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# Device-related pressure ulcers: **SECURE** prevention

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# Contents

Foreword	S4
Introduction	S5
Pathophysiology	S10
Devices	S16
Risk assessment	S22
Safe use of devices: prevention and management of DRPU	S28
Changing the focus of health professionals and policy-makers	S37
Future research and guidelines for product development	S41

# Foreword

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 little in decades. It is not surprising that these traditional devices, which interface with vulnerable skin and soft tissue, are frequently associated with device-related pressure ulcers (DRPU). These wounds are commonly hospital-acquired and can:

- Increase the risk of potentially life-threatening infections, such as sepsis
- Cause pain and leave scars, which may be highly visible and cause distress
- Result in permanent hair loss, altered body image and/or reduced quality of life
- Increase length of hospital stays and consume additional resources (time and products).

Moreover, as DRPU almost always develop in healthcare institutions, in many countries they are a cause of lawsuits.

The global scale of the problem is considerable, particularly in clinical settings where devices are used intensively, such as in operating theatres, intensive care units and emergency departments. Patients of all ages are affected, with the typical scenario being an environment dense with equipment, tubing, electrodes and wiring. All too often, these devices interact with fragile skin and tissues, such as that of children and aged individuals.

In February 2019, an international group of medical, clinical and bioengineering experts met in London, UK, to develop the first international consensus statement on DRPU. Following a rigorous process of scientific discussion, this consensus statement was drafted. It was then reviewed by an international committee of experts who were external to the panel. Accordingly, this consensus statement is a comprehensive synthesis of current understanding of the aetiology of DRPU and the technologies and clinical protocols that can be used to mitigate them.

Aimed at generalist and specialist clinicians, as well as biomedical and non-biomedical engineers in

academia, research and industry, this consensus statement is an evidence-based review of the aetiology, assessment, prevention and management of DRPU. It describes how medical devices and objects that come into contact with skin or apply forces onto it can cause deformation damage at the cellular and tissue level.

The consensus statement identifies and discusses devices most commonly associated with DRPU and the biomechanical reasons for the risks they represent. An important and innovative element of the panel's work has been to evaluate which engineering concepts and technologies can be used to protect the skin and deeper tissues from DRPU and assess if device-related tissue damage can be reversed. It also outlines strategies for changing the mindsets of health professionals and policy-makers on the need for DRPU prevention, including how to increase global awareness about their root causes, the scale of the problem and their financial implications.

Greater awareness of DRPU will lead to better adoption of prevention protocols and much-needed new designs and technologies. The consensus statement, therefore, specifies the requirements that will make medical technologies effective in DRPU prevention.

To guide the medical device industry, the panel has listed design recommendations for the shape, materials and construction of medical devices. The consensus statement discusses how bioengineering design can reduce high pressure and shear points, alleviate frictional forces and stress concentrations on skin and within deeper tissues, and optimise the microclimate.

In conclusion, for the first time in the literature, detailed advice is presented on how to safely apply medical devices and improve biomechanical and thermodynamic tissue conditions at the skin-device interface. Future research work required, including laboratory tests, clinical trials and computer modelling for DRPU prevention, is also discussed. Multidisciplinary efforts are the key to mitigating DRPU. The consensus group's team effort provides the cornerstone in working towards this goal.

*Amit Gefen — panel chair*

# Introduction

Pressure ulcers (PU) are defined by the European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Injury Advisory Panel (NPIAP, formerly National Pressure Ulcer Advisory Panel) and the Pan Pacific Pressure Injury Alliance (PPPIA) as:<sup>1,2</sup>

*'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, comorbidities and condition of the soft tissue.'*

This general definition defines all PU types and encompasses various causal factors. However, the focus of this consensus statement is pressure ulceration related to device use and/or misuse.

The key causal components of PU formation are pressure and shear. Friction contributes to shear but on its own is not a direct cause of PU. In many PUs, the main cause of pressure and the associated shear forces is body weight—for example, when a patient is immobilised in a supine position for extended periods on a support surface. Such pressure, friction and shear cause tissue deformation, inflammatory oedema and ischaemia that, together, lead to pressure ulceration in bony anatomical sites such as the sacrum, ischium, trochanter and heel.

In contrast, the NPIAP states that medical device-related pressure ulcers (MDRPU):<sup>3</sup>

*'...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 NPIAP extended the definition of a medical device to include objects such as spectacles and other devices without a medical purpose.

## Key points

- A device-related pressure ulcer (DRPU) may be caused by a medical device or a device, object, or product without a medical purpose
- Paediatric patients are particularly susceptible to DRPU
- Examples of devices associated with DRPU include: continuous positive airway pressure (CPAP) masks, endotracheal tubes, orthotic devices, bed frames and spectacles
- There is little or no published evidence on the costs associated with DRPU
- There is a need for greater recognition of DRPU, their causes, management and prevention. This document is intended to stimulate action

In order to differentiate device-related pressure ulcers (DRPU) from PU arising from body weight forces, the panel proposes defining a DRPU as follows:

*'A DRPU involves interaction with a device or object that is in direct or indirect contact with skin ... or implanted under the skin, causing focal and localised forces that deform the superficial and deep underlying tissues. A DRPU, which is 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 results in the appearance of skin and deeper tissue damage that mimics that of the device in shape and distribution.'*

The term 'medical device-related pressure ulcer' focuses the health professional and others on pressure ulceration related only to medical devices. Importantly, a device-related pressure ulcer (DRPU) may be caused by a medical device, object or product without a medical purpose. Throughout this consensus statement, the term 'DRPU' is used to emphasise the importance of understanding that a PU may be related either to medical or non-medical devices. This is covered in more detail in the third chapter of this document.

Briefly, medical devices associated with PU may include products 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 as orthotic devices, indwelling lines and bed frames. Paediatric patients are particularly susceptible. Devices or objects associated with PU that do not have a specific medical purpose may include the patient's own property and objects left on the patient's bed or support surface, such as cellular phones and jewellery.

Like PU, DRPU can be categorised as I–IV or unstageable, depending on their depth and the number of tissue layers involved.<sup>3</sup> However, DRPU can be difficult to classify as they often occur in regions with minimal soft tissue such as nasal bridge and ears. Nevertheless, most DRPU are category I and II, but up to a quarter may be unstageable.<sup>4</sup> A DRPU on the bridge of the nose, where the tissue has no padding, may rapidly progress from category I to category IV or unstageable.

## International pressure ulcer 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 EPUAP/NPIAP/PPPIA guidelines are the most widely cited. This consensus statement has taken account of guidelines used globally, including those from EPUAP/NPIAP/PPPIA.<sup>1–3</sup>

## Is a consensus statement specific to DRPU needed?

Patients managed using medical devices are more likely to develop a PU or skin breakdown.<sup>4,5</sup> For example, in an American hospital setting, the overall rate of PU in inpatients was 5.4%, of which 34.5% were DRPU.<sup>4</sup> Elsewhere, it has been observed that DRPU may account for as much as 61–81% of all hospital-

### A note on terminology

Globally, a number of different names are used to describe pressure ulcers (PU). Pressure injury (PI) is currently used by National Pressure Injury Advisory Panel (NPIAP; formerly National Pressure Ulcer Advisory Panel).<sup>3</sup> Other terms proposed are 'deformation injury' and 'pressure damage'. To date, PI has been adopted in Australasia, although not entirely in the US and Canada, and not in Europe. The terminology used 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 PU is used. It should be taken to encompass the other terminologies used to cover tissue damage or injury caused by pressure, shear and tissue deformation.

acquired PU (HAPU), depending on the care setting and patient subpopulations.<sup>6,7</sup> Despite this, DRPU is an understudied area.

There are some prevalence and incidence data on DRPU. A recent systematic review and meta-analysis reported that the estimated pooled incidence and prevalence of DRPU in over 126,000 patients in 29 studies was 12% and 10%, respectively,<sup>8</sup> although, as the authors state, these data are limited by the heterogeneity of the data collection.

## Occurrence by setting

Devices used in intensive care are particularly associated with DRPU.<sup>9–11</sup> In a recent systematic review of the incidence, prevalence and severity of DRPU in intensive care units (ICU), pooled data revealed incidence rates of 0.9% to 41.2% and prevalence rates of 1.4% and 121%. Again, the wide ranges reflect the heterogeneity of the data collection between the 13 studies evaluated.<sup>10</sup> Coyer et al. reported a DRPU prevalence of 3.1% in intensive care

patients,<sup>12</sup> while Wille et al stated that the overall incidence of DRPU or skin breakdown caused by pulse oximeters in a surgical ICU may be as high as 5%.<sup>13</sup>

Occurrence rates can be lower in other settings. An unpublished incidence audit of DRPU in Kyorin University Hospital, Japan, conducted over 12 months from 1 February 2018 to 31 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, that on general wards was 0.4%. This lower incidence is likely to be a result of the higher number of devices used in the ICU setting compared with general wards.

### Neonates, infants and paediatrics

DRPU account for up to 50% of all PU in some high-risk patient populations, such as neonatal and intensive care settings.<sup>14,15</sup> A third of all PU in children aged over one year are device related.<sup>16</sup> Infants who develop DRPU are likely to be younger post-partum, with shorter gestation; they develop DRPU more rapidly than patients with PU caused by body weight.<sup>17</sup> Mechanical ventilation and a respiratory diagnosis are associated with higher risk of DRPU in this population.<sup>18</sup> In newborns, devices may severely affect and distort nasal cartilage.

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).<sup>11,19–23</sup>

### Occurrence by type of device

Regardless of setting, there is a high association between DRPU and respiratory devices. Up to 68% of DRPU are associated with respiratory devices,<sup>9</sup> of which 20% are linked with bilevel positive airway pressure (BiPAP) or CPAP devices, where ulceration has occurred on the bridge of the nose and/or nasolabial fold.<sup>6</sup> In general-hospital patients with respiratory failure managed by non-invasive ventilation or CPAP, prevalence may be over 14%.<sup>5</sup>

Ham et al found a high association between trauma patients and endotracheal and nasogastric tubes.<sup>7</sup>

### Occurrence by anatomical location

In terms of anatomical location, a national audit of PU prevalence in the US reported that approximately 10% of all PU in a variety of healthcare settings were device related, with DRPU most often occurring on the face and ears, sacrum/coccyx, heels and buttocks.<sup>24</sup> DRPU were common across several medical specialty units.

Data derived from these studies reveal that DRPU constitute a significant percentage of institution-acquired PU and require significant attention from clinical, academic and commercial leaders. Table 1 summarises the key results.

### 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 the incidence of chronic diseases such as diabetes increases markedly.

In the US, the total cost of HAPU has been estimated at \$26.8 billion.<sup>25</sup> The total cost of PU to the National Health Service (NHS) in England has been estimated at over £530 million, based on a patient database audited between May 2012 and April 2013.<sup>26</sup>

These figures are not directly comparable because of the different health organisations involved 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.<sup>27</sup>

Nevertheless, there is little or no published evidence on the costs associated with DRPU, particularly the substantive indirect costs associated with litigation and insurance (in premiums or loss of coverage) as most DRPU are HAPU. Lawsuits related to DRPU often end with undisclosed court-approved settlements negotiated behind closed doors. The indirect effects of rising insurance premiums on clinicians and facilities have not been reported but, based on the known extent of litigation activities, it is reasonable to assume they are considerable.

Box 1 lists the elements that contribute to the cost (economic and other) of DRPU.<sup>28,29</sup> Often-overlooked

**Table 1. Summary of medical device-related pressure ulcers incidence and prevalence**

	Reference	Setting	Finding
<b>Overall trends</b>	Black et al. <sup>4</sup>	American hospital inpatients (n=2079)	PU occurrence: 5.4% DRPU occurrence: 34.5%*
	Jackson et al. <sup>8</sup>	Systematic review of 29 studies	Pooled DRPU incidence: 12% Pooled DRPU prevalence: 10%
<b>Data from intensive care settings</b>	Barakat-Johnson et al. <sup>10</sup>	Systematic review of 13 studies	Pooled DRPU incidence: 0.9–41.2% Pooled DRPU prevalence: 1.4–121%
	Coyer et al. <sup>12</sup>	Six ICUs in two major medical centres (one in US and one in Australia)	DRPU incidence: 3.1%
	Wille et al. <sup>13</sup>	125 patients in a surgical ICU	Frequency of pulse oximeter-induced digital injury: 5%
<b>Data from other settings</b>	Kyorin University Hospital unpublished DRPU audit	ICU and general wards in a Japanese hospital	DRPU incidence in ICU: 2.8% DRPU incidence in general wards: 0.14%
	Schlüer et al. <sup>16</sup>	204 children in 13 Swiss hospitals	Prevalence of PUs: 26.5% Prevalence of DRPU: 38.5%
	Visscher and Taylor <sup>17</sup>	741 neonatal intensive care patients	Premature neonates: 1.5 PU per 1000 days Term infants: 2.7 PU per 100 days

DRPU—device-related pressure ulcer; ICU—intensive care unit; PU—pressure ulcer

are the psychological and emotional costs to patients, which can contribute to the direct and indirect costs of patient care. The long-term impact on the wellbeing of a patient disfigured following a DRPU can be devastating, particularly as a significant proportion occur on the face and neck, with scarring having inevitable social and psychological challenges.

DRPU represent a large economic burden on healthcare systems, especially when indirect costs of litigation and insurance policies are factored in. Plaintiffs will typically sue the institute/organisation and, sometimes, the clinicians who provided the care. 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.<sup>30</sup> Factors that increase the risk of DRPU include:

- The patient's inability to sense the device and the associated pressure, friction and shear on their skin due to sedation, encephalopathy or neurologic disease
  - The patient's inability to reposition themselves.<sup>4</sup>
  - Duration of device use
  - The perceived need to secure a device tightly to ensure correct function.<sup>5,31</sup>
- DRPU develop faster than non-DRPU because of the vulnerability of the patient and body sites affected. They are most likely to be facility-acquired and located on the face and neck,<sup>32</sup> exit sites and stomas. Many factors are implicated in their development (for more detail, see chapter 3). Specific factors include:
- Devices often do not fit patients properly due to their generic designs and limited range of size, especially in paediatrics
  - Device materials are often very stiff and do not conform to tissue shape, causing localised skin distortions when they interact with skin and underlying soft tissue
  - Inadequate guidance is provided on device

**Box 1. Costs associated with device-related pressure ulcer (DRPU)**

- Medical costs of pressure ulcer (PU) management
- Practitioner time
- Personal impact on the patient
- Reduced quality of life for the patient and their family
- Psychological and emotional impact, such as disfigurement of the face and head
- Reimbursement withheld for hospital-acquired pressure ulcers (HAPU)
- Fines in some jurisdictions
- Litigation costs
- Potential court-ruled damages and settlements
- Cost of insurance policies, which are affected by the institution's litigation history
- Cost of device abandonment (e.g. prosthetics and orthotics)<sup>28</sup>
- Cost of changing medical intervention—for example, when continuous positive airway pressure (CPAP) fails in neonates, some need to be re-intubated<sup>29</sup>

application by both commercial suppliers and clinical educators

- Many individuals have comorbidities that 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
- Lack of clinician awareness of the importance of repositioning, offloading, rotating devices or correctly fitting or securing them.

The management of skin health is also complicated by the fact that medical devices often have a diagnostic or therapeutic purpose. For example, a respiratory device may be required for critical life support, so it may not be possible to remove or reposition it without compromising the patient's survival. Thus, the need to maintain device *in situ* may prevent skin assessment, leading to an existing DRPU not being identified.<sup>4</sup>

DRPUs have an adverse impact on the affected patient by causing additional morbidity and reducing quality of life. This often extends beyond discharge—for example, in cases of visible scarring (including

where there is potential loss of range of motion) and permanent hair loss.

The panel met to address the need for greater recognition of DRPU and its causes, management and prevention. This document is intended to stimulate action and covers:

- The anatomy and tissue composition in relation to the patient's age
- The pathogenesis of DRPU, with particular focus on why devices are associated with PU
- Devices, both medical and non-medical, associated with DRPU
- Assessment of DRPU
- Safe positioning and use of devices to prevent or manage DRPU
- Initiatives to raise awareness of DRPU among health professionals
- Medical device design characteristics and features relevant to DRPU and its prevention
- Future research required on prevention of DRPU, with particular reference to product design, regulation and monitoring technologies.

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

# Pathophysiology

This chapter reviews the pathophysiology of PU and DRPU. Table 2 summarises the key similarities and differences between PU and DRPU.<sup>33</sup> 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 (Fig 1).<sup>1,34-41</sup>

## Cell deformation

Patients who develop PU frequently have multiple risk factors and comorbidities.<sup>42-44</sup> 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

### Key points

- Principal causes of pressure ulcers (PU) are pressure, friction and shear, and the resulting sustained cell and tissue deformations. These effects are exacerbated by moisture and temperature
- There do not appear to be specific risk factors for device-related pressure damage (DRPU) aside from the actual use of the device
- A crucial difference between PU and DRPU is that body weight forces play a less prominent role in DRPU, with the force exerted from a device that is typically strapped or taped to the body
- Neonatal and paediatric skin are different to adult skin
- Most DRPUs can be prevented by improving the design of devices

**Table 2. Overview of features associated with pressure ulcers and medical device-related pressure ulcers. Adapted from Bader et al.<sup>33</sup>**

	Pressure ulcers	Device-related pressure ulcers
<b>Aetiology</b>	Both result from physiological responses of soft tissue involving cells, the interstitial space within extracellular matrix and blood and lymph vessels, with the importance of each depending on different magnitudes of strain and time <sup>173</sup>	
<b>Cause of deformation-induced damage</b>	Gravitational forces due to body weight	Caused by external applied forces (strapping and tape)
<b>Individual vulnerability</b>	Immobile and/or insensate patients. Areas with previous tissue damage	Illness, possibly with comorbidities; examples are patients in intensive care unit (ICU), patients with diabetes, and patients who cannot communicate discomfort or pain. Skin and soft tissue sites with previous damage.
<b>Nature of medical devices</b>	Examples are support surfaces, cushions, mattresses, bedside chairs, toilet seats, based on individual risk	Generic designs of medical devices not matched to individual characteristics
<b>Prevention strategies</b>	Pressure redistribution/relief and periodic repositioning	Improved design of devices; pressure relief through application of an alternative device; adequately designed prophylactic dressings
<b>Vulnerable tissue areas</b>	Adjacent to bony prominences such as sacrum or ischium	Any body site, but commonly the head or neck; application of load to tissues with limited prior mechanical conditioning.
<b>Microclimate</b>	Affected by support surface design, ambient conditions and individual's sweat response and clothing	Affected by device interface, including any seal the device creates with the skin or therapeutic heating or humidity

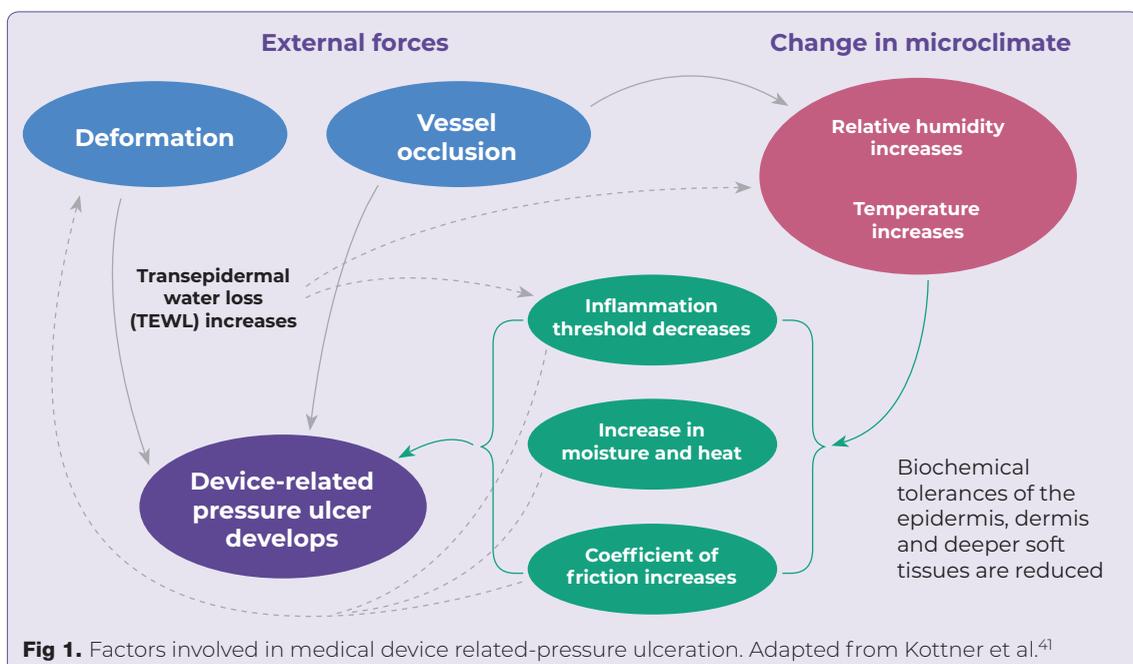
and lymphatic flow. The compression, which is always combined with shear, causes local ischaemia by occluding the microvascular network of capillaries in the skin and deeper tissue. Pressures required to cause local ischaemia depend on the magnitude of the shear and the individual's vascular functionality (cardiovascular system health).<sup>45,46</sup>

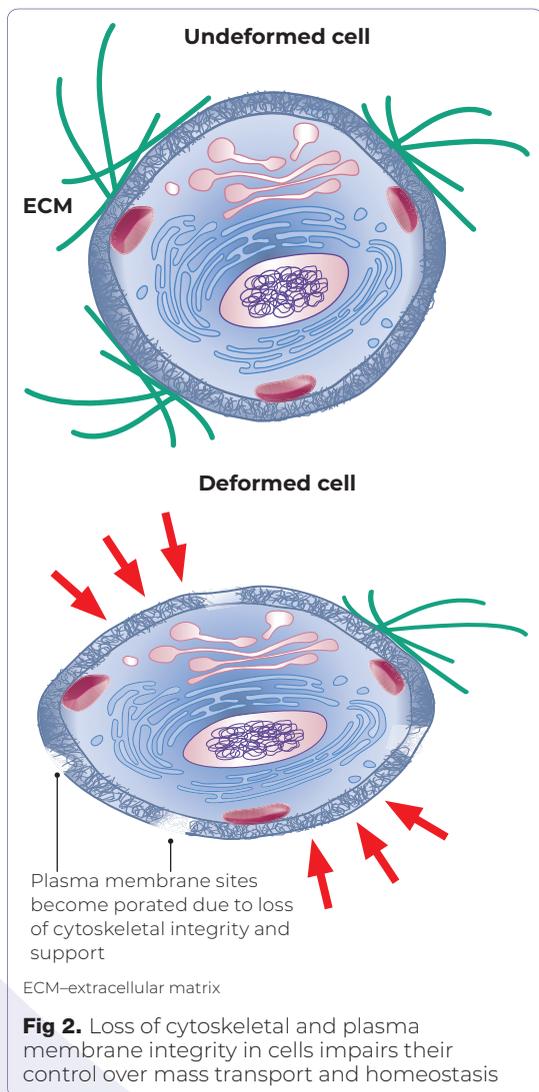
Inflammatory changes initially occur in cells directly exposed to sustained force and deformation. Fig 2 shows how progressive loss of cytoskeletal and plasma membrane integrity in these cells impairs their control over mass transport and homeostasis.<sup>47</sup> Inflammatory mediators<sup>48</sup> secreted from damaged and nearby immune cells lead to progressive inflammatory oedema, which increases interstitial pressures, the mechanical distortions of cells and tissues, and the growing obstructions within the vasculature and lymphatics.<sup>49</sup> Damage may be amplified in ischaemic tissue after reperfusion through the release of reactive oxygen species (ROS), termed reperfusion injury.

The magnitude and duration of the deformation will determine the extent of cell and tissue damage and subsequent inflammation, as well as the degree of ischaemia. For example, direct deformation causes pathological change to deep tissue in minutes.<sup>50</sup> Tissue-engineered living model systems indicate that skeletal muscle tissue is irreversibly injured by sustained deformation after approximately one hour of loading.<sup>51</sup> In contrast, the time it takes for purely ischaemic muscle damage to develop is 6–8 fold longer.

## Distorting effect of friction

Friction distorts tissue resulting in shear forces, which cause skin and subdermal damage, leading to pressure ulceration. Friction-related PU often develop in patients who are partially mobile or have neurological dysfunction that causes repetitive involuntary movement, such as in Parkinson's disease and Guillain-Barré syndrome.<sup>52</sup> In these fragile cases, inadvertent damage from friction or burns is frequently seen.<sup>53–56</sup> The patient, who may already be compromised because





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In some circumstances, some manual handling procedures may increase the likelihood of tissue damage. For example, when a patient slides down a surface, this can result in friction and high tissue distortions, causing shear if not controlled with the use of low-friction interfaces, such as slide sheets.

Frictional forces acting on the skin are affected by the local microclimate, with increased skin hydration, increasing the coefficient of friction by 26–43%.<sup>58</sup>

Attention must be paid to children with neurological or neuromuscular disease, such as Guillain-Barré or Miller Fisher syndromes, which is characterised by muscle weakness and abnormal muscle coordination that limits mobility. Neurological or neuromuscular diseases can also impair a child’s ability to maintain natural conscious body positions (also known as body position biometry). Muscle spasms (‘cramps’) prevent natural body positioning and limit the range of joint movement. This decreases mobility and may cause the bony prominences to push against a support surface or other object, increasing the risk of DRPU.

Articulated beds, which are 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 when the bed-head is raised.<sup>59</sup> Friction between the skin and the surface causes the skin to deform tangentially, causing shear forces<sup>60</sup> and subdermal tissue distortions. The tissues may be damaged because of either the physical force<sup>61</sup> (which causes necrotic cell death and mechanical failure of the extracellular matrix) or apoptotic cell death resulting from deformation-inflicted necrotic cell death and the inflammatory response. 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 repair is compromised.<sup>40</sup>

## Risk factors for DRPU

There do not appear to be specific risk factors for DRPU aside from the use of the device.<sup>4</sup> However, a crucial difference of DRPU to PU is that body weight forces play

of their skin morphology and/or involuntary repetitive movements 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 older people and those with less mechanical strength in the dermo-epidermal junction.<sup>57</sup>

a less prominent role, with the device typically strapped or taped to the body and exerting forces that drive the tissue deformation and distortion. The affected soft tissues may also be 'sandwiched'—that is, compressed, stretched and sheared between a device and bony surface. There are examples of DRPU caused by body weight: prosthetics (stump ulcers) and foot orthotics.

Often, the device or object has a small surface area, such as the edge of a face mask or a connector for an indwelling line. Although the load applied by such devices is typically small, the small surface area results in pressure magnitudes of >200mmHg against the skin.<sup>62</sup> Of particular note are large pressure gradients (where an area of high pressure is adjacent to an area of low pressure), which can cause large stresses and strains in the underlying skin and soft tissues.

Devices such as antiembolic stockings are often used inappropriately with no assessment of underlying perfusion or sensation, and so often cause damage. In many cases, the skin and underlying soft tissues where the device is placed are not conditioned to take external loads, reducing tolerance to pressure and shear forces and increasing the likelihood of injury.<sup>33</sup> This is not the case with more traditional PUs, where sacral, ischial and heel tissues are regularly exposed to pressure and shear forces (in lying or sitting postures), so have adapted over time to accommodate this.

Paediatric patients and/or patients with psychiatric disorders, dementia, under anaesthesia, receiving analgesia, unconscious or partially conscious, who have a central nervous system injury (brain or spinal cord), neurological damage (stroke or multiple sclerosis) or peripheral neural damage (diabetic neuropathy) may be unable to communicate discomfort, pain and the need for repositioning, resulting in loads that lead to DRPU.<sup>63</sup>

## Microclimate

Changes in skin physiology and its microclimate can lead to a higher risk of DRPU. Skin properties are influenced by intrinsic (age, medications, systemic diseases) and extrinsic (temperature and humidity of the skin surface) factors. The local microclimate adjacent to the skin has been defined as:<sup>64</sup>

*'the climate in a local region that differs from the climate in the surrounding region (ambient climate). It consists of temperature, humidity and airflow.'*

Excessive moisture at the skin interface and subsequent overhydration leads to softening of stratum corneum, increased permeability, susceptibility to irritants, barrier disruption of intracellular lipid lamellae and tissue breakdown by faecal/urine enzymes.<sup>41</sup>

Under-hydrated skin is also more susceptible to mechanical damage, cracks, fissures and inflammation because the epidermis has increased structural stiffness. Dry skin may also be a contributory factor in PU development.<sup>65</sup>

Temperature changes adjacent to the skin are also associated with local physiological changes. These include an increase in cutaneous stiffness under loading conditions,<sup>66</sup> a decrease in dermoepidermal adhesion<sup>67</sup> and an increase in metabolic demand. Thus, the skin may be less able to deform and there is a higher susceptibility to injury.

Some devices, such as humidified air/drug delivery (nebulisers) used in non-invasive ventilation, are a source of heat and moisture.

## Neonates and paediatrics

Much information on the aetiology and development of PU is based on its pathogenesis in adult skin. However, the skin (and its overall tissue composition) in neonates and children is different to that in adults.<sup>68</sup> Box 2 summarises the key features of neonatal skin.

Neonates and premature babies do not move or reposition themselves spontaneously, so are at higher risk of PU.<sup>69</sup> Skin of paediatric patients (from newborn neonate to 18 years of age) develops and changes over time.<sup>70,71</sup> Therefore, prevention of PU and DRPU must be targeted differently for children of different ages.

It is a clinical challenge to maintain skin integrity in injured neonates and children in ICU. Devices are the main causative factor for DRPU in paediatric ICU, which predominantly occur on the face and scalp,<sup>72</sup> followed by the heel, which, in contrast to adult patients, cannot be safely offloaded only by changing position.<sup>73</sup>

**Box 2. Skin features in neonatal patients**

- Underdeveloped subcutaneous fat tissue
- Immature cohesion between epidermis and dermis
- Dermal instability
- Alkaline skin surface
- Neonatal skin undergoes multiple physiological changes after it leaves the amniotic environment
- Fat, zinc and metallic deficiencies (molybdenum, chromium, calcium, iron, cobalt and sulphur)
- Increased risk of trauma (shearing and friction forces) because of low dermoepidermal cohesion
- Reduced calorie storage
- Reduced insulation and loss of surface temperature because of lower level of subcutaneous fat
- Reduced secretions and sebum production (the so-called mechanical coat protection)

Neonates, both pre-term and full term, are at high risk of DRPU<sup>17</sup> because of the immaturity of their skin,<sup>68,74,75</sup> its barrier function and their immune system, particularly the inflammatory response. The stratum corneum develops relatively late in gestation; in pre-term neonates its development may be related to exposure to the external environment.<sup>76</sup> The skin of neonates (particularly pre-term) and infants is thin and does not have the protective function of adult skin.<sup>68,71</sup>

Desquamation<sup>70,77</sup> is abnormal in very premature infants for some weeks after birth, signifying hyperproliferation of the epidermis.<sup>78</sup> Skin maturation and adaptation to the post-partum environment happens over an extended period of time, during which desquamation slowly increases.<sup>79</sup>

Compared with older adults, neonates, infants and children show a visible 'turnover' and increased production of keratin in hair, skin and nails. Several observations suggest that infant mechanisms of differentiation and desquamation are underdeveloped or poorly regulated compared with adults.<sup>80,81</sup>

Furthermore, a high metabolic rate and physiological oedema—common in sick children—increases risk of DRPU in these populations.

The increased fragility of the skin associated with prematurity and its associated comorbidities is challenging for clinicians to manage, with practice often relying on anecdotal evidence to prevent skin damage.<sup>82</sup>

Infant skin has more adipose tissue, with a higher water-to-lipid ratio, than adult skin. Full functionality and the acid mantle take several weeks post-partum to develop.<sup>17,83</sup> A dehydrated infant may be hypoxic because of poor skin perfusion, and the affected tissue may break down with only minor insult.<sup>71</sup>

Infants with multiple organ dysfunction syndrome are particularly at risk of PU.<sup>84</sup> Furthermore, an infant's immune system is immature, with underdeveloped monocytes and neutrophils that respond poorly to inflammatory cytokine stimuli.<sup>85</sup>

As a consequence of all these factors, infant skin is fragile and less tolerant of mechanical loading<sup>77,86</sup> and injury.<sup>17</sup>

## Inflammation

The overt visual signs of skin damage result from inflammation. The damaged cells and ECM release inflammatory mediator signals that promote infiltration of neutrophils and monocytes into the injury site. This increases 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.<sup>87-90</sup>

Increased vascular permeability allows fluid to enter the extravascular space, leading to build-up of oedema, which is initially not visible to the naked eye. Furthermore, newborn infants have a physiological oedema. The forming oedema gradually adds mechanical stress to cells and tissues and, if not contained, may exacerbate tissue damage.

ROS and proteinases<sup>90,91</sup> further degrade the tissue, eventually leading to visible tissue damage in a mechanism common to most hard-to-heal ulcers.

DRPU are caused by the same mechanisms as PU. The amount of time in which the tissues are continuously distorted has a critical effect on whether a DRPU develops or not.

Tissue loads may be exacerbated by changes that happen in the patient after the device has been fitted. For example, in patients undergoing fluid resuscitation or with lymphoedema or heart failure, oedema can develop after a device has been fitted.<sup>4,91</sup> This increases the volume of tissue under the device, resulting in cell and ECM distortion while the vascular and lymphatic networks in the affected area are impaired. Unless the device is refitted, the load applied to the skin will increase, heightening the risk of DRPU. Health professionals sometimes tighten the fixation system in an attempt to avoid device failure. The resulting DRPU heightens the inflammatory response, exacerbating the localised oedema. Internal tissue stresses and deformations increase, and blood perfusion and lymphatic function is reduced. Fig 3 is an example of an oedema-related DRPU.

### Effects of different types of device on inflammation

The designs of some medical devices have not taken into account the amount of heat trapped between the device and skin, which can be substantial—for example, under contours of oxygen masks.<sup>92</sup> Heat trapping under devices increases moisture and skin fragility, while elevating the metabolic demands of tissue at a time when there is a progressive shortage of metabolic supplies and clearance of waste products is impaired.

Medical devices, such as oxygen masks for non-invasive ventilation,<sup>93</sup> are sometimes held in place



**Fig 3.** A device-related pressure ulcer related to oedema: the sustained deformation-inflicted injury has triggered an inflammatory response<sup>40</sup>

with elasticated straps or tapes. This immobilises the device, but generates pressure and frictional forces at the device-skin interface, ultimately causing visible tissue damage at the skin surface<sup>94</sup> and/or subdermal damage, where interface pressures can be high. Oxygen face masks may create interface pressure at the nasal bridge of 47.6–91.9mmHg.<sup>95</sup> Oximeter devices clipped onto the earlobe may apply local pressure that exceeds capillary pressure.<sup>96</sup> Humidified therapies, may increase the amount of moisture present, in turn increasing the risk of DRPU. This causes local changes in the function of the stratum corneum.<sup>97</sup>

Some devices, such as spinal boards and cervical collars, are designed to create a mechanical constraint that protects the patient. However, the rigid nature of these designs can cause substantive pressure, shear, thermal loads and tissue deformations on the skin and underlying soft tissue.<sup>93,98</sup>

### Summary

- Devices may generate high stress concentrations in tissues, leading to cell and tissue damage pathways associated with sustained deformation<sup>86,99,100</sup>
- Devices intended to alleviate pressure and tissue loads may themselves increase load and thus the risk of DRPU<sup>86</sup>
- Insensate patients are especially at risk of localised high-tissue deformation, stresses<sup>96</sup> and stress concentrations
- Everyday activities such as toilet sitting increase tissue loads and reduce perfusion<sup>101</sup> and tissue oxygenation, placing individuals with reduced sensory and/or mobility at high risk.

Most common causes of DRPU can be prevented by improving the design of medical devices or by adding smart materials and structures at the interface between the skin and device. Use of technology-aided risk assessment (based on sensor readings and data analytics) and digital monitoring of devices and the health status of tissues underneath them will help mitigate DRPU. This is addressed further in chapters 6 and 7.

# Devices

Most medical devices that come into contact with a patient's skin and/or pass through it can expose the individual to the risk of DRPU. Paediatric patients may be predisposed to DRPU due to factors outlined in Table 3.

Table 4 gives examples of medical and non-medical devices that can be associated with DRPU.<sup>4</sup> Devices can be classified in a variety of ways. In Table 4, medical devices are classified according to their primary medical/clinical use.

## Range of devices that can cause skin damage

Devices (sometimes more than one per patient) can be used across clinical specialties, depending on the patient's clinical needs. They might also be used either temporarily during an acute-care episode (e.g. respiratory devices, patient-monitoring devices and indwelling lines) or for the rest of the patient's life (e.g. orthotics and prostheses, or wearable glucose monitoring meters). Increasingly, patient care is taking place in the community setting, with therapeutic and diagnostic devices being used over prolonged periods.<sup>8</sup>

DRPU are common across several medical specialty units. Devices commonly associated with DRPU are:

- Tubing devices such as oxygen tubing
- Nasogastric tubes and endotracheal tubes;

### Key points

- Device-related pressure ulcers (DRPU) are mostly associated with tubing such as oxygen tubing and endotracheal tubes, respiratory masks, splints, intravenous catheters and cervical collars
- Common anatomical sites include the face, ears, lower leg and heels. However, DRPU can occur anywhere that the skin is in contact with a device
- Extended use of devices is associated with a higher and increasing risk of DRPU
- Devices responsible for DRPU vary between clinical settings

- Respiratory masks including CPAP
- Splints
- Intravenous catheters
- Cervical collars.

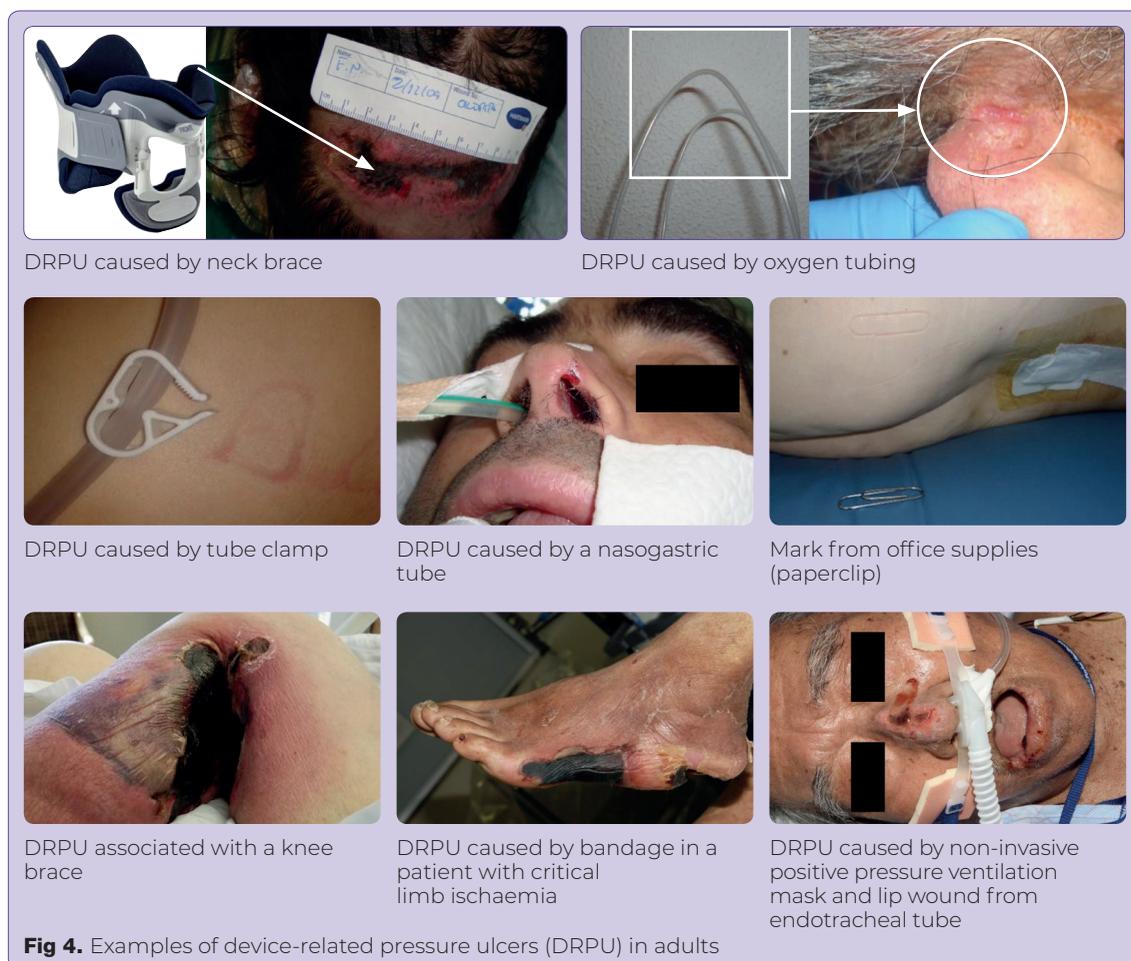
Graduated compression stockings present a DRPU risk for ICU patients.<sup>102</sup> Respiratory devices, which are often critical for patient survival, require an effective air seal, which is determined by the size and shape of the mask. Ill-fitting masks create focal pressure points and localised frictional forces that can lead to irreversible tissue damage within hours or less. Examples of DRPU in adults are shown in Fig 4.

**Table 3. Characteristics of neonatal skin that increase its vulnerability to device-related pressure ulcers (DRPU)<sup>174</sup>**

Serum albumin levels <2.5mg/dl	Stratum corneum is 50–70% thinner than that of adults
Reduced protein, arginine, vitamin A, C and zinc content	Suprapapillary epidermis is <80% of adults
Absence of acid mantle (pH>5.5)	Small corneo-keratinocytes due to high cell turnover rate
Thinner dermis than in adults (1–10 times less)	Skin microflora alteration
Reduced water content	Delayed full functioning of melanocytes
Reduced sebum production	Reduced skin capillary pressure
Immature sweat response for temperature regulation	Reduced amount of natural moisturising factors
Faster skin absorption	

**Table 4. Devices and objects associated with device-related pressure ulcers\***

<b>Devices with medical purpose</b>
<b>Respiratory devices:</b> oxygen face masks (non-invasive ventilation); continuous positive airway pressure (CPAP) masks; bilevel positive airway pressure (BiPAP) masks; endotracheal tube or securement devices; nasal prongs and tubing; high-flow nasal prongs; extracorporeal membrane oxygenation (ECMO); tracheotomy tube and securement
<b>Faecal and urinary devices:</b> stoma devices; urinary and faecal catheters; bed pans; toilet seats; condom catheters; penile clamps; bowel management systems
<b>Access devices:</b> all types of lines (catheter (arterial or venous) and associated lines/tubing); intercostal catheters; chest tubes and lines
<b>Support and immobilisation devices:</b> cervical collars; external fixators and pins; air casts /pneumatic support devices; restraints (not used in UK); splints (including for arterial lines); orthopaedic immobilisers, donut head supports; intraoperative devices such as frames used in neurosurgery
<b>Feeding and nutrition:</b> nasogastric tubes; orogastric tubes; percutaneous endoscopic gastrostomy tubes
<b>Patient handling:</b> spinal boards; transferring devices; wheelchairs
<b>Patient monitoring:</b> oxygen saturation probes/pulse oximeters (clamped on finger, toe or ear); blood pressure cuffs; electrocardiogram (ECG) dots and lines; electroencephalogram (EEG) electrodes and wiring; wearable monitoring devices/sensors (e.g. for blood glucose); intracranial pressure (ICP) monitoring (cannulae and tubing); extraventricular drains (EVD); forehead saturation probes; temperature probe devices/sensors
<b>Compression and deep vein thrombosis prevention:</b> sequential compression devices (SCDs); thromboembolic deterrent (TED) stockings; compression hosiery; all cotton elastic (ACE) wraps; heel offloading devices
<b>Treatment:</b> dialysis involving cannulae and tubing/lines; negative pressure wound therapy (NPWT); tubing associated with NPWT; intra-aortic balloon pumps (IABP) involving cannulae and tubing/lines; plaster casts including total contact casting to offload diabetic foot ulcers; ointment gauze <sup>175</sup> bandages used on patients with critical limb ischaemia
<b>Prosthetics and orthotics:</b> above- and below-knee prostheses; knee orthosis (braces); ankle foot orthoses
<b>Surgical devices:</b> forceps; tools; instruments
<b>Miscellaneous devices and objects:</b> bandages; identity bands on wrist/ankle; pens/scissors/flashlights/other healthcare provider personal items (dropped in beds)
<b>Hospital furniture:</b> bedframes; foot rests and any other rests
<b>Device components that are removed before use:</b> packaging elements, e.g. tops from syringes
<b>Devices used in tissue viability:</b> devices and objects associated with risk management; patient-positioning devices used for staff safety during repositioning or transferring; aircast boots; crutches; casts; wedges (foam and/or rubber); wheelchairs
<b>Objects without direct medical purpose/patient's or other's property</b>
Mobile/cell phones; jewellery; hearing aids; glasses; remote controls; office supplies
Anything the patient sits/lies on that is a foreign object, such as a hairbrush
*Examples are provided; the list is not intended to be exhaustive



In paediatrics, the following devices are particularly associated with DRPU,<sup>103,104</sup> respiratory devices, casts and orthotics, intravenous arm boards, intravenous tubing, oximetry probes and cervical collars.

EEG leads, extracorporeal membrane oxygenation (ECMO) cannulae and cooling blankets may cause DRPU on toes, neck, chin, head, arms, feet, nose, chest, ears, earlobe, face, knuckles and buttocks of infants.<sup>17</sup>

In all patients, other devices associated with DRPU include nasal prongs, anti-embolism stockings, ankle bands and epistaxis balloons.<sup>9</sup> Examples of DRPU in pediatric patients are shown in Fig 5.

## Impact by type of device

Common anatomical sites for DRPU include the face, ears, lower leg and heels. However, DRPU can occur anywhere a device contacts the skin.<sup>105</sup> 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.

Extended use of devices is associated with a higher and increasing risk of DRPU. Cervical collars are associated with a higher incidence of DRPU after five days of continued use, with many of these being



category IV.<sup>31</sup> Procedures and treatments administered concomitantly with a device may increase risk. For example, the use of pulse oximetry during vasopressor therapy<sup>13</sup> is associated with a higher incidence of DRPU.

The type of device associated with PU will vary depending on the setting. This is illustrated by the results of a (unpublished) DRPU incidence audit undertaken at Kyorin University Hospital in Tokyo, Japan, which were shared by a panel member. This is an acute care hospital with 1153 beds, 38 medical departments and an average of 2177 outpatients per day. The ICU consists of five critical care units, including one for neonates. The hospital undertakes a DRPU survey at a fixed point every month on the same

day. Cumulative data collected for one year (from 1 February 2018 to 31 January 2019) showed that DRPU associated with elastic stockings were most prevalent (n=13) in general wards, followed by compression bandages (n=4). In all of these cases, the devices were used to prevent DVT. The following devices were associated with DRPU in ICU but not the general wards: those used to manage body temperature (n=1), measure blood pressure (n=1) or use for pulse oximetry (n=3), surgical drainage (n=3) and splinting (n=8). Some devices were associated with DRPU in both general wards and ICU, but had a higher incidence in ICU: invasive arterial blood pressure measurement (n=7), tracheal cannulae (n=3) and non-invasive positive pressure ventilation (NPPV) masks (n=9).

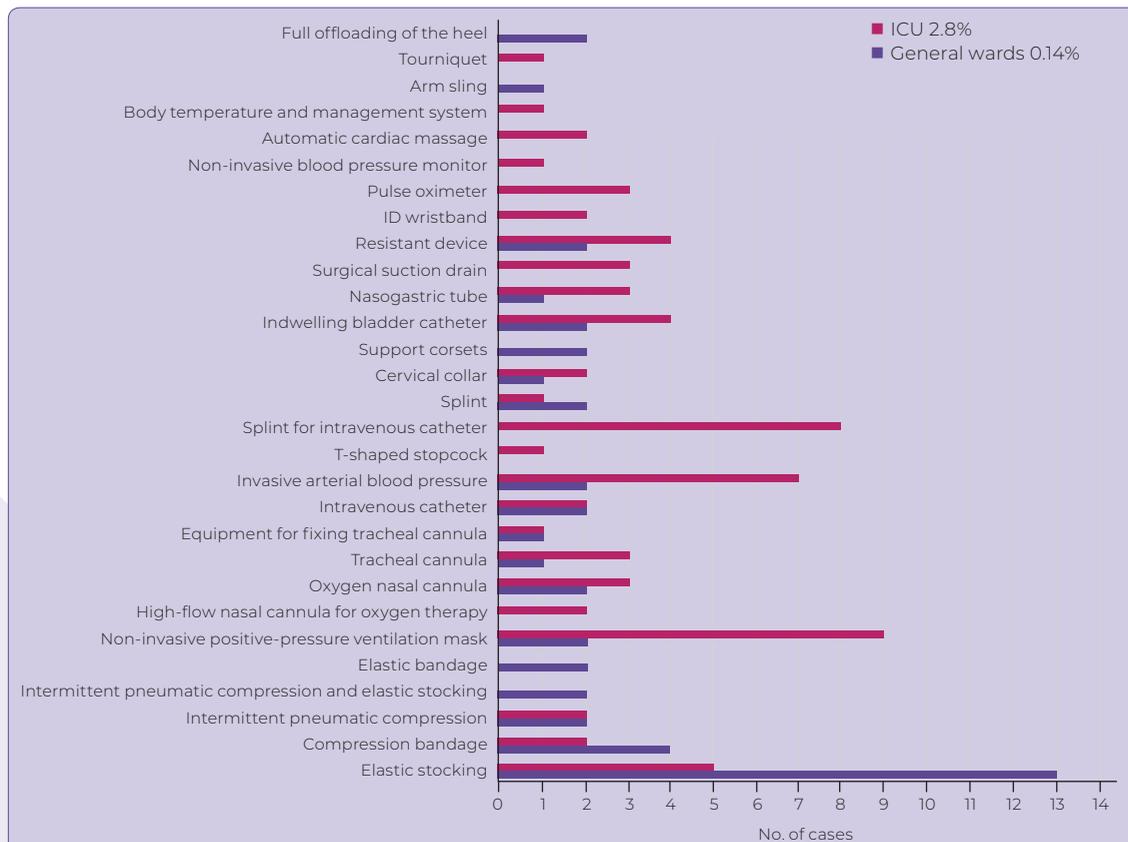
Results are presented in Fig 6. These findings are consistent with published data from other centres.<sup>106</sup>

### Categorisation

Table 5 presents an example of categorisation of medical devices, based on how they interact with the skin and the aetiology of the subsequent DRPU. This method of categorising devices focuses the health professional on the reasons for the associated DRPU risk. Devices comprised of hard materials and that have a small contact area with the skin create high localised pressure and frictional forces, and are commonly associated with DRPU. Devices with large skin-contact areas create lower pressure that is

sustained over long periods and causes substantial static frictional forces and shearing (Table 5). These devices include splints, pulse oximeters, non-invasive blood pressure cuffs (NIBP) and identity bands. Products used in deep vein thrombosis (DVT) prevention, such as elastic stockings and intermittent pneumatic compression (IPC) with or without elastic stockings, also fall into this category.

There is also a category for devices that present risk through moisture accumulation or pH alteration, which reduces the skin's tolerance to external stresses. This is a particular issue with respiratory devices as moisture expelled during respiration can cause humidification. Devices in this category include NPPV masks, nasal



**Fig 6.** Incidence of device-related pressure ulcers (DRPU) in intensive care unit (ICU) and general wards

**Table 5.** Aetiological classification of device-related pressure ulcer

	Small (small contact area) Hard material	Large (large contact area) Hard material	Devices that reduce the tolerance of the skin
			
<b>Aetiology</b>	High pressure	Low pressure	Moisture
	Sustained pressure	Sustained pressure	pH
	Tissue deformation	Tissue deformation	
<b>Device</b>	Nasogastric tube	Splint	<b>Respiratory</b> Non-invasive positive pressure ventilation (NPPV) mask
	Indwelling bladder catheter	Pulse oximeter	
	Intravenous catheter and three-way stopcock	Non-invasive blood pressure (NIBP) cuff	Tracheal tube
	Invasive arterial blood pressures	ECG patch	Tracheal cannula
	Central venous catheter	ID wrist band	
	Epidural catheter		
	Masks	<b>DVT prevention</b>	
	<b>Monitors</b>	Elastic stocking	
	Core thermometer	Intermittent pneumatic compression and elastic stocking	Stoma products
	Body temperature management system		
	ECG code		
	NIBP tube and connector		

oxygen cannulae and tracheal tubes and cannulae. Stomas are included in this category, as leakage of gastrointestinal contents onto the skin can cause chemical irritation and ingress of bacteria. Digestive and pancreaticobiliary enzymes in gastrointestinal contents increase the risk of skin damage.<sup>107</sup>

Some devices have risks associated with more than one category. The immature skin barrier in paediatric patients may be susceptible to toxicity, especially under occlusion. Stomas are included in this category because leakage of gastrointestinal contents onto the skin causes chemical irritation and bacteria infiltration.

Other relevant devices associated with a DRPU risk are external orthopaedic fixators, which are made of rigid (metal) components, often with curved, thin, sharp or geometrically-irregular elements and surfaces.<sup>108</sup>

# Risk assessment

As with any PU, assessing a patient's risk of DRPU is a critical step in prevention. Expert guidelines and best practice statements stress the importance of risk assessment.<sup>1,2,109-115</sup> This involves an awareness not only of the risk factors for pressure ulceration in general, but also recognition of the additional risk posed by the use of devices.

Examples of critical device-related, patient-related and organisational risk factors are listed in Box 3.

Clinicians, patients, their family and other healthcare workers should be aware of the risks posed. Their responsibilities are outlined in Box 4.

It is not enough merely to conduct one PU or DRPU risk assessment: risk assessments must be part of daily routine practice. The assessment should be used to direct the patient's management pathway, which should include strategies to prevent both PU and DRPU.

An example of a template that can be used to highlight the risk of DRPU to clinical staff is given in Fig 7. The template is derived from one used in a medical-surgical ward in a US-based hospital and can be adapted for use in wards, units or other settings. The form requires users to note whether a patient has DRPU and document when high-risk medical devices are being used. This should lead to staff undertaking a full risk and skin assessments in these patients.

## Risk assessment tools

A large number of PU risk assessment tools (RATs) has been published. When conducting a risk assessment, it is important to recognise that all patients with a medical device in place are at risk of pressure ulceration. RATs should be regarded as diagnostic tools for the identification of skin changes and trigger their management. RATs should therefore be used routinely and supplemented, where necessary, with information on the medical device and clinical judgement.

Most RATs rate a patient's risk level using a numerical score, which indicates whether a patient is at low, high or intermediate risk of pressure ulceration. However, it may be more appropriate to consider specific risk factors for the patient.

### Key points

- Risk assessment should be part of routine practice
- Risk assessment tools (RATs) should be used to identify skin changes and direct management
- Patients being managed with a medical device should be considered at high risk of device-related pressure ulceration (DRPU)
- It can be difficult to assess skin under some devices, such as external orthopaedic fixation frames, plates or splints
- RATs specific to DRPU need to be developed

### Box 3. Examples of device-related, patient-related and organisational risk factors for device-related pressure ulcers

#### Patient-related risk factors

- Focal or large area pressure
- Shear
- Humidity
- Moisture
- Duration of device use

#### Patient-related risk factors

- Age
- Medical condition
- Comorbidities
- Perfusion level, risk or skin changes identified by risk assessment tools (RATs)
- Skin condition
- Presence of a device and previous PU or other injury at the site where the device will be applied

#### Organisational risk factors

- The care setting
- Skill level of health professionals
- Lack of access to devices that come in a range of shapes and sizes
- Lack of access to appropriate equipment,
- The need to prioritise other potentially life-threatening issues

**Box 4. Risk awareness: key responsibilities for health and allied professionals**

**Patients, carers and family**

- Be aware of risks posed by personal possessions
- Take action to minimise risk
- Inform clinical staff of any discomfort or pain at the device site
- Inform clinical staff of any objects left between the patient and support surface
- Move or adjust the device if there are signs that the patient is in discomfort or pain

**Health professionals and other health workers including porters and housekeeping staff**

- Be informed about the risks posed by devices, objects and personal possessions
- Record use of devices in patient charts or bedside boards used to identify risk of falls
- Be aware of the risks in adult, paediatric and neonatal patients and, specifically, patients who cannot sense or report discomfort or pain
- Conduct device-specific risk assessment as part of routine pressure ulcer risk assessment
- Assess the risks to skin at the device site
- Modify the care plan/pathway in accordance with the identified risk
- Take proactive action to minimise the risk of device-related pressure ulcer (DRPU)
- Conduct regular skin assessments according to the risk level associated with the device and any patient-related factors
- Report any device-related injury
- Interact with manufacturers to identify and suggest design changes that will reduce the risk of DRPU
- Develop local protocols for risk assessment and use of medical devices
- DRPU—device relate pressure ulcer

**Validated risk assessment tools for use in paediatrics**

The Braden QD Scale has been shown to have acceptable predictive value for DRPU formation in the acute paediatric care setting. However, it is non-specific to the type of device(s) used and assesses risk only by the total number of devices used on a patient.<sup>116</sup> Other paediatric-

		Team safety huddle date			
Assessment/measure		07.00		19.00	
No. of patients on the ward					
No. of observation patients					
Pending admissions					
Stress test/surgery					
Invasive arterial blood pressures					
Central venous catheter					
Core measures:	CVA / TIA				
	CHF				
	COPD				
	Haemodialysis				
No. of days since last fall					
No. of days since last surgical site event					
No. of days since last PU/DRPU					
No. of days since last employee injury					
No. of days since last employee assault					
Detox / CIWA					
One-to-one staff patient ratio					
High fall risk / safety concerns					
Abusive / difficult patients					
Patients with PU					
Patients with DRPU					
High-risk devices:	Foley/Foley securement device				
	Oxygen tubing				
	BIPAP/CPAP				
	Nasogastric tube				
	Suprapubic catheter				
	Tracheostomy tube				
	Cervical collar				
	Orthopaedic device				
	IPC				
NPWT					
Patients with other skin concerns					
Anticipated discharges					
Staffing					
Location of specialty bed and pump					
Equipment issues					
Specialist equipment on unit					
Medication-dispensing machines are clear of discrepancies? (tick)		Yes	No	Yes	No
Good catches / staff recognition unit / organisational news. Anything to address? Document pain scores and reassessment within 1 hour. For pain meds, as needed, in accordance with parameters, you must follow order as written or obtain new or Rx order from MD					
BIPAP—bilevel positive airway pressure; CHF—congestive heart failure; CIWA—Clinical Institute Withdrawal Assessment for Alcohol; COPD—chronic obstructive pulmonary disease; CPAP—continuous positive airway pressure; CVA—cerebrovascular accident; DRPU—device-related pressure ulcer; IPC—intermittent pneumatic compression; NPWT—negative pressure wound therapy; PU—pressure ulcer; TIA—transient ischaemic attack					

**Fig 7.** Example of a template that could be used to highlight the risk of DRPU to health professionals. One template needs to be completed per ward

focused RATs are by Sterken et al.,<sup>117</sup> Peterson et al.,<sup>118</sup> Kiss and Heiler,<sup>119</sup> and Willock et al.<sup>12</sup> or still in development.

## Assessment

Any patient being managed with a medical device should be considered as at high risk of DRPU. The management plan must include frequency of assessment, as well as strategies to reduce risk. There is no predetermined frequency for assessments, which should be determined by the risk posed by the device, the patient's condition and clinical judgement. Inevitably, the frequency will be higher for high-risk devices or where the risk is associated with either a systemic condition, nutritional status or other patient-related factors. The local condition of the skin and underlying soft tissue, such as scars from previous injuries that have resolved but left fibrous tissue inclusions, local atrophy changes or oedema, should also be considered.

Health professionals should also be aware of the risk associated with devices and objects with no medical purpose. 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. Examples are given in Table 5, page S21.

## Paediatric patients

The most common site for body weight-related PU in paediatric patients is the occiput, where the largest bony prominence and highest interface pressures are located.<sup>15</sup> 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,<sup>121-124</sup> lengthy surgical procedures, ECMO bridge-for-life connections, and cerebral and cardiovascular activity probes.

## Example of a skin-integrity assessment protocol

The general principles of skin assessment are listed in Box 5. When risk is identified, the assessment must focus on the early signs of skin and tissue damage.

### Box 5. General principles of skin assessment<sup>176</sup>

All patients managed with a medical device must undergo a skin assessment

#### Skin should be assessed by:

- Colour
- Moisture
- Oedema
- Turgor/firmness
- Bogginess
- Temperature (heat and cold)
- Presence of signs of skin irritation, or tissue damage, or potential damage (non-blanchable/non-blanching erythema: skin that blanches and slowly returns to its normal colour)
- Bruising
- Presence of devices
- Scaling and dryness

#### Frequency of assessment:

- Determined by the risk level associated with the device, the patient's condition and clinical judgement
- More frequent assessment is required by patients managed with high-risk medical devices, or are considered at high risk

An example of advanced practice in assessment is the use of a skin-integrity protocol embedded in the clinical information system at the ICU at the Royal Brisbane and Women's Hospital, Queensland, Australia.<sup>125</sup> The protocol requires staff on each shift to complete a full head-to-toe, back-to-front skin assessment that includes skin under medical devices. Staff are guided to check under devices every three hours and to reposition the device or patient if necessary, ensuring that the device is not wedged or positioned such that it presents an risk of injury. The assessment is documented in the clinical information system using a series of drop-down menus and options to describe colour, warmth, moisture and turgor of the skin, as well as the presence of any skin injury and/or oedema. An example of a drop-down menu is shown in Fig 8.

**Intensive care unit: nursing assessment form**

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Equipment & patient safety	Neuro	CVS	Respiratory/ Renal	GIT	Skin integrity
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**Skin integrity/ assessment** Assessment comments

Skin temp	<input type="text"/>	<input type="button" value="▼"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Skin colour	<input type="text"/>	<input type="button" value="▼"/>	
Skin turgor	<input type="text"/>	<input type="button" value="▼"/>	
Skin moisture	<input type="text"/>	<input type="button" value="▼"/>	
Skin texture	<input type="text"/> <ul style="list-style-type: none"> <li>Normal</li> <li>Dry</li> <li>Diaphoretic</li> <li>Oily</li> </ul>		
Skin oedema			
Oral mucosa			
Nare mucosa			

**Pressure injury/risk assessment** Available links/ tips

Pressure injury risk assessment	<input type="text"/>	<input type="button" value="▼"/>	<input type="button" value="Pressure injury prevention WUG"/>
Mattress/bed type	<input type="text"/>	<input type="button" value="▼"/>	

CVS–cardiovascular system; GIT– gastrointestinal tract; WUG–work unit guideline

**Fig 8.** Computer drop-down menu with options to describe colour, warmth, moisture, oedema and turgor of the skin and the presence of a skin injury

## Inspecting skin under large devices and in insensate patients

It is not always possible or easy to observe the skin under devices such as external orthopaedic fixation frames, plates, splints and cervical collars. In such cases, if the patient is alert, the health professional should ask (mindful of the position of the device) if they are in any pain/discomfort or if there is an unusual sensation under the device, and then use their clinical judgement to complete the assessment. Clinical judgement is especially important for patients who do not have intact neurovascular function under the device or cannot verbalise discomfort. In such cases, non-verbal cues, such as grimacing or agitation, should be observed for.

It may be possible to assess the skin using direct palpation. A cervical collar stops the neck moving. 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 staff, log rolling the patient with the anterior collar in place, with the head held by a trained health professional. Braided or beaded hair, particularly if it is dark, can present difficulties during assessment. A DRPU can develop and bleed into the hair without being easily seen.

## Paediatric patients

Priorities for assessment of neonates, infants and paediatrics are listed in Box 6. It also describes

**Box 6. Assessment of neonatal and paediatric patients<sup>15</sup>**

**Frequently assess skin under:**

- Blood pressure cuffs
- Transcutaneous oxygen pressure probes
- Tracheostomy plates
- Nasal prongs and masks (continuous positive airway pressure, CPAP)
- Arm boards
- Plaster casts
- Traction boots

**In growing children, frequently readjust:**

- Orthotics
- Wheelchairs
- Wheelchair cushions

**Inspect beds, cribs and isolettes to ensure tubing, leads, toys and syringe caps are not under or on top of the patient's skin**

**Pressure damage assessment should be conducted for:**

- Skin around nasogastric and orogastric tubes
- Head dressings
- Hats

adjustments that might need to be made to devices to avoid the risk of DRPU. Fig 9 gives an example of a checklist approach to assessment of neonatal and paediatric patients in ICU.<sup>15</sup>

**Other clinical challenges**

Assessment can be difficult 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 age-related changes.<sup>126</sup>

Risk assessment should focus on the body site onto which the device has been or will be applied. However, patients with oedema or lymphoedema may be at risk, despite having skin that is generally in good condition. As noted previously, oedema may develop in previously non-oedematous skin after a device has been applied.

**Developing bespoke risk assessment tools**

Facilities should develop their own device-specific RAT that will work with their own protocols, based on the patient populations that they serve. The checklist in Fig 9 covers two settings: the operating room (OR) and the ICU. The checklist should be filled in at each staff changeover; the presence on a patient of specified devices should be noted with a check or cross, and any skin injury associated with the device documented.

Documentation of the presence of a device should lead to device-specific assessment, which should in turn inform the patient's care pathway.

**Next-generational risk assessment tool**

Current conventional RATs have low sensitivity and specificity for predicting PU formation,<sup>127-131</sup> their use does not necessarily lead to targeted PU prevention<sup>132,133</sup> 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 both biomedical and clinical research, potentially using innovative technology that allows assessment of tissue status. Such technologies include:

- Imaging
- Biocapacitance measurements
- Inflammatory biomarker measurements
- A combination of the above.

To the panel's knowledge, no medical device has an integral sensing and monitoring capability that will alert health professionals to impending local skin damage, either on or under the skin. This is a clear opportunity for industry. This is discussed in more detail in chapters 6 and 7.

**The SEM scanner**

A hand-held non-invasive device, the SEM Scanner (BBI), that assesses sub-epidermal moisture (SEM) has been launched.<sup>134</sup> The device, which scans at-risk skin sites

(sacrum and heels), is able to identify tissue regions that may break down several days before damage becomes visible. SEM accumulates before visible skin changes can be detected by eye, causing tissue biocapacitance (a measure of the fluid content in skin and underlying soft tissue) to increase due to the greater interstitial fluid content. The more fluid present, the greater the biocapacitance.<sup>135-137</sup> Tissue biocapacitance is associated with localised inflammation and oedema in the early stages of pressure-induced tissue injury.<sup>138</sup> The scanner therefore warns health professionals about elevated SEM several days before damage is visible at the skin surface.<sup>139</sup>

The SEM Scanner has not yet 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 unsuitable for assessing relatively small anatomical regions such as the nose, lips or bridge of the nose.

### Requirements for future risk assessment tools

The panel proposes that, in the future, visual skin assessments should be replaced with technology-aided skin evaluation procedures that use, for example, biophysical markers (such as tissue biocapacitance) or biomechanical markers (such as inflammatory mediators collected at the skin) to indicate skin health and extrapolate risk.<sup>48,62,93</sup> It may be possible to include visual markers on the device that can indicate load, tissue status, alert staff of the need to initiate other risk measures, monitor biomarkers and change colour when thresholds are detected.

### Clinical emergencies

Clinical management of risk may present challenges. If the medical device creating a risk of DRPU serves a critical purpose, moving or adjusting it will simply not be an option, as this would seriously compromise the patient's health. If the patient is having a clinical emergency, such as airway instability, the position of the device and the forces it is exerting on the lips or other tissues suddenly become lower clinical priorities and periodic assessments may not be completed.

<b>Device-related pressure ulcer (DRPU) checklist: devices used in paediatric/neonatal intensive care units</b>	
<b>Monitors</b>	<b>Respiratory</b>
Core thermometer	NPPV mask
Body temperature management system	Oxygen nasal cannula
ECG patch and code	Equipment for fixing tracheal cannula
Pulse oximeter	Tracheal tube
NIBP cuff, tube and connector	Tracheal cannula
<b>Tubes</b>	<b>Others</b>
Nastrogastric tube	ID wrist band
Indwelling bladder catheter	Splint
Intravenous catheter and 3-way stopcock	Other (specify)
Invasive arterial blood pressures	
CV catheter	
Epidural catheter	
<b>Deep vein thrombosis prevention</b>	
Elastic stocking	
IPC and elastic stocking	
<b>DRPU checklist: operating room/surgical theatre devices</b>	
<b>Monitor</b>	<b>Respiratory</b>
Core thermometer	NPPV mask
Body temperature management system	Oxygen nasal cannula
ECG patch and code	Equipment for fixing tracheal cannula
Pulse oximeter	Tracheal tube
NIBP cuff, tube and connector	Tracheal cannula
BIS monitor	<b>Others</b>
<b>Tube</b>	ID wrist band
Nastrogastric tube	Other (specify)
Indwelling bladder catheter	<b>Option</b>
Intravenous catheter and three-way stopcock	Tourniquet
Invasive arterial blood pressures	Fixation equipment from lateral
Central venous catheter	
Epidural catheter	
<b>Deep vein thrombosis prevention</b>	
Elastic stocking	
IPC and elastic stocking	

For abbreviations, please see page S51

**Fig 9.** Device-related pressure ulcer (DRPU) intensive care unit and operating room

# Safe use of devices: prevention and management of DRPU

**P**revention of DRPU 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 the focus of health professionals and policy-makers'. This chapter discusses the other aspects of prevention listed above, as well as the management of DRPU.

## Key aspects of DRPU prevention

PU or DRPU prevention requires a high level of awareness and rigorous adherence to practices that minimise the risks. The basic considerations for PU prevention are listed in Box 7. However, it is vital that health professionals also consider all the variables and characteristics related to DRPU.<sup>140</sup> This involves accounting for the physical form of a device, the clinical goal for its use, the type of tissue onto which it will be/is being placed, and the anatomical area affected. This will help identify interventions that will

### Box 7. Pressure ulcer prevention: steps and procedures

- Risk assessment
- Skin assessment and care
- Surface selection and care
- Regular moving or repositioning of person or device
- Incontinence and moisture management
- Nutrition and hydration
- Give information and share learning—involve patient and carers and document care delivered
- Use pressure reducing or redistributing support surfaces

### Key points

- Fundamental elements of prevention include risk assessment, skin assessment, care planning, care delivery and documentation
- The physical form of a device, the clinical goal associated with its use, the type of tissue and the anatomical area affected all need to be considered
- Consider introducing a clinical champion with the appropriate education and clinical background to develop and maintain standard procedures, and ensure their distribution
- Use the SECURE mnemonic (Skin/tissue, Education, Champion/collaborate, Understanding, Report, Evaluate) when developing pathways
- Procurement services should be aware of their role in device-related pressure ulcer (DRPU) prevention
- Prophylactic dressings should be considered
- Fundamentals of managing DRPU are similar to those for other types of pressure ulcer

reduce the incidence of DRPU. Vigilance, adherence to best practice for device application and awareness of potential causes of risk can help avoid poor placement of devices, mistakes and mitigate lack of staff training.<sup>141</sup> In this way, health professionals can reduce the risk of skin breakdown.

This is especially important in neonatal and pediatric patients admitted to critical care and during transport between units.<sup>104</sup> Devices applied to newborn and infants in an ICU may take up 25–30% of the body surface, underlining the importance of careful and consistent observation to prevent DRPU. Standard care based on expert consensus recommendations should be followed (Box 8).<sup>1,111,142</sup> The UK NHS National Institute for Health and Care Excellence (NICE) and the NPIAP/EPUAP/PPPIA

specifically recommend steps and procedures for neonates, infants and paediatric patients admitted to secondary or tertiary care and other settings if risk factors are present. They recommend the Braden Q scale be used for assessment. Skin assessment in paediatric patients should be from head-to-toe, with focus on the occipital area, ears, bony prominences, genital area, feet, heels and elbows. Skin temperature and erythema should also be assessed.

For patients of all ages, more frequent skin assessment is warranted in high-risk patients.

### Working as a team to implement protocols for best practice

Fundamental elements of PU prevention include risk assessment, skin assessment, care planning, care delivery and documentation. The objective of a DRPU prevention care plan is to minimise the risk posed by the use of a device.

DRPU prevention requires a team approach, where every health professional or worker who comes into contact with a patient makes it a priority from the outset.<sup>143</sup> A simple method of ensuring such focus is to incorporate DRPU into ward or facility documentation, as shown in Fig 7 (page S23).

DRPU prevention requires a high level of cross-functional collaboration and communication, which can be facilitated by documentation. The panel recommend that all facilities should have documented procedures, protocols and guidelines for device use (Boxes 8 and 9) that are available to all health professionals and other staff who come into contact with patients. Standard procedures should cover device selection and application with appropriate tapes and fixation methods. Each facility should nominate a clinical champion to develop standard procedures, disseminate them and ensure compliance. This approach has been shown to be effective.<sup>144</sup>

A facility's standard procedures should be based on recognised published guidelines and RATs. The NPIAP has published one-page guides on the prevention of DRPU in critical care,<sup>145</sup> paediatric populations<sup>146</sup> and in long-term care<sup>147</sup>, as well as a

general overview.<sup>148</sup> They include photographs of DRPUs that commonly occur in each setting and advice on prevention. Box 8 lists NPIAP guidance for preventing for PU and DRPU.<sup>2</sup>

The standard of care protocols should include all steps and procedures that need to be followed. The protocols should be described in enough detail for the protocol to be a stand-alone document that can be implemented without reference to another document. There may be circumstances where a protocol does not cover every possible eventuality—for example, when a patient suffers a life-threatening change in their clinical condition that requires immediate action. In such cases, clinical judgement and experience must be used.

Protocols are also needed for devices used palliatively by allied health professionals on paediatric

#### Box 8. NPIAP recommendations for prevention of device-related pressure ulceration<sup>2</sup>

- Adults and children on whom medical devices are applied are at risk
- Devices with the least potential to cause damage should be used
- Devices should be sized and fit appropriately
- Manufacturers' instructions for use should be followed
- Ensure securement without creating additional pressure
- Inspect the skin under the device twice daily and more frequently in patients who are vulnerable to fluid shifts and/or with general or localised oedema
- Use NPIAP classification scheme (note mucosal pressure ulcers cannot be staged)
- Remove devices as soon as medically feasible
- Maintain clean and dry skin under devices
- Reposition the patient and/or device to redistribute pressure and decrease shear
- Where possible do not place the patient on the device
- Rotate or reposition devices when possible
- Decrease pressure and shear with support
- Consider use of prophylactic dressings

**Box 9. Prevention of device-related pressure ulcer (DRPU): key procedures for device management**

- Inform patients and carers that devices and personal possessions can cause pressure ulceration
- Stress the need for visitors to remain vigilant about this at visits
- When selecting a device, consider its shape and size (relative to the patient), the patient's age and the type of intervention required
- Always follow the manufacturer's instructions for use
- Use additional measures to reduce pressure and shear. Make sure they are compatible with the device.
- Where possible, do not place the device over a pressure ulcer (PU) or broken skin
- Document the device and its level of risk
- Notify relevant staff of any risk associated with the device
- Assess the patient's risk status
- Conduct frequent skin assessments and check the skin under the device
- More frequent assessment will be required for high-risk patients
- Neonates, paediatric and bariatric patients should be regarded as at high risk
- Special attention should be paid if oedema is present
- Reposition the medical device at frequent intervals, if possible
- Consider changing the device interface when delivering an intervention. For example, swap nasal prongs with a full-face mask for the delivery of respiratory support
- Stop using a device as soon as is clinically possible
- Incorporate DRPU prevention into existing PU prevention pathways
- Ensure that DRPU prevention is part of the facility's routine practice
- Monitor DRPU incidence and prevalence; use rigorous and consistent procedures for this
- Work collaboratively and refer across specialties to prevent DRPU
- Give feedback to industry and collaborate with device developers and manufacturers

patients at the end-of-life. Non-medical devices can pose significant risks: examples include bedding that may fold under the patient, creating pressure and localised shear points, especially in neonates. Additional examples and management approaches are given in Table 6.

## Evidence base

There is limited published evidence on the effectiveness of many prevention measures and interventions. This may reflect institutional cultures where DRPU is under-reported due to risk of litigation. However, where evidence is available, it should be evaluated and integrated into procedures and protocols. For example, a recent meta-analysis suggested that hydrocolloid dressings can help prevent DRPU during non-invasive ventilation,<sup>149</sup> probably because they provide cushioning at the skin-device contact interface.<sup>150</sup> However, it should be noted that no commercial dressing has been designed specifically to prevent DRPUs.<sup>151</sup>

Health professionals and decision-makers in hospitals and care settings should be open to implementing evidence from all levels of the evidence hierarchy and not rely solely on randomised controlled trials (RCT). Evidence from cohort and case studies

**Box 10. Responsibilities of procurement services**

- Liaise with procurement services to increase awareness of their role in device-related pressure ulcer (DRPU) prevention
- Inform procurement about the role of materials used in medical devices (adhesives, silicones, additives and latex) in DRPU prevention. Obtain supporting information from the device manufacturer, as required
- Procurement services are often governed by local practices, laws and regulations. Ensure that those involved in procurement are fully informed of the regulations relating to medical devices and prevention of patient harm

**Table 6. Clinical practice approaches for the prevention of device-related pressure ulceration (DRPU)**

Device type/resource	Approach
Bilevel positive airway pressure (BiPAP) mask-related pressure ulcer (PU) in paediatric patients <sup>177</sup>	Select an appropriately sized mask
	Ensure effective delivery of respiratory therapy
	Update interface used to relieve pressure
	Skin should be assessed by a nurse or respiratory therapist every 4 hours
	Update record templates
BiPAP/ continuous positive airway pressure (CPAP) mask-related DRPU in surgical spine patients <sup>6</sup>	Collaborative approach
	Protective foam under all masks
	Mask not padded
	Stock dressings near masks and/or bundle them together
	Shape and fit dressings using patient-specific templates
Do not use ill-fitting full face masks	
Oronasal masks <sup>178</sup>	Personalised mask fitting device, designed using three-dimensional scanning
Modified SSKIN bundle <sup>72</sup>	Use devices with surfaces that are appropriate to the size of the patient
	Assess the need for adhesives
	Skin inspection by risk area and anatomical site, including the face and scalp
	Rotate devices
	Protect the skin under devices
	Incontinence management
	Optimise nutrition
	State actions needed: referral to a clinical specialist or no action

should be considered, as well as bioengineering research involving laboratory tests, computer (finite element) modelling and simulations relevant to device-design evaluations in the context of DRPU prevention. This is especially important because ethical considerations may seriously limit patient studies on DRPU in both paediatrics and adult populations. The Joanna Briggs Institute provides useful guidance on how to critique and appraise research evidence.<sup>152</sup>

## DRPU prevention in practice

### Care bundle approach

Where evidence exists, prevention strategies have been shown to reduce the incidence of DRPU in a

number of settings. The following example describes how implementation of a care-bundle approach reduced the rate of tracheostomy-related PU in children on invasive and non-invasive mechanical ventilation being transferred from a quaternary care children's hospital to the home setting.

The Plan-Do-Study-Act (PDSA) framework<sup>153</sup> was used to develop a care bundle for tracheostomy-related PU. During the bundle development phase, tracheostomy-related PU reduced from 8.1% to 2.6%. Once developed and implemented, it reduced still further to 0.3%. The process included online or didactic training of all nurses in the unit on PU risk assessment, full skin assessment and identification, and prevention of tracheostomy-related PU. Strategies included displaying information on the bundle in the

staffroom and publication of brochures explaining the risks, which were shared with patients.

The care bundle included the components that are listed below:

- Daily Braden Q RAT assessment
- Daily full-body skin assessment
- Device assessments, which were undertaken on every 8-hour shift
- Keeping device interfaces moisture-free
- Using a hydrophilic foam barrier under the tracheostomy tube flange and around the stoma to wick away fluid
- Reducing pressure and frictional forces, and using extended tracheotomy tubes in children whose necks were not clearly exposed or whose behaviour resulted in them pushing the tube down their sternum.

The team provided feedback to the manufacturer of the tracheostomy tube to aid its design and development, with the aim of reducing pressure at three locations where tracheostomy-related PU develop.

The care bundle was incorporated into the facility's electronic medical records (EMR) system, embedding it in the nurse workflow. Tracheostomy-related PU are reported in real time, tracheostomy tubes are changed according to the patient's anatomy, and tubes are placed during the tracheostomy in collaboration with otolaryngologists. Staff uptake of the bundle reached 100% in four months, demonstrating sustained quality improvement.<sup>153</sup>

This approach is transferable to other facilities and has been included in the panel's recommendation for prevention of DRPU.

## Publication of a guide

Another example of a DRPU prevention initiative is from Japan, where a detailed guide for general nurses and medical staff without a full understanding of DRPU was developed. The guidebook includes ten classifications of medical devices commonly associated with DRPU (Table 7). For each classification,

### Box 11. Requirements for reporting device-related pressure ulceration (DRPU)

- The DRPU category, if not on a mucosal membrane
- Anatomical location of the DRPU
- Size and shape of the DRPU
- Type of device involved
- Brand and model of device
- Control or serial number of device
- Expiry date of device
- Method of application
- Method of securement
- Protection or prevention strategy used with device
- Adjustments made during use
- Degree of adherence to the manufacturer's instructions for use

specific information is provided on risk assessment, selection and prevention. The importance of obtaining informed consent from patients and their families is highlighted.

## Optimising local implementation

A helpful mnemonic for an integrated pathway for DRPU prevention is SECURE (Fig 10), which stands for:

- Skin/tissue
- Education
- Champion/collaborate
- Understanding
- Report
- Evaluate.

Frontline clinicians with hands-on experience of devices and the risks they pose are well placed to drive the adoption of devices with the least risk of causing harm. Such an approach could work in a facility where suboptimal devices are used—for example, because of formulary constraints or lack of access to a wider range of device sizes and designs. Health professionals could also drive this by working closely with procurement and formulary staff (Box 10), presenting evidence, when available, to support the adoption of different devices.

## Management of DRPU

The fundamentals of managing DRPU are similar to those PU in general. These include use of a recognised classification system, such as the NPIAP system,<sup>2</sup> to describe the DRPU. This requires:

- Full patient assessment
- Accurate assessment of areas at risk of pressure damage
- Ongoing assessment, measurement and documentation of the DRPU
- Assessing and documenting progress
- Assessing, preventing and managing pain
- Using a high standard of local wound care.

DRPU present different challenges to PU, as body weight forces are not a dominant aetiology. It should be noted that DRPU on mucous membranes cannot be categorised.<sup>2</sup>

Considerations specific to DRPU include issues with continued use of devices for medical reasons. A DRPU caused by a mask may be managed by changing to a different design—for example, from a mask that transfers forces to the bridge of the nose to a full-face mask that transfers forces to the forehead. If it is not possible to change the make for clinical reasons, measures to reduce the causative factors should be used, when possible. This includes increased monitoring and use of prevention measures such as effective interface materials and structures.

Although it may not be possible to reposition a device such as a face mask to relieve pressure, repositioning or changing the means of securement may help to address this. For example, thin, soft interface structures with adequate mechanical and thermal energy absorption capacities may protect tissue by cushioning and/or redistributing load, while avoiding heat trapping.

## Reporting DRPU

Medical device regulatory bodies, such as the Food and Drug Administration (FDA) in the US, Health Canada,<sup>154</sup> Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and the Medical Device Directive in the EU have developed reporting

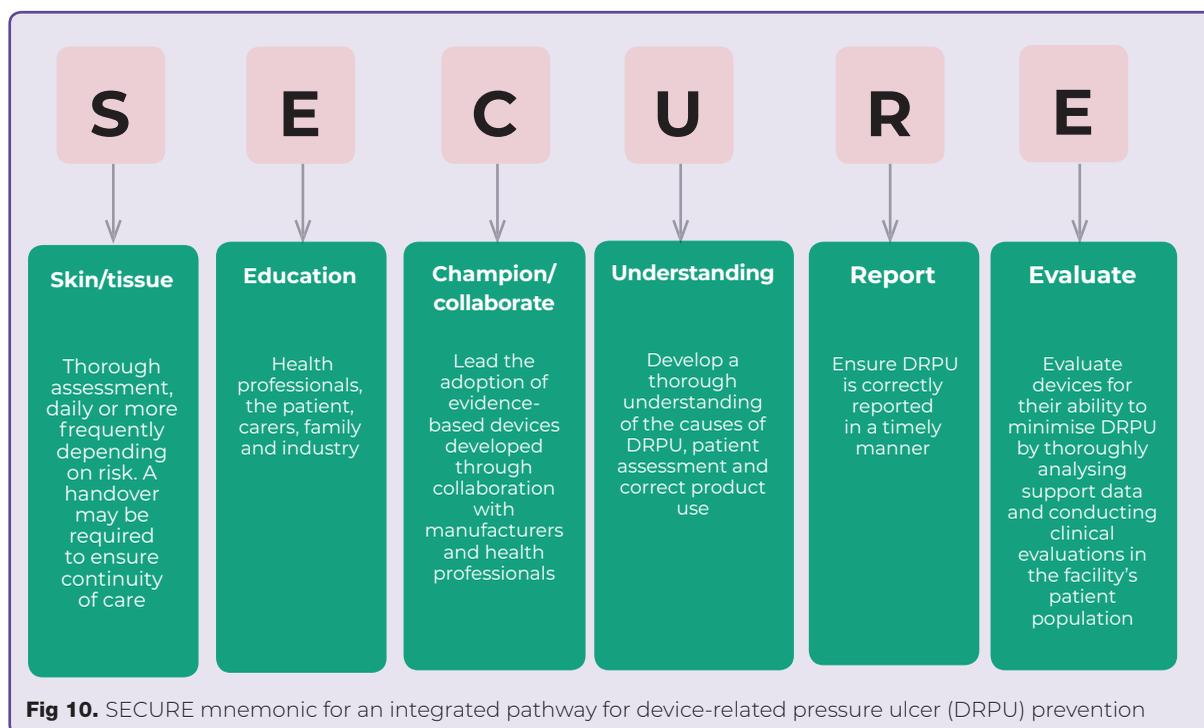
**Table 7. Classification of medical devices according to device-related pressure ulcer risk as presented in a Japanese clinical setting<sup>179</sup>**

1.	Elastic stockings used to prevent deep venous thrombosis Intermittent pneumatic compression (IPC)
2.	Non-invasive positive pressure ventilation
3.	Fixation device of orthopaedics, splint, cast
4.	Indwelling bladder catheter
5.	Faecal management system
6.	<b>Vascular access devices:</b> Intravenous catheter Invasive arterial blood pressure monitors
7.	Nasogastric tube
8.	Paediatrics nasogastric tube
9.	<b>Respiratory-related devices used in paediatrics:</b> Oxygen nasal cannula Equipment for fixing tracheal cannula Tracheal tube Tracheal cannula
10.	Paediatrics fixation device for catheter, splint

interfaces, where the public, patients or health professionals can report harm caused by therapeutic use of a device. Other countries have similar reporting systems.

Unfortunately, it is unclear how frequently health professionals use these reporting tools, and DRPU itself is not routinely reported. As such, there is little cumulative evidence on which medical devices commonly compromise the health of skin and underlying soft tissue. Typically, information about this is mainly communicated during institutional service evaluations or quality improvement activities.<sup>155,156</sup>

This means there is no consensus on which devices would benefit from further study on their design. To



**Fig 10.** SECURE mnemonic for an integrated pathway for device-related pressure ulcer (DRPU) prevention

provide high-quality, safe patient care, rigorous and consistent data on DRPU are required. Thus, a robust, evidence-based policy for reporting DRPU is essential to improve DRPU prevention.<sup>32,156-159</sup> In short, a culture of open reporting, supported by regulatory agencies, is required. This should result in manufacturers of unsafe devices reviewing and improving their products.

DRPU should be reported separately to PU. A root cause analysis should be conducted to inform the reporting of the DRPU. In the UK, NHS Improvement has issued new guidance on reporting of DRPU.<sup>160</sup> Further details on reporting requirements for DRPU are given in Box 11.

### Adhere to instructions for use

Manufacturers should provide instructions for use with their devices, which must consider the risk of DRPU. Health professionals are in turn expected to

read, understand and adhere to these instructions. However, medical devices are often taken out of their packaging away from the point of use, resulting in instructions for use not being available at the bedside. This is an issue that must be addressed. Occasionally, a health professional will improvise an (off-label) solution for avoiding skin damage when using a device. However, this may have biomechanical implications that are not fully understood, with the risk of unintended consequences. Therefore, it is important to follow the instructions for use and adhere to evidence-based protection measures.

### Regulators need to take action

We need to encourage regulators to ensure that medical devices are clearly labelled according to their risk of DRPU, based on clinical research evidence.

There is also an opportunity to develop standards to ensure that medical devices are designed with input

from bioengineers and undergo laboratory testing. Regulators should require companies to comply with these standards and document their devices' performance in terms of patient safety and DRPU prevention. Regulatory requirement that industry publishes its compliance with these standards will enable informed decision-making by healthcare institutions on purchasing and risk management.

This approach has, of course, been successfully used in the car industry for many years, where the results of crash tests, conducted in accordance with regulatory standards, are published for the benefit of buyers and users.

Furthermore, the regulatory bodies have not investigated reports of medical device harm, raising questions about the role of regulatory agencies in this field.<sup>158</sup>

## Medical device industry and manufacturers

Computer (finite element) modelling and phantoms can be used to design medical devices that minimise risk of DRPU.<sup>33</sup> This approach should be adopted when designing new medical devices or improving designs of existing ones. It should also be used when evaluating the mechanical and thermal energy absorbance of interface materials and structures. New designs need to take the causative factors of DRPU into account, including presence of sharp or curved device-surface geometries, frictional properties (high-friction coefficients), hard materials, pressure, shear and humidity, as well as their tissue loads and stress distributions and thermal energy management properties. The functional objectives of medical device design are shown in Box 12.

This approach was used to design a long soft-layered spinal board that would minimise the risk of DRPU. MRI scans of the sacral area in three volunteers were taken to inform a computer model of the tissue deformation that occurs when a patient lies on a spinal board. This preclinical modelling showed that the soft-layered design reduced tissue deformation

and thus the risk of deformation injury and pressure ulceration. Quantitative measures were provided by exposure to tissue loads for each design variant.<sup>98</sup>

In addition, technologies are available that sense interface pressure, shear, temperature and humidity.<sup>161,162</sup> Incorporating these technologies into medical devices will help avoid DRPU.

It is vital that manufacturers constantly engage with users of their products: this will help identify risks associated with existing devices and the development of strategies to minimise or eliminate them. Health professionals should be closely involved in all stages of the design process. This approach proved successful when designing a paediatric malnutrition assessment device.<sup>163</sup>

The medical device design process includes:

- An initial definition of user needs
- Identification of functional attributes required to meet these needs, including minimum performance standards
- Identification of existing technologies that meet these functional needs
- Design inputs including minimum performance standards
- Design validation
- Final prototype selection
- Clinical evaluation plan.

Particular scrutiny is needed when creating new designs for devices associated with a high risk of DRPU or indicated for high-risk patients. For example, the design of a device for neonates and paediatrics considered the proportional anatomical differences and tissue composition between this group and adults.<sup>164</sup>

The clinical evaluation plan should evaluate the potential risk of DRPU that could be attributed to the design. The product will be need to be redesigned if this risk is considered too high.

Manufacturers should change the labelling on the packaging to clearly indicate the level of risk of DRPU that might be associated with the device. The

instructions for use should include clear and detailed information on:

- How the device's design features address the risk of DRPU
- Instructions on application, fitting and securement
- Instructions on how to continuously monitor and adjust the device
- Information on the presence of interface materials and structures within the device that have been shown to be effective in preventing DRPU (supporting published bioengineering and clinical evidence on their efficacy should be cited).

## Health professionals and clinical researchers

Health professionals have a responsibility to apply medical devices in accordance with the instructions for use and to document this in the patient records. Clinical educators must ensure that carers and patients are aware of the potential harm associated with medical devices and consequently the need for correct application. This is particularly important in the community setting—for example, when orthotics or prosthetics are applied. Devices should be carefully selected to ensure a good fit with the patient's anatomy and contours. It should also be possible to be able to adjust them in response to changes in tissue characteristics, volume and contours (e.g. when oedema forms). For example, clinical evidence shows that improved fit is highly likely to reduce the risk of tissue damage on the nasal bridge when face masks are worn.<sup>94</sup>

Issues with specific products and device models should be reported and documented, and the results shared with the developers, manufacturers and, where necessary, regulatory authorities. This will put pressure on industry to redesign existing products and create new designs that specifically reduce the risk of DRPU. Clinical research evidence should be rigorously collected from all relevant settings to make a strong case to industry and/or the relevant regulatory bodies.

### Box 12. Functional objectives of medical device design

- Match stiffness or elastic modulus in design so that the elements contacting the skin are at a stiffness that is near that of skin and underlying soft tissue. Elastic modulus is an engineering measure of the stiffness of a material, indicating the ratio between the mechanical stress and deformation (strain) level
- Smooth tissue load gradients by matching device-tissue stiffness as described above and avoiding sharp or curved geometries in the device surfaces that contact the skin
- Minimise the coefficient of friction at the interface between devices and skin, thereby reducing frictional contact forces and shear distortions in skin and subdermally
- Minimise sustained tissue deformations, both at the skin surface and in deeper tissues
- Absorb mechanical loads applied by a device, so that as little as possible reaches the body tissues
- Improve thermodynamic effects by thermal energy management: minimise heat trapping between the device and skin, and allow heat clearance from devices that produce heat and/or adequate conduction of heat from tissue metabolism to the environment
- Use sensors to provide information on the mechanical loads applied, tissue temperatures and heat accumulation, the tissue health status and potential harms
- Use a shape and size of device that is relevant to the patient and can be adjusted if there is a change in volume or contours (e.g. as a result of oedema or lymphoedema)
- Ensure the device is compatible with incontinence management
- Manage moisture or wetness resulting from use of the device
- Provide continuous tissue protection by minimising any frictional properties at the skin-device interface, even if there is a build-up of perspiration or moisture, that temporarily increases skin and subdermal tissue tolerance to loads

# Changing the focus of health professionals and policy-makers

**R**educing the incidence of DRPU will require a change in the mindset of health professionals, health-service managers/decision-makers and policy-makers working in government and regulatory bodies. Health professionals and administrators will need to be aware of the risks that medical devices and other objects pose in terms of tissue injury. Health professionals will also need to know how to assess and minimise risk. Administrators will need to understand the potential consequences of DRPU in terms of human suffering, healthcare costs, risk of litigation and effects on insurance premiums or potential loss of coverage. They will then need to act on this understanding. Finally, policy-makers will need to recognise the human, clinical and economic burden of DRPU.

## Increasing awareness

At present, health professionals and administrators are often not even aware of the importance of DRPU and its associated risks.<sup>9,106</sup> Similarly, chart templates and patient documentation may not pay much attention to DRPU prevention.<sup>9</sup> There is a need, therefore, to raise awareness of DRPU through education, ongoing training and consistent reporting.

Preventing DRPU is not the sole responsibility of a tissue viability specialist or equivalent: the likelihood of a DRPU prevention programme being successful when led by a single group of specialist clinicians in a healthcare facility is low. All health professionals who manage patients in contact with devices must be aware of both the risks of DRPU and the strategies to prevent it. Administrators, purchasers, liability specialists (legal teams) and risk management staff in all types of medical facilities should be aware of the consequences of DRPU from financial (cost-benefit), legal and insurance (litigation) perspectives. Indeed, in English ICUs between 1995 and 2012, PU was among the harms that most commonly led to substantial compensation following litigation.<sup>165</sup>

The key to increased awareness is to monitor and document staff performance to ensure their knowledge of DRPU is sufficient and up to date.

## Key points

- Many health professionals and managers underestimate the psychosocial, clinical and economic impact of device-related pressure ulcers (DRPUs)
- There is a need to increase awareness on DRPU through education, training, and improved documentation and reporting
- Education can be provided by health professionals, academics, bioengineers or industry (if supported by independent experts). It is most likely to be effective if it includes practical demonstrations and exercises on best practice for the application of devices.
- It is vital that health professionals demand manufacturers provide robust evidence on the clinical efficacy of their medical devices in preventing DRPU
- Healthcare organisations should develop written guidance on best practice for the use of medical devices most associated with DRPU in their facilities

## Education and training.

Administrators and decision-makers involved in purchasing medical devices need education on DRPU. This will increase awareness and ensure that, as a minimum, the fundamentals of DRPU risk assessment and management are disseminated to all relevant areas of the institution. Ongoing education should also be routinely provided on innovations in medical device technology that can reduce the risk of DRPU.

## Sources of education

Education and training can be delivered by health professionals, academics or bioengineers. In addition, manufacturers are increasingly offering education and training on their products; it is vital this includes DRPU prevention. Education and training by industry should be accepted, provided it reflects best practice and is supported by independent experts who can critically review the statements and claims made.

Health professionals often use only medical devices available on local contracts and formularies.

Stakeholders therefore need to assess that the medical devices listed are fit-for-purpose. This will, in turn, drive the need for clinical education on this topic.

## Formats

Education and training is most likely to improve outcomes if it is practical, with hands-on, real-time experience. Current understanding of DRPU and the supporting evidence base should be presented at an appropriate level for the target audience.

The effectiveness of such education provision can be assessed with formal objective structured clinical examination or simply by observing practice, with a view to comparing the level of knowledge pre- and post-education. The insights gained can be used to improve the educational sessions and, eventually, clinical outcomes.<sup>166</sup>

## Bioengineering input

Hands-on education and training can be delivered in the wards, and often involves demonstrating how to apply devices onto real patients. However, another option is to use imaging phantoms, dummies or mannequins in simulation suites, which replicate clinical settings, patient conditions and emergencies, thereby avoiding any risk of harm to patients. Although clearly the ideal, to date no phantoms, dummies or mannequins have been fitted with implanted pressure sensors for training purposes. From bioengineering and industry perspectives, this is necessary to provide optimal training on, for example, how to avoid overtightening oxygen masks to the face.<sup>166</sup>

Bioengineers need to develop better phantoms, with sensors linked to software that provides feedback to trainees specifically on DRPU prevention. This has the potential to provide quantitative performance scores, based on good practice protocols, to health professionals. Moreover, quantitative data, such as how much force a health professional has applied onto the face of the phantom to tighten a mask, can be stored in digital databases, enabling comparison of feedback within departments and between departments, facilities and medical settings. This can

be used to measure the effectiveness of education and implementation of best practice. Industry can use the data to inform the design of better and safer devices. Online training modules can be developed for clinical settings that do not have access to simulation suites.

## Staff considerations

It must not be assumed that, because a health professional has been trained in the use of one type of a device, such as a catheter, that they know how to use all designs or 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 of other facilities. This is particularly important when staff are transferred from one facility to another.

Digital databases on staff performances are highly valuable as they can be used to identify gold standard practice in a facility. New staff members can be trained to meet this standard.

New employees must receive training on how to use and secure devices, with a view to minimising DRPU. For undergraduates, this information needs to be incorporated into education on PU prevention modules. Health professionals who must be trained include undergraduates, postgraduates and all members of the multidisciplinary team including allied health professionals and medical staff.

## Carers and relatives

Non-professional carers and family must also be made aware of the risk of DRPU. They should be taught how to inspect for signs of DRPU and to immediately notify a trained health professional if a medical device is misplaced and/or might cause tissue damage. They should also be informed of the risks associated with personal belongings and other objects used by the patient and taught how to manage these risks. Box 13 lists instructions that could be given to carers and family. However, as 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 health professional.

### Box 13. Advice and information for carers and family

- Regularly inspect the skin near and under the device for redness, swelling and breakdown
- Pay particular attention to areas where the skin is depressed by the device or any of its components
- Ensure the device is not placing undue pressure on the skin area with which it is in contact
- Regularly move tubing and any method of securement so that one area of skin is not continuously exposed to risk
- Ensure the patient does not lie on the device
- Ensure there is no object left between the patient and the surface they are sitting or lying on
- Ask the patient about discomfort or pain associated with the device
- Call the nurse or clinical specialist if any problems are observed

## Accessing evidence about devices

A critical step in reducing the incidence of DRPU is to raise awareness about it. Health professionals are the most important link in the awareness chain; they are the people faced daily with DRPU and the harm it causes. Health professionals can also drive awareness about DRPU among manufacturers and law and policy makers. Health professionals therefore need access to all available information and evidence on devices, including the materials used in their construction, and how to use them safely. However, there are barriers that prevent them from obtaining this information.

Unfortunately, very few products have published peer-reviewed evidence demonstrating that their use is associated with low exposure to tissue deformation and minimal heat trapping. Manufacturers should be petitioned to conduct or disclose such evidence.

Ideally, evidence should be based on standard test methods (STM), where the relative performance of a device can be compared with that of market

competitors. This could be achieved through laboratory studies and, potentially, clinical research. Laboratory evidence will be able to demonstrate the extent to which individual designs reduce the risk of tissue deformation, stresses and heat trapping. This is important because products from different manufacturers may differ in shape, structure or material composition. (Research techniques used for this comprise computer (finite element) modelling studies, phantom studies or both.)

High-quality published research evidence should be requested for any protective device, such as interface materials and structures, that the manufacturer claims will reduce the risk of tissue deformation or heat trapping. The research should be based on rigorous studies and clinical performances.

It is vital that published peer-reviewed research is also available in a format that is accessible to non-technical clinical or administrative staff. This can include executive summaries, infographics, presentations at a variety of conferences aimed at different audiences, including nurses, physicians, administrators, and use of digital and social media.

As a minimum, the evidence should comprise a paper on a design, brand or model of the device and be published in a peer-reviewed journal. The clinical evidence base should include outcomes of well-designed, statistically-valid studies, conducted on relevant patient populations, demonstrating reduced incidence of DRPU, ease of implementation and health-economic benefits.

## Role of policy-makers and regulators

Policy-makers (from healthcare organisations as well as insurance and regulatory bodies) have a role to play in DRPU prevention by ensuring the provision of education, training and guidance on prevention, procurement of safe devices and implementation of best practice.

Organisations must have written guidelines on the use of medical devices associated with a high-risk of

DRPU in their facility. The guidance must include information on how to select the correct size of device and apply it in accordance with the manufacturer's instructions for use. The policy must be updated after each new purchase decision or change of equipment.

Ideally, an institution's education policy should be led by a specified and skilled individual, such as a tissue viability nurse, lead nurse or equivalent person responsible for DRPU prevention. Their responsibilities should include:

- Inviting developers and companies to demonstrate medical devices
- Interviewing company representatives about how their medical devices reduce the risk of DRPU and/or how they should be applied
- Inviting experts to speak on biomechanics, clinical risk and approaches for reducing the risk of DRPU
- Ensuring that there is a document on file on DRPU prevention for each device used in the institution
- Updating education and training modules when new devices, models of existing devices or evidence-based practices become available
- Holding routine training sessions and monitoring their quality and impact via examinations, online questionnaires and observation of practice
- Establishing a succession plan that ensures that knowledge of and expertise on DRPU prevention is passed on—for example, through dedicated lectures, hands-on training and mentoring
- Acknowledging the needs of specific patient groups in device development.

### Need for standards and systems for rating risk

The panel recommends that regulators explicitly recognise the risks posed to patients by medical devices that are being or will be placed in contact with skin, and develop requirements for the design, evaluation and application of devices to address this. These standards should be developed by independent experts in tissue mechanics and biomechanics in collaboration with industry partners. Regulators

should then be responsible for assessing industry compliance with these standards.

A rating system for the level of risk of DRPU associated with medical devices needs to be devised. Based on this, icons can be developed and printed on the packaging, denoting the product's DRPU risk level. As an industry-wide standard, a medical device's instructions for use should include detailed instructions on how to avoid DRPU during use.

There is a strong case for incorporating this into the existing information for all medical devices, particularly those considered to be high risk. However, it should be compulsory for all new devices and variants of existing ones. There could be a special category for high-risk devices (with both new or established designs).

As an integral part of the technology and product evaluation process, manufacturers should be asked to present evidence to regulators on how they have mitigated the risk.

Finally, regulators should require a post-marketing database be set up on the occurrence of DRPU, detailing the site of injury by device make and model to enable researchers/manufacturers to identify and address areas of concern and alert health professionals. The database would need to be transparent and accessible to all.

# Future research and guidelines for product development

Many devices have not changed in design or the materials used since the 19th century when, for example, respiratory tubing and equipment as we know them first appeared. As a result, the unintended consequence of DRPU was not foreseen. Now that we understand more about the role of medical devices in the aetiology of DRPU, manufacturers have an opportunity to redesign existing devices to reduce the risk of DRPU. This could involve, for example, developing a range of sizes for all patients, gender-specific devices, and adapting designs for all ages and anatomical structures.

There is an opportunity for health professionals and manufacturers to work closely with biomedical and biomechanical engineers to develop designs for existing and new devices that will reduce the risk of DRPU. This can be achieved by designing different shapes, developing new materials and structures, and incorporating advanced technologies—all supported by contemporary laboratory methodologies for medical device research, development and design.

## Limitations in existing medical devices

Although it is possible that increased awareness of DRPU and good practice will reduce some of the risks associated with existing medical devices, they are unlikely to be eliminated. Current limitations on risk reduction are the result of:

- The design of existing medical devices and materials used in their construction are limited in terms of DRPU prevention
- No technologies for the early diagnosis of DRPU or mitigation of their risks are available for use in clinical settings
- No dedicated protective means have been developed
- Health professionals may expect DRPU to develop based on experience. The expectation becomes 'that's just what happens'.

## Key points

- There is greater understanding of how the design, structure and materials used in medical devices contribute to device-related pressure ulcers (DRPU)
- Health professionals, bioengineers and industry need to work closely together to develop designs for medical devices that will reduce the risk of DRPU
- The aim is to ensure that medical devices are designed in such a way that they reduce, to the greatest extent possible, tissue deformation and stresses, while also minimising heat trapping at the device-skin interface
- Laboratory tests can provide standardised quantitative evaluations to determine if these new designs are likely to achieve the desired safety outcomes

There have been important recent advances in understanding of the causes of DRPU and the role played by device design.<sup>33,167</sup> The influence of device shapes and sizes, the materials used to manufacture them and their structural effects are better understood. Specifically, the effects of the geometrical features and components of devices that will or might contact the skin are clearer. The impact that a product design can have on tissue deformation and heat clearance from either the device or the body tissues can be estimated.

Nevertheless, these new research advancements have not been incorporated into device designs and medical technologies. There is a general lack of awareness in the medical device industry and among health professionals that any device that will or might contact the skin needs to be designed to minimise the risks of DRPU.<sup>168</sup> Health professionals are also unaware that they should be pushing for peer-reviewed published evidence from the leading bioengineering and medical/clinical journals.

Reducing the incidence and prevalence of DRPU in all patient populations is a critical clinical and economic objective. Advances in device design and the development of new interface materials and structures that protect tissues from DRPU are needed to reduce DRPU. Multidisciplinary work by academics, developers and manufacturers, including regulators and health professionals, is needed to develop the testing means, standards and protocols specific to the field, which could then be enforced by regulators. Complete elimination of DRPU appears to be an unrealistic goal, given the research, development and technological gaps identified in this document. However, where knowledge and best practice can be deployed effectively, DRPU can and must be addressed.

### Input from developers and manufacturers

Medical device developers, manufacturers and industry can play a leading role in DRPU prevention. Medical device regulations, in most jurisdictions, are risk-led, with product classifications defined by the level of risk posed by the product. During its development, the risks related to a device are identified by a thorough understanding of user goals and needs. These are related to:

- The setting in which a device will be used, such as hospital or community
  - The target patient population: age, morbidities, key clinical objectives
  - The relevant characteristics of specific patient populations, such as the quality of their circulation and perfusion; their tissue structure and composition, including skin fragility; presence of possible atrophy changes and/or chronic conditions such as diabetes; effect of age on their skin or connective-tissue stiffness and strength
  - Any intrinsic or extrinsic factors that may compromise skin and subdermal tissue health and integrity, such as incontinence, extreme temperatures, humidity and comorbidities
- How it might be used by non-professional carers and relatives
  - The care pathways used: who does what, to who, and with what?
  - Other products, devices and interventions used alongside the device or that could interact with the it
  - Possible harms that can be caused by medical devices: DRPU in particular, but also others.

This information is used to define clear functional objectives, select materials, develop structural and geometrical features for the device design, identify possible sizes and constituent parts, and determine other design inputs and prototyping with quantitative measurable performance limits. Health professional input will also help minimise risk. Box 14 suggests key design inputs that should be addressed.

#### Box 14. Key design inputs for device developers and manufactures

- User goals: what does the end user want to achieve?
- Human factors: how will the device be used? How can the design minimise risk?
- Primary function of the device: ventilation, feeding, clearance of body fluids, access, support etc?
- Shape and size of the device relevant to the patient population: age, ethnicity, body habitus and body mass index (BMI)
- Mechanical properties of the device: its rigidity and stiffness compared with those of tissues, its ability to minimise pressure, frictional forces and tissue deformation
- Management of humidity: moving wetness and moisture away from the skin/urine management etc
- Minimising heat trapping at the skin-device interface
- Indications and alarms for medical staff when tissue is exposed to elevated forces or there is an immediate risk of device-related pressure ulcer (DRPU)
- Other protective features to increase tissue tolerance to forces and heat exposure, supported by published evidence

## Avoiding tissue deformation and stress

The medical device must be designed to manage, to the greatest extent possible, tissue deformation and stresses. It should also minimise the transfer of thermal energy to tissues and heat trapping at the skin-device interface, both for heat originating in the device and that released from body tissues. The design should also prevent the potential accumulation of moisture and wetness at the skin-device interface.

Tissue deformation and stress are addressed by selecting materials/material compositions with mechanical properties that reduce pressure and shear gradients created by the device. For example, soft or mechanical-energy absorbing interface materials or structures might be used, as long as they are not too soft and do not 'bottom-out'. The choice of material must be balanced with the device's clinical function.

As mentioned previously, the contours of any device that will or might 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.

Reducing the frictional forces between the device and skin by as much as possible will also minimise tissue deformation and exposure to stress. This can be achieved by using low-friction surfaces or coatings on the device, lubricants, or a combination of the two. For example, a ventilation mask must maintain a seal to function, which requires application of pressure and static frictional forces onto facial skin. The key to adequate device design is determining how to minimise these pressures and frictional forces while still allowing the mask to fulfil its medical purpose.

All of the above considerations should be carefully considered at the design stage. Outcomes of studies on pressure redistribution at the interface of masks show that this approach reduces skin and subdermal tissue stress.<sup>169,170</sup> Robust quantitative data on the effectiveness of other medical devices are still lacking in the literature.

The development of bespoke offloading devices is required, potentially in collaboration between

manufacturers of devices and manufacturers of prophylactic dressings.

## Thermal energy management

Some devices may actively create heat, whereas others allow heat trapping. It is critical that thermal energy (heat) management is addressed in the core design at an early stage in the process. Developers and manufacturers should ensure that heat is transferred away from the skin and not conducted into tissues.

## Role of computer modelling and technology in the design process

The design research described above should be done using computer modelling<sup>86,98,164,171</sup> and informed and reinforced with laboratory experiments, including with use of phantoms, dummies or mannequins.<sup>172</sup>

It is also important to consider the strong interaction between tissue deformation, stress and heat transfer. Multiphysics computer (finite element) models can be used to depict the concurrent biomechanical (tissue deformation/stress) and thermal state of tissues, including any possible structural-thermal interactions, and so should inform the design process.

Advanced phantoms or mannequins that replicate biological, mechanical and dimensional features of babies, paediatrics, young adults and older patients, or other patient groups such as those with spinal cord injuries or who are obese, cachectic, receiving palliative care or have diabetes, or women in delivery, are required.

These should have integrated sensing, data-sampling and user-feedback systems to provide in-use data on pressure and shear distributions, internal tissue deformations or stresses, as well as temperature, humidity, moisture, pH or wetness at the 'skin' surface.

## Input from health professionals

Health professionals are the gatekeepers for clinical research. Key areas that should be initiated and led by health professionals are listed in Box 15.

**Box 15. Key topics for additional device-related pressure ulcer (DRPU) research**

- Case studies including root cause analyses of DRPU
- Health economics of DRPU
- Barriers to improving practice (psychosocial research)
- Innovation in teaching DRPU prevention
- Development of educational and training modules
- Implementation research
- Recommendations to managers of facilities, administrators and procurement about products that better mitigate the risk for DRPU, based on published peer-reviewed evidence
- Feedback to industry and regulators based on published evidence
- Management strategies to prevent DRPU
- Involvement of patient and public involvement groups
- Design innovation

Health professionals should clearly express their clinical goals in order to drive innovation, the development of effective materials and structures, and designs with standardised quantitative performance outcomes. Product design that is informed by health professionals should focus not only on the device's primary clinical goal(s), but also on the parallel goal of minimising DRPU.

Health professionals may wish to consider undertaking clinical research into the causes, prevention and psychosocial effects of DRPU, potentially using advanced trial designs such as step-wedge and adaptive design. There is also potential to be involved in clinical research on physical and chemical biomarkers of DRPU to drive better real-time monitoring and diagnosis of tissue breakdown.

Lastly, health professionals in lead roles, tissue viability teams and head nurses and physicians can collect cost data for evaluations on the economic burden of DRPU in their institutes and the cost-benefits of changing equipment, products or suppliers, providing education and training, and implementing

awareness campaigns. These are valuable data that have the potential to influence administrators and decision-makers.

It is vital that health professionals work closely with multidisciplinary teams when involved in the development, improvement or design revisions of any device that will or might contact the skin or apply forces on a patient's body. This will help ensure that practical aspects of device use are weighed and integrated into the engineering design process.

## Researchers in academia

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

Researchers should 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 or structures that absorb mechanical and thermal energy, thereby preventing or at least minimising their potential adverse effects on body tissues.

Sensor technologies and mechanisms that alert health professionals when excessive forces occur between skin and a device<sup>161</sup> 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 or socket interface for prosthetics.<sup>161</sup>

## Technologies for prevention

Sensing and analysis technologies for pressure, shear stress and other biomechanical markers<sup>93,94,161,162,166</sup> and measures are already available or in development, as are biocapacitance examinations based on measurements of extravasated tissue fluid (an early marker of inflammation).<sup>134</sup> Ultrasound can also be used to assess physiological changes in tissue.<sup>136</sup>

University research laboratories have developed technologies to detect other physiological markers, particularly biochemical markers. Biomarker assays for analyses can be expensive, as they require molecular biology techniques and a high level of expertise. Hence, chemical biomarkers are not feasible for routine clinical use at this time. Furthermore, the optimal chemical biomarkers, which may be a combination of different types of markers, have yet to be identified.<sup>50</sup>

The development of lab-on-chip sensing is changing the face of translational (from laboratory research to clinical application) biomarker research and has had a significant impact in other healthcare areas, including blood lactate monitoring of patients with diabetes. Key areas for innovation in technologies include:

- Interface materials and structures to absorb compressive and frictional forces and manage humidity and moisture
- Interface materials and structures to dissipate thermal energy from devices, thereby minimising conduction to skin and underlying soft tissue
- Use of durable materials and structures in medical devices associated with DRPU, to ensure their mechanical properties are not impaired with use or over time
- Sensing technologies that accurately detect biomechanical factors associated with DRPU, such as excessive force, tissue deformation, thermal challenges, moisture, wetness, biocapacitance and pH changes, and perhaps also monitor levels of inflammatory biochemical markers secreted from skin
- Real-time monitoring of at-risk skin and underlying soft tissue for harmful changes
- Minimisation of friction, both static and dynamic, at the device-skin interface through the use of materials, coatings and lubricants (or a combination of these) with a low coefficient of friction
- 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 deformation and stresses for the time periods relevant to the device application
- Computer and laboratory bioengineering models, such as multiphysics anatomically-realistic finite element computational models and instrumented phantoms that recapitulate the features and responses of soft tissues to deformations, stresses and thermal conditions caused by application of medical devices. As stated above, these should become standardised tests for evaluating and rating the effectiveness of medical device design variants.

## Sensors

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

- 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 or pH challenges, which should be mitigated by the device
- Humidity, moisture and wetness, which should be mitigated by the device
- Incorrect device application or potentially harmful fitting and/or securement.

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

### The future

Future technologies may minimise or even eliminate the possibility of DRPU. Suspended contactless devices, for example based on magnetic fields, may be developed for the most fragile skin and critical areas such as ICU, where the largest number of these instruments is required to save lives.

Dedicated protective technologies, smart materials or structures, and tissue and environmental monitoring could potentially be fully integrated into a facility connected to a central or cloud computer system, enabling (big) data management and mining. Continuously updated normative data for a patient population could be used to determine the real-time risk presented by all devices attached to a patient in each type of ward or facility. In addition, data from sensors monitoring an individual could be analysed in real-time, e.g. via cloud computing, to detect trends indicating possible deterioration in tissue health status. 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 also be available to demonstrate whether or not best practice, according to current standards, had been applied. This would be useful for education, training, evaluation of clinical practice

standards and cost-benefit analyses. It would also assist reporting to government, regulatory, insurance and other bodies and authorities.

Such data should also be useful to academia and industry: they can be used to quantify goals for device design, including outcomes that need to be achieved.

This vision is not so far in the future as it may seem. 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 effort, time, translational research and investments. Understanding the scale and threat of DRPU and the heavy burdens it imposes on society—in suffering and costs—should lead the way towards a new generation of medical devices specifically designed to minimise the risk of DRPU.

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**Fig 9 (see page S27) abbreviations**

BIS–bispectral index; IPC–intermittent pneumatic compression; NIBP– non-invasive blood pressure cuffs; NPPV–non-invasive positive pressure ventilation.

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