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# Contents

Foreword **Sx**

Chapter 1: introduction **Sx**

Chapter 2: pathophysiology **Sx**

Chapter 3: devices **Sx**

Chapter 4: Risk assessment **Sx**

Chapter 5: Safe use of devices: prevention and management of injury **Sx** Chapter 6: Changing the focus of health professionals and policy-makers **Sx** Chapter 7: Future research and guidelines for product development **Sx**

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2020 **S3**

# Foreword

n February 2019, an international group of medical, clinical and bioengineering experts met in London, UK, to develop the first edition of the international consensus statement on device-related pressure ulcers (DRPUs). Following a rigorous process of scientific discussion, the consensus statement was drafted, then reviewed by an international independent committee of external experts and then published as a special supplement to the Journal of Wound Care in February 2020.1 The published consensus statement released days prior to the breakout of the COVID-19 pandemic was, at the time, the most comprehensive synthesis of current understanding of the aetiology of DRPUs and the technologies and clinical protocols that can be used to

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mitigate them.

The COVID-19 pandemic was, and still is, a game- changer in the context of DRPUs, as it instantaneously brought the effects of DRPU into sharp focus, particularly in regard to use of ventilation equipment and managing critically ill patients in the prone position for prolonged periods. Non-invasive equipment is used extensively worldwide to treat the breathing difficulties presented in patients who are COVID-19-positive and develop serious cardiorespiratory illness. With the rise in reports of DRPUs and the change in global circumstances, the topic of prevention and treatment of this skin damage became more time-sensitive than ever. The expert panel recognised this early during the development of the pandemic and as a first reaction to the change in circumstances, we published an update article to the full document with a specific focus on skin damage under personal protective equipment (PPE) among health professionals—a new category of DRPU which has not been widely experienced in our lifetime prior to the pandemic.2 However, this was clearly not sufficient to capture the new knowledge that has generated and accumulated over the course of the pandemic. Accordingly, to continue to support patients and health professionals, the original team of experts have gathered during March 2021 to update our consensus statement and adjust it to the pandemic state, sharing the new knowledge that was collected and the lessons that had been learned since the first edition was published. The

aim is to provide frontline staff with an updated, clear, simple strategy on how to mitigate the risk of DRPU during the pandemic and going forwards, with emphasis on in-depth guidance on development and implementation of long-term strategies for prevention of DRPUs.

Like the first edition, this second edition is aimed at generalist and specialist clinicians, as well as biomedical and non-biomedical engineers and other health professionals, in clinical practice, academia, research and industry. We first describe the updated aetiology and pathophysiology of DRPUs, describing how medical devices and objects that encounter the skin and apply forces onto it can cause cell and tissue deformation damage. This is followed by assessment, prevention, and management of DRPUs, including under the current pandemic circumstances.

The consensus statement identifies and discusses the devices that are most associated with DRPUs and the biomechanical reasons for the risks they represent, referring to the most recent scientific and medical literature in this regard. This second edition also aims to support efforts to inform and educate health professionals at all levels as well as policymakers, on the critical need for DRPU prevention through identification of the root causes of these injuries, the scale of the problem, the damage to the quality of life of patients and the financial implications on institutions, insurers, and governments. Greater awareness of the growing problem of DRPUs will lead to better adoption of prevention protocols and to much-needed new preventative technologies and design improvements. This updated, second edition consensus statement, therefore, specifies the revised requirements that will inform medical technologies on effective prophylaxis of DRPU, by considering shape, materials and construction features of medical devices and their effects on skin and underlying tissues.

In conclusion, under the historical circumstances of

the COVID-19 pandemic, we felt that it is critical to regroup the team of global experts to compile their detailed advice on prevention and treatment of DRPU and their insights and latest understanding of this

**S4 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

# Aims and terminology

problem. We are very pleased to present this second edition which reflects these multidisciplinary international efforts and is again a cornerstone in our persistent struggle to mitigate DRPU, during the pandemic and into the future.

*Professor Amit Gefen — Panel Chair*

1. Gefen A, Alves P, Ciprandi G et al. Device related pressure ulcers: SECURE prevention. J Wound Care 2020; 29(Sup2a): S1–S52 https://doi.org/10.12968/ jowc.2020.29.Sup2a.S1.
2. Gefen, A. and K. Ousey, Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage. J Wound Care, 2020. 29(5): p. 245-259.

## Purpose of this document

For this second edition, the panel met virtually to address the need for greater recognition of DRPUs and their causes, management and prevention. This document is intended to stimulate action and covers:

* + The anatomy and composition of tissue in relation to the patient’s age
  + The pathogenesis of DRPUs, with particular focus on why devices are associated with PUs
  + Devices, both medical and non-medical, associated with DRPU
  + Assessment of the patient with DRPU
  + Safe use of devices to prevent or manage DRPU, including the impact of altered processes of care that have occurred as a result of COVID-19 pandemic for both patients (for example, the increased use of proning), as well as on health professionals (such as prolonged use of PPE) and the general population
  + Initiatives to raise awareness of DRPUs among health professionals
  + Medical device design characteristics and features relevant to DRPUs and their prevention
  + Future research required on prevention of DRPUs, 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.

## A note on terminology

Globally, several different names are used to describe pressure ulcers (PUs). Pressure injury (PI) is currently used by National Pressure Injury Advisory Panel (NPIAP; formerly National Pressure Ulcer Advisory Panel)3 and the Pan Pacific Pressure Alliance. Other terms proposed are ‘deformation injury’, ‘pressure damage’ and ‘decubitus’. To date, PI has been adopted in Australasia, although not entirely in the US and Canada, and not in Europe. The terminology used is often site-specific.

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.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022 **S5**

# Chapter 1: introduction

ressure ulcers (PUs) are defined by the European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Injury Advisory

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Panel (NPIAP, formerly National Pressure Ulcer Advisory Panel) and the Pan Pacific Pressure Injury Alliance (PPPIA) as:1,2

*‘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.

The key causal components of PU formation are exposure to pressure and shear. Friction contributes to shear, but on its own is not a direct cause of PUs. 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 semi-Fowler’s position for extended periods on a support surface. Such pressure, friction and shear cause tissue deformation, local microcirculatory impairment and inflammation that, together, lead to pressure ulceration, typically observed in bony anatomical sites such as the sacrum, ischium, trochanter and heel. In contrast, the NPIAP states that medical device-related pressure ulcers (MDRPUs):3

*‘…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

#### 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 and neonatal patients and all people needing critical care are particularly susceptible to DRPUs
* Examples of devices associated with DRPUs 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 DRPUs
* There is a need for greater recognition of DRPUs, their causes, management and prevention to support practice innovation, research and device regulation. This document is intended to stimulate action.

devices without a medical purpose. To differentiate device-related pressure ulcers (DRPU) from PU arising from body weight forces, the panel proposes a definition and explanation of DRPU as follows:

*‘A DRPU involves interaction with a device or object that is in direct 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 that is caused primarily by body weight forces. The localised nature of the device’s interaction with the patient’s tissue 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

**S6 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Introduction

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 PUs may include products used to sustain life in sick patients— for example, continuous positive airway pressure (CPAP) masks, oxygen therapy tubing, endotracheal tubes, bilevel positive airway pressure (BIPAP) and monitoring devices such as arterial lines and pulse oximetry, or less critical devices such as orthotic devices, indwelling lines and bed frames. Paediatric patients are particularly susceptible. Devices or objects associated with PUs 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. During the COVID-19 pandemic, the PU resulted from use of PPE and prolonged use of respirators.

Like a PU, a DRPU can be categorised as I–IV or unstageable, depending on its depth and the number of tissue layers involved.3 However, a DRPU can be difficult to classify as they often occur in regions with minimal soft tissue such as the nasal bridge and ears. Nevertheless, most DRPUs are category I and II, but up to a quarter may be unstageable.4 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 once the skin integrity has been compromised. Damage to mucosal tissue, for example on the lips or nares, from medical devices are not staged but referred to as a mucosal DRPU.5

## International pressure ulcer guidelines

Guidelines on the prevention and management of PU, including to varying extents DRPU, have been published by several international consensus groups and wound management societies.

The 2019 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.1–3

## Epidemiology of device- related pressure ulcers

Patients managed using medical devices are more likely to develop a PU or skin breakdown, and DRPUs are relatively common.4, 6 For example, in an American hospital setting, the overall rate of PUs in inpatients was 5.4%, of which 34.5% were DRPUs.4 Elsewhere, it has been observed that DRPUs may account for as much as 61–81% of all hospital-acquired PUs (HAPUs), depending on the care setting and patient subpopulations.7,8 A recent systematic review and meta-analysis reported that the estimated pooled incidence and prevalence of DRPUs in over 126,000 patients in 29 studies was 12% and 10%, respectively,9 although, as the authors state, these data are limited by the heterogeneity of the data collection.

During the first waves of the COVID-19 pandemic, many care settings observed a sharp increase in the incidence or prevalence of DRPUs over and above these numbers.10–12 Some studies reported that around three-quarters of all DRPUs were among patients with a COVID-19-positive diagnosis.11,13 Some trends quickly emerged: one concern was the development of DRPUs related to the use of invasive and non-invasive ventilation equipment.10 Another was the widespread use of proning, in which critically ill individuals are laid face-down for long periods, resulting in higher rates of DRPUs seen on the face and PUs occurring in areas not usually reported such as the nipples or genitalia.13 A third high-profile observation related to health professionals at the frontline of the pandemic having to wear personal protective equipment (PPE) for very prolonged periods, which created DRPUs and other skin reactions.10

The COVID-19 pandemic has been, and still is, a game-changer in the context of DRPUs. Whereas previously, DRPUs were an understudied area, the increasing incidence observed during the pandemic and the changes in ways patients were positioned— which makes it more complex to position and check devices—has certainly raised the profile of this issue. During the first waves of the pandemic, much has

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022 **S7**

##### Introduction

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Reference** | | **Setting details** | **Finding** |
| **Overall** | Black et al.4 | American hospital inpatients (n=2079) | PU occurrence: 5.4% DRPU occurrence: 34.5%\* |
| Jackson et al.9 | Systematic review of 29 studies (126,150 eligible patients) | Pooled DRPU incidence: 12% Pooled DRPU prevalence: 10% |
| **Data from** | Barakat-Johnson et al.15 | Systematic review of 13 studies | Pooled DRPU incidence: 3.7% (95% CI  0–14.4%)  Pooled DRPU prevalence: 33.7% (95% CI  22.6–45.8%) |
| **intensive** |
| **care** |
| **settings** |
|  | Coyer et al.242 | Patients in six ICUs in two major medical centres (one in the US and one in Australia) | DRPU incidence: 3.1% |
| Wille et al.18 | 125 patients in a surgical ICU | Frequency of pulse oximeter-induced digital injury: 5% |
| **Data from** | Kyorin University | ICU and general wards in a | DRPU incidence in ICUs: 2.8% |
| Hospital unpublished | Japanese hospital | DRPU incidence in general wards: 0.14% |
| **other** |
| DRPU audit |  |  |
| **settings** |
|  | Schlüer et al.271 | 204 children in 13 Swiss hospitals | Prevalence of PUs: 26.5% Prevalence of DRPUs: 38.5% |
|  | Visscher and Taylor26 | 741 neonatal intensive care patients | Premature neonates: 1.5 PUs per 1000 days Term infants: 2.7 PUs per 100 days |
|  | Jiang et al.226 | Health and non-healthcare professionals in 161 hospitals in China | Prevalence of skin injuries: 42.8% Prevalence of DRPUs: 30% |
| Rosner et al.230 | Health professionals (n=31) in a New York hospital | Prevalence of skin breakdown: 18.1% within 3 hours; 44% after 3 hours of mask use  Acne: 53.1% |
| \*Proportion of PUs that were DRPUs. PU–pressure ulcer; DRPU–device-related pressure ulcer; ICU–intensive care unit | | | |

been learnt about the risks of DRPUs, and many insights into how the risk was reduced have since been developed and published, representing a huge and rapid advance in this field. The COVID-19 pandemic is likely to continue to affect global healthcare systems and it is anticipated that the associated increased risk of DRPUs will remain for several years to come. This is a good time for updated guidance and advice on how to minimise DRPUs, including those challenges specifically associated with a COVID-19-positive diagnosis, so that health professionals are well-informed to provide the very best care for their current patients and are well- prepared to manage the wider issue of DRPUs.

## Occurrence by setting

Devices used in intensive care are particularly associated with DRPUs.14*–*16 This is not surprising given that critically ill patients in intensive care units (ICUs) often have the highest number of devices in situ. In a 2019 systematic review of the incidence, prevalence and severity of DRPUs in ICUs, pooled estimates revealed incidence rates of 3.7% and prevalence rates of 33.7%. Again, the wide ranges reflect the heterogeneity of the data collection between the 13 studies evaluated.15 Since this review, Coyer et al. reported a DRPU prevalence of 4.3% in intensive care patients,17 Wille et al. stated that the overall incidence of DRPUs or skin breakdown caused by pulse oximeters in a surgical ICU

**S8 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Introduction

was 5%.18 Mehta et al. reported a point prevalence of DRPUs in the ICU setting of 19.2%.19

Occurrence rates can be lower in other settings. An unpublished incidence audit of DRPUs 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 DRPUs in ICUs was 2.8%, which is consistent with published data. By comparison, on general wards this 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. Table 1 summarises the key results.

## Neonates, infants and paediatrics

DRPUs have been reported in around 7% of all paediatric patients.20,21 DRPUs are more common in younger children and can account for up to half of all PUs identified in some high-risk patient populations, such as in neonatal and intensive care settings or in persons with conditions such as spina bifida.20,22–24,25 Infants who develop DRPUs are likely to be younger post-partum, with a shorter gestation; they develop DRPUs more rapidly than patients with PU caused by body weight.26 Mechanical ventilation and a respiratory diagnosis are associated with higher risk of DRPUs in this population.27 In newborns, devices may severely and permanently affect and distort nasal cartilage.28 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).16,29–35

Data collected by an author of this document in Italy during the height of the pandemic suggest that the relative burden of DRPUs in paediatrics is growing. Advances in paediatric medicine over the last decade mean that today, neonates, infants and children with very complex medical conditions can now receive treatment, whereas in the past this option may not have been available. These seriously ill children often need long periods in intensive care units and

intervention involving multiple medical devices. Data shown in Fig 1 shows that, as a result of this general trend, there is an increase in the proportion of PUs that are caused by DRPUs in paediatrics. It is clear that the burden of DRPUs in the paediatric specialty needs particular focus.

## Occurrence by type of device

Although many kinds of devices have the potential to cause DRPUs, there is a high association between DRPUs and respiratory devices, regardless of setting;19,36 up to 68% of DRPUs are associated with respiratory devices,14 of which 20% are linked with bilevel positive airway pressure (BiPAP) or continuous positive airway pressure (CPAP) devices, where ulceration has occurred on the bridge of the nose, cheeks and/or nasolabial fold.7 The incidence of PUs related to non-invasive ventilation (NIV) has been shown to range from 5–50% for 2–4 hours of continuous usage and up to 100% after 48 hours of wearing a face mask.37 Prevalence of PUs may be over 14% in general- hospital patients with respiratory failure managed by

* + DRPU  PU

120

100

Number of PU/year

80

60

40

20

0

2018 2019 2020

Fig 1. Change in proportion of DRPU over recent years. Over a 3-year period, despite a small overall decline in the number of PU generally, the proportion caused by medical devices (DRPU) increased from 32% in 2018, to 46% in 2020. Data provided by Guido Ciprandi.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022 **S9**

##### Introduction

NIV or CPAP.6 This has been particularly obvious in the context of the COVID-19 pandemic.11 Many other types of devices can also be associated with increased risk of DRPUs including, but not limited to, cervical collars, nasogastric tubes, drains, compression stockings, temperature probes, blood pressure cuffs, central venous catheters and many more. 19,38–42

## Occurrence by anatomical location

In terms of anatomical location, a national audit of PU prevalence in the US reported DRPUs most often occurring on the face, ears and heels.43

Data derived from these studies reveal that DRPUs constitute a significant percentage of institution- acquired PUs and require significant attention from clinical, academic and commercial leaders.

## Cost of device-related pressure ulcers

The costs associated with PUs in general are widely reported and are extremely high. In the US, the total cost of HAPU has been estimated at $26.8 billion.44 The total cost of PUs to the National Health Service (NHS) in England has been estimated at over £571 million, based on a patient database audited between 2017 and 2018.45

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, even if simple and low-cost prevention measures work, preventing PUs will save substantial amounts of money.46

Nevertheless, there is little or no published evidence on the costs associated specifically with DRPUs. Costs of managing DRPUs are likely to include a wide range of expenses (for example, treatment costs, health professionals' time needed to manage the wound and, in some jurisdictions, fines or litigation costs) as described in Box 1. In particular, the substantive indirect costs associated with litigation and insurance

**Box 1. Health-economic burden associated with device-related pressure ulcers (DRPUs)**

* Medical costs of pressure ulcer (PU) management
* Health professional 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 (HAPUs)
* Financial penalties in some jurisdictions
* Litigation costs
* Damage to quality and safety reputation of the institution
* Potential court-ruled damages and settlements
* Cost of insurance policies, which are affected by the institution’s litigation history
* Cost of device abandonment (for example prosthetics and orthotics)47
* Cost of changing medical intervention—for example, when continuous positive airway pressure (CPAP) fails in neonates, some need to be re-intubated,48 or an alternative securement needs to be used to avoid the injured area, and those of managing complications, such as wound infection and increased length of hospital stay

DRPU–device-related pressure ulcer; PU–pressure ulcer; HAPU–hospital-acquired pressure ulcer; CPAP—continuous positive airway pressure

(in premiums or loss of coverage) as most DRPUs are hospital acquired. Lawsuits related to DRPUs often end with undisclosed court-approved settlements negotiated behind closed doors. The indirect effects of rising insurance premiums on health professionals 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 DRPUs.47,48 Often overlooked 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

**S10 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Introduction

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. For neonates, this can lead to a distorted body image at an early stage.

DRPUs 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 health professionals 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 device-related pressure ulcers

Multiple factors increase the likelihood that a patient will develop a PU. Patient-related factors that increase the risk of DRPUs include:

* The patient’s inability to sense the device and the associated pressure, friction, and shear on their skin due to sedation, encephalopathy, neurologic disease or young age (infants and toddlers)
* The patient’s inability to reposition the device themselves4
* Duration of device use
* The need to secure a device tightly to ensure correct function and adequate life-support measures6,49
* Increased oedema at the site due to positioning (for example, facial oedema in prone patients)
* Build-up of heat and humidity under masks as oxygen flow is often humidified.

Other, external, factors include insufficient education provision on pressure ulceration resulting in poor quality care, or insufficient resource available to address patient need.

DRPUs develop faster than non-DRPUs because of the vulnerability of the patient and body sites affected. They are most likely to be facility-acquired and located on catheter line 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. This can be particularly problematic when hospital procurement systems and supply chain issues only permit a limited range of types or sizes of a particular device: one size does not fit all
* 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 application, both by commercial suppliers and clinical educators
* Many individuals have comorbidities or facial/body morphology 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. Uncontrolled oedema can follow fluid resuscitation, with securement straps exerting pressure
* Lack of health professionals' awareness of the importance of repositioning, offloading, rotating devices, when possible, or correctly fitting or securing them. There may also be a lack of awareness of alternative options, such as the use of hoods instead of masks.

The management of skin health is also complicated by the fact that medical devices often have a diagnostic or therapeutic purpose, making their use non- negotiable. 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. Therefore, the need to maintain a device in situ may prevent skin assessment, leading to an existing DRPU not being identified.4

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

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 11**

# Chapter 2: pathophysiology

his chapter reviews the pathophysiology of PUs and DRPUs. DRPUs are caused by the same mechanisms as PUs. Table 2 summarises the

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key similarities and differences between PUs and DRPUs.50 Principal causes of PUs are pressure, friction and shear, and the resulting sustained cell and tissue deformations, the effects of which are exacerbated by moisture and temperature (Fig 2).1,5,25,51–58

## Cell deformation

Patients who develop PUs frequently have multiple risk factors and comorbidities.59–61 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 of time in a bed or chair, pressure and shear forces caused by gravity act on the skin over the bony prominences. These compress, stretch and shear tissues, deforming the cells and extracellular matrix (ECM) components and obstructing vascular and lymphatic flow. The

**Table 2. Overview of features associated with pressure ulcers and device-related pressure ulcers. Adapted from Bader et al.50**

|  |  |  |
| --- | --- | --- |
| **Pressure ulcers** | | **Device-related pressure ulcers** |
| **Aetiology** | 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 time272 | |
| **Cause of deformation- induced damage** | Gravitational forces due to body weight | Caused by external forces applied by the device (strapping, tape and other securement mechanisms) |
| **Individual vulnerability** | Immobile and/or insensate patients. Areas with previous tissue damage.  Inability to communicate pain and discomfort | Illness, possibly with comorbidities; examples are patients in ICUs, patients with diabetes, and patients who cannot communicate discomfort or pain, patient with oedema following fluid restriction, patients with oxygen desaturation, critically ill patients who require continuous monitoring. Skin and soft tissue sites with previous damage.  Care givers managing COVID-19 patients and wearing protective equipment for prolonged periods without breaks |
| **Nature of** | Examples include support surfaces, | Generic designs of medical devices not matched to |
| **medical devices** | cushions, mattresses, bedside chairs, toilet | individual characteristics |
|  | seats, and floor (in the event of a fall) based | Masks, goggles, respirators, protective gloves, |
|  | on individual risk | particularly grade 3 PPE |
| **Prevention strategies** | Pressure redistribution/relief and periodic repositioning | Improved design of devices; pressure relief through application of an alternative device; adequately designed prophylactic dressings |
| **Vulnerable tissue areas** | On or 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 |
| **Microclimate** | Affected by support surface design, incontinence containment products, 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 |
| ICU—intensive care units; PPE—personal protective equipment; | | |

**S12 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Pathophysiology

compression, which is always combined with shear, causes local ischaemia by occluding the microvascular network of capillaries in the skin and deeper tissue.62 Pressures required to cause local ischaemia depends on the magnitude of the shear and the individual’s vascular functionality (cardiovascular system health).58,63,64 Inflammatory changes initially occur in tissues directly exposed to sustained force and deformation.65,66 In the context of DRPUs, this has been demonstrated through cell-scale computational modelling, which shows that external forces associated with use of medical devices can cause deformation-inflicted cell damage almost immediately.67 Fig 3 shows how progressive loss of cytoskeletal and plasma membrane integrity in these cells impairs their control over mass transport and homeostasis.68 Inflammatory mediators,65 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

#### Key points

* + Principal causes of pressure ulcers (PUs) are pressure, friction and shear, and the resulting sustained cell and tissue deformations. These effects are exacerbated by moisture and temperature
  + A crucial difference between PUs and DRPUs is that body weight forces are less significant in DRPUs, with the force being exerted from a device that is typically strapped or taped to the body. In short, body weight forces and loading play less of a role in DRPU development, although there are cases where DRPUs and PUs cannot be clearly classified
  + Neonatal and paediatric skin is different to adult skin; neonatal skin being much thinner, lacks padding, the cartilage is immature, and therefore injury can affect the deeper layers, down to the skeleton

the vasculature and lymphatics.69 Damage may be

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 13**

##### Pathophysiology

**Undeformed cell**

**ECM**

**Deformed cell**

Plasma membrane sites become porated due to loss of cytoskeletal integrity and support

ECM–extracellular matrix

Fig 3. Loss of cytoskeletal and plasma membrane integrity in cells impairs their control over mass transport and homeostasis

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 within minutes.70

Tissue-engineered living model systems indicate that skeletal muscle tissue is irreversibly injured by sustained deformation after approximately one hour of loading.71 Experiments on human volunteers show that tissue pressures associated with medical treatment over relatively short periods of time can result in increased levels of the inflammatory mediator interleukin-1 in the skin.65,66,72 In contrast, the time it takes for purely ischaemic muscle damage to develop is 6–8 fold longer.73

## Distorting effect of friction

Friction distorts tissue resulting in shear forces, which cause skin and subdermal damage, leading to pressure ulceration. Friction-related PUs 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.74 In these fragile cases, inadvertent damage from friction burn is frequently seen.75*–*78 The patient, who may already be compromised because 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 frictional forces can cause delamination of

skin and skin tears, particularly in older people and those with less mechanical strength in the dermo- epidermal junction.79

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Frictional forces acting on the skin are affected by the local microclimate, with increased skin hydration, increasing the coefficient of friction by 26–43%.80 Use of prophylactic dressings for the prevention of PU has been shown to reduce the coefficient of friction compared with moist skin on bed linen, therefore, reducing the risk of pressure ulceration.81

Attention must be paid to children with a neurological or neuromuscular disease, such as cerebral palsy, 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

***tracy.c***

*2022-01-24 20:39:25*

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Reviewer: GB is a paralytic disease, where would the friction stem from?

***Gefen***

*2022-01-25 11:00:47*

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The friction in neuromuscular diseases such as in Guillain-Barre syndrome is due to sudden, involuntary muscle contractions or overshortening (cramps or spasms) which cause involuntary movements.

**S14 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Pathophysiology

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 bony prominences to push against a support surface or other object, increasing the risk of DRPUs.

Friction between the skin and a surface causes the skin to deform tangentially, causing shear forces and subdermal tissue distortions.82 The tissues may be damaged because of either the physical force (which causes necrotic cell death and mechanical failure of the extracellular matrix)83 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.5

## Microclimate

Changes in skin physiology and its microclimate can lead to a higher risk of DRPUs. 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:84

‘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 or urine enzymes (wound exudate contains matrix metalloproteinases [MMPs] and saliva that drips onto tracheostomy tubes contains enzymes).57

Dry or 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,85 although the role of moisture in DRPU development remains

uncertain.86

Temperature changes adjacent to the skin are also associated with local physiological changes. These include an increase in cutaneous stiffness under loading conditions,87 a decrease in dermoepidermal adhesion and an increase in metabolic demand.88 Therefore, the skin may be less able to deform and there is a higher susceptibility to injury.

## 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.[89-92] 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. Newborn infants have a physiological oedema, which gradually adds mechanical stress to cells and tissues and, if not contained, may exacerbate tissue damage. Reactive oxygen species (ROS) and proteinases further degrade the tissue,92,93 eventually leading to

visible tissue damage.

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, localised or general oedema can develop after a device has been fitted or when a patient is placed in the prone position.4,93 Oedema 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 pressure load applied to the skin will increase, heightening the risk of DRPU. Health professionals sometimes tighten the fixation system

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 15**

##### Pathophysiology

to avoid device failure and, therefore, prevent subsequent patient morbidity and mortality (sudden respiratory or cardiac arrest due to loss of airway function). 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 4 is an example of a DRPU.

## Effects of different types of device on the

pathophysiology of injury

The designs of some medical devices have not taken into account the heat that may be trapped between the device and skin, which can be substantial—for example, under contours of oxygen masks.94 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,95 are sometimes held in place with elasticated straps or tapes. This immobilises the device, but generates pressure and frictional forces at the device-skin interface, as well as underneath the securement device , ultimately causing visible tissue damage at the skin surface and subdermal damage,96 where interface pressures can be high. Oxygen face masks may create interface pressures at the nasal bridge, reportedly as high as 84mmHg with optimally tensioned straps, but rising as high as 158mmHg when additional tension is applied.72 Oximeter devices clipped onto the earlobe may apply marked local pressure.97 Humidified therapies may increase the amount of moisture present, in turn increasing the risk of DRPU.98 Securement devices and techniques, such tapes applied across the face or twill applied to the back of the neck to secure an endotracheal and trachestomy tubes can cause DRPU.

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 and the straps used to confine the patient can cause substantial pressure, shear, thermal loads and tissue deformations on the skin and underlying soft tissue.66,99,100

## Risk factors

Small-scale studies are producing preliminary data for risk factors for DRPUs.101–103 A crucial difference of DRPUs to PUs is that body weight forces play a less prominent role, with the device securement typically strapped or taped to the body and exerting forces that drive the tissue deformation and distortion. (Although body weight can play a role if a device does not fit properly and gets lost within the skin folds.) The affected soft tissues may also be ‘sandwiched’—that is, compressed, stretched, and sheared between a device and bony surface. There are, however, examples of DRPUs caused by body weight, for example due to 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.72 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.

**S16 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

Fig 4. A device-related pressure ulcer related to oedema: the sustained deformation-inflicted injury has triggered an inflammatory response40

##### Pathophysiology

Devices such as anti-embolic stockings or sequential compression devices are often used inappropriately with no assessment of underlying perfusion or sensation, and may be incorrectly measured and applied, and, therefore, often cause damage. Stockings can create a particular risk for patients with arterial disease. 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, impairing skin perfusion and increasing the likelihood of injury.50 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—for example, development of calluses on the heel.

In general, when patients are unable to

communicate discomfort, pain and the need for repositioning, it can result in loads that lead to DRPUs.104 Patients at risk of developing DRPUs can include those who are agitated, under anaesthesia, receiving analgesia, unconscious or partially conscious, and those who have a central nervous system injury (brain or spinal cord), respiratory or vascular disease where there is poor oxygenation and perfusion, neurological damage (stroke or multiple sclerosis) or peripheral neural damage (diabetic neuropathy). Patients with severe respiratory disease often have limited oral fluid or nutritional intake as their respiratory masks need to remain in situ, which, combined with the microclimate under the mask and typically other patient-related factors, can place them at increased risk. Paediatric patients and neonates seem to be particularly susceptible to developing DRPUs.105 More recently, patients with severe COVID-19 also appear to be experiencing a relatively high proportion of DRPU.11,12 These subpopulations are discussed in more detail below.

## COVID-19 and device- related pressure ulcers

Health professionals have been faced with wearing PPE for extensive periods. Injuries to the skin of their face -the bridge of the nose, upper cheek, forehead and above the ears, as a result of extended wear of eye wear and respirator masks. These injuries are similar to patients who wear masks for non-invasive ventilation for extended periods.

Although COVID-19 itself does change the basic mechanisms of pressure ulceration, several factors may make COVID-19-positive patients more susceptible to skin injury. Firstly, the medical treatment of patients who are in respiratory distress with COVID-19 has led to very intensive use of medical devices and body positioning known to increase the risk of DRPUs. The need for longer use of medical devices, proning and concern that endotracheal tubes could become dislodged, inevitably leads to more prolonged tissue deformation and resulting inflammation with greater risk of tissue breakdown. Some pharmacological treatments used to manage severe COVID-19, including hydroxychloroquine (in countries where it is licensed for use) and remdesivir, have also been linked to the emergence of skin problems in some patients – so called ‘drug eruptions’ may feasibly affect skin integrity.106 Secondly, COVID-19 itself has been observed to exacerbate pre- existing inflammatory skin conditions.106 Several skin-related manifestations related to COVID-19 have emerged during the pandemic thought to be caused by the virus itself; a wide range of manifestations including inflammatory dermatosis, skin vasculitis, vascular dermatosis, erythematous rash, urticarial lesions, and chickenpox-like vesicles, have been described,107–110 as well as purpuric changes (which includes the well-known ‘COVID toes’)111 thought to be linked with viral-induced hypercoagulation and microvascular occlusion.109,112,113 These different types of skin involvement appear at various points of the disease and have been associated with long-term changes to the skin in some patients.107,108,114 Purpuric features of pressure injuries have been noted in many ICU COVID-19 patients, often with geometric borders, and some with bullae, which typically progress to

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 17**

##### Pathophysiology

**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 and fluid 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)

central ulceration with eschar.113 The NPIAP have highlighted the risk of misdiagnosing these purpuric lesions as a deep tissue injury (or vice versa),112,115 but have also warned that any microvascular occlusions of COVID-19 on tissue exposed to pressure and/or shear stress may exacerbate the risk of developing PUs, including DRPUs.112 Finally, the pathophysiology of COVID-19 in seriously ill patients can include the cytokine storm, and hypoxia and hyper-coagulation, systemic events that may exacerbate the pathophysiology of DRPU formation.116,117

To date, it is largely unproven whether these manifestations impact on the risk of DRPUs in patients with COVID-19 and hypotheses remain largely theoretical.118 Further research is needed in this area.

## Neonates/paediatrics and device-related pressure ulcers

Much information on the aetiology and development of PUs 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.119 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 PUs, and of course cannot communicate the cause of their discomfort, other than by crying.105 The skin of paediatric patients (from newborn neonate to 18 years of age) develops and changes over time, with complete epidermal maturation occurring by 34 weeks.120,121 Therefore, prevention of PUs and DRPUs must be targeted differently for children of different ages.

It is a clinical challenge to maintain skin integrity in neonates and children in ICU. Devices are the main causative factor for DRPUs in paediatric ICU, which predominantly occur on the face and scalp,122 followed by the heel and occiput, which, in contrast to adult patients, cannot be safely offloaded only by changing position.123

Neonates, both pre-term and full term, are at high risk of DRPUs because of the immaturity of their skin,26,119,124,125 its barrier function and their immune system, lower amount of subcutaneous fat and 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.126 The skin of neonates (particularly pre-term) and infants is thin and does not have the protective function of adult skin.119,121

Desquamation is abnormal in very premature infants for some weeks after birth,120,127 signifying hyperproliferation of the epidermis.128 Skin maturation and adaptation to the post-partum environment happens over an extended period of time, during which desquamation slowly increases.129 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

**S18 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Pathophysiology

or poorly regulated compared with adults.130,131 Furthermore, a high metabolic rate and

physiological oedema—common in sick children— increases risk of DRPUs in these populations.

The increased fragility of the skin associated with prematurity and its associated comorbidities is challenging for health professionals to manage, with practice often relying on anecdotal evidence to prevent skin damage.132 Skin securement of the medical device is necessary and the use of tape or twill is disproportionally sized and may make device securement difficult.

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.26,133 A dehydrated infant may be hypoxic because of poor skin perfusion, and the affected tissue may break down with only minor insult.121

Infants with multiple organ dysfunction syndrome are particularly at risk of PUs.134 Furthermore, an infant’s immune system is immature, with underdeveloped monocytes and neutrophils that respond poorly to inflammatory cytokine stimuli.135

As a consequence of all these factors, infant skin is fragile and less tolerant of mechanical loading and injury.26127,136

In the UK, NICE has issued a pathway, with supporting guidance, on the prevention of PUs in neonates, infants, children and young people (NICE, 2021). These principles also apply to prevention of DRPUs.

In addition, health professionals must be attentive to a paediatric patient’s growth phase; patients who are growing during a long-term period of hospitalisation who are being treated with long-term medical devices, must have a frequent appraisal of the size and fit of these devices.

In general, we believe that the importance of the skin as a key organ of both the mechanical and immune protection of young patients is often underestimated. In fact, loss of skin integrity, for example by developing a PU, can be catastrophic, potentially leading to rapid, polymicrobial infections,

which may be resistant to antibiotic therapies. We believe that a cultural shift is needed so that any holistic assessment of a paediatric patient reflects the critical importance of their skin integrity as a fundamental aspect of their medical condition, and not as a peripheral aspect of their care.

## Summary

* Devices and their securement may generate high stress concentrations in tissues, leading to cell and tissue damage pathways associated with sustained deformation136–138
* Insensate patients are especially at risk of localised high-tissue deformation, stresses and stress concentrations97
* Everyday activities such as toilet sitting increase tissue loads and reduce perfusion and tissue oxygenation,139 placing individuals with reduced sensory function or mobility at high risk.

Most common causes of DRPUs 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 DRPUs. This is addressed further in chapter 7.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 19**

# Chapter 3: devices

ost medical devices that come into contact with a patient’s skin and/or pass through it, can expose the individual to the risk of

M

DRPUs. Paediatric patients may be predisposed to DRPUs due to factors outlined in Table 3.

Table 4 gives examples of medical and non-medical devices that can be associated with DRPUs.4 Devices can be classified in a variety of ways, and in Table 4, medical devices are classified according to their primary medical or 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 (for example, respiratory devices, patient-monitoring devices and indwelling lines) or for the rest of the patient’s life (such as 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.9

DRPUs are common across several medical specialty units. Devices commonly associated with DRPUs include:39

#### Key points

* + DRPUs 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, DRPUs can occur anywhere that the skin is in contact with a device
  + Extended use of devices and some positioning, such as proning, can be associated with a higher and increasing risk of a DRPU
  + Devices responsible for DRPUs vary between clinical settings
* Tubing devices such as oxygen tubing
* Nasogastric tubes and endotracheal tubes
* Respiratory masks including CPAP and BIPAP
* Splints, casting and orthotic devices
* Intravenous and intra-arterial catheters and armboard
* Cervical collars.

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 and the ability to secure the device in place. Ill-fitting masks create focal pressure points and localised frictional

**Table 3. Characteristics of neonatal skin that increase its vulnerability to device-related pressure ulcers (DRPUs)273**

|  |  |
| --- | --- |
| 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 | |

**S20 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Devices

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

|  |
| --- |
| **Devices with medical purpose** |
| **Respiratory devices:** oxygen face masks (non-invasive ventilation); continuous positive airway pressure (CPAP) masks; bilevel positive airway pressure (BiPAP) masks; nasal prongs and tubing; high-flow nasal prongs; extracorporeal membrane oxygenation (ECMO)  **Faecal and urinary devices:** flanges on stoma appliances; urinary catheters; bed pans; toilet seats; condom catheters; penile clamps; bowel management systems  **Access devices:** all types of lines (catheter [arterial or venous] and associated lines/tubing); intercostal catheters; chest tubes and lines  **Support and immobilisation devices:** cervical collars; external fixators and pins; air casts (pneumatic support devices); restraints (used in the US in patients with certain documented clinical indications); splints (including for arterial lines); orthopaedic immobilisers, donut head supports; intraoperative devices such as frames used in neurosurgery  **Feeding and nutrition:** nasogastric tubes; orogastric tubes; percutaneous endoscopic gastrostomy tubes and their external bumper and clamps  **Patient handling:** spinal boards; transferring devices; wheelchairs, hoist slings  **Patient monitoring:** oxygen saturation probes/pulse oximeters (clamped on finger, toe or ear); blood pressure cuffs; electrocardiogram (ECG) dots, leads and lines; electroencephalogram (EEG) electrodes and wiring; wearable monitoring devices/sensors (eg, for blood glucose); intracranial pressure (ICP) monitoring (cannulae and tubing); extraventricular drains (EVD); forehead oxygen saturation probes; temperature probe devices/sensors; movement sensors (for patients at risk of falls)  **Compression and deep vein thrombosis prevention:** sequential compression devices (SCDs); thromboembolic deterrent (TED) stockings; compression hosiery; all cotton elastic (ACE) wraps; heel offloading devices  **Treatment**: 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 bandages used on patients with critical limb ischaemia;274 aircast boots  **Prosthetics and orthotics:** above- and below-knee, hand and arm prostheses; knee orthosis (braces); ankle foot orthoses, dental prostheses  **Surgical devices:** forceps; tools; instruments  **Miscellaneous devices and objects:** bandages; identity bands on wrist/ankle; pens/scissors/flashlights/other healthcare provider personal items (dropped in beds) |
| **Hospital furniture:** bedframes; foot rests and any other rests |
| **Device components that are removed before use:** packaging elements, for example, tops from syringes |
| **Devices used in tissue viability:** 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, malfunctioning or failing/incorrectly used devices, such as deflated mattresses, and device securement systems |
| **Objects without direct medical purpose / patient’s or other’s property** |
| 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 |

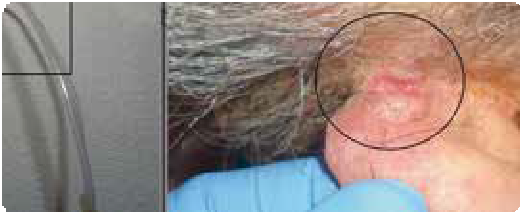
**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 21**

##### Devices

|  |
| --- |
| DRPU caused by a neck brace DRPU caused by oxygen tubing  DRPU caused by tube clamp DRPU caused by a nasogastric Mark from office supplies  tube (paperclip)  DRPU associated with a knee DRPU caused by bandage in a DRPU caused by non-invasive brace patient with critical positive pressure ventilation  limb ischaemia mask and lip wound from endotracheal tube  Fig 5. Examples of device-related pressure ulcers (DRPUs) in adults |

forces that can lead to irreversible tissue damage within hours. Examples of DRPUs in adults are shown in Fig 5.



In paediatrics, respiratory devices, casts and orthotics, intravenous arm boards, intravenous tubing, oximetry probes, cervical collars, name bands and security bands are particularly associated with DRPUs.140, 141

Examples of DRPUs in paediatric patients are shown in Fig 6.

In all patients, other devices associated with DRPUs include nasal prongs, anti-embolism

stockings, sequential compression devices, ankle bands and epistaxis balloons; EEG leads, extracorporeal membrane oxygenation (ECMO) cannulae, oxygen saturation monitoring and cooling blankets may cause DRPUs on toes, neck, chin, head, arms, feet, nose, chest, ears, earlobe, face, knuckles and buttocks.14,26

## Impact varies by anatomical location, duration of use and setting

**S22 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Devices

DRPU associated with tubing and thermometer

DRPU associated with peripherally inserted central catheter (PICC)

DRPU associated with tracheostomy tie

DRPUs associated with mask and retaining straps

Fig 6. Examples of paediatric device-related pressure ulcers (DRPUs)

Common anatomical sites for DRPUs include the face, ears, lower leg and heels. However, DRPUs can occur anywhere a device contacts the skin.142 Common sites include lips and face from endotracheal tubes and their securement, nose from nasogastric tubes, hand from splints, wrist from arterial line tubing and occiput following use of cervical collars.

Extended use of devices is associated with a higher and increasing risk of DRPUs. Cervical collars are associated with a higher incidence of DRPUs after 5 days of continued use, with many of these being category IV.49 Procedures and treatments administered concomitantly with a device may increase risk. For example, the use of pulse oximetry during vasopressor therapy is associated with a

higher incidence of DRPUs on the ear in adults and on the toes in infants.18

The type of device associated with PUs will vary depending on the setting. This is illustrated by the results of an unpublished DRPU incidence audit undertaken at Kyorin University Hospital in Tokyo, Japan, which were shared by a panel member. This facility 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 1 year (from 1 February 2018 to 31 January 2019) showed that DRPUs associated with elastic stockings

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S2 3**

##### Devices

were most prevalent (n=13) in general wards, followed by compression bandages (n=4). In all these cases, the devices were used to prevent deep vein thrombosis (DVT). The following devices were associated with DRPUs in the 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 DRPUs in both general wards and the ICU, but had a higher incidence in the 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 7. These findings are

consistent with published data from other centres.143

## Categorisation of medical devices

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 DRPUs. Devices with large

**S24 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Devices

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**

**Skin surface**

**Skin surface**

**Skin surface**

**Device** Nasogastric tube Splint **Respiratory**

Indwelling bladder catheter Pulse oximeter Non-invasive positive pressure

ventilation (NIPPV) mask

Intravenous catheter and three-way stopcock

Non-invasive blood pressure (NIBP) cuff

Oxygen nasal cannula

Invasive arterial blood pressures

ECG patch Tracheal tube

Central venous catheter ID wrist band Tracheal cannula Epidural catheter

Masks **DVT prevention**

**Monitors** Elastic stocking Intermittent pneumatic

Core thermometer

Body temperature management system

ECG code

NIBP tube and connector

compression and elastic stocking

Stoma products

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 and safety bands. Products used in 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 oxygen cannulae and tracheal tubes and cannulae.

Stomas are also 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.144 Around a quarter of patients who experience leaking can go on to develop pressure or

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S2 5**

##### Devices

moisture-related complications.145 Anecdotally, it is known that flange on stoma devices and mucosal injury from indwelling urinary and faecal catheters can be a cause of DRPUs, however they are under- represented in the clinical literature and more research is needed in this area.

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.

Other relevant devices associated with a DRPUs risk are external orthopaedic fixators, which are made of rigid (metal) components, often with curved, thin, sharp or geometrically irregular elements and surfaces.146

## What COVID-19 has taught us about device-related pressure ulcers

A substantial body of evidence has been published since the beginning of the COVID-19 pandemic reporting a high rate of DRPUs in this population. Between 50% and 88.7% of patients with severe COVID-19 have been reported to develop a skin injury (referred to as PUs in these papers, although many related to the use of devices)147–150 often with multiple DRPUs reported on the same patient.148,149

With time to reflect, several themes have emerged. Patients with severe COVID-19 have a particular set of clinical needs which combined to increase their risk of developing DRPUs. Many COVID-19-positive patients admitted to critical care have needed to be moved into the prone position,149 often for lengthy durations. This intervention has been found to improve prognosis;150 numerous randomised controlled trials have now demonstrated the positive effects of pronation for mechanically ventilated patients with acute respiratory distress.151 The benefits include improved ventilation and oxygenation ratios, improved respiratory mechanics through the reduction of over-inflated lung areas and reduced ventilator-induced injury.147,151 However, this

manoeuvre also increases the risk of developing PUs related to the position;48,149,150,13,147 specifically, both the use of proning and the length of time spent in prone position have both been shown to be risk factors for developing DRPUs.148,149 This is thought to be due to the fact that proning affects the mechanics of how the device interacts with skin and soft tissue. External securement fixation devices, particularly for endotracheal tubes, are also a risk factor when proning.

Secondly, the main manifestation of COVID-19 as a respiratory disease, causing breathing difficulties, meant that patients need intensive and often prolonged life-saving ventilatory support. This requires the extensive use of endotracheal tubes,148 tracheostomy tubes or ventilation equipment such as oxygen masks, CPAP/BiPAP masks and nasal prongs. The majority of DRPUs associated with COVID-19- positive patients (between 61% and 77%) are located on the face and associated with these types of devices,148,149,131 including a third of DRPUs which were oral/mucosal and related to endotracheal tubes.

**S26 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

# Chapter 4: risk assessment

s with any PU, assessing a patient’s risk of DRPUs is a critical step in prevention. Expert guidelines and best practice statements stress

A

the importance of risk assessment.1,2,152–158 This involves an awareness not only of the risk factors for pressure ulceration in general, but also recognition of the additional risk posed using devices.

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

Health professionals, patients, their family and other health professionals 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 PUs and DRPUs.

An example of a template that can be used to highlight the risk of DRPUs to health professionals is given in Fig 8. 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 a DRPU and to document when high-risk medical devices are being used. This should lead to staff undertaking a RAS for pressure ulceration and a skin assessment under or around devices, for DRPUs.

## Risk assessment tools

Many PU risk assessment tools (RATs) are available. These tools have been an important component of the care bundles that have been adopted to reduce hospital- acquired PUs over recent years. However, not all existing risk assessment tools take the risks of medical devices into account.

The Braden, Waterlow and Norton scales are all well known risk assessment tools that can be used in a broad spectrum of patient types and settings, however none of these tools assess the risk of DRPU. An alternative scale, the CALCULATE tool, has been described. This scale includes a section related to whether the patient requires mechanical ventilation,

#### Key points

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

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

**Extrinsic risk factors**

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

**Intrinsic risk factors**

* Age (the very young and very old)
* 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 in a range of shapes and sizes
* Lack of access to appropriate equipment,
* The need to prioritise other potentially life-threatening issues

including CPAP masks,159,160 so does take some aspects of risk associated with medical devices into account,

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 27**

##### Risk assessment

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **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 securement device |  | | | |  | | | |
| Oxygen tubing |  | | | |  | | | |
| BIPAP/CPAP |  | | | |  | | | |
| Nasogastric tube |  | | | |  | | | |
| Suprapublic catheter |  | | | |  | | | |
| Tracheostomy tube |  | | | |  | | | |
| Cervical collar |  | | | |  | | | |
| Orthopaedic device |  | | | |  | | | |
| IPC |  | | | |  | | | |
| NPWT, faecal containment device, endotracheal tubes,  ECMO/IAPB/LVAD lines |  | | | |  | | | |
| 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* | |  | | | |  | | | |
|  | | | |  | | | |
|  | | | |  | | | |
|  | | | |  | | | |
|  | | | |  | | | |
| 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 | | | | | | | | | |

**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
  + Be aware of potential to miss devices where there are large skin folds—full inspection is required

**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 action to minimise the risk of device-related pressure ulcers (DRPUs)
  + 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 DRPUs
  + Develop local protocols for risk assessment and use of medical devices

Footnote: DRPU–device-related pressure ulcer

Fig 8. Example of a template that could be used to highlight the risk of DRPUs to health professionals. One template needs to be completed per ward

however its relevance is limited to critical care and any risks related to other types of devices are not accounted for. It may be valuable to develop a risk assessment tool, with broad applicability that

**S28 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Risk assessment

considers the risks posed by medical devices. PURPOSE T mentions medical devices

This has been addressed recently by Seong et al. (2021)161 who developed and tested an algorithm specifically designed to assess the risk of DRPUs. Choi et al. (2020)162 also developed a RAT designed to assess the risk of developing an oral mucosal PU associated with the use of endotracheal tubes in patients receiving critical care. Some studies have identified that the use of endotracheal tubes, having had surgery, being in a semi-coma/coma and sedation all significantly increase the risk of development of DRPUs in a critical care population. This information may be of use in the future development of new RATs or modification of existing RATs.163 However, the focus, in terms of risk assessment, will always need to be on regular skin and mucosal assessment.

In the meantime, when conducting a risk assessment in relation to DRPUs, 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 to 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 is more appropriate to consider specific risk factors for the patient.

## Validated risk assessment tools for use in paediatrics

The UK NHS National Institute for Health and Care Excellence (NICE)155 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. As with all patients, 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.

The Braden QD Scale , which was developed in 2019, expands on the Braden Q 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.164 Other paediatric-focused RATs include the Neonatal Skin Risk Assessment Scale (NSRAS),165 the Pediatric Pressure Ulcer Prediction and Evaluation Tool (PPUPET)166, the Skin Injury Risk Assessment and Prevention (SIRA+P)167 and the Glamorgan paediatric pressure ulcer risk assessment scales. 168 Other important assessment tools are provided by Peterson et al.169 and Kiss and Heiler,170 or are still in development. The NSRAS considers the need for ventilatory support and so does partially address the risk of developing DRPUs. As with the Braden-QD, the PPUPET scale considers the number of medical devices needed.

## Assessment

Any patient being managed with a medical device should be considered at high risk of developing a DRPU. The management plan must include frequency of assessment, as well as strategies to reduce risk. There is no predetermined frequency for assessments, and therefore assessment frequency 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

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. The clinical need for the device should also be

condition,

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S2 9**

##### Risk assessment

**Box 5. General principles of skin assessment275**

**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 indentations, or tissue damage, or potential damage in lighter skin tones: non- blanchable/non-blanching erythema: skin that blanches and slowly returns to its normal colour; in darker skin tones, consider observing for skin discolouration when compared with unaffected skin176
* Bruising
* Scaling and dryness

**Frequency of assessment:**

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

reviewed regularly.

Health professionals should also be aware of the risk associated with devices and objects with no medical purpose. Any object or possession of the patient 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 PUs in paediatric patients is the occiput, where the largest bony prominence and highest interface pressures are located.23 Risk factors for PUs and DRPUs in paediatric patients include sedation, hypotension, sepsis, spinal

cord injury, traction devices, terminal illness, spina bifida, cerebral palsy, cardiovascular bypass surgery,171*–*174 lengthy surgical procedures, extracorporeal membrane oxygenation (ECMO) bridge- for-life connections, and cerebral and cardiovascular activity probes.

Priorities for assessment of neonates, infants and paediatrics are listed in Box 6, along with adjustments that might need to be made to devices to avoid the risk of DRPU. Fig 11 gives an example of a checklist approach to assessment of neonatal and paediatric patients in the ICU.23

## 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.

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.175 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 3 hours and to reposition the device or patient if necessary, ensuring that the device is not wedged or positioned such that it presents a 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 or oedema especially in the areas of DRPUs. An example of a drop- down menu is shown in Fig 10.

## 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

**S30 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Risk assessment

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Intensive care unit: nursing assessment form** | | | | | | | |
|  Show sessions log |  |  |  | New session |  |  |  |
|  | | | | 07/01/2020 13:34 |  | | |

Equipment & patient safety

Neuro

CVS

Respiratory/ Renal

GIT





Skin integrity

Skin integrity/ assessment Assessment comments

Skin temp Skin colour Skin turgor Skin moisture Skin texture

Skin oedema Oral mucosa Nare mucosa

Normal Dry

Diaphoretic Oily

Pressure injury/risk assessment Available links/tips

Pressure injury risk assessment Mattress/bed type

Pressure injury prevention WUG

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

Fig 10. Computer drop-down menu with options to describe colour, warmth, moisture, oedema and turgor of the skin and the presence of a skin injury

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 or 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, the health professional should be alert to non-verbal cues, such as grimacing or agitation.

It may be possible to assess the skin using direct palpation. A cervical collar stops the neck moving. When the patient is turned for assessment, the best

trained staff member holds the head in neutral position to avoid flexion. Chin and sternum may be inspected after removing the anterior collar. With the help of neurosurgery or trauma providers, the occiput can be inspected when the patient is log rolled, with the provider having complete control of the head. 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. Patients who have ambulance transport times while on an immobility backboard should have the occiput area evaluated early and often after admission.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 31**

##### Risk assessment

**Box 6. Assessment of neonatal and paediatric patients23**

**Frequently assess skin under:**

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

**In growing children, frequently readjust:**

* Orthotics
* Wheelchairs
* Wheelchair cushions
* Securement straps
* Splints and medical shoe insoles
* Prostheses

**Inspect beds, cribs and isolettes to ensure tubing, leads, toys and syringe caps are not under or on top of the patient’s skin. Assess carefully the stiffness of diaper edges and dress seams.**

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

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

## Other clinical challenges

Assessment can be difficult in some circumstances. For example, skin changes that signal potential injury are less visible in darkly pigmented skin.176 Erythema is often not visible in darkly pigmented skin. Sometimes though moistening the skin will help contrast color change in comparison to surrounding tissue. Darkly pigmented skin should also be palpated for oedema.

Furthermore, skin may be at higher risk of damage because of age-related changes.177

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. It commonly develops in patients who are hypovolaemic and given many litres of fluid after devices have been inserted and secured.

Patients with COVID-19 also present a clinical challenge, as described earlier. Challenges include difficulties in carrying out risk assessments in patients with COVID-19 due to infection control measures intended to reduce the risk for health professionals.178 In terms of risk assessment, it seems prudent to continue to adopt tried and trusted RATs in this population to assess their general risk of PU. Existing RATs already consider many factors that are also relevant in patients with severe COVID-19, for example, activity, mobility and nutrition levels. In the absence of detailed RATs relating to DRPUs in this population, and knowing that patients with severe COVID-19 are at high risk of developing DRPUs,10–12 and that COVID-19 can affect the skin with unknown implications on skin integrity,107–110 we recommend vigilance and adopting a cautious approach to the assessment of risk. Skin assessment should be carried out prior to the proning manoeuvrer whenever possible, while the patient remains in the prone position, head position changes should be performed; frequency is determined on an individual basis. 178

## Developing bespoke risk assessment tools (RATs)

Facilities should develop their own device-specific RATs that will work with their own protocols, based on the patient populations that they serve. RATs must, of course, be reliable and valid. The checklist in Fig 11 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. Staff changeover is an ideal time to assess skin under

**S32 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Risk assessment

medical devices. One staff member can release the ties to inspect the skin while the other supports the patient to prevent the patient from pulling out the device.

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

**P** – pathophysiology

**R** – risk factors (identify and document the risk factors

—ensuring preventative measures are put in place)

**O** – occurrence (when did the skin damge occur? Is it new? Has it happened before?)

**T** – teamwork (consider members of the MDT to include in the interventions)

**E** – equipment (including PPE?—What caused the damage including PPE?)

**C** – caution (care in selecting and applying the device)

**T** – technology (what technology can be used for prevention/management)

**I** – innovation (what’s new?)

**N** – nutrition (ensure nutritional and hydration need are met and recorded)

**G** – guidelines (follow the guidelines)

## Next-generational risk assessment tool

Current conventional RATs have low sensitivity and specificity for predicting PU formation in groups,179–183 their use does not necessarily lead to targeted PU prevention and they are not comprehensive enough to capture the specific risks associated with devices.184–186

high-risk

There is potential for innovative technology to facilitate assessment of tissue status. Such technologies include:

* Imaging and sequential photography
* Biocapacitance measurements
* Inflammatory biomarker measurements
* Sub-epidermal moisture (SEM) scanner suitable for smaller areas of the body. Although such devices are currently available for larger body areas, the technology has not yet been adapted to the smaller body areas implicated in DRPUs.186
* 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 chapter 7.

It is important to note that RATs will only valuable if they can accurately and precisely predict the likelihood of developing a DRPU. Rigorous and methodical analysis to validate any new RAT devices will be needed before these technologies can be relied upon.

## 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.65,72,96 It may be possible to include visual markers on the device that can indicate load, tissue status, near infrared or oxygen saturation at the site can 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 DRPUs 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 experiencing a clinical emergency, such as airway instability, the position of the device and the forces it is exerting immediately become lower clinical priorities and periodic assessments may not be completed.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S3 3**

##### isk assessment

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Device-related pressure ulcer (DRPU) checklist: devices used in paediatric/neonatal** | | |
| **Monitors** |  | **Respiratory** |
|  | Core thermometer |  | NIPPV mask |
|  | Body temperature |  | Oxygen nasal cannula |
|  |  |
|  | ECG patch and code |  | Equipment for fixing tracheal cannula |
|  |  |
|  | Pulse oximeter |  | Tracheal tube |
|  | NIBP cuff, tube and connector |  | Tracheal cannula |
|  |  |
| **Tubes** | **Others** |
|  | Nastrogastric tube |  | ID wrist band |
|  | Indwelling bladder |  | Splint |
|  |  | Other (specify) |
|  | Intravenous catheter and 3-way stopcock |
|  |
|  |
|  | Invasive arterial blood pressures |
|  |
|  | CV catheter |  |
|  | Epidural catheter |
|  | **Deep vein thrombosis prevention** | | |
|  | Elastic stocking |  | |
|  | IPC and elastic stocking |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **DRPU checklist: operating room/surgical theatre devices** | | |
| **Monitor** |  | **Respiratory** |
|  | 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 | **Others** |
| **Tube** |  | ID wrist band |
|  | Nastrogastric tube |  | Other (specify) |
|  | Indwelling bladder catheter |  | **Option** |
|  |  | Tourniquet |
|  | Intravenous catheter and three-way stopcock |
|  | Fixation equipment from lateral |
|  |
|  | Invasive arterial blood pressures |  |
|  |
|  |
|  | Central venous catheter |
|  | Epidural catheter |
|  | **Deep vein thrombosis prevention** | | |
|  | Elastic stocking |  | |
|  | IPC and elastic stocking |

For abbreviations, please see page S51

Fig 11. Device-related pressure ulcer (DRPU) intensive care unit and operating room

**S34 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

# Chapter 5: safe use of devices: prevention and management

of injury

revention of DRPUs can be viewed from a variety of perspectives. These include:

P

* 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 DRPUs.

## Key aspects of device- related pressure ulcer prevention

PU or DRPU prevention requires a high level of awareness and rigorous adherence to evidence-based practices that minimise the risks.39,187,188 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 DRPUs.189 This involves accounting for the physical form of a device, the clinical goal for its use, the type of

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

* + Risk assessment
  + Skin assessment and care
  + Support surface/device selection and care/ application
  + Regular moving or repositioning of person or device
  + Continence management
  + 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, padding under devices, 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 implementation
  + 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 like those for other types of pressure ulcer

tissue onto which it will be placed, and the anatomical area affected. 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.190 This is especially important in neonatal and paediatric patients admitted to critical care and during transport between units.141 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 DRPUs.

While many DRPUs are likely to be preventable, it is important to recognise that some life-saving medical devices can only be used in ways that make DRPUs difficult to prevent, assess and treat. This obstacle can often be at least partially overcome by adoption of evidence-based strategies.191 Standard care based on expert consensus recommendations should be followed (Box 8).1,155

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S3 5**

Safe use of devices: prevention and management

## 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 using 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.191,192 A simple method of ensuring such focus is to incorporate DRPUs into ward or facility documentation, as shown in Fig 8 (page S26).

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.193

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 DRPUs in critical care,187 paediatric populations,194 and in long-term care,195 as well as a general overview.188 They include photographs of DRPUs that commonly occur in each setting and advice on prevention. Box 8 lists NPIAP guidance for prevention of PUs and DRPUs.2

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 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

The evidence base for the prevention of PUs (not associated with medical devices) is well developed,

**Box 8. NPIAP recommendations for prevention of device-related pressure ulceration2,154**

* + 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

**S36 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

**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

with multiple systematic reviews and meta-analyses in this area.196–199 In contrast, there is considerably less high-level evidence that describes the effectiveness of many prevention measures and interventions specifically relating to DRPUs. This may reflect institutional cultures where DRPUs has been historically under-reported, or accepted as a normal consequence of treatment—known as ICU sores or plaster sores—and to be expected. As awareness of prevention strategies has grown over the last few years, so the evidence base is now developing, and some high-level studies are emerging. For example, one recent meta-analysis suggested that hydrocolloid dressings can help prevent DRPUs during non- invasive ventilation,200 probably because they provide cushioning at the skin-device contact interface,201 and a pilot randomised control trial (RCT) has been completed to compare outcomes of three prevention strategies.202

Where evidence is available, it should be evaluated and integrated into procedures and protocols; health

* 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 DRPUs
* Give feedback to industry and collaborate with device developers and manufacturers

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 RCTs, or higher-level evidence. Evidence from quality-improvement studies, cohort

**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

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 37**

##### Safe use of devices: prevention and management

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Device type/resource Approach** | | | | | | | |
| Bilevel positive airway pressure (BiPAP) mask-related pressure ulcer (PU) in paediatric patients276 | 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 patients42 | 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 masks277 Personalised mask fitting device, designed | | | | | | using 3D scanning |  |
| Modified SSKIN bundle122 | 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 | | | | | | |

and case studies 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 DRPUs, both in paediatric and adult populations. The Joanna Briggs Institute provides useful guidance on how to critique and appraise research evidence.203 The outcome being investigated also needs consideration: for example, prevention of DRPUs alone is a sufficient outcome measure for oxygen masks, as a percentage leak is not an influential variable, whereas for PPE equipment, no percentage leak can be countenanced, so a fit test will be required to ensure it is fit for purpose.

## Differential diagnosis

There are four types of skin breakdown resulting from external causes:

* PU
* DRPU
* Skin tear
* Medical adhesive-related skin injury (MARSI).

When planning prevention, it is important to diagnose which of the above four types of injury has occurred (Fig 14). This will involve determining the wound pathology, the patient risk factors and the circumstances that led to the injury. The four types of skin injury are defined below.

### Pressure ulcer

***tracy.c***

*2022-01-24 21:03:07*

--------------------------------------------

Reviewer: What does this mean? Document findings?

***tracy.c***

*2022-01-24 21:03:54*

--------------------------------------------

Reviewer: If foam is placed under a mask (at the pressure points), then it would be well padded. The two items in succession don’t make sense

***Gefen***

*2022-01-25 11:07:29*

--------------------------------------------

See above.

***tracy.c***

*2022-01-24 21:04:27*

--------------------------------------------

Reviewer: Wouldn’t these suggestions be true for all patients with masks, why just on surgical spine patients?

***Gefen***

*2022-01-25 11:07:22*

--------------------------------------------

Agree, "surgical spine patients" should be deleted. We should also delete "Mask not padded".

***tracy.c***

*2022-01-24 21:04:54*

--------------------------------------------

REviewer: does this exist?

***Gefen***

*2022-01-25 11:10:14*

--------------------------------------------

Yes fitting using 3D scanning exists, but is not yet applied clinically (at a large scale). I suggest that we add an asterisk saying that this technology is still in the laboratory research phase and not yet applied clinically in large scale.

***tracy.c***

*2022-01-24 21:05:18*

--------------------------------------------

REviewer: Not all devices can be rotated. What do you suggest for fecal containment devices? neck collars? Arterial lines?

***Gefen***

*2022-01-25 11:11:49*

--------------------------------------------

We should revise to "Rotate device where this is feasible and clinically appropriate".

***tracy.c***

*2022-01-24 21:06:03*

--------------------------------------------

Reviewer: see my earlier comment on nutrition

**S38 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

Skin breakdown

Yes

Body weight loading

No No

Device

Unstable, mechanical shot-term

external force

Yes

Body weight loading and device

Yes

**DRPU**

No

Yes

Adhesive device of tape

Yes

**MARSI**

Yes

Body weight loading alone

did not causepressure PU

ulcer and involved both

BW loading and device

**PU and DRPU**

Fig 14. Causes of pressure ulceration, device-related pressure ulcer and medical adhesive-related skin injury

The main cause of pressure and the associated shear forces is body weight loading.

### Device-related pressure ulcer

DRPU is defined in chapter 1 on page S6.

### Skin tear

Skin tears are traumatic acute injuries that can result in partial or full separation of the outer layers of the skin.1–3 These tears can be caused by shearing and friction forces or a blunt trauma. They result from short-term external forces, as opposed to the continuous external forces that cause PUs and DRPUs.

### Medical adhesive-related skin injuries

MARSI occur when superficial layers of skin are removed by medical adhesive resulting in erythema and/or other manifestation of skin trauma or reaction, including vesicles, bulla, skin erosion, and skin tears that persist longer than 30 minutes after removal of

the adhesive. MARSI not only affects skin integrity, but also causes pain, a greater risk of infection, a potential increase in wound size and delayed healing.

**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, including the duration of application

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S3 9**

##### Safe use of devices: prevention and management

**Device-related pressure ulcer** Redness that developed in the sacral region after lengthy surgery in the supine position

Redness that developed when the detached the upper arm came into contact with a detached arm rack

Redness that developed in skin under an arm strap, upper extremity in the supine position

**Pressure ulcer**

Redness caused by wrinkled sheets

**MDRPU**

Skin breakdown occurred when

the patient was proned, and a frame was used. Redness developed on the both sides of the chest

**PU**

1. Skin disorder in the prone position:

Epidermal peeling occurred in the mental region

**PU**

1. Skin disorders in the prone position using a frame: a skin ilaceration occurred on the left forearm when the position was

changed from the frame to supine position

**Skin tear**

1. Skin disorders in the prone

position: Redness occurred when the ENTROPY EEG module was

removed after

extubation

**DRPU and PU**

1. The nasogastric tube was still fixed to the cheeks by

tape and was sandwiched between the facial protection cushions, cheek skin was causing redness.

**DRPU and Pressure ulcer**

1. Skin disorders in the prone position:

Epidermis peeling occurred when the ENTROPY EEG module was removed after extubation

**MDRPU and PU with MARSI**

1. Skin disorders at lithotomy position and head lowering position (head-down tilt) in OR (da Vinci surgery): Redness occurred on the heel

**Pressure ulcer (shear and pressure)**

1. Skin disorders at

lithotomy position and head lowering position in OR (da Vinci surgery): When the levitator was removed (without foot pump), redness occurred along the boot

band on the

front of the tibia.

**DRPU**

1. Skin disorders at

lithotomy position and head lowering position in OR (da Vinci surgery): Redness occurred on the shoulders

**Pressure ulcer and DRPU**

1. Skin disorder at lithotomy position and head lowering position in OR: The hard part of the beans bag fixation was contacted directly to the skin and redness occurred

**DRPU**

1. Skin disorders at lithotomy position and head lowering position (da Vinci surgery): redness occurred in the sacral region

**PU (shear and pressure)**

1. Skin disorders in the lateral position using the hip positioner (hip surgery): blister and epidermis peeling occurred in the buttocks region where the hip positioner (pelvic support) was in contact with the pad

**DRPU**

1. Skin disorders in the lateral position: Redness occurred in the right lateral chest and right iliac crest in the lower right lateral position

**Pressure ulcer**

1. Skin disorders in the lateral position: In the lower right lateral position, the hard part of the beans bag fixation was contacted directly to the right axilla skin, and redness occurred

**MDRPU**

1. Skin disorder in the lateral position: redness occurred when

Fig 12. Examples of device-related pressure ulcers (DRPU) in adults. PU–pressure ulcer; MDRPU–medical-device- related pressure ulcer; MARSI– Medical adhesive-related skin injuriy

**S40 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

cords such as an electrocardiogram, sphygmomanometer, and electrosurgical cautery pad were caught between the bodies and the beans bag fixation

**DRPU**

1. Redness occurred at the corner of the mouth where the endotracheal tube was

contacted

**DRPU**

1. Redness occurred where the tube for nasal intubation tube contact the nostrils and ala

**DRPU**

electrocardiogram

**DRPU**

1. Redness occurred by the splint that had fixed the wrist joint due to the indwelling arterial catheter

**DRPU**

1. Redness occurred due to pressure on the lead wire and clip of the

pinched by the pulse oximeter

**DRPU**

* 1. Redness occurred while being compressed by an indwelling bladder catheter

**DRPU**

* 1. Redness occurred when the central thermometer was inserted into the rectum and

fixed to the inside of the thigh

**DRPU**

* 1. Redness occurred after remove the cuff of the tourniquet

**DRPU - Reactive erythema**

* 1. Epidermis peeling occurred after peeling the tape fixating the

**DRPU**

of the nose

1. Redness occurred because the electrocardiogram lead was pinched under the body

electrode patch ECG

**Tape tear MARSI**

1. Redness occurred where the nasal gastric tube contact the nostrils and on the rim of the nose

**MDRPU**

1. Epidermis peeling occurred when the eye patch was removed (MARSI)
2. Epidermis peeling occurred when the tape holding the endotracheal tube was peeled off (MARSI)
3. Bite block pressing on lips caused redness, blisters and swelling

**DRPU**

1. Transesophageal echocardiography pressed the lips, causing redness and blisters (no photo)

**DRPU**

1. Pressure from the three-way stopcock caused redness on the forearm

**DRPU**

1. Epidermal peeling occurred after removing the electrocardiogram patch (MARSI)
2. Redness occurred when the skin was pressed by the cord of the monitoring ECG

**DRPU**

1. Redness occurred due to pressure from defibrillator pad cord

**DRPU**

1. The edge of the sphygmomanometer manchette contacts the skin directly, causing redness

**DRPU**

1. Redness occurred while being squeezed by the sphygmomanometer tube connector

**DRPU**

1. Redness occurred: finger was
2. Itching blisters occurred due to pressure from the tourniquet cuff and the edges of the cuff

**DRPU**

1. elastic stockings caused redness and blisters on the head of the first toe

**DRPU**

1. Redness occurred where the foot pump tube and connector were contacted to the skin

Fig 12. Examples of device-related pressure ulcers (DRPU) in adults. PU–pressure ulcer; MDRPU–medical- device-related pressure ulcer; MARSI–medical adhesive-related skin injuriy

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 41**

##### Safe use of devices: prevention and management

Fig 12 illustrates the differential diagnosis.

## Care bundle approach

Where evidence exists, prevention strategies delivered using the care bundle approach have been shown to reduce the incidence of DRPUs in a number of settings, 204–212 with reductions in the incidence of DRPUs of between 75% and 100% reported.205,208,209

The following example describes how implementation of a care-bundle approach reduced the rate of tracheostomy-related PUs 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 was used to develop a care bundle for tracheostomy- related PU.213 During the bundle development phase, tracheostomy-related PUs 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 and DRPU risk assessment, full skin assessment and identification, and prevention of tracheostomy-related PUs. 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, including under ties
* Using a hydrophilic foam barrier under the tracheostomy tube flange and around the stoma if not contraindicated
* 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 onto their

**Table 7. Classification of medical devices according to device-related pressure ulcer risk as presented in a Japanese clinical setting278**

|  |  |
| --- | --- |
| **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. Vascular access devices:**  Intravenous catheter  Invasive arterial blood pressure monitors | |
| **7.** Nasogastric tube | |
| **8.** Paediatrics nasogastric tube | |
| **9. Respiratory-related devices used in paediatrics:**  Oxygen nasal cannula  Equipment for fixing tracheal cannula Tracheal tube  Tracheal cannula | |
| **10.** Paediatrics fixation device for catheter, splint | |

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 PUs develop.

The care bundle was incorporated into the facility’s electronic medical records (EMR) system, embedding it in the nurse workflow. In this facility, tracheostomy- related PUs 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 4 months, demonstrating sustained quality improvement.213

**S42 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

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

Several aspects of the care bundle demonstrated above are described in detail elsewhere in this document, including the need to train health professionals, regular risk assessment and the periodic adjustment or rotation of the medical devices. The section below introduces the evidence supporting the use of prophylactic dressings to reduce the risk of DRPUs.

The role of prophylactic dressings in DRPU prevention

One component common to many different care bundles is the adoption of a prophylactic dressing.39, 205,213,214 This approach is supported by the EPUAP who recommend that health professionals: 'consider the use of prophylactic dressings'.2 The primary rationale is that a dressing placed between the medical

device and the skin may be able to reduce the pressure, friction and shear forces acting on the skin, therefore, reducing the risk of pressure-related injury and skin breakdown.39

A range of dressings may be considered including, transparent films, hydrocolloids, silicone dressings and foam dressings, all of which can vary in their properties and features.40 The choice of dressing may depend on multiple patient-specific criteria, for example: the degree of moisture present; the need to address bacterial load; the condition of the involved skin; whether an adhesive or non-adhesive dressing may be more appropriate; the ease of applying a dressing in the involved body location; and the extent of the physical forces exerted by the medical device.39,40 A systematic review, albeit on a small number of studies, concluded that prophylactic dressings applied as part of a pressure ulcer prevention protocol may help to halve the risk of developing a PU.215 To date,

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S4 3**

##### Safe use of devices: prevention and management

there is no evidence, that any one type of dressing is more effective than any other.215 Reduced incidence of DRPUs in cohorts who received prophylactic dressings has been reported in a wide variety of medical devices including ventilation devices,94 tracheostomies,214 non-invasive ventilation devices,200 and under orthopaedic casts.216

It is important to note that prophylactic dressings should only be considered underneath devices, as long as the dressing will not impede the primary function of the device.

## Device-related pressure ulcer prevention in prone COVID-19 patients

Pronation, where patients suffering acute respiratory distress are placed in the prone position, increases the risk for development of PUs on the forehead, chest, pelvis, chin, shoulders, genitalia, iliac crest and knees, dorsal feet and toes.151 Device-related PUs associated with this position are most likely to develop on the mouth, ears and nose and may be exacerbated because the change in the patient’s position causes body weight to be applied to areas, such as the face, that would not normally be subject to body weight.

Prevention of DRPUs in these patients involves:

* regular skin assessment, including conducting an assessment prior to the proning manoeuvre and putting preventative measures in place including good skin hygiene and moisturisation178
* Prophylactic dressings to be used as an interface can be considered.
* The use of specific pressure redistribution surfaces to reduce pressure, shear and friction, particularly the head151,178,217
* Frequent off-loading of pressure and repositioning
* Adoption of the ‘swimmer’s’ position,178 ensuring that the elbow of the flexed arm is not positioned higher than the shoulder
* Use of tape to secure endotracheal tubes instead of ties

Patients often remain prone for 12–16 hours, with

the head repositioned every 2–4 hours. However, only small movements are possible because of the risk of dislodgement of tubes and devices. Head positioners are available that can be moulded to the shape of an individual patient’s face, allowing pressure to be distributed evenly, and channels to be created for the access of tubes and devices. These are still in development and are being assessed in the clinical setting.151 Another important consideration is the need for management of saliva, which may be more likely to leak from the mouth when the patient is in the prone position. Any resulting moisture may lead to maceration of the skin on the chin, which may exacerbate the risk of skin breakdown at the site of devices such as endotracheal tubes.

Use of prophylactic dressings under the device

might be helpful. Prophylactic dressings such as silicone foams or hydrogels can often be positioned to provide an interface between the device and the patient’s skin. Modelling has shown that application of these dressings can reduce the forces applied to a patient’s skin.218

## Device-related pressure ulcer prevention in health professionals using PPE

### Publication of a guide

Another example of a DRPU prevention initiative is from Japan, where a detailed guide for general nurses and medical staff was developed. The guidebook includes ten classifications of medical devices commonly associated with DRPUs (Table 7). For each classification, 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 13), which stands

**S44 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

for:

* **S**kin/tissue
* **E**ducation
* **C**hampion/collaborate
* **U**nderstanding
* **R**eport
* **E**valuate.

Frontline health professionals 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.

## Key aspects of device- related pressure ulcer management

The fundamentals of managing DRPUs are similar to those of PUs. These include use of a recognised classification system, such as the NPIAP system,2 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.

DRPUs present different challenges to PUs, as body weight forces are not a dominant aetiology. It should be noted that DRPUs caused by a mask may be managed by changing to a different design—for example, from a mask that transfers forces to the bridge to the nose to a full-face mask that transfers forces to the forehead. If it is not possible to change the mask for clinical reasons, measures to reduce the

**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 (for example, 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 minimalising 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

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S4 5**

##### Safe use of devices: prevention and management

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.

For example

**NIPPV mask**

1. Frequently monitor sites at risk of developing DRPUs
   * Dorsum of nose, cheek(malar), chin (mentum), forehead
2. Consider factors relating to aetiology
   * High pressure bony prominences, for example, dorsum of nose
   * Microclimate—high humidity
   * Reduced skin durability
   * If the mask has not been properly fitted, respiratory management will be suboptimal. There is a tendency to tighten the straps to improve respiratory management, but this increases the pressure on the tissue and increases the risk of DRPUs.
3. Some prevention strategies can also be used to help to manage DRPUs
   * Ensure an appropriate fit. Choosing the right mask size, good fitting, and easier respiratory management can help prevent DRPUs and is necessary for optimal respiratory management by using a mask template
   * With proper fitting, it is possible to reduce the pressure on the straps and reduce the pressure on the tissues.
4. Assessment of DRPUs
   * Change from nasal oral mask to full face mask if the DRPU is developed beyond the dermis (Figure below)
   * The nasal oral mask has higher risk of a DRPU at the

dorsum of the nose than a full-face mask. If a DRPU occurs in the dorsum of nose, if the depth of ulcer exceeds the dermis, and if the nasal oral mask is used as it is, there is a risk of bone exposure, so it is necessary to change to full face mask

* Review of mask tension each time—if face becomes oedematous may need loosening.

Considerations specific to DRPUs 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.

To manage DRPUs caused by feeding or nutrition tubes, consider where possible changing the tube to a smaller gauge size or a fine bore tube, ensure the tube is in the correct position—in other words, that it is ‘free’ or not touching the mucous membrane or skin of the nare, secure the tube to ensure the tube is ‘free’ in the nare, regularly assess the position and securement of the tube to ensure potential pressure from the tube is prevented.

## Reporting device-related pressure ulcers

Medical device regulatory bodies, such as the Food and Drug Administration (FDA) in the US, Health Canada,154 Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and the Medical

**S46 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

Yes 1. Fitting check: Selection of musk size by using template

Indication of NIPPV

2. Leaking check: Determine the tightness of the belt

* 1. Nasal oral mask

Yes

Fitting/leakage

check

No

* 1. Full face mask

Yes No

Fitting/leakage

Consideration whether to continue NIPP

check

Yes Yes

Apply the prophylactic dressing for DRUP Selection of the prophylatic dressing

Fig 15. Safe application of a NIPPV mask

Device Directive in the EU have developed reporting 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 a 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.219,220

This means there is no consensus on which devices

agencies, is required. This should result in manufacturers of unsafe devices reviewing and improving their products.

DRPUs should be reported separately to PUs. 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 DRPUs.225 Further details on reporting requirements for DRPUs are given in Box 11.

### Protecting the health professionals

With the emergence of the COVID-19 pandemic, vastly increased numbers of front-line health professionals were required to wear PPE for long periods, sometimes

8 hours,

would benefit from further study on their design. To

up to

without the breaks that would be

provide high-quality, safe patient care, rigorous and consistent data on DRPUs are required. Therefore, a robust, evidence-based policy for reporting DRPUs is essential to improve DRPU prevention.220–224 In short, a culture of open reporting, supported by regulatory

standard procedure in normal times. PPE can comprise surgical masks, respirators, face shields, surgical caps, gloves, boots and gowns. The result was a high prevalence of DRPUs ranging from 30% to 77% of healthcare providers.226–230 This was exacerbated by

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 47**

##### Safe use of devices: prevention and management

anxiety and fear of contracting COVID-19, which led to many health professionals tightening their face masks tighter than required.231 DRPUs most commonly were observed on the nasal bridge, cheeks, forehead, behind the ears and hands,10,226,229,232 particularly linked to longer duration of wear, sweating and the use of grade 3 PPE, such as N95/P2 respirators.226,227 Immediately after donning PPE, around half of health professionals felt uncomfortable and around a quarter felt anxious or afraid.229 Although other skin injuries were caused by PPE, for example, dermatitis and maceration caused by prolonged wearing of protective gloves, injuries other than DRPUs are not described in detail here.

Masks and goggles are tightly attached to the skin, often for hours at a time, leading to poor local blood circulation, tissue ischaemia and hypoxia, skin evaporation and accumulation of water vapour from exhalation. The softened skin is prone to indentations and has a reduced ability to resist external pressure and shear forces. Repeated friction behind the ear caused by face mask strings increases the risk of pressure injury, while waterproof boots and gloves reduce air permeability, leading to decreased evaporation of sweat and an increased risk of eczema and fungal infections.233,234 There is anecdotal evidence of pressure in the occiput region from the mask strap. Similarly, there is anecdotal evidence that wearing a mask is stopping health professionals from eating and drinking as much as they would normally, resulting in systemic dehydration.

One of the few studies to include non-health

professionals (not patients) in a cross-sectional study, assessed the impact of mask-wearing on underlying skin.235 In the study population, surgical masks (63.15%) and cloth masks (35.05%) were the most common, with a very low percentage of N95/P2 masks (<1%). Unlike the PUs from respirators, the most common adverse reaction was acne (39.9%) followed by rashes on the face (18.4%) and itch (15.6%) with a higher incidence among health professionals, and a higher risk with surgical compared to cloth masks. This helps to confirm that PPE-related DRPUs are largely associated with the intensive use of higher-grade PPE, principally

worn by healthcare providers during the pandemic.

## Prevention of personal protective equipment- related device-related pressure ulcers

Jiang et al. (2020), in their survey of hospital workers in China early in the pandemic, found a very low level of use of prophylactic dressings and lotions to protect the skin.226 They attributed this to lack of direction and training on how to prevent skin injuries and concern that the use of protective dressings may compromise the barrier function or seal of PPE. They also identified a lack of direction from management due to the need to concentrate all resources on a rapidly unfolding epidemic.

However, as the pandemic progressed, it became quickly apparent that DRPU-prevention protocols needed to be extended to include health professionals wearing PPE; many individuals and institutions took steps to protect their staff from harm. The published guidance236–238 on prevention of DRPUs due to the wearing of masks, goggles and respirators is consistent, and can be summarised in the following steps:

* Carry out frequent skin checks239
* Wear a properly fitting masks that is (ideally) designed for each individual,230,240 and ensure that fit-testing is carried out with a pass rate achieved

237,239

* Move the mask around to a different position at regular intervals or swap it for a mask with a different design, and, therefore, different pressure points240
* Take frequent mask breaks if possible230,235,237
* Apply moisturisers or gel beforehand to act as a long-lasting lubricant,230,240,241 but do not do this directly beforehand as this can cause slippage; avoid facial make-up235
* Use ear-savers behind the ears to minimise pressure from straps235
* Do not over-tighten goggles: their main purpose is to prevent splash and tightening is unlikely to

**S48 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

enhance the protective effect240

* Consider using prophylactic dressings underneath the PPE;237,239,242,243 use of dressings may, but ensure that they do not compromise the seal of the PPE; FIT testing may need to be repeated.243,244 Check exhalation and inhalation to confirm fit
* Position respirator mask strap on the back of the head where it does not cause pressure

PPE should always be applied in accordance with local guidance and policy.

A common approach is to include the use of lubricants, or prophylactic dressings underneath the contact points of the PPE. Many types of lubricant were found to be effective at reducing shear forces between PPE and the skin in the short-term, but this was found to decline over time. The best performing lubricants with longest-lasting activity were derived from different categories of lubricant, potentially making it difficult to identify the best option. Some of the most effective lubricants included talcum powder, a petrolatum-lanolin mixture, and a coconut oil-cocoa butter-beeswax mixture.241

A systematic review found that the prophylactic dressings most commonly reported for use underneath PPE are silicone foam dressings and hydrocolloid dressings.10 The use of prophylactic dressings underneath N95 respirators was found to considerably reduce localised forces and did not worsen the thermal and SEM readings at the skin-device contact sites.245 However these small studies did not check the impact of these dressings on mask fit. This has been shown to translate into reduced risk of DRPUs when thin prophylactic dressings are applied. In a study by Yildiz et al.,246 PPE-related DRPUs occurred in all participants in the control group, but no participants who received prophylactic dressings, although a small proportion developed erythema.246 An RCT comparing the efficacy of thin foam or hydrocolloid dressings showed very similar clinical outcomes between groups; no DRPUs were noted, a small proportion of patients reported device-related erythema and reported levels of comfort were similar; both dressings were found to be effective in preventing DRPUs associated with the use of PPE.247

The NPIAP state that thin dressings can be used under devices if they don’t impair the function of the PPE device—it is vital to confirm the seal of the mask when the dressing is in place with a fit test pass achieved before use.237 A new dressing needs to be applied every time the PPE is applied. Note, this practice is not permitted in some countries, including the UK.

Anecdotally, as a result of the increased risk of harm to health professionals working through the pandemic, risk assessments in most institutions have been extended to include the potential for skin damage in health professionals and non-medical staff, due to the requirement to wear PPE for prolonged periods. Injuries to the skin can then be recorded on incident management systems, in line with each institution’s protocol.

## Management of personal protective equipment- related device-related pressure ulcers

A key element of staff care, and, therefore, prevention, is implementation of rotas with sufficient breaks between shifts, when staff can check their skin for any signs of skin damage, and if there is, relocate to an area where PPE is not required.

Where PPE-related DRPUs have developed, management strategies have also emerged in the literature and are being adopted in clinical practice. Most mild skin indentations regress spontaneously.240 Cold water compresses followed by moisturisers can help, but washing with hot water or alcohol should be avoided. Minor abrasions can be treated with moisturiser, skin sealant, cyanoacrylate or a thin dressing.237,238 For health professionals with open facial wounds, an occupational health specialist should advise on the safety of returning to work. In addition, the availability of an alternative mask that may relieve pressure on the site of the open wound should be investigated.238 Any deep tissue or full-thickness injuries should be referred for professional wound management.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 4 9**

Safe use of devices: prevention and management

## Adhere to instructions for use

Manufacturers should provide instructions for use with their devices, which must consider the risk of DRPUs. 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.

## Medical device industry and manufacturers

### Regulators need to take action

We need to encourage regulators to ensure that medical devices are clearly labelled according to their risk of DRPUs, 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 relevant to DRPUs. Regulators should require companies to comply with these standards and document their devices’ performance in terms of patient safety and DRPU prevention. Regulatory requirements 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.223 Health professionals should be encouraged to report these harms via the appropriate regulatory mechanisms.

### Re-designing medical devices

Computer (finite element) modelling and phantoms can be used to design medical devices that minimise risk of DRPUs.50 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 DRPUs 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 DRPUs. 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, therefore, the risk of deformation injury and pressure ulceration. Quantitative measures were provided by exposure to tissue loads for each design variant.100

In addition, technologies are available that sense interface pressure, shear, temperature and humidity.248,249 Incorporating these technologies into medical devices will help avoid DRPUs.

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

***tracy.c***

*2022-01-24 21:01:02*

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Comment: what happened to spinal alignment?

**S50 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Safe use of devices: prevention and management

device.250

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.

Scrutiny is needed when creating new designs for devices associated with a high risk of DRPUs 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.251

The clinical evaluation plan should evaluate the potential risk of DRPUs that could be attributed to the design. The product will 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 DRPUs 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 DRPUs
* 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 DRPUs (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 (such as 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.252

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 DRPUs. Clinical research evidence should be rigorously collected from all relevant settings to make a strong case to industry and/or the relevant regulatory bodies.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 51**

# Chapter 6: changing the focus of health professionals and policymakers

always, requires a change in the mindset of health professionals, health-service managers/ decision-makers and policymakers working in government and regulatory bodies. The COVID-19 pandemic may have kickstarted this process, although much work remains to be done. Healthcare systems around the world showed during the COVID-19 pandemic how resilient and adaptable they could be in the face of extreme pressure. Once the high rates of DRPUs among COVID-19-positive patients became obvious, multi-disciplinary teams learned quickly and adapted existing knowledge in this area to expand existing procedures and protocols to their management of COVID-19-positive patients.253,254 In some cases, the initial rise in the incidence of DRPUs observed during the first wave began to decline as this learning was put into action.254 However, DRPU rates often remain higher than pre-pandemic levels,13,254 suggesting that further efforts are needed to address the problem. It remains the case that healthcare 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 be trained in how to assess and minimise risk. Administrators will need to understand the potential consequences of DRPUs 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, policymakers will need to recognise the human, clinical and economic

Reducing the incidence of DRPUs, now, as

#### Key points

* Many health professionals and managers underestimate the psychosocial, clinical and economic impact of DRPUs
* There is a need to increase awareness DRPUof s 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.
* lt 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 DRPUs in their facilities
* Policy makers should develop systems in their healthcare settings to protect their staff from the risk of skin damage from PPE

and monitored. This will be best achieved through education, ongoing training and consistent reporting. However, a literature review by Crunden et al. (2021)255 found there are national and international variations in reporting of PUs, with DRPUs often not specified as a separate category, with insufficient detail of devices that might be causing harm.

In terms of reporting, there is a need to formally

minimum dataset

burden of DRPUs.

define a

for reporting pressure-

## Increasing awareness

Before the COVID-19 pandemic, some health professionals and administrators were often not even aware of the importance of DRPUs and their associated risks.14,143 As in the past, chart templates and patient documentation may not pay much attention to DRPU prevention.14 There is still a need, therefore, to raise awareness not only that DRPUs occur, but also that they need to be rigorously recorded

related injuries. Suggestions include capturing the following information: device location, type of securement, PI stage for skin or category (mucosal), date/time, use of preventative measures (for example, barrier products/prophylactic dressings), repositioning and results of skin assessment, and length of time device has been in use.

Preventing DRPUs should not be the sole responsibility of a tissue viability specialist or equivalent: the likelihood of a DRPU prevention

**S52 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Changing the strategies of health professionals and policymakers

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 the risk of DRPUs 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 DRPUs from financial (cost-benefit), legal and insurance (litigation) perspectives. Indeed, in English ICUs between 1995 and 2012, PUs were among the harms that most led to substantial compensation following litigation.256

## Education and training

The key to increased awareness is to monitor and document staff performance to ensure their knowledge and practice of DRPUs is sufficient and up to date. This is best achieved through formal training. Administrators and decision-makers involved in purchasing medical devices need education on DRPUsand practice on its application and secrument. DRPUs. 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 DRPUs.

## 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. Training is most likely to be effective if it includes practical demonstrations and exercises on best practice for the application of specific devices.191 The development of virtual simulation games to encourage engagement with the training process is an interesting

and potentially powerful innovation;257–259 this approach has been employed in delivering the rapid training response needed during the COVID-19 pandemic across a much larger population of health professionals than would be possible with more traditional face-to-face training programmes.260 Development of experts, who are then available to support other staff in their institution has been shown to be an effective strategy.191,261

Health professionals often use only the medical devices that are 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 are most likely to improve outcomes if they are practical, with hands-on, real- time experience. Current understanding of DRPUs and the supporting evidence base should be presented at an appropriate level for the target audience.

The effectiveness of such educational 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.262

## 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

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S5 3**

##### Changing the strategies of health professionals and policymakers

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

* + Regularly inspect the skin near and under the device for skin colour redness, swelling and breakdown
  + Pay particular attention to areas where the skin is depressed by the device any of its components or mechanisms of securement
  + 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 sit or lie on the device and that the device is not trapped between limbs or skin folds
  + 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

example, how to avoid overtightening oxygen masks to the face.262

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, especially at short-notice, such as occurred during the COVID-19 pandemic when non-specialist staff were seconded to staff temporary critical care beds.11

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 DRPUs. 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 DRPUs. They should be taught how to inspect for signs of DRPUs 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.

## Accessing evidence about devices

A critical step in reducing the incidence of DRPUs is to

**S54 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Changing the strategies of health professionals and policymakers

raise awareness about it. Health professionals are the most important link in the awareness chain; they are the people faced daily with DRPUs and the harm they cause. Health professionals can also drive awareness about DRPUs among manufacturers and law and policymakers. 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 DRPUs, ease of implementation and health-economic benefits.

## Role of policymakers and regulators

Policymakers (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. The COVID-19 pandemic has provided much food for thought. The pandemic stress-tested the healthcare system more than ever before, exposing potential weaknesses in procurement, capacity/ demand and skills. Several of these issues are highly relevant in the context of DRPUs. Weaknesses in procurement and supply chain led to shortages of appropriate PPE in some countries, leading to harm to staff. The need in many places to equip additional critical care beds, because of the need to treat massive numbers of severely ill COVID-19-positive patients, may also have led to procurement issues or oversights, including those related to the equipment and consumables needed to prevent DRPUs. This expansion of critical care and expanded use of positioning techniques such as proning, also had implications on staff skills. At the same time as patient numbers were building, and the number of patients needing ventilation support or critical care was increasing, staff numbers were threatened due to sickness or the need to isolate. The result was that often care was provided by health professionals seconded from other wards and who may have lacked key skills, experience and knowledge, for example, how to monitor, assess, record, and prevent DRPUs. Initiation of policies that mitigate against the development of DRPUs in the context of the ongoing

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S5 5**

##### Changing the strategies of health professionals and policymakers

COVID-19 pandemic, is likely to represent a good investment; not only is the COVID-19 pandemic on- going, but the need to address DRPUs remains an unmet need in many areas of healthcare.

It is recommended that organisations have written guidelines on the use of medical devices associated with a high-risk of DRPUs 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; these decisions should not be made solely based on cost as different devices may have different DRPU-related outcomes.

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 DRPUs and/or how they should be applied
* Inviting experts to speak on biomechanics, clinical risk and approaches for reducing the risk of DRPUs
* 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 DRPUs 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 DRPUs 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 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 DRPUs, 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.

**S56 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

# Chapter 7: future research and guidelines for product

development

any devices have not changed in design or the materials used since the 19th century when, for example, respiratory tubing and

M

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 DRPUs, manufacturers have an opportunity to redesign existing devices to reduce the risk of DRPUs. 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 DRPUs. 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 DRPUs 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 DRPUs or mitigation of their risks are available for use in clinical settings

No dedicated protective means have been developed

●

* Health professionals may expect DRPUs 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 DRPUs
* Health professionals, bioengineers and industry need to work closely together to develop designs for medical devices that will reduce the risk of DRPUs
* 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 DRPUs and the role played by device design.221,263 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. It also needs to be appreciated that different face shapes and planes, often related to ethnicity, need to be taken into account in product design.

Nevertheless, these new research advancements

have not yet been incorporated into device designs and medical technologies. The need for dedicated technology and equipment has been highlighted during the pandemic, where changes to clinical practice in some cases forced off-label use of products for skin protection in the absence of dedicated solutions, with the potential risk of adverse skin

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 57**

##### Future research and guidelines for product development

reactions. 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.264 Health professionals are also unaware that they should be pushing for peer- reviewed published evidence from the leading bioengineering and medical/clinical journals.

**Biological structural thermal**

**Small**

**Large**

Reducing the incidence and prevalence of DRPUs 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 DRPUs. 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 DRPUs appears to be an unrealistic goal, given the current research, development and technological gaps identified in this

document. However, where knowledge and best practice can be deployed effectively, DRPUs 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

**S58 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Future research and guidelines for product development

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: DRPUs, 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.

## 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, if 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 or respiratory 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,

**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

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 5 9**

##### Future research and guidelines for product development

**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

while still allowing the mask to fulfil its medical purpose.

All 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.214,265 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 inadvertently 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,100,136,251,266 and informed and reinforced with laboratory experiments, including with use of phantoms, dummies or mannequins.267

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, children, 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.

Health professionals should clearly express their clinical goals 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

**S60 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Future research and guidelines for product development

should focus not only on the device’s primary clinical goal(s), but also on the parallel goal of minimising DRPUs.

Health professionals may wish to consider undertaking clinical research into the causes, prevention, and psychosocial effects of DRPUs, 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 DRPUs 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 DRPUs 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

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 DRPUs, based on (expected or assessed) individual tissue tolerance and physiology.

Researchers could also 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,248 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

have the potential to influence administrators and

decision-makers.

stress at the

prosthetics.248

limb residuum

or socket interface for

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 3D, anatomically realistic body parts of children, adults and older patients (including cachectic or obese patients, and those of differing ethnic backgrounds 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

The COVID-19 pandemic has also revealed knowledge gaps relating to the use of PPE by health professionals. Little is known about the long-term effects of DRPUs on the skin and the susceptibility of some people to skin injury. Testing of PPE beyond effectiveness of the seal has also not been rigorously explored; this has major safety implications not only in terms of protection from infectious disease, but also in terms of risks of DRPUs and other harms.

## Emerging technologies for prevention

Key areas for innovation in emerging 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 DRPUs, to ensure their

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S 61**

##### Future research and guidelines for product development

mechanical properties are not impaired with use or over time

* + Sensing technologies that accurately detect biomechanical factors associated with DRPUs, 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. Some of these technologies that are being successfully used in the clinic, such as infrared and SEM are described in chapter 4
  + 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
  + Artificial intelligence and telemedicine for remote assessment and monitoring of DRPU prevention strategies. Apps to help provide DRPU-related information may be well received. Novel technological approaches to the training of health professionals, for example introduction of training via ‘gaming’ technologies is becoming possible and has been discussed in chapter 6
  + Bespoke medical devices designed specifically to fit the individual. Although mass produced devices

predominate, it is possible to create bespoke devices using technologies such as 3D printing. In particular, during the pandemic 3D printing was used to generate generic PPE, to combat shortages.244 The potential for creating bespoke medical devices that fit the unique contours of an individual person, are most associated with prosthetics;268 the use of this technology for production of medical devices needed for acute medical care, such as those needed during ventilatory support have not been explored. Also, while bespoke medical devices may have the potential to protect patients from the risk of developing DRPUs, to date, this has not been explored. Most masks have been designed for a typical 'white male' face and are, therefore, not suitable for many females, non-typical males, and people of other ethnic origin.47 It is possible that, in the future, 3D printing of masks and goggles may be able to produce truly personalised PPE for each individual wearer. A centre in Australia is currently developing bespoke proning cushions that fit the contours of individual faces. These will be evaluated in proning simulation studies, followed by a clinical pilot trial. It is hoped that, ultimately, this will lead to the development of proning pillows, and, therefore, a reduction in DRPUs. Nevertheless, these technologies are not scalable, and more progress is needed.

* For the successful adoption and implementation of

any new technology, cost-benefit assessment is important.

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

**S62 JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

##### Future research and guidelines for product development

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 and analysis technologies for pressure, shear stress, microclimate and other biomechanical markers and measures are already available or in development,96,248,249,252,262 as are biocapacitance examinations based on measurements of extravasated tissue fluid (an early marker of inflammation).186 can also be used to assess physiological

Ultrasound

changes in tissue.269

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 currently. Furthermore, the optimal chemical biomarkers, which may be a combination of different types of markers, have yet to be identified.70

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.

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

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, for example, 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.

It may also be possible to combine multiple technologies into one integrated system, thereby streamlining the need to monitor multiple sensors. This approach has been used successfully in the management of PUs, by integrating a textile-based pressure sensing matrix and a mattress to create a 'smart' bed.270

Data would also be available to demonstrate whether 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.

the device or turning the

the device off.

Future technologies

heat-generating

may minimise

element of

or even

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

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

Dedicated protective technologies, smart materials or structures, and tissue and environmental

improvement, integration, scaling and commercialisation that require effort, time, translational research, and investments. Understanding the scale and threat of DRPUs 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 DRPUs.

**JOURNAL OF WOUND CARE** CONSENSUS DOCUMENT VOL 29, NO 2, FEBRUAR Y 2022

**S6 3**

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**S 67**

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