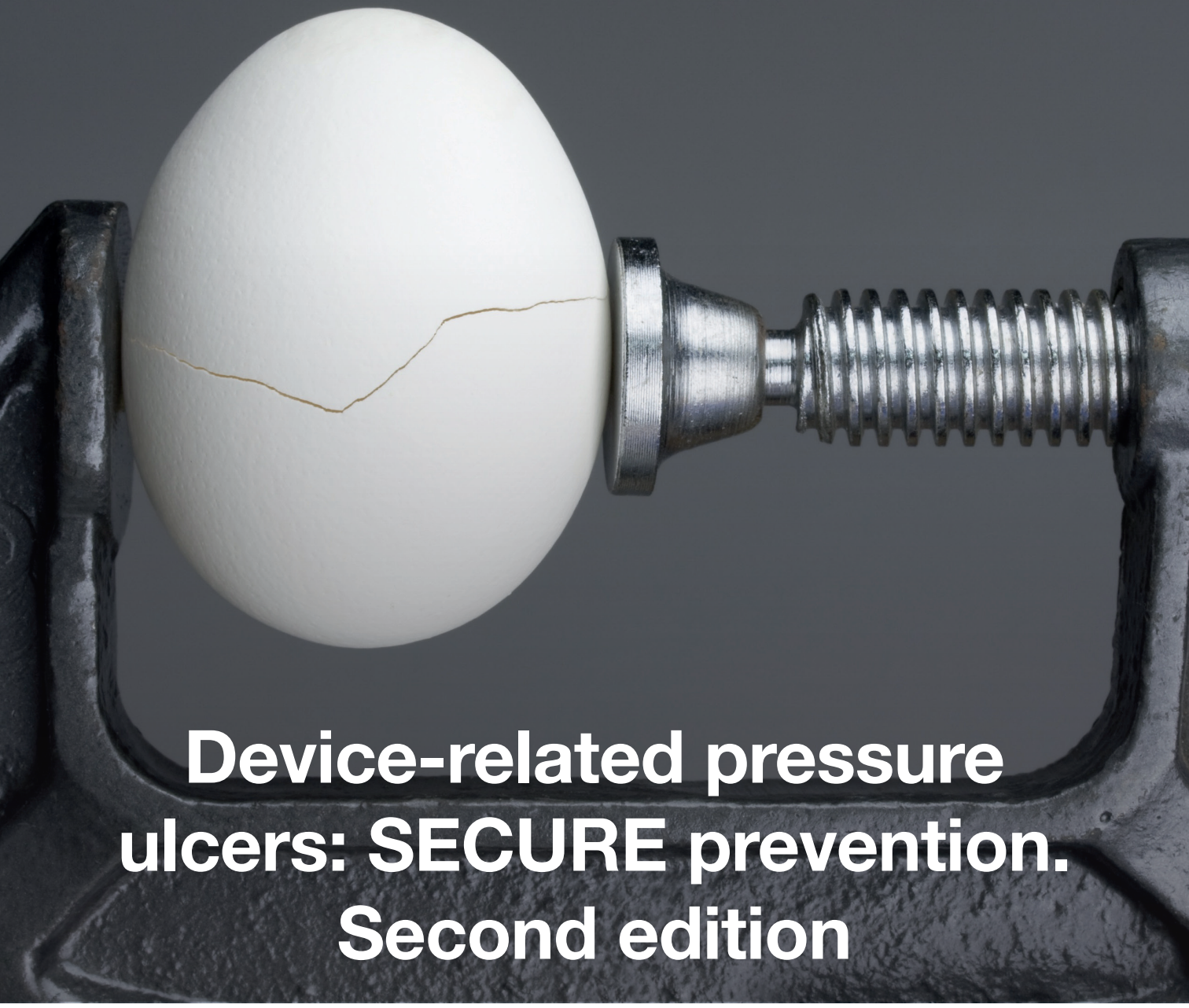
JWC International Consensus Document



Device-related pressure ulcers: SECURE prevention. Second edition

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Authors

Amit Gefen PhD, Professor of Biomedical Engineering, The Herbert J. Berman Chair in Vascular Bioengineering, Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Tel Aviv, Israel

Paulo Alves RN, MSc, PhD, Assistant Professor and Coordinator, Wounds Research Laboratory, Catholic University of Portugal, Institute of Health Sciences, Centre for Interdisciplinary Research in Health, Lisbon, Portugal

Guido Ciprandi MD, PhD, Chief Wound Care, Surgical Unit, Division of Plastic and Maxillofacial Surgery, Bambino Gesu' Children's Hospital, Research Institute, Rome, Italy

Fiona Coyer RN, Dip Nurs, PGCEA, MSc Nursing, PhD, Professor of Nursing (joint appointment), Intensive Care Services, Royal Brisbane and Women's Hospital, School of Nursing, Queensland University of Technology, Brisbane, Australia. Visiting Professor, Institute for Skin Integrity and Infection Prevention, University of Huddersfield, UK

Catherine T Milne MSN, APRN, ANP/ACNS-BC, CWOCN-AP, Connecticut Clinical Nursing Associates, Bristol Hospital Wound and Hyperbaric Medicine, Bristol, Connecticut, US

Karen Ousey PhD, RGN, MA, PGDE, BA, RN, FHEA, CMgr MCMI, Professor of Skin Integrity, Director, Institute of Skin Integrity and Infection Prevention, School of Human and Health Sciences, Huddersfield University, UK; Clinical Professor, Queensland University of Technology, Australia; Visiting Professor, Royal College of Surgeons in Ireland, Dublin, Republic of Ireland

Norihiko Ohura MD, PhD, Professor, Department of Plastic, Reconstructive and Aesthetic Surgery, Kyorin University School of Medicine, Tokyo, Japan

Nicola Waters PhD, MSc, RN, Senior Research Associate, Health, The Conference Board of Canada; Adjunct Professor, School of Nursing, University of British Columbia Okanagan, Kelowna, British Columbia, Canada

Peter Worsley mCSP PhD, Associate Professor in Rehabilitative Bioengineering, Clinical Academic Facility in the School of Health Sciences, University of Southampton, UK

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Editor: Tracy Cowan
Medical writers: Jerry Hutchinson and Jenny Smith
Project manager: Angela Shaw
Design: Fonthill Creative
Managing director: Anthony Kerr, anthony.kerr@markallengroup.com

Published by: MA Healthcare Ltd, St Jude's Church, Dulwich Road, London, SE24 0PB, UK
Tel: +44 (0)20 7501 6726. Web: www.markallengroup.com

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MA Healthcare

Executive summary

Although great strides have been made to tackle hospital-acquired pressure ulcers (HAPUs), there is a need for greater recognition of device-related pressure ulcers (DRPUs), including their causes, management and prevention. This consensus statement, an updated second edition, aims to continue raising awareness of these largely preventable injuries and, crucially, to stimulate action.

DRPUs are relatively common and account for a growing proportion of HAPUs. Updated information on the incidence of DRPUs is described in chapter 1. Although it is recognised that DRPUs increase the financial burden of healthcare, there is little formal analysis of their economic impact. This needs to be addressed; robust evidence on the burden of DRPUs and the value that can be released by adopting prevention strategies is needed to help drive action.

Our understanding of the pathophysiology of DRPUs has improved significantly over the past few years; this is described in chapter 2. One 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 onto the body. Devices and their securement may generate high stress concentrations in tissues, leading to cell and tissue-damage pathways associated with sustained deformation.

As more evidence is published on DRPUs, recurring themes are emerging, as outlined in chapter 3:

- The most vulnerable patients are bearing the brunt of DRPUs; paediatric and neonatal patients, and all those needing critical care are particularly susceptible. During the COVID-19 pandemic, a new high-risk population (people with severe COVID-19 infection) emerged. They are at increased risk of DRPUs because of their need for prolonged ventilatory support, especially when 'proning'
- Devices associated with DRPUs are often used to perform essential, life-saving functions. They include continuous positive airway pressure (CPAP) masks or endotracheal tubes. Minimising their use is clearly not an option, so practice innovation is needed
- Although the most common locations for DRPUs are the face, ears, lower legs and heels, any location where a device comes into close contact with the skin can be at risk. In the same vein, any device, whether needed for a medical purpose or not, has the capacity to cause injury if its use is not properly managed. Vigilance is needed for all patients.

What can be done? The importance of routine risk assessment is covered in chapter 4. Although use of a validated risk assessment tool is the vital first step, this will not be enough on its own. Several steps can be taken to ensure the safe use of devices. These are described in chapter 5 and include device repositioning, cushioning with prophylactic dressings and moisture control (only where possible and clinically appropriate). Of key importance is the development of an institutional protocol and champions to ensure all necessary steps are adopted.

For any of these changes to be put into practice, awareness of DRPUs needs to increase. A number of proposals are outlined in chapter 6. A change of focus among health professionals and policy makers, along with more investment in education and training, are needed. All patients being managed with a medical device must be considered as at high risk.

The pandemic introduced the world to the problem of DRPUs in health professionals caused by the extended wear of personal protective equipment. Health professionals also have a right to expect institutional protocols and provision of devices that protect them from DRPUs.

Cutting-edge ideas and technologies that may be available in the future are described in chapter 7. When designing new products, manufacturers of medical devices have a duty of care to investigate the risks of DRPUs associated with their products and mitigate them, wherever possible. Our developing understanding of how the design, structure and materials used in medical devices contribute to DRPUs will help us develop new solutions for tomorrow.

The first step is for everyone involved to ask themselves, 'what can I do to help?' There is work to be done—your journey to reduce DRPUs starts here!

Contents

Foreword

In February 2019, an international group of medical, clinical and bioengineering experts met in London to develop the first edition of an international consensus statement on device-related pressure ulcers (DRPUs). Following a rigorous process of scientific discussion, the statement was drafted, reviewed by an international independent committee of external experts and published in *JWC* in February 2020[1] shortly before the breakout of the COVID-19 pandemic. It was, at the time, the most comprehensive synthesis of understanding of the aetiology of DRPUs and the technologies and clinical protocols that can be used to mitigate them.

The pandemic was, and still is, a game-changer, as it instantly brought the effects of DRPUs into sharp focus, particularly in regard to the use of ventilation equipment and the management of critically ill patients in the prone position for prolonged periods.

With the rise in reports of DRPUs and the change in global circumstances, the topic of prevention and treatment of this form of skin damage became more time-sensitive than ever. The expert panel recognised this early during the pandemic and, as a first reaction to the change in circumstances, published an update article, to complement the consensus statement. This focused on skin damage under personal protective equipment (PPE) in health professionals—a new category of DRPUs that had not been widely experienced in our lifetime prior to the pandemic.[2]

This was not sufficient to capture the knowledge generated over the course of the pandemic. To continue supporting patients and health professionals, the consensus panel gathered in March 2021 to update their consensus statement, sharing the knowledge collected and the lessons learned since the first edition was published. The aim was to provide frontline staff with updated, clear, simple guidance on how to mitigate the risk of DRPUs during the pandemic and beyond, with in-depth content on the development and implementation of long-term prevention strategies.

Like its predecessor, this second edition is aimed at generalists and specialists, as well as biomedical and non-biomedical engineers and other health professionals in clinical practice, academia, research and industry. It starts by updating the aetiology and pathophysiology of DRPUs, explaining how medical devices and objects that encounter the skin and apply forces onto it can cause cell and tissue deformation. This is followed by the assessment, prevention and management of DRPUs, including under the current pandemic circumstances.

The consensus statement discusses the devices that are most associated with DRPUs and the biomechanical reasons for the risks they pose, with reference to the most recent scientific and medical literature. It also aims to inform policymakers and health professionals at all levels on the critical need for DRPU prevention through identification of the root causes, the scale of the problem, the damage they pose to quality of life, and the financial implications for institutions, insurers and governments.

Greater awareness of the growing problem of DRPU formation will lead to better adoption of prevention protocols and much-needed new preventive technologies and design improvements. This edition, therefore, specifies the revised requirements that should inform the development of medical technologies for the prophylaxis of DRPUs; these relate to the shape, materials and construction features of medical devices, with reference to their effects on the skin and underlying tissues.

In conclusion, under the historical circumstances of the COVID-19 pandemic, we felt it was critical to regroup the team of global experts to record their detailed advice on the prevention and treatment of DRPUs. We are pleased to present this second edition, which reflects these multidisciplinary international efforts. It is a cornerstone in our persistent struggle to mitigate DRPUs during the pandemic and beyond.

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, Ousey K. Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage. J Wound Care. 2020; 29(5): 245–59. https://doi.org/10.12968/jowc.2020.29.5.245

Aims and terminology

Purpose of this document

For this second edition, the panel met virtually to address the need for greater recognition of device-related pressure ulcers (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 a focus on why devices are associated with pressure ulceration
- Devices, both medical and non-medical, associated with DRPU formation
- Assessment of patients with DRPUs
- Safe use of devices to prevent or manage DRPUs, including the impact of altered processes of care that have occurred as a result of the COVID-19 pandemic for both patients (eg, the increased use of proning), health professionals (eg, the prolonged use of personal protective equipment (PPE)) and the general public
- 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 the prevention of DRPUs, with particular reference to product design, regulation and monitoring technologies.

The ultimate objective of this consensus statement 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 the National Pressure Injury Advisory Panel (NPIAP; formerly National Pressure Ulcer Advisory Panel)[1] and the Pan Pacific Pressure Injury Alliance (PPPIA). 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 different categories of PUs have been summarised by the NPIAP.[1] 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.

1. National Pressure Ulcer Advisory Panel (NPUAP). Pressure injury stages. 2016. https://tinyurl.com/tu3kjwh (accessed January 2022)

Glossary of abbreviations

- BIPAP: bilevel positive airway pressure
- CPAP: continuous positive airway pressure
- DRPU: device-related pressure ulcer
- DVT: deep vein thrombosis
- ECG: electrocardiogram
- ECMO: extracorporeal membrane oxygenation
- EEG: electroencephalogram
- EPUAP: European Pressure Ulcer Advisory Panel
- HAPU: hospital-acquired pressure ulcer
- ICU: intensive care unit
- IPC: intermittent pneumatic compression
- MDRPU: medical device-related pressure ulcer
- MMP: matrix metalloproteinases
- NIBP: non-invasive blood pressure cuffs
- NIPPV: non-invasive positive pressure ventilation
- NIV: non-invasive ventilation
- NPIAP: National Pressure Injury Advisory Panel
- NPWT: negative pressure wound therapy
- NSRAS: neonatal skin risk assessment scale
- PPE: personal protective equipment
- PPPIA: Pan Pacific Pressure Injury Alliance
- PPUPET: paediatric pressure ulcer prediction and evaluation tool
- PU: pressure ulcer
- RCT: randomised controlled trial
- ROS: reactive oxygen species
- SEM: sub-epidermal moisture
- SIRA+P: skin injury risk assessment and prevention
- TEWL: transepidermal water loss

Chapter 1: introduction

Pressure ulcers (PUs) are defined by the European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Injury Advisory Panel (NPIAP, formerly known as the NPUAP) and the Pan Pacific Pressure Injury Alliance (PPPIA) as:[1]

'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 pressure ulceration. 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):[2]

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

'A DRPU involves interaction with a device or object that is in direct contact with skin ... or is transdermally implanted under the skin, causing focal and localised forces that deform the superficial and deep underlying tissues. A DRPU, which is caused by a device or object, is distinct from a PU, which is caused primarily by body-weight forces. The localised nature of 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 DRPU focuses the health professional and others on pressure ulceration caused by contact with medical devices only. Importantly, a 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 pressure ulceration may be related either to medical or non-medical devices. This is covered in more detail in chapter 3.

Key points

- A 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 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, its causes, management and prevention to support practice innovation, research and device regulation. This document is intended to stimulate action

Briefly, medical devices associated with pressure ulceration 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) equipment, indwelling lines, monitoring devices such as pulse oximetry, or assistive devices such as orthotics, prosthetics 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 their bed or support surface, such as mobile/cell phones and jewellery. During the COVID-19 pandemic, many forms of skin damage resulted from PPE and the prolonged use of respirators.

Like a PU, a DRPU can be categorised as I–IV, unstageable or deep tissue pressure injury, depending on its depth and the number of tissue layers involved.[2] However, DRPUs 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.[3] 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 is not staged but referred to as a mucosal DRPU.[4]

International pressure ulcer guidelines

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

The 2019 EPUAP/NPIAP/PPPIA guideline is the most widely cited. This consensus statement has taken account of guidelines used globally, including those from the EPUAP/NPIAP/PPPIA.[1,2]

Epidemiology

Patients managed using medical devices are more likely to develop a PU or skin breakdown; DRPUs are relatively common.[3,5] For example, in an US hospital setting, the overall rate of PUs in inpatients was 5.4%, of which 34.5% were DRPUs.[3] 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.[6,7] 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,[8] 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.[9–11] Some studies reported that around three-quarters of all DRPUs were among patients with a COVID-19-positive diagnosis.[10,12]

Some trends quickly emerged. One concern was the development of DRPUs related to the use of invasive and non-invasive ventilation equipment.[9] 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 on the face and PUs occurring in areas not usually reported, such as the nipples or genitalia.[12] A third high-profile observation related to health professionals at the frontline of the pandemic having to wear PPE for prolonged periods, which resulted in DRPUs and other skin reactions.[9]

The COVID-19 pandemic has been, and still is, a game-changer in the context of DRPU formation. Whereas previously, DRPUs were an understudied area, the increasing incidence observed during the pandemic and the changes in ways that patients are positioned—which makes it more complex to position and check devices—has certainly raised the profile of this issue. During the first waves, much was learned about the risks of DRPU formation, and many insights into how the risk can be reduced have since been

Table 1. Summary of the incidence and prevalence of DRPUs

	Reference	Setting details	Finding
Overall	Black et al.[3]	US hospital inpatients (n=2079)	PU occurrence: 5.4% DRPU occurrence: 34.5%*
	Jackson et al.[8]	Systematic review of 29 studies (126,150 eligible patients)	Pooled DRPU incidence: 12% Pooled DRPU prevalence: 10%
Data from intensive care settings	Barakat-Johnson et al.[14]	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%)
	Coyer et al.[169]	Patients in six ICUs in two major medical centres (one in the US and one in Australia)	DRPU incidence: 3.1%
	Wille et al.[17]	125 patients in a surgical ICU	Frequency of pulse oximeter-induced digital injury: 5%
Data from other settings	Kyorin University Hospital unpublished DRPU audit	ICU and general wards in a Japanese hospital	DRPU incidence in ICUs: 2.8% DRPU incidence in general wards: 0.14%
	Schlüer et al.[274]	204 children in 13 Swiss hospitals	Prevalence of PUs: 26.5% Prevalence of DRPUs: 38.5%
	Visscher and Taylor[25]	741 neonatal intensive care patients	Premature neonates: 1.5 PUs per 1000 days Term infants: 2.7 PUs per 100 days
	Jiang et al.[229]	Health and non-healthcare professionals in 161 hospitals in China	Prevalence of skin injuries: 42.8% Prevalence of DRPUs: 30%
	Rosner et al.[233]	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*

DRPUs—device-related pressure ulcers; ICU—intensive care unit; PU—pressure ulcer; CI—confidence interval

developed and published, representing a huge and rapid advance in this field.

The pandemic is likely to continue to affect global healthcare systems and it is anticipated that the associated increased risk of DRPU formation 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 patients and are well prepared to manage the wider issue of device-related pressure ulceration.

Occurrence by setting

Devices used in intensive care are particularly associated with DRPUs.[13–15] 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.[14] Since this review, Coyer et al. reported a DRPU prevalence of 4.3% in intensive care patients.[16] Wille et al. stated that the overall incidence of DRPUs

or skin breakdown caused by pulse oximeters in a surgical ICU was 5%.[17] Mehta et al. reported that the point prevalence of DRPUs in a ICU setting was 19.2%.[18]

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, demonstrated the difference between ICU and general wards. The incidence of DRPUs in ICUs was 2.8%, which is consistent with published data. On general wards it was 0.4%. This lower incidence is likely to be a result of the higher number of devices used in ICU compared with general wards. Table 1 summarises the key results of DRPU incidence and prevalence data.

Neonates, infants and paediatrics

DRPUs have been reported in around 7% of all paediatric patients.[19,20] They are more common in younger children and can account for up to one 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.[19,21–24] Infants who develop DRPUs are likely to be younger post-partum, with a shorter gestation; they develop DRPUs more rapidly than patients with PUs caused by body weight.[25] Mechanical ventilation and a respiratory diagnosis are associated with higher risk of DRPU formation.[26] In newborns, devices may severely and permanently affect and distort nasal cartilage.[27] The incidence of DRPUs in paediatric patients may be as high as 28%, with non-invasive mechanical ventilation associated with ulceration (relative risk ratio 12.24).[15,28–34]

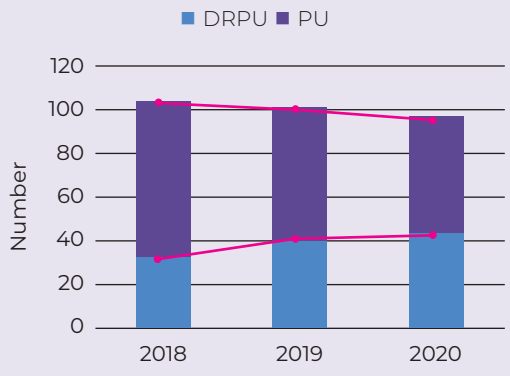


Fig 1. Change in the proportion of DRPUs in recent years in a single institution. Over a three-year period, despite a small overall decline in the number of PUs generally, the proportion caused by medical devices (DRPU) increased from 32% (33/104) in 2018 to 46% (44/96) in 2020. Data provided by Guido Ciprandi.

DRPU–device-related pressure ulcer; PU–pressure ulcer

Data collected by an author of this document in a single paediatric hospital 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 past decade mean that neonates, infants and children with 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 ICU and interventions involving multiple medical devices. Data presented in Fig 1 show that, as a result of this general trend, there was an increase in DRPUs in paediatrics treated in this hospital. During this three-year period, there were noticeably more DRPUs than PUs during the first year of life (n=69 neonates): 44 (37%) and 25 (14%), respectively. In line with the literature, DRPUs were most commonly observed in the occiput, ear, foot and amputation stump, with orotracheal and nasogastric tubes, central lines and ventilation masks being the main culprits. 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;[18,35] up to 68% of DRPUs are associated with respiratory devices,[13] of which 20% are linked with BIPAP or CPAP devices, where ulceration occurred on the bridge of the nose, cheeks and/or nasolabial fold.[6] The incidence of DRPUs 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.[36] Prevalence of skin breakdown may be over 14% in general-hospital patients with respiratory failure managed by NIV or CPAP.[5] This has been particularly obvious during the pandemic.[10] Many other types of devices can be associated with increased risk of ulceration including cervical collars, nasogastric tubes, drains, compression stockings, temperature probes, blood pressure cuffs, central venous catheters and many more.[7,18,37–40]

Occurrence by anatomical location

In terms of anatomical location, a national audit of PU prevalence in the US reported DRPUs most often occurred on the head and heels.[41]

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

Costs associated with PUs in general are widely reported and are extremely high. In the US, the total cost of HAPUs has been estimated at $26.8 billion.[42] 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.[43]

These figures are not directly comparable due to 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.[44]

Box 1. Health-economic burden associated with DRPUs

- Medical costs of PU management
- Health professional time
- Personal impact on the patient
- Reduced quality of life for patients and their families
- Psychological and emotional impact, such as disfigurement of the face and head
- Reimbursement withheld for HAPUs
- Financial penalties in some jurisdictions
- Litigation costs
- Damage to the 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)[45]
- Cost of changing medical intervention—for example, when CPAP fails in neonates, some need to be re-intubated[46] or an alternative securement method needs to be used to avoid contact with the injured area—and expense of managing complications, such as wound infection and increased length of hospital stay

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

There is little or no published evidence on the costs associated with DRPUs. Costs of managing DRPUs are likely to include a wide range of expenses, such as treatment costs, health professionals' time needed to manage the wound and, in some jurisdictions, fines or litigation costs (Box 1). The indirect costs associated with litigation and insurance (in premiums or loss of coverage) can be substantial as most DRPUs are hospital acquired. Lawsuits 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 costs (economic and other) of DRPUs.[45,46] 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 patients disfigured by 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 from an early stage.

DRPUs represent a large economic burden for 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 for patients, families and healthcare institutions.

Implicated factors

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, neurological disease or young age (infants and toddlers)
- The patient's inability to reposition the device themselves[3]
- Duration of device use
- The need to secure a device tightly to ensure correct function and adequate life-support measures[5,47]
- 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 provision of education 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. 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 sizes, 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 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 by suppliers and clinical educators on device application
- Many individuals have comorbidities or facial/body morphology that limit their tolerance to mechanical loads on vulnerable skin and soft-tissue sites, and/or that lead to uncontrolled oedema and a hostile local tissue microclimate. Fluid resuscitation can lead to uncontrolled oedema, with securement straps exerting pressure
- Lack of awareness among health professionals of the importance of repositioning; offloading; using rotating devices, when possible; or correctly fitting or securing devices. 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 a DRPU not being identified.[3]

DRPUs have an adverse impact on the patient by causing additional morbidity and reducing quality of life. This often extends beyond discharge—for example, in cases of visible scarring, including where there is a potential loss of range of motion, and permanent hair loss. Nevertheless, due to its therapeutic purpose, use of the device needs to continue.

Chapter 2: pathophysiology

This chapter reviews the pathophysiology of PUs and DRPUs. DRPUs are caused by the same mechanisms as PUs. Table 2 summarises the key similarities and differences between PUs and DRPUs.[48] 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).[1,4,24,49–56]

Key points

- Principal causes of 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 is much thinner, lacks padding and the cartilage is immature; therefore, injury can affect the deeper layers, down to the skeleton

Cell deformation

Patients who develop PUs frequently have multiple risk factors and comorbidities.[57–59] 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 compression, which is always combined with shear, causes local ischaemia by occluding the microvascular network of capillaries in skin and deeper tissue.[60]

Pressures required to cause local ischaemia depend on the magnitude of the shear and the individual's vascular functionality (cardiovascular system health).[56,61,62] Inflammatory changes initially occur in tissues directly exposed to sustained force and deformation.[63,64] 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.[65] Fig 3 shows how progressive loss of cytoskeletal and plasma-membrane integrity in these cells impairs their control over mass transport and homeostasis.[66] Inflammatory mediators,[63] secreted from damaged and nearby immune cells, lead to progressive inflammatory oedema, which increases interstitial pressures and the mechanical distortions of cells and tissues, and causes growing obstructions within the vasculature and lymphatics.[67] Damage may be amplified in ischaemic tissue after reperfusion through the release of reactive oxygen species (ROS), termed reperfusion injury.[68]

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.[69] Tissue-engineered living model systems indicate that skeletal muscle tissue is irreversibly injured by sustained deformation after approximately one hour of loading.[70] 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.[63,64,71] In contrast, the time it takes for purely ischaemic muscle damage to develop is 6–8 fold longer.[72]

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 occurs in Parkinson's disease.[73] In these fragile cases, inadvertent damage from friction burn is frequently observed.[74–77] 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 that can cause skin damage—for example, these forces may be exerted on their heel(s) as they push with their feet in order 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.[78]

Frictional forces acting on the skin are affected by the local microclimate, with increased skin hydration, increasing the coefficient of friction by 26–43%.[79] Use of prophylactic dressings to prevent pressure ulceration has been shown to reduce the coefficient of friction, when compared with moist skin on bed linen, thereby reducing the risk of pressure ulceration.[80]

Table 2. Overview of features associated with PUs and DRPUs (adapted from Bader et al.[48])

	Pressure ulcers	Device-related pressure ulcers
Aetiology	Both result from physiological responses of soft tissue involving cells, the interstitial space within the ECM and blood and lymph vessels, with the importance of each depending on different magnitudes of strain and time[275]	
Cause of deformation-induced damage	Gravitational forces due to body weight	Caused by external forces applied by the device (strapping, tape and other securement methods)
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 ICU, patients with diabetes; patients who cannot communicate discomfort or pain; patients with oedema following fluid restriction; patients with oxygen desaturation; and critically ill patients who require continuous monitoring. Skin and soft-tissue sites with previous damage. Caregivers managing COVID-19 patients and wearing PPE for prolonged periods without breaks
Nature of devices	Examples of medical devices include support surfaces, cushions, mattresses, bedside chairs, toilet seats and flooring (in the event of a fall), based on individual risk	Generic designs of medical devices not matched to individual characteristics. Masks, goggles, respirators, protective gloves, particularly grade 3 PPE Non-medical devices, such as cell/mobile phones
Prevention strategies	Pressure redistribution/relief and periodic repositioning	Improved design of devices; pressure relief through application of an alternative device; adequately designed prophylactic dressings or gel pads, strips or tubing
Vulnerable tissue areas	On or adjacent to bony prominences, such as the 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 the support-surface design, incontinence containment products, ambient conditions and the individual's sweat response and clothing	Affected by device interface, including any seal the device creates with the skin, or therapeutic heating or humidity

ECM—extracellular matrix; ICU—intensive care unit; PPE—personal protective equipment

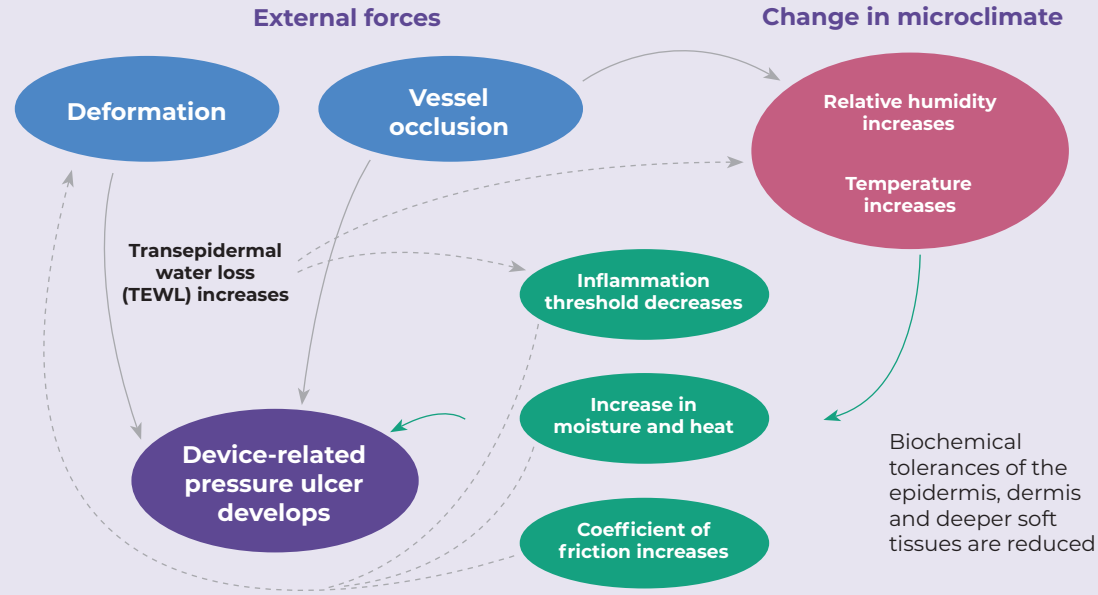


Fig 2. Factors involved in DRPU formation (adapted from Kottner et al.[276])

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 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 medical device, 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.[81] The tissues may be damaged because of either the physical force (which causes necrotic cell death and mechanical failure of the ECM)[82] 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.[4]

Microclimate

Changes in skin physiology and its microclimate can lead to a higher risk of DRPU formation. 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:[83]

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

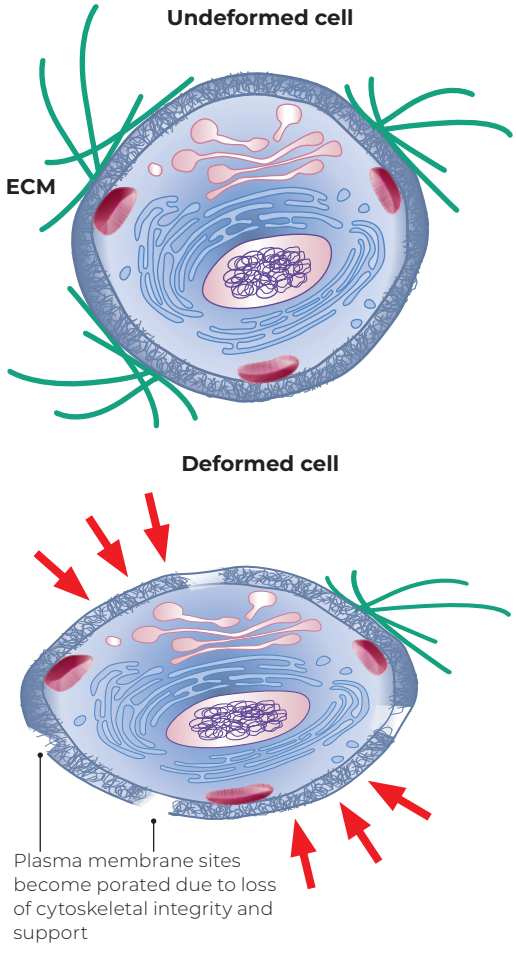


Fig 3. Loss of cytoskeletal and plasma membrane integrity in cells impairs their control over mass transport and homeostasis

Excessive moisture at the skin interface and subsequent overhydration leads to softening of the stratum corneum, increased permeability, susceptibility to irritants, disruption of the intracellular lipid lamellae barrier and tissue breakdown by faecal or urine enzymes. Urine and faeces contain corrosive enzymes; wound exudate contains matrix metalloproteinases (MMPs) which can degrade soft issue; saliva that drips onto tracheostomy tubes also contains corrosive enzymes that can denude the skin.[55]

Dry or under-hydrated skin is more susceptible to mechanical damage, cracks, fissures and inflammation because the structural stiffness of the epidermis increases. Dry skin may also be a contributory factor in PU development,[84] although the role of moisture in DRPU development remains uncertain and more research is needed.[85]

Warmer skin markedly increases the metabolic tissue demand for cellular oxygen and nutrients, making it more susceptible to ischaemic damage when subjected to pressure and shear.[60] Therefore, temperature changes adjacent to the skin are associated with local physiological changes. These include an increase in cutaneous stiffness under loading conditions,[86] a decrease in dermal-epidermal adhesion and an increase in metabolic demand.[87] As a result, the skin may be less able to deform and is more 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.[88–91]

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.

ROS and proteinases further degrade the tissue,[91,92] eventually leading to visible tissue damage.

The amount of time in which the tissues are continuously distorted has a critical effect on whether or not a DRPU develops.

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 who have lymphoedema or heart failure, localised or general oedema can develop after a device has been fitted or when placed in the prone position.[3,92]

Oedema increases the volume of tissue under the device, resulting in cell and ECM distortion; meanwhile, 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 ulceration. Health professionals sometimes tighten fixation systems to avoid device failure and prevent 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 shows an example of a DRPU related to oedema.

Device type and 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.[93] 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 the clearance of waste products is impaired.

Medical devices, such as oxygen masks for NIV,[94] are sometimes held in place with elasticated straps or tapes. These immobilise the device, but generate 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,[95] 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 to as much as 158mmHg when additional tension is applied.[71] Oximeter devices clipped onto the earlobe may apply marked local pressure.[96] Humidified therapies may increase the amount of moisture present, in turn increasing the risk of ulceration.[97] Securement devices and techniques to secure endotracheal and trachestomy tubes—for example, tapes applied across the face or twill placed on the back of the neck—can cause DRPUs.

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.[64,98,99]

Risk factors

Small-scale studies have produced preliminary data for DRPU risk factors.[100–102] 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. The affected soft tissues may also be 'sandwiched'—that is, compressed, stretched and sheared between the device and bony surface. It should be noted that there are examples of DRPUs caused by body weight, for

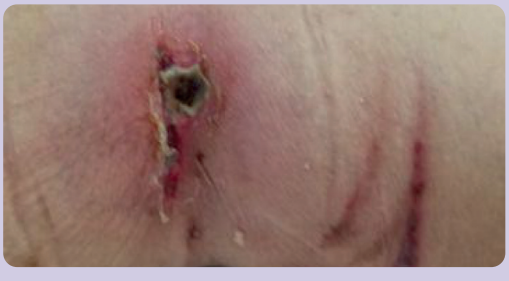


Fig 4. DRPU related to oedema: the sustained deformation-inflicted injury has triggered an inflammatory response[39]

example due to prosthetics (stump ulcers) and foot orthotics. In addition, body weight can play a role if a device does not fit properly and gets lost within the skin folds.

Often, a 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.[71] Of particular note are large pressure gradients (where there is an area of high pressure adjacent to an area of low pressure) that occur, which can cause large stresses and strains in the underlying skin and soft tissues.[103–105]

Devices such as anti-embolism stockings or sequential compression devices are often used inappropriately with no assessment of underlying perfusion or sensation, and may be incorrectly measured and applied. This can 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.[48] This is not the case with more traditional PUs, where sacral, ischial and heel tissues are regularly exposed to pressure and shear forces when the individual lies or sits down, and so have adapted over time to accommodate this—for example, with the development of callus on the heel.

In general, when patients are unable to communicate discomfort, pain and the need for repositioning, this can result in loads that lead to ulceration.[106] Patients at risk of developing DRPUs can include those who are agitated, under anaesthesia, receiving analgesia, unconscious or partially conscious and/or 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.[107] More recently, patients with severe COVID-19 also appear to be experiencing a relatively high proportion of DRPUs.[10,11]

COVID-19

Health professionals had to wear PPE for extensive periods during the pandemic. Extended use of eye wear and respiratory masks led to injuries on the bridge of the nose, upper cheek, forehead and ears. These injuries are similar to those observed in patients wearing masks for NIV for extended periods.

Although COVID-19 itself does change the basic mechanisms of pressure ulceration, several factors might make COVID-19-positive patients more susceptible to skin injury.

First, the intensive use of medical devices and body positioning has increased the risk of ulceration. The longer use of medical devices, proning and securement of endotracheal tubes to avoid dislodgement inevitably leads to more prolonged tissue deformation and inflammation, with a greater risk of tissue breakdown. In addition, in some patients, pharmacological treatments for severe COVID-19, including hydroxychloroquine (where it is licensed for use) and remdesivir have been linked to the emergence of skin problems, so-called drug eruptions, which can affect skin integrity.[108]

Second, COVID-19 itself has been observed to exacerbate pre-existing inflammatory skin conditions.[108] Several dermatological problems thought to be caused by the virus have emerged during the pandemic. Inflammatory dermatosis, skin vasculitis, vascular dermatosis, erythematous rash, urticarial lesions and chickenpox-like vesicles have been described.[109–112] Purpuric changes, which include COVID toes, also known as acro-ischaemic legions,[113] are thought to be linked with viral-induced

hypercoagulation and microvascular occlusion.[111,114,115] These manifestations, which appear at various points of the disease, have been associated with long-term changes to the skin in some individuals.[109,110,116]

Purpuric features of pressure injuries have been noted in many COVID-19 patients in ICU. They often have geometric borders or bullae, which typically progress to ulceration with eschar.[115] The NPIAP has highlighted the risk of misdiagnosing these purpuric lesions as a deep tissue injury (or vice versa).[113,114] It also warned that COVID-19-related microvascular occlusion of tissue exposed to pressure and/or shear stress can exacerbate the risk of ulceration.[114]

Third, the pathophysiology of COVID-19 in seriously ill patients can include the cytokine storm, hypoxia and hyper-coagulation. These systemic events can exacerbate the pathophysiology of DRPU formation.[117,118]

To date, it is largely unproven whether these manifestations increase the risk of DRPUs in patients with COVID-19 and hypotheses remain largely theoretical.[119] More research is needed.

Neonates and paediatrics

Much information on the aetiology and development of pressure ulceration is based on its pathogenesis in adult skin. However, the skin of neonates and children, including its overall tissue composition, is different to that of adults.[120] Box 2 summarises the key features of neonatal skin.

As neonates and premature babies do not move or reposition themselves spontaneously, they are at higher risk of ulceration. They cannot, of course, communicate the cause of their discomfort, other than by crying.[107]

The skin of paediatric patients (from newborn neonate to 18 years of age) changes over time, with complete epidermal maturation occurring by 34 weeks.[121,122] Therefore, prevention of ulceration 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 the paediatric ICU, which predominantly occur on the face and scalp,[123] followed by the heel and occiput. In contrast to adult patients, these areas cannot be safely offloaded other than by changing the patient's position.[124]

Box 2. Skin features in neonatal patients

- Underdeveloped subcutaneous fat tissue
- Immature cohesion between the epidermis and dermis
- Dermal instability
- Alkaline skin surface
- Multiple physiological changes after departure from 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 dermal-epidermal cohesion
- Reduced calorie and fluid storage
- Reduced insulation and loss of surface temperature because of lower levels of subcutaneous fat
- Reduced secretions and sebum production, the so-called mechanical coat protection

Neonates, both pre-term and full term, are at high risk of ulceration due to the immaturity of their inflammatory response in particular, but also their skin,[25,120,125,126] its barrier function and their immune system. The lower amount of subcutaneous fat present is another factor. The stratum corneum develops relatively late in gestation: in pre-term neonates its development may be related to exposure to the external environment.[127] The skin of neonates (particularly pre-term) and infants is thin and does not have the protective function of adult skin.[120,122]

Desquamation is abnormal in very premature infants for some weeks after birth,[121,128] signifying hyperproliferation of the epidermis.[129] Skin maturation and adaptation to the post-partum environment happens over an extended period of time, during which desquamation slowly increases.[130]

Compared with older adults, neonates, infants and children show a visible 'turnover' and increased

production of keratin in hair, skin and nails. Several observations suggest that infant mechanisms of differentiation and desquamation are underdeveloped or poorly regulated compared with adults.[131,132]

A high metabolic rate and physiological oedema, which is common in sick children, also increases the risk of DRPUs in these populations.[15]

The increased fragility of skin associated with prematurity and its associated comorbidities[128] is challenging for health professionals to manage, with practice often relying on anecdotal evidence to prevent damage.[133] Use of tape or twill that is disproportion in size to the medical device can make 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.[25,134] A dehydrated infant may be hypoxic because of poor skin perfusion and the affected tissue may break down with only minor insult.[122] Infants with multiple organ dysfunction syndrome are particularly at risk of ulceration.[135] Furthermore, an infant's immune system is immature, with underdeveloped monocytes and neutrophils that respond poorly to inflammatory cytokine stimuli.[136] As a consequence of all these factors, infant skin is fragile and less tolerant of mechanical loading and injury.[25,128,137]

In the UK, National Institute for Health and Care Excellence (NICE) has issued a pathway, with supporting guidance, on the prevention of PUs in neonates, infants, children and young people.[138] These principles apply to the prevention of DRPUs.

Health professionals must be attentive to a paediatric patient's growth phase; in growing infants, the size and fit of any medical devices being used in the long term must be regularly assessed.

In general, the importance of the skin in the mechanical and immune protection of young patients is often underestimated. Loss of skin integrity, for example due to ulceration, can be catastrophic, potentially leading to rapid, polymicrobial infections, which may be resistant to antibiotics. The panel believes a cultural shift is needed to ensure that appraisal of skin integrity is regarded as a fundamental aspect of holistic assessment.

Summary

- Devices and their securement may generate high stress concentrations in tissues, leading to cell and tissue-damage pathways that are associated with sustained cell deformation[137,139,140]
- Insensate patients are especially at risk of localised high-tissue deformation, stresses and stress concentrations[96]
- Everyday activities, such as toilet sitting, increase tissue loads and reduce perfusion and tissue oxygenation,[141] placing individuals with reduced sensory function or mobility at high risk
- COVID-19 is thought to be associated with several dermatological manifestations and purpuric features. It is not yet known if these increase the risk of DRPU.

Chapter 3: devices

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

Table 4 gives examples of medical and non-medical devices that can be associated with DRPUs.[3] Devices can be classified in a variety of ways; Table 4 classifies medical devices according to their primary medical or clinical use.

Key points

- DRPUs are mostly associated with tubing, such as that used with oxygen and endotracheal masks, respiratory masks, splints, intravenous lines 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 methods of positioning, such as proning, can be associated with a higher and increasing risk of DRPU formation
- Devices responsible for DRPUs vary between clinical settings

Range of devices that can cause skin damage

Devices can be used across clinical specialties, depending on the patient's clinical needs. Sometimes, more than one device is applied onto a patient. Devices might be used temporarily during an acute-care episode (eg, respiratory devices, patient-monitoring devices and indwelling lines) or for the rest of the patient's life (eg, orthotics, prostheses and wearable glucose monitoring meters). Increasingly, patient care is taking place in the community setting, with therapeutic and diagnostic devices being used for prolonged periods.[8]

DRPUs are common across several medical specialty units. Devices commonly associated with DRPUs include:[3,8]

- Tubing devices, such as oxygen tubing
- Nasogastric tubes and endotracheal tubes
- Respiratory masks, such as CPAP and BIPAP
- Splints, casting and orthotic devices
- Intravenous and intra-arterial catheters and armboards
- 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 it in place. Ill-fitting masks create focal pressure points and localised frictional forces

Table 3. Characteristics of neonatal skin that increase its vulnerability to DRPU formation[277]

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

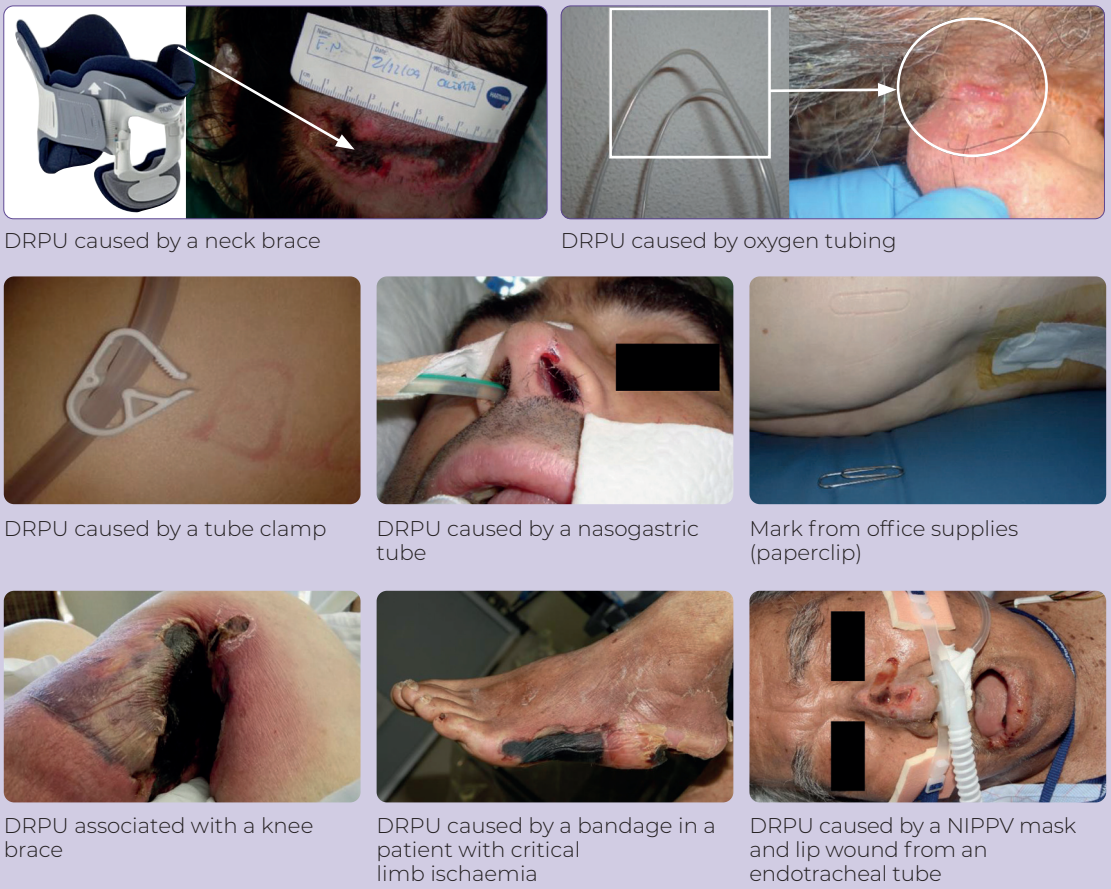
Table 4. Devices and objects associated with DRPU*

Devices with a medical purpose
Respiratory devices: oxygen face masks (non-invasive ventilation); CPAP masks; BIPAP masks; endotracheal holders; nasal prongs and tubing; high-flow nasal prongs; extracorporeal membrane oxygenation
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 on 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 the finger, toe or ear); blood pressure cuffs; ECG dots, leads and lines; EEG electrodes and wiring; wearable monitoring devices/sensors (eg, for blood glucose); intracranial pressure monitoring (cannulae and tubing); external ventricular drains; forehead oxygen saturation probes; temperature probe devices/sensors; movement sensors (for patients at risk of falls)
Compression and prevention of deep vein thrombosis: sequential compression devices; anti-embolism stockings; compression hosiery; all cotton elastic wraps; heel offloading devices
Treatment: dialysis involving cannulae and tubing/lines; NPWT; tubing associated with NPWT; intra-aortic balloon pumps with 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;[278] aircast boots
Prosthetics and orthotics: above- and below-knee, hand and arm prostheses; knee orthoses (braces); ankle and foot orthoses, dental prostheses
Surgical devices: forceps; tools; instruments
Miscellaneous devices and objects: bandages; identity bands on wrists or ankles; pens, scissors, flashlights and other health professionals' personal items (dropped in beds)
Hospital furniture: bed frames; foot rests and any other rests
Device components that are removed before use: packaging elements (eg, tops from syringes)
Mobility devices: crutches; casts; wedges (foam and/or rubber); wheelchairs
Devices and objects associated with risk management: patient-positioning devices used for staff safety during repositioning or transferring
Malfunctioning, failing or incorrectly used devices: deflated mattresses and device-securement systems
Objects without a direct medical purpose / patient's or other person's property
Mobile/cell phones; jewellery; hearing aids; glasses; remote controls; office supplies

Continued on the next page

Anything the patient sits or lies on that is a foreign object, such as a hairbrush

**Examples are provided, the list is not intended to be exhaustive*
BIPAP—bilevel positive airway pressure; CPAP—continuous positive airway pressure; ECG—electrocardiogram; EEG—electroencephalogram; NPWT—negative pressure wound therapy



DRPU caused by a neck brace

DRPU caused by oxygen tubing

DRPU caused by a tube clamp

DRPU caused by a nasogastric tube

Mark from office supplies (paperclip)

DRPU associated with a knee brace

DRPU caused by a bandage in a patient with critical limb ischaemia

DRPU caused by a NIPPV mask and lip wound from an endotracheal tube

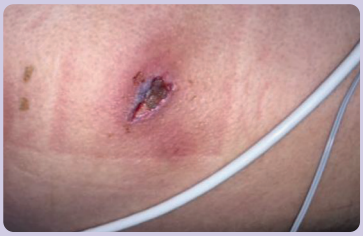
Fig 5. Examples of DRPUs in adults

DRPU—device-related pressure ulcer; NIPPV— non-invasive positive pressure ventilation

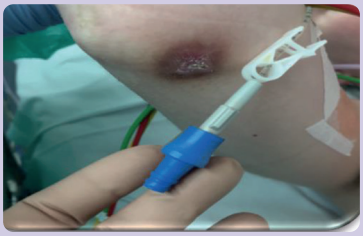
that can lead to irreversible tissue damage within hours. Examples of DRPUs in adults are shown in Fig 5.

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.[142,143] Examples of DRPUs in paediatric patients are shown in Fig 6.

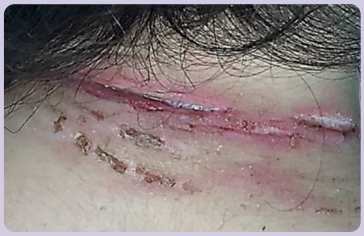
In all patients, other devices associated with DRPUs include nasal prongs; anti-embolism stockings;



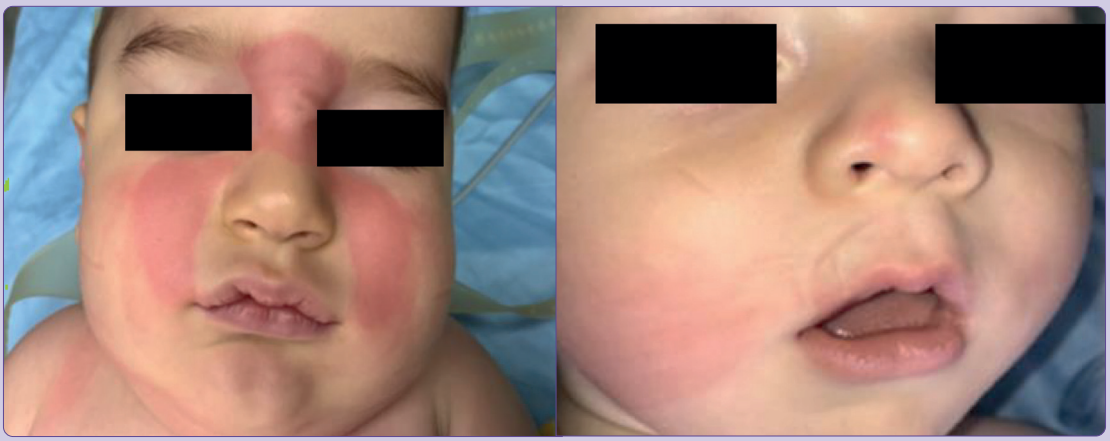
DRPU associated with tubing and thermometer



DRPU associated with a peripherally inserted central catheter



DRPU associated with a tracheostomy tie



DRPUs associated with mask and retaining straps

Fig 6. Examples of paediatric DRPUs

DRPU—device-related pressure ulcer

sequential compression devices; ankle bands; epistaxis balloons; EEG leads; extracorporeal membrane oxygenation (ECMO) cannulae; oxygen saturation monitoring and cooling blankets. These may cause DRPUs on the toes, neck, chin, head, arms, feet, nose, chest, ears, earlobe, face, knuckles and buttocks.[13,25]

Impact by anatomical site, duration and setting

Common anatomical sites for DRPUs include the face, ears, lower leg and heels. However, DRPUs can occur anywhere that a device comes into contact with the skin.[144] Common sites include the lips and face (endotracheal tubes and their securement), nose (nasogastric tubes), hand (splints), wrist (arterial line tubing) and occiput (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 five days of continued use, with many of these being category IV.[47] Procedures and treatments administered when a device is in place may increase risk. For example, 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.[17]

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 one year (from 1 February 2018 to 31 January 2019) showed that DRPUs associated with elastic stockings 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), to measure blood pressure (n=1) or for pulse oximetry (n=3),

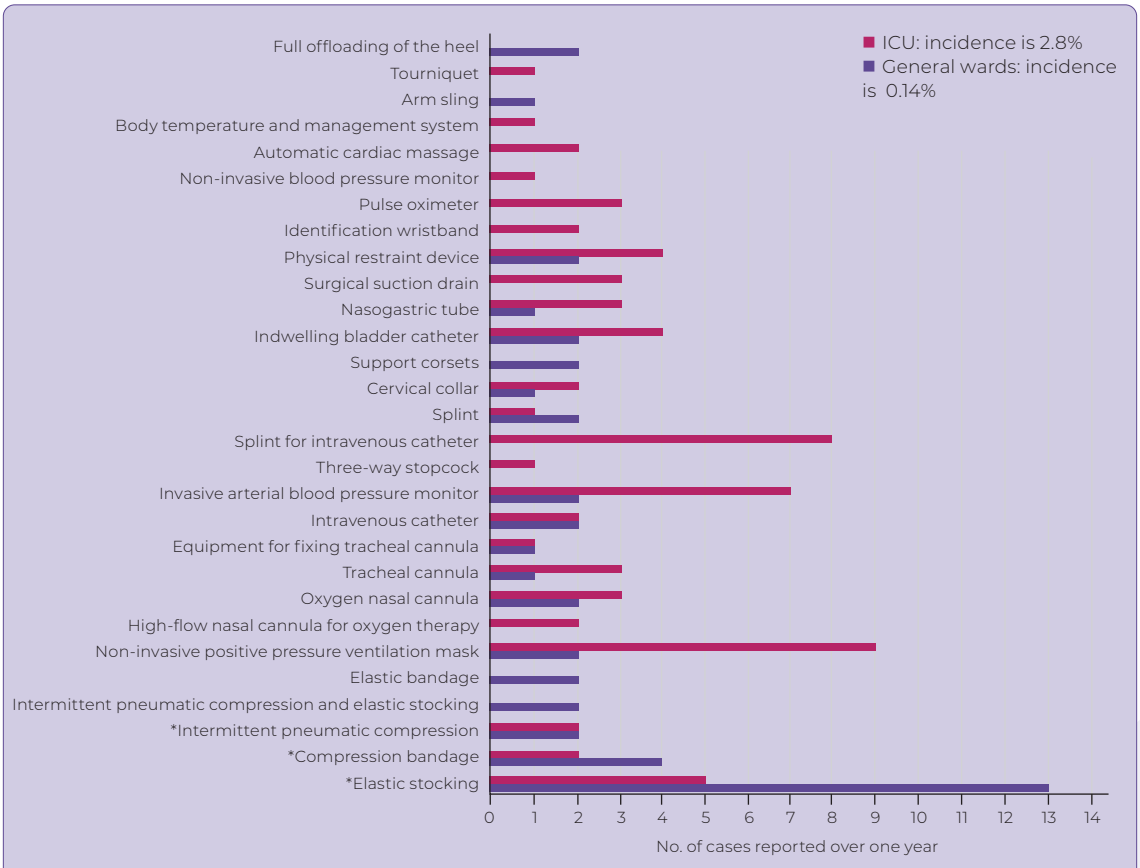


Fig 7. Incidence of DRPUs in an ICU and general wards, based on data collection over one year

DRPU—device-related pressure ulcer; ICU—intensive care unit
**Used to prevent deep vein thrombosis*

Table 5. Aetiological classification of DRPU

	Small: small contact area; hard material	**Large: large contact area; hard material**	**Devices that reduce the skin's tolerance to external stresses**
			
Aetiology	High pressure Sustained pressure Tissue deformation	Low pressure Sustained pressure Tissue deformation	Moisture pH
Device	Nasogastric tube Indwelling bladder catheter Intravenous catheter and three-way stopcock Invasive arterial blood pressure monitor Central venous catheter Epidural catheter Mask **Monitors** Core thermometer Body temperature management system ECG NIBP tube and connector	Splint Pulse oximeter NIBP cuff ECG patch Identification wrist band **Deep vein thrombosis prevention** Elastic stocking Intermittent pneumatic compression and elastic stocking	**Respiratory** NIPPV mask Oxygen nasal cannula Tracheal tube Tracheal cannula **Other** Stoma products

DVT—deep vein thrombosis; ECG—electrocardiogram; NIBP—non-invasive blood pressure; NIPPV—non-invasive positive pressure ventilation

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 (NIPPV) masks (n=9). Results are presented in Fig 7. These findings are consistent with published data from other centres.[145]

Categorisation

Table 5 presents an example of categorisation of medical devices, based on how they interact with the skin and the aetiology of the subsequent DRPU. This method of categorising devices aims to focus the health professional on the reasons for the DRPU risk. Devices comprised of hard materials that have a small contact area with the skin create high localised

pressure and frictional forces; these are commonly associated with DRPUs. Devices with large skin-contact areas create a 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 NIPPV masks, nasal oxygen cannulae and tracheal tubes and cannulae. Stoma devices 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.[146] Around a quarter of patients who experience leakage go on to develop pressure or moisture-related complications.[147] Anecdotally, it is known that the flange on stoma devices and mucosal injury from indwelling urinary and faecal catheters can cause DRPUs; however, more research is required.

Other devices associated with the risk of DRPU formation are external orthopaedic fixators, which are made of rigid (metal) components and often have curved, thin, sharp or geometrically irregular elements and surfaces.[148]

Lessons from COVID-19

Since the start of the pandemic, a substantial body of evidence has reported a high rate of DRPUs in infected patients. Between 50% and 88.7% of those with severe COVID-19 have been reported to develop a skin injury,[149–152] often with multiple DRPUs reported on the same patient.[150,151] (These papers refer to PUs, but many of these injuries related to the use of devices.)

With time to reflect, several themes have emerged. Patients with severe COVID-19 have a particular set of clinical needs that combine to increase their risk of DRPU formation. Many COVID-19-positive patients admitted to ICU were moved into the prone position,[151] often for lengthy durations. This intervention has been found to improve prognosis;[152] numerous RCTs have demonstrated the positive effects of pronation for mechanically ventilated patients with acute respiratory distress.[153] The benefits include improved ventilation and oxygenation ratios, better respiratory mechanics due to the reduction of over-inflated lung areas and reduced ventilator-induced injury.[149,153]

However, this manoeuvre also increases the risk of pressure ulceration: [12,46,149,151,152] both the use of proning and the length of time spent in the prone position have been shown to be risk factors for DRPU formation.[150,151] This is thought to be because proning affects how a device interacts with skin and soft tissue. External securement fixation devices, particularly for endotracheal tubes, are also a risk factor when proning.

The main manifestation of COVID-19 as a respiratory disease—breathing difficulties—means that patients need intensive and often prolonged life-saving ventilatory support. This requires the extensive use of endotracheal tubes,[151] tracheostomy tubes or ventilation equipment, such as oxygen masks, CPAP/BIPAP masks and nasal prongs. The majority of DRPUs observed in COVID-19-positive patients (61–77%) are associated with these types of devices and located on the face, [132,151,152] with a third being oral/mucosal and related to endotracheal tubes.

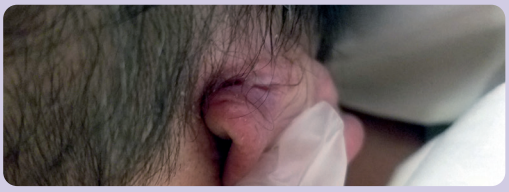


Fig 8. DRPU on a patient who had been wearing a surgical mask for a long time

Chapter 4: risk assessment

As with any PU, assessing a patient's risk of developing a DRPU is a critical step in prevention. Expert guidelines and best practice statements stress the importance of risk assessment.[1,138,154–159] This involves an awareness not only of the risk factors for PUs in general, but also recognition of the additional risk posed by devices.

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

Health professionals, patients, their families and other staff 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: this 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 9. The template is derived from one used in a medical-surgical ward in a US 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 risk assessment for PUs and a skin assessment under or around devices for DRPUs.

Risk assessment tools

Many PU risk assessment tools are available. These are an important component of the care bundles adopted to reduce HAPUs in recent years. However, not all assessment tools take the risks of medical devices into account.

The Braden, Waterlow and Norton scales are well-known risk assessment tools that can be used for a broad spectrum of patients and settings, but they do not assess the risk of DRPU formation. The CALCULATE tool includes a section on mechanical ventilation, including CPAP masks,[160,161] and so takes some aspects of risk associated with medical devices into account, but its relevance is limited to critical care. The Purpose-T tool does include medical devices.

Key points

- Risk assessment should be part of routine practice
- Risk assessment tools should be used to identify the likelihood of skin changes and the need for direct management
- Patients being managed with a medical device should be considered at high risk of DRPU formation
- 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 DRPU

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 of skin changes identified by risk assessment tools
- Skin condition
- Presence of a device and previous PU or other injury at the site where the device will be applied

Organisational risk factors

- 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
- Need to prioritise other potentially life-threatening issues

DRPU—device-related pressure ulcer; PU—pressure ulcer

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

Patients, carers and family

- Be aware of risks posed by personal possessions
- Take action to minimise risk
- Inform clinical staff of any discomfort or pain at the device site
- Inform clinical staff of any objects left between the patient and support surface
- Move or adjust the device if there are signs that the patient is in discomfort or pain
- Be aware of the 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 PU 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 DRPU formation
- Conduct regular skin assessments according to the risk level associated with the device and any patient-related factors
- Report any device-related injury
- Interact with manufacturers to identify and suggest design changes that will reduce the risk of DRPU formation
- Develop local protocols for risk assessment and use of medical devices

DRPU–device-related pressure ulcer; PU—pressure ulcer

It may be valuable to develop a risk assessment tool with broad applicability that considers the risks posed by medical devices. This has been addressed recently by Seong et al.[162] who developed and tested an

		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 one hour. For pain meds, as needed, in accordance with parameters, you must follow order as written*			

Fig 9. 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

For abbreviations, please see page S69

Box 5. Assessment of neonatal and paediatric patients[22]

Frequently assess skin under
- Blood pressure cuffs
- Transcutaneous oxygen pressure probes
- Tracheostomy plates
- Nasal prongs and masks (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

CPAP—continuous positive airway pressure; BIPAP — bilevel positive airway pressure

algorithm specifically designed to assess the risk of DRPU formation. Choi et al.[163] developed a risk assessment tool designed to assess the risk of oral/mucosal ulceration associated with the use of endotracheal tubes in critical care. Some studies have identified that use of endotracheal tubes in critically ill postoperative patients and those in a semi-coma/coma or under sedation significantly increase the risk of DRPU development. This information may be of use in the development of new risk assessment tools or the modification of existing ones.[164] However, the focus, in terms of risk assessment, will always need to be on regular skin and mucosal assessment.

When assessing the risk of DRPU formation, it is important to recognise that all patients with a medical device in place are at risk. Risk assessment tools should be regarded as diagnostic tools for the identification of skin changes and to trigger their management. They should be used routinely and supplemented, where necessary, with information on the medical device and clinical judgement.

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

Validated risk assessment tools for use in paediatrics

NICE[138] (for the UK) 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 when risk factors are present. NICE recommends the Braden Q scale be used for assessment. As with all patients, skin assessment in paediatrics 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 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.[165] Other paediatric-focused risk assessment tools include the Neonatal Skin Risk Assessment Scale (NSRAS),[166] the Pediatric Pressure Ulcer Prediction and Evaluation Tool (PPUPET),[167] the Skin Injury Risk Assessment and Prevention (SIRA+P)[168] and the Glamorgan

paediatric pressure ulcer risk assessment scales.[169] Other important assessment tools are by Peterson et al.[170] and Kiss and Heiler,[171] or are still in development. The NSRAS considers the need for ventilatory support, so does partially address the risk of DRPU formation. A mnemonic, developed by the consensus panel, that can be used to aid assessment is presented on page S70 of this consensus statement.

Assessment

Any patient being managed with a medical device should be considered as 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, which should be determined by the risk posed by the device, the patient's condition and clinical judgement. The frequency will be higher for high-risk devices or where the risk is associated with a systemic condition, hypoalbuminaemia 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 be considered. The clinical need for the device should be reviewed regularly.

Health professionals should 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. For examples of devices (by category), see Table 5, page S26.

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.[22] Risk factors for PUs and DRPUs in these patients include sedation, hypotension, sepsis, spinal cord injury, traction devices, terminal illness, spina bifida, cerebral palsy, cardiovascular bypass surgery,[172–175] lengthy surgical procedures, ECMO bridge-for-life connections and cerebral and cardiovascular activity probes.

Priorities for assessment of neonates, infants and paediatrics are listed in Box 5. Fig 10 gives an example of a checklist approach to the assessment of neonatal and paediatric patients in ICU.[22]

Example of a skin-integrity assessment protocol

The general principles of skin assessment are listed in Box 6. 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 a skin-integrity protocol embedded in the clinical information system at the ICU at the Royal Brisbane and Women's Hospital, Queensland, Australia.[176] The protocol requires staff on each shift to complete a full head-to-toe, back-to-front skin assessment that includes skin under medical devices. Staff are guided to check under devices every three hours and to reposition the device or patient if necessary, ensuring that the device is not wedged or positioned so that it presents a risk of injury. The assessment is documented in the clinical information system with descriptions of the colour, warmth, moisture and turgor of the skin, as well as the presence of any skin injury or oedema (Fig 11).

Large devices and insensate patients

It is not always possible or easy to observe the skin under devices such as external orthopaedic fixation frames, plates, splints and cervical collars. In such cases, if the patient is alert, the health professional should ask (mindful of the position of the device) if they are in any pain 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.

DRPU checklist: devices used in neonatal and paediatric patients			
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		**Other**	
	Nastrogastric tube		Identification wrist band
	Indwelling bladder		Splint
			Other (specify)
	Intravenous catheter and three-way stopcock		
	Invasive arterial blood pressure monitor		
	Central venous catheter		
	Epidural catheter		
Deep vein thrombosis prevention			
	Elastic stocking		
	IPC and elastic stocking		

DRPU checklist: operating room/surgical theatre devices			
Monitor		**Respiratory**	
	Core thermometer		NIPPV 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	**Other**	
Tube			ID wrist band
	Nastrogastric tube		Other (specify)
	Indwelling bladder catheter	**Options**	
			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		

Fig 10. DRPU checklist for ICU and operating room

For abbreviations, please see page S69

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 the neutral position to avoid flexion. The 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 it without being easily seen. The occiput should be evaluated early and often after admission in patients on an immobility backboard who have ambulance transport times.

Other clinical challenges

Risk assessment should focus on the body site onto which the device has been or will be applied. However, assessment can be difficult in some circumstances. For example, skin changes that signal potential injury are less visible, and erythema is often not visible, in darkly pigmented skin.[177] Sometimes, moistening the skin will help contrast a change in colour compared with the surrounding tissue. Darkly pigmented skin should also be palpated for oedema.

Skin may be at higher risk of damage due to age-related changes.[178] Patients with oedema or lymphoedema may be at risk, despite having skin that is generally in good condition. As noted above, 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.

For patients with COVID-19, infection control measures designed to protect health professionals can make it difficult to conduct risk assessments.[179] It seems prudent to continue using tried-and-trusted PU risk assessment tools in this patient population. Risk assessment tools consider many factors relevant to patients with severe COVID-19 infection, such as activity, mobility and nutrition levels. In the absence of detailed tools for assessing the risk of DRPU

development in this population and knowing that patients with severe COVID-19 are at high risk[9–11] and the virus can affect the skin with unknown implications for its integrity,[109–112] the panel recommends vigilance and a cautious approach to risk assessment. Whenever possible, the skin should be assessed before proning. When a patient is proned, the position of the head should be changed with a frequency determined by individual patient characteristics and circumstances.[179]

Developing bespoke risk assessment tools

Facilities should develop their own device-specific risk assessment tools that will work with their own protocols, based on the patient populations that they serve. Risk assessment tools must, of course, be reliable and valid. The checklist in Fig 9 covers two settings: the operating room and the ICU. It should be filled in at each staff changeover: the presence of specified devices on a patient 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 medical devices. For example, one staff member can release the ties to inspect the skin while the other supports the patient to stop them 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.

Next-generational risk assessment tools

Conventional risk assessment tools have low sensitivity and specificity for predicting PU formation in high-risk groups.[180–184] Their use does not necessarily lead to targeted PU prevention and they are not comprehensive enough to capture the specific risks associated with devices.[185–187] There is potential for innovative technology to facilitate assessment of tissue status. Such technologies include:

Box 6. General principles of skin assessment[279]

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

Skin should be assessed with reference to:

- 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 by comparing with unaffected skin[177]
- Bruising
- Scaling and dryness

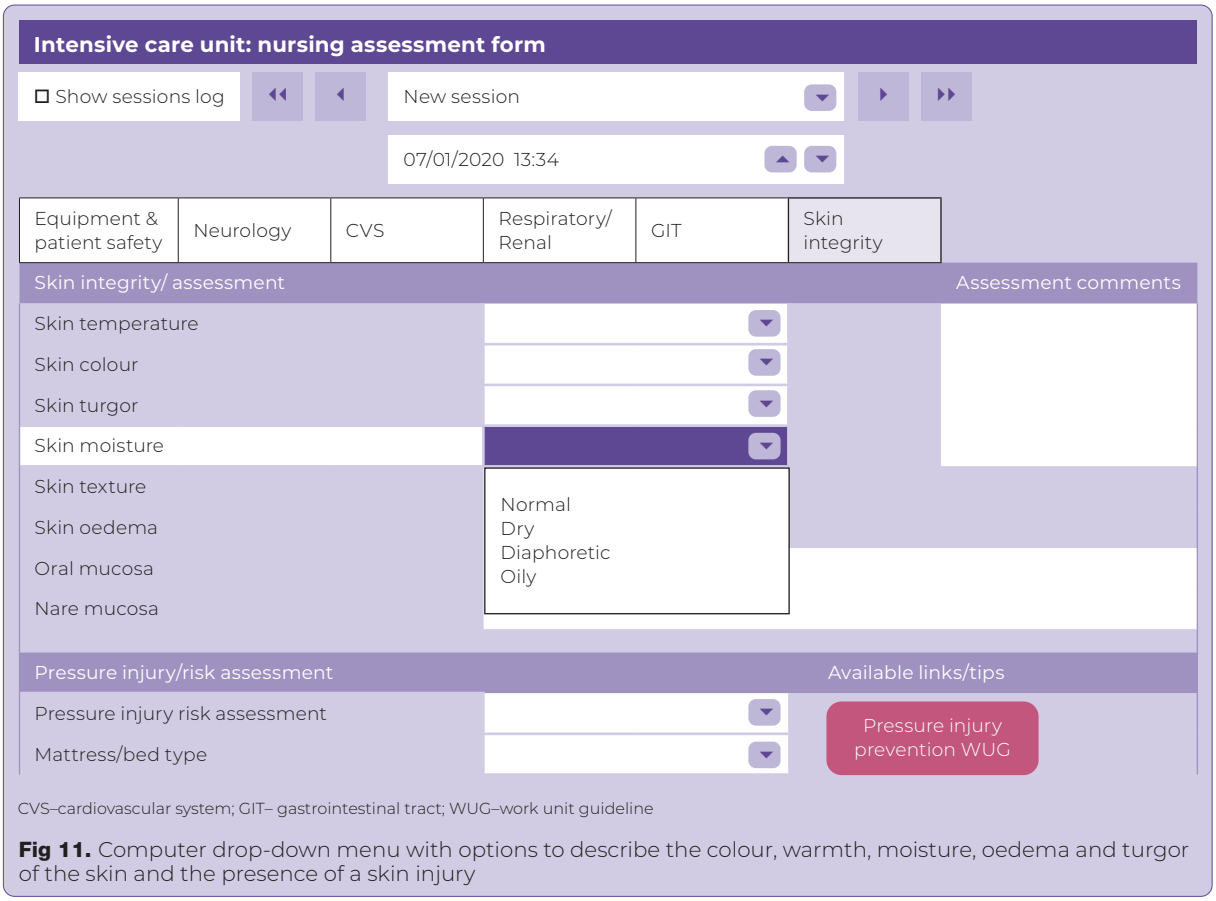
Frequency of assessment

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

- Imaging and sequential photography
- Biocapacitance measurements
- Inflammatory biomarker measurements
- Sub-epidermal moisture (SEM) scanner that is suitable for smaller areas of the body. Such devices are available for larger body areas, but the technology has not yet been adapted for the smaller body areas implicated in DRPU formation[187]
- A combination of the above.

To the panel's knowledge, no medical device has an integral sensing and monitoring capability that will alert about 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 risk assessment tools will only be valuable if they can accurately and



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

Fig 11. Computer drop-down menu with options to describe the colour, warmth, moisture, oedema and turgor of the skin and the presence of a skin injury

precisely predict the likelihood of DRPU formation. Any new risk assessment devices, therefore, will be need to be rigorously and methodically analysed.

Requirements for future risk assessment tools

The panel proposes that, in the future, visual skin assessments should be replaced with technology-aided, skin-valuation 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.[63,71,95] It may be possible to include visual markers on devices for load, tissue status, near infrared and/or oxygen saturation and to alert for the need to initiate other risk measures. Also required are visual markers that can monitor biomarkers and change colour when thresholds are detected.

Clinical emergencies

If the medical device associated with a risk of DRPU formation serves a critical purpose, moving or adjusting it will simply not be an option. In the event of 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.

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

Prevention of DRPUs can be viewed from a variety of perspectives. These include: protocols and standard procedures; clinical practice; product design; education and training; and procurement. Education and training are covered in chapter 6. This chapter discusses the other aspects of prevention, as well as the management of DRPUs.

Prevention

Key aspects

PU or DRPU prevention requires a high level of awareness and rigorous adherence to evidence-based practices that minimise risk.[38,188,189] The basic considerations for PU prevention are listed in Box 7. It is vital that health professionals also consider all the variables and characteristics related to DRPU formation.[190] This involves accounting for the physical form of a device, the clinical goal for its use, the type of tissue onto which it will be placed and the anatomical area affected. Vigilance, adherence to best practice for device application and awareness of the potential causes of risk can help avoid poor placement of devices, mistakes and mitigate lack of staff training.[191] This is especially important in neonatal and paediatric patients admitted to critical care and during transport between units.[143] Devices applied to newborn and infants in an ICU may take up 25–30% of the body surface, underlining the importance of careful and consistent observation to prevent DRPU formation.

Box 7. PU prevention: steps and procedures

- Risk assessment
- Skin assessment and care
- Support surface/device selection, care and application
- Regular moving or repositioning of the patient or device
- Continence management
- Moisture management
- Nutrition and hydration
- Provision of information and shared learning—involve the patient and carers and document the care delivered
- Use of pressure-reducing or redistributing support surfaces

PU—pressure ulcer

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 DRPU prevention
- Use of prophylactic dressings should be considered
- The fundamentals of DRPU management are the same as those for PUs

Although many DRPUs are likely to be preventable, 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 adopting evidence-based strategies.[192] Standard care based on expert consensus recommendations should be followed (Box 8).[1,138]

Implementation of best practice

Fundamental elements of PU prevention include risk assessment, skin assessment, care planning, care delivery and documentation. The objective of a DRPU prevention care plan is to minimise the risk posed by 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.[192,193] A simple method of ensuring such focus is to incorporate DRPUs into ward or facility documentation, as shown in Fig 9 (page S29).

DRPU prevention requires a high level of cross-functional collaboration and communication, which can be facilitated by documentation. The panel recommends that all facilities should have documented procedures, protocols 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.[194]

A facility's standard procedures should be based on recognised published guidelines and risk assessment tools. The NPIAP has published one-page guides on the prevention of DRPUs in critical care,[188] paediatric populations[195] and long-term care,[196] as well as a general overview.[189] 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.[1]

Standard of care protocols should include all steps and procedures that need to be followed. A protocol should be described in enough detail for it 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, such as 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.

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,[197–205] with reductions in the incidence of DRPUs of between 75% and 100% reported.[198,201,202]

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.

Box 8. NPIAP recommendations for prevention of PU and DRPU formation[1,156]

- 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 devices are secured 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 the NPIAP classification scheme (note mucosal PUs cannot be staged)
- Remove devices as soon as is medically feasible
- Keep skin under devices clean and dry
- 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 interface pressure and shear with support
- Consider the use of prophylactic dressings

DRPU– device-related pressure ulcer; NPIAP– National Pressure Injury Advisory Panel; PU—pressure ulcer

The Plan-Do-Study-Act (PDSA) framework was used to develop a care bundle for tracheostomy-related pressure ulceration.[206] During the bundle-development phase, the occurrence of tracheostomy-related PUs reduced from 8.1% to 2.6%. Following implementation of the care bundle, this fell to 0.3%. The implementation process included online or didactic training, for all nurses in the unit, on PU and DRPU risk assessment, full skin assessment and prevention of tracheostomy-related PUs. Strategies included displaying information on the bundle in the staff room and publication of brochures explaining the risks related to DRPU, which were shared with patients. The care bundle included:

- Daily Braden Q risk assessment tool
- Daily full-body skin assessment
- Device assessments, which were undertaken on every eight-hour shift
- Keeping device interfaces moisture-free, including under ties
- Using a hydrophilic foam barrier under tracheostomy tube flanges and around the stoma if not contraindicated
- Reducing pressure/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 sternum.

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

The care bundle was incorporated into the facility's electronic medical records system, embedding it into the nurse workflow. In this facility, tracheostomy-related PUs were reported in real time. Staff uptake of the bundle reached 100% in four months, demonstrating sustained quality improvement.[206] This approach is transferable to other facilities and is a panel recommendation for DRPU prevention. Other

Box 9. DRPU prevention: key procedures relating to the use of devices

- Inform patients and carers that devices and personal possessions can cause pressure ulceration
- Stress the need for visitors to remain vigilant about this
- 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 PU or broken skin
- Document the device and its level of risk
- Notify relevant staff of any risk associated with the device
- Assess the patient's risk status
- Conduct frequent skin assessments and check the skin under the device
- More frequent assessment will be required for high-risk patients
- Neonates, paediatric and bariatric patients should be regarded as at high risk
- Special attention should be paid if oedema is present
- Reposition the medical device at frequent intervals, if possible
- Consider changing the device interface when delivering an intervention. For example, swap nasal prongs with a full-face mask for the delivery of respiratory support
- Stop using a device as soon as is clinically possible
- Incorporate DRPU prevention into existing PU prevention pathways
- Ensure that DRPU prevention is part of the facility's routine practice
- Monitor DRPU incidence and prevalence; use rigorous and consistent procedures for this
- Work collaboratively and refer across specialties to prevent DRPUs
- Give feedback to industry and collaborate with device developers and manufacturers

PU—pressure ulcer; DRPU—device-related pressure ulcer

Table 6. Clinical-practice approaches for the prevention of DRPU formation

Device type/resource	Approach
BIPAP mask-related ulceration in paediatric patients[280]	Select an appropriately sized mask
	Ensure effective delivery of respiratory therapy
	Update the interface used to relieve pressure
	A nurse or respiratory therapist should assess the skin every four hours.
	Use protective foam under all masks
	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
Modified SSKIN bundle[123]	Use devices with surfaces that are appropriate to the size of the patient
	Assess the need for adhesives
	Inspect the skin by risk area and anatomical site, including the face and scalp
	Rotate devices, where appropriate
	Protect the skin under devices
	Manage incontinence
	Optimise nutrition
	State actions needed: referral to a clinical specialist or no action

BIPAP– bilevel positive airway pressure;
SSKIN—Surface, Skin inspection, Keep moving, Incontinence/moisture, Nutrition

aspects of the care bundle included training of health professionals, regular risk assessment and periodic adjustment or rotation of medical devices.

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, information is provided on risk assessment, selection and prevention. The importance of obtaining informed consent is highlighted.

Evidence base on prevention

The evidence base for the prevention of PUs (not associated with medical devices) is well developed, with multiple systematic reviews and meta-analyses.[207–210] In contrast, there is considerably less high-level evidence on the effectiveness of many DRPU prevention measures and interventions. This may reflect institutional cultures where DRPUs have 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 past few years, so has the evidence base. Some high-level studies are emerging. For example, a meta-analysis has suggested that hydrocolloid dressings can help prevent DRPUs during NIV,[211] probably because they provide cushioning at the skin-device contact interface,[212] and an RCT pilot has compared outcomes of three prevention strategies.[213]

Where evidence is available, it should be evaluated and integrated into procedures and protocols; health professionals and decision-makers in hospitals and care settings should be open to implementing evidence from all levels of the evidence hierarchy and

Table 7. Classification of medical devices according to DRPU risk, as presented in a Japanese clinical setting[281]

1.	Elastic stockings used to prevent DVT
	IPC
2.	NNPV masks
3.	Fixation devices for orthopaedics, splints, casts
4.	Indwelling urinary catheters
5.	Faecal management systems
6.	**Vascular access devices:**
	Intravenous catheters
	Invasive arterial blood pressure monitors
7.	Nasogastric tubes
8.	Paediatric nasogastric tubes
9.	**Respiratory-related devices used in paediatrics:**
	Oxygen nasal cannulae
	Equipment for fixing tracheal cannulae
	Tracheal tubes
	Tracheal cannulae
10.	Paediatrics fixation device for catheters, splints

DVT—deep vein thrombosis; DRPU—device-related pressure ulcer; IPC—intermittent pneumatic compression; NPPV—non-invasive positive pressure ventilation

Table 8. Causes of PU, DRPU and MARSI

Wound type	Cause
PU	The main cause of pressure and the associated shear forces is body weight loading
DRPU	Caused when a device or object exerts localised forces directly onto the skin. A full definition is given on page S7
Skin tear	Traumatic acute injuries that can result in partial or full separation of the outer layers of the skin.[1,2] Can be caused by shearing and friction forces or a blunt trauma. Skin tears result from short-term external forces, as opposed to the continuous external forces that cause PUs and DRPUs
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, bullae, skin erosion and skin tears persisting longer than 30 minutes after removal of the adhesive. MARSIs cause pain, increase the risk of infection, increase the wound size and delay healing

PU—pressure ulcer; DRPU—device-related pressure ulcer; MARSI—medical adhesive-related skin injury

not rely solely on RCTs or other higher-level evidence. Evidence from quality-improvement studies, cohort 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. 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.[214] The outcome being investigated also needs consideration: for example, DRPU prevention 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.

Implementation in practice

Differential diagnosis

There are four main 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 type of injury has occurred. This involves determining the wound pathology, patient risk factors and circumstances that led to the injury. The four types of skin breakdown are defined in Table 8. Key differences in their external causes are illustrated in Fig 12. An exercise that can be used to test skills in differentiating between PUs, DRPUs and MARSIs is given in Appendix 1 on page S60.

Prophylactic dressings

One component common to many different care bundles is the use of prophylactic dressings.[38,198,206,215] This approach is supported by the EPUAP, which recommends that health professionals should consider the use of prophylactic dressings.[1] The primary rationale is that placement of a dressing between the medical device and the skin might be able to reduce the pressure, friction and shear forces acting on the skin, in turn reducing the risk of pressure-related injury and skin breakdown.[38]

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.[39] Soft gel pads and strips can also be used.[216–218]

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 skin; whether an adhesive or non-adhesive dressing is more appropriate; the ease with which the dressing can be applied to the anatomical location; and the extent of the physical forces exerted by the medical device.[38,39]

A systematic review, albeit on a small number of studies, concluded that use of prophylactic dressings as part of a PU prevention protocol may help to halve the risk of ulceration.[219] To date, there is no evidence that any one type of dressing is more effective than any other in this regard.[219] Reduced incidences of DRPUs in cohorts given prophylactic dressings has

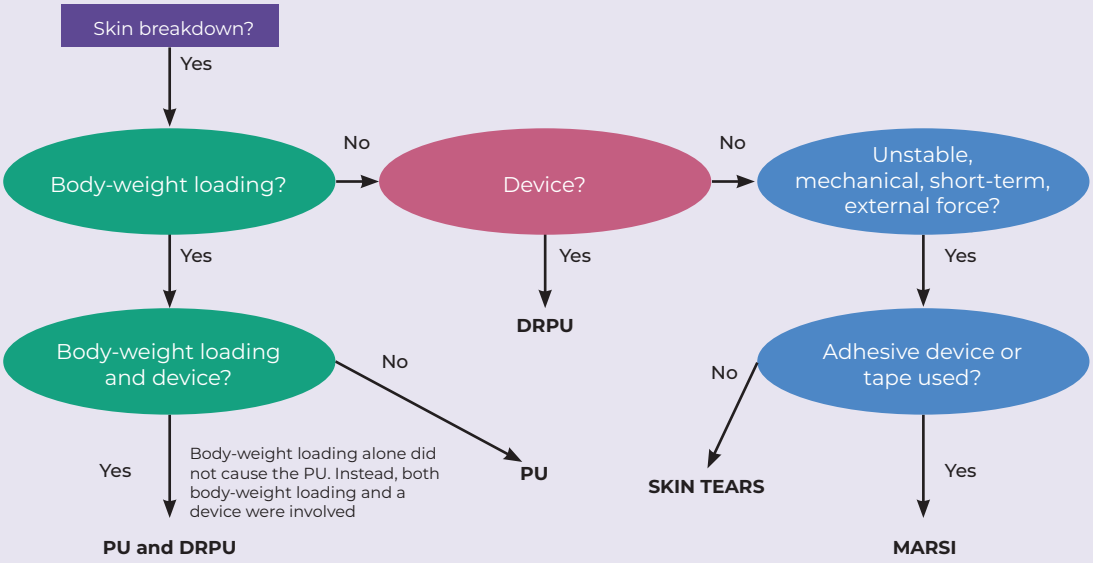


Fig 12. Causes of PU, DRPU, skin tear and MARSI formation

DRPU—device-related pressure ulcer; MARSI—medical adhesive-related skin injury; PU—pressure ulcer

Box 10. Aims and objectives for collaboration with procurement

- Liaise with procurement services to increase awareness of their role in DRPU prevention
- Inform procurement about the role of materials used in medical devices (adhesives, silicones, additives and latex) for 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 the prevention of patient harm

DRPU—device-related pressure ulcer

been reported for a wide variety of medical devices including ventilation devices,[93] tracheostomies,[215] NIV devices[211] and those placed under orthopaedic casts.[220] Use of a prophylactic dressing under a device should only be considered if it does not impede the primary function of the device.

Prevention and prone positioning

The prone position increases the risk of pressure ulceration on the forehead, chest, pelvis, chin, shoulders, genitalia, iliac crest and knees, dorsal feet and toes.[153] DRPUs associated with this position are most likely to develop on the mouth, ears and nose. This may be because body weight is applied to areas, such as the face, that would not normally be subjected to it. Prevention of DRPUs in prone patients involves:

- Regular skin assessment, including assessing the skin before the proning manoeuvre and implementing preventive measures including good skin hygiene and moisturisation[179]
- Consideration of the use of prophylactic dressings as an interface
- Use of specific pressure-redistribution surfaces to reduce pressure, shear and friction, particularly to the head[153,179,221]
- Frequent offloading of pressure and repositioning
- Placing the patient in the swimmer's position,[179] ensuring that the elbow of the flexed arm is not higher than the shoulder
- Use of tape, rather than ties, to secure endotracheal tubes

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 dislodging tubes and devices. Head positioners are being developed 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 being assessed in the clinical setting.[153]

Another important consideration is to manage 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, increasing the risk of skin breakdown at the site of devices such as endotracheal tubes.

Modelling has shown that application of prophylactic dressings, such as silicone foams or hydrogels, can reduce the forces applied to a patient's skin.[103] In addition, anecdotal reports of the prophylactic use of gel pads and strips in prone patients have emerged.

An integrated pathway for prevention

A helpful mnemonic for an integrated pathway for DRPU prevention is SECURE (Fig 13).

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.

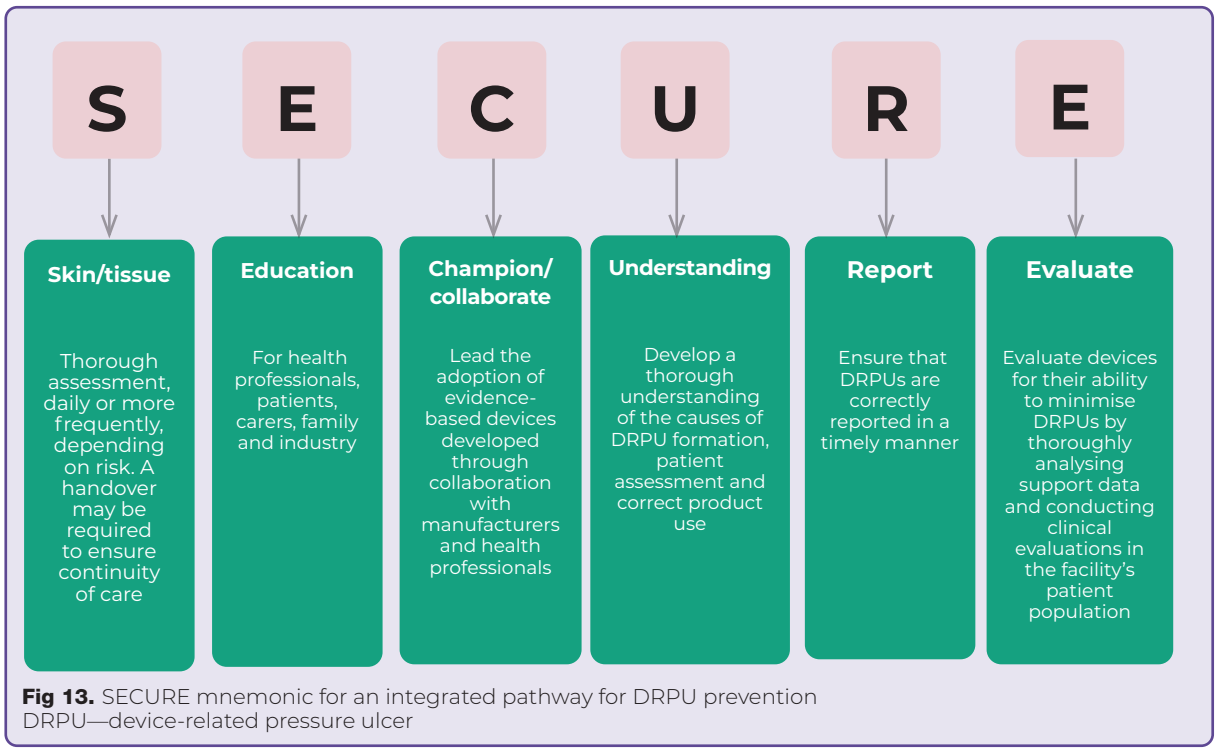


Fig 13. SECURE mnemonic for an integrated pathway for DRPU prevention
DRPU—device-related pressure ulcer

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,[1] to describe the DRPU. This requires:

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

DRPUs present different challenges to PUs, as body-weight forces are not a dominant aetiology.

DRPUs caused by a mask may be managed by changing to a different design—for example, from a mask that transfers forces to the nasal bridge 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 causative factors should be implemented, 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 the problem. 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 using a fine bore tube. Ensure the tube is in the correct position: that it is not touching the mucous membrane or skin of the nare. Secure the

Box 11. Information to include when reporting a 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 the device
- Control or serial number of the device
- Expiry date of the device
- Method of application
- Method of securement
- Protection or preventive strategy used with the device
- Adjustments made during its use
- Degree of adherence to the manufacturer's instructions for use, including the duration of application

DRPU—device-related pressure ulcer

tube to ensure it is 'free' in the nare and regularly assess its position and securement to prevent it from applying pressure to the skin.

Reporting DRPUs

Medical device regulatory bodies, such as the Food and Drug Administration (FDA) in the US, Health Canada and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK have developed reporting interfaces where the public, patients or health professionals can report harm caused by the therapeutic use of a device. Other countries have similar reporting systems.

Unfortunately, it is unclear how frequently health professionals use these reporting tools; DRPUs are 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.[222,223]

This means there is no consensus on which devices would benefit from further study on their design. To 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.[223–227] In short, a culture of open reporting, supported by regulatory agencies, is required. This should result in manufacturers of unsafe devices reviewing and improving their products.

DRPUs should be reported separately to PUs. A root cause analysis should be conducted to inform the reporting of the DRPU. The device that caused the DRPU should be specified. In the UK, NHS Improvement has issued new guidance on reporting of DRPUs.[228] Further details on reporting requirements for DRPUs are given in Box 11.

PPE-related DRPU
Protecting the health professionals

With the emergence of the COVID-19 pandemic, vastly increased numbers of frontline health professionals were required to wear PPE for long periods, sometimes up to 8 hours or more, without the breaks that would be 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%.[229–233] This was exacerbated by anxiety and fear of contracting COVID-19, which led to many health professionals tightening their face masks more than required.[234] DRPUs most commonly observed were on the nasal bridge, cheeks, forehead, behind the ears and on the hands.[9,229,232,235] This was linked, in particular, to a longer duration of wear, sweating and the use of grade 3 PPE, such as N95/P2 respirators.[229,230] Immediately after donning PPE, approximately half of health professionals felt uncomfortable and a quarter anxious or afraid.[232]

Although PPE has been observed to cause other skin injuries, such as dermatitis and maceration resulting from prolonged wearing of protective gloves, only DRPUs are 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, hypoxia, evaporation from the skin 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.[236,237] There is anecdotal evidence of pressure in the occiput region from mask straps. Similarly, there are anecdotal reports that wearing a mask is stopping some health professionals from eating and drinking as much as they would normally, resulting in systemic dehydration.

One of the few studies to recruit both health and non-health professionals (but not patients) assessed the impact of mask-wearing on the underlying skin.[238] Surgical masks (63.15%) and cloth masks (35.05%) were most commonly used, with a very low percentage of N95/P2 masks (<1%). The most common adverse reaction was acne (39.9%), followed by rashes (18.4%) and itch (15.6%), with a higher incidence among health professionals. There was a higher risk for surgical masks than cloth masks. This indicates that PPE-related DRPUs are largely associated with the intensive use of higher-grade PPE, which is principally worn by health professionals.

Prevention

In their survey of hospital workers in China conducted early in the pandemic, Jiang et al. found a very low use of prophylactic dressings and lotions to protect the skin.[229] They attributed this to lack of direction and training on how to prevent skin injuries and concern that protective dressings may compromise the barrier function or seal of PPE. They also identified a lack of direction from management as all resources were being focused on the rapidly unfolding epidemic.

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 guidance[239–241] on the prevention of DRPUs caused by masks, goggles and respirators is consistent. It can be summarised as follows:

- Conduct frequent skin checks[242]
- Wear a properly fitting mask that is (ideally) designed for each individual.[233,243] Ensure it has been fit-tested and a pass rate achieved[240,242]
- Move the mask around to a different position at regular intervals, or swap it for one with a different design and, therefore, different pressure points[243]
- Take frequent mask breaks, if possible[233,238,240]
- Apply a moisturiser or gel in advance to act as a long-lasting lubricant,[233,243,244] but do not do this directly beforehand as this can cause slippage. Avoid facial make-up[244]
- Use ear-savers behind the ears to minimise pressure from straps[244]
- Do not overtighten goggles: their main purpose is to prevent splash and tightening is unlikely to enhance their protective effect[243]
- Consider using prophylactic dressings underneath PPE.[169,240,242,245] Ensure that these do not compromise the seal of the PPE. FIT testing may need to be repeated.[245,246] Check exhalation and inhalation to confirm fit
- Position respirator mask straps on the back of the head where they do not cause pressure.

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

A common approach is to use lubricants or prophylactic dressings underneath the contact points of PPE. Polymer gel tubes have recently been developed to redistribute pressure around mask straps. A literature review found that many types of lubricant were effective in reducing shear forces between PPE and the skin in the short-term, but this declined over time. The best-performing lubricants with the longest-lasting activity were from different categories, 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.[244]

A systematic review found that the prophylactic

dressings most commonly reported for use underneath PPE are silicone foam dressings and hydrocolloid dressings.[9] 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.[247] However, these small studies did not check the impact of these dressings on mask fit.

In a study by Yildiz et al.,[248] PPE-related DRPUs occurred in all participants in the control group, but not in any of the participants who used prophylactic dressings, although a small proportion developed erythema.[248] 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 levels of comfort were similar. Both dressings were found to be effective in preventing DRPUs associated with the use of PPE.[249]

The NPIAP states that thin dressings can be used under devices provided they do not impair the function of the PPE device—it is vital to confirm that the mask has passed its fit test (and that the seal is good) before use.[240] A new dressing must be used every time PPE is applied. However, it should be noted that this practice is not permitted in some countries, including the UK.

Anecdotally, due to the increased risk of harm to health professionals during the pandemic, risk assessments in most institutions have been extended to include the potential for skin damage in health professionals and non-medical staff caused by the requirement to wear PPE for long periods. Injuries to the skin can then be recorded in incident management systems, in line with the institution's protocol.

Management

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

Where PPE-related DRPUs have developed, management strategies have emerged in the literature and are being adopted in clinical practice. Most mild skin indentations regress spontaneously.[243] Cold water compresses followed by use of moisturisers can help; washing with hot water or alcohol should be avoided. Minor abrasions can be treated with moisturiser, skin sealant, cyanoacrylate or a thin dressing.[240,241] In the case of open facial wounds, advice from an occupational health specialist should be sought on the safety of returning to work. The availability of an alternative mask that may relieve pressure on the open wound should be investigated.[241] Any deep-tissue or full-thickness injuries should be referred for professional wound management.

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.

This chapter has discussed prevention and management of DRPU. Appendix 2 on page S62 gives an example of how the principles described here can be applied to practice, with the use of NIPPV masks as an example.

Standards for industry

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 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. In contrast, regulatory bodies have not investigated reports of harm resulting from the use of medical devices, raising questions about the role of regulatory agencies in this field.[226] Health professionals should be encouraged to report these harms via the appropriate regulatory mechanisms.

Redesigning medical devices

Computer (finite element) modelling and phantoms can be used to design medical devices that minimise the risk of DRPU formation.[48] 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 into account the causative factors of DRPU formation, including the 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, 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 intended to minimise the risk of DRPU formation. 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 sustained deformation injury and pressure ulceration. Quantitative measures were provided by exposure to tissue loads for each design variant.[99]

In addition, technologies are available that sense interface pressure, shear, temperature and humidity.[250,251] 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 device.[252]

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 DRPU formation or indicated for high-risk patients. For example, the design of a device for neonates and paediatrics considered the differences in proportional anatomical and tissue composition between this patient group and adults.[253]

The clinical evaluation plan should evaluate the potential risk of DRPU formation 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 DRPU formation that might be associated with the device, based on clinical research evidence. Regulators need to be encouraged to ensure this is done. The instructions for use should include clear and detailed information on:

Box 12. Functional objectives of medical-device design

- Match the stiffness or elastic modulus in the design, so that the elements that have contact with the skin are at a stiffness that is near that of the skin and its 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 device surfaces that have contact with the skin
- Minimise the coefficient of friction at the device-skin interface; this will reduce frictional contact forces and shear distortions in the skin and subdermally
- Minimise sustained tissue deformations at the skin surface and in deeper tissues
- Ensure the mechanical loads applied by a device are absorbed, 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; 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; heat accumulation; the tissue health status; and potential harms
- Produce shapes and sizes of the device that are 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 continence management
- Manage moisture or wetness resulting from use of the device
- Provide continuous tissue protection by minimising any frictional properties at the skin-device interface, even if there is a build-up of perspiration or moisture that temporarily increases the skin and subdermal tissue tolerance to loads
- How the device's design features address the risk of DRPU formation
- 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 be possible to be able to adjust the device 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.[254]

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

Chapter 6: changing the focus of health professionals and policymakers

Reducing the incidence of DRPUs 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. During the pandemic, healthcare systems around the world showed 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, multidisciplinary teams learned quickly and adapted procedures and protocols to the needs of these patients.[255,256] In some cases, the initial rise in incidence of DRPUs observed during the first wave began to decline as this learning was put into action.[256] However, DRPU rates often remain higher than pre-pandemic levels,[12,256] suggesting that further efforts are needed to address the problem.

It remains the case that health professionals and administrators will need to be aware of the risks that medical devices and other objects pose in terms of tissue injury. Health professionals will also need to be trained on 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 burden of DRPUs.

Key points

- Many health professionals and managers underestimate the psychosocial, clinical and economic impact of DRPUs
- There is a need to increase awareness of DRPUs through education, training and improved documentation and reporting
- Education can be provided by health professionals, academics, bioengineers or industry, if supported by independent experts. It is most likely to be effective if it includes practical demonstrations and exercises on best practice for the application of devices
- It is vital that health professionals demand that manufacturers provide robust evidence on the clinical efficacy of their medical devices in terms of how they are designed to minimise the risk of DRPUs
- 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 to protect their staff from the risk of skin damage from PPE

Increasing awareness

Before the COVID-19 pandemic, some health professionals and administrators were often not even aware of the risk and impact of DRPUs.[13,145] This might not have changed. As in the past, DRPU prevention may not feature much in chart templates and patient documentation.[13] Therefore, there is still a need to raise awareness that not only do DRPUs occur, but that they need to be rigorously recorded and monitored. This will be best achieved through education, ongoing training and consistent reporting.

A literature review by Crunden et al.[257] found there are national and international variations in reporting of PUs, with DRPUs often not specified as a separate category and insufficient detail provided on the devices that might be causing harm. In terms of reporting, there is a need to formally define a minimum dataset for reporting pressure-related injuries. Suggestions include capturing the following:

- Device location
- Type of securement
- PU stage or category (including mucosal)
- Date and time of the injury
- Use of preventive measures (for example, barrier products or prophylactic dressings)
- Details on repositioning
- Results of skin assessment
- Length of time the device has been in use.

DRPU prevention should not be the sole responsibility of a tissue viability specialist or

equivalent: the likelihood of a DRPU prevention programme being successful when led by a single group of specialist clinicians in a healthcare facility is low. All health professionals who manage patients in contact with devices must be aware of the risk of DRPUs and the strategies to prevent them. 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. In English ICUs, in 1995–2012, PUs were among the harms that most led to substantial compensation following litigation.[258]

Education and training

The key to increased awareness is to monitor and document staff performance to ensure that 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 also need education on DRPUs and practice on application and securement. 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 routinely be 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 that this includes DRPU prevention. Offers of education and training by industry should be accepted, provided they reflect best practice and are 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.[192] The development of virtual simulation games, which can encourage engagement with the training process, is an interesting and potentially powerful innovation.[259–261] During the pandemic, online training was used to deliver the rapid education required to a much larger population of health professionals than would have been possible with more traditional face-to-face training programmes.[262] Development of experts, who are then available to support other staff in their institution, has been shown to be an effective strategy.[192,263]

Health professionals often use only medical devices that are available on local contracts and formularies. Therefore, stakeholders need to assess that those listed are fit-for-purpose. This will 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.[264]

Bioengineering input

Hands-on education and training can be delivered in the wards. This 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 technology is necessary to provide optimal training

Box 13. Advice and information for carers and family

- Regularly inspect the skin near and under the device for redness, swelling and breakdown
- Pay particular attention to areas where the skin is depressed by the device or methods 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 that they are sitting or lying on
- Ask the patient about any discomfort or pain associated with the device
- Call the nurse or clinical specialist if any problems are observed

on, for example, how to avoid overtightening oxygen masks located on the face.[264]

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 process 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 it.

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 if this is at short-notice, such as occurred during the pandemic when non-specialist staff were seconded to ICUs.[10]

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

New employees must receive training on how to use and secure devices with a view to minimising DRPU formation. For undergraduates, this information needs to be incorporated into education on PU prevention. 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 patients' families must also be made aware of the risk of DRPUs. They should be taught how to inspect for signs of DRPU formation and to immediately notify a trained health professional if a medical device is misplaced and/or might cause tissue damage. Non-professional carers and patients' families should also be informed of the risks associated with personal belongings and other objects used by the patient and taught how to manage and avoid them.

Box 13 lists instructions that could be given to carers and family. However, as this is a safety issue, those 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 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 medical 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 as 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 and presentations at conferences aimed at different audiences, including nurses and physicians, administrators, and the use of 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 a 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 not only ensuring provision of education, training and guidance on the prevention and procurement of safe devices, but also implementation of best practice.

Stipulation that satefy data need to be provided for individual medical devices might help health professionals justify their purchase in the event of any increase in price.

The COVID-19 pandemic has provided much food for thought. It stress-tested the healthcare system more than has ever been done before, exposing potential weaknesses in procurement, capacity, demand and skills. Several of these issues are highly relevant to DRPUs. Weaknesses in procurement and supply chains led to shortages of appropriate PPE in some countries, resulting in harm to staff. In many places, the need to equip additional critical care beds, given the massive numbers of severely ill COVID-19-positive patients, may 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 the greater use of positioning techniques, such as proning, had implications for staff skills. At the same time, as patient volume was increasing, with more needing ventilation support or critical care, 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, who may have lacked key skills, experience and knowledge—for example, on how to monitor, assess, record and prevent DRPUs.

Initiation of policies that mitigate against the development of DRPUs is likely to represent a good investment; not only is the pandemic still ongoing, but in many areas of healthcare the need to address DRPUs is overlooked.

It is recommended that organisations have written guidelines on the use of medical devices associated with a high-risk of DRPU formation in their facility. The guidance must include information on how to select the correct size of device, if possible, and apply it in accordance with the instructions for use. The policy must be updated after each new purchase decision or change of equipment. These decisions should not be based solely 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 the safety profile of medical devices
- Interviewing company representatives about how their medical devices can reduce the risk of DRPU formation 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 policy and procedure 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 can come into contact with the skin and develop requirements for the design, evaluation and application of these devices, to address these risks. These standards should be developed by independent experts in tissue mechanics and biomechanics in collaboration with industry partners. Regulators should be responsible for assessing industry compliance with them.

A rating system for the level of risk of ulceration associated with medical devices needs to be devised. Based on this, icons could 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 information on how to avoid DRPU formation during use. There is a strong case for incorporating this into the existing instructions for use for all medical devices, particularly those considered to pose a 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 (for 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 that 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 and manufacturers to identify and address areas of concern and alert health professionals. The database would need to be transparent and accessible to all.

Chapter 7: future research and guidelines for product development

Many devices have not changed in design or the materials used since the 19th century when, for example, respiratory tubing and equipment, as we know them, first appeared. As a result, the unintended consequence of DRPUs 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 medical devices to reduce the risk of injury. 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 that will reduce the risk of DRPU formation. 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 result from the following factors:

- The design of existing medical devices and the materials used in their construction is limited in terms of DRPU prevention
- No technologies for the early diagnosis of DRPUs or the mitigation of risk are available for use in clinical settings
- No dedicated laboratory test standards have been developed to evaluate the risk of ulceration incurred by medical devices that come into direct contact with the skin
- 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 DRPU formation
- 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 advances in understanding of the causes of DRPUs and the role played by device design.[224,265] 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 can come into contact with the skin are clearer. The impact that a product design can have on tissue deformation and heat clearance from either the device or the body tissues can be estimated.

Nevertheless, these new research advancements have not yet been incorporated into device designs and medical technologies. It also still needs to be appreciated that different face shapes and planes, often related to ethnicity, need to be taken into account in product design.

The need for dedicated technology and equipment was 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 risk of adverse skin reactions. There is a general lack of awareness in industry and among health professionals that any device that can come into contact with the skin needs

to be designed to minimise the risk of DRPU formation.[266] Health professionals are also unaware that they should be pushing for peer-reviewed published evidence from the leading bioengineering and medical/clinical journals.

Reducing the incidence and prevalence of 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 are needed to reduce the occurrence of DRPUs. Multidisciplinary work by academics, developers and manufacturers, including regulators and health professionals, is required 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 research, development and technological gaps identified here. However, where knowledge and best practice can be deployed effectively, DRPUs can, and must, be addressed.

Factors to consider during product development

Medical-device developers, manufacturers and industry can play a leading role in DRPU prevention. In most jurisdictions, medical-device regulations are risk-led, with product classifications defined by the level of risk posed by the product. During product development, risks associated with use are identified, based on a thorough understanding of user goals and needs. This relates to:

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

This information is used to define clear functional objectives, select materials and develop structural and geometrical features for the device design. It is also used to 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 from the device and 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 the 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, the contours of any device that can come into contact with 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 minimise tissue deformation and exposure to stress. This can be achieved by using low-friction surfaces or coatings on the device and lubricants, or a combination of the two. For example, a ventilation or respiratory mask must maintain a seal to function, but this requires application of pressure and static frictional forces onto facial skin. The key to adequate device design is determining how to minimise these pressures and frictional forces, while allowing the mask to fulfil its medical purpose.

These considerations should be carefully considered at the design stage. Outcomes of studies on pressure redistribution at the mask-skin interface show that this approach reduces skin and subdermal tissue stress.[215,267] 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 with manufacturers of medical devices and manufacturers of prophylactic dressings and pressure-area care devices.

Thermal energy management

Some devices may actively create heat, whereas others may 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.

Computer modelling and technology

The design research described above should be done using computer modelling.[99,137,253,268] This needs to be informed and reinforced with laboratory experiments, which should involve the use of phantoms, dummies or mannequins.[269]

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. This should inform the design process.

Advanced phantoms or mannequins are required that replicate the biological, mechanical and dimensional features of babies, children, young adults and older patients; other patient groups, such as those with spinal cord injuries or who are obese, cachectic, or have diabetes; those receiving palliative care; and women in delivery. These phantoms or mannequins should have integrated sensing, data-sampling and

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, monitoring vital signs, clearance of body fluids, access and support?
- Shape and size of the device, relevant to the patient population: age, ethnicity, body build and body mass index
- 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, including urine, and moisture away from the skin
- Ability to minimise heat trapping at the skin-device interface
- Inclusion of indications and alarms to alert health professionals when tissue is exposed to elevated forces or there is an immediate risk of DRPU
- Other protective features to increase tissue tolerance to forces and exposure to heat, supported by published evidence

DRPU—device-related pressure ulcer

Box 15. Key topics, aspects and uses for additional research on DRPU that should be led by health professionals

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

DRPU—device-related pressure ulcer

user-feedback systems to provide in-use data on: pressure and shear distributions; internal tissue deformations or stresses; temperature, humidity, moisture, pH and/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.

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

Health professionals may wish to consider undertaking clinical research on 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 the 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, nurse managers and physicians can collect cost data for evaluations on the economic burden of DRPUs in their institutions and the cost-benefits of changing equipment, products or suppliers, providing education and training, and implementing awareness campaigns. These are valuable data that have the potential to influence administrators and decision-makers.

It is vital that health professionals work closely with multidisciplinary teams when involved in the development, improvement or design revisions of any device that can come into contact with 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.

Input from researchers

Researchers in universities and industry should develop physical and in silico (computer-simulated) patient models that can be used to create bench-tests that can evaluate the risk of DRPU formation associated with particular devices. For example, computer models of 3D, anatomically realistic, body parts of children, adults and older patients (including cachectic or obese patients, and those from different ethnic backgrounds, where appropriate) can be used to perform objective, quantitative and standardised comparisons of tissue-stress concentrations caused by device design variants or modifications, or by the application of interface materials and structures to a device. This would identify the most biomechanically effective and cost-beneficial solution for each device.

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. They 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,[250] or when tissues show an inflammatory response to the applied forces, are another promising route for bioengineers to follow. An example is pressure and shear sensing to measure stress at the residual limb or socket interface for prosthetics.[250]

The COVID-19 pandemic has 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 for the risk of DRPU formation and other harms.

Emerging technologies for prevention

Key areas for innovation in emerging technologies that could aid prevention 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, which will minimise conduction to the skin and underlying soft tissue
- Use of durable materials and structures that will prevent the mechanical properties of medical devices impairing with use or over time
- Sensing technologies that accurately detect biomechanical factors associated with DRPU formation, such as excessive force, tissue deformation, thermal challenges, moisture, wetness, biocapacitance and pH changes. These could also, perhaps, monitor levels of inflammatory biochemical markers secreted from skin (Fig 14). Such 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 with a low coefficient of friction
- Translational research on interface materials and structures
- 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 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 the deformations, stresses and thermal conditions caused by the application of medical devices. As stated, 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.[270] Apps providing DRPU-related information might be well received. Novel technological approaches to the training of health professionals, such as the introduction of training via 'gaming' technologies, is becoming possible. This is discussed in chapter 6
- Bespoke medical devices specifically designed to fit the individual. Although mass-produced devices predominate, it is possible to create bespoke devices using technologies, such as 3D printing. During the pandemic, 3D printing was used to generate generic PPE to combat shortages.[246] The potential for creating bespoke medical devices that fit the unique contours of an individual person is most associated with prosthetics.[271] The use of

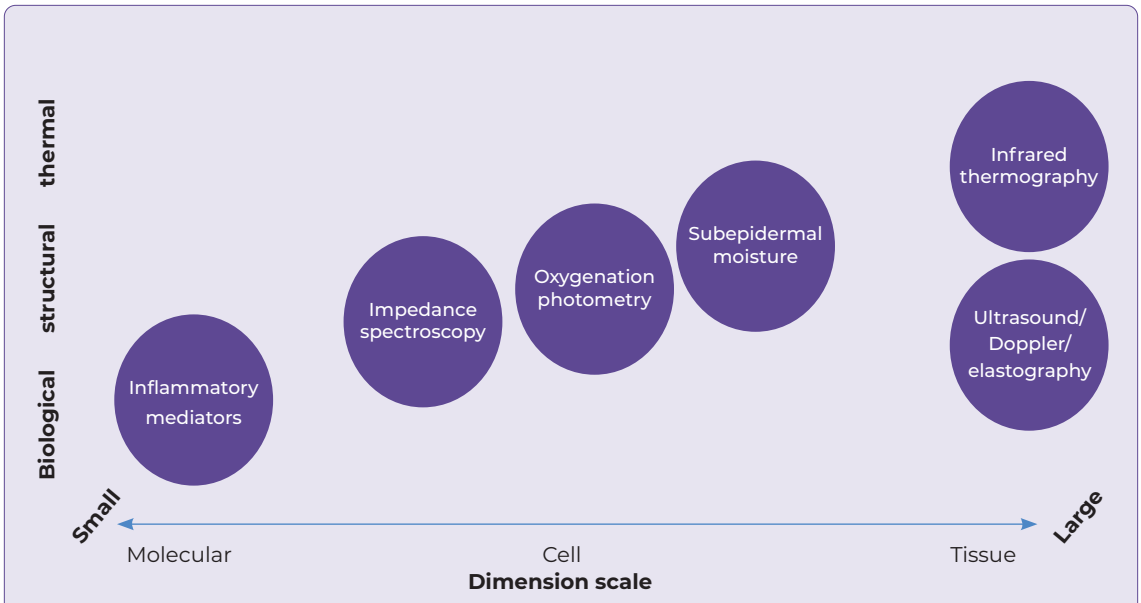


Fig 14. Integrating risk assessment and early methods of early diagnosis

3D printing technology to produce medical devices for acute care, such as ventilatory support, has not been explored yet, nor has its use to create bespoke medical devices that could protect against DRPU formation. Most masks are designed for a typical 'white male' face and are not suitable for many females, non-typical males and people of different ethnic origins.[45] It is possible that, in the future, 3D printing of masks and goggles may be able to produce truly personalised PPE. 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 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 should detect, measure and map critical values or conditions, and alert when they are reach. These include:

- Pressure and shear stress under devices, specifically indicating when a device applies excessive force
- Physiological sensing and monitoring of potential inflammation at the skin-device interface or in underlying tissues in its vicinity
- 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,[95,250,251,254,264] as are biocapacitance examinations based on measurements of extravasated tissue fluid (an early marker of inflammation).[186] Ultrasound can be used to assess physiological changes in tissue.[272] Thermographic assessment could, potentially, provide data on high-risk tissue that would not tolerate a medical device.

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, at present, chemical biomarkers are not feasible for routine clinical use. Furthermore, the optimal chemical biomarkers, which may be a combination of different types of markers, have yet to be identified.[69]

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, relieving the mechanical loads applied by the device, or turning off the heat-generating element.

Future technologies may minimise, or even eliminate, the possibility of DRPU formation. Suspended contactless devices—for example, based on magnetic fields—may be developed for the most fragile skin and critical areas, such as ICU.

Monitoring of dedicated protective technologies, smart materials or structures, and tissue and environmental factors could, potentially, be fully integrated into a facility connected to a server 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 indicative of a 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 normal ranges, both normative and in the patient's historical data, would trigger such alerts.

It may also be possible to combine multiple technologies into one integrated system, reducing the need to monitor multiple sensors. This approach has been used successfully in the management of PUs, with the integration of a textile-based pressure-sensing matrix and a mattress to create a 'smart' bed.[273]

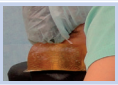
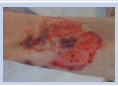
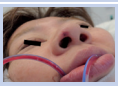
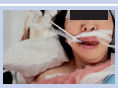
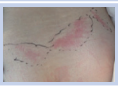
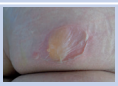
Such an approach could also produce data on whether or not best practice had been applied. This would be useful for education, training, evaluation of clinical-practice standards and cost-benefit analyses. It would also assist reporting to government, regulatory, insurance and other bodies and authorities.[270]

Such data should also be useful to academia and industry, who could use it to quantify goals for device design, including outcomes that need to be achieved.

This vision is not so far in the future as it may seem. In fact, all the technologies mentioned above exist and are available at different levels of maturation. It is only their improvement, integration, scaling and commercialisation that require effort, time, translational research and investment. Understanding the scale and threat of DRPUs, and the heavy burdens they impose on society in suffering and costs, should lead the way towards a new generation of medical devices specifically designed to minimise the risk of DRPU formation.

Appendix 1

Can you make a diagnosis?
Differentiating between PUs, DRPUs, skin tears and MARSIs

How would you diagnose the following?	
1. Redness in the sacral region following lengthy surgery on a patient in the supine position	
2. Redness in a patient's upper arm after it was placed on an arm support during surgery in the lateral position	
3. Redness caused by wrinkled sheets	
4. Redness that developed on the skin under an arm strap, with the upper extremity in the supine position	
5. Redness on both sides of the patient's chest following use of a frame for proning	
6. Epidermal skin damage in the chin crease following use of a gel head pad for proning	
7. Laceration on the patient's left forearm after being moved from the prone to supine position an operating frame	
8. Redness following removal of an entropy EEG pad after extubation of a prone patient on an operating frame	
9. Redness following attachment of a nasogastric tube to a patient's cheek with tape, which was then covered with a facial protection pad	
10. Epidermal peeling following removal of an entropy EEG pad after extubation of a prone patient on an operating frame	
11. Redness on the heels of a patient in the lithotomy (supine with legs flexed at 90 degrees at the hips) and head-down tilt positions during da Vinci surgery	
12. Redness on the anterior lower limb along the boot band (see arrow) following removal of the levitator without a foot pump in a patient in the lithotomy and head-down tilt positions during da Vinci surgery	
13. Redness on the shoulder of a patient in the lithotomy and head-down tilt positions during da Vinci surgery	
14. Redness on the side of the chest that was in direct contact with a beanbag positioner in a patient in the lithotomy and head-down tilt positions during da Vinci surgery	
15. Redness in the sacral region in a patient in the lithotomy and head-down tilt positions during da Vinci surgery	 
16. Epidermal peeling and blistering on the buttock area (lateral position) following direct contact with the pad of a hip positioner (pelvic support) in a patient in the lithotomy and head-down tilt positions during surgery (total hip replacement)	 
17. Redness in the right lateral chest and right iliac crest in the lower right lateral position (park bench position) during surgery	
18. Redness in the right axilla skin following direct contact with a beanbag positioner in a patient in the lower right lateral position during surgery	
19. Redness occurring when tubing from equipment, such as ECGs, sphygmomanometers and electrocautery pads, is caught between the skin and a beanbag positioner with the patient in the lateral position during surgery	

20. Redness in the corner of the mouth during direct contact with an endotracheal tube 

21. Redness in the nostrils during nasotrachaeal intubation  

22. Epidermal peeling following removal of an eye patch

23. Epidermal peeling after the tape holding an endotracheal tube is peeled off 

24. Redness, blistering and swelling caused by a bite block pressing onto the lips 

25. Redness and blistering caused by a transesophageal echocardiography probe pressing onto the lips

26. Redness caused by pressure from a three-way stopcock on the forearm 

27. Redness following use of a splint to maintain dorsal extension in the wrist with an indwelling arterial catheter in place. The splint was pressing hard onto the ulnar head 

28. Redness caused by an ECG lead positioned under the body

29. Epidermal peeling following removal of an ECG patch in a patient on steroids

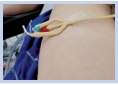
30. Redness in skin on which the cord of the monitoring ECG is pressing

31. Redness caused by pressure from the cord of a defibrillator pad

32. Redness caused by the edge of a sphygmomanometer cuff coming into direct contact with the skin

33. Redness in skin that has been squeezed by a sphygmomanometer tube connector

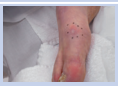
34. Redness in a finger pinched by a pulse oximeter

35. Redness occurring when an indwelling urinary catheter presses against the skin 

36. Redness occurring when a thermometer is inserted into the rectum and attached to the inside of the thigh

37. Redness following removal of a tourniquet cuff

38. Redness and blisters caused by the pressure of a tourniquet cuff that was not the correct size for the patient

39. Redness and blisters on the head of the hallux caused by anti-embolism stockings  

40. Redness caused by contact with the skin by a foot-pump tube and connector for the prevention of DVT 

Answers

1 PU. 2 DRPU. 3 PU. 4 DRPU. 5 PU. 6 PU. 7 Skin tear. 8 DRPU and PU. 9 DRPU. 10 MARSI. 11 PU caused by pressure and shear. 12 DRPU. 13 PU and DRPU. 14 DRPU. 15 PU caused by pressure and shear. 16 DRPU: this is not a PU because body-weight loading is not involved. 17 PU. 18 DRPU and PU. 19 DRPU: this is not a PU because body weight loading is not involved. 20 DRPU. 21 DRPU. 22 MARSI. 23 MARSI. 24 DRPU. 25. DRPU. 26 DRPU. 27 DRPU. 28 DRPU. 29 MARSI. 30 DRPU. 31 DRPU. 32 DRPU. 33 DRPU. 34 DRPU. 35 DRPU. 36 DRPU. 37 Reactive erythema. 38 DRPU. 39 DRPU. 40 DRPU.

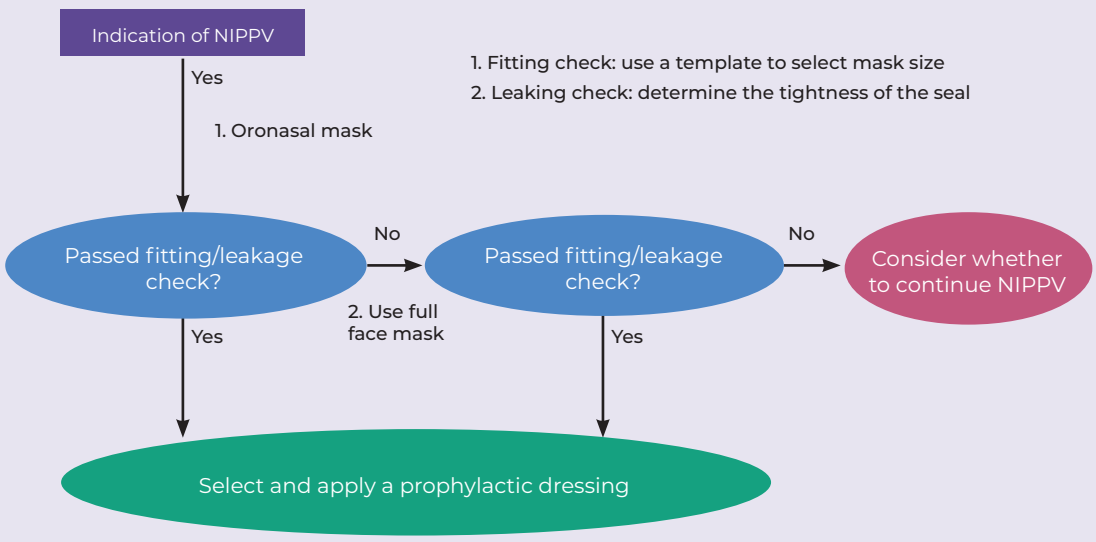
DRPU–device-related pressure ulcer; DVT—deep vein thrombosis; ECG—electrocardiogram: EEG— electroencephalogram; MARSI—medical-adhesive skin injury; PU–pressure ulcer

Appendix 2

Protocol for the prevention and management of NIPPV mask-related DRPU

A protocol for preventing and managing skin injury from NIPPV masks is outlined here. This begins with assessment of risk.

- Frequently monitor sites at risk of DRPU formation:
  - Bridge of the nose
  - Cheek
  - Chin
  - Forehead.
- Consider factors that can cause skin injury:
  - Presence of bony prominences, such as the bridge of nose
  - Microclimate (high humidity)
  - Reduced skin durability
  - Straps being tightened to improve respiratory management, which can increase pressure on the tissue.
- Implement the following prevention strategies:
  - Ensure an appropriate fit
  - Choose the right mask size with a good fitting; a mask template is required for optimal fit and respiratory management. This, in turn, helps prevent DRPU formation
  - With proper fitting, it is possible to reduce the pressure from the straps on tissue.
- In the event of a NIPPV mask-related DRPU:
  - Change the oronasal mask to a full-face mask if the DRPU extends beyond the dermis
  - Oronasal masks are associated with a higher risk of DRPU formation on the bridge of the nose, compared with full face masks. If a DRPU occurs at this location with an oronasal mask and it extends beyond the dermis, there is a risk of bone exposure. Again, it is necessary to change to a full face mask.
- Review the mask tension at each assessment. If the face becomes oedematous, the mask may need to be loosened.



Appendix 2: fig 1. Safe application of a NIPPV mask

NIPPV – non-invasive positive pressure ventilation

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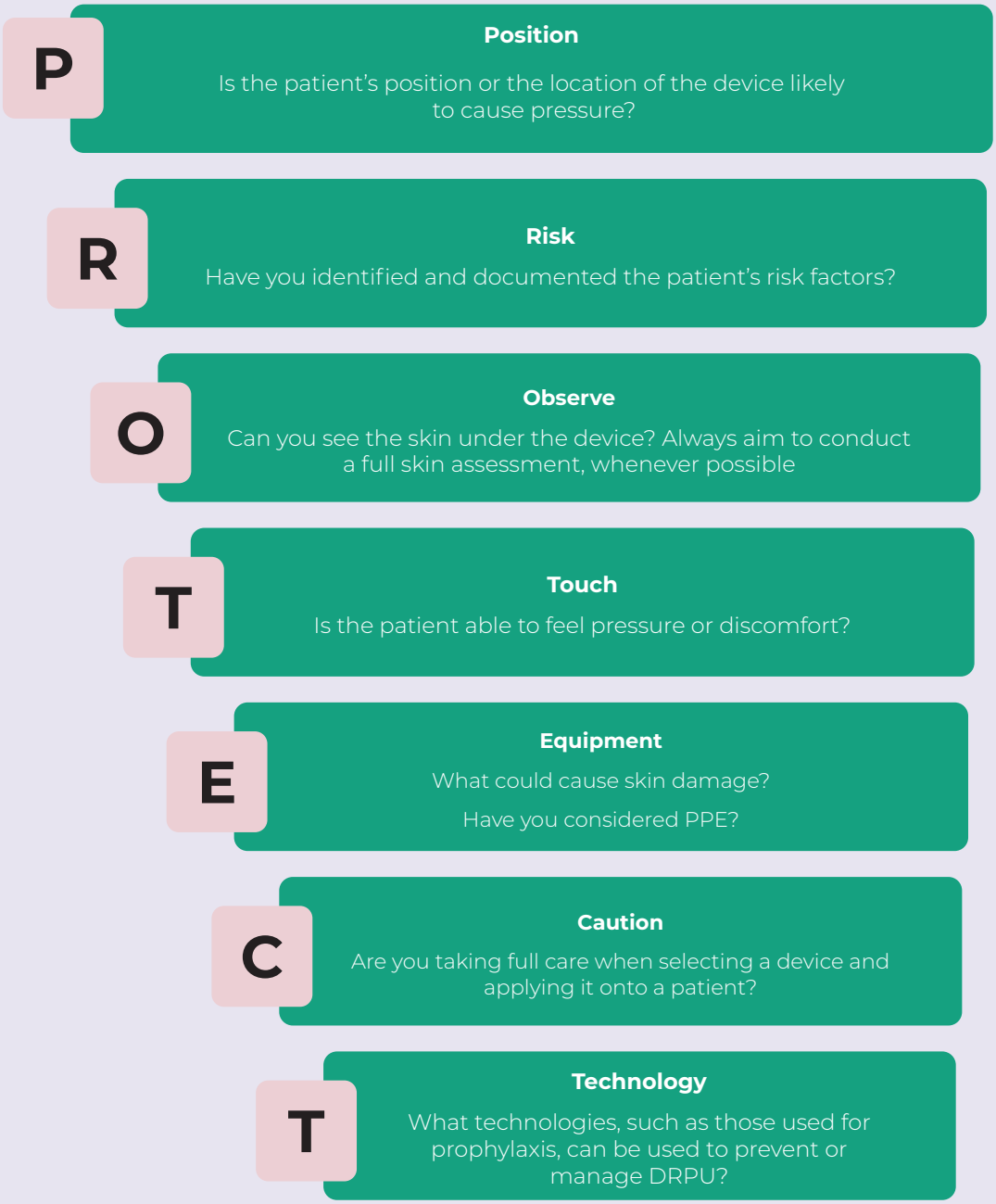
Fig 9 (see page S29) abbreviations
BIPAP–bilevel positive airway pressure; CHF–congestive heart failure; CIWA–Clinical Institute Withdrawal Assessment for Alcohol; COPD–chronic obstructive pulmonary disease; CPAP–continuous positive airway pressure; CVA–cerebrovascular accident; DRPU–device-related pressure ulcer; ECMO— extracorporeal membrane oxygenation; IAPB – intra-aortic balloon pump therapy; IPC–intermittent pneumatic compression; LVAD— left ventricular assist device; NPWT–negative pressure wound therapy; PU–pressure ulcer

Fig 10 (see page S32) abbreviations
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

mnemonic

The PROTECT mnemonic: questions to ask that can aid the assessment of patients with or at risk of DRPU



DRPU—device-related pressure ulcer; PPE—personal protective equipment

Activities associated with the SECURE mnemonic (see page S42 for its use in pathway development)

DRPU–device-related pressure ulcer

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