

A series on wound care in collaboration with the World Council of Enterostomal Therapists

Pressure Injuries Caused by Medical Devices and Other Objects: A Clinical Update

A review of practical resources, including mnemonics, to aid in prevention and identification.

ABSTRACT: At the April 2016 National Pressure Ulcer Advisory Panel (NPUAP) consensus conference, terminology and staging definitions were updated and two definitions were revised to describe pressure injuries (PIs) caused by medical devices or other items on the skin or mucosa. Here, the authors discuss the etiology and prevention of PIs resulting from medical and other devices, the frequency of such injuries, and the bodily sites at which they most often occur. They provide an overview of the current NPUAP guideline, highlight important risk factors, and explain why mucosal PIs cannot be staged.

Keywords: medical device–related pressure injuries, mucosal pressure injuries, National Pressure Ulcer Advisory Panel, pressure injury, pressure injury staging, pressure ulcer, SORE mnemonic, DEVICE mnemonic

Pressure injuries (PIs), formerly known as bedsores, decubiti, pressure sores, or pressure ulcers, have been a nursing concern since the time of Florence Nightingale. In April 2016, the National Pressure Ulcer Advisory Panel (NPUAP) shone a spotlight on this issue by convening a consensus conference in which associated terminology and staging definitions were updated. (The 2016 staging definitions can be found on the NPUAP website: www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages.) The term

pressure ulcer was replaced by *pressure injury* to underscore the fact that PIs may be present even when the skin is intact, and the definitions of medical device–related PIs (MDRPIs) and mucosal membrane PIs were revised.¹ (See Figure 1 for a depiction of intact, undamaged skin.) The NPUAP currently defines MDRPIs as PIs that “result from the use of devices designed and applied for diagnostic or therapeutic purposes,” noting that on the skin such PIs tend to take on “the pattern or shape of the device” (see Figure 2) and “should be staged using

the [NPUAP] staging system.”¹ The NPUAP defines mucosal membrane PIs as those “found on mucous membranes with a history of a medical device in use at the location of the injury,” noting that mucosal PIs cannot be staged because histologic characteristics of mucosal tissue do not allow clinicians to distinguish partial from full-thickness tissue loss.^{1,2}

In championing the prevention of PIs caused by medical and other devices, the NPUAP has raised awareness of the injury such devices can inflict on the skin or mucosal membranes and has clarified that the classification system used to stage PIs of the skin cannot be used to describe PIs of the mucosal membranes (see *Skin and Mucosal Pressure Injuries*³⁻⁹). The Joint Commission and the National Database of Nursing Quality Indicators have adopted the new terminology, and discussions between the NPUAP and the Centers for Medicare and Medicaid Services (CMS) about incorporating the revised language are under way.^{10,11} At press time, the CMS had recognized that a variety of terms are used in both long-term care facilities and long-term care hospitals to describe and document PIs. The CMS has further acknowledged that “it is acceptable to code pressure-related skin conditions in Section M [on skin conditions in the Minimum Data Set] if different terminology is recorded in the clinical record, as long as the primary cause of the skin alteration is related to pressure.”^{9,12} Nevertheless, setting-specific standards can be seen in some CMS terminology and in staging and coding instructions (see *Pressure Injuries and CMS Documentation Regulations*^{9,12-15}).

Although the change in terminology from *pressure ulcer* to *pressure injury* has been controversial, in this article we focus instead on the etiology and prevention of PIs resulting from medical devices and other objects. We also discuss the frequency of device-related PIs and the bodily sites at which they most often occur. We also review the evidence presented in current guidelines and identify the risk factors that may increase a patient’s vulnerability to device-related PIs.

ETIOLOGY AND FREQUENCY OF DEVICE-RELATED PIs

All PIs are believed to result from pressure or a combination of pressure and shear forces, though other factors, such as microclimate, nutrition, perfusion, comorbidities, and the condition of soft tissue, may influence a patient’s ability to tolerate pressure.^{1,16} As our understanding of PI etiology has evolved, awareness and concern about PIs caused by medical and other devices has increased in clinical practice. Surprisingly, however, research on the frequency of such injuries is limited.

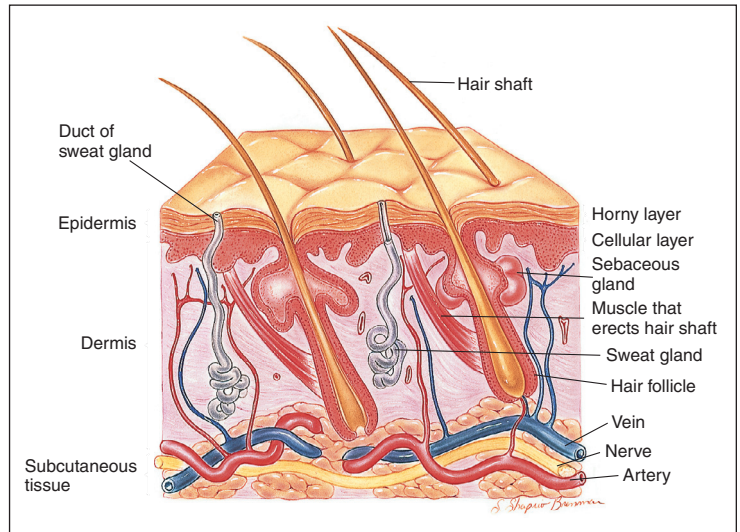


Figure 1. Layers of intact, undamaged skin. © 2013 Lippincott Williams and Wilkins. All rights reserved.

The general scope of PI frequency is reflected in the International Pressure Ulcer Prevalence (IPUP) Survey, which has been collecting data annually from participating facilities since 1989, when it was introduced by the medical technologies provider Hill-Rom. Its large database pulls information from a wide variety of care settings, including acute, long-term, long-term acute, rehabilitative, and home care. The most recent IPUP survey report provided data on 918,621 patients treated in U.S. facilities over a 10-year period and showed a decline in the prevalence of acute care facility–acquired PIs from 6.4% to 2.9% between 2006 and 2015; but the report did not specify the proportion of PIs related to medical or other devices.¹⁷

**Nurses should consider all
patients with a medical device to
be at risk for medical device–
related pressure injuries.**

For various reasons, there is relatively little information available on the risks or frequency of device-related PIs. First, some clinicians do not acknowledge them as PIs, either because they’re unaware of the NPUAP terminology or they disagree with the NPUAP



Figure 2. A pressure injury resulting from the hub of an iv line that was secured directly to the skin. Notice the imprint on the skin that matches the design of the hub. Photo © 2015 BA Delmore.

and believe that device-related PIs or at least mucosal device-related PIs should be categorized differently. Consequently, these types of PIs are not always

captured in prevalence or incidence data. Additionally, though the Glamorgan Scale acknowledges medical devices as potential PI risks, the Braden Scale, commonly used to assess PI risks in adults, does not take such devices into consideration.^{18, 19}

The extent to which medical devices cause PIs may, however, be gleaned from several studies that have specifically reported on these data. For example, in 2009, VanGilder and colleagues sampled 86,932 U.S. acute care patients and found that 1,631 of the 17,911 PIs (9.1%) were device related, with 785 of these facility acquired.²⁰ Device-related PIs were most commonly found on the ear (20%), sacral-coccyx region (17%), heel (12%), and buttocks (10%).

Black and colleagues reported on a subset of data (collected during eight quarterly PI incidence and prevalence studies conducted at the Nebraska Medical Center) that included 2,079 adult patients who were PI free on admission to a critical care, step-down, or medical-surgical unit.²¹ Of the 2,079 patients, 113 (5.4%) developed hospital-acquired PIs, 39 (34.5%) of which were related to medical device use. When probability was calculated, patients who were using a medical device were found to be 2.4 times more likely to develop a PI of any kind than patients who were not.

An analysis by Apold and Rydrych of hospitalized patient data collected through Minnesota's

Table 1. Key to the NPUAP, EPUAP, and PPPIA Strengths of Evidence and Strengths of Recommendation

Strengths of Evidence	
A	The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at risk for pressure ulcers), providing statistical results that consistently support the recommendation. (Level 1 studies required.)
B	The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at risk for pressure ulcers) providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies.)
C	The recommendation is supported by indirect evidence (e.g., studies in healthy humans, humans with other types of chronic wounds, animal models) and/or expert opinion.
Strengths of Recommendation	
👍👍	Strong positive recommendation: definitely do it
👍	Weak positive recommendation: probably do it
👎	No specific recommendation
👎	Weak negative recommendation: probably don't do it
👎👎	Strong negative recommendation: definitely don't do it

EPUAP = European Pressure Ulcer Advisory Panel; NPUAP = National Pressure Ulcer Advisory Panel; PPPIA = Pan Pacific Pressure Injury Alliance. Note: Level refers to the "level of evidence" assigned to a study based on study design and quality.

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Skin and Mucosal Pressure Injuries³⁻⁹

Understanding the essential differences.

Epithelial tissue functions to protect, secrete, and absorb.³ The stratified squamous epithelia occur in two forms: keratinized (meaning it contains the protein keratin, which makes tissue waterproof) and nonkeratinized (meaning it contains no keratin and thus must be kept moist).³ The epidermis, the skin's outermost layer, consists of the keratinized form, whereas the mucous membranes contain the nonkeratinized form.

Keratinocytes are found both in the keratinized epidermis⁴ and, in varying degrees, in the oral epithelium.^{5,6} In healthy epidermal tissue, keratinocytes are not activated; rather, they become activated when the tissue is injured, allowing the epidermis to heal through reepithelialization.^{4,7} Once the epidermal tissue is healed, the keratinocytes return to a deactivated state.

It has long been known that oral keratinocytes differ from epidermal keratinocytes. Depending on their location within the mouth (in the palate or in the tongue, for example), keratinocytes also differ in form, structure, and differentiation.

With the exception of the oral mucosa, which has a unique response to injury,^{5,6} mucous membranes do not keratinize⁸ and thus do not undergo reepithelialization. Keratinization is the process by which protein within epithelial tissue is hardened and made insoluble. Since the mucosal tissue, which lines body cavities, is constantly kept wet, it does not keratinize.

The National Pressure Ulcer Advisory Panel (NPUAP) addressed the problem of mucosal pressure injuries (PIs) in 2008, noting that mucosal tissue is "especially vulnerable to

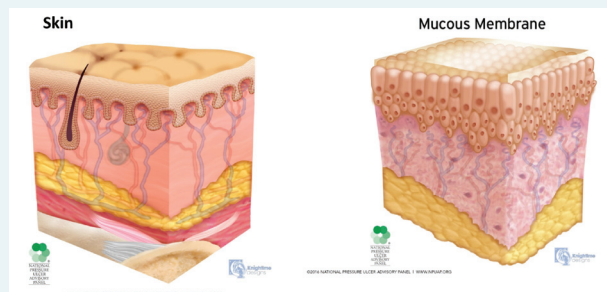


Figure 3. Skin vs. mucous membrane. Used with permission of the National Pressure Ulcer Advisory Panel, 2017.

pressure from medical devices" and cautioning that pressure applied to mucosal tissue by such devices as urinary catheters, or oxygen, endotracheal, orogastric, and nasogastric tubing, "can render it ischemic and lead to ulceration."⁸ However, since mucosal tissue differs histologically from skin tissue (see Figure 3), and the NPUAP PI staging system is based on skin and its underlying anatomical structures, mucosal PIs cannot be staged. Furthermore, clinical assessment of mucosal tissue does not allow partial tissue loss to be distinguished from full-thickness tissue loss. For these reasons, mucosal PIs are not coded in Section M on skin conditions in the Centers for Medicare and Medicaid Services' Resident Assessment Instrument of the Minimum Data Set (see Figure 4).⁹

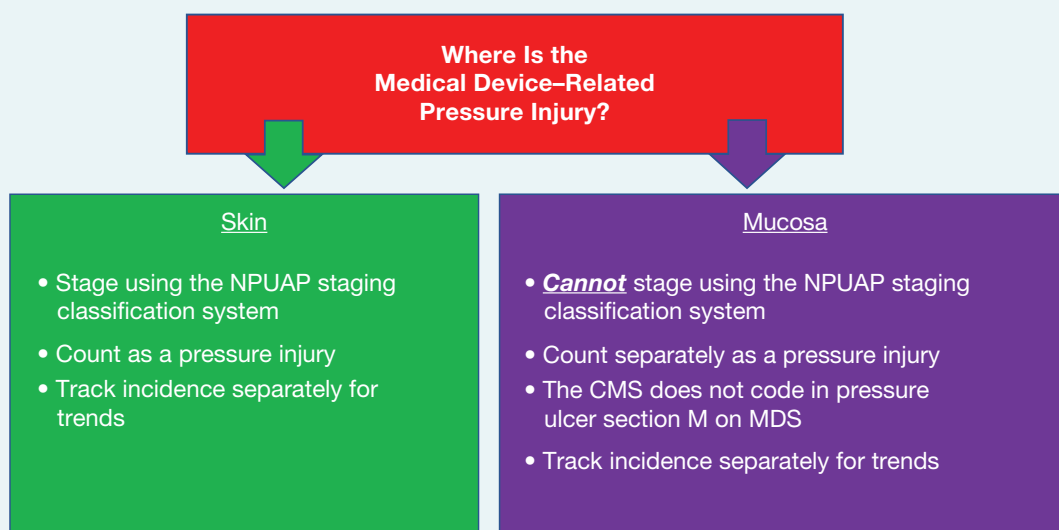


Figure 4. Staging and classification differences between skin and mucosal pressure injuries. © 2016 EA Ayello and BA Delmore. CMS = Centers for Medicare and Medicaid Services; MDS = Minimum Data Set; NPUAP = National Pressure Ulcer Advisory Panel.

mandatory statewide reporting system showed that for 63% of reported device-related PIs, there was no documentation of device removal at regular intervals for cleaning, pressure relief, or skin inspection, and 74% of such PIs were not discovered until they were stage 3 or more.²² The authors suggest that contributing factors may have included unfamiliarity with best practices for skin inspection and failure to replace ill-fitting devices, such as temporary cervical collars applied on admission to stabilize the spine, with better-fitting devices. The free movement of ill-fitting devices can exert shear forces on the tissue, which—depending on where the device is located—clinicians may be unable to relieve.

In a study of 200 ICU patients in a Missouri hospital who were receiving noninvasive ventilation either by nasal–oral mask or full-face mask, Schallom and colleagues found that patients considered full-face masks significantly more comfortable than nasal–oral masks and that full-face masks were associated with significantly fewer PIs (2% versus 20%); there were no significant differences, however, in mean

hours worn or percentage adherence between the two groups.²³

Mucosal medical device–related pressure injuries must be counted and tracked separately from skin pressure injuries.

The frequency of MDRPIs may be even higher in pediatric populations. When Visscher and Taylor conducted a two-year prospective study of 741 neonatal ICU patients at the Cincinnati Children's Hospital Medical Center, they found that nearly 80% of all PIs and 90% of PIs in premature infants were associated with medical devices.²⁴

Pressure Injuries and CMS Documentation Regulations^{9, 12-15}

For reimbursement purposes, the staging and classification of PIs must closely follow setting-specific standards.

The Centers for Medicare and Medicaid Services (CMS) issues documentation regulations that may vary depending on the type of facility—long-term care (LTC) facility, long-term care hospital (LTCH), rehabilitation center, or acute care hospital. Although patients continue to be at risk for device-related pressure injuries (PIs) when they transition from an acute care hospital to an LTC facility, an LTCH, or a rehabilitation facility, the CMS rules and regulations that govern these care settings differ, requiring nurses and other clinicians to closely follow the setting-specific documentation standards regarding staging and classification of PIs.

LTC facilities must complete the Resident Assessment Instrument (RAI) of the Minimum Data Set (MDS) upon patient admission and discharge, as well as quarterly. In their documentation, nurses and other health care providers working within these facilities must follow the directions for completing Section M on skin conditions, using the CMS definitions as set forth in the RAI of the MDS, which differ somewhat from those used by the National Pressure Ulcer Advisory Panel (NPUAP). Although nurses and other health care providers in the acute care setting do not code the MDS, their documentation is used by hospital coders for reimbursement purposes. For this reason, they need to document the type or etiology of all injuries; the stage of the injury if a PI, and whether it was present on admission or occurred during hospitalization.

Health care providers must bear in mind that there are differences in setting-specific standards, evident in CMS terminology, as well as in staging and coding instructions. While the CMS acknowledges that both the terms *pressure ulcer* and *pressure injury* may be used in the medical record documentation for LTC facilities and LTCHs, documents available on the CMS website indicate that, as of 2018, the word *injury* will appear only on the revised MDS 3.0 Section M form for inpatient rehabilitation facilities and LTCHs.^{13, 14}

In LTC facilities and LTCHs, the RAI manuals instruct clinicians *not* to code oral mucosal pressure ulcers in Section M (on skin conditions).^{9, 12} However, only LTC facilities are instructed to capture those ulcers in item L0200C (on abnormal mouth tissue).⁹ Similarly, the CMS *Updated Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) Training Manual* instructs clinicians *not* to code mucosal ulcers on the IRF-PAI.¹⁵ All three CMS documents emphasize that mucosal pressure injuries cannot be staged using the NPUAP skin pressure ulcer staging system because mucosa and skin differ anatomically.

At press time, the CMS had issued no reimbursement guidance for acute care hospitals other than the 2008 requirement to document any stage 3-or-higher pressure ulcers that are present on admission.

Figure 5. DEVICE Mnemonic for the Prevention and Treatment of Medical Device–Related Pressure Injuries

D	etermine that all medical devices <ul style="list-style-type: none">• are commercially manufactured for use in the clinical setting (not homemade).• can be placed without making contact with prior or existing pressure injuries.
E	valuate all devices, every skin–device interface, and the surrounding skin at least twice daily, and more often in patients with localized or generalized edema.
V	erify that all nursing staff have been taught how to correctly use and secure medical devices and understand that mucosal medical device–related pressure injuries must be counted and tracked separately from skin pressure injuries.
I	dentify all medical devices on all patients, especially those most vulnerable to medical device–related pressure injuries: critically ill patients, neonates, children, older adults, and bariatric patients.
C	onsider the following any time medical devices are in use: <ul style="list-style-type: none">• Does the patient still require use of the device—can it be rotated, repositioned, replaced, or removed?• Is the fit correct?• Can a prophylactic dressing be used beneath devices placed in high-risk areas (the nasal bridge, for example)?
E	ducate all staff to look for objects that might be in the bed or chair under the patient.

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This mnemonic was created from recommendations in the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline*. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014.

A worldwide challenge. Despite the recent attention device-related PIs have received in the form of guidelines and consensus statements by the NPUAP, European Pressure Ulcer Advisory Panel (EPUAP), and Pan Pacific Pressure Injury Alliance (PPPIA),^{1,25} they remain a problem worldwide. In a study of ICU patients in Saudi Arabia, 115 of the 431 patients (26.7%) had at least one MDRPI (11 had two, and one had three).²⁶ Of the 395 total PIs, 128 (32.4%) were MDRPIs. Endotracheal tubes and indwelling urinary catheters were each responsible for 47 (37%) of the MDRPIs. Other common sources included neck collars (n = 16; 12.5%), nasogastric tubes (n = 12; 9.4%), traction equipment (n = 2; 1.6%), and all other devices (n = 4; 3%).

CLINICAL GUIDELINE RECOMMENDATIONS

The *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline*,²⁵ which was developed through a formal consensus process by the NPUAP, EPUAP, and PPPIA, is considered the national standard for the prevention and treatment of PIs related to the use of medical devices. The guideline includes 19 recommendations focused specifically on MDRPIs, which cover how to assess patient risk, select and fit medical devices, assess the skin and the medical devices' effect on the skin, and ultimately prevent the

occurrence of MDRPIs.²⁵ For each recommendation, the guideline provides both strengths of evidence (using grades A, B, or C) and strengths of recommendation (using “thumbs up,” “thumbs down,” or “thumb neutral” illustrations) (see Table 1). The strength of evidence grade is based on the level of supporting evidence (study design and quality); the strength of recommendation rating was assigned by consensus vote and signifies the degree of confidence clinicians have that adhering to the recommendation “will improve patient outcomes.”²⁵

Among the MDRPI recommendations, a few overarching themes emerge, including the following²⁵:

- Consider all patients with a medical device to be at risk for MDRPIs (strength of evidence, B; strength of recommendation, “two thumbs up”).
- Inspect the skin surrounding and under any medical device at least twice a day for signs of pressure-related injury (strength of evidence, C; strength of recommendation, “one thumb up”).
- Inspect the skin more than twice a day if the patient is at risk for fluid shifts or shows signs of localized or generalized edema (strength of evidence, C; strength of recommendation, “two thumbs up”).
- Remove potential device-related sources of pressure as soon as medically possible (strength of



Figure 6. At left is the cervical collar that caused the pressure injuries at right, on the patient's neck and jawline. Photos © 2015 EA Ayello.

evidence, C; strength of recommendation, “two thumbs up”).

- Reposition the patient or device to redistribute pressure and reduce shear forces (strength of evidence, C; strength of recommendation, “two thumbs up”).

We've created a mnemonic to help clinicians remember many of these recommendations for preventing and reporting MDRPIs (see Figure 5). To order a copy of the complete clinical practice guideline or to download a free copy of the quick reference guide, visit the NPUAP website: www.npuap.org/resources/educational-and-clinical-resources/prevention-and-treatment-of-pressure-ulcers-clinical-practice-guideline. A revision of this guideline is currently under way and is expected to be available in 2019.

EXPANDING THE CONCEPT OF DEVICE-RELATED PIs

Clinicians and health care staff are familiar with medical devices that can cause PIs, such as pulse oximeters (which commonly cause PIs in young children), bilevel positive airway pressure (BiPAP) masks that fit over the bridge of the nose, electrocardiogram leads, sequential compression devices, endotracheal tubes, urinary catheters, nasogastric tubes, nasal cannulas, and cervical collars (see Figure 6). In addition to these medical devices, however, a variety of other items, including bedpans, needle caps, and diapers, can cause PIs. Depending on the practice setting, some items may be considered “stock items,” “objects,” “required medical devices,” or “electrical equipment.” For example, while thromboembolism-deterrent stockings may be considered a stock item in some facilities, in others they may be considered a required medical device.

Regardless of how they're labeled, however, they can cause PIs (see Figure 7).

Another potential risk is when objects such as corrective glasses or toys are left, not on a bedside table, but within the patient's bed or chair—along with items some patients hoard, such as plastic eating utensils, food items, and personal products. Commonplace electrical equipment, such as phones, music players, or electric razors, can find their way beneath a patient in a bed or chair. Call bells and electrical cords should be considered PI threats as well. We've created the SORE mnemonic to remind clinicians of other less obvious devices that put patients at risk for PIs (see Figure 8).



Figure 7. A pressure injury from a thromboembolism-deterrent stocking. Photo © 2016 BA Delmore.

VULNERABLE POPULATIONS

Although all patients are susceptible to device-related PIs, some populations are more vulnerable than others. These include neonates, infants, young children, older adults, and bariatric patients.

Neonates, infants, and young children are vulnerable because of issues such as skin prematurity or early development. They may be developmentally unable to communicate pain from a device (see Figure 9). Younger children are known to have occipital PIs because they have a larger head size in proportion to the rest of the body, and studies reveal that medical devices are the leading cause of PIs in this group,^{18, 19} especially in critical care areas, where medical devices are in greater use. In a 2014 study of 204 pediatric patients, Schlüer and colleagues found that 38.5% of all PIs were caused by external devices.¹⁹ Some clinicians are incredulous that neonates and other pediatric patients develop PIs, but as with any at-risk population, this population should be treated with care that includes consistent skin and risk assessment.

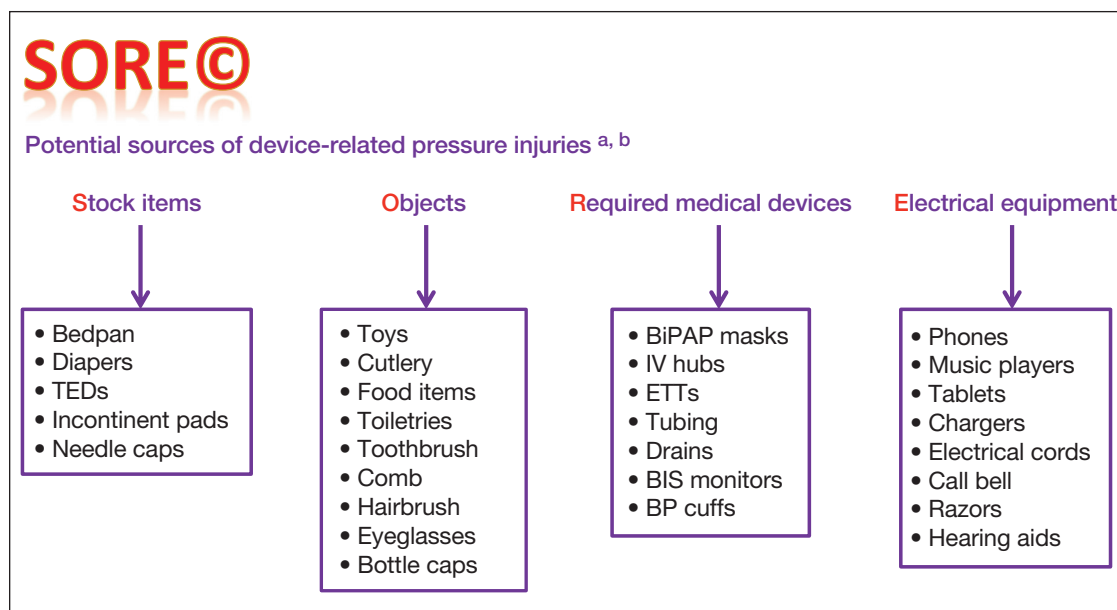
Older adults can be vulnerable to device-related PIs that result from skin changes such as cellular attrition, compromised performance of normal cellular functions, loss of dermal thickness, reduced cutaneous blood flow, loss of subcutaneous fat, decreased sensation, and decreased epidermal turnover. The aging

process and the critical and chronic illnesses associated with advanced age make older adults more vulnerable to PIs, including device-related PIs. When older adults are admitted to a health care facility, they are often immobile, undernourished, or have fluid and electrolyte disorders. Additionally, older adults may be unable to communicate pain because of cognitive decline or severe illness.

Bariatric patients are susceptible to PIs because they are likely to have perfusion problems, increased sweating, increased risk of skin infection due to skin folds, immobility, and shear forces owing to weight stress.²⁷⁻²⁹ Along with neonates and young children, bariatric patients may be more susceptible to MDRPIs because equipment, such as stretchers, mattresses, bed frames, chairs, compression devices, heel boots, and tracheostomy ties, are not properly sized for them.^{18, 27, 30} Another concern for bariatric patients is that devices, such as caps or tubing, may be obscured by skin folds. In our clinical experience, we've also observed that some bariatric patients feel there is a stigma associated with using specially fitted equipment and thus are reluctant to use it.

Patients undergoing surgery or receiving ICU care should be considered vulnerable to MDRPIs.³¹⁻³⁵ During surgery, patients may be immobile for a prolonged period (often four hours or more) and receive anesthetic agents that alter response to pressure and pain.³¹

Figure 8. The SORE Mnemonic: Developed to Raise Awareness of Potential Sources of Pressure Injuries



BiPAP = bilevel positive airway pressure; BIS = bispectral index; BP = blood pressure; ETTs = endotracheal tubes; TEDs = thromboembolism-deterrent stockings.

^aClassification as a medical device or equipment may vary with the practice setting.

^bThis list is not all-inclusive.

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Figure 9. At left is the IV tubing the infant lay on that caused the pressure injury on his face and head, at right. Photos © 2015 EA Ayello.

PIs that occur during surgery may not be detected for 72 hours or more after surgery.^{36, 37} Common sources include positioners, bispectral index monitors, table straps, and fasteners.

During an ICU stay, a patient may be at elevated risk for MDRPIs because of anemia, low albumin levels, hypotension, vasopressor therapy, and mechanical ventilation,^{32-35, 38-40} as well as recognized PI risks such as edema and immobility. Devices typically used in ICUs, including BiPAP masks and endotracheal tubes, may contribute to the development of MDRPIs.³⁸ Sequential boots and fecal management systems have also been implicated in PI formation.

MDRPI risk may be elevated further in surgical and ICU patients with a history of any of the following^{26, 38}:

- cancer
- cardiovascular disease
- peripheral vascular disease
- pulmonary disease
- neurologic disease
- diabetes mellitus

RAISING AWARENESS

Through its 2016 terminology changes, the NPUAP has tried to clarify some of the questions about the differences between MDRPIs that develop on the skin and those that develop on the mucosa. Raising awareness that medical devices can cause PIs is an important step in addressing the incidence of MDRPIs and other device-related PIs. Awareness of all potential PI sources and of specific patient populations that may be at elevated risk for PIs should increase vigilance by health care staff.

Successful PI prevention requires two critical elements: an interprofessional team and a comprehensive

prevention program that includes a sustainable plan.^{26, 36, 38, 41, 42} All clinicians and staff should know the plan for their facility or area and understand that each member is an integral part of the team. Successful patient outcomes can only happen when team members value and understand their role in preventing device-related PIs. ▼

For 41 additional continuing nursing education activities on pressure injuries, go to www.nursingcenter.com/ce.

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