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Reporting of Pressure Ulcers and Medical Device Related Pressure Ulcers in policy and practice: A narrative literature review.

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Abstract

Pressure ulcers (PUs) occur in a range of care settings, resulting in reduced quality of life for the individual. There has been a growing awareness that medical devices can cause PUs, although reporting has been limited. There is a need to evaluate PU reporting practice and identify whether standards exist for medical device-related pressure ulcers (MDRPUs).

**Aim** To synthesise academic and grey literature relevant to reporting of PUs and MDRPUs in healthcare settings.

**Methods** A systematic search of multiple scientific and grey literature databases was undertaken. Key search terms and Boolean operators were used to identify relevant literature . All sources of evidence discussing reporting practices were included in a synthesis. Primary topics are discussed in the corresponding analysis.

**Results** Thirty-one evidence sources met the inclusion criteria, including 16 journal articles and 15 policy and guidance documents . The results revealed a variation in reporting practices. MDRPUs were often not identified as a separate category in local and national systems. Policies for related patient safety reporting varied across all organisational levels, with more serious categories of PUs reported more consistently. Reporting to medical device regulatory bodies was not mandatory.

**Conclusion** This narrative review identified inconsistencies in local and national reporting of PUs and MDRPUs, prohibiting meaningful comparisons and improvements in patient safety. Lack of specific medical device data and low levels of voluntary reporting to regulatory bodies is likely to result in an under-reporting, with little evidence of specific devices which may be a patient safety concern.

Key words: Reporting, pressure ulcer, medical device, policy, guidelines.

1. Introduction

A pressure ulcer (PU), also termed pressure injury, is a localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure with shear ([EPUAP/NPIAP/PPPIA, 2019](#_ENREF_14)). PUs categories include 1-4 or unstageable, according to the wound depth and number of tissue layers affected. Pressure ulcers can result from diagnostic or therapeutic use of medical devices, with the skin damage taking the shape or pattern of the device (NPAUP EPUAP PPPIA 2019). PUs are preventable in most cases ([Black et al., 2010](#_ENREF_8)), and if detected early, potentially reversible.

Pressure ulcers are a complex and costly issue, present in all healthcare settings ([EPUAP/NPIAP/PPPIA, 2019](#_ENREF_14)). The costs of PU management are high, with a recent study in the USA estimating Hospital Acquired PUs (HAPUs) expenditure in excess of $26.8bn per annum ([Padula and Delarmente, 2019](#_ENREF_42)). In the UK [Guest et al. (2018)](#_ENREF_22) reported an estimated annual cost of £531 million for PU care. PUs are associated with high mortality, ill health and need for extended hospitalisation ([Bennett et al., 2004](#_ENREF_7), [Shahin et al., 2009](#_ENREF_44)). Moreover, patients with PUs suffer with pain ([Gorecki et al., 2011](#_ENREF_18)), and often psychosocial issues ([Spilsbury et al., 2007](#_ENREF_46)) .

Despite international drivers for prevention the prevalence and incidence of PUs has remained unacceptably high. A recent systematic review and meta-analysis of 42 studies identified a pooled prevalence of 12.8%, and pooled incidence rate of 5.4 per 10,000 patient-days ([Li et al., 2020](#_ENREF_31)). A seminal, secondary data analysis undertaken by [Black et al. (2010)](#_ENREF_8) revealed that 34.5% of HAPUs were medical device related (MDR). The study also found that patients supported by a medical device were 2.4 times more likely to develop a PU of any kind. The recent meta-analysis undertaken by [Jackson et al. (2019)](#_ENREF_29), estimated the pooled incidence of MDRPUs was 12% and prevalence was 10%, with studies reporting prevalence as high as 45% depending on the setting (e.g. in ICU wards). The most commonly reported devices related to PUs are respiratory devices, splints, braces, and tubing ([Arnold-Long et al., 2017](#_ENREF_3)).

Globally, patient care safety and quality are high on the healthcare agenda ([Third Global Ministerial Summit on Patient Safety, 2018](#_ENREF_49), [WHO, n.d.](#_ENREF_50)). Pressure ulcers are one of the indicators of quality of nursing care ([Gunningberg et al., 2008](#_ENREF_23)). Although PU reporting is an established practice, processes vary across healthcare systems. Moreover, data on MDRPUs are limited by the heterogenicity in data collection ([Jackson et al., 2019](#_ENREF_29)). This limits the ways data can be used for comparison, benchmarking, and learning. This literature review aims to synthesize current scientific and grey literature regarding reporting systems and processes for pressure ulcers with a focus on medical device-related PUs.

2. Methods

**2.1 Design**

A narrative literature review was undertaken. This approach allows flexibility and incorporation of all available sources, including research, and non-research publications ([Mays et al., 2005](#_ENREF_32)).

**2.1.1 Search strategy**

The search for relevant literature was completed in two stages:

i) searching research databases

ii) searching for grey literature.

A comprehensive literature search was undertaken in January 2021. Databases searched included: CINAHL Plus with Full Text (Ebsco), Medline (Ebsco), EMBASE Classic + Embase 1947-2021 wk2 (Ovid), PubMed, Web of Science Cole Collection, and ProQuest Dissertation and Theses A&I. Search terms were developed using concept mapping (Table 1) and applied using truncation, adjacency, and Boolean operators which were formatted to each specific database. All study designs were included, with studies not in English or unrelating to pressure ulcer reporting (local or national) excluded.

Table 1 Concept mapping and key terms.

|  |  |  |
| --- | --- | --- |
| CONCEPT | Reporting | Pressure ulcers |
| SYNONYMS | Policy  Guideline  Procedure  Document  Report | Pressure injuries  Bedsore  Decubitus  Pressure sore  Deep tissue injury |

Further literature was identified by screening of the publications’ reference lists, and searching using names of the key authors, to ensure exhaustiveness of the search. Grey literature search was undertaken using: OpenGrey, National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel website, and Google search engine. Simplified search terms were used: “pressure ulcer” or “pressure injury” and “reporting”.

The search strategy was developed by the research team, who also cross-checked a random sample of scientific and grey literature abstracts and full texts to check for consistencies.

**2.1.2 Quality appraisal**

Formal quality appraisal was not performed since the aim of the review was to synthesize the evidence regarding pressure ulcer reporting, rather than review their quality or appropriateness. No publications were excluded based on the design or purpose, due to the paucity of literature meeting the inclusion and exclusion criteria.

**2.1.3 Data extraction and analysis**

A data extraction form was developed based on [Gray et al. (2017)](#_ENREF_20) which includes methodological elements and study outcomes, and details relating to reporting ([Popay et al., 2006](#_ENREF_43)). Results of studies, policies, procedures, guidelines, white papers, and items included in reporting tools were narratively reported. To identify patterns and themes in the data, thematic analysis with constant comparison was applied ([Glaser, 1965](#_ENREF_17)).

**2.1.4 Issues of bias**

To minimise inclusion bias, any discrepancies in proposed inclusion of publications were discussed, decisions were made by consensus. All members of the research team were involved in discussions regarding each stage of the review and its outcomes, with final decisions made through mutual agreement.

3. Results

A search for published academic papers yielded 4,806 hits. After removing duplicates 3,443 titles were screened broadly. A focused abstract review was conducted on 183 articles, out of which 37 articles were read in full. Following the inclusion and exclusion criteria (Table 2) fifteen journal articles were included in the review. Searching reference lists returned one additional academic journal article.

Search of OpenGrey database did not yield any hits. Examination of websites of pressure ulcers advisory organisations and Google yielded 12 policy documents/ guidelines (6 on national level), and 3 reporting tools for review (Figure 1).

Figure 1 PRISMA flowchart

Number of records identified thorough database searching:

**N=4,806**

Number of records identified for title review

**N=3,443**

Number of records identified for abstract review

**N= 183**

Number of records identified for full text screening

**N=37**

Number of records accepted for final review

**N=16**

Duplicates Removed N=1,363

Excluded N=146

Not PUs n= 6

Not reporting n= 118

Unable to retrieve n= 22

Not in English n=4

Excluded N= 22

Not PUs n= 2

Not reporting systems n= 20

Additional search methods

N= 1

Grey literature **N**= 15

Policies/guidelines n= 12

Reporting tools n= 3

**TOTAL** **N=31** documents/articles

**3.1 Academic literature**

A summary and synthesis of academic literature relating to the PU and MDRPU reporting practice is presented.

Two main themes were identified in the academic literature: (1) variation and inconsistency in reporting pressure ulcers, and (2) organisational issues in reporting medical device-related pressure ulcers. Reviewed studies focused mostly on organisational (6/16) and local (4/16) reporting practices and half of the publications reported on a quality improvement initiative or a clinical audit. Detailed data about literature included in the review are available in Table 2.

**3.1.1 Variation and inconsistency in reporting pressure ulcers**

Academic literature identified PU reporting variation within and between countries. Systems currently in use locally, regionally, and nationally also lacked standardisation. [Jackson et al. (2016)](#_ENREF_28) analysed PU policies in six countries, describing a lack of agreement about data collection and reporting. A range of issues were identified regarding the definitions of pressure ulcers and quality of reporting metrics by an audit of monitoring in England, undertaken by [Smith et al. (2016)](#_ENREF_45) and [Coleman et al. (2016)](#_ENREF_12). Results indicated that PUs were under-reported across all available surveillance systems, and often miss-classified ([Coleman et al., 2016](#_ENREF_12), [Smith et al., 2016](#_ENREF_45)). Reports submitted to monitoring systems were based on the data from patient records, not physical examination. Patient records were found to be often incomplete. In addition,[Coleman et al. (2016)](#_ENREF_12) highlighted substantial variation in local implementation of the national policy framework for reporting adverse incidents.

Similar inaccuracies were reported in the study by [Barakat-Johnson et al. (2018)](#_ENREF_6) who examined hospital-acquired PUs reported in the Incident Information Management System (IIMS) of a tertiary hospital in Australia. The results showed that over 75% of HAPUs were erroneously reported ([Barakat-Johnson et al., 2018](#_ENREF_6)). Moreover, inconsistencies between patient records were found ([Barakat-Johnson et al., 2018](#_ENREF_6), [Hansen and Fossum, 2016](#_ENREF_24), [Li, 2016](#_ENREF_30)). [Backman et al. (2016)](#_ENREF_4) discovered a large proportion of PUs may not be reported in administrative data due to poor documentation in the patient record. Those administrative data are used for performance assessment, which may have financial implications for organisations. [Jackson et al. (2016)](#_ENREF_28) highlighted that penalties are imposed on healthcare facilities in Australia, and USA Centres for Medicate and Medicaid Services (CMS) operate a policy of non-payment for hospital-acquired pressure ulcers ([CMS, 2019](#_ENREF_11)).

**3.1.2** **Organisational issues in reporting medical device-related pressure ulcers**

As in the case of traditional PUs, there is a lack of standardised guidance for reporting MDRPUs. Despite using hospital acquired PU metrics as quality of care indicators, the awareness of MDRPUs is low ([Barakat-Johnson et al., 2017](#_ENREF_5), [Chavez et al., 2019](#_ENREF_10)) and the processes of reporting underdeveloped ([Barakat-Johnson et al., 2017](#_ENREF_5)). [Barakat-Johnson et al. (2017)](#_ENREF_5) concluded that the records were not a reliable source of information for MDRPUs since clinical staff would only record skin integrity. They also noted that documentation of prevention and skin monitoring under devices was not available until skin damage occurred ([Barakat-Johnson et al., 2017](#_ENREF_5)). Report from a quality improvement project, concerned with MDRPUs associated with respiratory equipment ([Padula et al., 2017](#_ENREF_41)), found differences in how PUs were categorised and documented by different staff groups (e.g. nurses and respiratory technicians). [Smith et al. (2016)](#_ENREF_45) found MDRPUs reporting varied between monitoring systems and organisations. This was further explored by [Coleman et al. (2016)](#_ENREF_12), who revealed a large proportion of trusts do not distinguish MDRPUs in their documentation, even though the majority included them in reports to national databases.

The problems of reporting relate also to technical limitations of the electronic medical record. [Chavez et al. (2019)](#_ENREF_10) reported that the Electronic Medical Record system used in the Veteran Affaires Nursing Outcomes Database had limited usability, as it was not designed for recording of MDRPUs or mucosal PUs. Nevertheless, some progress in reporting has been made at local levels. For example, [Apold and Rydrych (2012)](#_ENREF_2) described how a state-wide intervention initiated by the Minnesota Hospital Association, with support from the Minnesota Department of Health, led to development of a data collection tool for MDRPUs. From its inception in 2009, reporting requires identification of MDRPUs, along with information about category and device type ([Apold and Rydrych, 2012](#_ENREF_2)).

[Dealey et al. (2012)](#_ENREF_13) published a proposed guidance on pressure ulcer reporting, collated through an international consensus meeting. The proposed framework offered uniform set of statements to allow collection of accurate, meaningful, and consistent data ([Dealey et al., 2012](#_ENREF_13)). This has been adapted and implemented nationally in England from 2019 ([NHS Improvement, 2018](#_ENREF_36)). According to this guidance, MDRPUs have to be reported to national and local incident reporting systems as a separate category (NHS Improvement, 2018).

Table 2. Summary of journal articles included in the narrative review.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Author (year) | Topic/ Focus/  Question | Design | Setting/origin of reporting | Level of reporting  **(organisational, local, national)** | Target population | Type of reporting (mandatory (M)/ voluntary (V)) | Standardised categories and definition of PU | Main findings | MDRPUs included |
| [**Apold and Rydrych (2012)**](#_ENREF_2) | MDRPUs prevention | Audit | Hospitals in Minnesota, USA. | Local | Nursing staff | M | NPUAP 2007 | PUs cat. 3, 4 & unstageable (U)– state reporting; sDTI or progression to cat. 3/4/U not reported if POA; | Yes - category of device AND specific type of device |
| **Ayello, E. (2017)** | Centres for Medicare & Medicaid Minimum Data Set 3.0 | Clinical management, education | USA | National | Physicians, nurse practitioners, specialist nurses | M | CMS, adapted from NPUAP 2007 | PU cat : 4 numerical, U (3 types present) and DTI; facilities may use different classification for own use; mucosal PUs reported separately; interventions, characteristics and status of PU reported. | No |
| **Backman, C., et al. (2016)** | Accuracy of reporting in  one healthcare centre | Retrospective analysis of records and prevalence survey | Canada | Organisational | Physicians or clinician with primary care responsibility | M | NPUAP n.d. | Under-reporting in administrative records; insufficient data in patient record; potential differences in administrative data and prevalence data may be attributed to the source of report, i.e. physician or nurse record. | No |
| **Barakat-Johnson, M. et al. (2017)** | MDRPUs management and prevention | Exploratory, descriptive | acute tertiary hospital, 800 beds, Australia | Organisational | Nursing staff | M | NPUAP/EPUAP  /PPPIA 2014 | Insufficient data on prevention and skin checks under device in patient record; skin checks documented as intact or not intact only; treatment documented more consistently. | Yes |
| **Barakat-Johnson, M. et al. (2018)** | Hospital acquired PU reporting accuracy | Prospective, descriptive | acute tertiary hospital, 800 beds, Australia | Organisational | Nursing staff | M | NPUAP/EPUAP  /PPPIA 2014 | 75% of HAPUs inaccurately reported – erroneous staging, location, miss-labelling as HA, or miss- diagnosed. 96% miss- identified as cat. 1 or 2 PU, however cat 3 and 4 reported accurately.  Nurses felt obligation to report any skin damage to monitoring system, even if they were not PUs; often records duplicated due to shortcomings of the IT systems; organisational issues (e.g. staffing) prohibit record review and lead to unawareness of PU presence. | Not discussed |
| **Chavez, M., et al. 2019** | PU documentation practices | Quality improvement | 31 Department of Veteran Affairs facilities | Local | Nursing staff | M | WOCN 2016 | Barriers to accurate documentation: incorrect staging, misidentification of wound types; lack of understanding of policy and timeframes for (re)assessment; double data entry – multiple applications to use to record the same data; staffing issues (low staffing levels and high turnover). Template did not allow for reporting MDRPUs or mucosal PUs. Consistent data were achieved if a specialist nurse involved in PU staging and a PU committee existed in the organisation. | Yes |
| **Coleman, S. et al. (2016)** | Variation of PU reporting practices | Audit | 24 NHS trusts | Organisational & local | Nursing staff & Trusts | M & V | NPUAP/EPUAP  /PPPIA 2009 & adaptations | Majority of trusts report MDRPUs to monitoring systems, however 70% do not distinguish PUs and MDRPUs in own documentation; recording and reporting DTI varies between organisations; 50% of trusts did not report cat. 1 PU; variation in definition of POA between organisations; usually PU cat 3/4 subject to validation, completion rules and methods based on local policies; | Varied |
| **Collier, M. (2015)** | Variation of PU reporting practices | Editorial | n/a | Organisational and national | Nursing staff | M | n/a | Use of different staging guidelines between organisations; variation in reporting; limited comparison between organisations due to organisations collecting only point prevalence data. | No |
| **Dealey, C. et al. (2012)** | TVS consensus meeting 2011 | White paper | all UK healthcare organisations | 3 levels of reporting | Nursing staff & Trusts | M | NPUAP/EPUAP 2009 | International guideline definition of PU and staging system should be used; all cat 3 & 4 PUs should undergo RCA; RCA template should include a minimum data set; one definition of avoidable/ unavoidable should be used, i.e. Department of Health; standard incidence data collection method and calculation should be agreed; serious incidents should be reported in addition to incident reports and confirmed within 3 days; all PU cat 2+ require local report and a RCA. | No |
| **Hansen, R. and Fossum, M. (2016)** | Accuracy of reporting | Cross sectional, descriptive – nursing documentation audit and patient examination | Nursing homes in Norway | Organisational | Nursing staff | M | EPUAP 2009 | Prevalence based on record review – 26%, based on patient examination – 22%. Just over a half of patient had their PU recorded in notes and confirmed via examination by the researchers. 45% documented PU were not graded. Inadequate nursing records; gap between patient records and data from physical examinations. | No |
| **Jackson, D. et al. (2016)** | PU prevention & treatment policies in 6 countries | Comparative review and synthesis | 6 countries' policies re PUs | n/a | n/a | M & V | NPUAP/EPUAP  /PPPIA 2014 | Policies developed to reduce PU prevalence; inconsistent use of PU definition and terminology; limited data on PU incidence; no consistency between countries in data collection, staging and reporting despite international consensus and guidance; inconsistency between hospital coding systems and PU classification systems; variation in methodologies of reporting prevalence. | Not discussed |
| **Li, D. (2016)** | Hospital-acquired PUs in ICUs – accuracy of reporting | Retrospective, comparative, descriptive, correlational – records audit | 560-bed medical centre in Florida, USA; convenience sample of ICU patients (n=196) | Organisational | Nursing staff | M | NPUAP 2007 | Location of PU most consistently recorded in written records ; over 50% of records included wound colour and photo of the wound. Only 13% of records included wound type, dressing type or category/ stage; only 7 records had full PU description recoded. In 392 PU records, 314 had corresponding notes in patient record, only 2 included full PU description; omissions in recorded data were found on all levels of documentation. Poor and incomplete documentation did not follow recommendations of national and international guidance. | No |
| **Padula, C. et al. (2017)** | PU prevention | QI | 16-bed ICU & 19-bed intermediate care unit, Rhode Island | Organisational | Nursing staff & respiratory therapists | M | NPUAP/EPUAP/  PPPIA 2014  & NPAUP 2016 | Discrepancies in skin assessment between nurse & respiratory therapists; insufficient staging knowledge; introduced interdisciplinary rounds and education improved quality of records; interdisciplinary education had positive impact on awareness of quality outcomes, evidence based practice, and establishing shared accountability; policy change to include weekly documentation and measurement of wounds consistent with NPUAP terminology and staging updates. | Yes – type of device |
| **Pokorna, A. et al. (2019)** | PU analysis based on a nationwide data | Pilot analysis | Central Adverse Event Reporting System | National | Healthcare organisations | M | n.d | The national database for reporting AE uses standardised methodology for reporting. PUs were the most commonly reported AEs. Long term care facilities had the highest reporting rate per thousand patients; staffing levels had impact on PU rates; PU origin was not consistently reported. | No |
| **Smith, I. L., et al. (2016)** | Accuracy of reporting systems in England | Audit | NHS Trusts | Local & national | Nursing staff | M&V | NPUAP/EPUAP  /PPPIA 2009 | Number of PUs recorded in patient records and in national databases vary; PUs are under-reported in national databases; PUs are often mis-classified and under-reported across all categories; mis-identification of POA and HAPUs; data in clinical records was of low quality and accuracy; MDRPUs were under-reported more often than other PUs. | STh – no  IRS – yes  Locally - varied |
| [**Zaratkiewicz et al. (2010)**](#_ENREF_52) | Incidence tracking system for HAPUs | QI | Harborview Med Centre, Seattle- level 1 trauma/burn centre | Organisational | Nursing staff, respiratory technicians & physicians | M | NPUAP 2007 | Staff are prompted by the EMR to record POA PUs; other sections of the EMR provide place to report HAPUs; skin check completed weekly, EMR generates HAPU reporting form once PU identified; the record is available for all disciplines; respiratory therapists use EMR to report MDRPUs; specialist nurses provide consultation and recommendations which are electronically sent to the nominated primary care provider for review and co-signature. PU reports sent to specialist nurses automatically daily. Daily PU report includes patient data, location of PU, POA documentation, respiratory therapist documentation, e.g. oral, skin and neck assessments. Multidisciplinary team reviews patient HAPU and other PU metrics data monthly. | Not discussed |

AE – adverse event, CMS – Centres for Medicare & Medicaid Services, EMR – electronic medical record, EPUAP – European Pressure Ulcer Advisory Panel, HA – hospital acquired, HAPU – hospital acquired pressure ulcer, MDRPU – medical device-related pressure ulcer, NHS – National Health Service, NPUAP – National Pressure Ulcer Advisory Panel, PPPIA – Pan Pacific Pressure Injury Alliance, POA – present on admission, PU – pressure ulcer, RCA- root cause analysis, (s)DTI –(suspected) deep tissue injury U – unstageable, WOCN – The Wound , Ostomy and Continence Nurses Society.

**3.2 Policy and guidance**

Healthcare policy and clinical guidelines aim to standardise practice and improve quality, process, and outcomes of patient care. Policy documents from three European countries (England, Wales, and Republic of Ireland), Australia (New South Wales and Southern Australia) and USA were identified and reviewed (see Table 3).

**3.2.1 Learning from incidents**

PU incident reports have been developed to share learning and improve quality of care ([NSW Government, 2019](#_ENREF_40), [Government of South Australia, 2014](#_ENREF_19), [Health Service Executive, 2018b](#_ENREF_26), [Agency for Healthcare Research and Quality [AHRQ], 2014](#_ENREF_1)). Reports can also be submitted to a central government (e.g. in Ireland) for quality monitoring purposes. In countries like USA or Australia, reports are also linked to cost reimbursement and accreditation. Worldwide, reporting of MDRPUs is a relatively new concept included in policies and mandatory systems, thus the data on prevalence and incidence of these wounds are limited.

**3.2.2 Variation in staging & definitions**

The reviewed policy documents advised using the international staging system and definitions as published by NPUAP/EPUAP/PPPIA in 2014 ([Government of South Australia, 2014](#_ENREF_19), [NHS Improvement, 2018](#_ENREF_36), [NHS Wales, 2018](#_ENREF_38)). However, national and local variation in adoption of the international guideline exists. For example, the Irish policy referred to the international guidelines published in 2009 ([Health Service Executive, 2018a](#_ENREF_25)). Moreover, Ireland and Wales’ policies use the definition of un/avoidable PU based on the UK Department of Health definition. This definition has since been excluded by NHS Improvement (England) from its guidance, to align practices in other patient safety incidents ([NHS Improvement, 2018](#_ENREF_36)).

**3.2.3 Variation in pressure ulcers reporting**

All national and local reporting guidelines instruct PU status to be reported on admission to hospital. However, further steps differ considerably between countries. The New South Wales ([Government of South Australia, 2014](#_ENREF_19)) policy instructs that all PUs are recorded in a national database (Incident Information Management System (IIMS)) and reported to the appropriate team locally. Comparable rules can be found in the guideline published by the [The Royal Childern's Hospital Melbourne (2019)](#_ENREF_47) (using Victoria Health Incident Management System (VHIMS)) and those adopted in Ireland.

The Welsh system requires all identified PUs to be recorded and reported through a local reporting system and MDRPUs to be reported separately. Although, [NHS Wales (2018)](#_ENREF_38) policy requires all PUs to be investigated (at a certain level), as a minimum it sets out all PUs category 2 and above, unstageable, and suspected Deep Tissue Injury (DTI) should be investigated using a national review tool. This recommendation echoes the England guidance ([NHS Improvement, 2018](#_ENREF_36)) for local reporting.

In USA, national PU reporting is mandatory. The reviewed [California Hospital Association (2015)](#_ENREF_9) and the [Minnesota Hospital Association (2019)](#_ENREF_34) guidance only addresses reporting of the Hospital Acquired PUs (HAPUs), since occurrence of these PUs have impact on the organisation’s funding. No explicit policies or guidance on local reporting of pressure ulcers have been located through our searches.

**3.2.4 Reporting serious incidents & never events**

PUs can be classified as Serious Incidents (SI) if they present severe consequences to patients, carers, staff, or organisations, and where the potential for learning justifies investigation ([NHS England, 2015](#_ENREF_35)). Pressure ulcer categories reportable as a serious incident according to the reviewed policies are presented in Table 3.

The reviewed documents show similar approach to reporting SIs in different countries. Process initiation, however, varies between different nations. Reporting a PU as a Serious Incident is preceded by Root Cause Analysis (RCA) ([NSW Government, 2019](#_ENREF_40), [NHS England, 2015](#_ENREF_35)) and often a severity assessment (Ireland; NSW; South Australia). However, there is no standard at which a PU is considered a SI. The New South Wales (NSW) and the South Australia (SA) guidelines advise PU category 3 should be reported nationally ([NSW Government, 2019](#_ENREF_40), [Government of South Australia, 2014](#_ENREF_19)). However, the SA policy also instructs, PUs category 2 or greater should warrant a Root Cause Analysis (RCA). In Ireland, the HSE policy requires PU category 3 and above to be classified as Serious Reportable Events. Similar protocol exists in Wales, where additionally unstageable PUs and suspected DTI are reported to the national government.

Since 2008 the cost of care of hospital acquired PUs stage 3 and 4 are not reimbursed in the USA ([CMS, 2019](#_ENREF_11)). Unstageable pressure ulcers, which developed during hospital stay are subsequently staged as category 3 pressure damage for reporting purposes ([California Hospital Association, 2015](#_ENREF_9), [Minnesota Hospital Association, 2019](#_ENREF_34)). All policies regarded reporting SIs as a route to learning and quality improvement. In UK, reports are made to a national learning system ([NHS Improvement, 2019](#_ENREF_37)). However, often the incident reports are held and shared only within organisation or a group of associated organisations (personal communication).

**3.2.5 Variation in reporting MDRPUs**

The grey literature offered little guidance about reporting MDRPUs. On an organisation level MDRPUs are recognised and reported separately to other PUs. For example, [The Royal Children's Hospital Melbourne (2019)](#_ENREF_48) clinical guidelines included the device type when reporting MDRPUs in the national reporting system (VHIMS). More detailed report can be submitted through the All Wales DRPU Investigation tool, but healthcare facilities are at liberty to use it alongside a national general PU reporting tool. The new [NHS Improvement (2018)](#_ENREF_36) guidance in England requires the MDRPUs to be recorded as a separate category. However, it does not include specific device data. Such details can be usually found in local reporting systems, in a narrative form, and without standardisation as to details required.

Only one surveyed policy (Ireland) instructed that performance issues with a medical device (MD) that lead to patient harm, should be reported to the Health Products Regulatory Agency ([HSE, 2020](#_ENREF_27)). Related policies within the UK do not mention MD harm reporting, although a voluntary scheme exists, i.e. YellowCard ([MHRA, 2019](#_ENREF_33)).

Table 3 Summary of reviewed policies and national guidance documents

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Country | PU reporting policy/  guidance | Aim of reporting | Definition and staging standard | PUs reported nationally | MDRPUs reported locally/ nationally | MD Reg body | MDRPUs reported to regulatory body? | Serious incidents/ never events |
| England | NHS Improvement 2018  Guidance | Quality improvement | NPUAP/  EPUAP/  PPPIA 2014 | All PUs >= cat. 2 | Yes, as a separate category | MHRA | Voluntary | PU cat. 3 & 4 |
| Wales | NHS Wales  2018  Policy | Quality improvement | Definition: NPUAP/EPUAP  /PPPA 2014  Staging:  Essential Elements of Pressure Ulcer Prevention and Management | All PUs >= cat. 2 | Yes, as a separate category | MHRA | Voluntary | PU cat. 3, 4, SDTI & unstageable |
| Ireland | Health Service Executive  2018  Guidance | Quality improvement | Definition: NPUAP/EPUAP  /PPPA 2014  Staging: NPUAP/EPUAP  /PPPA 2009 | All categories | n/a | HPRA | Voluntary | PU cat. 3 & 4 |
| Australia  New South Wales | Pressure Injury Prevention and Management  Guideline 2014 | Quality improvement  Accreditation | NPUAP/  EPUAP/  PPPIA 2014 | All categories | n/a | TGA  (Australian Government) | Voluntary | PU cat. 3,4, SDTI & unstageable |
| South Australia | Pressure injury prevention and management  2016 | Quality improvement  Accreditation | PPPIA 2012 | All categories | n/a | TGA  (Australian Government) | Voluntary | PU cat. 3,4, SDTI & unstageable |
| USA | CMS | Reimbursement | NPUAP 2016 (adaptation) | All stages | n/a | FDA | Voluntary | PUs cat. 3 & 4 |

4. Discussion

This literature review aimed to synthesize current scientific and grey literature regarding PU reporting systems and processes. We found a paucity of publications on reporting of PUs and especially device related pressure ulcers. Similarly, policy documents are not easily available. Where scientific and grey literature was available, a significant degree of variation was observed.

The fundamental premise of policies and clinical guidelines is to promote standardised practice and improve quality of patient care ([Woolf et al., 1999](#_ENREF_51), [Jackson et al., 2016](#_ENREF_28)). Nonetheless, despite the emphasis of policies on collecting national prevalence data for PU, the lack of consistency in the data collection standards was apparent both within, and between countries ([Barakat-Johnson et al., 2018](#_ENREF_6), [Coleman et al., 2016](#_ENREF_12), [Jackson et al., 2016](#_ENREF_28), [Smith et al., 2016](#_ENREF_45)). In addition, inconsistency of hospital coding systems and classification limits the capacity to use data for PU prevention and to collate care quality indicators ([Backman et al., 2016](#_ENREF_4)). This was despite the instruction of most of the reviewed policies to use the international guidelines published by NPUAP, EPUAP and PPPIA as an underpinning document for PU categorisation, prevention, and management ([NHS Improvement, 2018](#_ENREF_36), [NHS Wales, 2018](#_ENREF_38), [NSW Government, 2014](#_ENREF_39)).

In many cases, organisations within a healthcare system have adopted a range of national and international guidelines to inform reporting practice, making direct comparisons challenging. On inspection, the mandatory systems often do not record contextual details regarding devices. Even if MDRPUs are recorded and reported within mandatory systems, the reports are omitting important details of the device implicated in patient harm ([NHS Improvement, 2018](#_ENREF_36), [CMS, 2019](#_ENREF_11)). In cases where data about devices are collected, they kept at a local level with no reporting to MD regulatory bodies. This severely limits shared learning from the MDRPU incidents. It is internationally agreed that devices which cause skin damage often, would benefit from further study into their design and safety features for high-risk patients ([Groeneveld et al., 2004](#_ENREF_21)), and should be managed through better regulation and evidence ([Gefen et al., 2020](#_ENREF_15)).

The Covid-19 pandemic showed that medical devices (e.g. ill-fitting protective personal equipment) can also cause skin damage to staff ([Gefen and Ousey, 2020](#_ENREF_16)). We did not include this skin damage reporting in our review as it does not concern patients.

### 4.1 Strengths and limitations

This literature review is first of its kind to the best of authors’ knowledge. We have identified significant gaps between policy and practice and highlighted the lack of standard reporting of MDRPUs. The most important limitation of this narrative literature review was reliance on the grey literature being published in English language. It is highly likely there are other publications in the public domain which we were unable to track and review. Using internet for searches of grey literature also poses limitation on what can be retrieved.

### 4.2 Clinical implications and future research recommendations

Due to the lack of contextualised reporting of PUs, MDRPUs and SIs in clinical practice it is currently impossible to ascertain specific factors which are implicated in PU formation. With regards to MDRPUs, there is little, or no evidence of which devices are implicated in skin damage. It is important to collect those data for care quality improvement and transparency, with reporting shared with regulatory agencies and industry to make the necessary improvements in device design and application guidance.

Future research should focus on establishing a standardised data collection instrument for reporting MDRPUs. It would make possible determining the impact on healthcare systems, systematic collection of data on harmful devices, and as a result improve patient safety and devices available to healthcare providers ([Gefen et al., 2020](#_ENREF_15)).

5. Conclusions

This review has shown variation in how PUs are recorded and reported between organisations, regions, and countries. Even more challenging circumstances surround MDRPUs. Here, the disparities are even more pronounced, with limited detail in the reporting process. Although MD authorities (e.g. US FDA, UK MHRA) offer voluntary reporting schemes, these opportunities are not routinely fulfilled. Due to the low frequency of reporting, there is no overview of devices which have been implicated in MDRPUs. As a result, improvement in care safety and device design is based on local knowledge rather than a robust evidence-based policy.

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