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Reporting medical device-related pressure ulcers: An international Delphi consensus study

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ABSTRACT

Background: Pressure ulcers that are caused from the application of medical devices for diagnostic or therapeutic purposes are commonly observed in acute care environments. Despite an improved understanding of the factors causing these wounds, there is no current consensus on reporting.
Objective: To develop an international consensus for reporting medical device related pressure ulcers.
Design: A modified RAND/UCLA Delphi study.
Settings: International experts from clinical, academic and industrial stakeholder.
Participants: 95 international clinicians and tissue viability experts.
Methods: A Delphi survey was developed through literature review and qualitative synthesis. It was electronically disseminated through gate keepers to international experts in the field, with three rounds of consensus feedback. Median values and Disagreement Index from Likert scales were used to establish consensus.
Results: The panel achieved consensus for reporting MDRPUs which included 30 items across 5 Themes which included i) Recording medical device care, ii) Reporting medical device-related pressure ulcer, iii) Device specific reporting, iv) Ulcer reporting and v) patient information.
Conclusions: This is the first international study to develop consensus on medical device related pressure ulcer reporting. This could be used to support standardised international reporting to improve care standards.
Tweetable abstract: This international Delphi consensus study established a core reporting data set for medical device related pressure ulcers. This study will inform the design of future reporting tools to support standardised practice.e.g. Tweetable abstract: international consensus on medical device related pressure injury monitoring @EPUAP @NPIAP @SkinSensing.

1. Background

A pressure ulcer (PU), also called a pressure injury, bedsore, or decubitus ulcer, is a localised injury to the skin and/or underlying tissue, usually over a bony prominence due to pressure or pressure in combination with shear [1]. In recent years, research into the biomechanics of skin and underlying tissues led to a better awareness of the factors leading to PU development. It is now understood that mechanical load type, magnitude, duration, individual tolerance and susceptibility, and risk factors, all, play a role in PU development [2]. The most common body sites where PUs develop include sacrum and heels [3], although they may present at any anatomical location, especially over a bony prominence [1].

It has been recognised that medical devices may also become implicated in pressure ulcer development. Although the first mention of a medical device-related pressure ulcer (MDRPU) appeared in The Lancet in 1972 [4], it was not until 2010, when a seminal paper by [5] was published, that the spotlight shone on MDRPUs. This study concluded that 34.5 % of all hospital-acquired pressure ulcers (HAPUs) were attributed to a medical device and that patients with devices were 2.4 times more likely to develop a PU of any kind [5]. A more recent study of medical device-related pressure ulcers (MDRPUs) in long-term acute care hospitals by [6] indicated that out of all HAPUs experienced by patients, 47 % were medical device-related. The most reported

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devices related to PUs are respiratory devices, splints and braces, and tubing [6].

MDRPUs may be difficult to prevent and treat as the device cannot always be moved or removed. Medical devices themselves create pressure, humidity and heat that develops between the skin and the device affecting the local microclimate [7]. They often need to be secured tightly to assure appropriate seal, and the materials used to secure the devices may hinder skin inspection [5,8]. In contrast to PUs, MDRPUs can cause skin damage where the device was attached to the patient's body, including not only bony prominences but also soft tissues and mucous membranes [1,9]. Although the aetiology of PUs and MDRPUs is similar, MDRPUs primarily develop due to friction in combination with shear from ill-fitted and poorly positioned medical device (MD) which constantly moves or rubs the skin and causes forces parallel to the skin [10].

In a recent publication, the Organisation for Economic Co-operation and Development (OECD) concluded that 15 % of hospital expenditures were consumed by the cost of treatment of safety failures, PUs being the costliest [11]. MDRPUs are considered to represent a substantive proportion of PUs, particularly in critical care settings. Despite medical devices primary function being therapeutic and monitoring patients' health state, they are the source of patient safety incidents, increased costs to organisations, and high costs to patients alike. But despite national drivers to improve patient safety, MDRPUs are not routinely reported. Consequently, there is uncertainty whether indeed MDRPUs represent substantive proportion of PU prevalence and cost presented to date, or those figures in fact underestimate the impact of MDRPUs. To provide high quality and safe patient care, data relating to MDRPUs, and associated devices implicated in skin damage are required. The rigour and consistency of these reports must be ensured to maximise patient benefit. The present study aims to develop international consensus on the reporting of medical device related pressure ulcers.

This study was part of a programme of research which included a narrative literature review [12] and an international qualitative study exploring reporting practice [13]. Subsequently, the aim of the present study was to reach consensus on the items to be included in a data set for the reporting of Medical Device-Related Pressure Ulcers from an international perspective. It was considered that participation of international experts may facilitate wider adoption of the data set and reporting tool in the future.

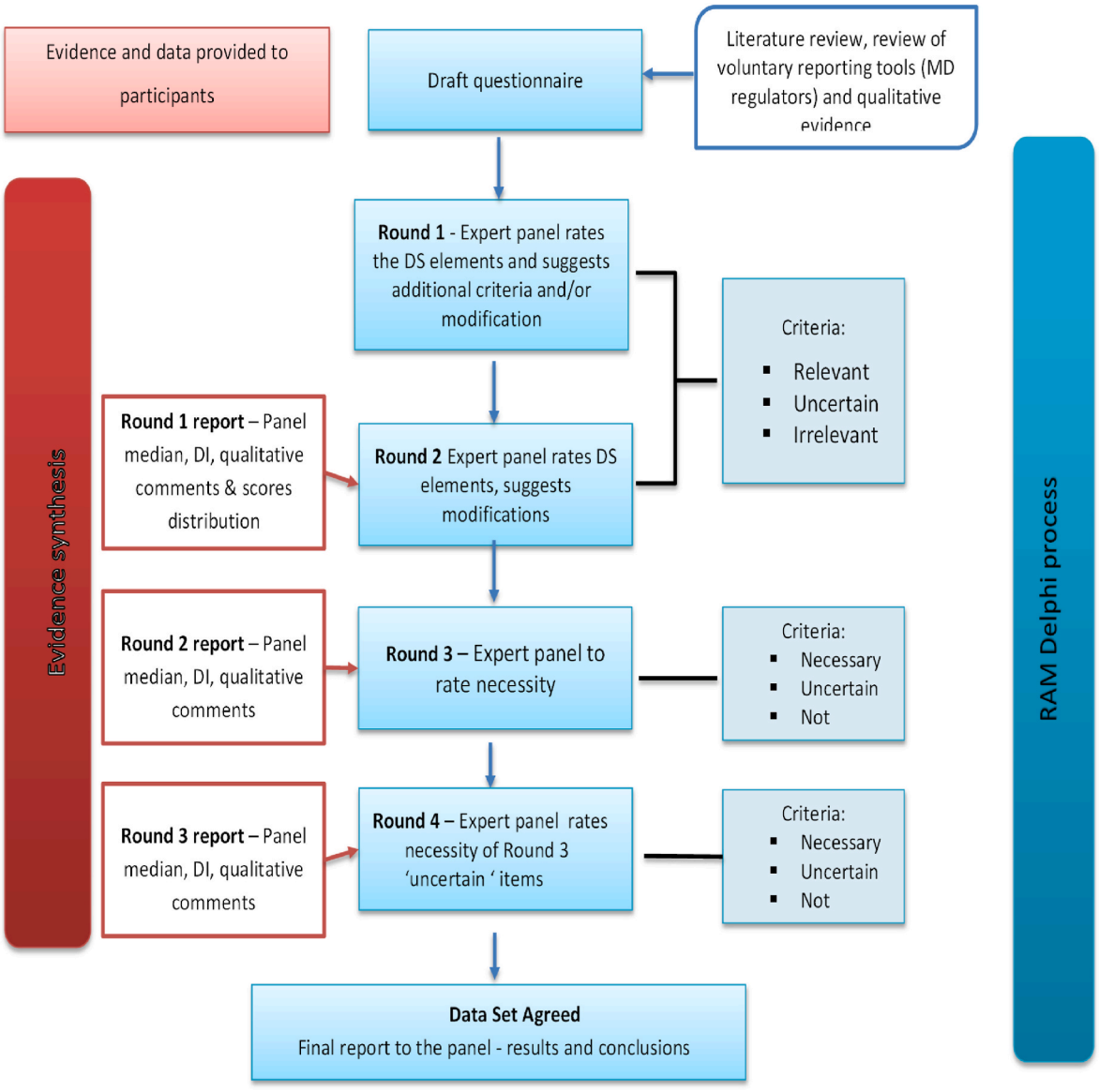

Fig. 1. Design of the consensus study drawing on the RAND/UCLA APPRIOPRIATENESS METHOD methodology and an overview of evidence provided to the panel.

2. Methods

A modified Delphi study drawing on RAND/UCLA (University of California, Los Angeles) Appropriateness Method (RAM) methodology [14,15] was used to maximise reliability and content validity. This incorporated the key features of a traditional Delphi study (i.e., structured interaction (but not face-to-face) and explicit synthesis of judgement and group decisions) with consideration of research evidence and expert opinion to facilitate consensus.

Fig. 1 provides an overview of the consensus process with the early stages (questionnaire round 1 and 2) focussing on appropriateness and the later stages (questionnaire round 2 and 3) focussing on necessity to reduce the number of items. The item is defined as appropriate if the expected benefit of inclusion in the data set exceeds the expected negative consequences, i.e. that collecting data on an item will overall be more beneficial because of the insights it provides, than the burden it may put on the reporter [16]. Whereas necessity was operationalised and the definition given to the participants within the survey, as a data item that is needed for a desired result, a prerequisite [15].

2.1. Participants/sample

A multi-speciality group with expertise in the pressure ulcer field was purposively sampled to include perspectives of clinicians, academics and device manufactures' representatives [17]. The panel sample was partly determined by practical and logistical factors, namely the resources available and the scope of the Medical Device-Related Pressure Ulcer consensus task [18,19]. It was also recognised that a higher number of panellists improves the reliability of composite judgements [20] which was found important for the acceptability of judgements made during the consensus process. Thus, we have made our decision on a panel size of 100 based on Keeney et al. who emphasizes that the size must be balancing the ability to generate a definite conclusion and the difficulty of managing a larger panel size [21].

The inclusion criteria for the panel members who were healthcare professionals included ten years' experience working within the domain of tissue viability and registration to a healthcare of medical professional body. As part of the panel academics were also included who had research/publication track record on pressure ulcers and/or medical device-related pressure ulcers. Finally, members from industry experience working with medical devices which interface with the skin or prophylactic dressings to protect the skin were included.

2.2. Recruitment

We enlisted the support of pressure ulcer related organisation (Advisory panels, societies, and industrial agencies) to advertise the study among their membership (according to their rules and regulations) via key gatekeepers. The information included details of the study and inclusion criteria for participation, hosted on newsletters, websites and emailed directly to membership lists. An invitation to participate in the consensus study with an explanation of the study's aims and objectives, was sent to members of pressure ulcer related organisations by the researcher. If participants fulfilled inclusion criteria, they were included in the mailing list.

2.3. Data collection

The consensus study was undertaken between October 2020 and March 2021 and consisted of 4 questionnaire rounds administered to an anonymous international panel of experts (Fig. 1). Questionnaires were administered and completed electronically using a commercial online survey platform (LimeSurvey). Participants in this study were given on average two weeks to complete the questionnaire in each round, with a period of one month to collate the responses and analyse the data.

For each round participants were provided with.

- A summary of findings of the narrative literature review [null].

A summary of the international qualitative study exploring reporting practice [null].

- The consensus questionnaire to rate their support for each item

From round 2 participants were also provided with a personalised report including their individual's score as well as the panels median score and disagreement index for each item and related comments.

2.3.1. Questionnaire design

The questionnaire items, developed in preparation for the study, included the proposed data set extrapolated from the qualitative study results [13]) and items aggregated from medical device regulatory bodies' voluntary reporting schemes identified in a narrative review [12]. The items were grouped thematically and ordered to improve the logical flow and thus understanding of the questionnaire.

1) Recording medical device care
2) Reporting medical device-related pressure ulcers
3) Medical device-specific reporting
4) Ulcer-specific reporting
5) General patient and co-morbidity data
6) Other items – free-text box to suggest any items relevant but missed in the questionnaire or any modifications (this was available in rounds 1 and 2).

The themes were the same throughout voting rounds 1 to 3, with the exception of the final qualitative theme 'Other items'. In the final, fourth round, experts were presented with a list of items they had not reached consensus on and were asked to re-rate them. Those items were simply presented in a list which followed the order of the themes from previous rounds. Experts rated their agreement with each statement on a 9-point Likert scale (where 1 indicated no support and 9 indicated strong support). The group median for each item was categorised into three tertiles. In this study categories were - median 1–3 disagree, 4–6 uncertain, and 7–9 agree. In round two, there was an additional option to keep the score the same as in round 1, and the distribution of scores for each item was presented. Rating of all statements was mandatory. There was an opportunity to add any items otherwise missing from the list of items and a space for comments at the end of each set of questions, as well as a separate open-ended question box at the end of the online questionnaire. In the final two rounds (rounds 3 and 4), experts were asked to rate the necessity of including items they previously agreed were relevant to reporting Medical Device-Related Pressure Ulcers. The scoring used a 9-point Likert scale, where 1 indicated the item definitely did not need to be included and 9 indicated strong support for inclusion in the set.

2.4. Data analysis

Level of agreement necessary for achieving consensus were decided a priori to the data collection and analysis, which is considered a good practice [19,22]. This also addresses the perceived robustness and clarity of cut-off point, which in Delphi studies, may impact trustworthiness of the results [19]. In this method, process an item is classified as 'appropriate', 'uncertain' or 'inappropriate' based on two variables [15], hence the questionnaire statements were summarised with.

1) The median panel rating;

And.

2) A measure of dispersion of panel ratings, which is an indicator of the level of agreement between the panellists with which the ratings

were made, the Disagreement Index (DI), which is based on the classic definition of disagreement.

To detect disagreement, the inter-percentile range (IPR: 0.3–0.7) was calculated, and IPR was adjusted for symmetry (IPRAS), see section 5.3.5 for the formula used for the calculation. Disagreement was established by calculating the ratio of IPR and IPRAS. Thus, there is disagreement if DI > 1, and if DI < 1, there is an agreement [15]. Using those two parameters, and following the established RAM, items were included and excluded in Round 2, with the corresponding thresholds presented in Table 2.

Qualitative data collected in rounds 1 and 2 were narratively summarised. Any new items that any panellist suggested were tabulated, and any duplication was noted. The addition of an item in the subsequent round of questionnaire was based on how frequently the experts mentioned the item in their feedback, in the free - text boxes. Any other qualitative comments were coded, thematically categorised as topic summaries, and analysed using content analysis.

2.5. Validity

Good practice guidelines were followed in designing and undertaking this study. This study applied principles of good practice in the planning and delivery of the consensus process incorporating the involvement of a mixed-speciality expert group [17]. Other key principles included careful preparation and consideration of relevant evidence throughout the consensus process. The questionnaire was a subject of piloting to ensure content validity. As a result, language and choice of vocabulary was improved upon to ensure clarity. All questionnaires were expected to be completed in private, without the external pressures of others who might have had strong convictions regarding the subject. Lastly, a measure of the dispersion of scores and the measure of central tendency were included in reporting of the study results [20].

2.6. Ethics

This study has already obtained University of Southampton Ethics Board (ERGO 2 49718). At the start of the online questionnaire, participants were asked if they read the study information sheet and to confirm their consent to participate, which was confirmed by ticking a box next to the consent statement. They were also reminded they had the right to withdraw from the study without giving reasons.

3. Results

In the first round, 95 international experts expressed willingness to participate in the consensus study. They all met the inclusion criteria and were subsequently invited to complete the first round of the study questionnaires. The number of participants in each round and response rates are summarised in Table 3. Despite attempts to maintain the number of experts throughout the rounds, numbers decreased by just over 50 % by the final round. However, overall response rates were high for each corresponding round (74–96 %).

In Round 1, the panel of experts represented twenty-three different countries, with the highest number of participants being based in the UK (24 %), the USA (19 %), and Australia (11 %). Participants represented a diverse professional background including academia (25 %), acute healthcare sector (63 %), industry (7 %), health service regulatory body (1 %), and community sector (3 %). One participant identified with both community sector and industry. Fifty-nine panellists (79 %) had ten or more years' experience in tissue viability or related research and sixty-nine participants (92 %) had ten or more years' experience in wound assessment and/or reporting.

Table 2
Panel's support criteria.

Table 5.5 Round 2 - Panel's support criteria. **Panel median**	**Disagreement Index (DI)** DI > 1 indicates disagreement	**Indication**
1–3	DI < 1	Exclude
4–6	Any	Uncertain
Any	DI > 1	Uncertain
7–9	DI < 1	Include

Table 3
Participant numbers and response rates.

Round #	Number of invited experts	Number of responses	Response rate	Responses received vs *initial* (95) invitations sent
1.	95	75	79 %	79 %
2.	75	65	87 %	68 %
3.	65	48	74 %	51 %
4.	48	46	96 %	48 %

3.1. Consensus development – the content of the data set

In the first round of questionnaires, experts rated 36 items (Table 3). After the first two rounds four items were removed, since they did not meet the criteria for inclusion. Two of those items related to medical device data, i.e. expiry date and whether device was sterile. The experts also agreed that photographs of a healed MDRPU and patient gender are not relevant to reporting. In the first round, there was no agreement between experts whether the risk assessment score was relevant, although the item eventually was included in the data set. Additionally, experts in the first round suggested three more items to be included, which were the type of MD securement used and its frequency of change, and whether the MD could be safely repositioned. Consequently, all three items were included in the subsequent questionnaire rounds and reached the consensus criteria for inclusion.

After four rounds of voting, 30 items met criteria for inclusion in the data set for reporting Medical Device-Related Pressure Ulcers and subsequently were used to develop a draft reporting tool (eAppendix A). Table 4 shows items included or excluded through the rounds and the final proposed data set.

After data analysis from the 3rd Round, seven items panel median fell into the 'uncertain' category, and out of those, there were four items where a disagreement between the experts was present. A fourth round was initiated to clarify whether those items were necessary or not for inclusion. Results of the final, fourth round indicated that consensus was reached on including the record of the patient's skin tone in the data set (median 6.5 and DI = 0.22). Six other items were left uncertain and hence were excluded from the final list.

3.2. Inclusion of pressure ulcer categories in reporting

In rounds 1 and 2, participants were asked to decide which pressure ulcer categories should be required to be reported using the data set under development. There was a good level of support for the inclusion all of the categories. In round 3, it was confirmed that this represented a necessary data entry and should be included in the proposed data set. New items proposed by participants were tabulated with supporting evidence, and consideration has been given to the frequency with which the same suggestion appeared in the data. As a result of this analysis, three items were added to the round 2 questionnaires and two items were added to the round 3 (Table 5).

Experts had the opportunity to add any general comments regarding the data set or its use. The dominant theme of the feedback revolved around the feasibility of collecting the data. The concern expressed by several experts was to develop a reporting tool that is short and easy to complete.

Table 4
Consensus development results and final list of items.

#	Proposed Item	Relevancy		Necessity		
		Round 1 Panel Median (DI)	Round 2 Panel Median (DI)	Round 3 Panel Median (DI)	Round 4 Panel Median (DI)	Items included in the proposed DS
	Theme 1: Recording medical device care					
1.	Medical reason for the device use	9.00 (0.16)	9.00 (0.13)	8.00 (0.75)		✓
2.	The number and type of medical devices in situ	9.00 (0.00)	9.00 (0.00)	9.00 (0.27)		✓
3.	The prevention used (e.g. type of prophylactic dressings	9.00 (0.13)	9.00 (0.13)	9.00 (0.13)		✓
4.	A record of when an MD was first applied	9.00 (0.16)	9.00 (0.00)	9.00 (0.13)		✓
5.	A record of the type of securement [‡]		9.00 (0.13)	8.00 (0.29)		✓
6.	How frequently the securement was changed [‡]		9.00 (0.26)	8.00 (0.29)		✓
7.	Documenting if the MD could be safely repositioned [‡]		9.00 (0.13)	8.00 (0.29)		✓
8.	A record of device repositioning	9.00 (0.13)	9.00 (0.00)	9.00 (0.29)		✓
9.	Recording comfort associated with the medical device	7.00 (0.65)	7.00 (0.37)	6.00 (1.61)	6.00 (0.37)	
10.	Information whether the Staff were trained to use the medical device	7.00 (0.65)	7.00 (0.69)	6.00 (0.91)	6.00 (0.52)	
11.	Whether the MD is used as prescribed or 'off label.'	7.00 (0.37)	7.00 (0.49)	6.50 (0.99)		✓
12.	Documenting patient communication regarding the Medical Device-Related Pressure Ulcer presence and/or development	8.00 (0.23)	8.00 (0.29)	7.00 (0.37)		✓
	Theme 2: Reporting medical device-related pressure ulcer					
13.	Pressure Ulcer category[a]	9.00 (0.00)	9.00 (0.00)	9.00 (0.00)		✓
	Theme 3: Medical device - specific reporting					
14.	The type of MD	9.00 (0.00)	9.00 (0.00)	9.00 (0.13)		✓
15.	The name of the manufacturer	7.00 (0.67)	8.00 (0.59)	5.00 (1.70)	5.50 (0.52)	
16.	The exact name/product	7.00 (0.65)	7.00 (0.75)	5.00 (0.99)	6.00 (0.52)	
17.	Recording if the device was single-use or reusable	5.00 (0.52)	5.00 (0.65)			
18.	Recording expiry date	5.00 (1.02)	5.00 (0.97)			
19.	Recording the device was sterile	5.00 (0.65)	5.00 (0.69)			
20.	Recording the batch & lot number	5.00 (1.08)	5.00 (1.04)			
21.	If the MD is still in place	8.00 (0.29)	9.00 (0.19)	8.00 (0.29)		✓
22.	The type of material the MD is made of	7.00 (0.75)	7 0.00 (0.75)	5.50 (1.70)	6.50 (0.52)	✓
	Theme 4: Ulcer - specific reporting					
23.	The body site where the Medical Device-Related Pressure Ulcer is located	9.00 (0.00)	9.00 (0.00)	9.00 (0.00)		✓
24.	Size of the Medical Device-Related Pressure Ulcer	8.00 (0.75)	9.00 (0.13)	9.00 (0.13)		✓
25.	The date and time of finding the Medical Device-Related Pressure Ulcer	9.00 (0.02)	9.00 (0.00)	9.00 (0.00)		✓
26.	Including photographs of the Medical Device-Related Pressure Ulcer	7.00 (0.67)	8.00 (0.59)	7.00 (0.72)		✓
27.	Including photographs after the Medical Device-Related Pressure Ulcer healed	5.00 (0.65)	5.00 (0.65)			
28.	The environment (i.e. Ward OR theatre location) in which the Medical Device-Related Pressure Ulcer was first observed	9.00 (0.00)	9.00 (0.00)	8.00 (0.29)		✓
29.	The short-term effect of the Medical Device-Related Pressure Ulcer on current patient care	7.00 (0.45)	8.00 (0.29)	6.50 (0.65)		✓
30.	A potential longer-term consequence of the Medical Device-Related Pressure Ulcer on the patient	6.00 (0.45)	7.00 (0.65)	6.00 (1.04)	6.00 (0.52)	
	Theme 5: General patient and co – morbidity data					
31.	Patient's age	9.00 (0.54)	9.00 (0.13)	8.50 (0.29)		✓
32.	Patient's gender	5.00 (1.70)	6.00 (0.75)			
33.	Patient's weight	7.00 (0.67)	8.00 (0.29)	7.00 (0.74)		✓
34.	Patient's nutritional status	8.00 (0.19)	9.00 (0.19)	8.00 (0.49)		✓
35.	Patient's primary diagnosis	7.00 (0.75)	8.00 (0.59)	8.00 (0.29)		✓
36.	Patient's co-morbidities	7.00 (0.67)	8.00 (0.37)	7.50 (0.47)		✓
37.	Pressure Ulcer Risk Assessment score	5.00 (2.26)	8.00 (0.75)	8.00 (0.49)		✓
38.	Skin assessment	9.00 (0.33)	9.00 (0.00)	8.00 (0.13)		✓
39.	When the patient was last repositioned	8.00 (0.75)	8.00 (0.29)	8.00 (0.49)		✓
40.	Patient's skin tone[b]			7.00 (0.74)		See below
	Including the record of the patient's skin tone[b]			6.00 (0.99)	6.50 (0.22)	✓
42.	Recording if the patient was proned with a medical device[b]			8.00 (0.29)		See below
	Recording if the patient was proned with a medical device in situ[b]			8.00 (0.29)		✓

NB. Greyed out boxes mean that the item was not considered at a round, because it was either included after feedback, excluded based on panel consensus, or included based on panel consensus.

[‡] Item added to round 2 due to feedback in round 1.

[a] In rounds 1 and 2, panels voted on the relevance of all categories of pressure ulcers. In round 3, the question was shortened to a general statement because the panel agreed in round 2 that all categories should be included.

[b] Questions added to round 3 due to feedback in round 2. Both relevance and necessity were scored in round 3.

"A minimum data set is important to be clear and concise to ensure staff will use it." (P40)

and

"*I think the minimum data set for reporting should be a sleek list (…)*" (P7)

It was emphasised that the nursing staff work under time pressure and asking them to complete a lengthy report may lead to a lack of compliance.

Table 5
New items suggested in Rounds 1 and 2 of the consensus study.

#	Proposed item	Round	No.of comments	Quote(s)
1.	What type of securement has been used	1	2	- "Securement - type of securement (tape, dressing, plaster etc), frequency of change of device securement." (P15) - "Most importantly to intubation would be how it is secured and when the tube is moved. Securement devices should be noted in the record and they become another MD." (P92)
2.	How frequent was the securement changed	1	1	As above
3.	Could the MD be repositioned safely	1	1	- "It might be useful to have something about whether it in fact could be repositioned or pressure relieving devices beneath it be used as many occur in these situations, but staff cannot prevent them occurring despite trying repositioning/ monitoring etc." (P87)
4.	Patient skin tone (or ethnicity)	2	2	- "Note no mention of skin tone – given challenges in darker skin tone, should this not be included?" (P8) - "Does there need to be a question related to the skin tone of the patient? It may be possible that we miss earlier pressure damage on patients with darker skin tones". (P23)
5.	Patient proned with MD in situ	2	2	- "(N)ow that COVID is part of our care - and proning injuries are now becoming more frequent - do we include an item about whether or not this patient was proned with the Medical Device-Related Pressure Ulcer in place?" (P75) - "Just remember that rules change when dealing with covid-19 especially with regards to devices in place and patients in prone position. Double vigilance is needed on both device management and risk assessment". (P5)

'*We have to be really careful about setting nurses up to fail.*' (P14)

and

'*There is a danger that if too much data is included that staff will find it too complicated and will not fill it in.*' (P86),

Where access to some data may be restricted due to the quality of the patient record.

'*I find documentation where I work is appalling in terms of comprehensive skin assessments, particularly under MD [medical device] and in relation to offloading of areas and repositioning patients. I'm currently trying to change this but feel there needs to be a cultural shift* (…).' (P72)

Accessibility of data in relation to, for example, medical device type and size, may lead to missing data.

'*The challenge with the above [recording medical device data], is this is a lot of information that the staff may not have to hand* '. (P17)

and

'*Recording of medical device [data] can be very time consuming, to make it a routine recording may not be feasible'* (P55)

4. Discussion

This consensus study was a first in-kind undertaken in the area on medical device-related pressure ulcers and involved a large international community of experts. They 23 countries and a range of clinical, academic, industrial and regulatory bodies. The panel achieved consensus for reporting MDRPUs which included 30 items across 5 Themes. This will be further developed in readiness for the future evaluation of a standardised tool in clinical practice settings.

A modified Delphi study drawing on the RAND UCLA structured consensus process [15] was adopted for this study which enabled consideration of evidence gathered through a narrative literature review [12] and international interview study [13], to propose an initial data set for a draft Medical Device-Related Pressure Ulcer reporting. In recognition that this study was concerned with an issue of international importance, and delivered online, the recruitment strategy employed was wide-reaching and ambitious, and the number of participants extended beyond the first estimation. The number and diversity of participants in the present Delphi are similar to those in recent studies in the field which aim to achieve consensus on Core outcomes for pressure ulcer prevention trials [23]. Indeed, the experts represented a range of settings and healthcare systems, which ensured a range of opinions was enabled to be expressed and considered in the process.

The Delphi approach enabled the expert panel to reach an agreement on the most relevant and necessary items to be included in the proposed data set for reporting MDPRUs, including additional items in the final data set. However, despite the final two rounds aiming to limit the number of items to be included through necessity rating, this did not yield anticipated reduction in items, which remained high (n = 30). Comments received in rounds 1 and 2 were concerned with the volume of data that would be included in the reporting. Indeed, nurses' primary concern is patient care, and it is well documented in literature that pressures (including administrative burden) lead to patient care being missed, which in turn has negative impact on staffs wellbeing and job satisfaction [24–26]. The feedback highlighted the fact that healthcare professionals are extremely busy with clinical work, thus any reporting needs to be fit for purpose, with clear objectives, with tools that are easy and quick to complete.

Five additional items were added and subsequently included in the agreed data set. These included patient's skin tone, whether the patient was in prone position with the device in situ, securement, its change frequency, and record of repositioning of the device. It has been recognised that skin tone variance may affect timely recognition [1]. Patients with dark skin tones rarely show a non-blanchable erythema (category 1 PU), instead presenting either increased or reduced pigmentation in the areas of skin irritation [27]. Clinicians have to be aware of the skin tone to provide individualised care and avoid healthcare inequality between patients [28]. It is worth noting, that even though in medical device research the focus here is on ethnicity, it has been acknowledged that ethnicity cannot be used as proxy for skin tone [29,30]. Including the 'skin tone' item in the reporting data set and form, may lead to improved awareness of MDPRUs in different ethnic groups, as well as robust data on devices which could benefit from improvement in design. Indeed, studies have observed significant differences in anthropometrics between ethnicities and genders [31–33]. However, many medical device designs are based on predominantly white, Caucasian male face measurements Institute of Medicine [34].

There were, however, items which did not reach the required

threshold for the inclusion in the proposed data set but may still be considered as relevant for reporting MDRPUs, e.g. the name of the medical device manufacturer [12]. The qualitative comments signal, that this exclusion might be based on feasibility of collecting this data by the healthcare professional. It is, however, important to consider, that without standardised collection of data relating to the devices (i.e. the device manufacturer and the name/product number) it is impossible to know which devices would benefit from change in their design or materials used to manufacture them [null]. Routine collection of those data would enable coordinated work with medical devices regulatory bodies, such as MHRA in UK (Yellow Card Reporting Scheme).

This consensus study was undertaken at a time, when the Covid-19 pandemic was spreading around the globe posing new challenges for the nursing staff, who had to treat large numbers of patients with acute respiratory distress syndrome (ARDS) [35,36]. It was suggested that with a rising number of MDRPUs relating to placing patients in prone position, a record whether a pressure ulcer was related to proning should be reflected in the data set. A recent study found that patients with pressure ulcers showed correlation between days of mechanical ventilation and time spent in prone position ($\rho = 0.47$, $P = 0.042$), prevalence of patients with pressure ulcer related to proning was approximately 30 % (CI = 18.8–41.5) and that most affected body site was the face (59 %, 32/54) [37]. Therefore it is important to raise awareness of the medical device care, appropriate prevention, and skin care of those patients [35]. The final two items included into the rating cycle, which subsequently reached the level of support required for inclusion in the data set related to data about securement and repositioning of the device. Repositioning of the device is a recognised and advised strategy for the prevention of Medical Device-Related Pressure Ulcer development [1]. There is also evidence that securement devices may lead to Medical Device-Related Pressure Ulcer development [38].

The interest from the members of wound and tissue viability organisations proved to be very high. As a result, 95 participants were sent the initial invitation, evidence on reporting, and first cycle questionnaire. This supported the validity and reliability of the results, a large panel from a geographically large area was established to take part in the consensus process. The inclusion of different backgrounds, a range of experiences, and the most up-to-date evidence ensured all opinions and point of views were included and therefore the results are as reliable as possible, and the validity is increased. This range, however, might have also led to differences in appropriateness ratings, due to different organisation of healthcare and availability of resources [17]. However, the lack of an in-person meeting, where the areas of uncertainty or lack of agreement could have been explored in an open discussion [2] is a methodological limitation of this study.

Although the consensus study resulted in a list of items relevant and necessary for inclusion in Medical Device-Related Pressure Ulcer reporting, further development work was required to design a reporting form and improve its usability and pre-testing with clinical nurses to assess acceptability and clarity of the form. Indeed, while this method was suitable to establish the content of the proposed data set for reporting Medical Device-Related Pressure Ulcers, wording of questions or statements within the reporting form could not be considered. Moreover, we need to explore whether collecting data on medical device-related pressure ulcers and medical devices will be as burdensome and difficult as some of the experts indicated. Further feasibility testing was also required to assess the form and its use in clinical practice. Experts also supported the use of the agreed data set for prevalence studies and supported its use on different levels for reporting (unit, hospital, and national) which presents an opportunity for standardised reporting, meaningful comparisons, and evidence-driven medical device improvements.

5. Limitations

The study design did not include face-to-face interaction at any stage of the consensus process. The classical Delphi starts with exploration of the panel's opinions on the issue under investigation and based on that a survey is constructed [39]. To mitigate this potential design limitation, the possibility of adding suggestions and comments in the first two rounds of the voting cycle was added. Another limitation of this study was being reliant on participants having internet access, which may have led to the study not being accessible to potential participants from less wealthy countries where internet access is not universal. In addition, involving participants with significant knowledge and experience, who are also members of leading international skin and wound care organisations, may have led to selection bias and questions whether the results are truly representative of the opinions of other experts and clinicians. To minimise those issues, further studies exploring which data should be collected at minimum, and which could be non-mandatory should be undertaken in the future with a range of clinicians involved in PU and Medical Device-Related Pressure Ulcer reporting.

6. Conclusions

In this study was first of its kind international consensus on Medical Device-Related Pressure Ulcer reporting and agreed a data set of 30 items which will underpin a novel reporting form for use in clinical practice. This study used a modified Delphi technique drawing on the RAND/UCLA Appropriateness Method, incorporating most recent academic and grey literature, alongside the evidence from a qualitative study exploring reporting practices in eleven countries worldwide. The tool will now be modified for formal evaluation in clinical settings.

7. Twitter handles & additional emails

Skin Sensing Research Group Twitter: @SkinSensing.

9. What is already known

- Medical device related pressure ulcers have a high prevalence in critical care settings
- There is limited consensus on reporting methods for device related pressure ulcers

10. What this paper adds

- Reporting data on device related pressure ulcers was developed through an international Delphi consensus
- The consensus revealed key themes of reporting device, wound and demographic data.
- These reporting metrics could inform the development of a device related pressure ulcer tool for clinicians.

8. Trial registration

Not registered.

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Declaration of competing interest

We would like to submit the above paper for publication in *Journal of Tissue Viability*. This is to state, on behalf of all the authors, that the work has not been published and is not being considered for publication elsewhere. There were no conflicts of interest for the above study.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jtv.2024.11.006.

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