clinicians and managers participated in interviews or focus groups separate from employees and junior clinicans.[191] The participant information and consent form is provided for reference (Appendix 6).

5.3.3 Interview and focus group procedures

Interviews and focus groups were conducted across various periods throughout the day to capture a variety of clinicians from numerous shifts. All interviews and focus groups were conducted away from the clinical area, audio recorded and notes taken. At the commencement of each interview and focus groups the facilitator reminded participants that participation was voluntary and provided a brief introduction of topic context. Additionally, for the focus groups the need for discretion and confidentiality was agreed upon. Participants provided self-reported written demographic data at the commencement of the interview or focus group. During interviews and focus groups a series of six clinical images of neonatal skin injuries, collected during a previous pilot audit, were used to promote discussion (Appendix 7).

Interviews and focus groups continued at each site until no new themes emerged.[207] Notes taken were reviewed and audio-recordings listened to between sessions to gain understanding and context and culture for subsequent sessions. Audio-recordings were transcribed verbatim, with exception of potentially identifying information which was omitted, and assigned a set of letters or letters and numbers (for example Site B FgB or Site C Int1). Transcripts were uploaded to NVivo 11 data management software for coding, and theme development.

5.3.4 Data analysis

To gain further understanding all transcripts were read twice before initiating analysis.[208] Then transcripts were searched for (i) terms, (ii) locations, (iii) associated risks and (iv) mechanical forces using descriptive and selective coding.[44] Additionally, key themes which pertained to conducting the prevalence study were identified through thematic analysis.[209] An inductive analysis approach was taken, in that themes were linked to data themselves rather than a theoretical approrach.[209]

Initial analysis was conducted by me (DA); with review by one of the advisory team (RR or KN). Data analyses and sufficiency were further discussed with the entire team during monthly team meetings during the data collection and analysis period.

Data were analysed as site specific data and are reported as combined data.

5.3.5 Results interviews and focus groups

A total of 153 clinicians participated in one of, 20 individual interviews or 25 focus groups (with between 2-8 participants for each group). There were no refusals to participate, withdrawals, or repeat interviews. Mean duration of individual interviews (Int) was 29 minutes (range 13-53 minutes) and 32 minutes (range 23-63 minutes) for focus groups (Fg). Clinicians' participation from each of three sites was 31% or greater. The majority had five years or more neonatal experience and were predominantly female (n=129, 84.3%) with similar representation across age categories. Majority of clinicians identified as neonatal nurses 59.4% (n=91), with others selecting registrars/nurse practitioners 7.8% (n=12); clinical nurse educators and managers 7.8% (n=12); neonatologist/senior medical 7.2% (n=11), or other roles/not answered 17.8%(n=27) (Table 5.3). No adult or formally trained tissue viability specialist attended a session.

Table 5.3
Characteristics of interview and focus group participants.

Clinician population	**Participant proportion n, %**	**Years of Neonatal experience**	**Neonatal experience n, %**
Site 1 (N=115)	38, 33%	<4 years	56, 36.6%
Site 2 (N= 263)	82, 31%	5-10 years	42, 27.5%
Site 3 (N=55)	33, 60%	11+ years	50, 32.7%
Gender	**n,%**	**Age**	**n, %**
Female	129, 84.3%	21-29	40, 26.1%
Male	17, 11.1%	30-39	43, 28.1%
Not answered	7, 4.6%	40-49	30, 19.6%
		50+	40, 26.1%

Data from the interviews-and focus groups yielded content from the expected categories ((i) terms, (ii) locations, (iii) associated risks and (iv) and mechanical forces). Two additional themes which pertained to the prevalence study were identified; skin injuries are described but rarely defined and injury severity is familiar but not used. Quotations related to descriptive words and phrases (i-iii) and themes are provided in the subsequent sections and a detailed lists for terms, locations, and associated risks is presented in Table 5.4.

5.3.5.1 Terms

Clinicians described a skin injury, using singular words such as "trauma" to or phrases

"...anything that harms the integrity, whether it's a bruise, an abrasion… it would be caused through pressure" (Site A, Fg2),

"...any form of trauma to the skin" (Site C, IntC) and "anything that breaches the skin integrity" (Site B, Fg13).

Other clinicians were more descriptive;

"...redness on the skin" (Site A, Fg1) or

"...tear, A break, pressure, rubbing, a bruise, lots of things. redness, swelling, sore, painful" (Site B, Fg10).

Clinicians in one focus group articulated how describing injuries was particularly difficult.

"...because dermatology is so hard to [describe] … there are millions of different words that mean different things to different people. So, while the words can be quite hard, the picture's more helpful but often the picture's not as helpful as going to the baby itself." (Site B, Fg11)

A total of 38 terms were identified from questions related to describing an injury from mechanical force.

5.3.5.2 Locations

Anatomical features were most often described in combination with a description of injury or in related to a medical device.

"...red knees" (Site A, Fg1), "we see them at probe sites, often at Spo2 site [oxygen saturation site], feet – feet in particular "(Site C, IntB),
"It's often under a device or like from CPAP [continuous positive airway pressure device], behind their ears, the head" (Site C, IntC).

Clinicians also described injuries that were not present in the literature, documents or the NSQHS standards.

"...around the mouth, umbilicus" (Site C, FgE),

"...skin breakdown on the neck" (Site B, Int19)

"...anywhere and everywhere" (Site B, Fg1).

5.3.5.3 Associated risks

Associated risks factors identified by clinicians were so diverse that several subthemes were generated to understand the data. The sub themes that arose were (1) gestational age and size (2) influence of device and treatments, (3) hospitalisation, and (4) clinician experience and knowledge.

- Gestational age and size

When clinicians described commonalities for patients who were most likely to acquire injuries, responses were often linked to decreased gestational age or preterm birth.

"The skin of a neonate, particularly a very early preterm" [is a risk factor] (Site A, Fg11)

"...extreme premature, teeny tiny ones" (Site C, FgC).

Some responses included a detailed justification for this risk.

"...are unique because the physiology and anatomy of [preterm] skin is different to adults. So, they've not got that many layers to the protection to start with [using hand motions to illustrate thin layers]. So, you straight away think their injury, there's not as much as protection in the first place" (Site A, Fg2).

Most commonly clinicians responded with a word related to gestation or size (see Table 5.4). Yet, despite the focus on ELBW or preterm neonates there were also concerns about risks for older neonates

"The older kids that have had CPAP for [ages]... or ventilation of some description for a substantial amount of time and…Those chronic babies… and you get chronic babies,

you're seeing breakdowns occurring. You know, once they've got one, generally they're going to get another one" (Site B, Fg12).

- Influence of devices and treatments

Clinicians clearly identified the connection between devices or treatments and injuries. Also 38 devices or treatments related to acquisition of injuries are reported in Table 5.4.

> *"They won't get injuries if we don't do stuff to them, and they're probably a lot more prone sometimes than some adults would be, especially quite early on with their skins being really fragile" (Site B, Int5).*

> *"It wasn't particular devise but really anything attached to the neonate…anything that you've stuck on that baby always has a potential to provide a pressure area" (Site B, Fg16).*

Clinicians also described how even with the gentlest of care, devices could still cause injuries;

> *"The little mark on the abdomen; because the [temperature probe covers] are really sticky, and the really are a bit tricky to get off; and I think even using the swabs that we have to help, the anti-adhesive swabs, doesn't always seem to allow it to come off smoothly" (Site C, IntB).*

> *"Most of our neonatal things are actually device related. They're not position related and all that sort of thing. They're device related." (Site B, Fg15)*

- Hospitalisation, part of neonatal care

Whilst many clinicians talked about devices, others suggested injuries occurred because of needing neonatal care and hospitalisation.

> *"They won't get injuries if we don't do stuff to them." (Site B, Int5).*

Some clinicians suggested it wasn't the hospitalisation, but the length of care and related treatments that made some neonates susceptible to injury.

> *"Well, they are going to need a lot more intrusive therapies for a lot longer, so I guess they are a higher risk as well, for the length of time, like it might be two or three months that they are going to have the constant pressure, at some point 24/7 on their body." (Site C, FgA)*

Risk factors related to transient conditions ("hypothermia, "hypotension") or acuity ("sicker babies") were also identified. Comorbidities unique to the neonatal population such as "neurological" or "abstinence conditions" were reported, but infrequently.

> *"You find the injury in a patient who has been hypothermic or hypotensive for a long period of time, lying on one place and its right in the spot where that child lay". (Site A, IntC)*

Other clinicians reflected how skin injuries were once an expected complication but were now under scrutiny.

> *"You realize the damage that we used to just say was part and parcel of being in the NICU…. now it's how can we prevent that." (Site C, FgD).*

- Clinician experience and knowledge

One of the surprising themes was related to how clinicians' knowledge of neonatal care provision could contribute to prevention of or acquisition of injury. Clinicians recognised that activities increased the risk for injury:

> *"Damage from things like CPAP prongs or masks, the skin electrodes; there's been a couple that have been left on for too long and it's caused some damage". (Site A, Fg25)*

> *"...poor tape placement on a fingernail" (Site B, Fg16).*

> *Some reported that experience, knowledge and responsibility, contributed to injury risk:*

"Getting people to be fastidious about the positioning of [devices] is difficult. Until they've seen a bad one, they [the younger nurses] don't stay on top of it quite as well." (Site B, Int15).

"Yes, it does come down to the 'art of neonatal nursing'. I do recall when we introduced [a new type of] prongs …we had a lot of pressure injuries from the prongs until everyone learnt how to use them, how to place them to avoid the injuries- we had septal necrosis to the extent where they had to have plastic surgery which you very rarely see now … We see other injuries but I think it evolves around education and experience in how to do it – it's more a nursing thing than a medical thing." (Site C, FgA).

"Yeah, some more education would be useful. ..prior to neonatology, [skin injury] is covered really poorly in medical school. It's not something that we actually learn about terribly much. It's kind of considered a secret nurses' business." (Site B, Fg11)

"When we get really fresh registrars, they know nothing about anything [about neonates], and so often what you are trying to teach them is stuff like ventilation and how to make decisions about ventilation, and fluids and blood pressure management, I suppose it's something [the skin] that we forget about to a degree. (Site C, IntB).

Table 5.4

Terms, locations, and associated risks for neonatal skin injury.

Terms used to describe an injury
38 terms
Most common: (n=28)
pressure, redness; (n=20) break to integrity; (n=16) breakdown
Occasional: (n=10)
bruise; (n=8) stripping; (n=7) trauma, trauma, tear; (n=6) mark; (n=5) abrasion, ulceration; (n=4) graze, colour change; (n=3) blister, poor tape placement, sore, indentation, deterioration; (n=2) wound, cut, excoriation, rubbing, break, mechanical, breech
Infrequent: (n=1)
dent, removal, blemish, device related, peel, ripped, loss of skin, exudate, necrosis, shearing, scratch, friction, scar
Meaningful phases:
battle scars, adverse event
Locations of injuries
Face (Nose, Cheek)
Knees
Scrotum/buttock
Behind ear/ear
Skin folds
Limbs
Other (*neck, heel, ankle, lips, elbow, hands, chest, forehead skin folds*)
Associated Risks
Gestational age and size (*prematurity, 24 weeks, extreme premature, teeny tiny ones, small, bigger babies, plumper babies, big term babies, birth weight*)
Influence of a device/treatments (i.v, [nasal] *prongs, masks, suction, tape really tight, skin sticking to tape, any baby can be on CPAP or ventilation, stoma bags, ear muffs, nappy, velcro*)

KEY: Table legend: i.v.-intravenous cannula, CPAP-Continuous positive airway pressure

5.3.5.4 *Etiology- mechanical forces*

Clinicians discussed mechanical forces mostly when describing an injury or associated cause.

> *"...friction in area of nappy" (Site A, Int4),*

> *"...just a little pressure thing" (Site B, Fg12)*

> *"A pressure area is a result of pressure or not positioning correctly, a device: a drip or a cannula … a naso gastric tube, or CPAP." (Site C, FgA)*

> *"Even healthy babies will get friction, … there is a respiratory need to be in the unit, and obviously they have been nursed prone, then more likely this one here with a friction burn on the knees… that could happen to a 40+weeker." (Site C, FgB).*

Mechanical forces were mentioned together with other etiologies:

> *"...there is moisture and friction… " (Site A, Int4),*

> *"...it's a shearing sort of skin tear (Site B, Fg2)*

> *"...this one here with a friction burn on the knees" (Site C, FgB).*

Of note, besides pressure, the mechanical forces of stripping, friction and shear were mentioned on occasion; with tear being the common force used

> *"The smaller babies with the shiny, thinner, redder looking skin are the most prone to tearing." (Site A, Int29).*

Overall, a number of mechanical force terms were mentioned when describing an injury or associated cause such as "*grazing*", "*breaking*", "*taken-off*", "*rubbing*", "*scratching*", and "*blunt force*".

5.3.5.5 Skin injury descriptions

Additional key sub-themes were identified. The first was descriptions of skin injury. Like the document analysis findings, clinicians most often described skin injuries, but rarely defined them. Injury descriptions were most often singular words, such as those in Table 5.4 with only a few confidently providing comprehensive definitions:

> *"...anything that harms the integrity, whether it's a bruise, an abrasion… it would be caused through pressure" (Site A, Fg2).*

The second sub-theme noted descriptions of severity. Several clinicians alluded to understanding injury depth but rarely discussed severity or staging.

> *"...breakdown, broken, deteriorating" (Site A, Fg1)*

> *"It doesn't necessarily break the skin, it's tissue damage of some kind." (Site C, IntA)*

> *"...broken skin" (Site B, Fg8),*

> *"...a breach in skin surface" (Site B, Fg14) or*

> *"...loss of epithelium or layers" (Site C, IntB).*

Clinicians from two sites reported being aware of severity scales but did not use them for neonates.

> *"[why is the depth difficult] 'cause we can't accurately measure the depth [for neonates], depending on where the PI is, you can't look at it and go…. You can say the width appears to be this many cm but you can't just look at the wound and go, the is the depth". (Site A, Fg1)*

> *"Yeah, like that [a skin injury], it's graded from just redness to broken down…We don't really use grading here, and I can't remember it. I remember it exists from adults." (Site B, Fg10)*

Clinicians at one site appeared to be more familiar with assessing severity with subjectivity in the interpretation of results for the neonatal population.

> *"How much sloughy-ness is enough to make it a Stage four… especially when you are talking about babies that are this big [motions to show ELBW baby] it's completely different than looking at an old bird's elbow." (Site C, FgA)*

> *"I guess it's all about interpretation… I might think it's a Stage two and a more senior nurse might come along and say that's really just a Stage one- it's up to whatever nurse is interpreting it [a lot of agreement from rest of group]." (Site C, FgA)*

5.3.6 Implications for Phase 2, (Stage 1): required content for education

Results from the interviews and focus groups indicated three major inconsistences in site culture related to neonatal skin injuries: skin injury language, defining injuries and assessment of injury severity. These three findings needed to be addressed before moving onto the next phase (Phase 2, (Stage 1). Additionally, mechanical force injuries were not consistently described in Phase 1. To accommodate for a number of forces related to injury etiology and distinguish them from other etiologies such as burns, the period prevalence study outcome needed to be clearly defined. Therefore, skin injury was defined as an acquired skin injury from a single or combination of mechanical forces such as pressure, friction, shear, stripping and/or tear.

To further address the breath of language and lack of universal definition, which could have confounded eligibility criteria, two resources were developed. The first was a figure illustrating mechanical forces (Figure 3.1, first presented in Chapter 3). Figure 3.1 demonstrated the action of each force and of particular importance, the force 'tear' was reported as often as friction or shear during interview and focus groups and was therefore included in Phase 2 educational resources.

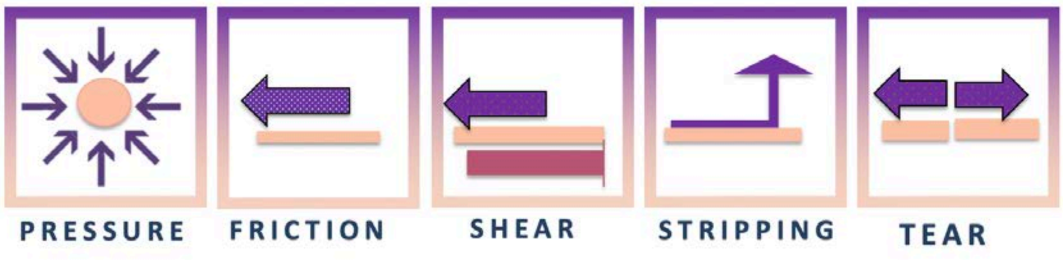

Figure 5.2 Five types of mechanical force and the direction(s) of the applied force.

The second resource was a skin injury severity staging and classification lanyard card, to address the inconsistency in injury assessment including severity. The two-sided pictorial palm and lanyard card was produced (Image 5.1) and provided to all clinicians at the three sites. The card contained definitions, and photographic examples of neonatal skin injuries to help contextualise and account for potential lack of experience. Staging and classifications for the card were modelled after the most common system identified in the background work (Chapter 3), the National Pressure Injury Advisory Panel (NPIAP) Stages[27] including Stages I-IV, deep tissue, unstageable injuries[27]. Additional classifications of epidermal stripping and skin tear injury definitions corresponded with work published prior to my PhD.[11,210] While these resources were developed by the PhD candidate and reviewed by the advisory team comprising of neonatal experts; they were endorsed by one of the adult tissue viability teams at one of the sites.

Image 5.1 Skin injury severity and classification staging cards for visual skin assessment.

Lastly to improve data collection for the period prevalence Phase 2, (Stage 1) and minimise inconsistences, an education session incorporating a summary of the background knowledge, the definition of mechanical force injuries, eligibility criteria neonatal skin injury classifications and staging was developed as a *PowerPoint* presentation. One of the key education messages was that skin injuries should be identified based on classic categorisation (see epidermal stripping: skin tear and stripping Image 5.1), but would be investigated concurrently to appreciate the overall risk, prevalence and relationship of skin injuries from mechanical force for the neonatal population. This 15-minute presentation also provided step-by-step instructions for data input (described in Chapter 6). Education sessions were provided for both nursing and medical clinicians at the start of each site roll out. A copy of the presentation with voice over instruction, was placed on all site computers as a resource for clinicians who could not attend an education session and-as a refresher. A condensed form of the presentation was placed on all data collection trolleys as a step-by-step guide (Images 5.2 a and b).

A **B**

Image 5.2 A and B: Data collection trolleys with resources and step-by-step instruction guides.

5.4 Summary

The combined data from document analysis, interviews and focus groups, demonstrated a culture of transparency and responsibility for skin injuries, while indicating a need for education sessions to strengthen the data collection in the next phase. It became evident that further methods were required to ensure that injury assessment and reporting was optimally consistent and that injury assessments could be validated.

Chapter 6 Development, Evaluation and Testing Tools for Neonatal Skin Injury Assessment

The previous chapters demonstrated that skin assessment is based on subjective visual observation, with specific attention to colour and texture. The reliability of this method is questionable due to the challenges of reproducing or confirming findings. In addition, site documents and clinician experience from Phase 1 indicated injuries were more often reported descriptively without well-defined nomenclature. Therefore, to validate the data generated by the forthcoming period prevalence study, a method of confirming clinician reported injuries was required. This chapter describes the evaluation of adjunct tools for visual assessment, including the feasibility of specialised wound cameras[211,212], mobile and device applications, and clinical image reference tools to capture a visual data source of skin injuries.

6.1 Clinical images, wound cameras, mobile and device applications

At the time of the PhD, specialised wound cameras had become increasingly popular to identify skin injuries within adult populations but applicably to neonatal setting was unclear.[211,212] Additionally, evolving technology has led to the development of applications which use mobile phone or device cameras which could be used to capture clinical images. Therefore, I sought to explore the feasibility of specialised wound cameras and device applications for neonatal skin injuries.[211,212] Of note, the use of applications as well as cameras, meant that results were possible in printed photographs,[213,214]digital images,[215] or both. For simplicity, the term clinical image is used to pertain to any outcome as they both refer to images from the hospital or health care setting.[216]

6.1.1 Identifying suitable tools

The World Wide Web was searched for commercially available cameras, devices or applications for assessing and photographing skin injuries. Additionally, data bases such as Ovid and PubMed, were searched for peer-reviewed papers. Industry contacts were contacted related to camera, device or application intention and functionality. Upon identification, considerations for each included the costs, related software and running expenses, and the output such as digital image or photographic print. Specific evaluation of each camera, device or application also focused on operator comfort, ease of use, infection control risks, maintenance, steps required to obtain image, and clarity of images when used for small wounds or injuries, as well as feasibility for the neonatal setting. Image 6.1 and Table 6.1 provide details on each of the technologies available in Australia.

A search of the peer-reviewed literature identified two cameras,[212,217] and one device[211] with two technologies identified from web searches, a commercial wound camera (WoundZOOM) and an Apple operating system application (WoundMap by MobileHealthWare). Cost of the various devices ranged from $45-$8,500, with prices often exclusive of necessary software. While the Handyscope Silhouette STAR, and Eykona Wound Measurement had been evaluated in clinical practice all images were of adult injuries or wounds[211,212,217], and no comparisons were reported.

Handyscope (Source: Borve, A. et al. (2015)[211])

Silhouette STAR (Source: Kieser and Hammond (2011)[217])

WoundZOOM (Product Manufacter image)

Eykona Wound Measurement (Source: Bowling et al. (2009)[212]

WoundMap (Product Manufacter image)

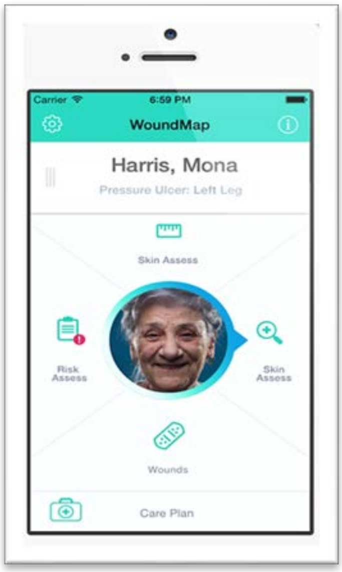

Image 6.1 Wound cameras, mobile and device applications.

The first step in evaluating the devices for use in the neonatal setting was assessed for infection control considerations. At this stage the Handyscope was excluded due to concerns for infection control as the lens was required to have contact with the skin. The remaining devices did not present infection control concerns and thus were further evaluated. The

Silhouette STAR and Eykona Wound Measurement were observed being used in adult healthcare provision, with the WoundZOOM evaluated over video link as a loan camera was unavailable in Australia. Elements of the evaluation included: operator comfort, feasibility of camera maintenance, and the number of steps required obtain images. It was observed that image capturing often took longer than the time suggested by manufactures for specialised wound cameras. Additionally, many of the devices were not validated for the expected size of neonatal injuries (<1cm) or had other limitations such as the device specific sensor being larger than the expected images (Eykona Wound Measurement). However, the WoundMap application seemed promising and to offer the most beneficial features by comparison.

6.1.2 Selection of the WoundMap application

The WoundMap application was selected for its enhanced flexibility with data entry and capture and user familiarity (see Home Screen Image 6.2). The additional benefits of the WoundMap application were: short cuts to image collection, the software was more intuitive for clinicians including icons and words to guide users through steps of data entry.[218] WoundMap~~,~~ allowed for data input including assessment detail and image(s) of the injury in as little as three minutes.[218] Data input for assessment criteria were available in a combination of drop-down menus or free text boxes such as patient identifier, anatomical location, and injury classification. Injury classification options within the application were 'pressure injury' or 11 additional pre-programed classifications such as 'trauma' or 'abrasion'. On selection of 'pressure injury', a further menu opened prompting selection of injury stages (NPIAP Stages)[5]. The application software also included the capability to generate a password protected PDF file, containing the entered identifiers, assessment criteria, and injury images which could be sent over email or protected storage and backup safeguarding confidentiality of the data.

However, one of the limitations for the application, was that it was only available on Apple Operating system (iOS). At the time this PhD research was undertaken, the iPad mini 4 was the most up to date cost efficient device, with internal camera specifications including a 32 mm, point and shoot camera design, focal length f/2.4, 3264-by-2448 resolution and 8-megapixel sensor. In consultation with a clinical photographer, it was confirmed that these were appropriate specifications for the required data collection; with the additional consideration that the total cost for the application and three iPads was equivalent to one of the other wound cameras.

The use of the WoundMap application seemed to resolve many of the perceived challenges. The application allowed some flexibility of data input within assessment criteria, enabling clinicians to report skin injuries using common terms and descriptive nomenclature. In addition, the application had room within some of the identifiers to incorporate reporting of multiple risk factors. Importantly, clinical images with corresponding descriptions of assessment could be saved within this application.

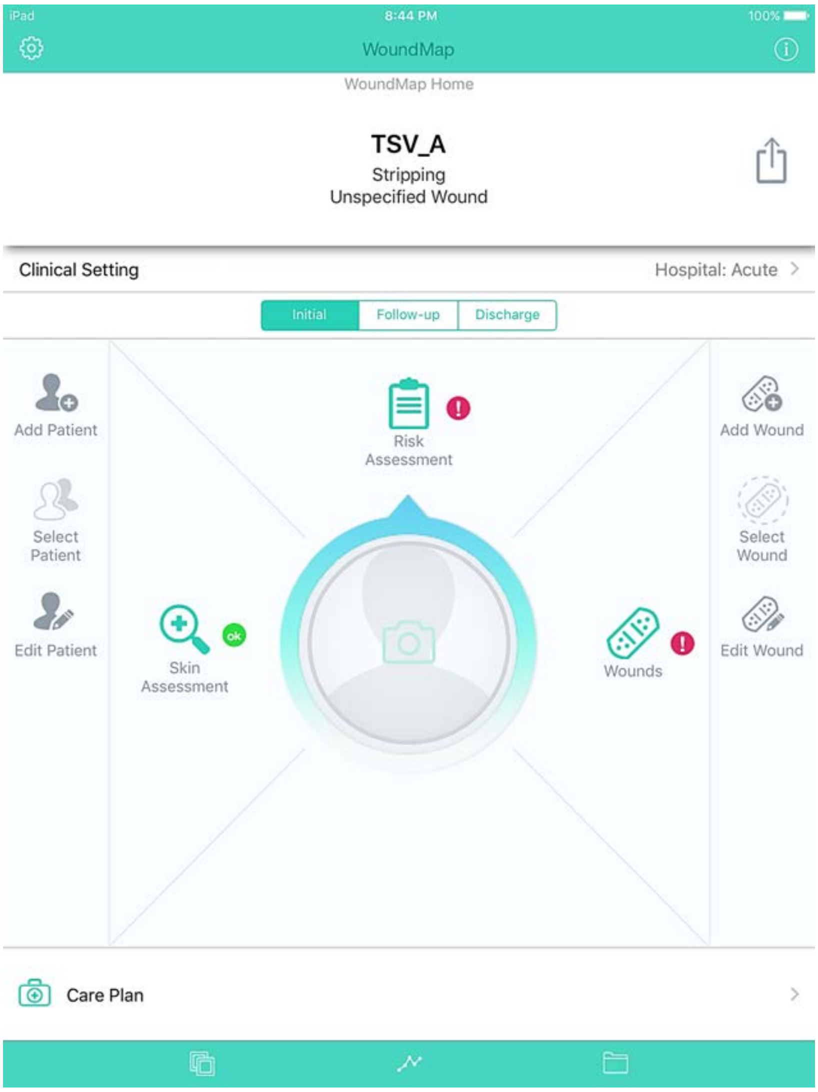

Image 6.2 WoundMap application home screen.

Table 6.1
Wound camera, device or application appropriateness for neonatal skin injuries.

Camera or Application	Publication, cost, and steps to image collection		Advantages	Limitations
Handyscope	**Publication**	Borve, A. et al. (2015)[211]	Lens that attaches to iPhone, uses iPhone camera, within built storage, programming	Images view zoomed in, will not capture perfusion of surrounding area or limb Lens needs contact with skin, risk for infection for patients
	Cost	$943 USD		
	Steps	*Excluded before assessed*		
Silhouette STAR	**Publication**	Kieser and Hammond (2011)[217]	Inbuilt image validity (manufacture stipulation) 5 laser lights focused meet to form star shape Measure wounds as small as 2cm	In demonstration camera stalled Above average computer knowledge needed to enter data before taking image Separate software package must be purchased for each camera Must be connected to laptop to take Image No guidance appropriate wound size measurement
	Cost	$6,500 + software AUD		
	Steps	3 screens		

Camera or Application	Publication, cost, and steps to image collection		Advantages	Limitations
WoundZOOM	**Publication**	None at time of assessment	Inbuilt image validity (manufacture stipulation) 4 laser dots frame injury, camera is in focus when dots still Optional zoom and megapixels Stores 9000 photos Size of large mobile phone Self-contained device, does not use laptop/computer to capture image	Demonstration conducted by video link on manikin One year warranty Supplier overseas (USA), for maintenance, or problems must be sent overseas No guidance appropriate wound size measurement
	Cost	$2295.00 per camera + $2065.50 software AUD		
	Steps	2 screens		
Eykona Wound Measurement	**Publication**	Bowling et al. (2009)[212]	Inbuilt image validity (manufacture stipulation) Device specific reference sensor placed next to injury/wound	Reference sensor (5cmx5cm) Demonstration identified that two people needed to secure image Not able to view image at time taken to verify clear No guidance appropriate wound size measurement
	Cost	$8,500 AUD		
	Steps	2-3 screens		

Camera or Application	Publication, cost, and steps to image collection		Advantages	Limitations
WoundMap	**Publication**	None at time of assessment	Inbuilt image validity (manufacture stipulation) Adjustable measuring scale that can be aligned with a physical tape measure in pre-image screen Uses iPhone camera, storage, and programming Designed for images collection by patients and sent to their health care providers Application protected by password on login, for confidentially	Requires Apple/ iTunes interface Limited current clinical evidence Demonstration resulted in image collection for area <0.5cm for wound measurement
	Cost	$45 AUD application + iPad/iPhone approx. $600)		
	Steps	3 screens		

KEY: USD- United States Dollar, AUD- Australian Dollar

6.2 Metric, graduated colour tool

One of the greatest limitations of visual assessment is the potential for inconstancy of colour assessment and interpretation of colour. In addition, there are particular challenges with clinical photography of neonates including: depth of field (image sharpness), the restrictive incubator environment, incubator humidification, as well as the size and depth of neonatal skin injuries. I envisaged that a graduated colour tape measure (also known as the metric graduated colour (MGC) tool) could address these challenges. The MGC tool would provide both metric and colour constants to assist with corroboration of assessments and images, as well as provide a focus point for the camera. Thus, in collaboration with a clinical photographer I sought to develop and evaluate a tool. This work was the last of my preparatory work before initiating Phase 2 of the research. The result of this collaborative work was published in the Journal of Tissue Viability, accompanied by a case series to demonstrate the use of the MGC tool. *Based on terminology used in general photography and the publishers' specifications the terms photograph and photography, due to the origin of the "photographic reference", "photographic standard" are used, as these are a specific outcome generated by a trained clinical photographer. This terminology is referring to a clinical image. The original article's list of references has been cross-referenced to the thesis reference list for continuity.

6.3 Article: Graduated colour tape measure: Development and demonstration of this tool in a case series of neonatal skin injuries

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Abstract

Aim: This study proposed to (1) develop a metric graduated colour tool and (2) demonstrate the effectiveness of the tool for use in the assessment of neonatal skin injuries.

Materials/Methods: Findings from wound literature informed the metric graduated colour

tool's development. Tool development included consideration of colours, size (comparative to neonatal skin injuries), cost, materials, feasibility and suitability for the neonatal clinical setting. Assessment of the tool's applicability with clinical images was then tested using digital cameras with specific evaluation of image sharpness and colour. Further evaluation was conducted within a case series of neonatal skin injuries.

Results: The metric graduated colour tool comprised of 15 colours, measures 60 mm (2.36in), displays metric dimensions, and offers a discernible reference for clinical images and injury/wound bed comparison. Images collected appeared enhanced with clear wound edges compared to previous methods. Four neonates who acquired skin injuries were included in the case series for which the tool provided reliable metric and colour comparison of epidermal stripping, extravasation, birth injury, and pressure injury. When used to compare injury assessments for series subjects, measurements of both increased and decreased severity were obtained.

Conclusion: A metric and colour tool can be used in conjunction with digital photographs to enhance objective assessment of neonatal skin injuries/wounds. The MGC tool provides the foundation for vital skin injury assessment and documentation essentials including injury bed colour, size and consideration of depth of damage.

Background

Neonatal skin injuries are increasingly recognized as they feature in the most common complications for hospitalized neonates.[48,150] Yet, it remains difficult to assess injury severity (specifically depth) with the naked eye given that neonatal skin tissue thickness is between 0.9 and 1.2 mm at birth and tissue depth becomes thinner with descending gestational age.[11,64] The frequency of neonatal skin injury is currently estimated between 9.25 and 43.1%, representing one-third to one quarter of the hospitalized neonatal population.[11] Distinctions between broken and unbroken neonatal skin for those born prematurely, may involve only a few millimetres of skin tissue. In addition consistency of neonatal skin injury assessments between clinicians is often difficult.[196] Thus objective assessments of neonatal skin injuries present challenges considering injury size in conjunction with a gap for neonatal assessment standardization[11]. The Australian Commission for Safety and Quality in Health Care has directed the reduction of hospital acquired complications prioritizing specifically skin injuries[13]; further creating the need for feasible, clinician-friendly, and neonatal specific tools to improve skin injury assessment and comparison.

Within the context of previous adult and paediatric studies, the presence or absence of skin injury is established by a change in skin colour.[215] The assessment of colours within wound beds is a universally accepted practice, which assists clinicians to describe and evaluate the phase of wound healing.[16] For example, the reddening of the skin is associated with erythema or vascular tissue, yellow indicates the presence of slough and infected tissue, and black suggests necrosis or dead tissue.[16,219] Similar colour assessments are assumed for neonatal wound healing and may be observed in clinical practice. However, neonatal skin colour and tone changes dramatically in the first few weeks of life, from a generalised red colour indicative of polycythaemia, to a yellow-golden hue symptomatic of jaundice, further complicating objective assessment.[220-222] These changes in colour and tone can occur within days and so comparisons of the injury/wound bed to surrounding skin are more difficult. Therefore, we propose that a graduated colour tape measure (also known as a colour reference tool) would enhance objective wound bed colour assessment.

Digital images have been used to capture injuries/wounds in the adult population for many years, however is a relatively new application for the neonatal population. This research team previously investigated four commercial 'wound' cameras marketed in Australia, against an application available for iPads/iPhones. In short, the trial found the iPad/iPhone application was the most intuitive and provided the sharpest images of neonatal injuries/wounds (unpublished data).

The use of digital images of skin injuries/wounds enriches descriptions and enable more objective assessment of adult skin injuries.[213-215,223] The identification, assessment and healing for adult melanomas and diabetic foot ulcers have been improved by adjunct clinical imagery within wound treatment practices.[211,212] Furthermore, clinical images have been used to test comparison and agreement of skin injury types and stages in a number of studies.[196,224] The popularity of clinical images continues to increase within the Australian HealthCare context, to the extent that the Australian Medical Association and the Medical Indemnity Industry released a guideline for clinicians for the collection of clinical images.[216]

Ideally images for the clinical setting should utilize a photographic reference tool to provide metric comparison, improve image focus and allow for future colour correction of images.[223] Reference tools described in the literature pertain primarily to adults. 'ColorChecker' charts, a photographic industry standard, have also been used as references and calibration targets for images taken under various lighting conditions.[225] Charts generally consist of 24 colour squares, representing colours from natural objects such as human skin or flowers. Whilst reference tools are commonly used in the adult population injury/wound assessments and clinical photography, the use in the neonatal population is limited (Table 6.2).

Challenges for neonatal clinical photography include varied aperture of cameras, depth of field (image sharpness), the restrictive incubator environment, incubator humidification, as well as the size and depth of neonatal skin injuries. Additionally, ambient lighting is recommended in the neonatal environment to protect neonatal development, therefore achieving ideal photographic lighting can be difficult.[226] Thus, clinical images taken in the neonatal environment are likely to need colour correction to compensate for poor photographic conditions. Colour correction involves using white areas on a reference tool to determine if lighting conditions have tainted the overall image tone. If image tone is affected, media or image software (e.g., Adobe Photoshop) can be used to correct for white balance.

Table 6.2
Injury wound assessment tool and colour comparison charts.

Common references in adult clinical photography	• Patient identification labels[213] • Standard or commercial tape measures[224] • Colour references[223,227]
Colour scales in adult reference tools	• Standard black and white[224] • Shades of grey[227] • Red, yellow and black (to demonstrate wound stages such as graduation, slough, necrosis, etc.)[223]
Staging reference tools for adult skin injuries	• Reference tool with staging examples • Metric indicators for size • Improved assessments by non-expert wound care nurses[228,229]
Wound Camera references for adult skin injuries	• Optical target for the 3D measurements of ulcers[212]

ColorChecker charts	• Comparison of overall skin health based on colour[230]
	    • Appearance of skin colour affects the perception of overall health
	• Animals photographed in uncontrolled lighting[231]
	    • Improved clarity of images, validated and strengthened colour assessments

Application of reference tools or clinical images for neonates	• Shades of red provided frame of reference[145] • Tool assisted in assessment of erythema indicating nappy dermatitis and epidermal stripping • Endoscopic images of intra-nasal complications related to continuous positive airway devices[157]

In a pilot study undertaken by this research team, a standard black and white hospital tape measure was used to provide metric reference within neonatal skin injury photos. Many of photos were poor quality and colour differentiation making injuries difficult to visualize and compare colours, thus posing issues when trying to classifying injuries. Additionally, the tape measure made of thin paper, was challenging to keep in place near the injury making injury size assessment difficult (see Image 6.3) In consultation with the hospital clinical photographer it was determined that the clarity of images was affected due to the size of the injuries coupled with the focal length of the camera which was ill-suited for small object photography (known as macro photography).

Image 6.3 Standard clinical image of Stage 1 injury to dorsum of right foot.

The research team hypothesized that a metric graduated colour (MGC) tool positioned near the injury would provide a colour reference for the injury bed, assist with image clarity, and allow for colour correction. Additionally, the MGC tool could improve objectivity for initial and repeated assessments of neonatal skin injuries. To the best of our knowledge neither metric nor colour reference tool has been used for assessments of neonatal skin injury. This paper describes the development and testing of the MGC tool in digital images in conjunction with a case series of neonatal skin injuries.

Materials and methods

Tool development

Tool development included consideration of colours, size (comparative to neonatal skin injuries), cost, materials, feasibility and suitability for the neonatal clinical setting. The tool needed to be produced on a material that was moisture resistant, stable, and cost efficient for single patient use. A variety of materials were considered with the chosen material having a lightly adhesive underside, similar to industrial labels. Colours were chosen to represent photographic standards, wound and skin injury phases, dark and pale skin tones and colour changes specific to the neonatal population (polycythaemia and jaundice). Whilst the colour orange is not apparent in injury beds, it was chosen to provide contrast between red and brown colours. In total 15 colours were selected, each colour representing a photographic reference and multiple types of skin injury/wound tissue (Table 6.3).

Table 6.3
Colour selection and references for the MGC tool.

White	Standard photographic reference Macerated tissue[11] Avascular tissue[11]	**Fuchsia**	Polycythaemia, "plethora" Erythema (blachable and non-blachable)[27]
Black	Standard photographic reference Tissue necrosis[16] Unstagable injuries[27]	**Red**	Erythema (blachable and non-blachable)[27] Bleeding tissue[16] Hypergranulation[16] Pheomelanins pigments[61]
Peach and Blush	Skin tone (dependant on melanin content)[61]	**Tan**	Skin tone (dependant on melanin content)[61] Scab/eschar[61]
Pink	Skin colour (dependant on melanin content)[61] Granulation tissue[16] Epithelisation[16]	**Brown**	Skin colour (dependant on melanin: eumelanin pigments)[61] Scab/eschar
Yellow	Jaundice[222] Slough[16] Blistered tissue Pheomelanins pigments (melanin content)[61]	**Chocolate**	Skin colour (dependant on melanin: eumelanin pigments)[16]
Mustard	Jaundice[222] Slough[16]	**Violet**	Haematoma Deep Tissue Injury[27]
Orange	Contrast between red and brown (photographic reference)	**Purple**	Haematoma Deep Tissue Injury[214]

After selection the colours were validated using an industry gold standard Pantone ColorChecker chart (Datacolour SpyderCHECKER24, 2015). The chart is approximately 8.26in x 10.6in and therefore could not be used in neonatal skin injury images due to the relative size of both the neonate and the injury. This resulted in the production of swatches of each of the 15 selected colours. These were then validated against the ColorChecker chart before each of 14 colours were resized onto a white background (total of 15 colours) producing an MGC tool measuring 60mm long, the width of each colour band being 4.2 mm. Additionally, the MGC tool is marked at graded intervals increasing by 1 mm, to a total of 60mm (6 cm) (Image 6.4). This size allows the MGC tool to be included in images alongside the injury/wound to provide a metric and colour assessment reference without overshadowing injuries.

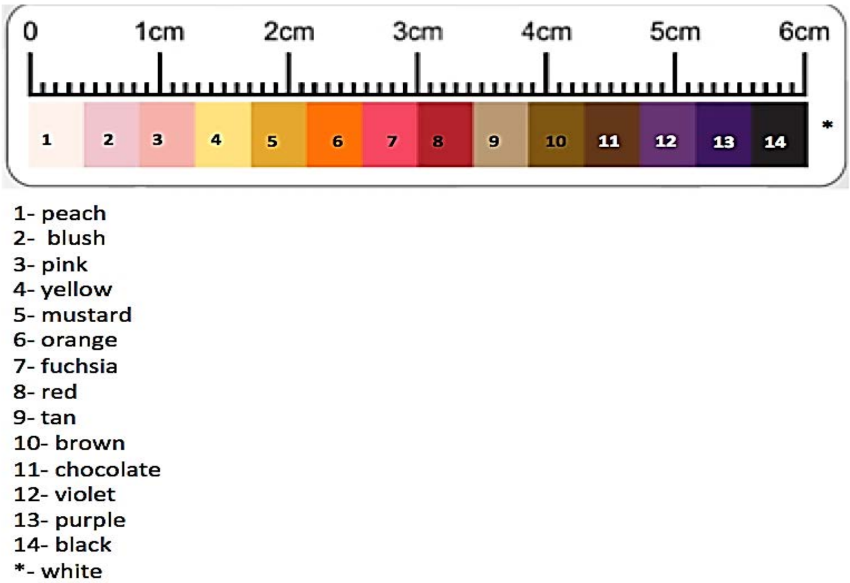

Image 6.4 MGC tool colour spectrum.

Case study methods

A series of participants with skin injuries from the Neonatal skin Injury and Pressure Injury Assessment (NIPIRA) study are presented to demonstrate the performance and feasibility of the MGC tool using an iPad camera. Ethics approval was obtained for the NIPIRA study from the Townsville Health District (HREC/13/QTHS/212), the Southern Dunedin Health Board (H16/099) and James Cook University (H6400). Parental consent was obtained for all neonatal skin injury images.

Results

MGC tool performance and feasibility

Prior to pilots with neonates, images of the MGC tool were shot under different lighting conditions to assess the clarity of the colour spectrum and metric aspect of the tool. Test images were shot in natural light, artificial light (night and day), and around the context of an incubator. The MGC tool was found to be an appropriate length and width and could be placed in the image field without overshadowing the proportionally smaller objects. The MGC tool performed well within the confined space of incubators and when examining the minimum and maximum distances from a target (injury/wound), provided clear images and allowed visualisation of the whole tool. Image 6.5 demonstrates a distance test. The MGC tool provided a focal point reference for images to be taken at a minimum distance of 10 cm and a maximum distance delineated by the incubator walls (approximately 25–35 cm) (Image 6.5). In keeping the entire tool in view this provided guidance to clinicians for the minimum distance 10 cm required to obtain clear images. The tool provided a robust reference for colour correction for images taken in dark lighting or that have an un-natural tint. The white content on the tool allowed the white balance to be corrected to bring the image to a normal tone through image software (Adobe Photoshop).

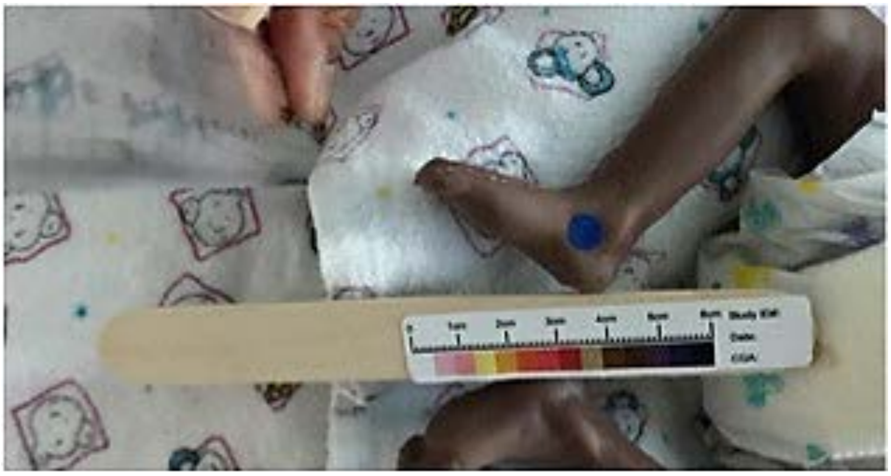

Image 6.5Minimum distance test within incubator, neonatal unit natural light.

Each MGC tool was produced for between $0.17–0.35 AUD (($0.09–0.19 GPP) volume dependent) making the tool cost efficient and feasible for single patient use. Additionally, the material selected was found to be stable for clinical image collection and the adhesive component provided additional benefits with the tool remaining in a fixed position or secured to another device alongside the injury/wound area.

Case series

Four neonates enrolled in the NIPIRA study, who sustained skin injuries are presented in the following case study to demonstrate how the tool provides reference for assessment of both injury/wound bed colour and measurement (Table 6.4).

Table 6.4

Neonatal skin injury cases and consecutive assessments using the MGC tool.

Case A- **Epidermal stripping**[30]	**Case B-** **Extravasation injury**[232]	**Case C-** **Birth injury/trauma**[61]	**Case D-** **Pressure injury**[27]
Male Birth gestation 25+0/40 weeks Birth weight 820 g Out-born, retrieved at 3 hours of age	Male Birth gestation 32+1/40 weeks Birth weight 2735 g Inborn	Male Birth gestation 24+5/40 weeks Birth weight 745g Inborn	Male Birth gestation 25+4/40 weeks Birth weight 750 g Inborn
Day 1 at time of injury	Day 3 at time of injury	Day 1 at time of injury	Day 16 at time of injury
Injury related to securement of vascular lines for retrieval with acrylate tape. Tape was NOT placed directly on skin, inadvertent attachment during retrieval.	Injury related to parenteral nutrition and intra lipids peripherally infused for 8 hours 55 minutes.	Injury of uncertain origin, likely birth injury, apparent immediately after birth.	Injury to bridge of nose related to positive pressure airway mask. Alternation between mask and prongs practiced before presentation.
<u>Management</u> Multidisciplinary review and ongoing follow-up. No specific dressings and wound management actions.	<u>Management</u> Elevation of limb, multidisciplinary review and ongoing follow-up. No treatment or injections around site.	<u>Management</u> Dressed with a silicone contact layer alternating with silicone foam. Multidisciplinary review and ongoing follow-up.	<u>Management</u> Alternation continued, mask time shortened. Multidisciplinary review and ongoing follow-up.
<u>Initial Assessment</u> Injury bed – 'pink' erythema compared to 'blush' skin colour	<u>Initial Assessment</u> 'Black' necrotic area (3mm^2) over injury bed – Stage IV extravasation. Surrounding skin 'fuchsia' – 'red' demonstrating inflammation and secondary tracking of erythema	<u>Initial Assessment</u> 'Violet' center 1.5mm^2 indicative of deep tissue injury from mechanical force injury, surrounded by 'red' suggesting erythema against a 'fuchsia' skin colour known as plethora	<u>Initial Assessment</u> Thin 'red' line, non-blanchable, 1mm wide, Stage1 compared to 'yellow' skin colour suggesting jaundice

Consecutive assessments D 3-Injury bed 'fuchsia', dry, no slough, (partial thickness injury) D 7-Injury bed 'pink', early epithelisation D 9- 'Pink', epithelisation with 'tan' and 'brown' eschar and generalised jaundice	Consecutive assessments D 11- Injury bed 'fuchsia' representing granulation and epithelisation D 19- 'pink' epithelisation, 'tan' eschar covering injury bed	Consecutive assessments D11- 'fuchsia-red' identifying granulation and 'mustard' and 'tan' eschar and thin slough	Consecutive assessments D 18- 'blush' injury bed, widened to 2-3mm, Stage 2 D 21- 'fuchsia' injury bed, 2mm wide, representing granulation in healing Stage 2
Outcome D 21 injury bed same as surrounding skin colour.	Outcome D 27 injury bed same as surrounding skin colour, no scar tissue evident.	Outcome 19 weeks, keloid scarring present.	Outcome D 37 injury bed same as surrounding skin colour.

KEY: D-Day

In the comparison of assessments, the tool assisted clinicians to detect that injuries/wound severity had increased in two of the cases (Cases A and D). Additionally, the MGC tool does provide metric reference for sizing, allowing for a more objective assessment of injury measurement changes (Case D). The MGC tool did provided a reference point that enhanced skin injury/wound assessment when zooming into digital images as it provided reference perspective for the size of an injury area in relation to the anatomical area demonstrated by Case C, Images 6.6 a and b. Lastly, colour correction for white balance was feasible for images taken with the MGC tool Images.

A B

Image 6.6 Zooming capacity of MGC tool for Case C in night time artificial light A (no zoom) and B (zoom).

A B

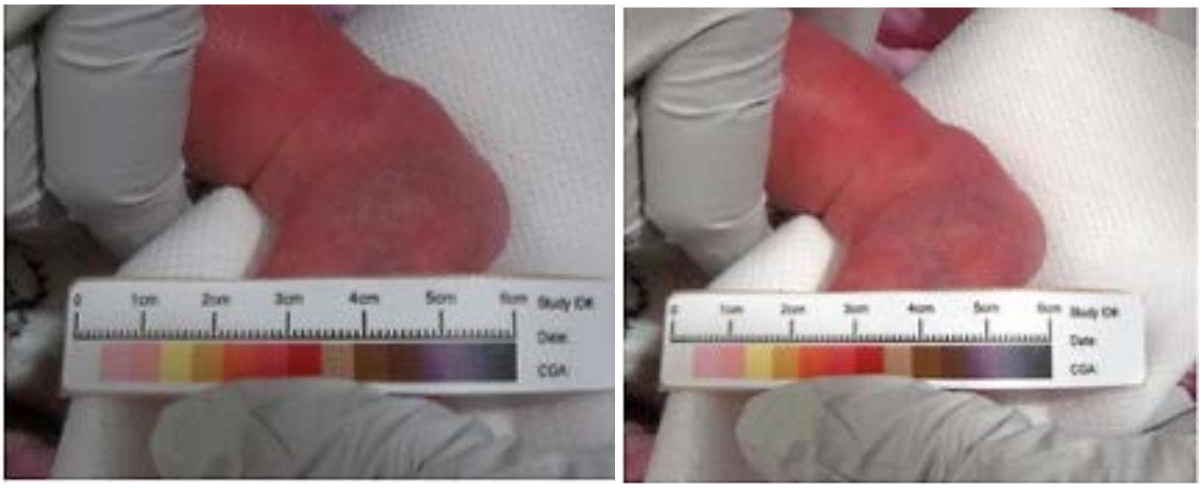

Image 6.7 A and B colour correction for white balance in Adobe Photoshop (version CS6) of haematoma below ankle.

Discussion

Results from this pilot study demonstrate the successful development of the MGC tool for use in the assessment of neonatal skin injuries/wounds and its contribution to enhancing digital images of these injuries. One-third to one-quarter of hospitalized neonates are at high risk of skin injuries often associated with medical devices making it impractical to leave such assessments for dermatological or wound experts. Thus, there is need for valid and available assessment tools for neonatal clinicians to improve injury identification, consecutive assessments, injury staging and healing phases.

The MGC tool shows promise in the assessment and photographing of neonatal skin injuries in this case series. The colour spectrum gave clinicians specific colour references to describe injury/wound beds and surrounding skin, which provides consistency in consecutive descriptions for changes to injury depth and colour. If clear images can be taken by clinicians, then identification, assessment and classification could be retrospectively reviewed by experts when deemed necessary; a process shown to improve melanomas detection and referrals in the adult population[211]. This process could then improve the reporting of neonatal skin injury frequency, size, epidemiologic data and injury-bed progression or healing.

High-quality skin injury/wound images are becoming an adjunct expectation of effective clinical assessments.[213] Additionally, field experts suggest measurement of injury/wound healing is essential such that quantification (size and depth) is free of observer bias.[212] Skin injury/wound photography is a rapidly emerging field, and this evolving technology is currently uncommon within the neonatal specialty. The MGC tool is a simple and cheap instrument, that facilitates capturing clinical photographs on the initial assessment of an injury/wound, overcoming potential delays waiting for a clinical photographer, and minimizing specific lighting or complex distance parameters for image collection. The MGC tool provides a consistent reference allowing for comparison of skin injury images from various facilities facilitating benchmarking.

The use of the MGC tool within neonatal skin injury images has been nested within a large multicentre study in which over 300 images have been collected. These images and the MGC tool are under further evaluation for applicability of colour correction, colour referencing and sizing for injury/wound beds. Thus, the MGC tool may have the potential to enhance clinical assessments of other neonatal skin conditions such as neonatal haemangiomas, surgical wounds and intrapartum or postpartum skin complications.

Limitations

The case series utilized 10 colors contained in the MGC tool, however the four remaining colours while not found in this case study, are likely to be helpful for neonatal skin assessments. Two of the colours (orange and white) are not expected to be seen for skin assessments and two colours (brown and chocolate) were not evident based on the participants due to lighter skin tones. It should be noted that the images with the MGC tool outlined in this paper have been captured with an iPad/iPhone camera and the findings regarding minimum and maximum distances and clarity are currently unknown with the use of other digital devices. It is plausible that injury images gained with the MGC tool taken with other digital devices, could allow neonatal clinicians and researchers to more efficiently describe and classify neonatal skin injuries, enabling objective comparison of injuries.

Conclusions

A metric and colour tool can be used in conjunction with digital photographs to enhance objective assessment of neonatal skin injuries/wounds. The MGC tool provides the foundation for vital skin injury assessment and documentation essentials including injury bed colour, size and consideration of depth of damage. There is an increasing expectation to provide clinical photographs as an adjunct to documentation for adult skin injuries and this should be the same for the neonatal population.

Disclosure and conflict of interest

We have no conflicts of interests to declare. Deanne August has a registered patent (2017904788 and 2019900648) for the metric graduated colour (MGC) tool relating to assessment and measurement in human skin and tissue. Support was received in part by the Mona Kendall Nursing Development Association through a research grant and by an Early Career Research Scholarship from Parker HealthCare and the Australian College of Neonatal Nurses. The funders have no role in the development of the tool, camera selection, decision to publish or preparation of the article. All images have been taken with parental consent for publication and taken under the standard hospital image collection policy.

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6.4 Summary

The feasibility of wound cameras, applications and devices, and development of the MGC tool were important steps to facilitate accurate data collection for Phase 2. The WoundMap application in particular allowed clinicians to report injury assessments in real-time, through uniform language and free text assessments, as well as supplementary clinical image collection.

Chapter 7 Multicentre Skin Injury Prevalence and Specialist Assessments

The preparatory work for the period prevalence study, as described in Chapters 5 and 6 provided the foundation for Phase 2 (Stage 1 and 2). The period prevalence study (Stage 1), including the educational components, were implemented across the sites in a staggered manner. This chapter reports skin injury frequency, severity, location, and potential extrinsic and intrinsic risk factors including antenatal steroid administration and medical devices. Data collection also included clinical images of injuries which were utilised to investigate consistency of adult and neonatal specialist assessments (Stage 2) (Figure 7.1).

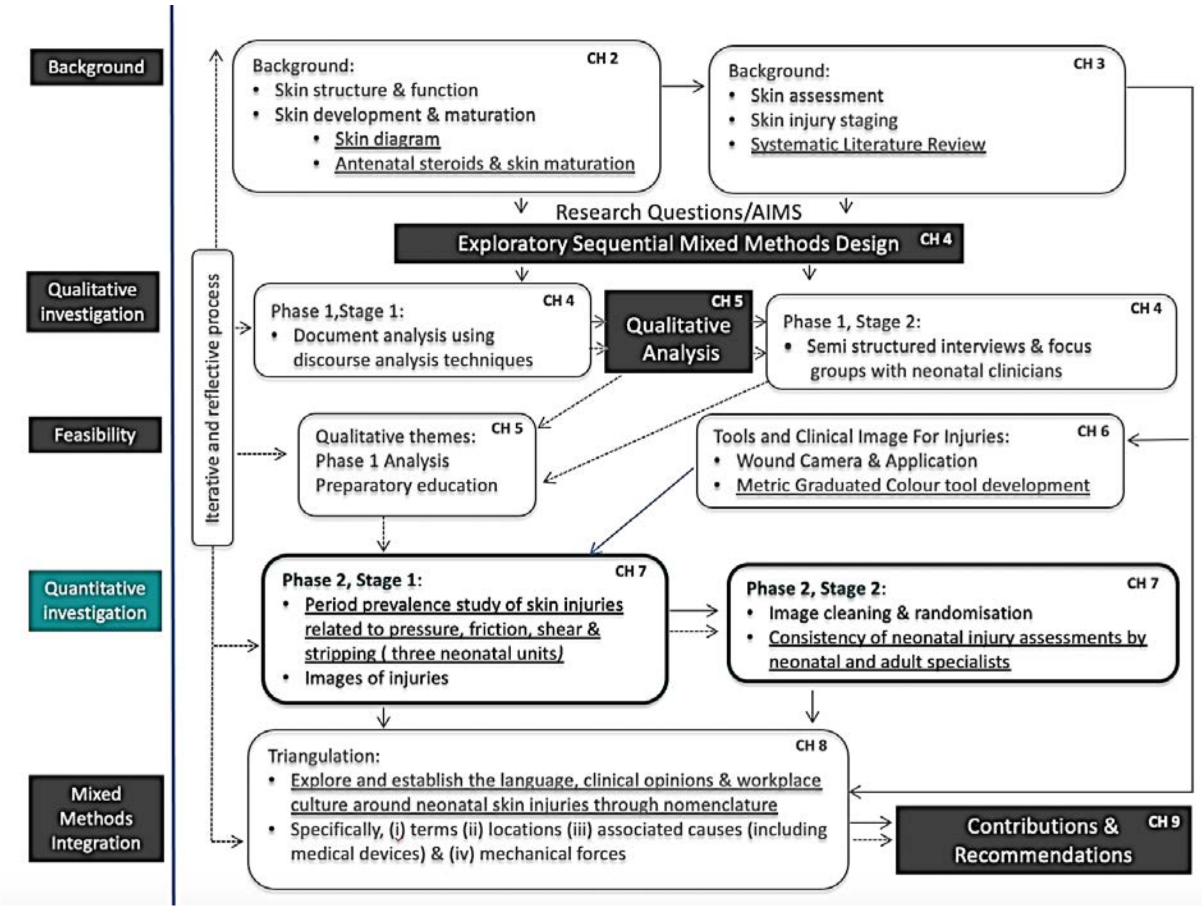

Figure 7.1 Thesis conceptual map with Chapter 7 content highlighted.
(Key: Underlined text = published or submitted for review; CH= Chapter).

7.1 Period Prevalence Study

The paper reporting neonatal skin injury period prevalence, classifications and risk factors was published in the Journal of Perinatal and Neonatal Nursing *Based on the publisher's specifications the American spelling and terms were utilised (e.g the National Pressure Ulcer Advisory Panel (NPUAP) classifications was the preferred term) In addition the list of references has been cross-referenced to the thesis reference list. The Participant information and consent form is available in Appendix 8.

7.2 Article: Fresh perspectives on hospital acquired neonatal skin injury prevalence from a multicentre study: length of stay, acuity and incomplete course of antenatal steroids

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Abstract

The object of this study was to explore neonatal skin injury period prevalence, classification and risk factors. Skin injury period prevalence over nine months, Chi-Square, Mann Whitney *U*, and independent sample *t* test compared injured and non-injured neonates with *P*-values < 0.05 considered statistically significant. Injury prediction models were developed using Classification and Regression Tree (CART) Analysis for the entire cohort and separately for those classified as high or low acuity.

This study took place in three Australian and New Zealand units. Neonates enrolled (N=501) had a mean birth gestational age of 33.48±4.61 weeks and weight of 2138.81±998.92 grams. Of the 501 enrolled neonates, 206 sustained skin injuries (41.1%), resulting in 391 injuries to the feet (16.4%, n=64), cheek (12.5%, n=49), and nose (11.3%, n=44). Medical devices were directly associated with 61.4%, (n=240) of injuries; of these medical devices, 50.0% (n=120) were unable to be repositioned and remained in a fixed position for treatment duration. The strongest predictor of skin injury was birth gestation ≤30 weeks followed by length of stay >12 days, and birth weight < 1255g. Prediction for injury based on illness acuity identified neonates <30 weeks and length of stay >39 days were at greater risk (high acuity), as well as neonates <33 weeks' gestation and length of stay > 9 days (low acuity).

More than forty percent of hospitalised neonates acquired skin injury, of which majority were associated with medical devices required to sustain life. Increased neonatal clinician education and improved skin injury frameworks, informed by neonatal epidemiological data, are vital for the development of effective prevention strategies.

Background

Neonatal skin injuries from mechanical force are currently associated with prematurity and birth weight (BW)[48]. Skin injuries as a complication were first identified in the 1980s and described as scars associated with prematurity which suggests an unpreventable complication of premature birth[233]. Current evidence indicates that injuries are associated with premature skin physiology and a combination of mechanical forces related to life saving care[48,174,175].

Current skin injury models and frameworks which incorporate aetiology with prevention appear to be based on adult epidemiologic data. Specifically, assessment tools such as the Neonatal Skin Risk Assessment Scale[122,234] and Braden Q Scale[24,235] were fashioned from adult models but verified by neonatal data; rather than larger scale epidemiologic investigations of neonates who sustained injuries. In addition, models which once predominantly focused on pressure injuries are broadening to include skin injury formation from any combination of mechanical forces and medical devices[172,188]. This is important as neonates are at risk for device related injury associated specifically with respiratory support equipment, medical adhesives, and vascular catheters[30,39,150,175,182,188]. Therefore, there is a need for studies to identify risk factors for neonates as the foundation for the development of a measure of risk and assessment specifically for neonates.

Recent reviews have identified that neonatal skin injury frequency ranges from 9.3 to 43.1%. This wide variation could be due to differing study methodologies making comparison of contributing factors for injury formation challenging[48]. Despite an unknown benchmark for injury frequency, governing organisations and healthcare facilities have an expectation that facility acquired skin complications are a never event[13]. Further complicating these expectations, neonatal skin injury assessment is reported as complex with gaps in skin care training for neonatal clinicians[175,188]. Thus, there is an urgent need to better understand the possible direct (extrinsic/modifiable) and indirect (intrinsic/non-modifiable) causes of skin injuries in neonates to minimise and/or prevent injuries from occurring [176].

We hypothesised that the prevalence of skin injuries is currently under-reported in neonatal units. The objective of this study was to explore the period prevalence, classification and risk factors of neonatal skin injuries.

Methods

The Neonatal Skin Injury and Pressure Injury Risk Assessment (NIPIRA) study was an exploratory mixed-methods study, which explored neonatal skin injuries and the epidemiological factors related to pressure, friction, shear and stripping. The study took place in Australia and New Zealand, investigating neonatal skin injuries using qualitative methods to collect data about contextual and social constructs, clinician's experiences with neonatal skin injuries, as well as photographic and observational methods. The qualitative and photographic results will be reported elsewhere.

Setting and location

The three participating neonatal units represent both metropolitan and regional tertiary neonatal care facilities. Each unit provides complex care, ventilation, retrieval services, and long-term nutritional and developmental care.[236]

Design

The period prevalence study was conducted at each unit over nine months in 2016 and 2017. *Inclusion criteria*: Neonates born less than 42 weeks of gestation, primary admission to a participating unit and informed consent was obtained anytime post admission or up to 24 hours after an injury was identified (due to availability of parents to provide consent). *Exclusion criteria*: (i) injuries unrelated to mechanical force such as surgical wounds, thermal/chemical burns, extravasation from peripheral/central catheters; (ii) injuries obtained during birth (e.g., scalp trauma); (iii) inherited conditions (e.g., epidermolysis bullosa or myelomeningocele); (iv) atopic dermatitis, staphylococcal scalded skin syndrome, hemaongiomas and other skin lesions (e.g., milia, erythema toxicum). Neonates who did not sustain injuries, comprised a control group for statistical analysis of injury risk factors. All neonates were followed until time of discharge or separation from the unit.

Sample size

At the time of calculating the sample size the minimum injury rate for neonates was unknown, thus the adult pressure injury rate of 7.0%[14,132], was used to calculate the minimum parameter. The upper parameter was calculated on a neonatal injury rate of 32.0% obtained from retrospective data[30]. Based on the one sample portion test (Wald z)[237], 150 neonates from each site were needed to provide a valid number of injuries with a power of 80%, alpha of 0.05.

Outcomes and variables

Primary outcome of skin injury acquired from a single or combination of mechanical forces (pressure, friction, shear and/or stripping) were defined in accordance with the National Pressure Ulcer Advisory Panel (NPUAP) classifications including Stages I-IV, Deep tissue, Unstageable injuries[27]. For epidermal stripping and skin tear injuries definitions corresponded with August et al.[11,210].

Variables for gestational age (GA) in weeks, birth weight (BW), method of birth and antenatal steroid courses were categorised based on definitions from the Australian & New Zealand Neonatal Network (ANZNN) Data Dictionary 2017[238]. The following variables were defined for the context of this research: length of stay (LOS) (number of days hospitalised), plurality (singleton, multiple birth); inborn (born at one of the tertiary hospitals participating in the study); outborn (born elsewhere) (born in route to hospital, at home, or at another hospital not part of the study site and a non-tertiary delivery of care); separation from unit (discharged home, transferred to another unit, deceased, or remained inpatient at study end) and cot humidification (use of cot humidification inclusive of neonates born <32 weeks as per site guidelines).

Medical devices associated with injury were grouped into three categories: (i) *fixed* device associated force that cannot be offloaded and force is likely to remain in that anatomical position for the duration of that treatment (e.g. endotracheal tube or intercostal catheter) *(ii)* *adjusted or loosened*- devices that could be adjusted or loosened intermittently, so the mechanical force is temporality offloaded but is likely to remain for the duration of that treatment (e.g. continuous positive airway interfaces or phototherapy goggles); or *(iii) movable*- devices that could be relocated or rotated during treatment and/or monitoring (e.g. saturation or temperature probe).

The American Academy of Paediatrics/American College of Gynaecologists infant acuity levels were used to measure neonatal illness severity[239]. Using the five-point care level for monitoring, treatments and interventions, neonates were grouped as *low acuity*- continuing care/intermediate care (level 1 or 2) or *high acuity*- intensive care/multi-system support/unstable requiring complex critical care (levels 3 to 5).

Data collection

To improve validity of data collection processes, clinicians were educated concerning (i) eligibility criteria; (ii) neonatal skin injury classifications and staging; (iii) requirement and use of the metric and colour graduated tape measure tool[240] (patent number 2019900648); (iv) injury identification, assessment and using the iPad camera and photographing the injuries; (v) data input using the iPad Apple Operating system (iOS) application (WoundMap, MobileHealthWare)[218] including use of drop-down menus and free text boxes. Additional resources available to clinicians included *PowerPoint* presentations with voice over instruction available on desktop computers, lanyard cards and posters with definitions and injury classification images, step-by-step instruction sheets for data input. Clinicians undertook data collection as part of routine skin inspection, in accordance with the Australian Safety and Quality Health Service standards which require inspection within the admission window and each shift thereafter[241]. Clinicians completed each occasion of data input within approximately 3 minutes.

Anatomical location and injury classification were collected/inputted from application drop-down menus or entry into a free text box. Due to the nature of the application, classification options were limited to '*pressure injury*' (any injury caused by mechanical force alone) or '*other*' (inclusive of 11 pre-programed injury classifications such as '*trauma*' or '*burn*' or free text descriptions). On selection of '*pressure injury*', a further menu opened, prompting selection of injury stages (NPUAP Stages).

Inputted data files were crosschecked with the neonate's medical chart and skin injury confirmed for eligibility by the principal investigator (DA). Missing data was extracted from clinical documents if available. Non-eligible injuries were excluded. If there was uncertainty, additional investigators (YK, RR, KN) confirmed inclusion or exclusion.

Analysis: Analysis was conducted using SPSS version 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Descriptive statistics express neonatal demographics and characteristics of injuries. Mean and standard deviation [SD] is reported for continuous, normally distributed data and as median and interquartile range [IQR] for continuous, non-normally distributed data. The Shapiro-Wilk test was used to check normality of the variables. Chi-Square, Mann Whitney, and Independent sample T-test were used to compare variables for groups of injured and non-injured neonates. A *p*-value < 0.05 was considered statistically significant.

Multivariate analysis was conducted using R Version 3.3.2 (R Core Team 2013. R: A language and environment for statistical computing, Vienna, Austria) with the RPART (Recursive Partitioning and Regression Trees) package. Recursive partitioning, called Classification and Regression Tree (CART) Analysis, uses variables to separate neonates into different homogenous risk groups by an algorithm used to determine prediction for injury. This algorithm selects a predictor that provides the best or optimal split, so that the subgroups are more alike compared to the outcome (skin injury or no skin injury) [242,243]. In contrast to traditional multivariate regression modelling, CART uses the best available information when variables are missing[244], using similar outcome patterns to determine which side of the split the variable is allocated. The paper reports the analysis of primary variables, of which many were unique from previous studies: birth GA, BW, gender, delivery type, inborn/outborn delivery, antenatal steroids, plurality, length of stay, illness acuity, and separation from unit. Secondary analysis for other possible risk factors related to device duration, nutritional factors, and sepsis are ongoing and will be reported elsewhere. CART analysis was conducted three times; once for the entire study population and then for high and low acuity groups.

Ethics

This study has received approval from the Townsville Hospital and Health Service Human Research Ethics Committee (HREC/13/QTHS/212), the Royal Brisbane & Women's Human Research Ethics Committee (HREC/16/QRBW/30); Human Research University of Otago New Zealand (H16/099) and The James Cook University Human Research Ethics Committee (H6400). Parental consent was obtained for all participants. All data were collected, stored and transferred in a secure manner with unique study identification.

Results

During the study period, 1776 neonates met the inclusion criteria, 860 (48%) parents were approached and 501 (58%) neonates were enrolled. Parents of 29 neonates declined participation, 324 were passive non-respondents, six families had significant language barriers and there were no withdrawals.

Mean gestational age was 33.48±4.61 weeks and birth weight 2138.81±998.92 grams. There were more males (54.9%, n=275) than females (45.1%, n=226). Median length of stay was 16.0 [8.0-38.2] days. Median time from birth to first injury was 4.08 (IQR 2.0-9.6) days, or 98.0 (IQR 48.0-231.5) hours. Demographics for the overall population, injured and non-injured groups are in Table 7.1.

Table 7.1

Demographics and clinical characteristics of neonates with and without skin injuries.

	All	**Without SI**	**With SI**	**p value**
N	501	295	206	-
Birth GA (mean ±SD)	33.46±4.61	35.30±3.60	30.75±4.60	<0.001
BW (mean ±SD)	2138.81±998.92	2350.00±891.70	1325.9±944.10	<0.001
Male, gender, *n (%)*	275 (54.9%)	160 (58.2%)	115 (41.8%)	0.725
Female, *n (%)*	226 (45.1%)	135 (59.7.8%)	91 (40.3%)	--
Plurality	-	-	-	0.822
Singleton	367 (73.3%)	215 (58.6%)	152 (41.4%)	
Multiple birth	134 (26.7%)	80 (59.7%)	54 (40.3%)	
Birth Method, *n (%)*	-	-	-	0.441
Spontaneous vaginal	177 (35.3%)	100 (56.5%)	77 (43.5%)	
Caesarean no labour	165 (32.9%)	95 (57.6%)	70 (42.8%)	
Caesarean labour	138 (27.5%)	89 (64.5%)	49 (35.5%)	
Assisted instrument vaginal	21 (4.2%)	11 (52.4.%)	10 (47.6%)	
Antenatal steroids	-	-	-	<0.001
Unknown	5 (1.0%)	2 (40.0%)	3 (60.0%)	
None	200 (39.9%)	147 (73.5%)	53 (26.5%)	
< 24 hrs first dose	68 (13.6%)	29 (42.6%)	39 (57.4%)	
Complete (more than 1 dose)	188 (37.5%)	96 (51.1%)	92 (48.9%)	
Given > 7 days before birth	40 (8.0%)	21 (52.5%)	19 (47.5%)	
Inborn, *n (%)*	409 (81.6%)	245 (59.9%)	164 (40.1%)	0.328
Outborn, *n (%)*	92 (18.4%)	50 (54.3%)	42 (45.7%)	
Length of stay (median, IQR)	16 (8-38.2)	11 (5-22.5)	37 (15-69)	<0.001
	-	-	-	
Acuity, required ICN *n (%)*	311 (62.1%)	142 (45.7%)	169 (54.3%)	<0.001
did not require ICN	190 (38%)	153 (80.5%)	37 (19.5%)	<0.001
Cot humidity *n (%)*	111 (22.2%)	20 (18.0%)	91 (82.0%)	<0.001
Separation from unit	-	-	-	0.01
Discharge home	249 (49.7%)	157 (63.1%)	92 (36.9%)	
Transfer to another unit	237 (47.3%)	136 (57.4%)	101 (42.6%)	
Deceased	12 (2.4%)	1 (8.3%)	11 (91.7%)	
Study end date before discharge	3 (0.6%)	1 (33.3%)	2 (66.7.%)	

KEY: SD-standard deviation, IQR-inter quartile range (25-75%), SI- skin injury, ICN- intensive care nursery, GA and BW

Period prevalence

Mechanical force injuries were acquired by 206 neonates (41.1%, N=501). Of the 206 neonates whom sustained injury, 109 (52.9% of the injured population) acquired more than one injury with a total of 391 injuries reported (Table 7.2). Stage 1 (un-blancheable erythema) was reported most frequently (44.0%, n=59/134), followed by epidermal stripping (26.5%, n=35/134); with only a single report of a Stage 4 and an Un-stageable injury. Of the 391 injuries, the feet were injured most frequently (16.4%, n=64), followed by cheek (12.5%, n=49), nose (11.3%, n=44) and abdomen (9.2% n=36). Only 7.9% of injuries occurred over bony prominences such as elbow, compared to 49.1% overriding a long bone, such as metatarsals.

Table 7.2
Skin injury frequency.

Total injuries reported	***n (%) 391***
Mechanical force	134 (34.3%)
Stage 1	59 (44.0%)
Stage 2	26 (19.4%)
Stage 3	3 (2.2%)
Stage 4	1 (0.8%)
Un-stageable	1 (0.8%)
Deep tissue injury	9 (6.7%)
Epidermal stripping	35 (26.1%)
Combination aetiology or 'other'	257 (65.7%)*
Anatomical locations	
Feet (including toes)	64 (16.4%)
Cheek (face)	49 (12.5%)
Nose (septum, bridge)	44 (11.3%)
Abdomen	36 (9.2%)
Hands (including fingers)	28 (7.2%)
Neck	26 (6.6%)
Upper limbs (except elbow)	22 (5.6%)
Other head (lip, under eye, philtrum)	18 (4.6%)

Behind ear (anterior fold)	17 (4.3%)
Knees (anterior)	14 (3.6%)
Axilla	12 (3.1%)
Lower limb (excluding foot and knee)	11 (2.8%)
Heel	10 (2.6%)
Gluteal, (including gluteal fold)	9 (2.3%)
Chest	9 (2.3%)
Ear (helix, lobe, tragus)	8 (2.0%)
Groin	8 (2.0%)
Back	3 (0.8%)
Elbow	2 (0.5%)
Hip	1 (0.3%)
Location by tissue structure	
Over long bone (wrist, foot)	192 (49.1%)
Soft tissue, ligament (neck, groin)	118 (30.2%)
Cartilage (ear, nose)	50 (12.8%)
Bony prominence (heel, elbow)	31 (7.9%)

KEY: *Analysis of injuries categorised as 'other' in this paper, are reported in qualitative outputs elsewhere

Of the 391 injuries 61.4%, (n=240) were directly associated with a specific medical device. Injuries were most frequently associated with medical adhesives 47.5% (n=114), vascular access devices 20.0% (n=48) and respiratory devices 18.8% (n=45). Furthermore, 50.0% (n=120) of devices were fixed such as endotracheal tube, while 29.2% (n=70) could be loosened or adjusted. Movable devices accounted for 20.8% (n=50) of injuries (Table 7.3).

Table 7.3
Skin injuries association by device type.

Total injuries, N	***391***
	n (%)
Device related	**240 (61.4%)**
Not identifiable, unknown/uncertain	151 (38.6%)
Adhesives and securements	***114 (47.5%)***
Adhesive standard	71 (29.6%)
Saturation probe	29 (12.1%)
Adhesive (non-standard)	3 (1.3%)
Electrocardiogram leads	9 (3.8%)
Endotracheal tube fixation device	1 (0.4%)
Stoma appliance/base plate	1 (0.4%)
Vascular Access Devices	***48 (20.0%)***
PIVC	28 (11.7%)
CVC	1 (0.4%)
PIVC hub	9 (3.8%)
CVC clamp	3 (1.3%)
Intra-arterial line	1 (0.4%)
Splint (vascular assess board)	6 (2.5%)
Respiratory interface & devices	***45 (18.8%)***
CPAP prongs	23 (9.6%)
Humidified high flow prongs	3 (1.3%)
Sub-nasal prongs	1 (0.4%)
CPAP mask	11 (4.6%)
CPAP attachment (chin strap, hat)	5 (2.1%)
Endotracheal tube, pharyngeal tube	2 (0.8%)
Other monitoring and care devices	***26 (10.8%)***
Temperature probe	10 (4.2%)
Non-invasive blood pressure cuff	1 (0.4%)

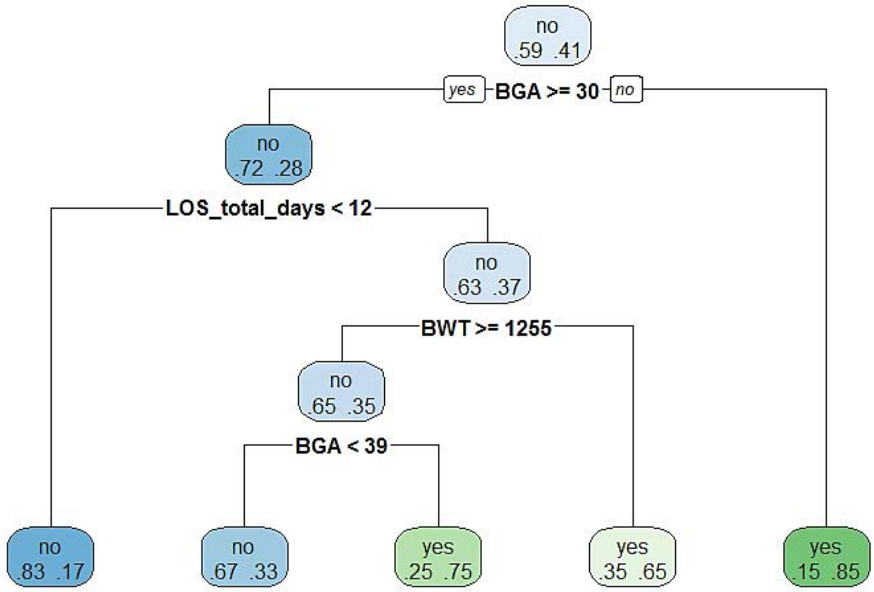
Monitoring cable	1 (0.4%)
Saturation/identification poesy (wrap)	4 (1.7%)
Identification badge	3 (1.3%)
Bed/crib/incubator	1 (0.4%)
Nappy	4 (1.7%)
Tourniquet	1 (0.4%)
Umbilical cord clamp	1 (0.4%)
Other invasive catheters and devices	***7 (2.9%)***
Ventriculoperitoneal shunt	1 (0.4%)
Intercostal catheter	2 (0.8%)
Gastric tube (nasal/oral)	4 (1.7%)
Device rotation capacity	
Rotation or movable	50 (20.8%)
Adjustable or loosen	70 (29.2%)
Fixed position for treatment	120 (50.0%)

KEY: CPAP- continuous positive airway pressure, PIVC- peripheral venous catheter, CVC- central venous catheter

Univariate analysis between injured and non-injured neonates showed no difference for gender and place of birth (inborn compared to outborn). Analysis did indicate differences in LOS ($p<0.000$), cot humidity ($p<0.000$) GA at birth ($p<0.000$), BW ($p<0.000$) and separation from unit ($p<0.01$) based on groups (Table 7.1).

Risk factor for skin injury

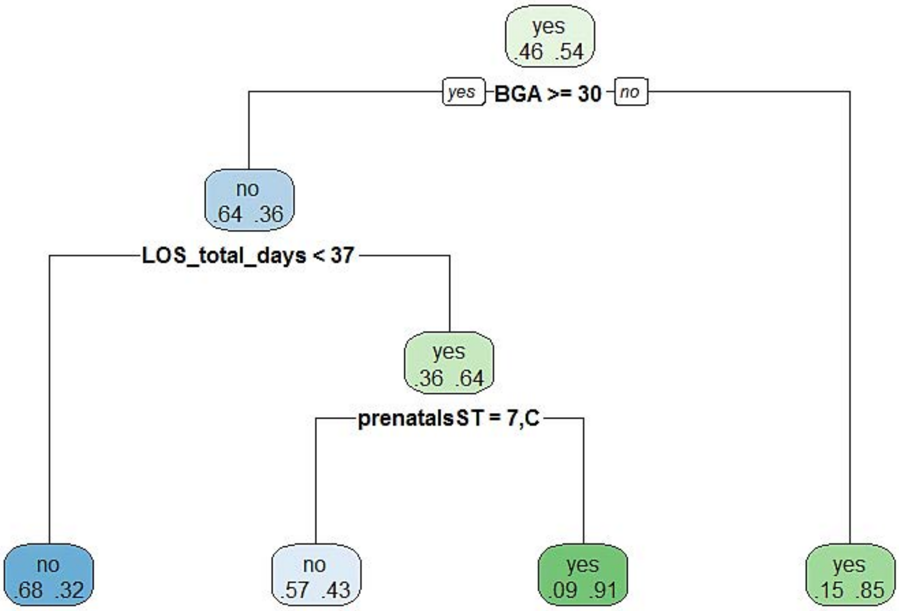
Based on CART analysis the most important predictor of skin injury was GA equal to or less than 30 weeks at birth. The next predictors presented in order of strength of prediction included LOS greater than 12 days, and BW less than 1255g. If a neonate was born greater than 1255g but between 30+1 and 39 weeks, the risk is increased (see Figure 7.2). Decimals within each CART tree box represent the probability of skin injury (e.g., .83= 83%). Decimals on the left, within each box, represent the probability of neonates within a variable group being injury free and decimals on the right represent probability of being injured; with the darker the box the higher the prediction.



Legend: BGA=birth gestational age (reported in weeks), LOS= length of stay (reported in total days), BWT=Birth weight (reported in grams), probability of skin injury (e.g., .85= 85%).

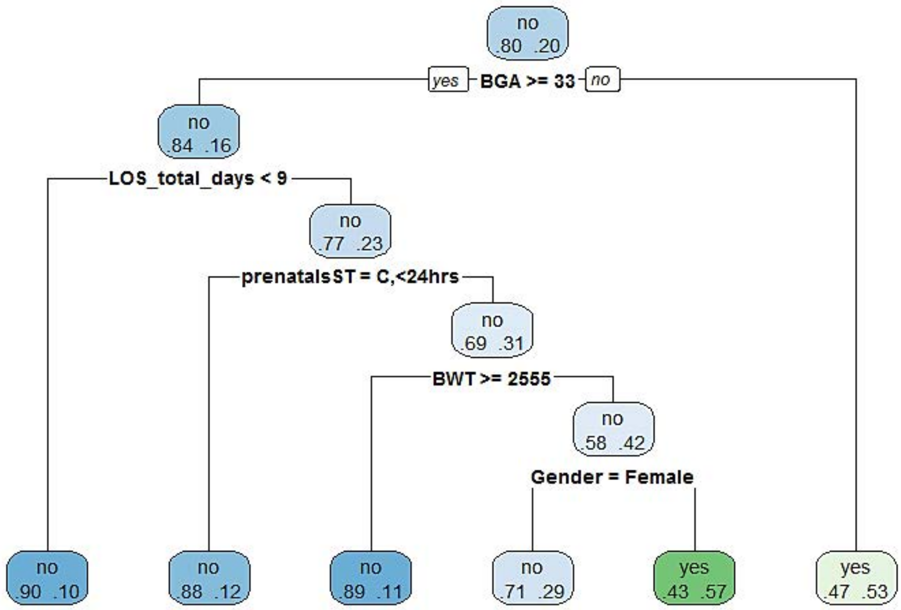
Figure 7.2 CART analysis entire population.

The study population was then divided into high acuity (level ≥3) or low acuity (level ≤2). The strongest prediction of injury for high acuity was birth GA equal to or less than 30 weeks; then LOS greater than 39 days, followed by antenatal steroid courses (non-complete or < 24 hours dose). The strongest prediction of injury for low acuity were GA equal to or less than 33 weeks; followed by LOS greater than 9 days, then antenatal steroids courses (non-complete, single dose or none), then BW equal to or less than 2555g, finally and male gender (see Figure 7.3 and 7.4).



Legend: BGA=birth gestational age (reported in weeks), LOS= length of stay (reported in total days), prenatal ST= prenatal steroids courses that were complete and/or more than seven days before birth), probability of skin injury (e.g., .85= 85%)

Figure 7.3 CART analysis acuity level ≥3.



Legend: BGA=birth gestational age (reported in weeks), LOS= length of stay (reported in total days), prenatal ST= prenatal steroids courses that were incomplete and/or less than 24 hours days before birth), BWT= birthweight (reported in grams), probability of skin injury (e.g., .53= 53%)

Figure 7.4 CART analysis acuity level≤2.

Discussion

To the best of our knowledge the NIPIRA study is the first of its kind to investigate neonatal skin injuries using a multi-methods approach. This paper reporting on the observational aspect of the study, has demonstrated that medical device associated injuries are common and injuries are more likely to occur in overriding bone and soft tissue locations, which differ from reported sites for injury in older populations (ischial tuberosities or scarum)[5,27]. The aetiology of adult skin injury is associated with pressure or shear, friction or moisture over vulnerable tissue along with factors such as immobility, age, diabetes and malnutrition [5,27]. Additionally, our results differentiate neonates from older infants whom acquire injuries over the occipital bone[137,245,246], as we did not find in our study. Our study has demonstrated that neonates are at risk for skin injury from mechanical forces along with factors such as a birth GA less than 30 weeks, LOS greater 12 days, and fixed medical devices and time from birth to first injury within the first week of life.

Skin injuries associated with medical devices were once considered different to classic pressure injuries, despite injury formation involving mechanical forces as well as a device. This study supports the findings of a recent literature review, that neonatal skin injury frequency is most often associated with medical devices (68-90%)[48]. Of note, respiratory interfaces were associated with 18.8% of injuries compared to a higher rate reported previously (>20%), which may reflect awareness of CPAP interface release and/or device rotation widely practiced in neonatal units[155,247]. Thus, quality improvement activities and care bundles for high-risk neonates are likely to impact on a portion of injuries related to rotatable (29.2%) and movable (20.8%) devices but not all[151]. More importantly these results highlight that the greatest proportion of devices, an extrinsic risk, are not modifiable with current care delivery models, with 50.0% needed to remain in that anatomical position for the duration of that treatment. Thus, the premise of offloading mechanical force to minimise tissue damage, which is the underlying principle for adult skin health is unlikely to assist in preventing these neonatal skin injuries[132]. Devices that can be only paused, adjusted or remain fixed will continue to present challenges for clinicians. A future focus on the delivery of care related to specific device types (medical adhesives and vascular assess) or injury locations (feet or cheek), might assist in identifying safer practices for fixed devices. Consequently, these results emphasise the goal of the 'never event' for neonatal skin injuries, being unlikely achievement for this hospitalised population with current care practices.

The very nature of fragile premature skin adversely places the neonate at risk for any skin injury despite aetiology[11]. Previous studies have suggested that prematurity and lower birth weight were associated with injury, but our results found neonates with injuries were slightly older (30.75±4.6 GA at birth) and heavier (1325.9±944.1 BW)[39]. Therefore, the results of this study demonstrate that neonates of all ages including preterm, late preterm, as well as high acuity, long term neonates are at risk for injury. While, neonatal GA and BW are easily measured but not modifiable risks. In addition, GA and BW are not considerations for the number of devices or frequency of device offloading and in fact smaller and sicker neonates are likely to have more devices. While past studies have analysed risk based on GA and BW [39], our team conducted CART analysis to consider acuity as a practical risk, providing clinicians with insights into which neonates in their care are most at risk for injury based on level of illness.

Given that moisture levels are a factor for adult acquired skin injuries, the role of ambient moisture was investigated in this study. for the formation of neonatal injury remains uncertain[248]. Consistent with recent research, our study found cot humidification non-predictive in multivariate analysis, despite being found to be significant in univariate analysis[29]. Further research needs to be undertaken to evaluate whether moisture levels have a role in neonatal injuries such as cot humidification delivered at the exact time of the injury and moisture on the surface of potential skin injury sties.

This study found that non-complete or less than 24 hours to the first dose of antenatal steroid coverage is a risk factor for skin injury. These results confirm that a lack of antenatal steroids may effect lung development, but may also have a strong hinderance on skin health[47,113] or simply indicate overall risk for morbidity including skin injury[249].

More than half the neonates in this study had multiple injuries. Further exploration of neonates who acquire multiple injuries compared to those who acquire a singular injury. may help to identify effective prevention and/or intervention studies. These studies could include injuries where aetiology is non-identifiable or uncertain, a factor not addressed in our study.

Most importantly, this study highlights that neonatal skin injury risk factors differ from the ones contained within published and validated risk assessment tools, which place more emphasis on mobility and tissue perfusion, and sensory perception. Comparatively none of the validated tools take into consideration the medical devices, length of stay or acuity. Of the significant risk factors identified within this study, only LOS can be considered extrinsic/modifiable. While GA, BW, and incomplete course of antenatal steroids are all indirect, intrinsic and non-modifiable risks associated with being born prematurely. Despite the lack of modifiable risk factors, governing organisations and healthcare facilities will likely continue to consider neonatal skin injuries an avoidable event. Therefore, neonatal clinicians must target prevention campaigns to reduce injuries associated with rotatable and movable devices; with specific attention to prevention during the first week of life for all

GAs. The adoption of a standardised neonatal skin integrity and injury assessment within clinical practice will also allow for accurate benchmarking which could contribute towards identifying modifiable risk factors and improved practices for fixed devices. In addition, reduction of injuries associated with fixed devices will likely require collaboration with medical device industry and biomedical engineering to accelerate device innovation.

There are a few limitations to be noted, including the use of clinicians for skin injury assessment. However, the research team provided preparatory education packages including in-services, palm cards, PowerPoint tutorials, and quick guides with images and injury descriptions. Data collected was later verified by researchers whom reviewed the clinical images of the injuries. Furthermore, the research team expected some variance in clinical assessments and therefore included image collection of injuries in addition to assessments. These images and the subsequent assessments are under further analysis within another study. While this is the largest investigation of neonatal skin injury in the last five years[2,28,39] not all families were able to be approached about potential participation. Initially the team envisioned achieving consent from all parents of neonates who met inclusion criteria, however a number of challenges occurred. Challenges were related to families who remained at referring facilities, unwell mothers or stressed parents for whom informed consent was considered inappropriate, specific demographics for whom visitation to hospitals is culturally taboo and parents who chose neither to consent or decline (40%, n=324) but instead remained passive about participation.

Conclusions

This study found 41.1% of hospitalised neonates acquired a skin injury, of which 61.4% of injuries were directly associated with a specific medical device. Such devices are most often required to sustain life and are 'fixed' for the duration of treatment. The most important predictors of skin injury were birth GA (≤ 30 weeks), LOS and BW (≤ 1255g), most of which are non-modifiable. Increased neonatal clinician education and improved neonatal skin injury frameworks, informed by neonatal epidemiological data, are vital for the development of effective prevention strategies.

7.3 Consistency of neonatal skin injury assessments

Injury images taken as part of the Phase 1 during routine skin assessment were stored as an additional data set. The following manuscript reports the consistency of specialists' assessments of neonatal skin injuries and is under review by the *Journal of Tissue Viability*. *Of note, this journal utilised the British spelling of etiology ("aetiology") and the article's list of references has been cross-referenced.

7.4 Article: Evaluation of the consistency of neonatal skin injury assessment using clinical images and the metric and graduated colour tool

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Abstract

Aim: To evaluate consistency in the assessment of neonatal skin injuries

Materials and Methods: Injury images collected during a multicentre period prevalence study (n=297) were screened for optimal quality before 60 images, stratified for size and colour, were randomly selected for assessment by three neonatal and two adult specialists. The principal investigator's assessments were the baseline for comparison and consistency.

Injury characteristics and assessments were reported as descriptive statistics. Comparison of injury assessments for colour and stage were calculated using Chi-square, with *p*-value of <0.05 considered significant.

Results: Neonatal specialists assessed injury elements more confidently than adult specialists reporting 59-60 (98-100%) injuries visible compared to 51-53 (85-93%) respectively. Neonatal specialists attributed mechanical force to 93% of the skin injuries compared to 70% by adult specialists. Consistency of colour assessment was achieved more often with neonatal specialists (n=50, 85%), compared to adult specialists (n=41, 73%). Neonatal specialists' consistency for injury staging (n=107, 60%) was higher compared to adult specialists who were uncertain (n=8,16%) and less consistent (n=47, 44%). When comparing specialists as a group, consistency with baseline assessment was significantly different between neonatal and adult specialists for colour ($p<0.010$) and injury stage ($p<0.009$).

Conclusion: Field of expertise (neonatal versus adult) differences were noted likely related to experience and understanding of empirical differences between neonatal and adult skin structure and maturity. These results highlight the need for specialist neonatal skin injury and wound training for clinicians involved in assessment, treatment and best practices for neonates.

Keywords

neonatal, skin, injury, assessment consistency, colour, stage, colour reference, digital images

Introduction

Visual skin assessment is used to confirm skin integrity in the absence of a diagnostic test [196,250].Furthermore, neonatal skin assessment can be complex compared to adult skin assessment due to the numerous ways injuries manifest in the developing neonatal skin [46,57]. Therefore clinicians assessing neonatal skin injuries are likely to benefit from the knowledge of neonatal skin developmental biology and injury progression to identify and classify neonatal skin injuries accurately [18]. A recent multicentre study reported that one out of every four neonates acquired a skin injury during hospitalisation [53], therefore necessitating valid skin assessment skills. Additionally, neonatal skin injury prevalence is considerably higher than the adult population prevalence, further highlighting the need for neonatal specific skin assessment skills, tools and reporting frameworks to assist clinicians [13].

While currently considered the gold standard, visual skin assessment may provide inconsistent confirmation of skin integrity. Skin assessment requires examination of healthy skin colour, with variances of colour used to inform signs of injury or disease [12,220]. A skin assessment is also comprised of injury assessment including injury size, classification (severity or stage) and aetiology. However, an individual's visual examination and thus perception is subjective, which affects consistency of injury assessment [2]. This has been demonstrated by inconstancies in visual skin assessment, with up to 52% (n=190) of injuries inaccurately identified in individual clinician assessments reported in a study [195]. To minimise some of this subjectivity, the use of a second assessor to repeat a skin assessment is considered best practice, but levels of agreement for assessments in clinical settings are inconclusive [120,196]. A study which used seven assessors to evaluate images of skin injuries in adult subjects reported only fair agreement for diagnosis and only moderate agreement for severity [196]. However, another study with two assessors inspecting adult sacral pressure injuries reported assessment consistency in 95% of cases and 0.77 degrees of agreement [251]. Consecutive injury assessments by the same clinician are unlikely in many hospital settings including neonatal units, due to the rotating shift work pattens and allocation of patient workloads. Another element impacting the consistency of injury assessment, is the current Australian healthcare model; in which injury assessments are most often completed by a single neonatal clinician, and then infrequently verified by a second member of the neonatal team. On occasion neonatal teams may consult with a skin integrity expert, trained in adult skin injury and wound care or paediatric surgical teams. Additionally, neonatal clinicians trained in neonatal assessment are also less likely to have formal or informal training in wound and skin care [175], adding the potential for further variation to injury assessments. Assessment subjectivity may be improved by using a consistent assessment tool, as reported in one study investigating adult pressure injuries which demonstrated improved assessment of injury severity through the application of a consistent assessment tool [229]. However, similar injury assessment tools have not yet been evaluated for neonatal skin injuries.

Digital images of skin injuries acquired through clinical photography can complement visual skin assessment for injury documentation and re-assessment [197,211,214,229]. Adjunct clinical images have enhanced assessment of skin cancer [211], diabetic foot ulcers [212] chronic wounds [252,253] and pressure injuries [197] for adult subjects. One study reported up to 97% specificity and sensitivity for skin injury assessments verified by a second assessor using a clinical image [197]. Additionally, with the increasing availability of smartphone technology, high-quality digital images have been successfully collected on these devices and transferred to a second assessor for evaluation[211]. One study reported equal diagnostic capabilities for chest x-rays viewed in person compared to x-rays photographed and viewed on a mobile phone [254]. Yet clinical images for the neonatal population have primarily been used in case studies or series [145,255]. Two recent neonatal studies utilised clinical photography [256,257] but had limitations related to control of image consistency and assessment in comparison to adult studies [196,251].

A handful of studies have utilised photographic standards or references, or 'ColourChecker' charts, as calibration targets within the image field to control for various lighting conditions [225,231,252,253]. However, these references have not used use for neonates, as the standard reference would likely present inherit challenges related to the size of reference (8.5 x 5.7 cm) overshadowing the neonate and the injury [49]. With these references in mind and the emergence of handheld devices for injury photography; we developed a custom made single-use metric and colour tool for clinical photography, known as the Metric Graduated Colour (MGC) tool [49]. Our preliminary evaluation of the MGC tool identified it was helpful for skin injury assessment, particularly related to documentation of injury bed colour, size and severity [49]. The tool was subsequently utilised within a multicentre period prevalence study of neonatal skin injuries from mechanical force, the Neonatal skin Injury and Pressure Injury Risk Assessment (NIPIRA) study, undertaken between 2016 and 2017 [53]. The study presented in this paper, is an extension of our previous work [49,53] and reports on the evaluation of consistency in the assessment of neonatal skin injury aetiology and skin colour, injury size, injury colour and injury severity by neonatal and adult specialists using the MGC tool as a reference tool.

Materials and methods

Subjects

The neonatal injury images within this study were drawn from the NIPIRA study [53]. Subjects were neonates less than 42 weeks of gestation, admitted to one of three neonatal facilities over nine months, and acquired a mechanical force skin injury captured by a digital image [53]. Ethical approvals were granted by hospital Human Research Ethics Committees and partnering Universities. Informed consent was obtained from parents of participants, included image collection.

Data collection

Injury images were taken during routine skin assessment by bedside clinicians as part of study procedures. All images were collected within 24 hours of initial injury discovery. To control for misidentification of other skin conditions, clinicians were provided with education and individual lanyard cards containing images and descriptions of neonatal skin injuries from a mechanical force at the onset of the NIPIRA study [53] (Supplementary image 1). Clinicians were taught how to use the iPad camera, place the MGC tool in the image field, and use of the Apple application which was used for injury classification or description (WoundMap)[218]. The iPad Mini 4 camera specifications included a 32 mm, point and shoot camera, with focal length f/2.4, 3264-by-2448 resolution and 8-megapixel sensors [258]. Injury description and image collection was obtained in less than 3 minutes, minimising the handling of the neonate and the bedside clinician's workload. To further assist in image consistency, education for clinicians included optimal image collection parameters, particularly minimum and maximum distances. Specifically, by ensuring the entire MGC tool was visible within the image field (approximately 10 cm minimum), and the image taken no further than the distance of incubator/care system walls (25-35 cm maximum) optimal image collection could be achieved. Considering the neonatal environment and varied lightly conditions, the MGC tool provided a consistent reference and could be used later to undertake image 'cleaning' or white balance [252] This was important in this pragmatic trial as clinicians were not provided detailed training in lighting conditions for clinical photography.

Materials

The MGC tool measures 6 cm in length and 1 cm wide, displays metric dimensions in 0.1mm increments, includes 14 colours and was produced on slightly moisture-resistant material. The colours within the MGC tool were specifically selected to represent the colours unique to skin assessment and the neonatal population including various skin tones, skin injury phases, and photographic standards: red/pink/yellow/mustard/chocolate/violet/purple/brown/black (skin injury phases), peach/blush/tan/brown (dark and pale skin tones), fuchsia (neonatal polycythaemia), and yellow/mustard (neonatal jaundice). Several colours represented more than one category; for example, brown could be a healthy skin tone as well as eschar of an injury. The 14th colour on the tool, orange, was included despite its reported rare occurrence in injury beds or skin tone, to provide a contrast between red and brown colours. The tool's white boarder created a photographic reference or standard, with the black section of the tool serving as an injury assessment colour and photographic reference for image colour correction. Additional description of the development, design and other clinical considerations for the MGC tool has been published elsewhere (patent 2020201469) [49].

Image sample screening and randomisation

A total of 297 de-identified images of neonatal skin injuries were collected as part of the NIPIRA study [53]. Images were screened for 1) entire MGC tool in view, 2) clear, crisp focus and 3) optimal exposure and colour balance (or could be achieved with simple white balance colour correction). Images that meet these criteria were eligible for randomisation and those that did not were excluded. Additionally images that had been used for educational purposes for the NIPIRA study, and therefore reviewed repeatedly by the principal investigator (DA) were excluded to minimise potential evaluation bias [212]. Initial screening of the 297 images was undertaken by the principal investigator and the clinical photographer (IH), with a total of 90 excluded for the following reasons: 72 images did not utilise the MGC tool, seven had been repeatedly viewed by the principal investigator and 11 had insufficient exposure or focus (Figure 7.4). Next, cleaning of the remaining 207 images and grouping based on injury size, was conducted by the principal investigator, and verified by the clinical photographer. Where simple colour correction was needed, Adobe Photoshop 2019 was used [19]. Further cleaning (cropping) of images was undertaken by the principal investigator for cases where site-specific context or identifying features (anatomical regions) were evident, to enhance blinding and minimise potential assessment bias associated with injury knowledge.

A pragmatic approach was undertaken by the investigation team in determining the image sample size for assessment, including consideration of the volunteer specialist assessors time and response bias. It was determined that a total of 60 images would provide a range of injury bed colours, types and severities, and minimise response bias which may have occurred with a larger number of images, but still reasonable for the volunteering specialists [259]. Then, to minimise selection bias and to ensure representation of different injury sizes, colours and severity, the images were firstly stratified into two groups based on injury size; resulting in 53 small injury images (<0.5cm) and 154 large injury images (> 0.5cm). The investigation team determined that 30 images from each size group (small and large) would be randomly sampled for assessment following further stratification by primary injury bed colour, such as brown, pink/red, purple/black, yellow and assigned a number for the purpose of random sampling.

The number of images for random sampling from each stratum was calculated based on the proportion of images within each colour category. For example, 66% of the small injury images contained red or pink injury beds, so 66% of 30 (total number of images in small/large groups) resulted in 20 images with red or pink injury beds randomly selected for inclusion. This process was repeated for each stratum in both the small and large injury groups (Figure 7.5). Of note, three groups required rounding to a whole number to complete image counts. Random sampling for each stratum in both groups was undertaken by entering the image numbers into a random generator (**https://www.randomizer.org/**). Next the randomly selected 60 image numbers were placed into another online randomiser which reorganised the list into an indiscriminate order (**http://www.randomlists.com/**), and were subsequently re-numbered 1 to 60 for the ease of specialist assessment. Due to the random nature of the sample, there was no control for lighting, natural skin colour, gestational age or anatomical location of injury. Characteristics of anatomical locations included in the 60 images were: feet (n=12, 20%); upper limbs excluding hands (n=9, 15%); cheek (n=7, 12%);

abdomen (n=5, 8%); knee (n=4, 7%); eye or lip (n=4, 7%); hands, neck, axilla, gluteal fold each (n=3, 5%; N=12); nose or ear each (n=2, 3%; N=4) and remaining anatomical locations (chest, elbow, lower limb excluding foot/knee each (n=1, 2%; N=3); with frequencies of locations representative of findings from the NIPIRA study[53].

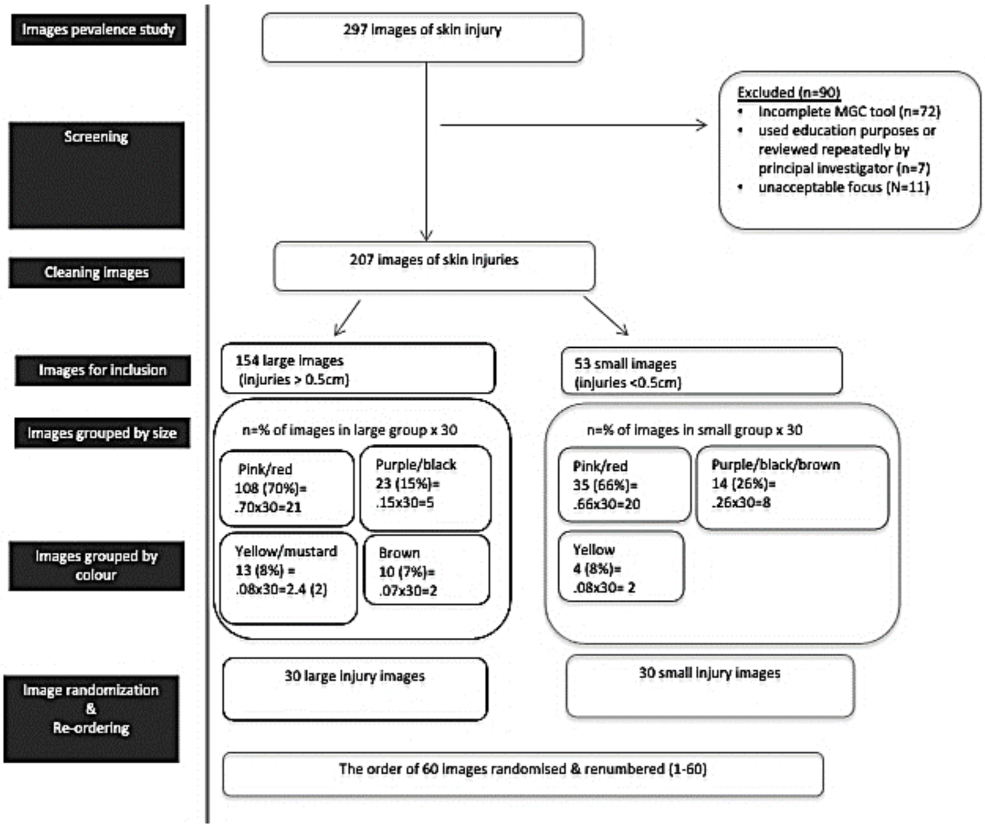

Figure 7.5 Process of image screening, inclusion, grouping and randomization.

Assessment instrument

The principal investigator developed the assessment instrument specifically for this study. The instrument consisted of six Excel worksheets (version 16.5), each populated with the image numbers and information and/or questions. Eight sets of responses were expected as some questions had sub-questions for data clarity (for example, *Is the skin injury visible?*). The first two worksheets provided introduction specific instructions and areas for the assessment of (i) healthy (intact) skin, (ii) injury bed colour and (iii) injury bed size. A large-scale numbered version of the MGC tool was provided to assist in selected of injury bed colour. The third worksheet included instructions and response space for (v) aetiology assessment (result of mechanical force yes, no, unsure) and (iv) mechanical force injury severity. Instructions including injury definitions and the severity card with injury images were provided, which were the same as those provided to clinicians during the NIPIRA study (with Stages from the NPUAP Classification system 1-4, Deep tissue, Unstageable injuries [27], and epidermal stripping and skin tear injuries [37,210], (Supplementary image 1)). Of note, the research team made the unanimous decision to use the term severity in relation to skin injury, instead of classification [120], as severity is the language used more commonly within this clinical research setting. Instruction guides were also provided as a separate PDF document and further instructions included if the specialist could not see an injury, subsequent questions related to injury size, colour, and severity were not expected be answered. Lastly, to ensure conciseness and clarity of instructions and worksheets, the assessment instrument was piloted by three co-investigators independently and minor revisions made before use in the study by specialist assessors. The assessment instrument and the 60 images were provided to assessors on a secure device.

Specialist assessors

A purposive sampling strategy was used to recruit specialist assessors. Five specialist assessors were initially approached to participate through conversation, and later followed up by a formal email invitation detailing the work required. All five accepted, each having more than five years of experience within respective disciplines of neonatology or wound/skin care, and currently practising within their field of expertise. Three of the specialist assessors were practicing in neonatology (two clinical nurses and one neonatologist) and did not have training or postgraduate qualifications in wound care. The remaining two were clinicians with expertise in adult wound care (a nurse and a nurse practitioner) and did not have neonatal training or neonatal postgraduate qualifications. For the purposes of this paper, neonatal specialist assessors are identified by N1, N2, N3, and adult skin specialist assessors identified by A4, A5. None of the specialists were part of the MGC tool development team and while the neonatal specialists may have been aware of the MGC tool and the NIPIRA study, their exposure to the tool and study had been limited. The principal investigator who has a background in neonatology and training in wound care was considered the expert [E6] and the baseline for the evaluation of consistency of assessment. Assessments were completed by E6 prior to reviewing the specialist assessor responses.

Analysis

The principal investigator sought advice and guidance on study design, statistical procedures and analysis from a statistician [DL] throughout all stages of the study. While some injury classifications can be ranked in ordinal steps, such as Stage 3 and Stage 4, variations between these stages may not be scaled evenly. Similarly, colours could be ranked in an ordinal fashion, but are more categorical in nature. Therefore, linear comparisons could not be made, and consistency of assessment was the identified outcome, and was measured as having been achieved when specialists reported the same colour spectrum, colour or stage of injury as the expert. For example, the same spectrum could include one assessment of red and another of pink, and therefore consistency was achieved as both belong within the same portion of a colour wheel (also known as hue) [260]. Descriptive statistics expressed characteristics of injury details and specialist responses. Consistency of assessments were compared between individual specialist assessors [N1 vs N2 vs N3 vs A4 vs A5] and between the expert and speciality groups [E6 against all N or all A].) Assessments were compared for consistency using tabulated chi squared for proportion with *p*-values of <0.05 considered significant. Analyses were conducted with SPSS version 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).

Results

Each specialist assessor (n=5) reviewed 60 images and completed the assessments and returned responses within two months of receiving the assessment instrument.

Assessment of healthy skin colour, injury visibility, and size of injuries

Three specialists [N1-N3] and the expert [E6] were able to select healthy skin for all 60 images using the MGC tool as an assessment reference tool. Specialist A4 could select healthy skin colour for 31 (51.7%) of the images. Comparatively, A5 responded that the tool could not be used to assess healthy skin colour but provided a colour selection for all 60 images. Specialists N1, N3, A4, A5 and E6, assessed a range of seven colours for healthy or 'intact' skin including: peach, blush, pink, fuchsia, red, tan and orange. Additionally, N1 and

E6 assessed a healthy skin colour as chocolate; and N2 and E6 assessed yellow as healthy skin. For N2, assessments included a range of five healthy skin colours including peach, blush, pink, fuchsia, and orange.

All 60 injuries were visible for N1, N3 and E6. Specialist N2 identified 59 of 60 injuries (98%), A5, 56 (93%) and A4 identified 51 (85%) visible injuries. For these three specialists, assessment of size, aetiology, injury bed colour, and severity could only be reported for the visible injuries. Assessment of injury size correlated with injury visibility for the majority of assessors, with N1, N3 and E6 able to use the MGC tool to assess the size of all visible injuries (n=60), as could N2, 59 of 59 visible injuries and A5, 56 of 56 visible injuries. However, A4 could only assess size for 24 of the 51 injuries initially identified as visible.

Assessment of injury aetiology

Assessment of injury aetiology were consistent between N1, N3 and E6, reporting all injuries (100%) were related to mechanical force (MF) or a combination of forces. N2 reported 55 of 59 (93%) injuries were related to a MF, two injuries unrelated and two unanswered. Specialist A4 assessed 42 of 51 (82%) skin injury images could have been attributed to MF, and nine (18%) unrelated to MF. Specialist A5 assessed 32 of 56 (57%) skin injuries attributed to MF, while 17 (30%) were assessed as unrelated to mechanical force, and aetiology of seven (13%) injuries unanswered.

Injury bed colour

Consistency in assessment of injury bed colour between specialist assessors N1, N2 and N3 and E6 occurred between 85-87% of the time, whereas consistency between A4, A5 and E6 was only achieved between 73%-75% of the time (Table 7.4). Further breakdown of consistency for exact colour and colour spectrum between specialist assessors and E6 are presented in Table 7.4. For colour spectrum, the proportion of consistent assessments between the five individual specialists and the expert was not statistically significantly different (Table 7.4, $p = 0.15$).

Injury severity

Specialists identified injury severity most commonly as stripping/tear, followed by Stage 1, Stage 2, and deep tissue injury. An Unstageable severity was identified in one case by specialists N1, N2, N3, A4 and E6, with no reports of Stage 3 or 4 injuries. N1, N2 and N3 reported injury severity that was consistent with E6 between 53-67% of the time (Table 7.5). A4 and A5 were more often uncertain of injury severity (16%) and consistency of assessment with E6 was only achieved for 43% of the time (Table 7.5). For injury severity, the proportion of consistent assessments with the expert and between the five individual specialists, was statistically significant, $p = 0.026$ (Table 7.5).

Table 7.4

Consistency of injury bed colour assessment.

Specialist Assessors	**N1**	**N2**	**N3**	**A4**	**A5**	**N1 vs N2 vs N3 vs A4 vs A5; vs E6**
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	***Chi-square, *p*-value**
Injuries visible (N=286)	60 (100)	59 (98)	60 (100)	51 (85%)	56 (93%)	
Consistency of colour assessment with E6	**52 (87%)**	**50 (85%)**	**52 (87%)**	**38 (75%)**	**41 (73%)**	6.73, 0.151
Inconsistent colour assessment with E6	**8 (13%)**	**9 (15%)**	**8 (13%)**	**13 (25%)**	**15 (27%)**	-
Exact colour consistency with E6	**26 (43%)**	**24 (41%)**	**19 (32%)**	**21 (41%)**	**14 (25%)**	**-**
Red/pink/peach/fuchsia	*13(50%)*	*20 (84%)*	*12 (63%)*	*14 (67%)*	*10 (71%)*	-
Brown/chocolate	*2 (8%)*	*1(4%)*	*1 (5%)*	*2 (9%)*	*1(7%)*	-
Violet/purple/black	*10 (38%)*	*2 (8%)*	*5 (26%)*	*4 (19%)*	*2 (14%)*	-
Yellow/tan/mustard	*0*	*0*	*0*	*0*	*0*	-
Orange	*1 (4%)*	*1 (4%)*	*1 (5%)*	*1 (5%)*	*1 (7%)*	-

Spectrum colour consistency with E6	**26 (43%)**	**26 (44%)**	**33 (55%)**	**17 (33%)**	**27 (48%)**	**-**
Red/pink/peach/fuchsia	*24 (92%)*	*19 (73%)*	*27(82%)*	*16 (94%)*	*20(74%)*	-
Brown/chocolate	*1(4%)*	*0*	*2(6%)*	*0*	*1(4%)*	-
Violet/ purple/black	*1(4%)*	*7(27%)*	*4(12%)*	*1(6%)*	*6(22%)*	-
Yellow/tan/mustard	*0*	*0*	*0*	*0*	*0*	-
Orange	*0*	*0*	*0*	*0*	*0*	-

KEY: - vs-versus, *Tabulated Chi-square

Table 7.5
Consistency of injury severity assessment.

Specialists	**N1**	**N2**	**N3**	**A4**	**A5**	**N1 vs N2 vs N3 vs A4 vs A5; vs E6**
	n (%)	n (%)	n (%)	n (%)	n (%)	*Chi-square, *p*-value
Injuries visible (N=286)	60 (100)	59 (98)	60 (100)	51 (85)	56 (93)	
Consistency of severity assessment with E6	**40 (67%)**	**31 (53%)**	**36 (60%)**	**23 (45%)**	**24 (43%)**	**11.04, 0.026**
Stage 1	*8(20%)*	*5(16%)*	*12(34%)*	*6(26%)*	*5(21%)*	
Stage 2	*11(27%)*	*9(29%)*	*7(19%)*	*3(13%)*	*4(17%)*	
Stage 3	*0*	*0*	*0*	*0*	*0*	
Stage 4	*0*	*0*	*0*	*0*	*0*	
Deep tissue injury	*8(20%)*	*8(26%)*	*7(19%)*	*4(17%)*	*6(25%)*	
Unstageable	*1(3%)*	*1(3%)*	*1(3%)*	*1(4%)*	*0*	
Stripping/tear	*12(30%)*	*8(26%)*	*9(25%)*	*9(39%)*	*9(37%)*	
Inconsistent severity assessment with E6	**20 (33%)**	**24 (41%)**	**24 (40%)**	**20 (39%)**	**23 (41%)**	
Specialist unsure of severity	**0**	**4 (7%)**	**0**	**8 (16%)**	**9 (16%)**	

KEY:- vs-versus, *Tabulated Chi-square

Injury bed colour and staging by speciality groups

Consistency of assessments of red, pink, peach and fuchsia injury beds were the most consistent; followed by violet, purple and black. Overall, consistency of injury bed assessment of the same colour spectrum with E6, was significantly different between neonatal (N1-N3) and adult (A4-A5) specialist assessor groups ($p = 0.010$, Table 7.6). Assessment of injury severity between expert and specialists for the same stage was also statistically significant ($p = 0.009$, Table 7.6). Adult specialists were more frequently uncertain of the stage of an injury (16%) compared to their neonatal counter parts (2%) (Table 7.6).

Table 7.6
Injury colour and severity assessment consistency grouped by speciality.

Specialist group	**N1-N3**	**A4-A5**	**Neonatal vs Adult**
	n (%)	n (%)	*Chi-square, -value
Injuries visible (N=286)	179 (99%)	107 (89%)	
Consistency of colour assessment	**154 (86%)**	**79 (72%)**	**6.60, 0.010**
Red/pink/peach//fuchsia	*115 (75%)*	*60 (76%)*	
Brown/chocolate	*7 (5%)*	*4(5%)*	
Violet/purple/black	*29(18%)*	*13(16%)*	
Yellow/tan/mustard	*0*	*0*	
Orange	*3 (2%)*	*2 (3%)*	
Inconsistent colour assessment	**25 (14%)**	**28 (26%)**	
Injury assessments (N=286)	**179**	**107**	
Consistency of severity assessment	**107 (60%)**	**47 (44%)**	**6.77, 0.009**
Stage 1	*25(23%)*	*11(23%)*	
Stage 2	*27(25%)*	*7(15%)*	
Stage 3	*0*	*0*	
Stage 4	*0*	*0*	
Deep tissue injury	*23(22%)*	*10(22%)*	
Unstageable	*3(3%)*	*1(2%)*	
Stripping/tear	*29(27%)*	*18(38%)*	
Inconsistent injury severity assessment	**68 (38%)**	**43 (40%)**	
Specialist assessors unsure of severity	**4 (2%)**	**17 (16%)**	

KEY:- vs-versus, *Tabulated Chi-square

Discussion

The NIPIRA study, [53] including this sub-study and the period prevalence, are one of very few studies which have investigated neonatal skin injury through photographic images and evaluated specialist assessment consistency. The use of both neonatal and adult specialist assessors, while unique, reflects the clinical circumstances within many neonatal units in Australia and New Zealand. Such that many large generalist hospitals which include neonatal units, have dedicated adult skin and wound specialist teams but few neonatally trained skin and wound specialists. Therefore, adult specialists are often called upon for neonatal injury consultations. This investigation has quantified an inconsistency of assessments between individual specialists as well as discrepancies between neonatal specialists and adult skin care specialists for the first time. Neonatal specialists appear to be familiar with neonatal skin injuries caused by mechanical force (greater than 93%), which may be related to an empirical understanding of the sub-specialty experience and neonatal pathophysiology. Comparatively, adult specialists were more uncertain of mechanical force injuries and reported that 15% and 28% of injuries were not related to these forces. The contrast in assessments from the two disciplines may be explained in the results of a related qualitative investigation, in which neonatal clinicians identified additional mechanical forces and risk factors compared to other data sources influenced by traditional injury theory [53]. Despite commonalities in neonatal specialists assessment, some inconsistency still occurred, which is similar to previous studies of adults injuries where only moderate agreement was reached with more than two assessors [196]. In comparison, this study explored injury colour as well as severity and interestingly found assessments were more consistent for injury colour compared to severity (Stage, Table 7.6).

This study demonstrated a number strengths and challenges for use of colour as a primary indicator for injury presence and severity currently considered the gold standard [197,220,261]. The most consistent assessments within this study were red or pink injury beds, which may be related to the frequency of these injuries in clinical practice [53]. Comparatively, violet, purple and black injury beds were identified with less consistency and are realistically uncommon in neonatal clinical practice. In addition, specialists rarely identified injury bed as yellow, whereas four images were categorised as yellow by the expert. Interestingly and unexpectedly, the colour orange was identified as an injury bed colour; despite that this colour is not perceived to be part of injury bed assessment [16]. Inconsistent perceptions of colour are not limited to injury, with other investigations identifying challenges with visual assessment of colour as a primary indicator of clinical finding such as bile or healthy skin colour [227,262]. Another unexpected finding was the colours brown, black or violet were harder to distinguish if the injury was less than 0.5cm in size. This may have additional implications for neonates with darker healthy skin tone, as it may pose further challenges disguising injuries and tissue damage [95].

This investigation was designed to mirror current clinical practice where injury bed colour is also the main indicator for clinicians' assessment of severity of tissue damage[197,229]. Despite the initial promising results from the earlier work around the MGC tool [49] and that specialists were able to complete assessments, some limitation remains for the use of the tool to distinguish healthy skin colour. Thus, this study has prompted questions related to the gold standard of visual assessment, particularly the confirmability of colour, and therefore injury, warrants further investigation in comparing consistency with and without the use of a colour tool.

While, standardised controls for image consistency (MGC tool and lighting correction) did not produce expected results, inconsistencies in clinical practice may also arise from perception or interpretation of injury colour and severity. Inconsistency in severity may lead to inconsistent care but also presents ongoing challenges for clinicians considering that healthcare facilities can attract funding penalties for certain injury severities[149]. The frequent reporting by specialists of superficial and less severe injuries (Stage 1 and stripping) in this study, may have been related to the practical challenges assessing depth of injury for neonates who's skin depth is only 0.9-1.2 mm thick [46]. Therefore, the common practice of clinician visual assessment for neonatal injury severity could easily be under or overestimating severity. Comparably, measurement of skin injury depth with the assistance of technology is emerging as a contender to visual assessment for other patient populations. For example, injury measurements of diabetic foot ulcers generated by camera software, are now regularly used to inform clinical decisions [212]. Other technologies use mobile phone cameras parried with computer learning to generate measurements and types of tissue injury such as necrosis or granulation [263,264].

In comparison this study used visualised injuries at the bedside and a clinical image with remote specialist assessment, rather than image analysis software to confirm injury presence or severity. This decision was based on feasibility testing completed by this team, in which measurement tools such as those used for diabetic foot ulcers [212] were found unsuitable to capture neonatal injuries due to the metric size of injuries. Other costly skin integrity tools such as subepidermal moisture measurements [265] or static speckle contrast analysis [266], may assist in the assessment of injury severity but to date are unvalidated in neonates. As this study has demonstrated challenges with the gold standard, there is a need for cost effective, feasible and accurate diagnostic measurements for the neonatal skin injures.

Within the Australian healthcare model, adult skin specialists are commonly involved in recommending tools and management for injuries to all age groups. Interestingly, this study found adult specialists had more difficulty identifying the injury (93% and 85%) and reported aetiology undistinguishable for (16.7%) of injuries. Despite the neonatal specialists' lack of formal skin or wound care training in this study, they were more likely to, independently and as a group, identify the injury and other elements. Considering that the prevalence of hospital-acquired skin injury is higher for neonates than adults [50], questions arise around the current considerations for the healthcare model and training considerations for specialists. Neonatal specialists view intact neonatal skin on a daily basis, therefore are more likely to use their understanding of neonatal pathophysiology or experience to draw upon when making assessments. Perhaps the current practice of using adult skin specialists trained in adult wounds, tools and management should be re-evaluated. Instead, a blended team of neonatal and adult skin experts should be consulted. Ideally, such experts should be familiar with both fetal and neonatal skin development in addition to formal training in adult and neonatal skin integrity fundamentals. However, there is currently a global paucity of specialists with this cross-training.

With surmounting doubt around the accuracy of visual assessment, uncertainty of feasibility of wound cameras, and a shortage of appropriate experts; future neonatal injury initiatives should focus on cross-training and education for clinicians or the use of telemedicine to link with experts. Reports within the peer-review literature demonstrate low levels of formalised education, with one study reporting less than 11% of neonatal staff with skincare training [175]. Additionally another study reported knowledge related to the prevention of stripping injuries (also known as medical adhesive related skin injury) was more often sourced from colleagues than peer-review publications and international guidelines.[194] Thus, the establishment of training and education programs might allow for more consistent assessments of neonatal skin injuries whilst other measurement modalities are being established. Telemedicine might assist with a temporary solution, as it is used regularly for other areas of dermatology [211]. In this model neonatal clinicians could refer and consult on injuries with experts, located in another geographical location, compared to reliance on traditional paper-based and textual referral systems or non-expert re-assessment.

Limitations

The sample size of specialist assessors was small, as it was based on the convenience of selecting a purposive sample. Future work including a larger number of assessors from both specialist groups may result in different findings. While use of the MGC tool provided a consistent reference for images; the *use of the tool may not have controlled for* surrounding environmental colours *or an individual* specialists' *interpretation of colour*. Another limitation was specialist assessors were not asked to provide a measurement size (mm) for each injury, therefore results related to the assessment injury size (mm) should be viewed with caution.

Conclusions

Assessment of neonatal skin injury was more consistent for colour than severity. Field of expertise (neonatal versus adult) differences were noted in the assessment of colour, size and severity of neonatal skin injuries, which are likely related to experience and understanding of empirical differences between neonatal and adult skin structure and maturity. These results highlight the need for specialist neonatal skin injury and wound training for clinicians who are involved in assessment, treatment and best practices for neonates.

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Competing interest

The principal investigator holds an independent patent (2020201469) to protect the intellectual property of the MGC tool. No commercial or other gain have been received for its use within this or any other study. The principal investigator has received unrestricted funding from the Mona Kendall Development Research Grant, The Townsville Hospital and Health Service Research Trust Fund, College of Medicine and Dentistry at James Cook University, the Graduate Research School of James Cook University and a Parker Healthcare and Australian College of Neonatal Nurses Research Scholarship.

Consent

Guardian consent obtained for all images collected.

Ethics

Approvals were granted from the corresponding hospitals and universities (HREC/13/QTHS/212), (HREC/16/QRBW/30); (H16/099) and (H6400).

Contributions

DA lead the development of research conception, design, methods and enrollment; coordinated and conducted data collection, contributed to the statistical analysis, statistical interpretation, and drafting of the initial manuscript. DL supervised the sample size, data accuracy, statistical analysis and critically reviewed the manuscript. RR contributed to the development of the research design, methods, critically reviewed the manuscript. KN contributed to the development of the research conception, research design, methods, and critically reviewed the manuscript. YK contributed to the development of the research conception, design, methods, sample size and data collection, critically reviewed the manuscript. All authors read, approved the final manuscript and agreed with all aspects of the work to ensure accuracy and integrity of the work.

7.5 Summary

Evidence from the studies suggests that skin injury frequency is higher for neonates than adults and devices are most often required to sustain life and are ‘fixed’ for the duration of treatment and therefore non-modifiable. Additionally, inconsistencies in neonatal skin injury assessment occur between neonatal and adult skin disciplines. Thus, in an effort to consolidate evidence to inform practice I sought to triangulate four data sources to identify sets of terminology, locations, associated risk factors and the related mechanical forces for neonatal skin injuries. Results from triangulation are reported in Chapter 8.

Chapter 8 Nomenclature of Skin Injury Identification & Assessment

As skin injury confirmation is based on visual assessment reported using language rather than numerical data, ambiguity of nomenclature could result in misinterpretation impacting on patient outcomes and quality of care. This chapter reports the data triangulation across this mixed-methods research to determine the nomenclature used to describe, define, identity, and communicate neonatal skin injuries[53]. *Based on the publisher's specifications direct quotations were used in text while italics were only used for tables and the original references have cross-referenced.

8.1 Article: Neonatal skin assessments and injuries: nomenclature, workplace culture, and clinical opinions – method triangulation a qualitative study

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Abstract

Aim and objective: To explore and establish the language, clinical opinions and workplace culture around neonatal skin injury nomenclature. Specifically, what nomenclature is used to describe, define, identity, and communicate neonatal skin injuries including (i) terms (ii) locations (iii) associated risks and (iv) mechanical forces.

Background: Skin injuries are affirmed or denied based on visual assessment with findings reported by language rather than measurements. However, if language or nomenclature is ambiguous, assessments could be misinterpreted effecting health care delivery.

Design: Qualitative inquiry including applied discourse analysis and between-method triangulation, within a larger exploratory mixed-methods study.

Methods: Data were collected over two years from four sources: literature, documents, interviews/focus groups, and free text injury assessments. Data analysis included content analysis, selective coding and thematic analysis. The collective data were further explored using discourse analysis and triangulation to achieve collective conclusions about opinions, emotions, feelings, perceptions and workplace cultures. The COREQ checklist provided structure for the reporting of study methods, analysis and findings.

Results: A total of 427 data points were collected from literature, documentation and two clinical data sources. Data convergence revealed that neonatal skin injuries are described by numerous terms with preferences for *"injury*", "*trauma"* or "*redness".* Injuries occur in over 20 anatomical locations and risks for injuries included hospitalisation, specific treatments, and prematurity. Essential medical devices, clinical condition, lack of clinician experience and over-active neonates were uniquely associated risks. There was incongruency between sources. The literature and documents empathise pressure as the primary force related to skin injury; whilst varied forces were identified within interviews, focus groups and free text injury assessments.

Conclusions: The variety of unique terms, locations and risks for injury indicate the need for updated neonatal skin injury frameworks. If frameworks and policies continue to be created without the empirical knowledge of neonatal clinicians, misrepresentation of neonatal skin injury locations and risk will continue to dominate the literature.

Relevance to clinical practice

The recognition and management of neonatal skin injuries are related to language used to describe assessments in the absence of diagnostic confirmation; which has implications for both the neonate and the healthcare team.

What does this paper contribute to the wider global clinical community?

- The language used to describe neonatal skin injuries demonstrates complex decision-making and assessment of patients requiring hospitalised medical care
- Majority of documents and literature present a narrow focus of the actual locations, associated risks and mechanical forces that contribute towards injury
- Interviews and focus groups with clinicians present a boarder focus around neonatal skin injury locations and risk factors
- Knowledge of neonatal skin assessment and injuries appears learned from experience, therefore comprehensive skin inspections and multidisciplinary rounds discussing skin injuries, with particular attention to anatomical locations and medical devices may impact on practice improvement

Introduction

Nomenclature or language used within healthcare facilities can impact on clinicians' perceptions about particular conditions and treatments provided.[204] Nomenclature is considered a collection of language or terms used to define or describe something, which if used commonly, can be an expression of workplace and organisational culture[204] and allows for effective communication.[267] However, if nomenclature within healthcare settings is ambiguous, assessment could be misinterpreted and health care delivery delayed or inappropriate.

Currently the presence of a skin injury is affirmed, contended or denied based on visual assessment.[49,250] Injury assessments are often documented and handed over using ambiguous descriptions such as 'redness' which could indicate a number of skin injuries or diagnoses. Additionally, the identification of a skin injury is likely dependent on a clinician's opinion and experience, with language the common indictor used to quantify a skin injury; unlike an outcome set by numbers such as a temperature. For example, medial adhesive related skin injury (MARSI) is defined by redness, specifically erythema (redness) or pinkness remaining 30 minutes after adhesive removal[143]; which demonstrates the ambiguity of initial assessments without context. Similarly, language with descriptions which have defined boundaries such as a Stage 1 pressure injury, described as a persistent non-blanchable (erythema) redness remaining after 30 minutes relief from a mechanical force,[95] are more likely to result in consistent use and interpretation of the nomenclature. Therefore, language used with defined boundaries (definitions) is likely to reduce ambiguity of descriptive assessment findings; minimise misinterpretation of injury type or severity; and therefore, improve delivery of care and patient outcomes.

A bibliometric analysis which explored nomenclature for adult pressure injury assessment, suggested that language used to describe injuries impacted on clinician's perceptions of assessment and severity.[268] The word "injury" was inclusive of numerous injury presentations incorporating early signs and late stages of skin injury. Comparatively, the most common term for injury, "ulcer", is suggestive of an advanced or end point of damage to skin from pressure (a mechanical force). Therefore, Dunk and Arbon (2009)[268] recommended adopting the term "injury" for skin integrity descriptions rather than ulcer to better communicate the condition parameters. Ulcer has also been defined as the loss of any epithelium,[269] adding to the diversity of interpretation of a single term. Thus, language and the interpretation of that language within clinical settings to describe or define neonatal skin injuries is likely to exemplify and influence the manner in which injuries are assessed and prioritised by clinicians. Interestingly, while Dunk and Arbon (2009)[268] identified eight terms used to describe skin injury, a review of neonatal skin injuries found additional nomenclature such as skin breakdown and trauma.[11] This variance indicates that language used within the neonatal speciality may be broader than adult settings; and may also suggest that the language used in clinical practice could also vary between adult and neonatal settings. With ten years between these two reviews, historical use of language may further explain some of the differences.

The language within national standards or guidelines is likely to influence skin injury assessments and nomenclature. Within the Australian context, the National Safety and Quality Health Service (NSQHS) standards specify eight key areas for healthcare outcomes.[270] The 5th standard prioritises the prevention and management of pressure injuries. In 2018 NSQHS released the Hospital-Acquired Complications Information Kit;

which identified pressure injuries as the most significantly preventable complication and therefore the highest priority for elimination within healthcare settings.[13] These NSQHS documents are considered a benchmark for healthcare provision, and therefore set standards for nomenclature and an expectation that local document nomenclature should mirror these standards. Thus, national and local documents could similarly affirm or hinder the continuity of skin injury assessment, and reviewing local practice documents related to neonatal skin injuries could provide additional insight into healthcare practice and culture.

Of interest, current literature about neonatal skin injury assessment, is significantly based on expert opinion rather than investigation, and substantially focused on potential risks for injury. Only a handful of studies have reported neonatal clinician's assessment descriptions of neonatal skin injuries; with little focus on actual injury descriptions.[38,130,175] Risk factors suggested in this literature, indicating anatomical locations or procedures which require attention, are likely to impact injury assessments. In 1999, neonatal nurses reported skin injuries were likely to occur in 21% of the population, with most concern for injuries occurring during the first 10 days of life.[38] Sixteen years later, an expert panel identified a number of likely associated causes for neonatal skin injury risk but provided limited assessment descriptions.[130] Evidence that skin injury risks are associated with medical devices continues to emerge,[175] which is unsurprising given that this population is most often dependent on lifesaving medical care. There continues to be a paucity of literature related to exploration of multi-disciplinary clinical opinion, local documents, surveillance data, and the relationship of sources to injury descriptions and/or assessments. Therefore, we investigated neonatal skin injury nomenclature for assessment, location, risk, mechanical force; and from these findings inferences were drawn about clinical practice and workplace culture.

Aim and objectives

The aim and objectives were to explore and establish the language, clinical opinions and workplace culture around neonatal skin injuries through nomenclature. Specifically, what nomenclature is used to describe, define, identity, and communicate neonatal skin injuries including (i) terms (ii) locations (iii) associated risks and (iv) mechanical forces.

Methods

An exploratory mixed-methods study investigating neonatal skin etiology was undertaken in three tertiary neonatal units in Australia and New Zealand over 26 months (2015-2017). A mixed methods design allowed for collection of multiple sources of data of which four were utilised for this qualitative enquiry: literature, documents, interviews/focus groups, and free text injury assessment descriptions. For this study individual site sources such as documents, were reviewed and analysed as a collective group rather than site specific data. Discourse analysis and Method Triangulation were then applied to the four data sources to achieve collective conclusions.[51,52] Specifically, discourse analysis involved the systematic examination of discourses (language, text, and other features of communication) from the sources as well as the opinions, emotions, feelings, perceptions and workplace cultures revealed by those discourses.[203,204] The unique data collection and analytical techniques for each data set are described in the respective subsequent sections. For this study (i) a term was considered as single word or phrases (ii) location was considered an anatomical location/region (iii) an associated risk was a medical devices or co-morbidities (iv) and a mechanical force was movement against or sustained to the tissue and underlying structures. Analysis for all data sources were initially conducted by the principal investigator (DA) and then reviewed by a second investigator (RR or KN). Terms, responses, codes and interim themes were further discussed with the entire team during meetings, held at monthly intervals both during data collection and analysis. The entire team was consulted regarding data sufficiency, final themes, and significant statements. The Consolidated criteria for REporting Qualitative research Checklist (COREQ)[191] provided structure for the reporting of study methods, analysis and findings (Appendix 6).

Reflexivity statement

To increase the trustworthiness of the study, the research team undertook a reflexivity process throughout data collection and interpretation; considering factors such as investigator status, situation, and pre-existing assumptions.[190,191] The investigation team, comprised of clinicians, academics and researchers with postgraduate and doctoral qualifications, have experience in qualitative and quantitative research methods. The principal investigator (DA, PhD candidate) conducted the interviews and focus groups at two sites. The principal investigator's background in neonatal nursing and auditing for NSQHS standards assisted in understanding data sources and implications for neonatal care. To avoid potential bias at the third site where the principal investigator was an employee, interviews and focus groups were facilitated by an experienced interviewer (EM). At the commencement of interviews/focus groups, both interviewers introduced themselves, briefly outlined their experience and described the context of the topic to establish non-judgemental environment.

Ethics

Ethics approvals were granted from the respective hospitals and universities.

Literature

Electronic searches of Ovid, PubMed, CINAHL, and Cochrane Library databases, using eleven key terms: skin injury, pressure injury, pressure ulcer, iatrogenic skin injury, skin, epidermal stripping, epithelial striping, skin stripping, skin tear, scars of prematurity, anetoderma of prematurity, and infant/neonate. The search dates were fixed between January 1980 and August 2015, to English peer-reviewed papers which described neonatal skin injury/ies in human subjects, including poster abstracts and discussion papers. The early date (1980) was selected to ensure capture of literature from the point of significant innovations in neonatal care, such as antenatal steroids and pulse oximetry, and the later date (2015) was the time point in which other study components commenced. Studies were excluded if the study population was older than six months of age; changes to skin were a result of surgical wounds, dermatitis, venous/ capillary punctures, burns (thermal or chemical) or dermatologic medical conditions (including epidermis bullosa); and letters to the editor. Titles and abstracts were screened and if at least one of the key terms was identified, the full text was reviewed, assessed against exclusion criteria and data extracted if inclusion criteria met. Skin injury terms were analysed using document and content analysis techniques.[271] Terms were categorised as root terms with or without descriptors and plotted chronologically based on the publication year first appeared in peer-reviewed literature and repeated use over time. Data was entered into Microsoft Word Document tables and illustrated in Microsoft PowerPoint.

Participating neonatal units

The three participating tertiary neonatal units were in metropolitan and regional areas in Queensland, Australia and the South Island of New Zealand. Each site provides complex care, ventilation, retrieval services, long-term nutritional support, with family-cantered care models, and interdisciplinary developmental care follow-up. Cot capacity for the units ranged across the three sites, with the smallest capacity of 16 cots and 70 cots at the largest faciality.

Document analysis

Following ethics approval, participating neonatal units provided electronic and/or paper-based copies of skin care or skin assessment related policies, procedures, guidelines, educational tools, and documentation forms. Each participating site was assigned a letter (Site A, B or C), and then documents and transcripts were designated a number (for example Site B Dc12). Criteria in the 2011 NSQHS standards for pressure injury prevention and management were used as the framework for content searching of documents.[3] Within the context of this framework, documents were also searched specifically for terms, locations, associated causes, and mechanical forces related to skin injury; which were analyzed using descriptive and selective coding.[201,202] Data were entered into an Excel Spreadsheet v14.7, 2011. The second stage of document analysis involved searching, selecting, evaluating and synthesizing document data and organising the data into major themes or categories through content analysis.[51,272] Data selected included statements, language, process or recommendations related to skin injury practice, assessment, identification, management or prevention. Discourse analysis techniques were then used to identify inferences formed by language and culture related to neonatal skin injuries.

Interviews and focus groups

To explore opinions, knowledge, perceptions and experiences about neonatal skin injuries, face-to-face interviews and focus groups were conducted.[205,206]Neonatal nurses, nursing managers, neonatologists, registrars, and nurse practitioners were purposively sampled and invited by email to participate. Nursing and medical students, assistants in nursing, and non-clinical staff were excluded. To avoid supervisor bias, senior clinicians and managers participated in interviews or focus groups separate from junior clinicians.[191] Interviews and focus groups were conducted away from the clinical area and audio-recorded. Demographic data were self-reported and collected at the commencement of the interviews or focus groups. The need for discretion regarding group conversation and confidentiality was re-iterated and agreed upon at the commencement of each focus group.

The interview guide consisted of 11 semi-structured questions and prompts developed from the findings of the literature review, current practice and document analysis. For example: *"How would you describe a neonatal skin injury? (Prompts: What are the unique features of a neonatal skin injury? What do they look like? What would you document in your assessment? What words would you use to describe one?)"*. Interviews and focus groups continued at each site until no new themes emerged.[207] Audio-recordings were transcribed verbatim with the exception of potentially identifying information and designated a set of letters or letters and numbers (for example Site B FGB or Site C Int1). Transcripts were uploaded to NVivo 11 data management software for coding, and theme development. Interview and focus group data were searched for terms, locations, associated causes, and mechanical forces; results of which were further analysed using descriptive coding, selective coding and thematic analysis.[202]

Free text injury assessments

Skin injury assessments collected electronically as part of a prevalence study, identified that 41% of neonates had an injury related to mechanical force.[53] Clinicians undertook assessments as a part of routine skin inspection, on admission and once a shift until discharge, in accordance with Safety and Quality Health Care Standards.[241] Palm cards and reference sheets including examples of descriptions and images of injuries, were available to clinicians at all sites. The principal investigator (DA), undertook in person assessment, review of injury image(s) or clinical records to confirm injuries met the inclusion criteria. Clinicians could enter skin assessments as a free text description, or choosing one of 12 pre-programed injury descriptions such as trauma or abrasion from the Wound MAP application.[218] The free text option was utilized for 257 (65.7%) entries. These free text assessments were transferred into excel and analysed using descriptive coding, selective coding and content analysis techniques.[51,202] Free text assessments were also entered into NVivo, V.11 and a word frequency query (including stem words) conducted.

Triangulation

To assess the credibility of patterns identified from different data sources, Between-Method Triangulation was conducted on data from each of the four sources, by exploring, combining and converging the data.[41,52] Additional discourse analysis was applied to the collective data, establishing patterns for similarities, differences or additional themes.[204] Patterns were determined and synthesised into a Microsoft Word Document table; and grouped for congruency of discourses or emerging discourses.[273,274] Inferences about attitudes and workplace culture related to skin injury assessment and prevention, as expressed across triangulated data were identified. To ensure confirmability, discourses, patterns and themes generated by the principal investigator (DA) were reviewed by a second investigator (RR) for endorsement, additional discourses and context.

Results

The four data sources resulted in a total of 427 data points: 66 published literature, 59 documents, 45 interviews (n=20) and focus groups (n=25), and 257 free text injury assessments. The data sources demonstrate numerous terms, locations, associated causes, and mechanical forces related to skin injury which also varied across sources. Results in this paper are presented by individual data source and then as triangulated data. Terms from each data source, including source demographics and frequency, are provided in Table 8.1, whereas Table 8.2 provides results for locations and associated risks identified from the four data sources.

Literature

The literature comprised mostly of expert opinion, case study or discussion articles (n=36) with under half using quantitative or investigative methods (n=30). Articles were primarily published after 1999, with 45 papers between 2000-2015.

Terms

From these 66 papers, 28 skin injury terms were identified with the most frequent being "pressure ulcers", "epidermal stripping" or "skin breakdown". Within the same paper, terms or phrases were often used interchangeably such as "pressure ulcer" used with "pressure injury" or "pressure ulcer" with "erosion". Many of the terms consisted of a 'root word' and 'descriptor'. Two groups of 'root words' were identified which were coupled with 'descriptors' such as "skin" + 'descriptor' (n=11) or "pressure" + 'descriptor' (n=5). Terms that did not fit into either of these groups and lacked commonalties were categorised as other (n=12) (Table 8.1).

Table 8.1

Neonatal skin injury assessment terms identified from each of the four data sources.

Data source	n	Source demographics	Terms n	Root terms or descriptors, source and/or word frequency (where applicable)
Literature	66	1980-2015 Peer-reviewed literature (n=36) Expert opinion or reviews (n=30) Quantitative or investigative studies	28	Root term and descriptor(s) (n=16) or other (n=12): *Skin* • *Breakdown a, barrier compromise b, trauma c, damage d, barrier damage e, stripping f (epidermal stripping g)* • *Injury h (medical adhesive related injury i, adhesive injury j, iatrogenic skin injury k)* *Pressure* • *Ulcer* [l]*, area* [m]*, sore* [n]*, injury* [o]*, necrosis* [p] *'Other'* • *Erythema (blanchable and non-blanchable)* [q] • *Excoriation* [r] • *Erosion* [s] • *Dermatologic disorder* [t] • *Tension blister* [u] • *Adhesive tape damage* [v] *(label injury)* [w] • *Wound* [x] • *Anetoderma of prematurity* [y] • *Scars from prematurity* [z] • *Denuded skin* [ii] • *Nasal injury* [iii]
				Most frequently identified nomenclature (n=17) Pressure ulcers (n=9) Skin breakdown (n=7) Epidermal stripping *Remaining infrequent terms can be seen in Figure 8.1*
Documents	59	(n=22) Observation/assessments (n=29) Guideline (n=1) International (n=28) Local	17	Most frequently identified nomenclature: (n=19) *Pressure ulcers* (n=10) *Epidermal stripping* (n=9) *Skin breakdown*

		(n=2) Parent information documents (n=2) Policy (adult) (n=4) Other (e.g., reports)		(n=5) *Nasal pressure injuries* *(n=13) Remaining terms identified at least once included: trauma, wound, integrity (loss of), tear, blanching, excoriation, damage, abrasion, bruising, narrowing, ischemia, redness, erythema*
Interviews and focus groups	45 (20 interviews, 25 focus groups)	(n=91) Neonatal nurses (n=5) Clinical educators (n=7) Managers (n=12) Nurse practitioners/registrars (n=2) Senior medical staff (n=9) Neonatologists (n=27) Self-identified as other	*37*	Frequency of root terms or descriptors content analysis in response to the question:-"*Describe an injury from mechanical force (prompts such as pressure, friction, shear or stripping)?"* (n=28) *Pressure (area, injury etc)* (n=28) *Redness* (n=20) *Break to integrity* (n=16) *Breakdown* (n=10) *Bruise* (n=8) *Stripping* (n=7) *Trauma or tear* (n=6) *Mark* (n=5) *Abrasion or ulceration* *(n=27) Remaining terms identified at least once included: graze, colour change, blister, sore, indentation, deterioration, wound, cut, excoriation, rubbing, break, breach, dent, blemish, peel, ripped, loss of skin, exudate, necrosis, shearing, scratch, friction, scar, battle scars, loss of epithelium, harm to baby*
Free text injury assessments	257	Bedside clinicians who identified a skin injury and entered free text injury assessments	*345 words**	*Word Frequency Query (including stem words) identified by NVivo for skin injury assessments** (n=75) *Redness (e.g., red, redness)* (n=56) *Pressure* (n=56) *Skin* (n=38) *Tape (e.g., taping, tapes)* (n=33) *Area* (n=31) *Removal* (n=30) *Blister(s)* (n=26) *Strip (stripping, stripped)* (n=26) *Bruised (bruise, bruised, bruises, bruising)* (n=25) *Tear* **Remaining words were identified which were counted less than 25 times*

Superscript letters correspond with individual sources for terms

a- (Afsar, 2010; Ashworth & Briggs, 2011; Huffines & Logsdon, 1997; Kuller, 2001; Lund, Kuller, Lane, Lott, & Raines, 1999; Lund & Osborne, 2004; Maguire, 1999; Mohamed, Newton, & Lau, 2014; Newnam, McGrath, Estes, Jallo, Salyer, & Basss, 2013; Vance et al., 2015)

b- (Darmstadt & Dinulos, 2000)

c- (Fischer, Bertelle, Hohlfeld, Forcada-Guex, Stadelmann-Diaw, & Tolsa, 2010; Garvin, 1997; Lund et al., 1999; McGurk, Holloway, Crutchley, & Izzard, 2004; Munson, Bare, Hoath, & Visscher, 1999; Rutter, 2000; Yong, Chen, & Boo, 2005)

d- (Cartlidge, 2000; Hoath & Narendran, 2001; Schumacher, Askew, & Otten, 2013)

e- (Darmstadt & Dinulos, 2000)

f- (Lund, 2014)

g- (Csoma et al., 2015; Gordon & Montgomery, 1996; Irving, 2001; Lund, 2014; Malloy & Perez-Woods, 1990; Ness, Davis & Carey 2013)

h- (Malloy & Perez-Woods, 1990; Newnam et al., 2013)

i- (Lund, 2014; O'Neil & Schumacher, 2014)

j- (Ness, 2013) **k**- (Cousins, 2014; Irving, 1999; Malloy & Perez-Woods, 1990; Sardesai, Kornacka, Walas & Ramanathan, 2011; Squires & Hyndman, 2009)

l- (Baharestani & Ratliff, 2007; Bonell-Pons, Garcia-Molina, Balaguer Lopez, Montal, & Rodriquez, 2014; Csoma et al., 2015; Fujii et al., 2010; Fujioka, Oka, Kitamura, & Yakabe, 2008; Garvin, 1997; Gray, 2004; Harris, Coker, Smith, Uitvlugt, & Doctor, 2003; McCord, McElvain, Sachdeva, Schwartz, & Jefferson, 2004; McLane, Bookout, McCord, MCain & Jefferson, 2004; Ness et al., 2013; Quigley & Curley, 1996; Rodriguez-Key & Alonzi; Schindler Mikhailov, Cashin, Malin, Christensen & Winters, 2013; Schluer, Cignacco, Muller, & Halfens, 2009; Vance et al., 2015; Visscher & Taylor, 2014; Jane Willock & Maylor, 2004)

m- (Jones, Tweed & Marron, 2001)

n- (Lund, 1999; Taylor & Dalbec, 1989)

o- (August, Edmonds, Brown, Murphy, & Kandasamy, 2014)

p- (Hodgeling et al., 2012; Irving, 2001; Jatana, Oplatek, Stein, Phillips, Kang & Elmaraghy, 2010)

q- (Cutting, 2008; Sibbald, Kranser & Woo., 2011) (August et al., 2014; Fischer et al., 2010; Lund et al., 1997; McLane et al., 2004) (Boyle & Oh, 1980; Visscher, 2014)

r- (Dollison & Beckstrand, 1995; Lund et al., 1986)

s- (Cousins, 2014)

t- (Csoma et al., 2015) (Campbell & Banta-Wright, 2000)

u- (Lund, 2014)

v- (Cartlidge et al., 1990)

w- (Migoto, de Souza, & Rosetto, 2013)

x- (Baharestani, 2007; Forest-Lalande, 2001; V. Irving, Bethell, & Burton, 2006)

y- (Colditz, Dunster, Joy, & Robertson, 1999; Goujon, Beer, Gay, Sandre, Gouyon & Vabres, 2010; Prizant, Lucky, Frieden, Burton, & Suarez, 1996; Yu, Shin, Kang, & Kim, 2007)

z- (Cartlidge et al., 1990; Davies, Gault, & Buchdahl, 1994)

ii- (Munson et al., 1999)

iii-(Hodgeling et al., 2012)

Plotting terms chronologically from 1980 (Figure 8.1), "erythema"[275] was the earliest term identified followed by "epidermal striping",[276] "excoriation",[36] and "scars from prematurity".[34] More recent additions to nomenclature included "nasal injury",[277] "MARSI",[143] and "iatrogenic injury".[278] Some terms were only referred to by a single source such as "adhesive label injury"[147] (Figure 8.3.1). Additionally, the term "pressure" appeared less frequent than the collective group of terms such as "damage", "trauma", "break" and "injury".

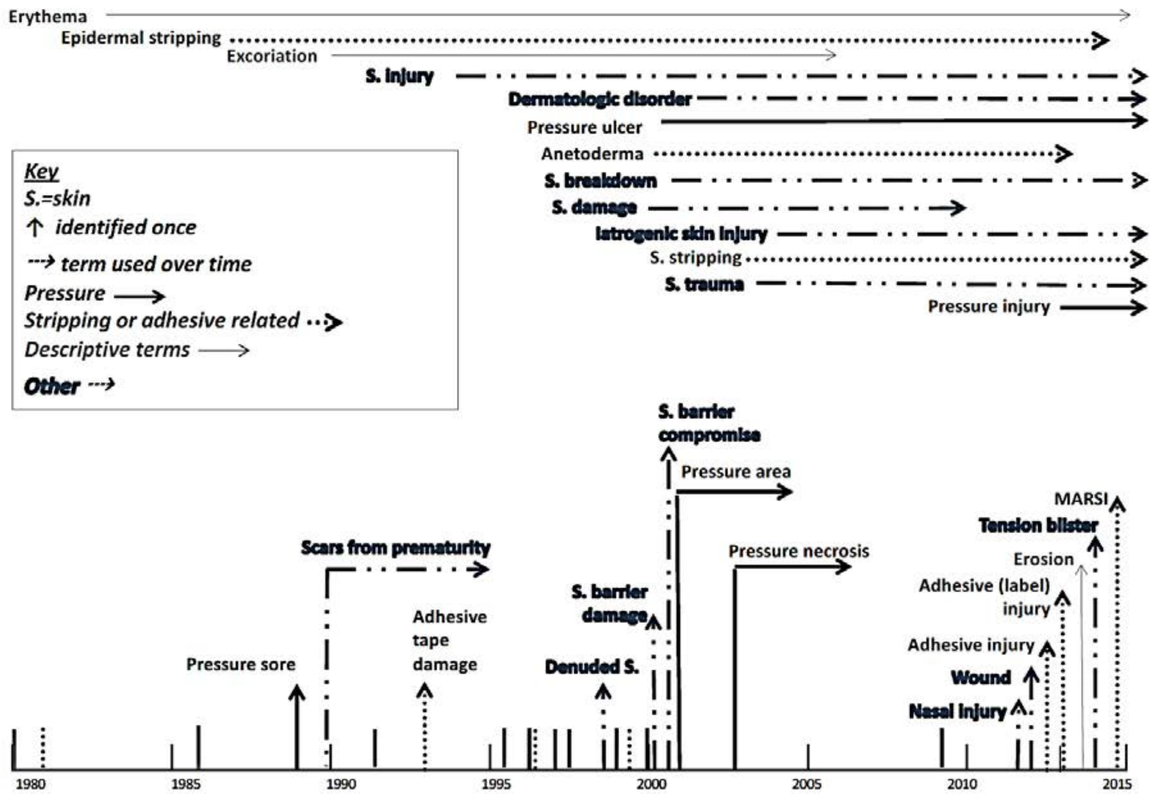

Figure 8.1 Terms plotted from 1980-2015 by first appearance in peer-review literature and repeated over time.
(Larger version available in supplementary file.)

Locations

Injuries occur in numerous anatomical locations of a neonates' body with a recent systematic review identifying the most frequently injured regions as the "nasal area", "lower limbs", followed by the "chest", "abdomen", "back", "upper limbs" and "face"[48] (Table 8.2).

Multiple opinion pieces identified the "occiput" as the highest risk location,[279,280] but this was not demonstrated in the systematic review with only 3 of 21 studies reporting this as an injury location.

Associated risks

Overall, the literature lacked agreement for associated risks related to neonatal skin injuries (Table 8.2). Many of the expert opinion sources proposed traditional risk factors such as "mobility", "activity", "moisture", "friction/shear", "nutrition", "tissue perfusion", "oxygenation" and "gestational age".[24,121-123,130] Comparatively, multiple clinical studies identified risk factors such as "gestational age", "birth weight", "medical devices", "length of medical device" and "length of stay".[48]

Mechanical forces

The terms "pressure" and "stripping" were most common, while "friction" and "shear" were only mentioned in combination with pressure when describing forces.[48] Most often, a single type of force was used to describe a number of attributions. For example the term "pressure" was used to describe injuries attributed to the force of "pressure" alone,[29] device related pressure[277] or pressure from surfaces .[39]

Table 8.2
Locations and associated risks identified from data sources.

Source	**Reported location of injuries**	**Proposed associated risks**
Literature	*Source** *Nose (nares, septum, bridge)* *Lower limbs (Foot, dorsum foot, toe, heel)* *Abdomen (umbilicus)* *Ear (earlobe)* *Upper limbs (knuckle)* *Face- non-nose (head, chin, forehead)* *Cheek* *Chest (nipple)* *Neck* *Head (back of head, occiput)* *Buttocks* *Hip* *Back*	*Gestational age, birthweight, medical devices (reparatory interfaces, adhesives and saturation probes), medical device length institution length of stay (August et al., 2018)*[48] *Mobility, activity (ability to ambulate), sensory perception, moisture, friction/shear (ability to move self), nutrition (Curley et al., 2003)*[121] *Physical condition (GA), mental state, mobility, activity, nutrition, moisture (Huffines & Logsdon, 1997)*[122] *Mobility/activity, sensory perception: responsiveness, GA, tissue perfusion and oxygenation, nutrition moisture, friction/shear (McLane et al., 2004)*[24] *Difficulty positioning, anaemia, equipment, reduced mobility, prolonged surgery, persistent pyrexia, poor peripheral perfusion, low serum albumin, weight <10th percentage for age, inadequate nutrition, incontinence inappropriate for age, hypothermia, poor tissue oxygenation, reduced conscious level, weight >90th percentage for age, self-care ability inappropriate for age, hypotension (Willock et al., 2005)*[123] *Medical devices, post menstrual age/birth weight, activity movement, comorbidities, skin integrity/tolerance, moisture/chemicals, nutrition/hydration, critical status, fragile skin, surgery (Vance et al., 2015)*[130]
Documents	*Nose* *Under numerous specific devices*	*Individual procedures, treatments* *Pressure/mechanical forces*

Source	Reported location of injuries	Proposed associated risks
Interviews and focus groups	*Reponses to "Are there any particular location where these injuries are likely to occur?"* • *Faces (nose, cheek)* • *Knees* • *Scrotum/buttock* • *Behind ear/ear* • *Skin folds* • *Limbs* • *Other (neck, heel, ankle, lips, elbow, hands, chest, forehead skin folds).*	*Proposed associated risk themes from responses to the question "What would be some of the commonalities or types of patients who are more likely to have injuries"?:* <u>Hospitalisation</u> • Environment ("humidity", "nappy", "bedding", "sheets") • Influence of a device ("i.v", "prongs", "masks", "suction", "tape really tight", "stoma bags", "ear muffs") • No limits to intervention ("any baby can be on CPAP or ventilation [get injuries]") • Position ("how they are lying", "[being] on their knees", "lying in one place") • Practice and experience ("not just size but our practice", "got to be really mindful of moving at least, moving [devices] at least four-hourly", "people need to be fastidious about positioning [of devices]') <u>Neonatal health and condition</u> • Hazard of being premature ("prematurity", "24 weeks", "extreme premature", "teeny tiny ones", "small birth weight", "sicker babies") • "Bigger/older babies" ("plumper babies", "big term babies", "bigger babies") • Health conditions and diagnoses ("hypothermia", "hypotension", "circulation"; "sepsis", "sedated", "HIE-type", "severe spina bifida", "drug addicted babies", "babies of mothers infected", "phototherapy", "cooling")

Source	Reported location of injuries	Proposed associated risks
		• "Skin is fragile" ("skin is thinner"; "their skin is fragile", "really fragile skin") • "Skin sticks to things" ("Skin sticking to tape", "when it sticks… it sticks good")
Free text injury assessments	Source** • *Feet (including toes)* • *Cheek (face)* • *Nose (septum, bridge)* • *Abdomen* • *Hands (including fingers)* • *Neck* • *Upper limbs (except elbow)* • *Other head (lip, under eye, philtrum)* • *Behind ear (anterior fold)* • *Knees (anterior)* • *Axilla* • *Low limb (excluding food and knee)* • *Heel* • *Gluteus (including fold)* • *Chest* • *Ear (helix, lobe, tragus)* • *Groin* • *Back* • *Elbow* • *Hip*	Visual assessments • "Pink and shiny", "red area", "purple fingertip", "crease red/pink", "pus filled blisters", "excoriated area in crease" Associated instrumental causes • "Red spots umbilical tapes", "iv hub", "mark tape removal", "removal of [saturation] probe", "wounded, [hydrocolloid] pad", "string ett [endotracheal tube tie]", "marks from prongs" Non-instrumental causes • "Small skin tear", "friction, red", "pressure injury rubbing", "pressure wound", "pressure area", "small skin breakdown and tear", "skin breakdown" Combination of causes • "Friction, tape and nappy", "pressure probe on unknown time", "red area lying prone", "bub pulled out gastric tube", "friction, iv clamp, now scratch"

KEY: *Sourced from August et al. (2018)[48]
** Sourced from August et al. (2020)[53]

Document analysis

A total of 59 documents were received from the three study sites (Table 8.1). Two sites had hospital wide policies, both of which used definitions focused on adult pressure injury prevention, and one site had a skincare guideline for low-birthweight neonates. None of the sites had a single document outlining neonatal skin injury definition, assessment, or associated risks.

Terms

The terms applied most frequently within documents were “pressure ulcers” (n=19), “epidermal stripping” (n=10), “skin breakdown” (n=9), and “nasal pressure injuries” (n=5). Thirteen additional terms were used at least once such as “nasal trauma” or “skin break”.

Locations

Locations at risk for injury were present in both local guidelines and assessment documents. The assessment documents were the most explicit with specific anatomical areas. In comparison, the guidelines focused on specific treatments or procedures such as adhesive removal or respiratory interface application, with cursory mention of potential injury location.

> *“It is important to have correct size hat, prongs or interface and ensure correct positioning of prongs/mask to avoid damage.” (Site A, Dc16)*

> *“Nares / septum / head / ears must be assessed with each care time for pressure injuries or trauma and recorded on the physiological observation chart”. (Site C, Dc13).*

All three sites provided assessment documents which included a section for skin assessment under a single header prompt such as “Skin” [within “Head to Toe Assessment”] (Site A, Dc2) or “Skin” [under “Physical Assessment”] (Site C, Dc10); with space for findings. Similar sections were provided within both medical and nursing documents. The medical documents related to admission and discharge, compared to the nursing documents which were daily or more than once a shift.

Primary nursing assessment/observation documents additionally provided unique skin integrity or perfusion checks for specific anatomical regions (“head”, “neck”, “nares” or “probe”) (n=7). These documents provided capacity for location assessments more than once a shift, inferring the area required frequent assessment or actions to minimise injury potential. Reference to the nasal region was the only common location from all three sites’ assessment documents, with documents from two sites prompting assessment of the anatomical location (“nares” or “septum”) while the other had prompts for checking the device (“prongs”).

Associated risks

A number of guidelines noted population specific risk factors such as gestational age and/or low birth weight. "Immaturity of the epidermis in infants < 28 weeks’ gestation predisposes them to skin breakdown” (Site B, Dc11). Other risk factors were embedded within specific treatments, procedures or considerations from individual guidelines such as respiratory interface or pre-operative preparation. Potential risks were also highlighted by reporting structures, such as incidence systems, two of which were designed for adults using the National Pressure Ulcer Advisor Panel structure. One reporting system specific for neonates, included 10 skin associated complications such as “ear ischemia” and “skin damage from tapes” (Site B, Dc8).

Mechanical forces

Pressure and stripping were the mechanical forces utilised the most within documents; whilst friction and shear were rare. Additionally, mechanical force terms were more often related to an injury outcome; such as “to avoid pressure areas” or “avoid epidermal stripping”; with little background information describing the relationship of mechanical forces to etiology and injury formation.

Interviews and focus groups

A total of 153 clinicians were involved in either 20 individual interviews or 25 focus groups with between 2-8 participants in each group. There were no refusals to participate, withdrawals, or repeated interviews. Mean duration of individual interviews was 29 minutes (range 13-53 minutes) and 32 minutes (range 23-63 minutes) for focus groups. Clinician participation from each of the three sites was 31% or greater and the vast majority had five years or more neonatal experience. Participants were predominantly female (n=129, 84.3%), with similar representation across age categories. (Table 8.3). Discipline was self-reported with the majority identifying as neonatal nurses 59.4% (n=91); others included registrars/neonatal nurse practitioners 7.8% (n=12), clinical nurse educators and managers 7.8% (n=12,) or other roles/not answered 25% (n=38).

Table 8.3

Combined interviews and focus groups participant proportion and demographics.

Staff population	Participant proportion n, %	Neonatal experience	n,%
Site 1 (N=115)	n=38 (33%,)	<4 years	56, 36.6%
Site 2 (N= 263)	n=82 (31%)	5-10 years	42, 27.5%
Site 3 (N=55)	n=33 (60%)	11+ years	50, 32.7%
Gender	**n,%**	**Age**	**n,%**
Female	129, 84.3%	21-29	40, 26.1%
Male	17, 11.1%	30-39	43, 28.1%
Not answered	7, 4.6%	40-49	30, 19.6%
		50+	40, 26.1%

Terms

When participants were asked to describe a skin injury, their descriptions ranged from singular words such as "*trauma*" to

> *"...anything that harms the integrity, whether it's a bruise, an abrasion….. it would be caused through pressure" (Site A, Fg2).*

Other participants were more descriptive in the language they used

> *"...damage to intact skin whether that be a change in colour or a change in consistency of the skin or a breakdown of the dermal or epidermal or muscular layers, caused by various, caused through trauma, pressure, stripping" (Site C, FgD).*

Participants also recalled terms they might use in skin injury assessments such as

> *"....breakdown, broken, deteriorating, pressure, friction, colour change, stages, stripping, cuts and bruises, scratches, pustules, rash, surrounding skin condition" (Site C, FgA).*

Participants further referred to the terms "*intact*", "*non-intact*", "*damage*" to suggest integrity confirmation

"...when the skin is no longer intact" (Site A, Fg1);

"...skin is intact but reddened" (Site A, Fg1);

"...disruption to the integrity of the skin" (Site B, Int2); or

"It doesn't necessarily break the skin. It's tissue damage of some kind." (Site A, Int1).

In addition to the common terms, participants from all three sites provided examples of unique language such as

"...battle scars" (Site B, Int5),

"...harm caused to the baby" (site A, Int13),

"...loss of epithelium and layers" (Site C, IntB),

"...skin taken off" (Site A, Fg3), or

"...an area mistaken for cute rosy checks [describing epidermal stripping on the face]" (Site B, Fg14).

Anatomical locations

Participants most often described specific anatomical features in combination with an assessment such as "*red knees*" (Site B, Fg11), or in combination with an associated risk such as a medical device. Examples of injury location with devices included

"...chests, legs, hands, feet from IVs and all sorts of things on bottoms" (Site A, Int1);

"We see them at probe sites, often at Spo2 sites, feet – feet in particular" (Site C, IntB), or

"...where the CPAP is attached to the baby" (site B, Fg13).

Some of the anatomical locations suggested by participants were not identified in neonatal literature such as:

"...around the mouth, umbilicus" (Site C, FgE);

"...on the neck" (Site B, Int19);

"...between the toes" (Site A, Int7) or

"...anywhere and everywhere" (Site B, Fg1).

Associated risks

Participants discussed considerations for injury formation, grouped into ten skin injury risk themes and two overarching groups: hospitalisation or neonatal health and condition. Themes related to hospitalisation included: environment, influence of devices, no limits to intervention and/or hospitalisation, position, and clinical practice or provider experience. Themes under neonatal health and condition included: hazard of being preterm, *"bigger/older babies", health conditions, "skin is fragile", and the "skin sticks to things".* Examples of short quotes for each theme are presented in Table 8.2, and a selection of extended quotes are provided below for a number of themes within each group

Hospitalisation

No limits to intervention

Participants suggested injuries occurred as a result of needing neonatal care and hospitalisation

"They won't get injuries if we don't do stuff to them." (Site B, Int5);

"You realise, the damage that we used to just say was part and parcel of being in the NICU,… now it's how can we prevent that?" (Site C, FgD); and

"I think that all babies would be equally vulnerable to them. You know, there's no limit to who's on CPAP, there's no limit to who's got legs that get tugged and pulled and poked and things." (Site A, Int1).

Influence of devices

Therapeutic treatments and medical devices were frequently reported as influencing skin injury formation.

"Anyone that's got devices on…anything that you've stuck on that baby always has a potential to provide a pressure area." (Site B, Fg16),

"...the Velcro of the [saturation probe] wrap, you know, the hard Velcro" (Site A, Int5)

"They have a lot more equipment on them than an adult would have… we take up most of their surface area alone with that." (Site C, FgB)

The time that devices were in contact with skin required specific consideration, with participants suggesting specific time periods contributed towards injury formation;

"We've got to be really mindful with moving at least, moving [devices] at least four-hourly." (Site A, Int30)".

In addition, the length of hospitalisation, the number or length a device was in situ were suggested to be interrelated to injury

"Well, they are going to need a lot more intrusive therapies for a lot longer, so I guess they are at higher risk as well, for the length of time, like it might be two or three months that they are going to have the constant pressure, at some point 24/7 on their body." (Site C, FgA).

Practice and experience

Medical participants described that competing interests for practice considerations of other vital organs, meant that skin injury prevention was often a lower priority.

"When we get really fresh registrars, they know nothing [about neonates], and so often what you are trying to teach them is … how to make decisions about ventilation, and fluids and blood pressure management, I suppose it's [the skin] something that we forget about to a degree." (Site C, IntB)

"More education would be useful. I think it's [skin injury] covered really poorly in medical school. It's not something that we actually learn about terribly much. It's kind of considered a secret nurses' business. You learn about it very briefly in geriatrics and it's considered a geriatric problem." (Site B, Fg11)

Medical and nursing participants additionally expressed that specific experience in neonatal care could contribute to prevention or risk for injury.

"…getting people to be fastidious about positioning the CPAP prongs is difficult. Until they've seen a bad one, they don't stay on top of it." (Site B, Fg4).

"…It does come down to the art of neonatal nursing …we had a lot of pressure injuries from the prongs until everyone learnt how to use them, how to place them to avoid the injuries - we had septal necrosis to the extent where they had to have plastic surgery which you very rarely see now …but I think it evolves around education and experience in how to do it." (Site C, FgA)

Neonatal health and condition

Hazard of being preterm

Prematurity was a unique consideration for injury. One participant described that premature/neonates should be developing in a liquid intrauterine environment with all needs provided by the placenta.

"They are still supposed to be floating on the 24hour Jacuzzi, on the 24-hour buffet, and they are not, and we are trying to do that [deliver care] on the outside." (Site C, FgA)

Skin is fragile

Likewise, participants specifically identified that neonatal and adult skin were different.

> *"They won't get injuries if we don't do stuff to them, and they're probably a lot more prone than some adults would be, especially quite early on with their skins being really fragile." (Site B, Int5)*

> *"[Their risks are] unique because the physiology and anatomy of the skin is different to adults. So, they've not got that many layers for protection to start with [using hand motions to illustrate thin layers]". (Site A, Fg2)*

Bigger/older babies

Participants believed that skin injuries were not only related to prematurity, as they reported "*bigger*" and "*older babies*" were also likely to develop injuries:

> *"The older kids that have had CPAP or ventilation of some description for a substantial amount of time and…those chronic babies [too]… you'll see breakdowns occurring. You know, once they've got one, generally they're going to get another one." (Site B, Fg12)*

Skin sticks to things

Whilst skin fragility was mentioned in combination with lower gestational age, participants additionally proposed that neonatal skin had properties of fragility and stickiness. Fragility was commonly mentioned as a risk.

> *"I guess, a lot of them have fragile skin and quite bony on top their skin is just quite fragile (Site B, Int5)".*

with others suggesting that "fragile skin" type existed for this patient population;

> *"I've seen skin that just scars with everything we do to it." (Site A, IntC2)".*

Examples of the capacity of skin to cling to adhesive were also frequent.

"...skin sticking to tape (Site A, Fg2)" and "when it sticks to tapes… it sticks too good (Site A, Fg3)".

Participants also reported that despite gentle care tape related injuries still occurred.

"The little mark on the abdomen; because they [temperature probe covers] are really sticky, and they really are a bit tricky to get off; and I think even using the swabs that we have to help, the anti-adhesive swabs, doesn't always seem to allow it to come off smoothly." (Site C, IntB).

Mechanical forces

Participants discussed mechanical forces mostly when describing an injury or associated cause.

"The smaller babies with the shiny, thinner, redder looking skin are the most prone to tearing." (Site A, Int29), or

"...friction in area of nappy" (Site A, Int4c).

"Even healthy babies will get friction, … There is a respiratory need to be in the unit, and obviously they have been nursed prone, then more likely this one here with a friction burn on the knees… that could happen to a 40+weeker." (Site C, FgB).

Mechanical force terms were most often mentioned when describing an injury or associated cause such as *"grazing", "breaking", "taken-off", "rubbing", "scratching", "tearing" and "blunt force".*

Free text injury assessments

As described in the methods section, clinicians had the option of selecting one of 12 pre-programmed drop-down menu items for injury type or enter assessment as free text. The free text option was selected for 257 injuries (65.7%) and comprised 345 words. The free text injury assessments were searched for terms, risk factors and mechanical forces separately but are reported in this section together to minimise repetition.

Terms, (iii) Associated risks and (iv) Mechanical forces

The terms used most often in order of frequency, were “redness” (n=75), “pressure” (n=56), “skin” (n=56), “tape” (38) and “area” (33). All terms used are displayed in Figure 8.2, a word cloud, where the word size and shade indicate the frequency of use; the larger and darker the word, the more frequently used.

Figure 8.2 Free text injury assessment term frequency word cloud.

Free text injury assessments revealed a rich variety of nomenclature for injury description, related risk factors and mechanical forces. Four themes were identified: (i) visual assessments such as “*pink, shiny*”; (ii) associated instrumental causes such as “*tape removal*”; (iii) non-instrumental causes such as “*rubbing and abrasion*”; and (iv) combination of aetiology or description such as “*skin tear, stripping, extravasation*”. Further independent sub-themes were elicited, the first related to time to injury such as “*tape removal 12 hours prior*” or “*pressure from 6 hours on mask*”. The second was related to severity or size of injury such as “*small broken area*” or “*skin damage, irritation, unbroken*”. Further review of the non-instrumental causes, identified that several non-device elements were considered to contribute to injury formation. Consequently, content analysis was undertaken, which identified common forces of *'pressure', 'friction', 'shear' and 'stripping'*; and revealed six other forces associated with injury (Table 8.2).

Locations

The anatomical locations from surveillance data have been reported previously[53] and are summarised in Table 8.2 for the purpose of triangulation.

Triangulation

Exploring, combining and converging the data revealed that neonatal skin injuries are described by numerous terms; occur in various anatomical regions; are associated with essential medical devices, and arise from clinical condition or lack of clinician experience. Formal data sources (literature or documents) emphasise pressure as the primary mechanical force related to skin injury, while numerous forces were suggested from the clinical data sources (interviews and focus groups or free text injury assessments).

Terms

All four sources demonstrated preferences for skin injury language with numerous terms such as "injury", "trauma" or assessment changes such as "redness" and "break".

Comparatively "erythema" was identified less often in the sources, with the exception of the literature. While language patterns existed, diversity of language was present through all data sources. Furthermore, clinical data sources (interviews and focus groups or free text injury assessments) more often described changes in skin colour such as "red", "pink" or "purple"; compared to categorical injury descriptions such as "pressure injury Stage 2" or "MARSI" which were more prominent in the formal data sources (literature and documents).

Locations

All data sources established that the nose was one of the most at risk anatomical locations. However, up to 20 additional locations were revealed including locations rarely reported in the literature or documents, such as the "umbilicus", "neck", and "behind the ear". Anatomical locations at risk for injury reflected soft tissue or areas overriding bone rather than bony prominences.

Associated risks

Associated risks for skin injury, were most often related to hospitalisation such as treatments or devices and prematurity, contrasting to hypothesised traditional risk factors and risk assessment tools such as immobility. Besides hospitalisation, the strongest consideration was given to gestational age and the undeveloped structure of preterm skin which is likely to have poor capacity to cope with devices required for care. Comparatively, risk factors such as co-morbidities or related medical conditions were found in the literature, and occasionally in the interview and focus groups, but rare within documents or free text injury assessments. However, clinical practice sources uncovered novel associated causes such as increased neonatal movements, positioning, staff experience, and illness severity.

Mechanical force

Mechanical force pressure was evident in all four sources, with the literature and documents having fewer additional terms. Non-instrumental themes of mechanical forces such as "*rubbing*", are poorly acknowledged within documents and literature. While clinical sources provided rich nomenclature to describe associated aetiologies for skin injury with emergence of forces such as breaking and splitting.

Congruent, incongruent and emerging discourses

Time and chronological setting had little effect on the congruency of data, as the richness of data was present in both contemporary sources (interviews, free text injury assessments) and the literature which spanned over three decades (Figure 8.1). Rather than a number of isolated complications, the data highlighted that neonatal skin is an organ for which the entire system is considered when assessing risk or injury. Clinical data sources revealed a broad pattern of nomenclature and associated risks and forces. The literature and documents provided more focused information about terms, locations, associated risks and forces; with the documents providing the narrowest view. Table 8.4 compares the data sources and the congruency of discourses.

Table 8.4

Between method triangulation for congruency of discourses or emerging discourses from all four data sources.

	Literature		Documents		Interview and focus groups		Free text injury assessments	
Terms	✓✓+	Skin+ descriptor Pressure + descriptor Other (e.g. erythema) *Terms from Figure 8.1*	✓☒	Pressure ulcers Epidermal stripping Skin breakdown Nasal pressure injuries Other (e.g. trauma)	✓✓+	Pressure (area, injury etc.) Redness Break to integrity Breakdown Bruise Stripping Trauma Tear Mark Ulceration Terms from Table 8.1	✓✓+	Visual assessments Combination Redness (e.g., red, redness) Pressure Skin Area Blister(s) Stripping, stripped Bruised (e.g., bruise, bruised) Tear Terms from Table 8.1
Anatomical locations	✓✓	Nose Lower limbs Abdomen Ear Upper limbs Face- non-nose Cheek Chest Neck Head Buttocks Hip Back Bony prominence	✓☒	Nose Areas of procedures Areas of devices	✓++	Nose Knees Face Ears Limbs Abdomen *Behind ear* *Under neck* Bottom *Umbilicus* *Everywhere* Areas of devices	✓++	Feet Cheek (face) Nose (septum, bridge) Abdomen Hands (fingers) *Neck* *Behind ear* Upper limbs (excluding elbow)

Associated risks	✓ ☒	Gestational age Birth weight Devices (particular devices) Adult risk factors (e.g., immobility, sensory perception, moisture, nutrition) *Device length in situ,* *Length of stay*	✓	Medical devices Prematurity Procedures and treatment	✓++	NICU Environment Hazard of being prem *Bigger babies too* Health and condition of baby *Hospitalisation* Influence of device *No limit to intervention,* *Position,* *Skin is fragile,* *Skin sticking to tape* *Clinician practice or experience* *Increased mobility*	++	Associated instrumental Non-instrumental *Time of contact*
Mechanical forces	✓	Pressure Pressure +/- Friction and shear *Stripping*	✓ ☒	Pressure Pressure +/- Friction Avoid pressure or stripping	✓++	*Grazing* *Breaking* *Taken off* *Rubbing* Pressure Stripping Shear *Scratching* *Tearing* Friction *Blunt force* Squeezing Abrasion	✓ +	Pressure Friction Shear *Stripping* *Pinching* *Rubbing* *Tearing* *Abrasion* *Splitting*

KEY:✓ **Congruent** Discourse ☒ Incongruent Discourse ✚ *Emerging discourse (Italicised and underline);*

Discussion

This is the first study to investigate multidisciplinary and combined data sources to identify terms, locations, associated causes and mechanical forces of neonatal skin injuries. Convergence of the four data sources has provided important insights regarding variances for nomenclature used within the neonatal speciality to describe and define skin injuries. Whilst, similarities exist there is marked incongruency of discourses between clinical data sources and formal sources. Furthermore, the volume of terms from the chronological review, literature and clinical data sources portrays breadth of awareness for skin injury, but a lack of boundary for assessment nomenclature.

These results highlight a preference for descriptive terms and assessment elements such as size ("*small*"), integrity ("*intact*" vs "*non-intact*") and colour ("*pink*", "*red*" or "*purple*") which could be related to a number of factors. Overall, there appears to be a shift from classic terminology, such as erythema, towards less formal descriptions such as "*redness*". Additional contrasts include a less frequent use of the term "*ulcer*" within neonatal data sources in comparison to the adult literature.[268] Instead, terms such "*break*", "*trauma*" or "*damage*" were used interchangeably, potentially suggesting that neonatal skin injuries are viewed as accidents or unintentional. Terms such as "*trauma*" or "*injury*" may also communicate immediate intention of neonatal clinicians to attend to the issue as opposed to the less urgent or pre-existing finding such as "*ulcer*". Whilst the research team acknowledge the potential influence of the utilisation of "*injury*" rather than "*ulcer*" within NSQHS Standards,[13] these documents were infrequently discussed by clinicians or referenced within local documents. Thus, there appears a preference for descriptive terms which maybe unique to the sub-speciality. These changes in terminology might also reflect an evolution of understanding for hospital acquired skin injuries as a consequence of healthcare innovation. This progression starting with the decubitus ulcer in immobile adult patients, to pressure ulcers for patients with complex co-morbidities[268] and the recent iatrogenic skin injury in neonates related to medical devices.[281] Effective communication in healthcare settings is based on the capacity to describe and explain something; and therefore, without common language as a basis for discussion, agreement, or knowledge-based, practice maybe absent.[282]

This study has additionally highlighted that language has an important role in the communication of severity or depth of an injury, and language preferences might allude to practical assessment challenges. While the term "*ulcer*" can simply describe the loss of epithelium,[269] it is also considered an open sore with an element of depth, which may have specific implications for neonatal practice. Participants in this study commented that injury depth assessment was challenging, therefore the interpretation of depth may explain why neonatal clinicians appear to reject the term "*ulcer*". Likewise, the replacement of severity terms with descriptions such as "*intact*" or "*broken*" skin were seen in the clinical data sources. It is not surprising that assessment of skin depth, intactness or ulceration is challenging; considering that neonatal skin thickness is only 1.2mm thick at term gestation and thinner for subsequent younger gestations.[46] While the exact reasons are unclear, this preference could suggest either ownership of local language and culture, or uncertainly or inability to assess severity. Future studies could investigate neonatal skin injury classifications that include intensity and extent, to overcome estimations in severity, while providing clinicians with capacity for improved description in their assessments.

This study has demonstrated a clear agreement that the nasal region is a location at high risk for injury. The remaining anatomical locations were repeatedly mirrored in the clinical data sources (interviews and focus groups or free text injury assessments), and similar to those identified in another recent study.[175] However, the formal data sources (literature or documents) were more focused on anatomy and tissue structure of that area, such as bony prominences; and lacked emerging locations where injuries occurred. Furthermore, these results have alluded to neonatal clinicians' consideration for skin assessment as a head-to-toe activity, which is particularly appropriate considering the numerous locations in which injuries occur. These findings support the notion that current bedside clinicians are intuitively aware of the injury locations for this population. However, it is unclear if this knowledge is passed between experienced and novice clinicians highlighting the need for formal education.

Associated risk factors from clinical data focused on devices, procedures and treatments, which were reflective of physical factors such as surface (sheet type), device ("probe") or treatment ("phototherapy" or "cooling"). Risk factors related to transient conditions ("hypothermia") or acuity ("sicker babies") were also identified. Comorbidities unique to the neonatal population including neurological or abstinence conditions were reported within the focus groups but other comorbidities such as sepsis were less frequently described. This disassociation of comobilities with injury risk suggests a lack of connection between physiologic risk factors which affect circulation such as anemia or sepsis. Clinical data sources also highlighted new concerns including observed increased movements of neonates, which contribute to sustained force such as movement against the surface or device, rather than the device fixed to the neonate causing a sustained force. This point was mentioned more prominently by nursing staff compared to medical staff, highlighting separation of experience by roles.

Incongruency of mechanical forces, supports the argument that empirical knowledge evident in clinical sources is lacking in the literature and documents. The exact force of the device maybe unknown and therefore poorly controlled for patients who cannot communicate or follow directions. Thus, the importance of contributing forces maybe more essential when considering prevention and treatment rather than assessment. This study has identified that multiple forces were important for clinicians. In contrast, shear was infrequently mentioned which could be related to the fact that it is difficult to conceptualise, demonstrate or witness. However, stripping, related to adhesive removal, was mentioned almost as frequently as pressure. This may be explained by a likely relationship between stripping injuries and the weight of devices fixed to the skin, which place force and tension on poorly connected skin layers. Thus, the concern for stripping related injuries appears more prominent for this population. The nomenclature and assessments for adult skin injury follow strict aetiologies such that pressure related skin injuries are considered separate to injuries related to medical devices.[172] This could be associated with a lower frequency of device related injuries and more prevalent injuries on bony prominences from bed surfaces in adult population. In contrast, neonatal clinicians, most often considered combinations of forces, rather than a singular force.

This study has importantly identified that clinician experience and required medical devices increase the risks of injury. It may be that memorable experiences, that build intuition have a stronger influence for the perception of neonatal skin injury compared to formal education. However, with highly specialised workforce such as in neonatal care and a diverse set of associated causes, specific skin injury education for clinicians is required. The formal sources seem to divide skin injury into segments related to particular devices, whilst clinicians noted that products change or are updated frequently. This indicates a need for skin injury education to be more focused on the injury formation and pathophysiologic factors so that these concepts can be considered despite experience with the device or inexperience with neonates. The need for population specific skin injury education has been previously suggested,[175] but not currently available. This re-enforces the need for more formalised neonatal specific skin care education. Furthermore, the findings from this study, that skin injury risks are related to system-based challenges such as staffing and equipment correspond with contemporary skin injury models which incorporate these challenges as well as mechanical forces.[14]

Review of the language has highlighted that participating units demonstrated workplace culture where skin injuries are a high priority and a topic relevant to current practice. This discourse matches the expectations from NSHQS for surveillance of skin injuries, yet there is a lack of a framework for risk assessment, prevention and 'best-practice', currently available for neonatal clinicians. Neonatal sources demonstrate a system of transparency and trust for assessment and reporting which are evidenced by prompts within nursing and medical documents. However, the style of providing free text or blank spaces encourages generalised descriptions increasing the potential for diversity of language. While the volume of communication demonstrates importance, the variety presents significant challenges especially for benchmarking and reporting, specifically because this outcome is measured by categorical groups. Without a common nomenclature and definition, the evaluation of skin injury prevalence as well as effectiveness of prevention or interventions, will likely be inconsistent. This has been previously demonstrated in adult population studies, with over half of adult skin injuries reported inaccurately categorised (n=253, 69.7%) due to uncertainty of type, or stage, especially with superficial injuries.[195] In the absence of a diagnostic process, neonatal clinicians could be caught in the same predicament, assessing and describing early findings or differential diagnosis. Furthermore, with potentially unmodifiable risks for neonatal skin injury, those institutions who actively monitor and document injuries will be unequally fined with the application of fiscal penalties for hospital acquired skin injury complications.[149] Additionally, the abundance of language with inconsistent injury assessments are likely to affect how coders interpret clinical data for those same fiscal penalties.[27,149]

Conclusions

This is the first study to review skin injury language from international and local data sources, incorporating multidisciplinary perspectives. Language is one of the most useful insights to workplace culture, yet the implications for language on skin injury assessment is poorly recognised. The richness of these results affirm that neonatal clinicians are aware and concerned about skin injuries. However, despite this awareness the contrasting information from formal sources highlights a disconnect between documents, expectations and clinical practice.

This study has identified important data which should be used to inform future theoretical framework(s) or models for neonatal skin injuries; especially considering the increasing rate of prematurity worldwide. Consistent and neonatal specific definitions for skin injuries are needed to give guidance and boundaries to quantify descriptive outcomes, which will impact neonatal skin injury benchmarking. In the wrong context the richness of language for neonatal skin injuries might suggest clinicians are unaware of this problem; but in the scope of this larger work neonatal clinicians are an essential source of insight and advocation for their patients. Therefore, the knowledge and experience of neonatal clinicians should inform the further development of policy and guidelines; and without this empirical knowledge, misrepresentation of locations and risk for neonatal skin injuries will continue to dominate the literature.

Relevance to clinical practice

The recognition and management of neonatal skin injuries are related to language used to describe assessments in the absence of diagnostic confirmation; which has implications for both the neonate and the healthcare team.

8.2 Summary

The range of discourses arising from this triangulation identified clear gaps within current literature and hospital documents compared to clinical experiences. A few minor limitations were considered after acceptance of this publication and at the time of thesis submission. In addition to the 11 key terms used of additional terms (e.g "bed sore", "decubitus ulcer", nomenclature", "classification", or "vocabulary") could have yielded additional results. Whilst the aim of study to establish the language, clinical opinions and workplace culture around neonatal skin injuries was achieved; additional data related to participant's education or training in adult or formal wound care was not identified and may have proven additionally insightful. These results imply an understanding of injury with diverse communication and descriptions. This diversity makes comparison of outcomes difficult and creates challenges for determining best practices. The final chapter summaries the contributions to this aspect of neonatal care.

Chapter 9 Contributions, Recommendations and Implications

This thesis makes a substantial contribution to the science of neonatal skin assessment and skin injuries related to mechanical forces. The research identified non-modifiable extrinsic and intrinsic risk factors additional to those that have been previously reported. Furthermore, this research has achieved many firsts including the investigation of homogenous neonatal groups through CART analysis, to identify predictors of injury as well as considerations for acuity. These outcomes were achieved through a contemporary framework of mechanical force skin injury; in that skin injuries were categorised separately (pressure injury or skin tear), but were investigated concurrently to appreciate the overall risk, prevalence and relationship of these skin injuries for the neonatal population. These outcomes have direct implications for neonatal clinical practice.

9.1 Contributions to neonatal skin care

The first three chapters have contributed to enhancing an understanding of neonatal skin structure, applicability of current risks factors and assessment tools for skin injury. To assist in understanding the intricacies of neonatal skin development, an evidence-based diagram depicting skin maturation across the gestational ages was created. This illustration is the first of its kind to demonstrate fetal/neonatal skin development across the entire gestational age span. More specifically, previous diagrams were limited to ages of 28 weeks and less[91] and did not include important structures such as the periderm. The diagram has been utilised within a University post-graduate neonatal course, recommended as a resource for hospital-based neonatal training modules and incorporated into an international neonatal thermoregulation guideline[283]. The systematic review of antenatally administered steroid's effect on fetal skin maturation led to the incorporation of steroid administration as a possible extrinsic risk factor for skin injury within this research. Additionally, a review of the current neonatal risk assessment tools identified that tools were developed from older pediatric population data, or included risks not reflective of the neonatal population, and many lacked validation. Furthermore, the examination of neonatal classification or severity systems identified inconsistencies in research methods and outcomes measures. These findings identified further gaps in knowledge and practice implications for current risk assessment tools, risk factors including within tools and the severity systems. The examination of risk factors, risk assessment tools and severity systems also led to a number of invited speaker invitations, imparting this knowledge at national and international scientific forums.

The systematic review on frequency of neonatal skin injury related to mechanical forces, established a number of key findings for neonatal practice. The injury anatomical locations differed to locations reported in adults and pediatrics, occurring in areas of soft tissue compared to bony prominences. Frequency of injury was reported as high as 43%, establishing a higher rate than the adult population benchmark (16%).[14] The findings of the review also identified inconsistencies in injury inclusion/exclusion criteria and methods utilized for injury identification, with injury severity often not reported, thus making it difficult to compare outcomes. The findings of this review have direct implications for benchmarking activities such as pressure injury audits and national standards reporting. To date this systematic review has 17 indexed citations.

Another unique set of work, was the document analysis and data from clinician experiences resulting in another peer-review publication. This is distinctive research, as no document analysis has previously been undertaken in relation to neonatal skin injuries, nor have multidisciplinary clinicians had the opportunity to speak freely about their practice. Important outcomes include the absence of a single term or set of nomenclature for neonatal skin injury, limited information on injury etiology, and few references to studies of frequency of neonatal skin injury. Triangulation revealed, rich and deep injury descriptions but broad concepts with inconsistent terminology and limited reference to injury staging/severity. Importantly in addition to the accepted mechanical forces related to injury (pressure, friction, shear, stripping and tear), this research identified additional forces which contribute to injury such as grazing, breaking, taken-off, rubbing, scratching, and blunt force. These findings point to the need for contemporary neonatal skin policies, procedures and assessment forms including a recognition of all mechanical forces.

In addition to the outcome of the CART analysis, the period prevalence study established a hospital-acquired neonatal skin injury prevalence of 41%, consistent with the findings from the systematic review. This is a considerably higher frequency than the adult population, challenging the pre-existing notion that neonates are less prone to hospital acquired skin injury. Older neonates were also at risk for injury, further challenging perceptions of the population at risk. Importantly, most injuries were associated with fixed devices, therefore the risks were non-modifiable with current care delivery modalities. New insights related to devices attributing the most risk, included vascular access and medical adhesives rather than the common perception of nasal interfaces. Additional risk factors such as length of stay, acuity and incomplete course of antenatal steroids have added to knowledge of neonatal specific risks for injury.

This research has revealed the urgent need for repeatable measurement and assessment methods that can be used to quantify neonatal skin injury presence and severity. For example, wound cameras and devices were not feasible for the neonatal environment or measuring the size of skin injuries. However, a unique skin injury assessment method and MGC tool was developed, published and has been applied in two other studies; a randomised control trial for neonatal pupil dilation[284] and period prevalence study of neonatal birth skin injuries (unpublished at this time). The MGC tool and assessment method shows promise in supporting consistency for clinical assessments. These may contribute to improving current models of skin injury assessments which demonstrate some inconsistency, particularly related to assessors from varied specialties (adult and neonatal). Without reliable methods for data acquisition, comparisons within and between neonatal skin injuries will remain subjective affecting benchmarking. This has implications for the utilisation of skin injury as outcome measure for clinical trials and quality improvement projects. Lastly, the treatment of neonates who acquire skin injuries cannot be effectively evaluated, as improvements will be inconsistently assessed.

9.2 Strengths and limitations

9.2.1 Strengths

The strengths of this multicentre mixed methods research are numerous and have been highlighted in publications included in this thesis. Importantly, the multicentred, international nature of the research, means that the outcomes can be generalised to the broader hospitalized neonatal population. Adding to the generalizability of these outcomes, was the inclusion of data from medical and nursing clinicians, as well as adult wound specialists. The importance of this research is recognised as worthy of dissemination by the number of publications and conference presentations. Another strength was the effort undertaken to disseminate the evidence through forums and journals where it would reach neonatal clinicians.

9.2.2 Limitations

As with all pragmatic research, limitations for each of the studies were identified and published within corresponding articles. This included a consideration that the skin development diagram may need revision as new evidence emerges, such as related to development of rete ridges and dermis recently identified. Similarly, the specific development and anatomy of mucosal membrane was undertaken but was outside the scope of this work. However, considering the number of injuries to the nasal area and structure, particular focus on this anatomical region would be informative for future research and practice.[285] Additionally, the document analysis is reflective of the time of data collection and analysis (prior to end 2017), and some of the results might differ if done with an updated National Standards (2017 or 2021). While no exclusions were made for interdisciplinary team members for interviews or focus groups (e.g tissue viability specialists), focused recruitment of adult skin care specialists at the same hospitals may have produced important comparisons to understanding facility-based nomenclature and culture. Similarly, questions regarding neonatal clinicians' training or education in adult or formal wound care could have assisted in understanding knowledge and nomenclature choices from participants of interviews or focus groups. While additional forces which contribute to injury were identified by clinicians (such as grazing, breaking, taken-off) in Chapter 8; tissue viability specialists or other experts might argue these are different labels for the same forces. Whilst 500 neonates were included in the period prevalence study, with more funding and research staff, a larger sample size could have been achieved. In regards to the consistency study, invited specialists only reported on their ability to measure injuries (yes/no), the metric measurement of injury could have been included. While the iOS application was promising and functioned during the study period, it has now been withdrawn from the market.

9.3 Conclusion

Neonatal skin injuries are a hospital acquired complication that will remain a consideration for neonatal clinicians in forthcoming years with patients as young as 22 weeks requiring continuous monitoring and invasive devices. Despite improvements in technology, such as wireless monitoring, the skin continues to be the interface for treatments, procedures and care. The complexities of neonatal skin maturation and structural development will continue to create challenges for healthcare delivery. This research has summarised, confirmed and provided new evidence related to epidemiologic factors for neonatal skin injuries from mechanical force, which provides lasting evidence to inform neonatal care.

9.4 Recommendations

9.4.1 Healthcare policy and reporting

Healthcare policy and reporting, informs and provides a foundation for clinical care; but does not always direct care delivery. This research is clear evidence that neonatal clinicians were aware and concerned about the injuries their patients acquired, but the facility and governmental policies were barriers to data collection for benchmarking and reporting of population specific risks. Therefore, to support the diligent care of clinicians and improve outcomes for neonates the following recommendations are made:

- Standards and guidelines for skin care and injury prevention
    - Consensus is required between neonatal and adult wound experts for neonatal skin injury assessment, outcomes and risk factors. This includes agreement on injury classification scales for types and locations of injury.
    - Neonates need to be recognised as a unique population.
    - Recommendations for anatomical locations of highest risk should be population specific.

- It is essential that risk factors for skin injury are supported by neonatal epidemiologic data.
- It should be recognised that not all hospital acquired neonatal skin injuries are preventable, and data collection should differentiate between fixed and non-fixed devices.
- Panel membership in developing standards and guidelines should include both adult and neonatal trained specialists. This is important to ensure recommendations are contemporary to avoid outdated practices such as stand-alone risk assessment tools and practices that are not applicable to neonates such as ambulation care plan.
- This research would suggest that there is need for a skin safety model or framework for neonatal skin injury similar to those that exist for the adult population.[6,14]

- Considering the relationship between devices and neonatal injury, there should be a mechanism to monitor the frequency of device related complications for this population.
- Similar to other core neonatal outcomes of care (infection or retinopathy of prematurity), data on skin injuries should be collected as part of national and international databases.

9.5 Clinical practice and education

Changes for clinical practice and education are needed to refine the current awareness for injuries, and support a more objective reporting of injury outcomes. Changes are necessary to clinical practice and more formal skin injury education for neonatal clinicians is required. As years of neonatal experience did not equate to improved assessment or knowledge of skin injury prevention, specific educational strategies to support a deeper understanding to enhance memory are needed. Such as case based, experiential learning, and journal club to encourage critical thinking related to practice issues such as placement and securement of fixed devices. Recommendations include:

9.5.1 Clinical practice

- Similar to other medical imaging, clinical images need to become part of the minimum clinical data, and shift the perception of images for use in litigation
- Audits need to include categorization of the type of device to account for those injuries which are preventable due to the nature of the device; adjustable (nasal interfaces) and movable (temperature and saturation probes); comparted to injuries that are not preventable related to fixed devices (endotracheal tube).
- Prevention strategies for injuries should focus on a bundled approach inclusive of: risk assessments, education on offloading forces, with interventions such as prophylactic dressings, patient repositioning systems and standardised protocols.
- Regular skin injury rounds [150], or
- yearly audits as a part of neonatal standard safety care. Rounds should include nursing and medical clinicians with varied levels of experience.
- Clinicians should give equal importance to compressive skin and injury assessments, and not rely on risk assessment tools.
- Neonatal specialists should seek formalised wound and skin care training, as neonates are the population most at risk for injury and specialized neonatal experts' knowledgeable in their unique physiology will help promote best practice assessment and prevention activities.
- Considerations for the level of pain associated with skin injuries should be a part of assessment, and non-pharmacological or pharmacological given, as is practiced for other populations.[120]

9.5.2 Education

- There is a need for the development of cross-discipline, formal neonatal skin training; to support entry level and advanced practice neonatal clinicians. Key training elements should include

    - Skin structure and development
    - Skin and injury assessment
    - Injury severity and categorisation
    - Risk factors and risk assessment tools as part of a bundled approach
    - Prevention strategies, including structured recommendations for fixed, adjustable, movable and devices.

- Medical and nursing postgraduate courses should incorporate skin as a major organ for consideration with care delivery.

- Based on the variety of language and interpretation of nomenclature, education and evaluation would be warranted for staff who work within hospital system to interpret clinical documentation into fiscal penalties related to skin injuries (coding), and the implications of these interoperations.

9.5.3 Future research

9.5.3.1 Recommendations for future research include:

- Investigation of the long-term impact of injuries, including the actual cost of neonatal skin injuries, compared to the fiscal penalties suggested by national standards.
- Exploration of the impact and consumer perception for the correlation between treatment delivery and neonatal skin injuries, inclusive of distress and perceptions of pain.
- Development, adaptation or formal psychometric testing of neonatal skin injury classification systems and/or properties.
- Evaluation of methods for skin injury assessment and measurement such as electron microscope, TEWL, pH, ultrasound, sub-epidermal moister (SEM) scanners (as an early predictor for injury).
- Formal evaluation (validity and reliability including inter-rater reliability) of the NIPIRA or similar assessment tools and the effectiveness of the education.
- Exploration of the role of individual forces on neonatal skin, especially those related to the formation of skin tears and epidermal stripping.
- Exploration of technologies such as device application, injury images and associated data.
- Exploration the role of artificial intelligence in injury recognition and severity assessments.
- Evaluation and comparison of device types (other than nasal interfaces) and securement (adhesive types) with the primary outcome of skin injury.
- Further explore the effects of antenatal steroids on skin development and injury risk.

- Exploration of the concept of skin injury failure in neonates, similar to kidney failure, already established in adult and paediatrics.

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Appendices

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Appendix 1: The Townsville Hospital and Health Service Human Research and Ethics Committee Approval

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Appendix 3: Royal Brisbane and Women's Hospital Human Research and Ethics Committee Approval

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Appendix 4: Dunedin Hospital and Health Service and Ethics Committee Approval

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Appendix 5: Interview and Focus Group Guide

NIPIRA STUDY
Neonatal Skin Injury and Pressure Injury Risk and Assessment Study
The Townsville Neonatal Unit
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NIPIRA STUDY

Neonatal Skin Injury and Pressure Injury Risk and Assessment Study

(Introduction to Interview or Focus Group-) Brief background, you may see me taking notes

Thank you taking time to meet with me to talk about skin injuries in neonates. This discussion/interview is a time for you to share your thoughts, clinical opinions and experience about neonatal skin injuries. We know that neonatal patients are one of the most 'at-risk' age groups for skin injuries and part of this study is about trying to learn what neonatal clinicians already know and understand about these injuries before identifying them in neonatal patients. These are broad questions; feel free to give details and examples (there are no right or wrong answers).

I will need to record the answers for these interviews/ groups so that they can be transcribed and then analyzed for similar themes. You will not be identified on the transcripts. Is everyone happy for me to record the discussions? Due to the group nature of the recording we will not be able to withdraw material once the session has started.

(Focus group only)- What is discussed here will remain confidential, so can we please refrain from using names when talking to keep the confidentiality on the recording. Does anyone feel uncomfortable with the contents of this discussion remaining private? (Allow for discussion if someone suggests hesitation). Any questions or concerns before we start?

How would your describe a neonatal skin injury (SI)?
How would you describe a neonatal pressure injury (PI)?

Prompts: Are there differences between SI and PI?
Is there anything unique about Neonatal SI?
Is there anything unique about Neonatal PI compared to other PIs?
How do you understand the differences between the staging of PI or SI's?
Can you explain these differences between stage 1 and 2 PI?
Can you explain these differences between stage 3 and 4 PI?

Where on neonates do you see the majority of SI/ PI?

Prompts: What anatomical locations on neonatal patients?

(Pictures- option1) Are these some of the injuries you were describing? What can you tell us about these pictures/ what is your reaction to these pictures?

Please share your experience of the types of patients who most often have SI from pressure, shear, friction, stripping?

Prompts: What age/ type of patients?

Where on neonates do you see the majority of SI/ PI?
Prompts: What anatomical locations on neonatal patients?

How do you go about managing neonatal SI in practice, can you describe the process for me?
Prompts: Do you use risk assessment tools (RAT)/ any prevention practices
treat injuries if found/ prevent further breakdown
How well do feel/ think you manage them?
How does the RAT rating change your practice?

This study is partially interested in neonatal SI caused from Pressure, Shear, Friction, and stripping. Can we talk about the care involved with neonatal SI how do you feel about it for your patients?

Prompts:
Care can include identification, treatment, prevention
Is there any part in care SI that you find more comfortable than others?
What is your role in identification of these injuries?
Identifying, classifying, reporting, treating
Do you feel your role is appropriate?

How do junior staff learn about skin injuries?

What education have you received on neonatal SIs?
Prompts: How does the SI education compare to other education such as infection control, medication safety etc.?

Appendix 6: Participant Information and Consent Form for Focus Group and Interview Phase 1, (Stage 2)

Queensland Government

JAMES COOK UNIVERSITY AUSTRALIA

NIPIRA STUDY

Neonatal skin Injury and Pressure Injury Risk and Assessment Study

The Townsville Neonatal Unit

+61 7 4433 3605

E-Mail: Deanne.August@health.qld.gov.au

Participant Information Sheet

Title: Neonatal skin Injury and Pressure Injury Risk and Assessment Study

Short Tile: NIPIRA study

Project Number: HREC/13/QTHS/212 & JCU H6400

College: Medicine and Dentistry, James Cook University

Principal investigator: Deanne August

Location: Townsville Hospital Health Service

You are invited to take part in the interview/ focus-group portion of the Neonatal skin Injury and Pressure Injury Risk and Assessment Study.

Participation is voluntary but we hope you consider in contributing to this area of research. Please review the following information and consider what your participation will require. We would be happy to answer any questions and you will find the contact details of the investigators on page 2. Please remember that *you may withdraw from the study at any time* without effect to your employment or repeated requests to participate from the research team.

The purpose of the project:

Current studies support that neonatal patients are one of the most 'at-risk' age groups for skin injuries[1-3]. Although large paediatric studies investigating skin injures have been conducted involving neonatal populations, few studies have been done with current and selective neonatal populations. This study aims to review risk factors neonatal patients sustain skin injuries (such as pressure injuries and epidermal stripping).

Your Participation:

Neonatal clinicians have an important role in identifying, preventing and managing the skin injuries for their patients. Your participation would include providing your clinical opinions and experience related to neonatal skin injuries in either a focus group or an interview.

Focus Groups and Interviews

You will be notified if you are invited to take place in interview or focus groups. Invitation to one of the two methods will be done to accommodate the schedules and availability of multiple levels of health care professionals.

Focus groups will include 4-6 participants, occur in a separate room from clinical care and be scheduled for a shift you are already working. Group discussions are expected to take between 40 to 60 minutes and are audio recorded. At the initiation of focus groups, the need for confidentiality of discussions will be announced and agreed upon by all present. Any individual uncomfortable with such an agreement can choose to leave before discussions take place.

Questions/ Discussions will be semi-structured, with a few required questions from the research team, but there will also be time for participant suggestions. An example of a question is: *what information is important when identifying a neonatal skin injury?* Answers will be transcribed and collated to look for common themes. These common themes will provide informative results that will influence the staff education sessions for the second section of the NIPIRA study. Your answers will not be disclosed, but collated results will be available at the completion of this study.

Information related to your work location, level of working, and discipline will also be collected. All answers/ recordings will be stored in a password protected or locked locations. Interviews will be conducted in the same manner with the exception that they will involve one participant and one researcher.

There are no expected risks from this project but the team is happy to discuss any feedback regarding the process if it should occur. Benefits of participation are limited to participation in improved clinical outcomes.

Interview/ Focus Group Date/ time & location:

____

If you have any questions please contact the principal investigator:

Principal Investigator:
Deanne L August
PhD student College of Medicine and Dentistry
Clinical Nurse
James Cook University
Phone:

Supervisor:
Dr Yoga Kandasamy
Neonatologist, Townsville Hospital Health Service/ Adjunct Associate Professor
College of Medicine and Dentistry
James Cook University

Supervisor:
Dr Robin Ray
Senior Lecturer
College of Medicine and Dentistry
James Cook University

Co-Investigator:
Dr Karen New
Midwifery Clinical Academic Fellow
The University of Queensland
School of Nursing, Midwifery and Social Work

If you have any concerns regarding the ethical conduct of the study, please contact:

HREC Chairperson

Townsville Hospital Health Service

TSV-Ethics-Committee@health.qld.gov.au.

Human Ethics, Research Office

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Appendix 7: Staff Participant Informed Consent Form

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Appendix 8: Clinical Images Used for Discussion During Interviews and Focus Groups

Image A

Image B

Image C

Image D

Image E

Image F

Appendix 9: Participant Information Sheets and Consent Forms for Period Prevalence Study Phase 2, (Stage 1)

Queensland Government

JAMES COOK UNIVERSITY AUSTRALIA

NIPIRA STUDY
Neonatal skin Injury and Pressure Injury Risk and Assessment Study
The Townsville Neonatal Unit
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Participant Information Sheet

Title: Neonatal skin Injury and Pressure Injury Risk and Assessment Study

Short Tile: NIPIRA study

Project Number: HREC/13/QTHS/212 & JCU H6400

College: Medicine and Dentistry, James Cook University

Principal investigator: Deanne August

Location: Townsville Hospital Health Service

Congratulations on the birth of your baby. This is an information sheet for the Neonatal skin Injury and Pressure Injury Risk and Assessment (NIPIRA) study.

Your baby is invited to take part in a research study that is observing babies in the neonatal unit for potential skin injuries. What we do know is that babies' skin is not yet mature when born and the literature suggests that it may take months and up to one year to mature. What we are yet to understand is the full effect of medical devices and adhesive tapes on babies' skin. These devices and tapes are an essential part of the care of your baby; and while the nurses and doctors take care to prevent any damage to the skin while in hospital, complications can still occur. These complications we define as skin injuries, sometimes called pressure injuries. This study is looking to identify and collect information on babies' skin condition to determine if in future, a risk assessment tool can help identify which babies may be more 'at risk' to sustain injuries.

The study is being conducted by Deanne August, a PhD candidate in the College of Medicine and Dentistry at James Cook University.

Study Protocol:
What does this study mean for your baby?

As part of routine care, nurses and doctors examine your baby's skin on a daily basis. We call these examinations skin assessments. If a skin injury is found on your baby normal hospital policy will be followed which may include: reporting, documentation and treatment of the injury as needed (treatments could include the application of a dressing to the injury). If you give us permission by signing the consent form, the NIPIRA study team will be informed and a photograph will be taken of the injury. The specialised tape measure will be placed in the area of the injury so that the size and colour of the injury can be measured while photographs are taken. Only the injury site will be photographed and all care will be taken to ensure that your baby cannot be identified from the photograph. This photograph will be collected, along with the skin assessment, and injury measurements to help investigators understand why injuries occur. The study team will document the type of injury and may collect information from your baby's chart about their birth age, weight, nutrition, and treatments while in the neonatal unit. The measurements and photographs will be undertaken at the time of routine cares to ensure that your baby is not disturbed unnecessarily and to minimise any additional handling. The injury assessment should not take longer than 5 minutes and not pose any discomfort for your baby. This study does not involve taking any blood or additional treatments.

Participation in this study is completely voluntary and your baby can stop taking part in the study at any time without a reason. Withdrawing your baby from the study will not affect any aspect of your baby's care.

All information about your baby will be allocated a code, so no personal identifying information is kept. The data from the study will not identify your baby in any way. The research outcomes will be presented at scientific conferences and published in nursing and medical journals.

If you have any questions please contact the principal investigator:

Principal Investigator:
Deanne L August
PhD student College of Medicine and Dentistry
Clinical Nurse
James Cook University
Phone:

Supervisor:
Dr Yoga Kandasamy
Neonatologist, Townsville Hospital Health Service/ Adjunct Associate Professor
College of Medicine and Dentistry
James Cook University

Supervisor:
Dr Robin Ray
Senior Lecturer
College of Medicine and Dentistry
James Cook University

Co-Investigator:
Dr Karen New
Midwifery Clinical Academic Fellow
The University of Queensland
School of Nursing, Midwifery and Social Work

If you have any concerns regarding the ethical conduct of the study, please contact:

HREC Chairperson
Townsville Hospital Health Service
+61 7 4433 1440
TSV-Ethics-Committee@health.qld.gov.au.

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Appendix 10: Recruitment Advertising Brochure

References

August DL, Edmonds L, Brown DK, Murphy M, Kandasamy Y. Pressure injuries to the skin in a neonatal unit: Fact or fiction. *Journal of Neonatal Nursing.* 2014; 20 (3):129-137.

Australian Wound Management Association. *Pan Pacific Clinical Practice Guideline for the Prevention and Management of Pressure Injury.* Cambridge Media Osborne Park: Australian Wound Management Association; 2012.

Dunbar N, Cullinan A. Australian Safety and Quality Goals for Health Care: Consultation Paper. In: Australian Commission on Safety and Quality in Health Care, Version 3 (3) Australian Government; 2011: 1-51.

Visscher, M., Taylor, T. Pressure Ulcers in the Hospitalized Neonate: Rates and Risk Factors. Scientific Reports 4. 2014.

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This brochure was created by the THHS NIPIRA team

The NIPIRA study
has been reviewed and approved by the
Human Research Ethics Committee
for the Townsville

HREC/13/QTHS/212
SSA/14/QTHS/37
JCU H6400

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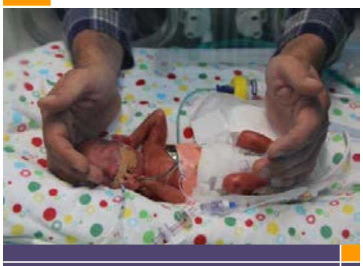
PO BOX 670, Townsville QLD 4810
The NIPIRA study
IMB
07 4433 1111

The Neonatal Skin Injury and Pressure Injury Risk Assessment (NIPIRA) Study



A collaboration between Queensland Health and James Cook University

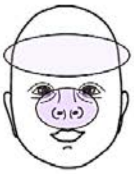
JAMES COOK UNIVERSITY AUSTRALIA

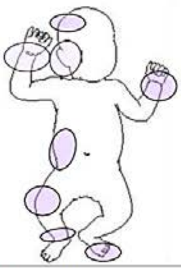
Queensland Government

What is a skin injury?

A skin injury, sometimes called a pressure injury, is defined as damage or breakdown of the skin that may extend to underlying tissue from force. These injuries can be caused by pressure or other factors affecting your baby.

The diagrams below show places where an injury may occur.





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Skin is the largest organ in the human body. The skin is a barrier to infection and enables your baby to sense touch.

Why should we study them?

The skin is a natural barrier to infection and it is important that we look after it. Skin injuries can develop quickly, may cause pain, leave scars and delay recovery. Full skin inspections are carried out with routine neonatal care.

This study will learn more about which babies' suffer from skin injures so we can learn if and how we may prevent them.

Where do they occur?

Typically skin injuries occur over bony areas. These injuries may be on the surface of the skin, may affect deeper tissues or may caused by the removal of adhesives. In the neonatal population skin injuries most often occur as a results of devices such as intravenous cannulas, oxygen prongs, oxygen saturation probes (SpO_2 probes), and identification bands.

What to look for?

You know your baby best. Inform staff if you observe changes:

- in colour (red/purple/blue) or condition of your baby's skin
- to how the skin feels (dry, shiny areas, blistering)

Who else can help?

The nurse and doctors looking after your baby are well informed about the study elements and can assist with treatment if an injury is found.

Appendix 11: Recruitment Advertising Poster

NIPIRA Study

Neonatal Skin Injury and Pressure Injury Risk Assessment

Parents we need your help with the NIPIRA Study. This is a study in which we like to observe your baby's skin while in hospital.

While in hospital some babies may experience skin injuries. It is difficult to predict which babies will have these skin injuries and why they occur. Nurses and doctors regularly check your baby's skin and may find one of these injuries. The NIPIRA study will collect information from babies who have and babies who do not have skin injuries. Babies who do not have injuries are just as important to the study, to help us understand why the injuries occur.

Interested?

Ask your baby's nurse how you can participate.

This study is supported by: JAMES COOK UNIVERSITY AUSTRALIA; Queensland Government