Title

An international consensus on device-related pressure ulcers: SECURE prevention

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Foreword

While there is continuous progress in medical technologies and design of devices, many of the most commonly used medical devices such as endotracheal and nasogastric tubes, oxygen tubing, non-invasive ventilation masks, urinary catheters, cervical collars and casts have changed very little over a period of decades. For example, endotracheal tubes similar in design to the ones used today (including the "cuff" balloon for fixing the tube to the trachea and preventing air leakage) were described in medical articles in the 19th century. While sterilisation procedures for these tubes improved substantially, very little has changed in the basic engineering design. It is not surprising therefore that these traditional devices are also the ones which are most frequently associated with medical device-related pressure ulcers (MDRPUs).

These injuries are a common hospital-acquired condition that may also increase the risk of developing potentially life-threatening infections (e.g. sepsis); cause pain, leave scars which may be very visible and cause distress; result in permanent hair loss, altered body image and/or quality of life; increase length of stay; consume additional resources (time and products). Moreover, as MDRPUs almost always develop within a healthcare organisation, they are a primary cause of lawsuits in many countries focusing on liability of the medical team and facility, with associated costs of litigation, damages or settlements.

The global scale of the problem is considerable, particularly in clinical settings where devices are used intensively, such as in operation theatres, intensive care units and emergency care. Patients of all ages are affected, including pre-term infants, neonates, children, adults and the elderly, with the typical scenario being an environment dense with equipment, tubing, electrodes, wiring and the like, as well as fragile skin and tissues such as in paediatrics and aged care.

The present group of global medical, clinical and bioengineering experts, chaired by the undersigned, met for two days of intensive deliberations in London United Kingdom from 28th February 2019, to develop the first International Consensus Statement on MDRPUs. We have implemented a rigorous process of scientific discussions, drafting of the chapters and thorough review process by an international review committee of experts who were external to the panel. Accordingly, this Consensus Statement is the most comprehensive synthesis of our current understanding of the aetiology, relevant medical considerations and the up-to-date technologies and clinical protocols to mitigate the problem of MDRPUs.

Aimed at generalist and specialist clinicians, as well as biomedical and non-biomedical engineers in academia, research and industry, this Consensus Statement forms, for the first time, a complete and coherent source of evidence-based critical review and guidance on the aetiology, assessment, prevention and management of MDRPUs. It describes the aetiological aspects of deformation-inflicted damage at the cell and tissue levels relevant to the pathogenesis of injuries caused by devices and objects that contact the skin or apply forces on skin. These, include medical devices but also other objects such as patient property (e.g. cellular phones and jewellery) and packaging elements (without a medical purpose). The primary focus, is, however, MDRPUs and the application of the above aetiological knowledge to MDRPU prevention and treatment strategies.

We identify and discuss the devices that are most commonly associated with MDRPUs and the biomechanical reasons for the risks that these devices represent. A particularly important and innovative element of the work of our panel has been to evaluate which engineering concepts and technologies can be used to protect the skin and deeper tissues from MDRPUs and assess if tissues have developed precursor device-related (still likely reversible) damage. Furthermore, we have outlined specific plans that are needed to change the mindsets of practitioners and policy-makers on the need to prevent MDRPUs, including for example how to increase global awareness about root causes, the scale of the problem and its financial implications.

We are certain that greater awareness of MDRPUs will lead to better adoption of prevention protocols (including education and training) and new designs and technologies which are much needed in this field. Accordingly, we have specified fundamental requirements to make future medical technologies effective in prevention of MDRPUs, considering aspects of the quality of fit between the device and the body contours of a patient and safe application procedures. The panel has listed design recommendations that make a good technology for MDRPU prevention with regard to shape, materials and construction, as a guide to the medical device industry. We also refer to how bioengineering design considerations and methodologies may reduce high pressure and shear points applied by devices on skin, alleviate frictional forces and stress concentrations on skin and within deeper tissues, and also, generate optimised microclimate conditions at and near skin-device interfaces.

In conclusion, the work of the panel provided, for the first time in the literature, detailed explanations concerning how devices should be used and applied safely in clinical settings, and how to improve biomechanical and thermodynamic tissue conditions at skin-device interfaces for effective tissue protection. The future research work that is needed in the field, including laboratory tests and computer modelling for MDRPU prevention, is discussed as an outcome of these scientific and clinical research deliberations. Multi-disciplinary efforts are the key to success in mitigating MDRPUs, and the team effort of the present consensus group provides the corner stone in working towards this goal.

Chapter 1. Introduction

The Panel recognises that globally a number of different names are used for PUs. In addition to "Pressure Ulcer", "Pressure Injury" (PI) is currently used by NPUAP (NPUAP, 2016), and "Deformation Injury" (Gefen, 2017) and "Pressure Damage" has been proposed. To date, PI has been adopted in Australasia although not entirely in the USA and Canada, and not in Europe or the UK. The terminology may be specific to a hospital or university. The term "Deformation Injury" focuses on the primary fast-acting damage mechanism – tissue deformation - that leads to rapid cell death and tissue breakdown. Throughout this document the term "Pressure Ulcer" (PU) is used and should be taken to encompass the other terminologies used to cover tissue damage or injury caused by pressure, shear and tissue deformation.

Pressure ulcers (PUs) are defined by the European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Ulcer Advisory Panel (NPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) as (NPUAP et al, 2014a):

'Localised damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue (NPUAP, 2014a)'.

This general definition defines all PU types, encompassing various causal factors. However, the focus of this consensus statement is PU related to device use and/or misuse and the associated design and application considerations. A key causal component of PU formation, as in the international definition, is pressure, friction and shear. In many PUs the main cause of pressure and the associated shear forces is body weight when, for example, a patient is immobilised in a supine position for extended periods on a support surface. Such pressure, friction and shear exposures cause tissue deformations, inflammatory oedema and ischaemia that altogether lead to PU in common bony anatomic sites such as sacrum, ischium, trochanter, heel and other sites. By contrast the NPUAP states that medical device-related pressure ulcers (MDRPU):

'...result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system (NPUAP, 2016).'

The NPUAP extended the definition of a medical device to include objects such as spectacles and other devices without medical purpose.

In order to differentiate DRPU from PU which arise because of body weight forces, the panel proposes defining a DRPU as follows: [panel to consider waiting to see what the definition in the guidelines (eg NPUAP etc) say, so that we are not at odds with it]

'A DRPU involves interaction with a device or object which is in direct or indirect contact with skin ('indirect' refers to e.g. through clothing or under the bedding) or implanted under the skin, causing focal and localised forces that deform the superficial and deep underlying tissues. A DRPU, caused by a device or object, is distinct from a PU which is caused primarily by body weight forces. The localised nature of device forces result in the appearance of skin and deeper tissue damage mimicking that of the device in shape and distribution.'

The term "medical device-related pressure ulcer" (MDRPU) focuses the clinician and others on PU related only to medical devices. Importantly, a device-related pressure ulcer may be caused by a medical device or a device, object, or product without a medical purpose. Throughout this consensus the term "device-related pressure ulcer" (DRPU) has been used to emphasise the importance of understanding that PU may be related either to medical or non-medical devices. This is covered in more detail in Chapter 3, Devices Associated with DRPU. Briefly, medical devices associated with PU may include products that are used to sustain life in sick patients, for example continuous positive airway pressure (CPAP) masks, oxygen therapy tubing, and endotracheal tubes, or less critical devices such orthotic devices, indwelling lines and bed frames. Paediatric patients are particularly susceptible; the devices related to DRPU in paediatric patients are also covered in detail in Chapter 3. Devices or objects that do not have a specific medical purpose may include the patient's own property, objects left on the patient's bed or support surface, for example cellular phones and jewellery. Both DRPU and PU not directly related to devices may present at any of staging level depending on the depth of wound and number of tissue layers involved defined by NPUAP (2016) (1 to 4 and unstageable). DRPUs may be difficult to classify as they often occur in regions with minimal soft tissue coverage e.g. nasal bridge and ears. Nevertheless, most DRPU are Stage 1 and 2 but up to a quarter may be unstageable (Black et al, 2010). A DRPU on the bridge of the nose, where the tissue has no padding, may rapidly progress from Stage 1 to Stage 4 or unstageable.

International PU guidelines

Guidelines on the prevention and management of PU, including to varying extents DRPU, have been published by a number of international consensus groups and wound management societies. The NPUAP/EPUAP/PPPIA Guidelines are the most widely cited. This consensus statement has taken account of guidelines used globally including those from NPUAP/EPUAP/PPPIA, which have been implemented in many countries such as Australia, Japan [NO to provide reference], Israel [AG to provide reference], Portugal, the UK and Italy. The 2009 and 2014 NPUAP/EPUAP/PPPIA Guidelines have been translated from English into many languages (such as Chinese, Czech, Danish, Finnish, French, German, Greek, Italian, Japanese, Norwegian, Portuguese, Spanish and Swedish, to name a few) and these translated versions are available for download via the EPUAP and NPUAP websites.

Why is a consensus statement specific to DRPU needed?

DRPU is an understudied area that varies widely. The prevalence of PU is widely reported to be variable by the type of setting (Woo et al, 2017; Gardiner et al, 2016; García-Molina et al, 2018; Carlsson and Gunninberg, 2017; Razmus and Bergquist-Beringer, 2017; Kayser et al, 2018). A recent systematic review and meta-analysis reported the estimated pooled incidence and prevalence of DRPU in over 126,000 patients in 29 studies to be 12% and 10% respectively (Jackson et al, 2019). In specific cases where the prevalence and incidence of DRPU are reported, the overall rate of PU in inpatients in a US hospital setting was 5.4%, of which 34.5% were accounted for by DRPU (Black et al, 2010). The overall incidence of DRPU or skin breakdown may be as high as 5% (Wille et al, 2000) but for patients with respiratory failure managed by non-invasive ventilation or CPAP the figure may be over 14% (Yamaguti et al, 2014). Patients managed using medical devices are more likely to develop a PU or skin breakdown than those not (Black et al, 2010; Yamaguti et al, 2014) and DRPU may account for between 60.7% and 81% of all hospital acquired PU (Clay et al, 2018; Ham et al, 2017). Up to 68% of DRPU are associated with respiratory devices (Barakat-Johnson et al, 2017), and 20% of these are specifically associated with BiPAP/CPAP devices causing PU on the bridge of the nose and/or nasolabial fold (Clay et al, 2018).

Devices used in intensive care are particularly associated with DRPU (Barakat-Johnson et al, 2017; Barakat-Johnson et al, 2019; García-Molina et al, 2018). In a recent S/R of DRPU in ICU in over 11,500 patients, inconsistencies in the staging and reporting of DRPUs, along with other variations in data collection methods, study design, as well as reporting, were found which affect the reported incidence and prevalence rates (Barakat-Johnson et al, 2019). An incidence audit of DRPU in Kyorin Hospital, Japan, conducted over 12 months from 1st February 2018 to 31st January 2019 clearly demonstrated the difference between ICU and general wards. The incidence of DRPU in ICU was 2.8% which is consistent with published data. By comparison, the incidence on general wards was 0.36% (Figure XXXX). This lower incidence is likely to be because higher numbers of devices are used in the ICU setting compared with general wards.

DRPU account for up to 50% of all PU in some high-risk patient populations such as neonatal and

Chapter 1. Introduction

intensive care settings. A third of all PU in children over 1 year of age are device-related (Schlüer et al, 2014). Infants who develop DRPU are younger post-partum, with shorter gestation, and develop DRPU earlier than patients with PU caused by body weight (Visscher and Taylor, 2014). Mechanical ventilation and a respiratory diagnosis are associated with higher risk of DRPU in this population (Schindler et al, 2007). The incidence of PU in paediatric patients may be as high as 28% with non-invasive mechanical ventilation associated with PU formation (relative risk ratio 12.24) (García-Molina et al, 2018; Li et al, 2015; Jayaratne et al, 2014; Newnam et al, 2015; Iwai et al, 2011; Gunlemez et al, 2010). In new-born patients, devices may severely affect and distort nasal cartilage. DRPU have been reported in 3.1% of intensive care patients (Coyer et al, 2014) mostly associated with endotracheal and nasogastric tubes and trauma patients (Ham et al, 2017). An audit of PU prevalence in the US reported that approximately 10% of all PU in the US in a variety of health care settings are device related, with DRPU most common on the face and ears, sacrum/coccyx, heels and buttocks (Van Gilder et al, 2009). DRPU were common across several medical specialty units.

The data derived from the aforementioned studies reveals that DRPUs constitute a significant percentage of faculty acquired PUs and warrant significant attention from clinical, academic and commercial leaders.

Cost of DRPU

The costs associated with PU in general are widely reported and are extremely high, with a rising trend as populations age and as chronic diseases such as diabetes spread epidemically. In the US the total cost of hospital-acquired PU has been estimated at $26.8 billion (Padula et al, 2019a). The total cost of PU to the NHS in England has been estimated at over £530 million based on a patient database audited between May 2012 and April 2013 (Guest et al, 2018). These figures are not directly comparable because of the different health organisations and methods used to collect data, and the settings to which they relate. However, it is clear that even if simple and low-cost prevention measures work, preventing PU will save substantial costs (Padula et al, 2019b). Nevertheless there is little or no published evidence for the costs associated specifically with DRPU, particularly the substantive indirect costs associated with litigation and insurance (in premiums or loss of coverage) as most DRPU are hospital-acquired injuries [link to reference not working]. It is noteworthy that lawsuits related to DRPU often end with court-approved settlements that are negotiated behind closed doors and not disclosed. Damages and lawyer fees are estimated to total to figures in the same scale of direct medical costs, especially in the US where there are no strict caps to ruled medical damages. The indirect effects of rising costs of insurance premiums to clinicians and facilities have not been reported, but based on the known extent of litigation activities, it is reasonable to assume that they are considerable.

Box A (Biddiss and Chau, 2007; Cummings and Polin, 2016) lists the elements that contribute to the cost, economic and other, of DRPU. Often-overlooked costs include psychological and emotional costs to patients. Such impact can contribute to the direct and indirect costs incurred in patient care, and the greater long-term impact on the wellbeing of a patient disfigured following a DRPU can be devastating. This is particularly of note, because a significant proportion of DRPUs occur on the face and neck, with scarring having inevitable social and psychology challenges. DRPU are typically relatively small and, in direct costs, may cost less to manage per ulcer than a large PU on the sacrum.

Nevertheless, they represent a large economic burden on healthcare systems, especially when considering indirect costs of litigation and insurance policies as above. Plaintiffs will typically sue the institute/organisation, and sometimes, the clinicians who provided the care, personally. Even a conservative cost estimate based on a 10% prevalence implies a significant burden to patients, families and healthcare institutions.

Factors implicated in DRPUs

Multiple factors increase the likelihood that an ICU patient will develop a PU (Lima et al, 2017). Factors that increase the risk of DRPU include the patient's inability to sense the device and its associated pressure, friction and shear acting on the skin due to sedation, encephalopathy, neurologic disease, the inability of the patient to reposition themselves (Black et al, 2010), duration of device use, and the perceived need to secure a device tightly to ensure correct function (Davis et al, 1995; Yamaguti et al, 2014). DRPU develop faster than non-DRPU because of the vulnerability of the patient and body sites affected and are most likely to be facility acquired on the face and neck (Kayser et al, 2018), exit sites and stomas. There are many factors implicated in DRPUs, discussed in Chapter 3. Specific factors include:

1. Often devices do not fit patients appropriately, due to their generic designs and limited size options, especially in paediatrics
2. Device materials are often very stiff and do not conform to tissue shape causing localised skin distortions when they interact with skin and sub-dermal tissues
3. Inadequate guidance is provided regarding device application by both commercial suppliers and clinical educators
4. Many individuals have comorbidities which limit their tolerance to mechanical loads on vulnerable skin and soft tissue sites and/or lead to uncontrolled oedema and a hostile local tissue microclimate
5. Lack of clinician awareness of the importance of reposition, off-loading or rotating devices or correct fitting or securement of the device.

The management of skin health is also complicated by the fact that the device often has a diagnostic or therapeutic purpose. For example, a respiratory device may be required for critical life support and its removal or repositioning may therefore not be possible without compromising the patient's survival. Thus, the need to maintain device in situ may prevent skin assessment leading to existing DRPU not being identified (Black et al, 2010). DRPU have an adverse impact on the affected patient through additional morbidity and reduced quality of life often beyond discharge from hospital, e.g. due to visible scarring (including where there is potential loss of range of motion) [panel to add case study boxouts by FC?], permanent loss of hair, additional healthcare system resources through increased time and specific treatments to manage DRPU, and increased costs.

The panel convened to address the need for greater recognition of DRPU, their causes, management, and prevention. This consensus statement is intended to stimulate action and covers:

- The anatomy and tissue composition in relation to the age of the patient
- The pathogenesis of DRPU with particular focus on why devices are associated with PU
- The devices, both medical and those without medical purpose, commonly and less commonly associated with DRPU
- Assessment of DRPU
- Safe positioning and later use of devices to prevent DRPU and manage them
- Initiatives to raise awareness of DRPU among healthcare professionals
- Medical device design characteristics and features relevant to DRPU and their prevention
- Future research focused on prevention of DRPU through product design, regulations, and monitoring technologies

The ultimate objective for this consensus statement is to improve patients' outcomes and safety during episodes of care.

Chapter 2. Pathophysiology of DRPU

Here we review the pathophysiology of PU in general and then describe the pathophysiology of DRPU. Table XXXX summarises some key similarities and differences between PU and DRPU (Bader et al, 2019).

The principal causes of PU are pressure, friction and shear, and the resulting sustained cell and tissue deformations, the effects of which are exacerbated by moisture and temperature (NPUAP et al, 2014a; Coleman et al, 2014; Brienza et al, 2015; Stekelenburg et al, 2007; Ceelen et al, 2008; Zeevi et al, 2008; Schwartz et al, 2018). Figure X shows a conceptual diagram (Kottner et al, 2018) of the factors that are involved in PU, including DRPU formation [editor: this figure needs to be inserted. JH doesn't have it]. Patients who develop PU frequently have multiple risk factors and comorbidities (Gardiner et al, 2016; Fogerty et al, 2018; Coleman et al, 2013). In most cases, a PU forms at an anatomical location where there is a bony prominence beneath the skin. When an individual spends prolonged periods in a bed or chair, pressure and frictional forces caused by gravity act on the skin over the bony prominences , which compress, stretch and shear tissues, deforming the cells and extracellular matrix (ECM) components, and obstructing vascular and lymphatic flows. Compression, which is always combined with shear, causes local ischemia by occluding the microvascular network of skin capillaries. The pressures required to cause local ischaemia depend on the magnitude of shear in combination with compression and the vascular functionality (cardiovascular system health) of the individual (Linder-Ganz and Gefen, 2007; Pieper, 2012). Changes in the first cells exposed directly to the sustained forces and deformations (Figure XX), due to their progressive loss of cytoskeletal and plasma membrane integrity and as a consequence, their control over mass transport and homeostasis, triggers inflammatory changes (Bader and Oomens, 2018). Inflammatory mediators (Soetenes et al, 2018) secreted from damaged and nearby immune cells lead to progressive inflammatory oedema, which increases the interstitial pressures and further increases the mechanical distortions of cells and tissues, as well as the growing obstructions of the vasculature and lymphatics (Gray et al, 2016). Damage may further be amplified in ischaemic tissues after reperfusion, through the release of reactive oxygen species (ROS), termed reperfusion injury. The damage that results from cell and tissue deformations and the inflammatory damage associated with these first cell death events occurs earlier than the damage caused by ischaemia although the timing depends on the magnitude and duration of the deformation. For example, direct deformation causes pathological change in related to deep tissue injury minutes (Oomens et al, 2015), and tissue-engineered living model systems indicated that skeletal muscle tissue is irreversibly injured by sustained deformations after approximately 1 hour of loading (Gefen et al, 2008). In contrast, purely ischemic muscle damage develops over a 6-8 fold longer time.

Friction distorts tissue which causes shear forces, causing skin and subdermal damage and, ultimately, development of PU. PU related to friction often develop in patients who are partially mobile or with neurological dysfunction that causes repetitive involuntary movement, for example in Parkinson's disease. In paediatric patients, friction-related DRPU have been reported in children affected by Guillain-Barre or Miller Fisher syndromes, which are responsible for insensitivity in the distal extremities: in these fragile cases inadvertent friction damage and damage from burns are frequently seen (Hilz et al, 1992; Chalela, 2001; Kalita et al, 2016; Harms, 2017). The patient, who may already be compromised from skin morphology and/or involuntary, repetitive movements associated with neurosensory deficits, or have reduced tissue tolerance, may exert pressure and frictional forces, for example, on a heel as they push with their feet to reposition themselves. High friction can cause delamination of skin and skin tears particularly in the elderly and those with less mechanical strength in the dermo-epidermal junction (Leyva-Mendivil et al, 2017).

Standard practices in hospitals may increase the likelihood of tissue damage. For example, movement of a patient by sliding can cause friction and high tissue distortions causing shear if it is not controlled using e.g. low-friction interfaces such a slide sheets. Frictional forces acting on the skin are affected by the local microclimate, with increased hydration of the skin increasing the coefficient of friction by 26–43% (Gerhardt et al, 2008). Particular attention must be paid to those children in whom the ability to maintain natural conscious body positions during both mobility and immobility—aka biometry—is impaired due to a neurological or neuromuscular disease (primary or secondary). In these cases muscle spasms ("cramps") prevent natural body positioning and limit the range of motion of joints which decreases mobility and may cause more bony prominences to push against a support surface or other object, which altogether increases the risk of DRPU. Articulated beds, widely used in hospitals to adjust the patient's positioning, are associated with an increased risk of friction and shear damage because the heel may be dragged up to 15cm during articulation, such as raising the head of bed (Fletcher, 2015). Friction between the skin and the surface causes the skin to deform tangentially, causing shear forces (Dealey et al, 2015) and subdermal tissue distortions. The tissues may be damaged either directly through the physical force per se (Reger et al, 2010) (necrotic cell death and mechanical failure of the extracellular matrix (ECM)) or by apoptotic cell death as a result of the direct, necrotic deformation-inflicted cell death and the development of the inflammatory response that follows. Recent evidence suggests that apoptotic cell death may be instigated by signals released during mechanically-induced cell membrane changes. In either case the capacity for the tissue to repair is compromised.

There do not appear to be specific risk factors for DRPU aside from the actual use of the device (Black et al, 2010). A crucial difference, however, is that body weight forces play a less prominent role, with the device typically strapped or taped to the body exerting forces that drive the tissue deformations and distortions (Figure XX; Table XXXX). The affected soft tissues may also be in a 'sandwich' situation, being compressed, stretched and sheared between a device and a bony surface. In many, but not in all cases, the device or object has a small surface area, for example the edge of a face mask, a connector for an indwelling line, or tubing/wiring components of a variety of devices. Thus, although the loads devices are applied with are typically small, the small surface area results in high pressure magnitudes against the skin in excess of 200mmHg (Worsley et al, 2016). Of particular note, are the large pressure gradients i.e. an area of high pressure adjacent to an area of low pressure, which can cause large stresses and strains in the underlying skin and soft tissues. However, in some cases devices such as antiembolic stockings (or TEDs) are often used inappropriately with no assessment of underlying perfusion or sensation so frequently cause damage). In many cases, the skin and underlying soft tissues where the device is placed are not conditioned to take external loads. This reduces the tolerance to pressure and shear forces and increases the likelihood of injury (Bader et al, 2019). This is not the case for more traditional PUs, where sacral, ischial and heel tissues are regularly exposed to pressure and shear forces (in lying or sitting postures) and have adapted over time to accommodate this.

Skin physiology and microclimate

Changes in skin physiology and its microclimate can lead to higher risk of DRPU development. Skin properties are influenced by several intrinsic (e.g. age, medications, systematic diseases) and extrinsic (e.g. temperature, humidity next to the skin surface) factors. The local microclimate adjacent to the skin has been defined as "the climate in a local region that differs from the climate in the surrounding region (ambient climate). It consists of temperature, humidity, and airflow" (Imhof et al, 2009). Excessive moisture at the skin interface and subsequent over-hydration leads to softening of stratum corneum, increased permeability, susceptibility to irritants, barrier disruption of intracellular lipid lamellae and tissue breakdown by faecal/urine enzymes (Kottner

Chapter 2. Pathophysiology of DRPU

et al, 2018). Under-hydrated skin is also more susceptible to mechanical damage, cracks, fissures and inflammation because the epidermis has increased structural stiffness. Indeed, dry skin may also be a contibutory factor in PU development (Lechner et al, 2017). Temperature changes adjacent to the skin are also associated with local physiology changes. These include an increase in cutaneous stiffness under loading conditions (Patel et al, 1999), a decrease in dermo-epidermal adhesion (Hatje et al, 2015) and an increase in metabolic demand. Thus, the skin may be less able to deform and there is a higher susceptibility to injury.

Special population: neonates and paediatrics

A clear understanding of the aetiology and development of PU is being developed but much of the information is based on PU pathogenesis in adult skin. It is important to recognise that the skin and overall tissue composition of a neonate and a child during early development are different to that of an adult. Table XXX Ch2 summarises the key skin features in neonatal patients.

Children and neonates are not miniature adults. The differences in biology and physiology of neonates and children compared with adults (Eichenfield et al, 1999) mean that different approaches must be taken to prevention of PU, including DRPU, in these different age groups. Neonates and premature babies do not exhibit spontaneous movement and repositioning and so are at higher risk for PU (Ness et al, 2013). The skin of a paediatric patient, from new-born neonate to 18 years of age constantly develops and changes over time (Schlüer, 2017; Butler, 2007). Therefore, PU prevention, both conventional and DRPU, must be targeted differently for children of different ages. It is a clinical challenge to maintain skin integrity in critically ill and injured neonates and children in ICU because of the acuity of their condition, the mechanical ventilation used, the technical machines assisting their vital functions (dialysis, extracorporeal membrane oxygenation (ECMO)), severe metabolic imbalance and the type of interventions used (Schindler et al, 2007). The use of devices is the prime causative factor for development of DRPU in paediatric ICUs, with ulcers predominantly on the face and scalp (Smith et al, 2019). The second most common anatomical site for DRPU is the heel which, in contrast to adult patients, cannot safely be offloaded only by change of position (Rivolo et al, 2019).

Neonates in particular, both pre-term and full term, are at high risk of DRPU (Visscher and Taylor, 2014) because of the immaturity of the skin (Cartridge, 2000; Okah et al, 1995; Eichenfield et al, 1999) and its barrier function, and their immune system—particularly the inflammatory response. The stratum corneum develops relatively late in gestation, and in pre-term neonates its development may be related to exposure to the external environment (Agren et al, 2006). The skin of neonates and infants is thin with different biomechanical properties than in adult skin, particularly in pre-term neonates, and does not provide the protective function of adult skin (Eichenfield et al, 1999; Butler, 2007). The skin of infants exhibits biomechanical properties such as stiffness, strength and extensibility that resemble those of elderly skin but are highly distinguishable from those of young adults. Desquamation (Schlüer, 2017; Alexander and Cook, 2006) is abnormal in very premature infants for some weeks after birth, signifying hyperproliferation of the epidermis (Visscher et al, 2009). Skin maturation and adaptation to the post-partum environment happens over an extended time when desquamation slowly increases and in a different manner in all the body areas (Stamatas et al, 2011). Neonates, infants and children in comparison with very elderly patients shows a visible "turnover", and increased production of keratin in hair, nails and other horny organs. However, several observations suggest that infant mechanisms of differentiation and desquamation are either underdeveloped or poorly regulated in comparison to adults (Fluhr et al, 2012; Hoeger and Enzmann, 2002). Furthermore, a high metabolic rate and physiological oedema—common in sick children—increase risk of DRPU in infants.

Compositionally the skin of an infant further differs from that of an adult with greater proportions of adipose tissue with higher water to lipid ratio. Full functionality and establishment of the protective acid mantle takes several weeks post-partum to develop (Visscher and Taylor, 2014; Evans and Rutter, 1986). A dehydrated infant may be hypoxic because of poor skin perfusion and the affected tissue may break down with only minor insult (Butler, 2007). Infants with multiple organ dysfunction syndrome are particularly at risk of PU (Cohen et al, 2017). Furthermore, as mentioned above, the infant's immune system is immature, with immature monocytes, and neutrophils that respond poorly to inflammatory cytokine stimuli (Simon et al, 2015). As a consequence of all the above factors, the infant skin is fragile and less tolerant to mechanical loading (Levy et al, 2017; Alexander and Cook, 2006) and injury (Visscher and Taylor, 2014).

The inflammatory cause of skin damage

The overt visual signs of skin damage are the result of inflammation initiated by the forces caused by pressure, shear and sustained tissue deformation. The damaged cells and ECM release inflammatory mediator signals that promote infiltration of the site of damage by neutrophils and monocytes, increase the permeability of the vasculature and lymphatics, orchestrating a cascade of inflammation that is intensified by prolonged exposure to the forces and loads on the tissue (Chen and Rogers, 2007; Yager and Nwomeh, 1999; Zhao et al, 2016; Schultz et al, 2011). Increased vascular permeability allows fluid to enter the extravascular space leading to build-up of oedema which is initially present at the micro-scale and not visible to the naked eye. Furthermore, new-born infants have a physiological oedema. The forming oedema gradually adds mechanical stress to cells and tissues, and if not being contained, may exacerbate tissue damage. Reactive oxygen species (ROS) and proteinases (Roger et al, 1995; Schultz et al, 2011) further degrade the tissue, eventually leading to the formation of visible tissue damage in a mechanism common to most chronic ulcers. Detailed understanding of the cell damage mechanisms and the injury pathways from a physiological, mechanobiology and bioengineering perspectives, will aid the evaluation of existing devices, support the improvement of medical device designs and pave the way to eliminate the problem of DRPU, in collaboration with clinical colleagues. Multidisciplinary research involving team work of academics, clinicians and industry is the only route for achieving this goal.

DRPU are caused by the same mechanisms as PU; pressure, friction, shear and tissue deformations exacerbated by moisture and temperature. The exposure time during which tissues are continuously distorted is clearly a critical factor affecting the clinical outcome—of whether a DRPU develops or not. The contribution of the time factor has been described by the widely-used Gefen curve—a sigmoid-type relationship between the magnitude of loading (mechanical deformation or stress in a tissue) and exposure time to the loading, which defines the injury threshold (tolerance) of the tissue subjected to the loading (Gefen et al, 2019; Gefen, 2009a; Gefen, 2009b; Gefen et al, 2008; Linder-Ganz et al, 2006).

In addition, the designs for devices do not account for heat trapping between the device and skin which can be substantial, for example under contours of oxygen masks (Gefen et al, 2019). Heat trapping under devices increases moisture and skin fragility, while elevating the tissue metabolic demands under progressive shortage of metabolic supplies and waste product clearance.

Where a device has been used for a medical purpose it may be retained using elasticated straps or tapes that prevent movement of the device over prolonged periods as in oxygen masks (Worsley et al, 2018) for non-invasive ventilation. The device is immobilised and generates pressure and frictional forces at the device-skin interface. This ultimately causes visible tissue damage (Visscher et al, 2015) at

Chapter 2. Pathophysiology of DRPU

the skin surface and/or subdermally where interface pressures can be high. Oxygen face masks may create interface pressure at the nasal bridge of between 47.6 and 91.9mmHg (Brill et al, 2017). Oximeter devices clipped on the earlobe may apply local pressure that exceeds capillary pressure (Goodell, 2012). Some devices may increase the risk of DRPU because of increase the amount of moisture, a known risk factor for PU formation. This is particularly the case where some devices deliver humidified therapies as part of the intervention causing local changes in the function of the stratum corneum (Alqahtani et al, 2018).

The tissue loads may be exacerbated by changes that happen in the patient once the device has been fitted. A device that is properly suited to the patient may have been selected and applied appropriately for the patient's existing status. However, in patients undergoing fluid resuscitation, and those with lymphoedema, or with heart failure, oedema can develop after a device has been fitted (Callaghan and Trapp, 1998; Black et al, 2010). The oedema increases the volume of tissue under the device and the distortions of cells and ECM, as well as the vascular and lymphatic networks in the vicinity of the site of application. Unless the device is refitted, the load applied to the skin increases, increasing the risk of DRPU.

Furthermore, the clinician may tighten the fixation system to reduce the likelihood of device failure. Figure XXXX is an example of an oedema-related DRPU. The localised oedema itself can be escalated by the inflammatory response associated with a PU which develops under the device, leading to an additional increase in internal tissue stresses and deformations and reduce blood perfusion and lymphatic function. Paediatric, psychiatric or dementia patients or persons under anaesthesia, analgesia, unconsciousness or partial consciousness conditions may be unable to communicate discomfort, pain, and the need for repositioning, leading to continued exposure to the loads that lead to DRPU (Dixon and Ratliff, 2005).

Mechanobiology, employing finite element computational modelling as well as cell culture and tissue-engineered living model systems, analyses the effects of mechanical loads and exposure times on tissue. This approach has shown that:

- High stress concentrations in tissues may be generated by devices, leading to the aforementioned cell and tissue damage pathways associated with sustained deformation (Levy et al, 2017a; Levy et al, 2017b; Oomens, 2013) exposures
- Devices intended to alleviate pressure and tissue loads may themselves increase load and raise the risk of DRPU (Levy et al, 2017b)
- Insensate patients, such as those under anaesthesia, epidural analgesia, a central nervous system injury (brain or spinal cord) or damage (e.g. stroke or multiple sclerosis) or peripheral neural damage (e.g. diabetic neuropathy) are especially at risk from localised high tissue deformations, stresses (Linder-Ganz et al, 2009) and stress concentrations, as they cannot report, respond or react upon such tissue load exposures
- Everyday activities such as toilet sitting increase tissue loads and reduce perfusion (Lustig et al, 2018) and tissue oxygenation, thereby being a high-risk condition for individuals with reduced sensory and/or mobility capacities, as listed above.

Most common causes of DRPU are preventable by improvements in the design of traditional devices such as rigid tubing, electrodes, masks and collars and/or addition of smart materials and structures at the interfaces between these devices and the skin. Additionally, better standards of practice that include technology-aided risk assessment (based on sensor readings and data analytics) and digital monitoring of current devices and the health status of tissues underneath the device would be required for mitigating DRPU. Finite element (FE) modelling also enables population-based analyses, where the variability of individuals shape morphology (e.g. face shape) and soft tissue compliance can be assessed against device design principles (Steer et al, 2019). The foundations for all the above is revised device designs which should account for mechanobiology knowledge and findings, and biomechanical understanding of the interactions between the skin and various existing and new devices. This is addressed further in Chapters 6 (Changing the mindset of practitioners and policy-makers) and 7 (Future research).

Chapter 3. Devices associated with DRPU

Almost any device with a medical purpose which comes into contact with a patient's skin, and/or that passes through the skin, may expose the individual to the risk of DRPU (Figure XXXXX Ch3). The factors that are associated with increased risk of DRPU are outlined in Figure X, Chapter 2. Paediatric patients may be predisposed to DRPU by a number of factors outlined in Table XX Chapter 3. Table X Chapter 3 provides examples of devices that may be associated with DRPU (Black et al, 2010) and examples of objects that do not have a medical purpose, which may be associated with PU.

Devices may be classified in a variety of ways. In Table X we classify medical devices generally according to their primary medical/clinical use. Another example of how medical devices used in paediatric care are categorised in one specialty Paediatric Hospital in Italy (Bambino Gesu' Children's Hospital, Rome, Italy) is shown in Tables 1 and 2. This hospital uses an extensive list of medical devices known to be associated with DRPU in the care of paediatric patients. The list serves as an example of how this specialist hospital addresses paediatric DRPU. Note that devices, sometimes more than one per patient, may be used across clinical specialties depending on the clinical needs of the patient. Devices may also be used temporarily during acute care, for example respiratory devices, patient monitoring, indwelling lines, or for the rest of a patient's life. This latter case includes orthotics and prostheses, or wearable glucose meters for example. Increasingly, patient care takes place in the community setting where therapeutic and diagnostic devices may be used over prolonged periods.

DRPU are common across several medical specialty units. Certain devices are associated with DRPU more than others: tubing devices e.g. oxygen tubing, nasogastric tubes and endotracheal tubes; respiratory masks including CPAP; splints; intravenous catheters and cervical collars (Jackson et al, 2019). Static graduated compression stockings present a DRPU risk for ICU patients (Hobson et al, 2017). Respiratory devices are often critical to patient survival and require an effective air seal. The seal is maintained by selecting the mask with the appropriate size and shape for the patient and by pulling the mask onto the face. Selecting a device with an inappropriate size or shape creates focal pressure points and localised frictional forces which over a relatively short time; within hours or less, can lead to irreversible tissue damage. In the paediatric population, respiratory devices, casts and orthotics, intravenous arm boards, intravenous tubing, oximetry probes and cervical collars are particularly associated with DRPU (Murray et al, 2013; Widiati et al, 2017). A Swiss audit of the point prevalence of PU in 412 paediatric patients in 14 hospitals reported that 44% of patients in the paediatric ICU (PICU) had at least one PU (Schlüer et al, 2012) although the fraction represented by DRPU was not reported. EEG leads, ECMO cannulae, and cooling blankets may cause DRPU in infants who may develop DRPU on their toes, neck, chin, head, arm, foot, nose, chest, ear, earlobe, face, knuckle and buttocks (Visscher and Taylor, 2014). In all patients other devices associated with DRPU include nasal prongs, anti-embolism stockings, ankle bands and epistaxis balloons (Barakat-Johnson et al, 2017). Common anatomic sites for DRPU include the face and ears, lower leg and heels but DRPU can occur anywhere a device contacts the skin (Apold and Rydrych, 2012). Common sites include lips from endotracheal tubes, nose from nasogastric tubes, hand from splints, arm from arterial line tubing, and occiput following use of cervical collars. Mucous membranes are also at risk of PU development with device use.

Extended use of devices is associated with higher and increasing risk of DRPU. Cervical collars are associated with a higher incidence of DRPU after 5 days of continues use, many of which are full thickness injuries (Grade 4) (Davis et al, 1995). Procedures and treatments used concomitantly with a device may increase risk. For example, the use of pulse oximetry during vasopressor therapy (Wille et al, 2000) is associated with a higher incidence of DRPU.

There was a clear difference in the type of devices associated with PU in each setting. DRPU associated with elastic stockings were most prevalent (N=13) in general wards with 3 recorded for compression bandages. Two or fewer DRPU were associated with all other devices. Some devices were notable for the absence of DRPU on general wards compared with ICU where devices commonly used in patient care in ICU were associated with DRPU. These include devices used, for example, in body temperature management, blood pressure measurement, pulse oximetry, surgical drainage, and splinting. Devices associated with more DRPU in ICU than in general wards included invasive arterial blood pressure measurement, tracheal cannulae, and NPPV masks. These findings are consistent with previously-published data from other centres; they serve to emphasise the need for prevention and where prevention measures should be targeted.

Figure XXX presents an example of categorisation of medical devices by the type of interaction with the skin and the associated aetiology previously presented in Figure XX (Chapter 2) based on the audit in Kyorin. This method of categorising devices focuses the health care professional on the particular reasons for the associated DRPU risk as outlined in Box [number], Chapter 2 [what Box is JH referring to?]. Focus on the device-related risk factors enables informed use of currently available medical devices with emphasis on DRPU prevention. In this example, devices manufactured using hard materials with a small contact area creating high localised pressure and frictional forces, used to treat or monitor patients, include those known to be commonly associated with DRPU (Table X Chapter 3). Devices with large skin contact areas that create lower pressure sustained over long periods but still substantial static frictional forces and shearing on the skin include splints, pulse oximeters, NIBP cuffs and identity bands. Products used in deep vein thrombosis (DVT) prevention, elastic stockings and intermittent pneumatic compression (IPC) with or without elastic stockings, also fall into this category. We further categorise devices that present risk through moisture or pH alteration which reduces the tolerance of skin to external stresses. This is a particular issue with respiratory products because of moisture expelled during respiration and humidification delivered by the device. Devices in this category include non-invasive positive pressure ventilation (NPPV) masks, nasal oxygen cannulae and tracheal tubes and cannulae. It should be recognised that some devices present risk in more than one of these categories. The immature skin barrier in paediatric patients may be susceptible to toxicity especially under occlusion. Stomas are included in this category because of the possibility of leakage of gastrointestinal (GI) contents onto the skin, causing chemical irritation and bacteria infiltration. Indeed, digestive and pancreaticobiliary enzymes in GI contents are a known risk for skin damage (O'Flynn, 2019). Other relevant devices associated with a MDRPU risk are external orthopaedic fixators which are made of rigid (metal) components, often with curved, thin, sharp or geometrically-irregular elements and surfaces (Castro-Aragon et al, 2009).

Chapter 4. Risk assessment for DRPU

As with any PU, assessing a patient's risk of DRPU formation is a critical step in their prevention through effective risk management and timely interventions. Expert guidelines and best practice statements stress the importance of risk assessment (AAWC, 2010; NPUAP et al, 2014a; NPUAP et al, 2014b; NICE, 2014; UK NHS, 2018; Canadian Institute for Health Information, 2016; Stechmiller et al, 2018; Chen, 2018). As noted previously, the risk factors for DRPU, aside from the use of a medical device, are the same as for other types of immobility- and body weight-related PU. However, the additional risk posed by the use of devices of all types (Table XX, Chapter 3) means that additional awareness among all staff who interact with the patient is required.

It is not enough merely to conduct a PU and DRPU risk assessment. Risk assessment is not a process followed only once, as a patient's risk may change over time. Risk assessments must therefore be part of routine daily practice. The purpose of the assessment is to provide input into the management pathway for the patient, accounting for risk level and the individual drivers of risk. In addition to the patient management steps that are required to prevent PU from other causes, for example pressure relief or removal, friction management and skin care, the management pathway must include specific steps and procedures to mitigate the risk posed by devices and objects which are in contact with the individual. An example of how the risk of DRPU may be highlighted for clinical staff is provided in Figure XXXXX Ch4. The template is derived from one used in a US-based hospital and can be adapted for use in wards, units or other settings. DRPU are specifically included and patients managed with devices are identified to ensure that full risk and skin assessments are conducted.

Risk assessment tools (RATs)

A large number of PU risk assessment tools (RATs) have been published. The panel recommends [editor: see boxout content suggested by JH] that when conducting a risk assessment, it is important to ensure that the practitioner understands and recognises that a patient with a medical device is at a particular risk of PU. In essence, RATs should be regarded as a form of diagnostic tool to identify skin changes and target the appropriate management. Appropriate assessment and monitoring procedures must be adopted throughout the care of the patient to ensure that they are not being harmed. The RAT used should be that, or those, used routinely in the health care setting, supplemented where necessary with the medical device information and clinical judgement. Where current practice in a facility does not include routine risk assessment for PU, one of the RATs should be adopted. An example of a RAT focused on the risk of DRPU in paediatric patients, the Braden QD Scale, has been evaluated and shown to have acceptable predictive value for DRPU formation in the acute paediatric care setting. The Braden QD Scale is, however, non-specific to the type of device(s) used and assesses risk only by the total number of devices used on a patient (Curley et al, 2018). Other paediatric-focused RATs are in development or available (Sterken et al, 2015; Peterson et al, 2015; Kiss and Heiler, 2014; Willock et al, 2016). However, it is clear that new risk assessment tools which are based on patient-specific biomedical data analytics and technology-aided measurements of tissue health status and physiology are required in the field, to replace the traditional ones that have not been developed for the direct purpose of mitigating DRPU (Chen, 2018). Figures XXX and XXXX show suggested examples of how a device-specific RAT may be structured.

Most RATs rate a patient's risk level using a numerical score composited from a number of assessment domains. The score is used to determine whether a patient is at low, high or intermediate risk of PU. However it may be more appropriate to consider specific risk factors for the patient.

DRPU risk factors

Any patient being managed with a medical device should be regarded as at high risk of PU, specifically DRPU, formation. The list of devices shown in Table XX, Chapter 3 provides some guidance but must not be regarded as a comprehensive and complete list. Risk assessment focused on the device element must assume that all devices present a risk and assessment must be conducted accordingly. The management plan must include frequency of assessment as well as strategies to mitigate risk. There is no predetermined frequency for assessments. The frequency of assessment should be dictated by the risk posed by the device, the patient's individual condition, and clinical judgement. Inevitably the frequency of assessment must be higher for high-risk devices, or where the risk is associated with either a systemic condition, nutritional status or other patient-related factors. In addition, the local condition of the skin and subdermal tissues, such as scars from previous injuries which resolved but left fibrous tissue inclusions, local atrophy changes or oedema should be taken into account.

Practitioners should also be aware of the risk of PU caused by devices and objects with non-medical purpose. Table XX Chapter 3 provides examples of such objects. Any object or patient's possession that might become trapped or act as a focus for localised pressure must be noted and a management plan developed to account for it. Some examples include:

- Jewellery that may become trapped between the patient and a surface
- Spectacles that are left on the patient or may be left on the bed unnoticed
- Hearing aids that may cause injury to the ears or interfere with the fitment of a medical device where the fixation involves the ears
- Cellular phone, wallets, coins, keys or hair braids in a patient's pocket.

Assessment

Because any patient with a medical device is at risk, it is important to recognise that in most cases where the risk is identified the assessment is focused on early signs of skin and tissue damage. An example of advanced practice in assessment is provided where staff in the ICU at the Royal Brisbane and Women's Hospital, Queensland, Australia conduct patient skin assessments using a skin integrity protocol embedded in the clinical information system. The protocol requires staff on each shift to complete a full, head to toe, back to front, skin assessment which includes skin under devices. Staff are guided to check under devices every three hours and reposition the device or the patient if deemed necessary, ensuring that the device is not wedged or positioned such that it presents an injury risk. The assessment is documented in the clinical information system using a series of drop-down menus and options to describe colour, warmth, moisture, oedema and turgor of the skin and the presence of any skin injury. An example of a drop-down menu, accompanied by a comment box if needed, is shown in Figure XXX Ch4 drop-down menu.

It is important to note that the skin under some devices can be observed, but for some devices observation is not possible or easy to do because of how the device is used, or because access for skin inspection is limited. Examples are under external orthopaedic fixation frames, plates or splints, tissues beneath surgical collars possibly because of late decision-making on its removal and associated oedema. In such cases, clinicians must use clinical judgement informed by asking the alert patient if there is any pain/discomfort or unusual sensation under the device and being mindful of device positioning. Clinical judgement is especially important for the patient who does not have intact neurovascular function under the device or who cannot verbalize discomfort. In these instances other indicators to assess for are non-verbal cues such as grimacing or agitation. Direct palpation may be possible to assess the skin. A surgical collar prevents the neck moving but in order to palpate the occiput the neck must be flexed. The occiput may be inspected after removing the anterior collar and, with the help of neurosurgery or trauma, log roll the patient with the anterior collar in place and the head held by the MD. Braided or beaded hair can present difficulties in assessment, particularly with dark hair. A DRPU can develop and bleed into the hair, and cannot easily be seen.

Chapter 4. Risk assessment for DRPU

The most common site for body weight-related PU in paediatric patients is the occiput, coinciding with the largest bony prominence and highest interface pressures (Baharestani and Ratliff, 2007). Risk factors for PU in paediatric patients include sedation, hypotension, sepsis, spinal cord injury, traction devices, terminal illness, spina bifida, cerebral palsy, cardiovascular bypass surgery (Baldwin, 2002; Neidig et al, 1989; Zollo et al, 1996; Okamoto et al, 1983), long-duration surgical procedures, ECMO bridge for life connections, and cerebral and cardiovascular (CV) activity probes.

Assessment may present difficulty in some circumstances. Skin changes that signal potential injury are less visible in darkly pigmented skin. Furthermore, skin may be at higher risk of damage because of changes during aging that are detrimental to the skin's biomechanical properties (Langton et al, 2019). Risk assessment should be conducted by the body site that the device will be used on before it is applied or is already in use on. A patient with generally good skin condition may be at risk if they have oedema or lymphoedema. As noted previously, oedema may develop in previously non-oedematous skin after the device has been applied. A patient may be systemically healthy, but locally, where the device is used, there may be high risk which is not captured in a routine risk assessment. Current conventional RAT have low sensitivity and specificity for predicting PU formation (Griswold et al, 2017; Chen et al, 2016; Fletcher, 2017; Walsh and Dempsey, 2011; Ranzani et al, 2016), their use does not necessarily lead to targeted PU prevention (Lovegrove et al, 2018) or prevent PU (Johansen et al, 2014), and they are not comprehensive enough to capture the specific risks associated with devices. It is important therefore that RATs specific to DRPU are developed, based on biomedical and clinical research, potentially utilising new technology that allows assessment of tissue status e.g. using imaging, biocapacitance measurements, inflammatory biomarker measurements or a combination. Together with industry, such RAT should be developed promptly into clinical products and procedures, put into practice and replace the existing RAT. To our knowledge, no medical device has integrated sensing and monitoring that alert clinicians to impending local skin damage, either on or under the skin. This is a clear development opportunity for industry that is addressed in Chapters 6 and 7.

A hand-held non-invasive device, the SEM Scanner (BBI) that assesses sub-epidermal moisture (SEM) is available (Moore et al, 2017). This device scans at-risk skin sites (sacrum and heels) and is able to identify tissue regions that may break down several days before damage becomes visible. The SEM accumulates before visible skin changes can be detected by eye, causing the tissue biocapacitance to increase due to the greater interstitial fluid content. Water has greater capacitance than tissue proteins; the more water the greater the biocapacitance (Peko Cohen and Gefen, 2019; Gefen and Gershon, 2018; Gefen, 2018). The SEM Scanner warns clinicians about SEM several days before damage is visible at the skin surface (O'Brien et al, 2019). The device offers objective and reliable assessment of tissue damage before signs are visible to the unaided eye for the sacral area and heels (Moore et al, 2017), but currently has not been validated for other skin sites, and cannot assess skin under non-removable devices such as casts. In addition, the current size of the sensor makes it unsuited to assessing relatively small anatomical regions such as the nose, lips or bridge of the nose.

Figure XXXXXX Ch4 shows an example of an approach to assessment of neonatal and paediatric patients (Baharestani and Ratliff, 2007). Facilities should develop their own device-specific RAT that will work with their own protocols, based on the patient populations that they serve. Two suggested structures based on a checklist are shown, one for the OR and one for the ICU. In practice checklists would be used by clinical staff attending patients with devices. The checklist is used at each staff changeover. The presence of specified devices on a patient are noted with a check or cross. Any skin injury associated with the device is noted. The presence of a device drives device-specific assessment and adjustment of the care pathway according to the findings. Again these existing protocols are lacking technological support to detect developing injuries under intact skin or precursors of early cell death or tissue damage that is not yet clinically significant, but may rapidly become clinically significant if no intervention is taken. Biomedical engineering scientists should work with clinical researchers and industry to bridge this technological gap as soon as possible.

Most if not all assessment protocols are currently limited in the sense that they completely rely on a lesion or skin irritation to be visible, which is already too late. Technology-aided skin evaluation procedures should replace the visual skin assessments in the future, using for example biophysical markers (tissue biocapacitance discussed above) or biomechanical markers e.g. inflammatory mediators collected at the skin to indicate skin health and extrapolate risk (Worsley et al, 2018; Worsley et al, 2016; Soetens et al, 2019). The device itself or protective means may include visual markers indicating load, tissue status or risk measures.

Clinical management of risk may present challenges. In many cases a device associated with a DRPU may not be serving a critical function that precludes it being adjusted. Examples may be the lie of a tube or electrical cable, a line connector, or a pulse oximeter. However, there may be competing or conflicting clinical priorities where the use of the device serves a critical purpose and moving it is not an option without seriously compromising the health of the patient. A patient may have a clinical emergency, such as airway instability, so that focus on the position and forces of the devices exerted on the lips or other tissues suddenly become lower clinical priorities and periodic assessments may not be completed.

Chapter 5. Safe use of devices, management and prevention of DRPU

Prevention of DRPU [editor: should we add a diagram of the most common sites of DRPU formation, related to epidemiology, categorised by age of patient (neonate, paediatrics and adults)] can be viewed from a variety of perspectives. These include:

- Protocols and standard procedures
- Clinical practice
- Product design
- Education and training
- Procurement.

Education and training are covered in Chapter 6, "Changing practitioners' mind set". This chapter discusses the other aspects of prevention.

Prevention of PU, whether conventional body weight-related or device-related, requires high level of awareness and diligent adherence to practices that minimise the risks posed by patient care. Medical and Nursing team approaches and preventive interventions must consider all the variables and characteristics related to DRPU and the anatomical area being managed (Karadag et al, 2017). It is important to account for the physical form of a device, the clinical goal, the type of tissue and the anatomic area affected. Diligent consideration of these factors allows a picture of the patient and the type of interventions, both more and less urgent, required to reduce the incidence of DRPU. Vigilance, operating procedures, and warnings, based on prior experience, can counteract poor device-and-user interface, and mistakes and lack of training among staff (Amoore and Ingram, 2003).

With this approach clinicians can promptly identify medical device/s and properly consider their use to minimise any skin breakdown at different phases of care. This is especially important in neonatal and pediatric patients admitted to critical areas and during transport in different units (Widiati et al, 2017). In newborn and infants in an Intensive Care Unit devices may be used on 25–30% of the body surface underlining the importance of diligent and consistent observation to prevent DRPU. Studies show that active engagement of end users facilitates effective device use.

Standards of care based on expert consensus recommendations should be followed (NPUAP et al, 2014a; NICE, 2014; Stop the pressure, 2017) (Box 1 Ch5). The UK NHS National Institute for Health and Care Excellence (NICE), and the NPUAP/EPUAP/PPPIA specifically recommend steps and procedures for neonates, infants and paediatric patients admitted to secondary or tertiary care and in other settings if risk factors are present, and recommends the Braden Q scale for assessment. Skin assessment in paediatric patients should cover head to toe and focus on the occipital area, ears, bony prominences, genital area, feet, heel and elbows, and assess skin temperature and erythema. Repositioning should regular according to individual need and local practice guidelines, either with the assistance of a clinician or the patient themselves, using equipment if required. More frequent skin assessment is warranted in high-risk patients. Pressure redistribution appropriate to the age of the patient, and barrier preparations should be used. The NPUAP offers specific recommendations for DRPU prevention (NICE, 2014) (Box 2 Ch5).

DRPU prevention requires a culture that encourages a team approach where all individuals in contact with patients focus on it as soon as they encounter a patient with a device (Gill, 2015). A simple method of ensuring focus is to incorporate DRPU in periodic ward or facility documentation. An example is the "Safety Huddle" document shown in Figure XXXXX Ch4. This example is from a Medical-Surgical unit and specifically reviews DRPU. DRPU prevention requires a high level of cross-functional collaboration and communication which can be facilitated by documentation. The panel recommends that all facilities should have documented procedures/protocols/guidelines for device use (Box 3 Ch5), both medical and non-medical, which are available to all clinical and other staff who come into contact with patients. Procedures should cover device selection and application using appropriate tapes and fixation methods. We recommend that each facility should nominate, and make responsible and accountable, a clinical champion with appropriate education and clinical background to develop and maintain standard procedures, and ensure their dissemination. This approach has been shown to be effective (Orsted et al, 2009).

The facility's standard procedures should be based on recognised published guidelines and RATs. The standard of care protocols should include, where possible, all steps and procedures that should be followed, in enough detail that the protocol is a stand-alone document, the implementation of which does not require reference to another document. The panel recognises that there may be circumstances where a protocol does not cover every possible eventuality, and where for example a patient may suffer a life-threatening change in their clinical condition that requires immediate action that may not be specified in a protocol. In this and many cases clinical judgement and experience must be used. An example is when the clinical condition of a paediatric patient deteriorates and the patient is at end-stage. In this case a device may be used palliatively and the care delivered by an allied healthcare professional. It is critical that the standard procedure is backed up by awareness among clinicians of the risks posed by non-medical devices. Examples include bedding which may become folded under the patient creating pressure and localised shear points, especially with neonates (Table X Ch3).

It is important that procurement functions are aware of their role in DRPU prevention. Direct communication with the manufacturer of a device to identify as much information as possible about all the materials used for making the device, including adhesives, silicones, additives, latex, and all the procedures required for cleaning or sterilising the device, may help in reducing the risk of DRPU in paediatric patients. In many cases procurement is governed by unique local practices, laws, and regulations. Those involved in procurement must be fully informed of the regulations and liaise with clinical staff on their role in DRPU prevention.

The current fundamental elements of prevention include risk assessment, skin assessment, care planning, care delivery, and documentation. The objective of the PU and DRPU prevention care plan is to minimise the risk posed by the use of a device. Risks may be categorised as factors related to:

1. The device
2. The patient
3. The care.

The critical device-related risks are focal or large area pressure, shear, humidity and moisture, and duration of device use. Patient-related factors include age, medical condition, comorbidities, perfusion level, risk or skin changes identified by RAT, skin condition, presence of a device, and previous ulceration or other injury at the site intended for application of a device. Organisational factors include the care setting, skill levels of clinical staff, availability of different sizes/shapes of devices to choose from, availability of appropriate equipment, need to prioritise other, potentially life threatening issues.

The NPUAP has published specific one-page guides on preventing DRPU generally (NPUAP, 2017a), in critical care (NPUAP, 2017b), in paediatric populations (NPUAP, 2017c), and in long-term care (NPUAP, 2017d). Photographs of common DRPU for each setting are given, with advice on prevention. The steps in prevention of DRPU, in addition to the steps for general PU prevention, are adapted from the NPUAP guidance and are shown in Box 4 Ch5.

The published evidence that prevention measures are effective is limited for many interventions, and this may be associated with institutional cultures of

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under-reporting the real occurrence of DRPU due to risks of litigation. However, where evidence is available it should be evaluated and integrated into procedures and protocols [panel to list examples of where evidence does exist for specific devices, and present this in a box]. An example comes from a recent meta-analysis suggesting that of the use of hydrocolloid dressings helps prevent DRPU during non-invasive ventilation (Cai et al, 2019) likely because it provides cushioning at the skin-device contact interface (Black and Kalowes, 2016). Approaches to prevention of DRPU by specific procedures for use with many types of devices have been proposed. However, it is important to note that no commercial dressing is currently known to have been designed specifically for prevention of DRPUs. Clinical staff and decision-makers in hospitals and care settings should be more open to implementing evidence from all levels of the evidence hierarchy (i.e. not relying solely on randomised controlled trials (RCT)). Evidence from cohort and case studies should be considered, in addition to bioengineering research, involving laboratory tests and computer (finite element) modelling and simulations which are relevant to device design evaluations in the context of DRPU prevention. This is also especially important because ethical considerations may seriously limit patient studies related to DRPU, in paediatrics as well as in adults. This is similar to how research and development is conducted in the automotive industry, where crush test dummies and computer models are commonly used to investigate possible injury scenarios and improve protective means, in non-human trial settings, primarily due to ethical considerations. Moreover, the Food and Drug Administration in the US is now encouraging use of computer modelling and simulations, and employment of synthetic/artificial/in silico patient surrogates to support the research, development of design of new medical devices, which is leading to discovery of modes of action and potential routes for device improvements, cost-effectively.

Risk reduction measures should be followed using best practice as previously outlined. Addressing the risk factors should be focused on the main causes of DRPU, bearing in mind that this may inadvertently cause unintended consequences elsewhere. In this regard, too much padding for example may increase the risk of DRPU. Clinicians should remain diligent in monitoring patients using devices.

Where evidence exists, prevention measures have been shown to reduce the incidence of DRPU in a number of settings. The following example describes a process that reduced DRPU, demonstrates a collaborative approach, embeds practice in the unit, and engages with industry on improved technologies and future product designs. An intervention model built around a framework of Plan-Do-Study-Act (PDSA) for improvement was followed (Boesch et al, 2012). The approach reduced the rate of tracheostomy-related PU (TRPU) in a quaternary care children's hospital managing transfer of children on invasive and non-invasive mechanical ventilation to the home setting. The framework was used to develop a care bundle for TRPU. During the bundle development phase, TRPU reduced from 8.1% to 2.6%. Once developed and implemented, the bundle further reduced TRPU to 0.3%. The process included on-line or didactic training of all nurses on the unit in PU risk assessment, full skin assessment and identification, and prevention of TRPU. Measures included displaying the TRPU bundle information in the staff break room and brochures explaining the risks to share with patients. The bundle included:

- The Braden Q RAT conducted every 24 hours
- Full body skin assessments conducted daily
- Device assessments every 8-hour shift
- Keeping device interfaces moisture/wetness free
- Hydrophilic foam barrier was used under the tracheostomy tube flange and around the stoma to wick away fluid
- Extended style tracheotomy tubes in children in whom the neck was not clearly exposed to reduce pressure and frictional forces and in children with behaviours that pushed the tube down the sternum.

The team provided feedback to the tracheostomy tube manufacturer to aid design and development. Design focus was on pressure reduction at three locations where TRPU develop. The bundle is now embedded in the facility's nurse work flow by incorporating it in the electronic medical records system to ensure sustainable implementation. TRPU are reported in real time, tracheostomy tubes are changed according the patient's anatomy, and tubes are placed at the time of tracheostomy by collaboration with Otolaryngology. Staff uptake of the bundle reached 100% in 4 months, demonstrating sustained quality improvement without detriment to the patients.

The practice described above is transferable to other facilities and has been included in the panel's recommendation for prevention of DRPU (Box 4 Ch5).

Figure XXXX Ch5 shows examples of how the risk of DRPU may be managed for devices with small or large surface area and those that present a moisture of pH challenge to the tolerance of skin.

DRPU prevention in practice

The following is an example of how DRPU prevention can be implemented in practice. This particular example is from Japan, where a detailed guide for general nurses and medical staff without a full understanding of DRPU was published. The guidebook defines DRPU as:

'Injury of the skin or subcutaneous tissue caused by pressure with a medical device. It is necessary to distinguish MDRPU from pressure injury of the skin or subcutaneous tissue caused by pressure self-loaded by the patient's weight.'

Clinicians' attention is focused on 10 classifications of medical device that are commonly associated with DRPU (Table XXXX Ch5) and includes sections for each device classification on prevention, DRPU risk assessment, and selection and fitting of devices to prevent DRPU. Clinicians are advised on care required when applying a device and when the patient is wearing a device, informed consent for the patient and family with a focus on medical safety.

A helpful mnemonic for an integrated pathway for DRPU prevention is SECURE which stands for:

- Skin/tissue: thorough assessment, daily or more frequently according to risk. Handoff may be appropriate for continuity of care
- Education: educate healthcare professionals, the patient, carers and family, and industry
- Champion / Collaborate: lead the adoption of evidence-based devices developed through collaboration with manufacturers and clinical colleagues
- Understanding: develop a thorough understanding of the causes of DRPU, patient assessment, and correct product use
- Report: ensure that DRPU are correctly reported in a timely manner
- Evaluate: evaluate devices for their ability to minimise DRPU by thoroughly analysing support data and conducting clinical evaluations in the patient population of the facility.

The panel further recommends that front-line clinicians, with the benefit of hands-on experience of devices and the risks they pose, are well-placed to drive the adoption of available devices with the least risk of causing harm. Such an approach could work in a facility where sub-optimal devices are in use, for example because of formularies, or where a wider range of sizes and designs could reduce the DRPU risk to patients. Clinicians could also drive this by working closely with procurement and formulary staff, presenting evidence where it exists for adoption of different devices. This would be supported by a structured reporting system in local, national and international healthcare settings. For example, in the US, reporting is conducted by the MAUDE facility hosted by the Food and Drug Administration (FDA),

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or the 'Yellow Card Reporting' scheme from the UK Medicines and Healthcare products Regulatory Agency (MHRA). Standard practice of reporting DRPUs will improve our understanding of common device types and sizes which inflict harm, creating a culture of open reporting and levying support from regulatory agencies to impose change on manufacturers who create unsafe devices.

The evidence should encompass clinical and economic outcomes, and focus on product design that minimises risk by accounting for mechanobiological knowledge and tissue biomechanics considerations. Computer FE modelling and simulations, and phantom studies in artificial/synthetic patient surrogates, would provide strong evidence for the potential efficacy of devices, where clinical and/or economic evidence are weak. Minimally such computer modelling evidence may justify running evaluations with the interventions that emerge as superior in the simulations, in the vulnerable populations in a facility. Clinical studies should be conducted to demonstrate the effectiveness of devices in minimising or preventing the incidence of DRPU. Over time, diligently-conducted modelling and clinical studies will enable better medical device design. Clinicians can also request support data on the designed-in safety of devices from manufacturers, from data derived from clinical, lab based and computational studies. On a wider scale, safety of devices is a key element of the Medical Device Directive in the EU and with Health Canada (Health Canada, 2018) through improving how devices may enter the markets, strengthening monitoring and follow-up studies and analyses.

Treatment of DRPU

The fundamentals of managing DRPU are similar to those for managing other types of PU. These include using a recognised classification system to describe the DRPU, for example the NPUAP system; a full assessment of the patient; assess the care plan to account for the PU; regularly assess, measure and document the DRPU; assess and document progress; assess, prevent and manage pain; use a high standard of local wound care. DRPU present different challenges than non-DRPU do because body weight forces are not a dominant cause. It should be noted that DRPU on mucous membranes cannot be staged.

Considerations specific to DRPU include issues with continued use of device for medical reasons; the device may be essential to support patient survival. A DRPU caused by a mask may be managed by changing to different mask, e.g. from one that is transferring forces to the bridge of the nose to a full-face mask transferring those forces to the forehead. Nevertheless, the same mask may need to be used for clinical reasons. In this case, measures to reduce the causative factors should be used where possible. This includes increased monitoring and the use of prevention measures such as effective interface materials and structures. Repositioning to relieve pressures, for example with a face mask, may not be possible [good place to support these statements with case studies, e.g. paediatric CPAP as suggested by FC]. However, repositioning the securement may address the issue. In this case, thin soft interface structures with adequate mechanical and thermal energy absorbance capacities (demonstrated in computer modelling and laboratory experimental work) may provide tissue protection, by facilitating cushioning and/or load redistribution, while avoiding heat trapping between the mask contours and skin.

Reporting DRPU

In order to develop a complete picture of DRPU the panel recommends that DRPU should be reported as such and not conflated with general reporting of PU. A root cause analysis should be conducted to inform the reporting of the DRPU. In the UK, new guidance has been issued by NHS Improvement on reporting DRPU (NHS Improvement, 2019). DRPU should be reported with the information shown in Box XXXX.

Manufacturers must provide instructions for use (IFU) for products, which must consider the risk of DRPU, and clinicians are expected to read, understand and adhere to the IFU. Often the product is removed from packaging remote from the point of use so the IFU is not with the product at the bedside, an issue that must be addressed. Occasionally a clinician will improvise a solution based on assumed likelihood of success, a use pattern known as "off-label". However, using a device off-label may have biomechanical implications that are not fully understood, or may not be intuitive, potentially leading to unintended consequences. It is therefore important to adhere to protection measures that are research-supported and evidence-based along with a device.

Researchers in academia

Researchers in universities as well as in industry should develop physical and in silico patient surrogates for creating new bench-tests for medical devices, to evaluate the associated risk for DRPUs. For example, computer models of three-dimensional, anatomically-realistic body parts of paediatric, adult and elderly patients (including cachectic or obese patients where appropriate) may be used for performing objective, methodological, quantitative and standardised comparisons of the tissue stress concentrations caused by design variants of a device or alternative device modifications, or by the application of a device with interfacing materials and structures. This would identify the most biomechanically effective and cost-beneficial solution for each device and medical problem.

Likewise, researchers should focus on development of physical phantoms of patients or body parts, including neonates, women during delivery, geriatric, cachectic or obese patients, which should be embedded with sensors such as force and pressure sensors, shear sensors, temperature sensors, humidity sensors etc. as standard test apparatuses for evaluating the risks from devices and potential technological solutions. Such work could lead to standards e.g. for the maximum force, pressure and/or shearing a specific device may apply for safe attachment, or how to design contact surfaces of devices with skin (including their geometrical features and material selection). Researchers should also develop new methods, technologies and products for risk assessment and early detection of tissue damage specific to DRPU, based on (expected or assessed) individual tissue tolerance and physiology. Lastly, researchers could develop smart devices and protective materials and structures that absorb mechanical and thermal energy, thereby preventing or at least minimising the potential adverse effects of these on body tissues. Sensor technologies and mechanisms that alert clinicians when excessive forces occur between skin and a device (Laszczak et al, 2016) or when tissues show an inflammatory response to the applied forces, are another promising route for bioengineers to follow. An example is pressure and shear sensing to measure stress at the limb residuum/socket interface for prosthetics (Laszczak et al, 2016).

Regulators

Medical device regulatory bodies, such as US Food and Drug Administration (FDA) and Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom have developed voluntary reporting interfaces, where any member of public, patient or health professional can report harm due to the therapeutic use of a device. An example reporting platform is the US FDA MAUDE website (US Food and Drug Administration, 2019), highlighting incidences of device-related harm. Other countries have similar reporting systems although it is unclear how frequently clinicians and healthcare staff utilise these reporting tools. As such, there is little evidence of specific medical devices, which commonly compromise the health of skin and sub-dermal tissues. This is despite there being strong evidence from clinical reports that particular devices e.g. respiratory masks can compromise skin health (Kayser et al, 2018). It is also of note that recent reports

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have shown a lack of investigation following reports of medical device harm, questioning the role of regulatory agencies in this field (Jewett et al, 2019).

Despite national drivers to improve patient safety to reduce pressure ulcer harm, DRPUs are not routinely reported. Typically these are communicated in the context of service evaluation or quality improvement activities of healthcare organisations (Zaratkiewicz et al, 2012; Nist et al, 2016). Currently, due to the low frequency of reporting, and despite both mandatory and voluntary reporting tools available, there is no overview of which devices would benefit from further study into their design and safety features for high-risk patients. Moreover, the reporting tools do not explicitly gather information about MDRPUs.

In order to provide high quality, safe patient care, data relating to MDPRUs is required. The rigour and consistency of these reports must be ensured to maximise patient benefit. Thus, establishing a robust, evidence-based policy for reporting of DRPUs will be the base of future improvement in prevention of medical device-related pressure ulcers (Groeneveld et al, 2004; Jewett, 2019; Kayser et al, 2018; Nist et al, 2016; Zaratkiewicz et al, 2010).

Regulators' role in reducing the risk of DRPU is to draft regulations that account for risk. Most regulators do this already; examples are the Medical Device Directive in Europe, FDA regulations in the USA, and others around the world. Health Canada has initiated a programme to improve the safety of medical devices through their Action Plan on Medical Devices: Continuously Improving Safety, Effectiveness and Quality initiative (Health Canada, 2018). The panel encourages Regulators to focus on labelling of medical devices to indicate clearly where a device poses a risk of DRPU.

Based on the aforementioned bioengineering work, standards could be developed. Regulators should require companies to comply with these standards and document the performances of their devices with regard to patient safety and the risk for DRPU. Regulatory requirements from industry to publish their compliance with standards and laboratory testing will allow informed decision-making concerning purchase of equipment, and reasonable institutional risk management in using that equipment, including with regard to litigation aspects. In fact, this proposal is similar to what has been done for many years, successfully, in the automotive industry, concerning crash tests that are conducted according to standards and their results are disclosed for the benefit of buyers and users.

The medical device industry and manufacturers

The industry and manufacturers' role in reducing the risk of DRPU is to promptly adopt the current knowledge or design analysis by computer (finite element) modelling and patient phantoms, and further create design inputs that minimise DRPU risks (Bader et al, 2019). This approach should be adopted for redesigning or improving existing products and to design new medical devices. Moreover, the above approach should be used to develop and test interface materials and structures in order to evaluate and rate their contributions to mechanical and thermal energy absorbance, employing a quantitative, standardised manner. New products should account for the causative factors including sharp or curved device-surface geometries, frictional properties (high friction coefficients), hard materials, tissue loads and stress distributions, pressure, shear, humidity, and thermal energy management. The functional objectives are shown in Box 5 Ch5.

This approach was used to predict the tissue deformations caused by a design of spine board with soft layering. MRI scans of the sacral area in 13 individuals informed a computer model which was used to examine the tissue deformation when a patient lies on the board. This preclinical modelling showed that the soft layered design reduced tissue deformation and the risk of deformation injury and PU (Oomens et al, 2013), and quantitative indications were provided regarding exposure to tissue loads for each design variant. Technologies that sense interface pressure and shear as well as temperature and humidity are available (Laszczak et al, 2016; Bader and Worsley, 2018) but should be integrated and translated for the purpose of DRPU prevention. Their incorporation into new devices, driven by aetiological understanding of DRPUs, is an important development that will drive the incidence of DRPU down by continuous monitoring and alerting clinicians to conditions that will likely lead to DRPU.

Engagement with clinical users is crucial in this process. This is part of the requirements of adequate medical device design process and regulations in order to identify risks and develop strategies to minimise or eliminate them from a product. Manufacturers should closely involve clinicians throughout a new product design (NPD) process, an approach that has been successful in paediatric malnutrition assessment device development (Thaete et al, 2019). The medical device design process includes:

- Initial user needs definition
- Identifying functional attributes required to meet the needs including performance standards and limits
- Technology scouting to find existing technologies that meet the functional needs
- Design inputs including performance standards and limits
- Prototyping and design validation
- Final prototype selection
- Clinical evaluation plan (CEP).

NPD must account for the known high-risk devices and patient groups. A particular example is devices for neonates and paediatric patients that account for the proportional differences in anatomy and tissue composition between this group and adults that leads to poor fit (Levy et al, 2015). The risks and incidence of DRPU should be evaluated in the CEP and products redesigned where the risk is too high. Manufacturers should change labelling and develop new instructions for use (IFU) package inserts that explicitly address the risks of DRPU. Such IFU should provide detailed and clear instructions that focus on prevention of DRPU. Factors to address include highlighting design features that address the risk; specific instructions on application, fitting and securement; specific instructions on continuous monitoring and adjustments; and use of recommended interface materials and structures that were specifically designed and tested and have the published bioengineering and clinical evidence demonstrating efficacy in DRPU prevention.

Clinicians and clinical researchers

The clinician's role in reducing the risk of DRPU is to apply devices according to the manufacturer's IFU and document this in the patient records. The clinical educator's role is to ensure that both carers and patients are aware of importance of device application and their potential harm. This is particularly important in the community setting in relation for example to orthotics and prosthetics. Devices should be carefully selected to ensure a good fit with the patient's anatomy and contours and allow adjustability to changes in tissue behaviour volume and contours (e.g. when oedema forms). Clinical evidence to support the role of fit and humidity in nasal bridge damage (Visscher et al, 2015) shows that improved fit is highly likely to reduce potential deformation-inflicted tissue damage. Issues with specific products and device models should be reported and documented and the results shared with the developers, manufacturers and where needed, with regulatory authorities. Altogether, this will put pressure on industry to redesign and, eventually, consider DRPU risks in the original design work of new products. Evidence should be rigorously collected from clinical research in the relevant medical settings to make such cases strong when applying to industry and/or to regulatory bodies.

Chapter 6. Changing the strategies of practitioners and policy-makers

Reducing the risk and incidence of DRPU requires not only a team approach (Chapter 5), but also a shift in the mind-set of practitioners, decision-makers in institutes and policy-makers in government and regulatory bodies. Clinicians and administrators alike must be aware of the risks that medical devices and other objects pose for tissue injury. Clinicians should also know how to assess the risks and skin condition, know how to apply, monitor and adjust devices to minimise the risk and how to ensure that other objects do not cause injury. Administrators need to understand the potential consequences of DRPU with respect to human suffering, healthcare costs, the risk of litigation and consequent effects on insurance premiums or potential loss of coverage. They must act upon this multifaceted understanding. Frequently clinicians and administrators are not even aware of the importance of DRPU and associated risks (Barakat-Johnson et al, 2017; Kim and Lee, 2019). Clinicians at all levels, including nurses, allied health professionals and physicians need to be educated with regard to DRPU prevention. Furthermore, current chart templates and practice of documentation and inpatient records may not have DRPU prevention (Barakat-Johnson et al, 2017) at the forefront. There is therefore a need to raise awareness through education, continuous training and enhanced consistent reporting. Preventing DRPU is not the sole responsibility of the tissue viability specialist or their equivalent, and chances of DRPU prevention program success using only single groups of specialist clinicians in a healthcare facility are low. All practitioners who manage patients with devices must be aware of the risks and strategies to mitigate these risks to prevent DRPU. Administrators, purchase decision-makers, liability specialists (legal teams) and risk management personnel in all types of medical facilities should be aware of the consequences of DRPU from financial (cost-benefit), legal and insurance for litigation perspectives. PU in ICUs were among the harms that most commonly led to substantial compensation following litigation between 1995 and 2012 in England (Pascall et al, 2015).

The key to increased awareness is documented education and continuous training programs, with monitoring of staff performances to ensure adequate and current knowledge on implementation. In addition, practitioners should raise awareness among medical device developers and manufacturers by reporting to regulatory agencies (FDA, MHRA, TGA (Australia) for example). When procuring devices clinicians should ask for the published, peer-reviewed evidence that is specific for the design of that product, either existing or new, and how it is designed with DRPU prevention considerations at its core. While very few products may have evidence demonstrating a low exposure of tissues to deformations and minimal heat trapping when the device is applied, continuous efforts to disclose such evidence will push the industry to invest more in patient safety, rather than rolling the ball to the practitioners who are typically the ones liable for the consequences of a DRPU. It is in the best interest of clinicians and equipment developers/manufacturers alike to conduct and publish the evidence that is required for demonstrating the efficacy of a product in minimising exposure to tissue deformations and heat trapping. The aforementioned bioengineering approaches (Chapter X), provide the means to evaluate the relative performance of devices to protect from tissues strains and have the scope to inform design principles and material choices. The need for education and awareness does not stop with industry and practitioners alone. Policy-makers must also understand the importance and impact of DRPU clinically, economically (cost of care, litigation, insurance for hospital-acquired injuries), and clearly, for patients and their families. This section discusses these matters.

Education and training.

Education and training should not only focus on practicing clinicians and be limited to the care teams but should also expand to administrators and decision-makers who are involved in the process of purchasing medical devices for the organisation, to ensure that awareness concerning DRPUs and at least basic-level knowledge on the topic diffuses to all organisational branches/arms that concern the matter. New information and devices that drive best practice in DRPU regularly become available. It is important that the education and continuous training are developed and repeated routinely to disseminate the new information building-up in the literature, the majority of which is cited in this Consensus Statement. The education and training may be delivered by an organisation's practitioners, by clinical academic specialists, by bioengineers who are experts on the matter, but increasingly manufacturers offer education and training on their products, which must include aspects of DRPU prevention. This education and training by industry should be accepted as long as it meets best practice, and is supported by experts external to the company who can critically review the statements and claims. Developers and manufacturers are best placed to introduce device improvements and new devices. This presents an opportunity for practitioners, bioengineers, scientists and researchers, policy-makers and regulators to reinforce the importance of DRPU prevention and the related requirements for technological improvements and educational programs that will facilitate that. In particular, the requirements for device design and manufacture that account for DRPU risks should be presented to industry by all the above stakeholders, prior to release of improved device versions or de novo device designs. Nevertheless, practitioners often use only products that are available on local contracts and formularies, indicating the importance of ensuring that the products listed are fit for purpose following assessment by all stakeholders and education of users.

Education and training are best delivered using hands-on real-time experience to improve outcomes, after the theory of current understanding of DRPU and published evidence has been adequately presented, and communicated at the level of professional education that is characteristic to the target audience. Formal objective structured clinical examination (OSCE) or observation of practice to monitor the level of knowledge, prior and post the delivery of the educational sessions is important and will improve the educational sessions themselves, and eventually, the clinical outcomes (Brill et al, 2017). In order to establish clinical knowledge new tools are required, similar to those developed by seminal researchers in the field of traditional posture related PUs [panel to provide reference on Beeckman tools PUCLAS].

Hands-on education and training using patients is delivered on clinical wards. In addition, simulation using artificial clinical settings—physical phantoms or dummies—is known to effectively train practitioners in a no-risk environment. Simulation suites are set up to replicate clinical settings, patient conditions and emergencies safely, enabling practitioners to learn techniques for patient management without the risk of harming patients. This is an ideal environment in which to educate and train practitioners in the safe use of devices and strategies to minimise the risk of DRPUs. However, while there are training mannequins available, currently there are no specific phantoms or patient dummies fitted with implanted pressure sensors for training clinicians to minimise the risk of DRPU. From the bioengineering and industry perspectives, such phantoms are needed, for example to train clinicians not to overtighten oxygen masks to the face by having force or pressure sensors embedded in the phantom that will alert when the mask is overtightened (Brill et al, 2017). Additional bioengineering research is needed in this regard, particularly in developing dedicated and better phantoms where the relevant sensors, clinician's evaluation software and feedback to trainees are focused on DRPU prevention. Once that research characterises good practice protocols, the phantoms and dummies will be able to provide quantitative scores of performances to medical staff,

Chapter 6. Changing the strategies of practitioners and policy-makers

which is highly needed as feedback in clinical education and training programs at all levels and settings—from university to continuous education (Boldingh et al, 2015). Moreover, the measures of quantitative performances (e.g. how much force did a nurse apply on the face of the dummy to tighten the mask) will be kept in digital databases, and so the feedback can be comparative within a department, across departments, facilities and medical settings, which is of enormous value in clinical education research as well as implementation. In clinical care settings remote from simulation suites that makes delivery of hands-on simulation training impractical, on-line training modules can be developed. Clearly, the data collected will also be useful to industry, for design of improved and safer devices.

It must not be assumed that because a practitioner has been trained in the use of one design of a device, for example a catheter, they know how to use all designs or design variants of that device. Training must be provided for different designs and design variants where device use and securement differ, or where a facility's protocols may differ from those in other facilities. Staff transferring from one facility to another are a particular focus in this regard. All practitioners, whether currently in a facility, transferring to a new facility, and experienced or inexperienced, should be trained. Digital databases documenting staff performances, as mentioned above, are highly valuable in this regard, because they establish a gold-standard of performance and practice in the facility, and so a new staff member should be trained to meet the current standards. Standards can be improved continuously at the department level, or across the institute, over time, by delivery of additional education and training. New employees joining an institution or agency must receive training on use and securement of the devices that they will use in the facility. For undergraduates, this information needs to be incorporated into education on pressure ulcer prevention modules. Practitioners who must be trained include undergraduates, postgraduates, and all members of the multidisciplinary team; clinicians including allied health, medical and nursing staff. An example of the expertise that may be required in an interprofessional multidisciplinary team is shown in Table XX Ch6.

Non-professional carers and family must also be made aware of the risk of DRPU and be trained to inspect and immediately notify a trained clinician if a device is misplaced or may be in a state that causes or may cause tissue damage. These individuals play a large part in the care and management of patients using devices outside the hospital setting, and sometimes within the premises of the facility. They should therefore be aware of the risk from medical devices and also personal belongings and objects used by the patient, and understand managing the risk. Box 1 Ch6 below lists the instructions that should be given to carers and family. Note however that this is a safety issue. Carers and family who do not have the confidence or ability to follow these guidelines should be advised to seek immediate help from a clinician.

A critical step in reducing the incidence of DRPU is raising awareness—the principle objective of this consensus statement. Clinicians are the most important link in the awareness chain; they are the people faced daily with DRPU and the harms they cause and can drive awareness among manufacturers and law and policy makers that DRPU are largely unaddressed. Clinicians need access to all available information and evidence on devices, including the materials used in them and their safe use. However there are barriers that prevent the clinician from obtaining the information. This consensus aims to start raising awareness.

Evidence should ideally be based around some standard test methods (STM) where the relative performance of the device can be compared to market competitors. This could be achieved through laboratory studies and potentially clinical research in the appropriate setting. Laboratory evidence such as computer (finite element) modelling studies, phantom studies or a combination thereof should show, using high-quality bench-level research, a reduced risk from tissue deformations, stresses and heat trapping examined under the influence of the specific device as defined by its specific commercial brand or model. This is important because products from different manufacturers may differ in shape, structure or material composition. Likewise, high-quality published research evidence should be expected and requested for any protective device (such as interface materials and structures suggested to mitigate the deformation-inflicted or thermal risk from a device), based on rigorous studies and clinical performances. Developers and manufacturers must present the relevant peer-reviewed publications in the literature, including the study methodologies, designs, data and related technical information in a way that is accessible to non-technical clinical or administrative staff. For example, executive summaries, infographics, presentations at various conferences focused on different audiences (e.g. nurses, physicians, administrators etc.) and other forms of communication of the findings, including e.g. digital and social media could be included. Risks mitigated by a device should be, minimally, tissue deformation and microclimate. The base of evidence should be, minimally, a peer-reviewed journal publication specific to the design, brand or model of the device. Clinical evidence should include outcomes from well-designed, statistically-valid studies in a relevant patient population that demonstrate reduced incidence of DRPU or a potential thereof, ease of implementation and the health economic benefits.

Policy-makers and regulators

Policy-makers in healthcare institutes and organizations as well as insurance and regulatory bodies must be involved in DRPU prevention through awareness of the risk, financial implications and potential liability consequences of DRPU occurrence. Their involvement should be through education, training, guideline preparation, and procurement of safe devices and application standards. An organisation must have their own written guidelines on how to select sizes and apply medical devices known to be high-risk for DRPU used in their facility on their patient populations. The policy must be relevant to devices currently used in the organisation and be updated as needed so that it is revised with each new purchase decision or change of equipment. When a new device from an existing supplier or from a manufacturer new to the facility is introduced, the policies must be updated such that the IFU provided by the supplier/manufacturer with regard to DRPU prevention are accurately reflected in the institutional guidelines. Ideally the education policy should be led by a specified and skilled individual, for example the tissue viability team, lead nurse or equivalent person responsible for DRPU prevention. The responsibility for education on DRPU prevention policy should be at the level appropriate to the facility, for example ward or hospital, or Procurement department. The education and continuous training responsibilities should be to:

- Invite developers and companies to demonstrate products and interview their representatives on how the products mitigate DRPU and/or how the products should be applied to minimise DRPU risks
- Invite experts on the subject matter to speak (e.g. in seminars) about the biomechanics, clinical risk and approaches for reducing the risk of DRPUs.
- Have a written DRPU prevention document on file, specific to each applied device.
- Update education and training modules when new devices, new models of devices or new evidence-based practices are available
- Arrange routine training sessions and monitor the quality of the delivered training and its impact via examinations, online questionnaires, practical guidance sessions following demonstrations e.g. using patient dummies etc
- Establish a succession plan that ensures continuity of DRPU prevention knowledge expertise, for

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example through dedicated lectures, hands-on training and mentoring

- Acknowledge patient group-specific needs in device development.

The panel recommends that Regulators explicitly recognise the risks to patients posed by medical devices that contact skin or that are in potential contact with skin, and incorporate design, evaluation and device application requirements that address the risks. Product design and design evaluations should be addressed via standard test methods, and the industry should be assessed by regulators for compliance with such standards when developed, including design reviews by independent experts in tissue mechanics and biomechanics who are knowledgeable about DRPUs. These standards should be developed by independent experts in tissue mechanics and biomechanics who are knowledgeable about DRPUs working with industry partners. Product labelling requirements that include specific indications of the risk posed by a device based on the outcomes from clinical research, and guidelines for device application, are further required. A symbol denoting the risk of DRPU applied to packaging, and detailed instructions on avoiding DRPU written into the IFU, should be used across the industry. This approach could be applied to existing devices, particularly for high-risk devices, but must be applied to improved and new devices. Existing or new devices associated with high risk for DRPU could be regulated into a higher device classification, and evidence for how developers and manufacturers have mitigated risks should be presented to regulators as an integral part of the technology and product evaluation process. Regulators should require a post-marketing database that is transparent to all that report DPRUs detailing the site of injury by device make and model to enable researchers/manufacturers to identify areas of concern and mitigate them and to alert clinician [editor: panel to add case studies with costs?].

CHANGING THE MINDSET OF PRACTITIONERS AND POLICY-MAKERS

Chapter 7. Future research and guidelines for product development

Advances in our understanding of the pathophysiology of DRPU (see Chapter 2) and the interaction of devices and objects with the skin, were in most cases not available to manufacturers of devices during the design process. Many devices have not changed in design or material construction since the rise of modern medicine in the 19th century when, for example, respiratory tubing and equipment as we know them today appeared. As a result, although the primary clinical goals of the devices may be well served, the unintended consequences, DRPU, were not foreseen. Now that we have a much better and greater understanding of the aetiology of DRPU and the role of devices, manufacturers have an opportunity to redesign existing devices to account for the risk of DRPU [editor: comment in JH's draft: industry will only act if these DRPUs are reported and regulatory agencies (e.g. FDA, MHRA) put pressure on companies], including, for example, sizing appropriate to all patients from the largest to the smallest, gender-specific where appropriate and across all ages and anatomic structures. There is an opportunity to work closely with biomedical and biomechanical engineers to design and develop improved and new devices that account for the risk of DRPU by using different shapes, materials, structures and incorporation of advanced technologies—all supported by contemporary laboratory methodologies for medical device research, development and design.

Some reduction of the risk of DRPU posed by devices is possible by high awareness and good practice with current products, although as already noted, the risks are unlikely to be eliminated. The current limitations on risk reduction are due to the following factors: (i) Medical devices are currently limited in design and materials with regard to DRPU prevention, (ii) No technologies are immediately and clinically available for early diagnosing or for mitigating DRPU risks, (iii) No dedicated protective means have been developed, and (iv) clinicians may expect DRPU to develop based on experience; the expectation becomes "that's just what happens".

Important recent advances in understanding the causes of DRPU and the role played by device designs have been made (Gefen, 2018; Bader et al, 2019). The influence of the shapes and sizes of devices, the materials used to manufacture devices and the structural effects are now better understood. Specifically, the effects of the geometrical features and components of devices that contact or may potentially contact the skin is clearer. The impact that engineering design can have on resulting tissue deformations and heat clearance from either the device itself or the body tissues can be estimated. Nevertheless, these new research advancements have not been implemented into device designs and medical technologies to date, and, accordingly, DRPU still occur much too frequently due to inadequate device designs. In part, this is a consequence of devices historically designed without accounting for the now-known aetiology of DRPU, unknown at the time of the original design work. In addition, there is general lack of awareness in the medical device industry as well as among practicing clinicians that any device that contacts the skin or that may contact the skin needs to be designed to minimise the risks for DRPU (Gefen, 2015). Clinicians are further unware that they should be pushing to receive peer-reviewed published evidence in this regard, from the leading bioengineering and medical/clinical journals focusing on the science and the ones which are trade/industry journals.

Reducing the incidence and prevalence of DRPU in all patient populations is a critical clinical and economic objective. Advances in device design and development of new, dedicated and effective interface materials and structures to protect tissues from DRPU, informed by industry and academic led research is needed to reduce DRPU. Multidisciplinary work by academics, developers and manufacturers, including regulators and practitioners, is further needed to develop the testing means, standards and protocols specific to the field, which could be enforced by regulators. Eliminating DRPU completely appears to be unrealistic, given the research, development and technological gaps that have been reviewed in this consensus statement. However, where knowledge and best practice can be deployed effectively, DRPU can and must be addressed at present, and more so, in the near future. Scientists in academia, regulators, the medical device industry and manufacturers all have a role in this. Crucially, so do clinicians who use medical devices daily and see the problems caused by them. This chapter covers the future research recommended by the panel to drive this critically important objective.

Role of industry, developers and manufacturers

Device developers, manufacturers and the industry that supports them with new materials and sensor technologies can adopt a leading role in new developments focused on prevention of DRPU. Medical device regulations in most jurisdictions are risk-led with product classifications defined by the level of risk posed by a product. For product development, the risks related to devices are identified by a thorough understanding of user goals and needs related to:

- The setting in which a device will be used; hospital, community, etc
- The target patient population: age, morbidities, key clinical objectives
- The relevant characteristics of the specific patient populations, such as function of the inflammatory system, quality of circulation and perfusion, tissue structure and composition (including skin fragility, possible atrophy changes, chronic conditions such as diabetes or aging that may affect skin or connective tissue stiffness and strength)
- Any intrinsic or extrinsic factors that may compromise skin and subdermal tissue health and integrity, e.g. incontinence, extreme temperatures and humidity, background diseases etc.
- The patient's surroundings, family and carers: impact on adjacent groups
- The care pathways used: who does what, to whom, and with what
- The other products, devices and interventions used alongside the device or that potentially interact with the device under examination
- The possible harms from devices: DRPU in particular but others should also be considered.

This information is used to define clear functional objectives, material selection, development of device structures and geometrical features, possible sizes and constituent parts, and other design inputs and prototyping with quantitative measurable performance limits for the device. The above requires consultation and advice from experts, with experience in the medical device arena and who are knowledgeable about the aetiology and risk of DRPUs. Manufacturers that adopt this integrated innovation practice, involving end users throughout the process, will design devices that minimise the risk for DRPU—a claim that could be supported by demonstrating such documented efforts. Box XXXXX suggests key design inputs that should be addressed.

The device must be designed to manage tissue deformations, reducing the magnitudes of localised tissue deformations and stresses to the greatest extent possible. Furthermore, a device should minimise the transfer of thermal energy to tissues and heat trapping at the skin-device interface (for heat originating in the device, if the device produces heat, or, for heat released from the body tissues due to metabolism). A device design should also address the potential accumulation of moisture and wetness at the skin-device interface. Tissue deformation and stress are addressed by selection of materials and material compositions (such as 'sandwiches' of materials or composite materials) with mechanical properties close to those of skin and underlying tissues, in order to reduce the pressure and shear gradients created by the device. This may be addressed using soft or mechanical-energy absorbing interface materials or structures (as

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long as they are not too soft and 'bottom-out'), but must be balanced with the clinical function of the device. In addition, the contours of any device that contact or may contact the skin must not include sharp surfaces or elements, or highly curved regions, as these will produce high localised deformations and tissue stress concentrations. Another important aspect of minimising tissue deformation and stress exposures is to reduce the frictional forces between the device and skin to the extent possible. This can be achieved by using low-friction surfaces or coatings on the device, or by means of lubricants, or through a combination of these. For example, a ventilation mask must be able to maintain a seal to function, but this requires application of pressure and static frictional forces on facial skin. How these pressures and frictional forces are managed and minimised to the least extent that allows the mask to deliver its medical purpose is key to an adequate device design, and all the above considerations should be carefully taken into account already at the core design stage. Outcomes from studies with pressure redistribution at the interface of masks show that this approach reduces skin and subdermal tissue stress and so this is a feasible approach (Cohen et al, 2019; O'Toole et al, 2017).

However, robust quantitative data of the effectiveness of other devices is still lacking in the current literature. The development of bespoke offloading devices is required, potentially in collaboration between companies that manufacture devices and those who manufacture prophylactic dressings. It is critical that thermal energy—heat—management be addressed in the core design. Developers and manufacturers should ensure that heat is transferred away from the skin, and not conducted into tissues. Some devices may actively create heat while others allow build-up of normal (or fevering) body heat at the skin-device interface (heat trapping) and this must be managed in early phases of the design process, be evaluated through bioengineering experimental measurements and computer modelling and be minimised to the extent possible.

The design research prior to clinical evaluation—in both aspects of minimising tissue deformations/stresses and minimising heat trapping—should be done using computer modelling (Oomens et al, 2013; Katzengold and Gefen, 2018; Levy et al, 2015; Levy et al, 2017)informed and reinforced by experimental investigations in laboratory systems and with physical phantoms, instrumented dummies or mannequins (Schettino, 2001).

An important aspect that should be considered in such engineering design processes is that the deformation and stress states of tissues and the heat transfer in tissues and from tissues to the environment are all physically coupled, and accordingly, there are strong interactions between these states. This implies that multiphysics computer (finite element) models that are able to describe the biomechanical (tissue deformation/stress) state concurrently with the thermal state of tissues, including any possible structural-thermal interactions, should be used in the design process. Furthermore, advanced physical phantoms and mannequins that replicate the biological, mechanical and dimensional features of babies, young adults and the elderly, or other patient groups such as obese, cachectic and diabetic patients, or women in delivery, are required. These should have integrated sensing and data sampling systems, and user-feedback systems which altogether provide in-use data on pressure and shear distributions, internal tissue deformations/stresses as well as temperature and humidity, moisture or wetness at the 'skin' surfaces of the instrumented dummies.

The role of clinicians

Practitioners are the gatekeepers for clinical research. Key areas which should be initiated and led by practitioners are shown in Box XXXXXX. Practitioners should engage with device developers and manufacturers to ensure their involvement in product improvements and new product development (NPD) throughout the innovation process discussed above. Their clinical goals should be expressed clearly to drive effective materials and structures, innovation and device design with measurable, quantitative and standardised performance outcomes. With regards to DRPU protection this could include levels of tissue deformations as per company's studies and technical information and temperatures at the skin-device interface etc. NPD, informed by practitioners, should focus not only on the primary clinical goal(s) for a device but also the adjacent goal of minimising DRPU, based on the above bioengineering measures that arise from aetiological DRPU research. In addition to informing bioengineering and medical engineering research, practitioners can drive practical aspects and relevant clinical research, including management strategies to prevent DRPU, stratified by risk, for example obese patients, paediatrics, spinal cord injuries, diabetic neuropathy, prosthetics and palliative care. Practitioners should undertake clinical research into DRPU causation, prevention and psychosocial effects using advanced innovative trial designs (e.g. step-wedge, adaptive design). They should be involved in clinical research focused on physical and chemical biomarkers for DRPU in their patient populations to drive better real-time monitoring and diagnosis of tissue breakdown. Lastly, clinicians in lead roles, tissue viability teams and head nurses and physicians can collect cost data to inform cost-benefit analyses related to the current economic burden of DRPU in their institutes, and the effectiveness of changes in equipment/products/suppliers, education and training and awareness campaigns on the expenditure related to DRPU. These are valuable data, and, if adequate, collected and analysed, will be influential when presented to administrators and decision-makers whenever there are opportunities for improving patient safety. It is critically important that clinicians work closely together with bioengineers in multi-disciplinary teams in all projects focusing of development, improvement or design revisions of any device that contacts skin or may apply forces on a patient's body. This will ensure DRPU risk is considered in advance, and that practical aspects of use provided by clinicians are weighed and methodologically integrated into the engineering design process (Box XXXXXXX).

Adoption of new technologies and processes that reduce the risk of DRPU must be driven and supported by clinicians.

Technologies for prevention

Sensing and analysis technologies for pressure and shear stress and other biomechanical markers (Worsley et al, 2018; Laszczak et al, 2016; Bader and Worsley, 2018; Brill et al, 2017; Visscher et al, 2015) and measures, as well as biocapacitance examinations via measurements of extravasated tissue fluid (an early marker of inflammation) are already available or in development (Moore et al, 2017). Biocapacitance (SEM Scanner) measurements are currently detected at the time when the SEM Scanner is applied to the patient's skin and manufacturer indications are currently provided only with regard to the sacrum and heels. Ultrasound may also be used to assess physiological changes in tissue (Gefen and Gershon, 2018). Technologies to detect other physiological markers, particularly biochemical markers, are available in university research laboratories but the optimal chemical biomarkers (which may be a combination of different types of markers) have not yet been identified (Bader and Oomens, 2018). Moreover, biomarker assays for analyses are currently expensive (e.g. require molecular biology techniques such as blotting) and further require high level of expertise, and therefore, chemical biomarkers are not feasible for routine clinical use at this time. The development of lab-on-chip sensing is changing the face of translational biomarker research and has already had a significant impact in other healthcare areas e.g. blood lactate monitoring for diabetic patients. In view of the above, key areas for innovation in technologies include:

- New interface materials and structures to absorb compressive and frictional forces and manage humidity and moisture.
- New interface materials and structures to dissipate thermal energy from devices that produce heat or heat produced in the body tissues, so conduction to skin and subdermal tissues is minimised

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- The durability of materials and structures used in device types associated with DRPU or in protective means to ensure that mechanical properties do not change adversely in use or over time.
- Sensing technologies and indication mechanisms that accurately detect and report biomechanical factors in the context of DRPUs such as excessive forces or tissue deformations, thermal challenges, moisture and wetness, biocapacitance or pH changes and, in the farther future, perhaps monitor the levels of inflammatory biochemical markers secreted from skin.
- Real-time monitoring of at-risk skin and subdermal tissues for harmful changes.
- Minimisation of device-skin friction, both static and dynamic, through low coefficients of friction at the skin-device interfaces, which can be accomplished through new materials and coatings, lubricants or their combined effects.
- Translational research on interface materials and structures
- Research on mechanobiological approaches to improve the tolerance of skin and deeper tissues to sustained cell and tissue deformations and stresses, for the time periods relevant to the application of the device
- Computer and laboratory bioengineering models, such as multiphysics anatomically-realistic finite element computational models and instrumented dummies/mannequins that recapitulate the features and responses of soft tissues to deformations/stresses and thermal conditions applied by devices. These should become standardised, objective and quantitative test setups to evaluate and rate the effectiveness of device design variants.

DRPU prevention is likely to be best addressed by technologies embedded in devices that target the need for real-time monitoring and reporting of critical indicators of potential harm to tissues. These technologies should detect, measure, map and alert to critical values or conditions of:

- Pressure and shear stress under devices, specifically indicating when excessive forces are applied by a device
- Physiological sensing and monitoring of potential inflammation at the skin-device interface or in underlying tissues in the vicinity of that interface
- Thermal/heat/pH challenges (which should be desirably mitigated by the device or protective means, through the core design of the device)
- Humidity, moisture and wetness (which should be desirably mitigated by the device or protective means, through the core design of the device)
- Device application, alarming the clinician or user on incorrect and potentially harmful fitting and/or securement.

Sensing technologies at the device interface offer the potential for immediate and automatic early interventions, for example relief of the mechanical loads applied by the device or turning the heat-generating element of the device off, when high-risk conditions are detected.

In the foreseeable future, technologies that today do not exist may be developed to minimise or even eliminate the possibility of DRPU. Suspended contactless devices (e.g. based on magnetic fields) may be developed for the most fragile skin and critical areas, such as in intensive care units, where the largest number of these instruments is required to save lives.

Dedicated protective technologies, smart materials and structures, and tissue and environmental monitoring would be fully integrated into a facility connected to a central or cloud computer system, enabling (big) data management and data mining, and machine learning from the accumulated data. Continuously updated normative data for a patient population would be referenced to determine the real-time risk presented by all the devices attached to a patient per each type of ward or facility. In addition, data from the sensors that monitor the individual will be analysed in real-time e.g. via cloud computing to detect trends of changes indicating possible deterioration in tissue health status, and such digital risk assessments would be instantaneously communicated to the relevant patient carers, via wireless devices. Outputs that fall outside the normal ranges, not just with respect to a normative range but also with respect to the patient's historical data, would trigger such alerts. Data would be available to demonstrate that best practice according to current standards had been applied which would be useful for education [editor: add box on how DRPU prevention should be facilitated by dedicated purpose-designed evidence-based technology?], training, evaluation of clinical practice standards, cost-benefit analyses and easy reporting to government, regulatory, insurance and other bodies and authorities. The above data should also be useful to academia and industry as defining the standard of care in any future device design or design revision projects, which would facilitate definitions of quantitative goals and expected outcomes for each such design project. This vision is not so far in the future as it may seem to be. In fact, all the technologies mentioned above exist and are available, at different levels of maturation. It is only their improvement, integration and commercialisation that require efforts, time, translational research and investments. Understanding the scale and threat of the DRPU problem, and the so heavy burdens of DRPU on society—in suffering and costs—should drive this additional research integration process towards a new generation of medical devices that have been originally designed to minimise the risk for DRPU.

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