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Core outcomes for pressure ulcer prevention trials: results of an international consensus study

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Abstract

Background There is substantial heterogeneity between trial outcomes in pressure ulcer prevention research. The development of core outcome sets is one strategy to improve comparability between trial results and thus increase the quality of evidence.

Objectives To identify core outcomes for pressure ulcer prevention trials.

Methods A workshop was held with service users to discuss their views and understanding of the outcomes identified by a scoping review and to identify any missing outcomes. In a next step, a Delphi survey comprising three rounds was conducted to evaluate a compiled list of outcomes by their importance. Afterwards the preselection from the Delphi survey was discussed in a virtual consensus meeting with the aim of agreeing on a final set of core outcomes. Individuals who had completed all three rounds of the Delphi survey were eligible to participate in this meeting. Participants included practitioners, service users, researchers and industry representatives. The OUTPUTs project is registered in the COMET database and is part of the Cochrane Skin Core Outcome Set Initiative.

Results The workshop did not reveal any missing outcomes, but highlighted the need for further efforts to make lay people understand what an outcome is in a study setting. The Delphi survey took place between December 2020 and June 2021. After the three rounds, 18 out of 37 presented outcomes were rated to be critically important. In the following consensus meeting, six outcomes were prioritized to be included in the core outcome set for pressure ulcer prevention trials: (i) pressure ulcer occurrence; (ii) pressure ulcer precursor signs and symptoms; (iii) mobility; (iv) acceptability and comfort of intervention; (v) adherence/compliance; and (vi) adverse events/safety.

Conclusions Based on a comprehensive list of outcomes in pressure ulcer prevention research, there was clear agreement on the six identified core outcomes in three international Delphi rounds and in the consensus meeting. Although outcome measurement instruments need to be identified next, the six identified core outcomes should already be considered in future trials, as service users, practitioners, researchers and industry representatives have agreed that they are critically important.

What is already known about this topic?

- There are numerous trials on pressure ulcer prevention, but evidence on the effectiveness of preventive measures is limited due to heterogeneity between trial outcomes.

- The development of a core outcome set is one strategy to improve comparability between trial results.

What does this study add?

- A service user workshop, a three-round Delphi survey and an online consensus meeting with practitioners, service users, researchers and industry representatives were conducted to identify core outcomes for pressure ulcer prevention trials.
- Six core outcomes were defined: (i) pressure ulcer occurrence, (ii) pressure ulcer precursor signs and symptoms, (iii) mobility, (iv) acceptability and comfort of intervention, (v) adherence/compliance and (vi) adverse events/safety.

What are the clinical implications of this work?

- Better evidence of interventions for pressure ulcer prevention will help health professionals and service users to decide which interventions are most appropriate and effective.
- Better evidence may contribute to better pressure ulcer prevention.

Pressure ulcers (PUs) are a clinically relevant skin and soft tissue disease that occurs in all healthcare settings worldwide.[1–4] The prevalence of PUs in acute care settings around the world is estimated to range from 6% to 19%,[3] and a pooled prevalence of 13% was reported in hospitalized adults.[1] Empirical evidence indicates that, at least in Western countries, the prevalence has remained largely the same over the last 15 years.[2,4] Even if certain PUs may be regarded as unpreventable, there is substantial potential to reduce their occurrence.[2] There are numerous studies[5] and clinical guidance[6] on PU prevention; however, the evidence on the effectiveness of preventive strategies is limited. Two main reasons are the poor quality of some study designs and the lack of comparability of study outcomes, limiting the ability to conduct meaningful meta-analyses.[1,3,5,7] Outcomes are measured in studies to capture the effects of an intervention, such as the effects of a special pressure-distributing mattress, or a programme to promote mobility. For example, a harder mattress may cause earlier measurable erythema in response to the increased pressure on the soft tissues. Erythema is an example of a study outcome and a PU precursor sign.[8]

To counter the problem of outcome heterogeneity the concept of the core outcome set (COS) has been established in many medical fields (as promoted by the COMET Initiative: www.comet-initiative.org). A COS defines the critical outcomes that are considered to be essential and should be measured as a minimum in each clinical trial of a specified area.[9] The Outcomes for Pressure Ulcers Trials (OUTPUTs) project was set up to develop a COS for trials investigating the clinical efficacy or effectiveness of PU prevention interventions including repositioning, mobility promotion, support surfaces, offloading, prophylactic dressings, textiles, preventive skincare and nutrition in adult patients aged ≥ 18 years who are at risk of pressure ulceration. There are no restrictions concerning the healthcare setting or geographical area.[10]

Based on a scoping review, an overview of outcomes used in previous PU prevention research was compiled and published.[5] A scoping review seemed to be appropriate to provide a broad overview of outcomes in various publication types. Evaluations of risk of bias or quality of evidence, which are defining characteristics of systematic reviews, were not necessary. The review was conducted in 12 major databases, and both outcomes and relevant concepts in PU prevention were extracted and afterwards inductively grouped into domains.[5,10] The domains were then categorized according to the outcome domain taxonomy proposed by the COMET group.[11] There is no strict demarcation between the terms 'outcomes' and 'outcome domains', as both are used to describe what to measure. Differences only exist in how broadly the 'what' is defined. In this manuscript, both terms can be considered synonymous.[12]

Patients and methods

A workshop with service users (people with elevated PU risk and/or with a PU, or informal caregivers) from the Pressure Ulcer Service User Network (PURSUN) was held in Leeds, UK. The purpose of this workshop was to discuss their understanding of each outcome captured by the scoping review and to identify any ambiguities or any missing outcomes from a service user's perspective. The group was provided with information about COSs and an overview of the OUTPUTs project was presented, explaining the aims and results so far. Contrary to the protocol, a second workshop was not held. Instead, it seemed more reasonable to involve the service users in creating clearly explained texts for the subsequently planned Delphi survey. The introduction text and descriptions for each outcome to be presented in the survey were reviewed by the service users and revised based on their feedback.

A Delphi survey followed by an online consensus meeting were conducted with participants from the following five stakeholder groups: health professionals, service users, researchers who mainly conduct clinical trials, researchers who mainly conduct systematic reviews and industry representatives. The methodological approach was based on recommendations provided by the Cochrane Skin Core Outcome Set Initiative (http://cs-cousin.org) and the Harmonising Outcomes Measures for Eczema (HOME) roadmap,[13] and experiences of other COS groups for the development of COSs.[9,14,15] This report follows COS-STAR[16] and the project was registered in the COMET database (registered in 2015).[17] A protocol was published previously.[10]

Delphi survey

A Delphi survey comprising three rounds was conducted to rate the relevance of the outcomes identified previously.[5] To raise awareness of the survey, announcements with links to the survey were placed on the websites of the European Pressure Ulcer Advisory Panel, the National Pressure Injury Advisory Panel, the Pan Pacific Pressure Injury Alliance and the Tissue Viability Society (UK) and/or the respective mailing lists were made available to send invitations. It was expected that this would cover a broad geographical range including relevant societies from lower-income countries. As no comparable organizational structures currently exist for Africa and South America, a MEDLINE search was conducted for PU papers (not limited to prevention) by authors from these regions, who then were invited via email. Furthermore, the professional network of the OUTPUTs team was used, and individuals were contacted via invitation email. To get in touch with service users, members of the PURSUN group and service users known to the project members were contacted and invited to participate.

Based on the results of the scoping review 68 outcomes were extracted.[5] Evidence suggests that having a higher number of items presented in Delphi studies reduces the response rates.[18] To minimize the attrition rate, we aimed to keep the number of questions in the Delphi survey as low as possible, and outcomes were further summarized or excluded with justification. Decisions were made by two project members and then reviewed independently by all project members. Disagreements were discussed in regular online meetings. Each modification was justified in writing and is transparently displayed (Table S1; see Supporting Information). For example, the outcome 'fatigue' was merged with 'energy and vitality', and 'nutritional status' was excluded due to being intervention specific. In the end, 37 outcomes with definitions were presented in the first round of the Delphi survey (Table S2; see Supporting Information).

Using the online platform 'COMET Delphi Manager', the participants rated the relevance of the presented outcomes on a nine-point Likert scale during periods of about 4 weeks per round.[19] We decided to apply a nine-point numerical rating scale based on the recommendations of the GRADE working group.[20,21] Following previous COS developers, the scale was divided into three sections[22–24] and we adhered to the consensus definition recommended by the Outcome Measures in Rheumatology initiative.[25,26] Scores of 1–3 indicated outcomes that are not important; 4–6 indicated outcomes that were important without being critical; and 7–9 indicated outcomes of critical importance. Consensus that the outcome should be part of the COS was reached when ≥70% participants scored 7–9 and ≤ 15% participants scored 1–3. In case of ≥70% participants scoring 1–3 and ≤ 15% participants scoring 7–9, consensus was reached that the outcome should not be part of the COS. Any other scoring distribution meant that there was no consensus. It was stated on each page that a more detailed description and/or example would appear when keeping the mouse pointer over the presented outcome (Table S2).

Participants had the opportunity to suggest new outcomes that were not listed in the first round and seemed important to them. The proposed outcomes were then reviewed by the OUTPUTs team. If they were not already covered by an existing outcome and the proposed outcome was not intervention specific, it was added to the list and presented in the second Delphi round together with all outcomes from the first round. Participants were shown their own score from the previous round, and bar graphs were displayed to show how different stakeholder groups had scored the outcomes. The same was done in the third Delphi round, but in this final round only those outcomes of unclear importance (no consensus on inclusion or exclusion) were presented for evaluation. The corresponding flowchart is shown in Figure 1.

Online consensus meeting

A virtual meeting using the Webex videoconferencing service was scheduled for approximately 3 h. Individuals who had completed all three rounds of the Delphi survey were eligible to participate. The project team sent invitations to eligible participants using a stratified sampling approach taking stakeholder group and geographical location into account.

The meeting was chaired by a moderator experienced in leading consensus meetings (J.J.K.). Other tasks, such as giving an introductory presentation or facilitating the subgroups, were distributed among the OUTPUTs members. Technical support was present throughout the whole meeting.

All outcomes that met the inclusion criteria in the Delphi survey were up for discussion (Table 1). Outcomes for which there was no consensus in the Delphi survey were omitted from the consensus meeting (Table 2). At that point we deviated from our protocol because no outcomes met the exclusion criteria and the number of outcomes to be discussed would have been beyond the scope of an online consensus meeting, which should not last longer than 4 h.[15] Prior to the meeting, we emailed participants the outcomes without consensus and informed them that we would only discuss outcomes that met the inclusion criteria. The participants were asked if they had any objections or would like to discuss

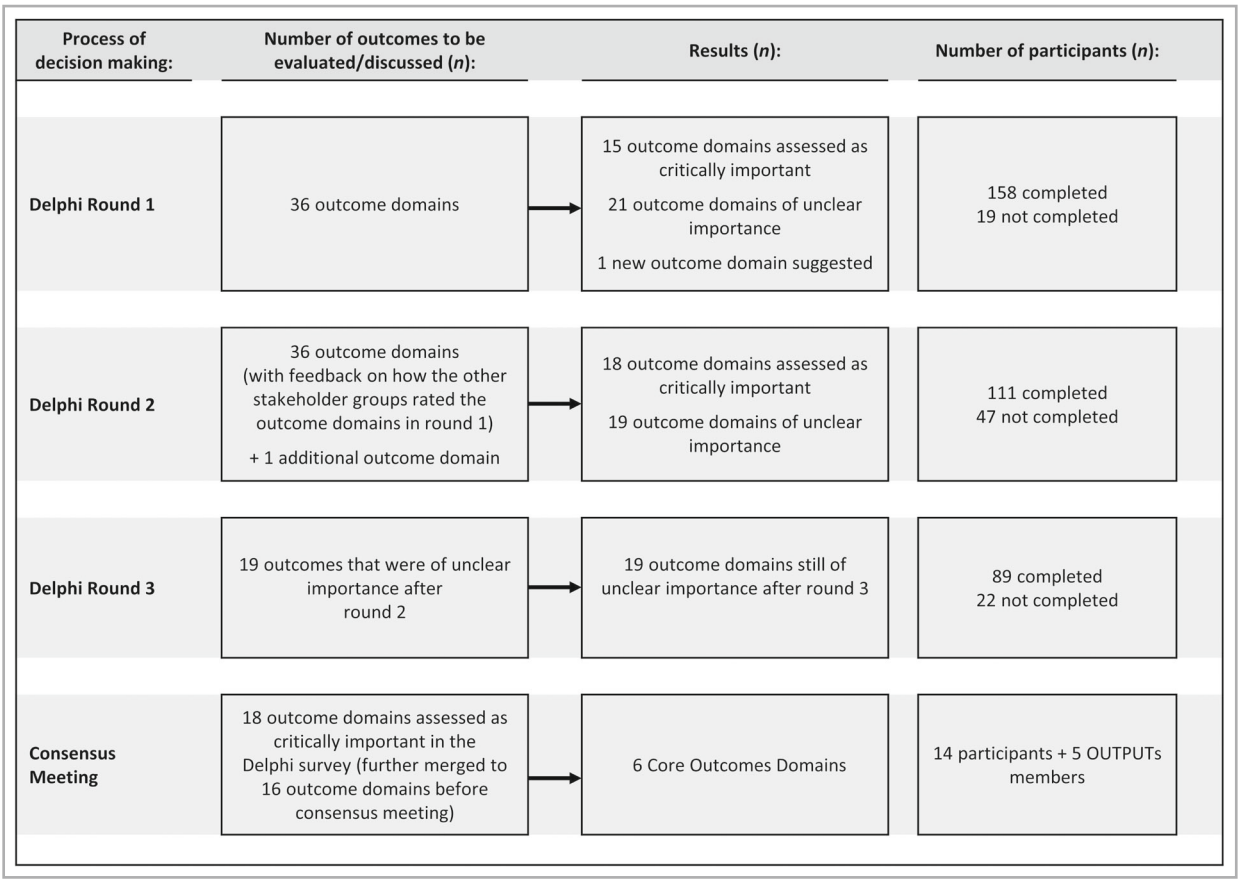

Figure 1 Delphi survey and consensus meeting flowchart.

outcomes from those omitted. However, this was not requested by anyone. Prior to the meeting a detailed information pack, including an overview of the Delphi results and an agenda, was sent to the participants.

During the online meeting, participants were given the opportunity to share opinions on the importance of each outcome under the guidance of the moderator. This was done in the whole group as well as in smaller groups (three groups of five to six persons each) during breakout sessions. To structure the discussion, the outcomes were allocated to three categories A, B and C, according to the number of stakeholder groups that assessed the outcomes to be critically important in the Delphi survey (Table 1). For category B outcomes it was assumed that there would be the most need for discussion as they were voted critically important by three or four of the five stakeholder groups. These outcomes were therefore discussed in small group sessions. A detailed description of the procedure is provided in Table S3 (see Supporting Information). Where the moderator considered it necessary, an anonymous electronic confirmation vote was performed. Participants answered the question 'In your opinion, is the outcome "X" critically important and should be included in the COS?' with a 'yes/no' function. All participants and the OUTPUTs project group members were eligible to vote. The outcome had to be confirmed by ≥70% of the voters to be considered a core outcome.

Results

Participants

One male and five female PURSUN members participated in the service user workshop (four with experience of living with PU risk, and two informal caregivers). Tables 3 and 4 show the participant characteristics for the Delphi survey and consensus meeting, respectively. In total, 158 individuals participated in the first round of the Delphi survey. The largest stakeholder group was formed by the 'practitioners' (n = 102). Round 3 was completed by 89 participants. Most of these individuals reported living in Europe (n = 56), followed by Australia or New Zealand (n = 18). In the consensus meeting, four practitioners, three patients or informal caregivers, three industry representatives and four researchers participated.

Workshop with service users

The workshop took place in Leeds on 25 September 2017. It did not result in any additional outcomes. However, one important finding was that at times the group encountered difficulties differentiating between outcomes and interventions and recognizing what an outcome for a trial actually is. It was

Table 1 Delphi survey: outcomes that were included after round 2

Outcomes		Percentage scoring 7–9 after Delphi round 2					
		Total group n = 111	Prac n = 68	SU n = 7	Ind n = 9	Res-CT n = 16	Res-SR n = 11
Category A: voted critically important by all five stakeholder groups							
1	PU occurrence – whole body	93·7	96	100	100	81	91
2	PU occurrence – defined body sites	94·6	96	100	100	88	91
3	PU occurrence – device related	95·5	97	100	100	93	82
4	Mobility	89·2	91	100	89	75	91
5	Adverse events/safety	92·8	90	100	100	94	100
6	Pressure ulcer precursor signs/skin changes	95·5	96	100	100	94	91
7	Pain associated with pressure areas (when there is no pressure ulcer)	88·3	93	71	100	81	73
8	Acceptability of intervention and comfort	88·3	93	71	100	75	82
Category B: voted critically important by three or four stakeholder groups							
9	Patient's position	82·9	91	86	78	75	46
10	Pain associated with intervention	88·3	94	57	100	81	73
11	Pressure ulcer prevention self-care	82·0	88	100	89	63	55
12	Adherence/compliance	90·0	96	67	100	69	91
13	Patient satisfaction	79·3	85	71	100	63	55
14	Patient's perception of being involved in decision making	71·8	75	86	78	63	55
Category C: voted critically important by one or two stakeholder groups							
15	Physical functioning	72·1	81	100	44	44	64
16	Autonomy/independence	71·2	82	100	44	38	55
17	Resource use	73·1	79	40	89	63	55
18	Quality of life in general	76·6	82	86	67	63	64

Ind, industry representatives; Prac, practitioners; Res-CT, researchers mainly conducting clinical trials; Res-SR, researchers mainly conducting systematic reviews; SU, service users (patients or informal caregivers).

Table 2 Outcomes not meeting the Delphi consensus threshold after round 3

Outcome		Percentage scoring 7–9 in Delphi round 3					
		Total group n = 89	Prac n = 50	SU n = 7	Ind n = 7	Res-CT n = 16	Res-SR n = 9
1	Sleep	33	40	43	29	6	33
2	Patient's balance	28	34	43	14	13	22
3	Energy and vitality	19	18	43	29	13	0
4	Interface pressure	51	62	33	57	33	22
5	Blood perfusion	48	64	20	43	20	22
6	Oxygen and carbon dioxide in tissue	30	40	20	57	0	11
7	Skin temperature	47	56	20	100	19	22
8	Skin and tissue physiological parameters	49	56	0	100	36	22
9	Tissue deformation	55	66	20	100	33	22
10	Skin and tissue inflammatory biomarkers	44	52	40	71	14	22
11	Social functioning	46	50	86	57	25	22
12	Role functioning	25	24	67	14	13	33
13	Self-efficacy	29	32	83	29	7	11
14	Motivation and readiness for enhanced self-care	51	60	71	43	38	11
15	Self-consciousness	25	26	71	29	6	11
16	Self-esteem	27	28	71	14	13	22
17	Emotional wellbeing	46	50	86	57	19	33
18	General health	58	68	71	71	38	22
19	Patient's body perception	32	36	57	43	13	11

Ind, industry representatives; Prac, practitioners; Res-CT, researchers mainly conducting clinical trials; Res-SR, researchers mainly conducting systematic reviews; SU, service users (patients or informal caregivers). For each item, there was an option 'unable to score'. The percentages refer only to the participants who assigned a score.

Table 3 Delphi survey: characteristics of participants

	Delphi survey		
	Round 1	Round 2	Round 3
Number of participants	158	111	89
Stakeholder groups			
Practitioners	102	68	50
Patients and informal caregivers	9	7	7
Industry representatives	13	9	7
Researchers mainly conducting clinical trials	21	16	16
Researchers mainly conducting systematic reviews	13	11	9
Age			
18–29 years	6	4	3
30–49 years	55	35	28
50–64 years	85	63	51
≥ 65 years	12	9	7
Experience with pressure ulcers			
0–5 years	20	11	9
5–10 years	16	13	10
10–15 years	25	18	15
> 15 years	97	69	55
Residence			
North America	27	13	7
South America	5	2	1
Africa	1	1	0
Europe	86	66	56
Asia	15	9	7
Australia or New Zealand	24	20	18

Table 4 Consensus meeting: characteristics of participants (n = 14)

Country of residence	Number
Australia	2
Belgium	2
Denmark	1
Germany	1
Spain	1
Sweden	1
Switzerland	1
UK	4
USA	1
Affiliation to stakeholder group	Number
Practitioners (e.g. nurses, medical doctors)	4
Patients and informal caregivers	3
Industry representatives	3
Researchers	4

recognized that for the ongoing work further efforts are needed to clarify what an outcome is.

Delphi survey

The three Delphi rounds took place between December 2020 and June 2021, followed by the consensus meeting on 15 October 2021. After the first round, the outcome 'patient's perception of being involved in decision making' suggested by a participant was added to the list. Of these 37 outcomes, 18 outcomes reached consensus as being 'critically important' after the second round (Table 1 and Figure 1); 19 outcomes were of unclear importance (no consensus) and were therefore presented again in the third round. None of those met the condition to be included after the final round (Table 2 and Figure 1).

The outcomes 'PU occurrence – whole body', 'PU occurrence – defined body sites' and 'PU occurrence – device related' were rated to be critically important by >90% of participants. The almost concordant results made the OUTPUTs team realize that PU occurrence appears to be critically important to nearly all participants, but also that the decision on how exactly the occurrence of PU should be captured (everywhere, only at defined body sites, measure device-related PU separately) should be decided at a later stage, when the outcome measurement instrument set is being developed, as this requires more detailed investigation and discussion. Therefore, the OUTPUTs team decided to merge the three outcomes and only present the more general term 'PU occurrence' to the consensus meeting. Table 1 presents the outcomes that were available for discussion during the consensus meeting.

Online consensus meeting

Discussing category A outcomes

In the first whole-group session the following six outcomes of category A were discussed: pressure ulcer occurrence, mobility, adverse events/safety, pressure ulcer precursor signs/skin changes, pain associated with pressure areas (when there is no pressure ulcer) and acceptability of intervention and comfort.

Discussions arose about the outcome 'pressure ulcer precursor signs/skin changes'. It was agreed that this outcome should not be limited to the skin surface but should include all skin and tissue layers and all relevant precursor signs. The question of whether tingling prior to PU development is covered by this outcome led to the suggestion to reword it as 'pressure ulcer precursor signs and symptoms'. Precursor signs refer to an observable phenomenon (e.g. erythema), whereas symptoms are subjective experiences and refer to patient-reported outcomes. It was then noted that the outcome 'pain associated with pressure areas' is a symptom, so it was suggested to include this outcome as an aspect of 'pressure ulcer precursor signs and symptoms'. An anonymous vote was taken and the proposal was approved by 89% (Table 5).

There was another vote on 'mobility', as the question was raised whether mobility is critical for all types of interventions. It was countered in the discussion that mobility as an outcome is relevant not only for mobility interventions. Interventions could have effects on mobility without having the goal of addressing mobility, for example a nutrition

Table 5 Consensus meeting: results of anonymous voting (14 invited participants and five OUTPUTs members were eligible to vote)

Combining two outcomes of category A to new outcome?	Yes	No	No answer	Percentage of total 19 voting 'yes'
Pressure ulcer precursor signs and symptoms (comprising 'pressure ulcer precursor signs/skin changes' and 'pain associated with pressure areas')	17	0	2	89%
In your opinion, is the outcome XY critically important and should be included in the core outcome set?	Yes	No	No answer	Percentage of total 19 voting 'yes'
Category A outcome				
Mobility	16	0	3	84%
Category B outcome				
Patient's position	6	12	1	32%
Pain associated with intervention	5	13	1	26%
Pressure ulcer prevention self-care	4	15	0	21%
Adherence/compliance	18	0	1	95%
Patient satisfaction	6	13	0	32%
Patient's perception of being involved in decision making	3	15	1	16%
Category C outcome				
Physical functioning	4	15	0	21%
Autonomy/independence	3	16	0	16%
Resource use	10	9	0	53%
Quality of life in general	3	16	0	16%

intervention could have an effect on mobility by lowering or increasing the energy to move. The mobility outcome was supported by 84%.

For the other outcomes of category A there was agreement that they should be included in the COS, therefore no anonymous voting was necessary. It was found that adverse events are generally poorly reported in published literature and that inclusion in the COS would increase the awareness and standardization of reporting adverse events. With regard to the outcome 'acceptability of intervention and comfort', the question was raised as to how this would be captured, for example, in ventilated patients. It was noted that this is a common problem with patient-reported outcomes. It will be the challenge of future work to identify measurement tools that are suitable to capture this patient-reported outcome in the mentioned subgroup.

Discussing category B outcomes

In all three small group sessions 'adherence/compliance' was identified as the outcome of highest importance. Its inclusion was approved by 95% of eligible voters (Table 5). There was agreement that 'pain associated with intervention' is very important, but may only be relevant for certain interventions and is already partly covered by 'acceptability of intervention and comfort'. There were further discussions about some possible overlaps, for example between the outcomes 'patient's perception of being involved in decision making' and 'adherence/compliance'. It was mentioned that even though all category B outcomes represent separate outcomes, the strong interrelation with 'adherence/compliance' and 'acceptability of intervention and comfort' justifies not to include them, in order to keep the COS feasible. This was confirmed via anonymous voting.

Discussing category C outcomes

Capturing 'resource use' as a core outcome seemed relevant to some. An opposing view was that requiring this outcome to be reported in every single study would be too burdensome for some studies. It would include factors such as cost-effectiveness analysis, which would simply not be feasible to be analysed by each single study.

There were also service user voices pointing out that 'physical functioning', 'autonomy/independence' and 'quality of life' are relevant from a service user perspective and the wish was expressed to keep either 'quality of life' or 'autonomy/independence'. One reseracher replied that these outcomes are surely important, as there are preventive interventions where patients are not able to do things they normally do, but it was questioned whether the discussed outcomes should be part of the minimum set.

As there was no clear tendency to exclude the category C outcomes, the chair decided to vote on each of them. Finally, none of the category C outcome domains were voted to be included (Table 5).

Core outcomes

Six outcomes were determined to be core in pressure ulcer prevention trials (Table 6).

Discussion

The originally planned face-to-face meeting took place as an online meeting due to the COVID pandemic. In order to best deal with the challenges of an online meeting and to make the most of the benefits of the digital format, we drew on the experience and recommendations of other project groups.[15,27]

After the meeting we asked for feedback by email, and the very good feedback from the participants confirmed our own perception of a successful meeting (Table S4; see Supporting Information).

The OUTPUTs project followed the current standards of COS development[9,28] and went through a multistage process. Nevertheless, there are some limitations. Based on the scoping review, 68 outcomes were identified. This high number was considered not feasible to be presented in the Delphi survey. Therefore, we classified these into 36 overarching outcomes. This increased the conceptual complexity and might have made the process more abstract to the participants. To counteract this we always provided definitions and examples. There are ongoing debates on how 'granular' outcomes should be and methodological guidance is needed.[29–32]

For the Delphi survey we chose a nine-point numerical rating scale and named the three sections of the scale according to the suggestion of the DelphiManager tool from the COMET initiative,[19] where the section including the scores 1–3 was labelled 'not important'. In our case, the exclusion criteria seemed to be too strict, as there was not a single exclusion. In hindsight, we assume that the term 'not important' was not appropriate. It is too much of a barrier to assign grades 1–3, as many outcomes seem to be important in some way. Perhaps more people would have assigned scores 1–3 and the Delphi survey would have fulfilled the purpose of reducing the number of outcomes had the scale section been labelled differently, for example 'somewhat important' or 'moderately important'.

We made substantial efforts to include a high and representative number of Delphi participants. Several multinational stakeholder groups were finally involved in the surveys and the online consensus meeting. Nevertheless, compared with other COS development projects the total number of participants might be considered low, and there was no representative from Africa and only one from South America who completed all rounds of the Delphi survey. However, we feel that the prioritized outcomes are applicable globally, because even in resource-poor environments interventions may be different, but outcomes are not. Service user representation was also low, but we feel that the service user views were adequately taken into account because of the following reasons: (i) the scoping review included qualitative evidence describing service user views; (ii) a separate servicer user workshop was conducted; and (iii) in the consensus meeting there was equal representation of all stakeholder groups and service user shared their views.

Developing core outcomes for prevention is a major methodological challenge. It seems to be easier to describe treatment effects changing existing diseases or health states, instead of describing intervention effects, when the health state remains stable and no signs or symptoms are expected to occur.[10,33] This challenge is also reflected in the prioritized outcomes. PU precursor signs and symptoms and PU occurrence are two outcomes, referring directly to tissue damage. However, even in high-risk settings, the majority of participants in PU prevention trials will not develop any signs of ulceration.[34,35] Therefore, other aspects are important in order to measure prevention effects.[36,37] Although mobility is an established risk factor for pressure ulceration,[38] it is conceptualized as an intervention effect here, because the preventive intervention (e.g. soft support surface) affects the ability to move in beds or chairs. The type of intervention also affects the domains 'acceptability and comfort' and 'adherence/compliance', which were considered critical by all stakeholders. While these concepts are associated with patient characteristics, the impact of the preventive intervention on these aspects is substantial and they are therefore an outcome. Care will be taken to capture the meaning of the outcomes when developing the most appropriate outcome measurement instruments.[12] Although the measurement methods have not yet been determined, the six identified core outcomes should already be considered in studies, as various stakeholders agreed that they are critically important.

Table 6 Core outcomes for pressure ulcer prevention trials

Core outcome	Description
1. Pressure ulcer occurrence	Pressure ulcers that develop anywhere on the body (reporting pressure ulcers specifically for defined body sites or device-related pressure ulcers will be decided at a later stage)
2. Pressure ulcer precursor signs and symptoms	Early pressure ulcer warning signs and symptoms including pain (not restricted to the skin)
3. Mobility	Patient's ability to move (e.g. turn over in bed and/or walk)
4. Acceptability and comfort of intervention	How well the patient accepts the prevention technique and the patient's comfort or discomfort
5. Adherence/compliance	Adherence and compliance of patients. Do patients use prevention techniques in the way they are intended to?
6. Adverse events/safety	Harmful or negative events that occur during the trial, for example injuries, falls, skin irritation or allergic reactions

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Conflicts of interest

The authors declare they have no conflicts of interest.

Data availability

The data are available on request from the authors.

Ethics statement

Ethical approval was obtained for the Delphi survey from the ethics committee of the University of Lübeck (Germany) on 19 December 2019 (19-423). For the online consensus meeting, an amendment was submitted to the aforementioned ethics committee and was approved by the committee on 5 October 2021.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Table S1 Outcomes dropped or merged prior to the Delphi survey in order to reduce the list to a feasible number.
Table S2 Outcomes that were included in the Delphi survey and the corresponding help texts (n = 37).
Table S3 Agenda of the online consensus meeting.
Table S4 Feedback of participants of the consensus meeting.

References

1 Li Z, Lin F, Thalib L, Chaboyer W. Global prevalence and incidence of pressure injuries in hospitalised adult patients: a systematic review and meta-analysis. *Int J Nurs Stud* 2020; **105**:103546.
2 Mervis JS, Phillips TJ. Pressure ulcers: pathophysiology, epidemiology, risk factors, and presentation. *J Am Acad Dermatol* 2019; **81**:881–90.
3 Tubaishat A, Papanikolaou P, Anthony D, Habiballah L. Pressure ulcers prevalence in the acute care setting: a systematic review, 2000–2015. *Clin Nurs Res* 2018; **27**:643–59.
4 Tomova-Simitchieva T, Akdeniz M, Blume-Peytavi U *et al.* [The epidemiology of pressure ulcers in Germany: systematic review]. *Gesundheitswesen* 2019; **81**:505–12 (in German).
5 Lechner A, Kottner J, Coleman S *et al.* Outcomes for Pressure Ulcer Trials (OUTPUTs) project: review and classification of outcomes reported in pressure ulcer prevention research. *Br J Dermatol* 2021; **184**:617–26.
6 Kottner J, Cuddigan J, Carville K *et al.* Prevention and treatment of pressure ulcers/injuries: the protocol for the second update of the international Clinical Practice Guideline 2019. *J Tissue Viability* 2019; **28**:51–8.
7 Haesler E, Kottner J, Cuddigan J. The 2014 International Pressure Ulcer Guideline: methods and development. *J Adv Nurs* 2017; **73**:1515–30.
8 Kottner J. The clinical relevance of nonblanchable erythema in pressure ulcer prevention. *Br J Dermatol* 2020; **182**:262–3.
9 Williamson PR, Altman DG, Bagley H *et al.* The COMET Handbook: version 1.0. *Trials* 2017; **18**:280.
10 Lechner A, Kottner J, Coleman S *et al.* Outcomes for Pressure Ulcer Trials (OUTPUTs): protocol for the development of a core domain set for trials evaluating the clinical efficacy or effectiveness of pressure ulcer prevention interventions. *Trials* 2019; **20**:449.
11 Dodd S, Clarke M, Becker L *et al.* A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. *J Clin Epidemiol* 2018; **96**:84–92.
12 Prinsen CA, Vohra S, Rose MR *et al.* How to select outcome measurement instruments for outcomes included in a 'Core Outcome Set' – a practical guideline. *Trials* 2016; **17**:449.
13 Schmitt J, Apfelbacher C, Spuls PI *et al.* The Harmonizing Outcome Measures for Eczema (HOME) roadmap: a methodological framework to develop core sets of outcome measurements in dermatology. *J Invest Dermatol* 2015; **135**:24–30.
14 Katiri R, Hall DA, Buggy N *et al.* Core Rehabilitation Outcome Set for Single Sided Deafness (CROSSSD) study: protocol for an international consensus on outcome measures for single sided deafness interventions using a modified Delphi survey. *Trials* 2020; **21**:238.
15 Gorst SL, Barrington H, Brookes ST et al. *Online consensus meetings for COS development: issues to consider*. Available at: https://www.comet-initiative.org/Downloads/Issues%20to%20consider%20for%20online%20consensus%20meetings.pdf (last accessed 5 July 2022).
16 Kirkham JJ, Gorst S, Altman DG *et al.* Core Outcome Set-STAndards for Reporting: the COS-STAR Statement. *PLOS Med* 2016; **13**:e1002148.
17 COMET Initiative. *Outcomes for Pressure Ulcer Trials (OUTPUT)*. Available at: http://www.comet-initiative.org/studies/details/283 (last accessed 5 July 2022).
18 Gargon E, Crew R, Burnside G, Williamson PR. Higher number of items associated with significantly lower response rates in COS Delphi surveys. *J Clin Epidemiol* 2019; **108**:110–20.
19 COMET Initiative. *Delphi Manager*. Available at: http://www.comet-initiative.org/delphimanager (last accessed 5 July 2022).
20 Schunemann HJ. [GRADE: from grading the evidence to developing recommendations. A description of the system and a proposal

regarding the transferability of the results of clinical research to clinical practice]. *Z Evid Fortbild Qual Gesundhwes* 2009; **103**:391–400 (in German).
21 Schünemann H. *Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach* 2013. Available at: https://gdt.gradepro.org/app/handbook/handbook.html (last accessed 5 July 2022).
22 Tong A, Manns B, Hemmelgarn B *et al.* Standardised Outcomes in Nephrology – Haemodialysis (SONG-HD): study protocol for establishing a core outcome set in haemodialysis. *Trials* 2015; **16**:364.
23 Bennett WL, Robinson KA, Saldanha IJ *et al.* High priority research needs for gestational diabetes mellitus. *J Womens Health (Larchmt)* 2012; **21**:925–32.
24 Schmitt J, Langan S, Stamm T, Williams HC. Core outcome domains for controlled trials and clinical recordkeeping in eczema: international multiperspective Delphi consensus process. *J Invest Dermatol* 2011; **131**:623–30.
25 Boers M, Kirwan JR, Wells G *et al.* Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. *J Clin Epidemiol* 2014; **67**:745–53.
26 Toupin-April K, Barton J, Fraenkel L *et al.* Toward the development of a core set of outcome domains to assess shared decision-making interventions in rheumatology: results from an OMERACT Delphi survey and consensus meeting. *J Rheumatol* 2017; **44**:1544–50.
27 Katiri R, Hall DA, Hoare DJ *et al.* Redesigning a web-based stakeholder consensus meeting about core outcomes for clinical trials: formative feedback study. *JMIR Form Res* 2021; **5**:e28878.
28 Kirkham JJ, Davis K, Altman DG *et al.* Core Outcome Set-STAndards for Development: the COS-STAD recommendations. *PLOS Med* 2017; **14**:e1002447.
29 Lange T, Kottner J, Weberschock T *et al.* Outcome assessment in dermatology clinical trials and Cochrane reviews: call for a dermatology-specific outcome taxonomy. *J Eur Acad Dermatol Venereol* 2021; **35**:523–35.
30 Kottner J, Jacobi L, Hahnel E *et al.* Core outcome sets in dermatology: report from the second meeting of the International Cochrane Skin Group Core Outcome Set Initiative. *Br J Dermatol* 2018; **178**:e279–85.
31 Oei W, Fledderus AC, Spuls PI *et al.* Development of an international core domain set for medium, large and giant congenital melanocytic naevi as a first step towards a core outcome set for clinical practice and research. *Br J Dermatol* 2021; **185**:371–9.
32 Young AE, Brookes ST, Avery KNL. A systematic review of core outcome set development studies demonstrates difficulties in defining unique outcomes. *J Clin Epidemiol* 2019; **115**:14–24.
33 van't Hooft J, Duffy JMN, Daly M *et al.* A core outcome set for evaluation of interventions to prevent preterm birth. *Obstet Gynecol* 2016; **127**:49–58.
34 Hahnel E, El Genedy M, Tomova-Simitchieva T *et al.* The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention compared with no dressings in high-risk intensive care unit patients: a randomized controlled parallel-group trial. *Br J Dermatol* 2020; **183**:256–64.
35 Stephens M, Bartley C, Dumville JC. Pressure redistributing static chairs for preventing pressure ulcers. *Cochrane Database Syst Rev* 2022; **2**:CD013644.
36 Tomova-Simitchieva T, Lichterfeld-Kottner A, Blume-Peytavi U, Kottner J. Comparing the effects of 3 different pressure ulcer prevention support surfaces on the structure and function of heel and sacral skin: an exploratory cross-over trial. *Int Wound J* 2018; **15**:429–37.
37 Gefen A, Kottner J, Santamaria N. Clinical and biomechanical perspectives on pressure injury prevention research: the case of prophylactic dressings. *Clin Biomech (Bristol, Avon)* 2016; **38**:29–34.
38 European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and treatment of pressure ulcers/injuries. Available at: https://internationalguideline.com/static/pdfs/Quick_Reference_Guide-10Mar2019.pdf (last accessed 5 July 2022).