# DEVICE-RELATED PRESSURE INJURIES

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## Introduction

Device-related pressure injuries (DRPIs) are pressure injuries (PIs) that result from items exerting mechanical load on the skin and tissues. The term DRPIs generally refers to PIs that occur under or adjacent to a medical device applied to the body for diagnostic or therapeutic purposes (including but not limited to oxygen delivery devices, tubes, splints, braces and electrodes). However, non-medical devices (including but not limited to bed clutter such as phones, remote controls or call devices, furniture, jewelry and clothing) can also result in DRPIs if they (usually inadvertently) remain in contact with skin and tissues in a way that exerts additional pressure. Damage to the skin and underlying tissue usually conforms to the shape of the device, where the device-skin interface can be exposed to high pressure.

DRPIs occur more often in high acuity care settings (e.g., intensive care units [ICUs]) due to the frequent use of medical devices in these settings. A meta-analysis of 26 studies reported a pooled incidence of DRPIs in adults of 19.3% (95% CI 13.5– 26.6%), although there was high heterogeneity due to the wide range of individual demographics and clinical care variations.[1] In adult critical care settings the pooled incidence of DRPIs was 19% (95% CI 12.4– 25.6%, n = 17 studies). Neonates, infants and children are at particularly high risk of DRPIs, with over half of PIs in pediatric populations arising from the use of medical devices.[2,3] A meta-analysis of three studies reported a pooled prevalence of DRPIs in pediatric settings (up to age 21 years) as 7% (95% CI 5.5–8.8%), with the face, occiput and ears as the most common anatomical locations.[2] However, the prevalence is likely to be much higher in intensive care pediatric settings. **Regardless of age or clinical setting, an individual should be considered at risk of a PI as soon as a device has been applied.**

## General Considerations

### Clinical question: What are the general considerations for preventing device-related pressure injuries for individuals at risk?

**DRPI1: It is good practice to select a medical device with consideration to its:**

- **design and construction material,**
- **correct sizing/shape for the individual, and**
- **ability to be correctly applied and secured.**

**(Good practice statement)**

### Supporting information

The design, shape and sizing of the device, together with the duration of time it remains in contact with the skin and tissues, contribute to DRPIs.[4] Many medical devices are based on generic designs employing rigid and inelastic polymer materials, frequently secured to the individual using tape, adhesive or strapping.[5] While these designs and materials have traditionally been used to facilitate the device function, the mismatch in mechanical properties between a stiffer device and softer skin and underlying tissues creates focal deformations and mechanical stress concentrations in tissues in contact with the device.[6,7] Poor fit or securement can increase externally applied forces (pressure and shear) to the skin and tissue, exacerbating the risk of a DRPI.[5,7] Selecting an appropriate device is a fundamental principle in preventing DRPI.

**Implementation considerations**

- Customize protocols for selection, fitting and use of available medical devices relevant to the health service and setting.
- Ensure there is a wide range of medical devices available to enable devices to be well-fitted to the individual. A well-fitted device will conform to the contours of the individual.[7]
- Frequently evaluate and, where feasible, resize or reposition devices used in individuals at risk of fluid shifts,[5] weight or body composition changes,[7] or growth (e.g., edema, weight gain/loss, or in growing children).
- Define all the medical devices in use in the health service and develop standardized protocols for reducing the risk of DRPIs based on device type.
- Regularly audit all the medical devices available in a health service to identify and address gaps in size and type of devices available. Work with procurement services to address these gaps.[7-10]
- Audit the construction material of medical devices and work with procurement services to replace rigid devices with devices manufactured from softer materials when available, appropriate and consistent with the individual's preferences.[7,11]
- Follow the manufacturer guidelines and avoid off-label use of medical devices.

<u>Additional considerations for neonates and children</u>

- Ensure the health service has a range of mask sizes and other oxygen delivery devices available for neonates and children.[9]
- Frequently evaluate and resize longer-term devices used by growing children and adolescents (examples include but are not limited to wheelchairs, orthotics, protheses and compression garments).[7]

**DRPI2: It is good practice to regularly assess for signs of early skin, tissue and mucus membrane injury by checking underneath and around medical devices and their securements.**

**(Good practice statement)**

### Supporting information

Regular and comprehensive assessment to identify early signs of skin and tissue damage enables management of the risk as early as possible by reducing or redistributing pressure at the skin-device interface. Principles of assessing skin and its underlying tissue are outlined in the guideline section *Skin and Tissue Assessment*.

- Undertake and document a baseline skin and mucous membrane assessment prior to the application of a medical device. Regularly assess the color, moisture, turgor/firmness, bogginess and temperature of the skin and tissues under and/or around the device. Observe for signs of irritation or damage (e.g., bruising, non-blanchable erythema or, in skin of a darker tone, a difference compared to unaffected skin).[7,12] Document all assessment findings and communicate them to the multidisciplinary team.
- Regularly assess the area around the device for signs of edema or fluid shifts.[5]
- Increase frequency of skin and tissue assessment when the individual has a higher risk, for individuals with skin conditions, diaphoresis and those who are unable to sense or communicate their discomfort/pain.[5,7,13]
- Ask the individual about pain or discomfort and adjust or remove the device accordingly where possible.[5,7]
- Record the application and location of all medical devices in the individual's medical record. When conducting a skin assessment, undertake a full body inspection to ensure that no device is missed (e.g., in skin folds or underneath the individual).[5,7]
- Remove the medical device to observe the skin underneath when this will not interfere with the individual's management or the device's function.[11]
- Remove or loosen the device's securements to observe the skin underneath when this will not interfere with the individual's management or the device's function. Indentations left by the device are an early sign of pressure that could be addressed by loosening the securements or judicious placement of a prophylactic dressing under the securements.
- Implement organizational strategies to increase the frequency of assessments. In multidisciplinary settings, multiple health professionals (e.g. a respiratory therapist and a nurse) could alternate in conducting a skin and tissue assessment, increasing the overall frequency of assessments.
- Encourage individuals to immediately report any issues, including pain or discomfort, regarding their longer-term devices and, if able, to undertake regular self-assessment.

Additional considerations for neonates, infants and children

- Be aware that neonates and children are at higher risk of DRPIs.[3]

Additional considerations for individuals who are independent in their care

- Inform self-caring individuals/individuals and/or their informal carer about the risks of DRPIs, and the risk of "device" related injuries from other items (e.g., items left under an immobile individual, jewelry, hair braids and accessories) and to check the bed or chair for presence of objects.
- Teach the individual and/or their informal carer to safely and regularly inspect the skin under and around the device, and to adjust or remove the device if this is safe.

Additional considerations for individuals who have spinal cord injury or neurological impairment

- Assess for signs of skin, tissue and mucous membrane damage more closely in individuals who have reduced sensation.

## Reducing pressure, shear and moisture when a medical device is in use

**DRPI3: It is good practice to reduce and/or redistribute pressure at the skin-device interface by:**

- **removing the medical device as soon as medically feasible,**
- **regularly repositioning the medical device, its securements and/or the individual,**
- **physically supporting the medical device in order to minimize pressure and shear, and/or**
- **alternating the type of device in use when possible.**

**(Good practice statement)**

**Supporting information**

The amount of time a device is in contact with skin and tissues is a recognized risk factor for a DRPI.[4] For this reason, devices should be removed as soon as clinically feasible. If the device must remain in-situ, strategies to relieve pressure should be implemented, including repositioning, rotation, physical support and using an alternate device if possible. If signs of early skin and tissue damage occur, removing the device, changing to a different device or increasing the frequency of repositioning are all good practice options.

**Implementation considerations**

*Evaluating the need for a medical device*

- Replace an extrication cervical collar with an acute care rigid collar as soon as feasible and remove cervical collars as soon as possible, as indicated by clinical condition and in consultation with a qualified health professional.[14] At an organizational level, developing clear protocols for maximum immobilization in a cervical collar and pathways for review can facilitate early removal.[14,15]
- Evaluate the need for all medical devices[13] on the individual's admission, including for individuals admitted via ambulance.
- Wherever possible, remove devices. Develop protocols to expedite the appropriate medical and allied health consultation and advice to enable removal of medical devices at the earliest feasible opportunity.[16]
- When the device is still required, ensure it is the most appropriate device for the individual and meets their personal preferences.[13]

*Repositioning and alternating the medical device*

- Regularly release devices and securements when possible.
- Reposition and offload medical devices (e.g., tubing).
- Do not position medical devices underneath the individual unless it cannot be avoided. When unavoidable, consider using pressure offloading devices to reduce the individual's load on the device.
- Ensure devices and tubing do not touch the skin wherever possible. Non-woven gauze or absorbent padding can be wrapped around tubes or place underneath the tube to reduce the pressure at the skin-device interface.
- Ensure that the tubes and devices have enough length to prevent dragging or tension on the skin and tissue prior to repositioning the individual. Reposition the device prior to repositioning individual if possible (e.g. catheter bags and tubes).[17]
- Alternate oxygen delivery devices between a correctly fitting facial mask and nasal prongs to reduce the severity of PIs for individuals receiving oxygen therapy, when it is appropriate and safe.[12]
- Alternate the site placement of devices when possible (e.g., pulse oximeter).

*Device securements*

- Secure devices with the least amount of tension needed to maintain the device's position and function.[6]
- Regularly monitor the tension of device securements[3] and where possible seek the individual's self-assessment of comfort.
- Monitor developing or resolving edema and loosen or tighten securement as needed.
- Consider where ties/bows/knots are positioned on the individual such that the material does not create extra pressure.

Clinical question: Should an endotracheal tube fixation device versus no fixation device/tape be used to prevent endotracheal tube-related pressure injury occurrence in individuals at risk?

**DRPI4: We suggest using an endotracheal tube fixation device to secure an endotracheal tube.**

**Clarifier:**

- **DO NOT use an endotracheal tube fixation device when the individual is in the prone position.**
- **The evidence was specific to adult individuals.**

**(Conditional recommendation, very low certainty of evidence)**

**Evidence summary**

The meta-analysis included five studies [8,18-21] that compared use of a commercial endotracheal tube (ETT) securement device* to using adhesive tape for preventing DRPIs. Two of these studies employed randomized designs.[18,20] In the studies the ETT fixation device was used for up to two weeks in adults. The studies either excluded individuals placed in the prone position or did not report positioning. The meta-analysis showed that using an ETT fixation device was associated with a non-significant lower rate of ETT-related PIs (relative risk [RR] 0.36, 95% confidence interval [CI] 0.12 to 1.10, p = 0.07, relative effect of 21 fewer per 1,000 individuals treated [from 29 fewer to 3 more]). There is very little confidence that this effect estimate represents a true effect. The evidence was downgraded due to inconsistency, imprecision and all studies having high or unclear risk of bias. Undesirable effects (e.g., self-extubation, duration of ventilation and mortality) were not significantly different in the study that reported secondary outcomes.[20] An additional retrospective study[22] showed that ETT fixation devices can be associated with an increase in DRPIs when the individual is in the prone position, and consensus guidance[23-25] suggests ETT securement devices are avoided during proning. In the Guideline Governance Group's expert opinion, the desirable effects are likely to outweigh undesirable effects, with this clinical caveat. Although this recommendation probably increases health inequity due to the variable availability of commercial securement devices, the Guideline Governance Group considered the intervention is probably acceptable to most stakeholders and probably feasible to implement.

**Implementation considerations**

- For adults in the prone position, it is recommended to remove the ETT securement device and use twill ties or tape fixation for the duration of proning.[22-25]
- Assess the suitability of a commercial ETT securement device for each individual.
- Follow the manufacturer's instructions for applying and caring for a commercial ETT securement device.
- Continue to assess the facial skin and tissues, lips, tongue and mucus membranes under and around the ETT and its securement device.[5,6]
- The optimal frequency of repositioning the ETT when using a securement device is unclear[26] but should be guided by regular inspections and the manufacturer's instructions (e.g., repositioning the tube side-side at least every two hours[21,27]).
- Implement organization strategies to increase frequency of regular repositioning of the ETT. In multidisciplinary settings, multiple health professionals (e.g. a respiratory therapist and a nurse) could alternate in implementing device repositioning, increasing the overall frequency of device repositioning.
- Be vigilant in assessing for facial and lip edema that may contribute to pressure at the skin-device interface and is a contraindication for some securement devices.[21,26]
- Consider protecting the skin surrounding the device with a no-sting barrier film.[18]

* All the studies used the same securement device with adult individuals, as described in the data extraction tables. The fixation device is designed with moisture resistant barrier pads and adjustable straps and secures the ETT tube off the individual's lip.

Clinical question: What are the general considerations for preventing device-related pressure injuries for individuals at risk?

**DRPI5: It is good practice to manage moisture at the skin-device interface.**

**(Good practice statement)**

## Supporting information

Moisture (e.g., due to diaphoresis, incontinence, oronasal secretions or placement of an occlusive material) can accumulate underneath a device that is affixed to the skin. Excessive skin moisture can lead to skin maceration, increasing susceptibility to a DRPI.[5,28] Medical devices are often used in anatomical locations that are susceptible to increased moisture (e.g., around the nose and mouth), which contributes to the high incidence of DRPIs on the face and head,[1,2] particularly in neonates and infants. Being aware of this risk and taking measures to manage moisture under and around medical devices can assist in preventing DRPIs.

**Implementation considerations**

- Diligently assess the skin, tissue and mucus membranes in areas of high moisture such as the face.[12,17] Consider how the selected medical device might influence skin temperature and humidity.
- Consider using a skin barrier/skin sealant under and around a medical device in areas of high moisture.[3,11]
- Consider using wicking fabric in skin folds around securement devices.[3,29] Be aware of the risk of wicking fabric drying out underneath a medical device and becoming a potential source of pressure.
- Consider wrapping tubing in non-woven gauze or absorbent padding if there is high moisture (e.g., from perspiration or oronasal secretions). Replace the non-woven gauze or absorbent padding when it becomes moist, if possible.
- Consider using products that hold devices away from the skin (e.g., extending tracheostomy tube length).[5]
- Increase the frequency of suctioning for individuals with high oronasal secretions.[17]

<u>Additional considerations for neonates and children</u>

- Diligently and regularly implement moisture management strategies. Neonates and children are vulnerable to high levels of moisture and have an increased risk of medical device-related pressure injuries.
- Apply a skin barrier/skin sealant and allow it to dry before applying a facial mask.[3] Consider use of a thin foam or hydrocolloid dressing over the bridge of the nose and under the mask to reduce pressure. However, be aware of the potential for skin damage from the preventive dressing adhesive.

Clinical question: Should any preventive dressing versus no preventive dressing be used for individuals at risk of device-related pressure injuries?

**DRPI6: We recommend using a preventive dressing underneath medical devices when the preventive dressing will not interfere with the position or functionality of the medical device.**

**(Conditional recommendation, very low certainty of evidence)**

**Evidence summary**

The meta-analysis included four randomized controlled trials (RCTs)[30-33] that compared using any preventive dressing underneath a medical device to not using a preventive dressing for individuals at PI risk. The studies explored hydrocolloid dressing applied to children with silicone nasotracheal tubes,[31] polyurethane foam dressing or 2-layered foam dressing applied to adults with oronasal oxygen delivery masks,[30] hydrocolloid nasal barrier dressing applied to neonates with binasal continuous positive airway pressure (CPAP) masks,[33] and foam surgical tape applied to adults with nasotracheal tubes.[32] The meta-analysis showed that using any preventive dressing was associated with a non-significant lower rate of device-related PIs (RR 0.70, 95% CI 0.41 to 1.20, p = 0.20, relative effect of 180 fewer per 1,000 individuals treated [from 353 fewer to 120 more]). There is very little confidence that this effect estimate represents a true effect. The evidence was downgraded due to risk or unclear risk of bias across most studies, indirectness (large variability in the types of preventive dressings and clinical use) and serious inconsistency and imprecision. None of the studies reported adverse events as an outcome measure. Several studies provided evidence of the costs associated with using the intervention, and the Expert Working Group also noted that in clinical practice, preventive dressings under medical devices may require more frequent replacement due to high levels of moisture, especially for neonates and infants. The Guideline Governance Group determined that resource costs associated with the intervention are moderate, but no cost effectiveness evaluations were identified. There would probably be an increase in inequity associated with this recommendation, but it is likely to be feasible and acceptable to implement, particularly in tertiary care settings.

**Implementation considerations**

- Undertake and document a skin assessment under and around the device prior to applying a preventive dressing.
- Continue to assess the skin and tissue under all medical devices. If the preventive dressing is not transparent, lift the preventive dressing to conduct the assessment.[5]
- Manage moisture. Preventive dressings may be difficult to adhere in the presence of excess moisture.
- Select the preventive dressing carefully. In the presence of moisture, cotton and non-woven gauze dressings can absorb moisture, becoming harder underneath the medical device and increasing the risk of DRPI unless they are changed regularly.
- Select preventive dressings that allow adequate heat and moisture release to prevent skin maceration and irritation. The preventive dressing's ability to absorb and retain moisture without causing maceration should be considered to avoid undesirable effects.
- If the device is tightly fitted, consider the risk that application of a preventive dressing might increase the pressure. A thinner preventive dressing may be an option.[5]

Additional considerations for neonates and children

- Select preventive dressings with consideration to its functionality (e.g. moisture vapor transmission rate) in the physical environment, particularly for neonates in a humidicrib/incubator/isolette.
- Diligently and regularly implement moisture management strategies when a preventive dressing is in place.
- Consider the most appropriate type of preventive dressing to reduce the risk of medical adhesive related skin injury (MARSI) in neonates.

## Future research

The evidence available to address most clinical questions on preventing DRPIs was of very low certainty. This was primarily because the studies were at high risk of bias due to challenges designing blinded studies without confounding factors and with sufficiently large populations. The Guideline Governance

Group noted the following gaps in the evidence addressing the topics in this section that require future research:

- There is an overall paucity of research that is co-designed with consumers or that focusses on patient reported outcome measures (PROMs, e.g., comfort, etc.) associated with medical device use. Given that many individuals use medical devices over the long term, research that includes this perspective would be of particular value.
- There is a paucity of evidence on effectiveness of different strategies to prevent DRPIs in neonates and children. Given that the pediatric population experiences the highest incidence of DRPIs, exploration of strategies in this group is of particular importance.
- There is limited evidence on the effectiveness of leave-on topical products (e.g. moisturizers) based on prespecified mechanisms of action regarding prevention of DRPIs. Given that leave-on topical products are commonly used under and around medical devices, explanative proof-of-concept studies and effectiveness studies are warranted.

The Guideline Governance Group noted there was no comparative evidence to address the following clinical questions:

- The effectiveness of a naso-tracheal tube fixation device versus no naso-tracheal tube fixation device.
- The effectiveness of a repositioning medical device versus no device repositioning.
- The effectiveness of alternating the type of oxygen delivery device versus not altering the type of oxygen delivery device.
- The effectiveness of a pressure redistributing respiratory device versus a standard respiratory device.

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