Core Outcome Set in incontinence-associated dermatitis Research (CONSIDER): international and multidisciplinary consensus on a core set of outcome domains in incontinence-associated dermatitis research

**Abstract**

**Aim.** To report the development of a core set of outcome domains for clinical research involving adults with incontinence-associated dermatitis or at risk, independently from any geographical location or skin colour.

**Background.** The management of incontinence-associated dermatitis is important in caring for incontinent patients. The lack of comparability of clinical trial outcomes is a major challenge in the field of evidence-based incontinence-associated dermatitis prevention and treatment. Core outcome sets may therefore be helpful to improve the value of clinical incontinence-associated dermatitis research.

**Design.** Systematic literature review, patient interviews and consensus study using Delphi procedure.

**Methods.** A list of outcome domains was generated through a systematic literature review (no date restrictions – April 2016), consultation of an international steering committee and three patient interviews . The project team reviewed and refined the outcome domains prior to starting a three-round Delphi procedure conducted between April - September 2017. The panellists, including healthcare providers, researchers and industry were invited to rate the importance of the outcome domains.

**Results.** We extracted 1852 outcomes from 244 articles. Experts proposed 56 and patients 32 outcome domains. After refinement, 57 panellists from 17 countries rated a list of 58 outcome domains. The final list of outcome domains includes erythema, erosion, maceration, IAD-related pain and patient satisfaction.

**Conclusion.** Erythema, erosion, maceration, incontinence-associated dermatitis -related pain and patient satisfaction are the most important outcome domains to be measured in incontinence-associated dermatitis trials. Based on this international consensus on what to measure, the question of how to measure these domains now requires consideration.**Registration** This project has been registered in the Core Outcome Measures in Effectiveness Trials (COMET Initiative) database and is part of the Cochrane Skin Group - Core Outcomes Set Initiative (CSG-COUSIN).

**Keywords** Clinical nursing research, Contact dermatitis, Core outcome set, Dermatology, Domains, Incontinence-associated dermatitis, Nursing, Outcome assessment, Outcomes, Outcomes research

**Summary statement**

**Why this research is needed?**

* Incontinence-associated dermatitis is a burden for both patients and for their caregivers. Adequate prevention and treatment of incontinence-associated dermatitis are therefore essential.
* A wide range of products is available but studies on the efficacy and (cost-) effectiveness cannot adequately be compared because of the large variety of outcomes used and their related measures.
* To date, there is no consensus on which outcomes to measure in clinical effectiveness trials in the field of incontinence-associated dermatitis.

**What are the key findings?**

* Core outcome domains to be reported in incontinence-associated dermatitis clinical trials have been identified.
* Erythema, maceration, erosion, IAD-related pain and patient satisfaction are considered as most important to measure.

**How should the findings be used to influence policy/practice/research/education?**

* Researchers should focus on the identified core outcome domains when planning and conducting clinical trials in the field of incontinence-associated dermatitis.
* Research is needed to identify most appropriate ways to measure the core outcome domains.

INTRODUCTION

Incontinence-associated dermatitis (IAD) is an irritant contact dermatitis caused by the prolonged and repeated exposures of the skin to urine and/or faeces. It is characterized by erythema and oedema of the perianal and/or genital skin. In some cases, IAD is accompanied by bullae, erosion or secondary cutaneous infection (Gray et al. 2012). Skin surface wetness, chemical and physical irritants trigger inflammation and skin damage (Beeckman et al. 2009, Mugita et al. 2015). Patients with IAD may experience discomfort because of pain, itching, burning or tingling (Van Damme et al. 2015). In addition to these physical complaints, IAD has an impact on the psychological and social functioning such as the loss of independence (Beeckman et al. 2015, Van Damme et al. 2015).

Background

Managing IAD is an important challenge for healthcare professionals. Prevention and treatment of IAD include skin cleansing and the topical application of leave-on products for skin protection and healing (Kottner and Beeckman 2015). A Cochrane review on skin care interventions for managing IAD revealed a substantial heterogeneity of reported outcomes and instruments in IAD research (Beeckman et al. 2016). The lack of comparability between studies about efficacy and (cost-) effectiveness of products and procedures complicates standardization of IAD prevention and treatment. To overcome this challenge, the development and use of a Core Outcome Set (COS) should improve the situation.

A COS is a consensus-derived minimum set of outcomes that should be measured and reported in clinical trials of a specific health condition (Williamson et al. 2017). A COS may also be suitable for use in other types of research and clinical audits (Williamson et al. 2017). It does not limit the researchers to choose additional outcomes and measurements (Schmitt et al. 2014).

Different methodological frameworks are available to guide the development of a COS, such as the Core Outcome Measures in Effectiveness Trials (COMET) Initiative, the Outcome Measures in Rheumatology (OMERACT) group and the Harmonizing Outcomes Measures for Eczema (HOME) roadmap endorsed by the Cochrane Skin Group Core Outcomes Set Initiative (CSG-COUSIN) (Boers et al. 2014b, Schmitt et al. 2014, Williamson et al. 2017). A stepped approach is suggested in all frameworks: first the selection of core outcome domains (‘what’ to measure) and second to determine the measurement instruments (‘how’ to measure). All frameworks emphasize the importance of involving relevant stakeholders throughout the whole process. The involvement of stakeholders increases the number of ideas, establishes credibility and ensures relevance that would not have otherwise been considered (Boers et al. 2014b). The perspective of patients living with the health condition is also considered essential (Williamson et al. 2012b, Young and Bagley 2016).

To date, there is no consensus on which outcomes to measure in clinical effectiveness trials in the field of IAD (Van den Bussche et al. 2017). The use of a COS will contribute to the reduction of outcome reporting bias and it will enhance the comparability of study results worldwide leading to a stronger evidence-base (Kirkham et al. 2013, Williamson et al. 2012a, Williamson et al. 2017). The Core Outcome Set in IAD Research (CONSIDER) project aims to develop a COS in the area of IAD.

THE STUDY

Aim

The aim of this project was to develop a consensus-based set of core outcome domains to be applied in clinical research involving adults with IAD or at risk of IAD, independently from any geographical location or skin colour.

Design

The project consists of four phases: preparation (phase 1), development of a core set of outcome domains (phase 2), development of a core set of outcome measurements (phase 3) and the dissemination and monitoring (phase 4). This article describes phases 1 and 2, using the Core Outcome Set-Standards for Reporting (COS-STAR) statement to enhance reporting quality (Kirkham et al. 2016). Study methods are described in brief as they have been presented in detail previously in the published protocol (Van den Bussche et al. 2017).

The project team (PT) consisting of four people (KV, DD, JK, DB) designed and coordinated the study. An International Steering Committee (ISC) of six experts in the field of dermatology, geriatrics, wound care, trials and nursing (HB, MP, SS, SE, LS, AMD) guided the development of the COS. Four people (TL, NV, SV, AV) provided methodological support during the study conduct.

**Data collection**

This research project was performed between April 2016 - September 2017 in two phases: (1) the generation of the list of outcomes and (2) a three-round Delphi procedure with panellists.

An overview of the COS development process is provided in Figure 1.

*Generation of the list of outcomes*

A list of outcomes was generated based on a systematic literature review (with no date restrictions up to April 2016), consultation with the ISC and interviews with three patients from April 2016 – June 2016. Patients with a present or past experience of IAD and a good cognitive function were recruited via patient associations in Belgium and the Netherlands and the geriatric ward of the Ghent University Hospital. Two patients living at home responded via e-mail to the call disseminated via the patient associations. One patient diagnosed with IAD was considered eligible to participate by the head nurse of the geriatric ward.

A detailed description of the literature review was published previously (Van den Bussche et al. 2017). Four electronic databases, Web of Science, PubMed, CINAHL and the Cochrane Library were systematically searched for relevant papers dating through April 6, 2016. Two reviewers (KV & DD) independently assessed all records obtained, a third reviewer (DB) reviewed if necessary. Data extraction of all primary and secondary endpoints was performed by one author (KV). If the paper did not explicitly mention the outcomes that they measured, then the reviewer inferred these from the given data.

The independent data extraction of 10% of the papers by a second reviewer and subsequent inter-rater agreement calculation was challenging, because of the complexity of reporting in the original papers. The project team discussed outcomes addressing similar concepts and classified these using the OMERACT framework (Boers et al. 2014a). This long list of outcomes was presented to the ISC prior to the Delphi study.

*Delphi procedure*

A list of practitioners and researchers was created by one author (KV) from the included studies in the literature review. Other healthcare providers and researchers were added to this list using additional searches. A deviation from the protocol was the addition of stakeholders from industry and recommended colleagues by participating panellists to increase the size of the panel. The ISC members were invited as panellists as well. The final list of potential panellists was managed by one member of the project team (KV) and remained blinded to all those selected for participation.

A three-round Delphi was conducted. Panellists were invited by email to participate. The online survey was developed and hosted by the CSG-COUSIN. In the first round, the panellists were randomly divided into two groups prior to the invitation to participate. Group 1 rated the importance of the outcome domains on a three-point scale: (1) not important enough to be considered in the COS for IAD, (2) important but not critical to be considered in the COS for IAD and (3) critical, should be included in the COS for IAD. Group 2 rated the importance of the outcome domains on a nine-point scale with descriptors on the ends of the spectrum: from (1) not important for inclusion in COS for IAD, to (9) critical, should be included in COS for IAD. Both groups were given the opportunity to choose the option ‘I can’t rate the importance of the outcome because I don’t know the outcome’, to add feedback or rationale per outcome and to add additional outcomes. The outcome domains were sorted alphabetically to avoid weighting of outcome domains due to the order. Outcome domains rated critical in both groups were included in the second round. In the second round, the nine-point scale was used for all panellists to rate the importance of the outcome domains. In the third and final round, the panellists were asked to approve the remaining outcome domains on a three-point scale: (1) Yes, I approve, (2) Yes, I approve but with minor suggestions and (3) No, I have major concerns.

A variation from the protocol was that only responders were invited to participate in the next round. Consensus was defined as at least 70% of all panellists rating the outcome domains as ‘critical for inclusion in a COS for IAD research’. Descriptive statistics were used to summarize the demographic characteristics and the responses of the panellists for each Delphi round.

After the last roundthe project team discussed the results and made final decisions, taking into account the panellists’ additional comments.

Ethical considerations

Ethical approval was obtained by the Ethics review Committee (April 2016 – B670201628231). Return of a completed questionnaire was taken as consent to participate by the ISC and the panellists. All patients received written information about the theoretical purposes of the study and the way participation will strengthen clinical decision-making, contribute to patient-centered health care and improved IAD research. Oral and written informed consent was obtained from the participating patients. Participants’ information was treated anonymous and confidential.

Data analysis

Demographic data, as well as responses to the questionnaires, were described using frequency distributions. All statistical analyses were performed using SPSS statistical package version 24 (SPSS, Inc., Chicago, IL, USA).

Validity and Reliability

Several aspects supported the validity and reliability of the development process. The members of the project team and the ISC are all outstanding experts in the field of IAD. A protocol has been developed and published a priori (Van den Bussche et al. 2017). Two researchers (KV and DD) screened the literature and extracted the data and a third researcher (DB) was consulted in case of disagreement. The patient perspective was considered using interviews with patients and including all types of possible outcomes into the initial list.

RESULTS

Characteristics of the panellists

A sample of 153 panellists (healthcare providers, researchers and industry) was invited to participate. Fifty-seven of the panellists (37.3%) participated in the first Delphi round, of which 43 (75.4%) participated in the second round and 37 (86.0%) participated also in the third round. A flowchart of the response rates of each round is presented in Figure S1 (see supplementary information). Socio-demographic characteristics, disciplines of expertise and experience of the panellists (presented per group and per round), can be found in Table S1 (see supplementary information).

List of potential core domains

The systematic literature search resulted in 3826 records: 1407 in Web of Science, 1726 in PubMed, 489 in CINAHL and 204 in the Cochrane Library, of which 1190 duplicates were removed. Based on the screening of title and/or abstract, 2018 records were excluded. Based on the screening of the full texts, additional 384 records were excluded. In total, 234 records were relevant for outcome extraction. Hand searches identified ten additional relevant articles. Outcomes were extracted from the final group of 244 articles. The results of the search and screening process are presented in Figure 2. Data extraction from the literature search resulted in 1852 outcomes, the consultation with the experts of the ISC resulted in 56 outcome domains and the three patient interviews resulted in 32 outcome domains. The project team reviewed and refined the outcomes into outcome domains.

The list of potential outcome domains generated by the project team and the ISC included 58 outcome domains. Fifteen were classified into the core area ‘life impact’, three in ‘resource use/economic impact’ and 40 in ‘pathophysiological manifestations’. The list used at the start of the Delphi study is presented in Table S2 (see supplementary information).

Delphi round 1

The first round was performed between 7 April 7 – 7 May 2017. The results are presented in Table 1. Thirteen domains were considered critical for inclusion by at least 70% of the panellists from both groups. The remaining 45 domains did not reach this threshold and were not retained. Several panellists emphasized overlap between the outcome domains, possible problems regarding the potential capacity of patients to give feedback (e.g. due to cognitive or conscious state) and consequently to provide data for some of the outcome domains (e.g. ‘self-reported symptoms’ and ‘pain’) and a potential for further detailed description of outcome domains. No additional outcome domains were collated.

To address these concerns, a proposal was developed for the second round to: (1) merge the outcome domains ‘denudation’ and ‘skin loss’ with ‘erosion’ because of the similarities; (2) include ‘burden of care – patient perspective’ and ‘physical comfort’ in ‘IAD-related Quality of Life’ because of overlap; (3) incorporate symptoms such as ‘burning’ and ‘stinging’ (as part of ‘self-reported symptoms’) in the definition of ‘pain’, resulting in the separate outcome ‘itching’; (4) separate the ‘clinical signs of infection’ from the ‘clinical signs of inflammation’; and to (5) incorporate ‘erythema’ in ‘clinical signs of inflammation’ because of overlap.

In total, nine outcome domains were presented to the panellists in the second round: ‘clinical signs of inflammation’, ‘clinical signs of infection’, ‘cost-effectiveness’, ‘erosion’, ‘IAD-related Quality of Life’, ‘itching’, ‘maceration’, ‘pain’ and ‘patient satisfaction’. Appropriate definitions were searched for these domains and were presented in the second round for rating.

Delphi round 2

The second round was performed between 20 June – 4 July 2017. The results are presented in Table 2. Six domains met the a priori criteria for inclusion. The remaining domains ‘cost-effectiveness’, ‘IAD-related Quality of Life’ and ‘itching’ did not reach the threshold. No additional outcome domains were collated.

Based on the results and the comments of the panellists, it could be concluded that: (1) there was no agreement regarding definitions; (2) the number of ratings of ‘not important’ [1-3] was sometimes very high (even if ≥ 70% of panellists score ‘critical for inclusion’); and (3) there was overlap between some of the domains (e.g. ‘clinical signs of inflammation’ and ‘pain’).

International Steering Committee consultation

The results of the first and second Delphi round were presented to the ISC. The ISC was asked to give input on: (1) the results of the second Delphi round which indicated disagreement regarding the concepts; (2) the proposal to further summarize the concepts to key clinical signs/concepts to avoid overlap; (3) the definitions; and (4) the next potential steps.

Based on the comments of the ISC, the decision was made to include ‘IAD-related Quality of Life’ and to change definitions. All members of the ISC agreed on organizing a third Delphi round. In total, seven outcome domains were presented to the panellists in the third round: ‘erythema’, ‘erosion’, ‘maceration’, ‘IAD-related pain’, ‘major colonization and infection of IAD’, ‘IAD-related Quality of Life’ and ‘patient satisfaction’.

Delphi round 3

The third round was performed between August 28to September 10, 2017. The ratings of the seven outcome domains are presented in Table 3. All outcome domains except ‘Major colonization and infection of IAD’ were approved by at least 70% of the panellists. Some fundamental concerns were raised by the panellists on both ‘major colonization and infection of IAD’ and ‘IAD-related Quality of Life’.

Final decisions

Given the comments and voting behaviour of the panellists, the project team decided to omit the outcome domains ‘major colonization and infection of IAD’ and ‘IAD-related Quality of Life’. This does not imply that these outcome domains were not considered important or relevant, but that the results of the Delphi process did not allow them to be classified as ‘critical’. Based on the results of the three-round Delphi study and consultation of the ISC, the project team agreed on the following final core set of five outcome domains as follows: ‘erythema’, ‘erosion’, ‘maceration’, ‘IAD-related pain’ and ‘patient satisfaction’.

DISCUSSION

The purpose of this study was to develop a consensus-based core set of outcome domains to be applied in clinical research involving adults with IAD or at risk, independently from any geographical location or skin colour. The final COS for IAD in adults comprises five domains: ‘erythema’, ‘maceration’, ‘erosion’, ‘IAD-related pain’ and ‘patient satisfaction’.

The outcome domains ‘erythema’, ‘maceration’ and ‘erosion’ are clinical signs and symptoms and reached the highest level of consensus in this study. They are critical elements of the clinical picture of IAD and are often included in IAD definitions (Gray et al. 2012, Mugita et al. 2015). Our results indicate that these signs are critical domains to be captured in all clinical studies in this area.

‘IAD-related pain’ and ‘patient satisfaction’ reached a high level of consensus for inclusion in this core domain set. Both outcome domains comprise several components. Pain for this COS refers to the magnitude, the frequency and the quality of pain. ‘Patient satisfaction’ refers to the degree to which the individual regards the intervention or the procedure where it is delivered as useful, effective, or beneficial. As indicated by the panellists, it is important for the choice of instruments to consider the capacity of patients to provide feedback (e.g. due to cognitive or conscious state). However, it will not always be possible to provide data for some of these outcome domains (Patrick et al. 2008). Several patient symptoms such as pain and burning, are included in several IAD assessment instruments, but no data were found for the domain ‘pain due to IAD’ in the (quasi-)RCTs included in a recent Cochrane review on interventions related to IAD prevention and treatment (Beeckman et al. 2016).

From a COS perspective, the five identified domains are proposed as core concepts for ‘what’ to measure as outcomes in clinical IAD trials. The current results do not provide evidence ‘how’ best to measure the five identified domains. This will be subject to future research.

The following outcome domains were considered important but not critical for inclusion and were therefore omitted: ‘cost-effectiveness’, ‘IAD-related Quality of Life’ and ‘major colonization and infection’. ‘Cost-effectiveness’ was excluded from the COS since not reaching the 70% threshold in the third and final Delphi round.

Although OMERACT recommends the inclusion in a COS of at least one outcome reflecting each core area, such as ‘resource use/economic impact’, empirical evidence is emerging that this is not always considered appropriate (Chiarotto et al. 2015, Williamson et al. 2017). Currently, little is known about the economic impact of IAD (Gray et al. 2007).

The outcome domain ‘major colonization and infection’ proved to be important throughout the entire Delphi process but no agreement regarding the description of that domain was obtained. Several panellists remarked that ‘clinical signs of infection’ are not necessarily always associated with IAD and therefore not critical. The signs in the definition were considered too general to allow an accurate diagnosis at the bedside. Since it is difficult to diagnose wound infection based on clinical observation, a (semi-)quantitative swab or other diagnostic tests should be considered (Cefalu et al. 2017, Institute 2016). However, this technique is time-consuming, expensive and often highly false-positive (Bowler et al. 2001). ‘IAD-related Quality of Life’ incorporated ‘burden of care – patient perspective’ and ‘physical comfort’ after the first Delphi round. Although considered important throughout the Delphi process, several panellists underlined that ‘Quality of Life’ could be highly influenced by other factors unrelated to an intervention, such as co-morbid conditions, the inability of some patient groups to rate this outcome and the lack of current measurement instruments.

Our results do not mean that the excluded outcome domains are not important or relevant in clinical IAD trials. However, a COS represents a minimum number of critical outcomes to be measured and reported in all trials in a specific area. Trialists can select additional outcomes if deemed relevant (Schmitt et al. 2014).

Strengths and limitations

This is the first study conducted to obtain international and multidisciplinary consensus on core outcome domains to be reported in IAD clinical trials. Guided by the initiatives like COMET, OMERACT and the HOME roadmap endorsed by CSG-COUSIN, a literature review, expert and patient consultation and an international, multidisciplinary Delphi procedure were conducted (Boers et al. 2014b, Schmitt et al. 2014, Williamson et al. 2017). A study protocol was published a priori and the COS-STAR statement was used to ensure a high standard of reporting (Kirkham et al. 2016, Van den Bussche et al. 2017). Another strength is the comprehensive list of outcomes initially obtained through an extensive search strategy, patient and expert interviews. This study also included opinions of several stakeholder groups (healthcare providers, researchers, industry) from around the international arena. Europe was represented most frequently (64.9% of panellists from 11 countries), followed by USA (22.8% of panellists from two countries). The input of different stakeholders from different cultures increases the generalizability and applicability of this COS (Boers et al. 2014a).

This study had several limitations. The search for patients was difficult due to the acute nature of the condition in often care-dependent elderly and ICU patients. The inclusion of only three patients may limit the patients’ perspective on the search for outcomes. Patients were interviewed to contribute to the COS development, but they were not included in the subsequent Delphi rounds. Although patient views were considered, they were not included as research partners (Gargon et al. 2017). This could have influenced the prioritization of the outcome domains and the exclusion of ‘IAD-related Quality of Life’. However, this outcome domain was not mentioned by the patients during the interviews.

Methodological guidance for COS development is available but several details are unclear (Sinha et al. 2011, Williamson et al. 2017, Williamson et al. 2012b). For instance, there is no reference standard for data extraction such as the level of abstraction. Since the independent data extraction by two reviewers was not performed, it is possible that some outcome domains were not identified. There is also no reference standard for conducting Delphi methods and for consensus definitions (Brookes et al. 2016, Diamond et al. 2014). Currently, the nine-point scale is most often used in COS studies to measure agreement between Delphi study participants. The decision rules, often based on cut-offs, during the Delphi rounds are currently being questioned (Kottner et al. 2017). The use of strict thresholds to decide whether COS domains are kept or left out are considered arbitrary (Thorlacius et al. 2017). The usefulness of this procedure can be questioned as it is recommended to use the full range of information from rating scales otherwise they are not needed in that specific format (Beckstead 2014, Streiner et al. 2015). Driven by this methodological uncertainty, we decided to use two different scoring systems (a three-point and a nine-point scale) in the first Delphi to allow methodological reflection. This was a deviation from the protocol.

Given the extent of the long list of 58 outcome domains, the project team decided to present only the outcome domains with 70% agreement (category ‘critical for inclusion’) instead of re-scoring all outcome domains that did not reach that threshold. For the same reason, only feedback on the general findings was provided. Although we included panellists from around the international arena, responses were not distributed equally [Asia (1.8%), Australia (7%) and Africa (3.5%)]. The decision not to include a consensus meeting in the COS development was a pragmatic one. Although several COS development studies hold a final consensus meeting, evidence on the design and results of a face-to-face meeting is lacking (Williamson et al. 2017).

CONCLUSION

The COS for IAD in adults consists of the following outcome domains: ‘erythema’, ‘maceration’, ‘erosion’, ‘IAD-related pain’ and ‘patient satisfaction’. It is recommended that all trials and non-randomised studies in this area should use these domains with the aim of improving transparency and to enhance comparability. Therefore, we recommend researchers to use this COS when preparing a new clinical trial. The next step will be to develop a core set of measurement instruments to be used to measure these outcome domains in adults with IAD or at risk, independently from any geographical location or skin colour. The selection of instruments will focus on those that have demonstrated adequate measurement properties for these domains with the least applicant and participant burden.

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