Towards an international language for incontinence-associated dermatitis (IAD)

design and evaluation of psychometric properties of the Ghent Global IAD Categorization Tool (GLOBIAD) in 30 countries

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Towards an international language for Incontinence-Associated Dermatitis (IAD): design and evaluation of psychometric properties of the Ghent Global IAD Categorisation Tool (GLOBIAD) in 30 countries

Running head GLOBIAD: design and evaluation of psychometric properties

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What's already known about this topic?

- Incontinence-associated dermatitis (IAD) is an irritant contact dermatitis in incontinent adults.
- Ten IAD severity categorisation instruments were developed of which some were found to be time-consuming and (linguistically) complex for use in clinical practice.
- A universal IAD classification system is needed to guide practice, inform educational platforms, and support research.

What does this study add?

- The GLOBIAD is based on input from international experts and was psychometrically tested by 823 health professionals from 30 countries.
- Accuracy of the diagnosis erythema versus skin loss was high when IAD is classified based on images.
- Identifying clinical signs of infection is prone to error.

Summary

Background Incontinence-associated dermatitis (IAD) is a specific type of irritant contact dermatitis with different levels of severity. An internationally accepted instrument to assess the severity of IAD in adults with established diagnostic accuracy, agreement, and reliability is needed to support clinical practice and research.

Objectives To design and psychometrically evaluate the Ghent Global IAD Categorisation Tool (GLOBIAD).

Methods The design was based on expert consultation using a three-round Delphi procedure with 34 experts from 13 countries. The instrument was tested using IAD photographs reflecting different severity levels in a sample of 823 health professionals in 30 countries. Measures for diagnostic accuracy (sensitivity and specificity), agreement, inter-rater reliability (multi-rater Fleiss kappa), and intra-rater reliability (Cohen's Kappa) were assessed.

Results The GLOBIAD consists of two categories according to the presence of persistent redness (Cat.1) and skin loss (Cat.2), both subdivided based on the presence of clinical signs of infection. The agreement for differentiating between Cat.1 and Cat.2 was 0.86 [95% confidence interval (CI) 0.86-

0.87], with a sensitivity of 90% and a specificity of 84%. The overall agreement was 0.55 (95%CI 0.55-0.56). The Fleiss Kappa for differentiating between Cat.1 and Cat.2 was 0.65 (95%CI 0.65-0.65). The overall Fleiss Kappa was 0.41 (95%CI 0.41-0.41). The Cohen's Kappa for differentiating between Cat.1 and Cat.2 was 0.76 (95%CI 0.75-0.77). The overall Cohen's Kappa was 0.61 (95%CI 0.59-0.62).

Conclusions The development of the GLOBIAD is a major step forward towards a better systematic assessment of IAD in clinical practice and research worldwide. Further validation is however needed.

INTRODUCTION

The prevention and treatment of diaper dermatitis in babies and small infants has been recognised for decades as a topic of dermatological research and practice[1]. This cutaneous problem not only occurs in paediatric patients but is also common in adults that is widely accepted as incontinence-associated dermatitis (IAD)[2]. IAD is a specific type of irritant contact dermatitis caused by prolonged contact of the skin to urine or faeces, and characterised by erythema and oedema of the perianal or genital skin. In some cases, the clinical picture is accompanied by bullae, erosion or secondary cutaneous infection[3]. The aetiology of IAD is complex and multifactorial[4]. Excessive skin surface moisture resulting in skin maceration, chemical and physical irritation increases the skin surface pH and enhances the permeability of the skin compromising the skin barrier function[5]. Therefore, the skin is more permeable to irritants and pathogens[6]. The most common microorganisms associated with IAD are *Escherichia coli* and *Clostridium difficile* from the gastrointestinal tract, *Candida albicans, Pseudomonas aeruginosa*, and *Staphylococcus aureus* from the perineal skin[3-5,7].

The epidemiology of IAD varies across different countries, health care settings and patient populations. The prevalence of IAD is estimated between 5.7 and 27% with the highest in acute care settings, and the incidence of IAD between 3.4 and 50%[3,8]. While certain patient populations may be more vulnerable to IAD, wide variations in the prevalence of IAD could be explained by the lack of internationally agreed diagnostic criteria to differentiate IAD from other skin conditions such as superficial pressure ulcers[9]. In line with the National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP) pressure ulcer classification system, the systematic assessment of IAD using a valid and reliable international classification tool is recommened[9].

A recent Cochrane review revealed a substantial heterogeneity of reported outcomes and instruments in IAD research[10]. To date, ten IAD-related instruments have been developed[11-20] of which three were developed for IAD risk assessment[14,19,20], nine for describing the severity of IAD[11-13,15-20], and two instruments for the classification and treatment of IAD[18,19]. Five instruments propose global assessment and categorise IAD as mild, moderate or severe[13,15-20], whereas the others use a

(cumulative) scoring system to delineate the severity or risk on a continuum or dimension[11,13-16]. Four instruments assess patient-specific symptoms such as pain and burning[11,12,19,20]. An ideal instrument should measure IAD consistently and accurately[21]. Content validity was only assessed in four instruments using experts [14-16,20]. Psychometric properties of five instruments were tested through the assessment of patients[14,22] or photographs[15,16,23]. In addition, several instruments[11,13,17] were found to be time-consuming and complex for use in clinical practice[24].

Therefore, in 2015 an international expert panel proposed a simplified IAD severity categorisation tool[25]. It included three categories: no redness and skin intact (at risk, category 0), red but skin intact (category 1), and red with skin breakdown (signs can include vesicles, denudation and/or skin infection) (category 2)[25]. However, this classification was not developed in a formal way and its psychometric properties have not been tested. The aim of this study was to further develop this tool and to evaluate its psychometric properties.

METHODS

A two-phase psychometric instrument development and validation study was conducted. Phase 1 included the design and content validation, phase 2 included the evaluation of the psychometric properties of the instrument.

Phase 1. Instrument design and content validation

The initial version of the simplified tool was used for content validation. To achieve consensus on the content validity of the tool, the Delphi method was used to allow a panel of experts to provide feedback on the tool and present arguments in order to justify their viewpoints. The panel consisted of 34 experts from different fields of IAD expertise (clinical n=17; research n=21; education n=11) from Australia (n=2), Austria (n=4), Belgium (n=4), Czech Republic (n=1), France (n=1), Germany (n=1), Norway (n=1), Italy (n=2), South Africa (n=1), Spain (n=13), Turkey (n=1), United Kingdom (UK; n=2), and the United States (US; n=1). In the first round, the expert panel was invited by e-mail including the link to an online survey (software package LimeSurvey®). The experts were asked if they agree with and had any comments on the proposed purpose, the structure (e.g. number of items), and the categories of the tool. Next, the experts were asked if they had any comments concerning the definitions and the proposed diagnostic criteria of the three categories and if they had any additional comments. After the first round, the results were summarised and presented to the participants. In the second and third rounds, the participants were asked if they agreed with and had any comments on the revised tool.

Phase 2. Evaluation of psychometric properties

The aim was to examine diagnostic accuracy, inter-rater and intra-rater reliability and agreement of the instrument. Thirty-four photographs were selected by two experts in IAD diagnostics, who have extensive expertise in research and clinical practice (DB & SS). An online survey was developed (software package LimeSurvey®) and translated into 14 languages of the 30 participating countries by native speakers with extensive content expertise. Back-translation was not performed. The survey included information on the procedure and confidentiality, demographic questions, the tool, and the photographs. Diagnostic accuracy was measured by comparing the ratings of the participants with those of the two experts (reference standard). Inter-rater reliability and agreement was examined within the ratings of the participants. Intra-rater reliability and agreement with one week interval between ratings was examined for all participants.

Participants

An online survey was set-up between January and March 2017 in a convenience sample of health professionals. Participants were recruited in Australia, Austria, Belgium, Canada, Croatia, Czech Republic, Denmark, France, Germany, Hungary, Italy, Norway, Portugal, Saudi Arabia, Slovakia, Spain, the Netherlands, Turkey, UK, and the US. The call to participate, including the link to the online survey, was sent by e-mail to the EPUAP, NPUAP, the European Wound Management Association, the Pan Pacific Pressure Injury Alliance (representing Wounds Australia, New Zealand Wound Care Society, Hong Kong Enterostomal Therapist Society, and Wound Healing Society Singapore), the Wound, Ostomy and Continence Nurses Society, Wounds Canada, the Canadian Association for Enterostomal Therapy, and the Wound Healing Association of Southern Africa. The wound care organisations disseminated the call by publishing on their website or e-mailing to members.

Photographs

Thirty-four photographs of IAD were selected and categorised by two experts in IAD diagnostics (Table S1; see Supporting Information). This set of photographs included two photographs from patients with a darkly pigmented skin. The sample size calculation was performed in the statistical software package R[26] using the function CI4Cats in the kappaSize R-library (version 1.1)[27,28] to determine the number of photographs needed to study the inter-rater reliability with four outcome categories. The confidence interval (CI) approach was used to estimate the sample size for kappa calculation (κ). A minimum of 33 photographs was required, based on an anticipated value of κ of 0.8 (based on previous research[29]), an expected lower bound for a one-sided 95% CI of 0.7, and the prevalence rates per category (cat. 1A=25%, cat. 1B=15%, cat. 2A=30%, cat. 2B=30% – the estimated prevalence in daily practice).

Ethical considerations

The procedure was approved by the ethics committee of Ghent University Hospital (B670201627633). All participants received full information before the start of the study. In the questionnaires, the purpose and procedure were fully explained, and anonymity and confidentiality were assured. Return of a completed questionnaire was taken as consent to participate.

Data analysis

Diagnostic accuracy, agreement and reliability were calculated. The primary outcome measure was the four category classification of the 34 photographs according to the Ghent Global IAD Categorisation tool (GLOBIAD) based on persistent redness, skin loss and clinical signs of infection. As secondary outcome measures, two binary measures are considered: first, the classification for persistent redness or skin loss, second, the classification for with or without clinical signs of infection.

Summary measures of overall and specific agreement for all levels of the outcome measures were calculated. The summary measures were the estimated mean with 95% CI, the estimated median value and the interquartile range (IQR), and the $2{,}5^{th}$ and $97{,}5^{th}$ percentile of the characteristic, based on the evaluations of the individual raters to the reference standard. The diagnostic accuracy for secondary outcome measures were assessed by summary measures for sensitivity and specificity of each rater to the reference standard.

The inter-rater reliability and agreement among raters was assessed by Fleiss kappa for multiple raters[30]. The scores of the reference standard were not included in the multi-rater Fleiss kappa. The intra-rater reliability and agreement were examined by comparing the first and second rating of the same photographs for participants who participated twice within one week. No feedback was provided between the test and re-rest. The photographs were presented in a random order to reduce potential bias. Summary measures of Cohen's kappa, overall and specific agreement for all levels of the outcome measures were calculated for each individual rater.

The criteria for the κ coefficient by Landis & Koch were used to interpret the results (<0.00=Poor, 0.00–0.2=Slight, 0.21–0.40=Fair, 0.41–0.60=Moderate, 0.61–0.80=Substantial, and 0.81–0.99=Almost perfect)[31]. All measures were calculated in R, version 3.4.1[26]. The concordance function in the R-library raters, version 2.0.1, was used to obtain Fleiss kappa and 95% CIs, and the kappa2 function in the irr (inter-rater reliability and agreement) R-library, version 0.84, for the Cohen's kappa.

RESULTS

Instrument design and content validation

The tool that emerged after the third Delphi round can be found in Figure S1 (see Supporting Information). An overview of the instrument design process is presented in Figure 1.

A first point of discussion was the purpose of the instrument. Several experts emphasised the need for a simplified and clear tool to classify IAD. The two-fold purpose of the instrument was approved after the second Delphi round. During the Delphi procedure, different items were added to the categories (such as a range of clinical signs of infection). A number of items were incorporated in a glossary of terms to enhance clarity. These terms were defined according to the terminology of the International League of Dermatological Societies and approved in the third Delphi round[32]. The addition of pain, as one of the signs of inflammation, and other patient symptoms emerged as very important for the experts to be included in each category. A final point of discussion was the in- or exclusion of category 0 describing patients with intact skin but at risk. After the second Delphi round, it was decided to delete category 0 to be in line with the existing disease classifications in medicine. The absence of a condition is rarely classified and would cause difficulties during psychometric evaluation. The GLOBIAD consists of two main categories: (1) persistent redness and (2) skin loss. Each category is subdivided into IAD (A) without and (B) with clinical signs of infection. Next to these critical criteria, additional criteria are given. Each category is visualised with characteristic images. Category 1A is displayed in Figure 2.

General characteristics of the participants

A total of 823 participants (84.6% female) completed the first step and 463 completed the second step (Table 1). More detailed information about the country of work of the participants can be found in Table S1 (see Supporting Information).

Diagnostic accuracy and agreement

The diagnostic accuracy and agreement between participants and the reference standard is presented in Table 2. The average overall agreement ranged from 0.55 (95% CI 0.55-0.56) for all categories to 0.64 (95% CI 0.64-0.65) for differentiating between categories A and B, to 0.86 (95% CI 0.86-0.87) for differentiating between categories 1 and 2. The lowest mean specific agreement was found for categories 1B and 2B (respectively 0.47 (95% CI 0.45-0.48) and 0.47 (95% CI 0.46-0.48)). The highest mean specific agreement was found for category 1A (0.72; 95% CI 0.71-0.73). A mean sensitivity of 90% (95% CI 0.89-0.91) and a mean specificity of 84% (95% CI 0.83-0.85) was found for categorising 1 and 2. Sensitivity and specificity categorising A and B was much lower. A higher overall agreement was found in participants who described themselves as expert, ranging from 0.61 for all categories to 0.70 for differentiating between categories A and B, to 0.88 for differentiating categories 1 from 2.

Inter- and intra-rater reliability

The Fleiss Kappa ranged between 0.32 (95% CI 0.32-0.32) for distinguishing categories A and B, 0.41 (95% CI 0.41-0.41) for all categories, and 0.65 (95% CI 0.65-0.65) for categories 1 and 2 (Table 3).

Higher Fleiss Kappa coefficients were found in more experienced and more educated clinicians. Thirty-four photographs were re-assessed by 463 participants with an average time interval of 14 (SD 8.12) days (Table 4). The average overall intra-rater agreement was 0.71 (95% CI 0.70-0.72), and the mean kappa assessing intra-rater reliability was 0.61 (95% CI 0.59-0.62). The intra-rater agreement for differentiating between categories 1 and 2 was 0.88 (95% CI 0.88-0.89) and for the intra-rater reliability, the mean kappa was 0.76 (95% CI 0.75-0.77). Intra-rater agreement and reliability was lower for differentiating between categories A and B.

DISCUSSION

IAD is highly prevalent among individuals with urinary and/or faecal incontinence[3]. The heterogeneity of reported outcomes and instruments point towards a need for standardised classification[10]. The aim of this study was the design and evaluation of the psychometric properties of the GLOBIAD with the input from a group of international experts and clinicians to create an internationally agreed description of IAD, and to standardise the documentation for clinical practice and research.

Content and face validity of the GLOBIAD were supported by international expert review and input. The key diagnostic criteria for IAD are persistent redness, skin loss, and clinical signs of infection. The agreement among experts after Delphi process was 100%. IAD is classified as persistent redness or skin loss, two of the most distinguishing features of IAD according to the opinions of 34 international experts. The clinical presentation of skin loss and erythema could be explained by the underlying pathophysiology of IAD[3-5]. The presence of erythema and skin loss is also consistently reflected in all available IAD assessment tools[11-20]. The assessment of clinical signs of infection was considered important and clinically relevant by the experts when categorising IAD due to the choice of intervention. This is in line with the high prevalence of cutaneous infections (between 19 and 63%)[6,7,33-35]. Finally, the aim of the tool does not include risk assessment therefore category 0 was deleted.

In this study, diagnostic accuracy and reliability of GLOBIAD were examined in an international sample of 823 health professionals. Sensitivity and specificity estimates indicate a high degree of diagnostic accuracy for distinguishing between intact but erythematous skin and skin loss when health professionals apply this tool based on the presented images. Diagnostic accuracy of assessing clinical signs of infection seemed to be more difficult. Local signs indicating an infection include erythema, warmth, swelling, purulent exudate, and pain[36] of which some cannot be assessed on photographs. Since it is difficult to diagnose wound infection based on clinical observation alone, a (semi-)quantitative swab of the wound could be considered[36,37]. However, this technique is time-consuming, expensive, and of limited accuracy[38]. Correct and early detection of clinical signs of infection by the

health professional is crucial in the management of IAD[38,39]. Inadequate treatment can cause delayed wound healing, prolonged hospitalisation, and an increase in costs[40].

Results of the inter-rater reliability estimates can be interpreted in a similar direction. Participants were more able to distinguish between intact and eroded skin compared to identifying signs of infection. For content validity reasons, it was decided to include the clinical signs of infection in the final tool. Intra-rater reliability and agreement across all four categories was 'substantial' according to the proposed interpretation by Landis and Koch. However, they might be too low to be used for individual clinical decision making as one may expect an almost perfect agreement when diagnosing the severity of IAD[41].

The strengths of the study was the sound content and face validation by a large group of international stakeholders which will facilitate and contribute to the global dissemination of the tool. This study had limitations. The use of photographs provides a two-dimensional perspective only and important clinical signs of infection like warmth, swelling, pain, and itching were not detectable. Further validation in clinical practice (including patients affected by IAD) and other methods for validity testing are required. In addition, it is also well-known that the 'base rate' (Table S1; see Supporting Information) influences the reliability estimates[41]. Because the number of images with clinical signs of infection were lower (based on an estimated prevalence in clinical practice), sensitivity and specificity, and reliability may have been affected. In addition, there were only two images of darkly pigmented skin. This may limit the applicability of the results to all skin phototypes. Translations were done by native speakers with extensive content experience in the field of IAD but back-translation was not performed[42].

IAD as well as pressure ulcers are frequently classified incorrectly[9,29,43]. In this study, a higher inter-rater agreement and reliability were found in more experienced and higher educated clinicians. Correct classification of IAD requires a profound knowledge and clear understanding of the pathophysiology, signs and symptoms[43]. Correct scoring and the reliability of IAD assessment will enhance when sufficient and adequate education and training is provided[43]. The GLOBIAD was developed as a simple, easy and time-saving instrument that can easily be implemented by educators[24]. More research is needed to evaluate the reliability of GLOBIAD and to find out whether better classification skills would improve IAD prevention and treatment.

In conclusion, the development of GLOBIAD is a major step towards a better systematic assessment of IAD in clinical practice and research worldwide. The use of a valid and reliable IAD categorisation tool improves clinical decision making and research in IAD. The GLOBIAD is available in 14 languages. Based on the current results it is recommend to put major weight on the categories 1 and 2.

Clinical signs of infection contain too much measurement error. We would expect differentiation between infected and not infected improved with education. Future research will need to show that.

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References

1 Blume- Peytavi U, Hauser M, Lünnemann L *et al.* Prevention of diaper dermatitis in infants—A literature review. *Pediatric dermatology* 2014; **31**: 413-29.

2 Gray M, Bliss DZ, Doughty DB *et al.* Incontinence- associated Dermatitis: A Consensus. *Journal of Wound Ostomy & Continence Nursing* 2007; **34**: 45-54.

3 Gray M, Beeckman D, Bliss DZ *et al.* Incontinence-associated dermatitis: a comprehensive review and update. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2012; **39**: 61-74.

4 Beeckman, Schoonhoven, Verhaeghe *et al.* Prevention and treatment of incontinence-associated dermatitis: literature review. *Journal of advanced nursing* 2009; **65**: 1141-54.

5 Mugita Y, Minematsu T, Huang L *et al.* Histopathology of incontinence-associated skin lesions: inner tissue damage due to invasion of proteolytic enzymes and bacteria in macerated rat skin. *PloS one* 2015; **10**: e0138117.

6 Foureur N, Vanzo B, Meaume S *et al.* Prospective aetiological study of diaper dermatitis in the elderly. *British Journal of Dermatology* 2006; **155**: 941-6.

7 Campbell JL, Coyer FM, Mudge AM *et al.* Candida albicans colonisation, continence status and incontinence- associated dermatitis in the acute care setting: a pilot study. *International wound journal* 2017; **14**: 488-95.

8 Van Damme N, Van den Bussche K, De Meyer D *et al.* Independent risk factors for the development of skin erosion due to incontinence (incontinence- associated dermatitis category 2) in nursing home residents: results from a multivariate binary regression analysis. *International wound journal* 2017; **14**: 801-10.

9 Beeckman D, Schoonhoven L, Fletcher J *et al.* EPUAP classification system for pressure ulcers: European reliability study. *Journal of advanced nursing* 2007; **60**: 682-91.

10 Beeckman D, Van Damme N, Schoonhoven L *et al.* Interventions for preventing and treating incontinence- associated dermatitis in adults. *The Cochrane Library* 2016.

11 Brown D. Perineal dermatitis: can we measure it? *Ostomy/wound management* 1993; **39**: 28.

12 Long MA, Reed LA, Dunning K *et al.* Incontinence-associated dermatitis in a long-term acute care facility. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2012; **39**: 318-27.

13 Lutz JB, Leighton B, Kennedy K. Comparison of the efficacy and cost-effectiveness of three skin protectants in the management of incontinent dermatitis. In: *Proceedings of the European Conference on Advances in Wound Management*. 1996.

14 Nix DH. Validity and reliability of the Perineal Assessment Tool. *Ostomy/wound management* 2002; **48**: 43-6, 8-9.

15 Borchert K, Bliss DZ, Savik K *et al.* The incontinence-associated dermatitis and its severity instrument: development and validation. *Journal of Wound Ostomy & Continence Nursing* 2010; **37**: 527-35.

16 Bliss DZ, Hurlow J, Cefalu J *et al.* Refinement of an Instrument for Assessing Incontinent-Associated Dermatitis and Its Severity for Use With Darker-Toned Skin. *Journal of Wound Ostomy & Continence Nursing* 2014; **41**: 365-70.
17 Clarke-O'Neill S, Farbrot A, Lagerstedt M-L *et al.* An exploratory study of skin problems experienced by UK nursing home residents using different pad designs. *Journal of Wound Ostomy & Continence Nursing* 2015; **42**: 621-31.
18 Scotland NAoTVN. Skin Excoriation Tool for Incontinent Patients. In. Edinburgh: NHS Quality Improvement Scotland. 2008.
19 Junkin J, Selekof JL. Beyond "diaper rash": Incontinence- associated dermatitis: Does it have you seeing RED? *Nursing2016* 2008; **38**: 56hn1-hn10.
20 Steininger A, Jukic-Puntigam M, Urban W *et al.* Eine Delphi-Studie zur Inhaltsvaliditätsprüfung des deutschen Inkontinenz-assoziierten Dermatitis Interventions Tools (IADIT-D). *Pflegewissenschaft* 2012; **12**: 85-92.
21 Streiner DL, Kottner J. Recommendations for reporting the results of studies of instrument and scale development and testing. *Journal of advanced nursing* 2014; **70**: 1970-9.
22 Braunschmidt B, Muller G, Jukic-Puntigam M *et al.* The Inter-Rater Reliability of the Incontinence-Associated Dermatitis Intervention Tool-D (IADIT-D) Between Two Independent Registered Nurses of Nursing Home Residents in Long-Term Care Facilities. *Journal of Nursing Measurement* 2013; **21**: 284-95.
23 Beeckman D, Verhaeghe S, Defloor T *et al.* A 3-in-1 Perineal Care Washcloth Impregnated With Dimethicone 3% Versus Water and pH Neutral Soap to Prevent and Treat Incontinence-Associated Dermatitis: A Randomized, Controlled Clinical Trial. *Journal of wound, ostomy, and continence nursing* 2011; **38**: 627-34.
24 Clarke-O'Neill S, Farbrot A, Eidrup M-LL *et al.* Is it Feasible to Use Incontinence-Associated Dermatitis Assessment Tools in Routine Clinical Practice in the Long-term Care Setting? *Journal of Wound Ostomy & Continence Nursing* 2015; **42**: 379-88.
25 Beeckman D, Campbell J, Campbell K *et al.* Proceedings of the Global IAD Expert Panel. Incontinence-associated dermatitis: moving prevention forward. In, Vol. 2015: Wounds International. 2015.
26 R CT. R: A language and environment for statistical computing. In. Vienna, Austria. 2017.
27 Rotondi MA, Donner A. A confidence interval approach to sample size estimation for interobserver agreement studies with multiple raters and outcomes. *Journal of clinical epidemiology* 2012; **65**: 778-84.
28 Rotondi MA. Package 'kappaSize'. *URL http://cran.r-project.org/web/packages/kappaSize/kappaSize.pdf* 2013.
29 Defloor T, Schoonhoven L. Inter- rater reliability of the EPUAP pressure ulcer classification system using photographs. *Journal of clinical nursing* 2004; **13**: 952-9.
30 Fleiss JL. Measuring nominal scale agreement among many raters. *Psychological bulletin* 1971; **76**: 378.
31 Landis JR, Koch GG. The measurement of observer agreement for categorical data. *biometrics* 1977: 159-74.
32 Nast A, Griffiths C, Hay R *et al.* The 2016 International League of Dermatological Societies' revised glossary for the description of cutaneous lesions. *British Journal of Dermatology* 2016; **174**: 1351-8.
33 Junkin J, Selekof JL. Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society / WOCN* 2007; **34**: 260-9.
34 Campbell JL, Coyer FM, Osborne SR. Incontinence- associated dermatitis: a cross- sectional prevalence study in the Australian acute care hospital setting. *International wound journal* 2016; **13**: 403-11.
35 Black JM, Gray M, Bliss DZ *et al.* MASD part 2: incontinence-associated dermatitis and intertriginous dermatitis: a consensus. *Journal of Wound Ostomy & Continence Nursing* 2011; **38**: 359-70.
36 Schultz GS, Sibbald RG, Falanga V *et al.* Wound bed preparation: a systematic approach to wound management. *Wound repair and regeneration* 2003; **11**: S1-S28.

37 Cefalu JE, Barrier KM, Davis AH. Wound Infections in Critical Care. *Critical Care Nursing Clinics of North America* 2017; **29**: 81-96.
38 Bowler P, Duerden B, Armstrong DG. Wound microbiology and associated approaches to wound management. *Clinical microbiology reviews* 2001; **14**: 244-69.
39 Posnett J, Gottrup F, Lundgren H *et al.* The resource impact of wounds on health-care providers in Europe. *Journal of wound care* 2009; **18**: 154-61.
40 Sen CK, Gordillo GM, Roy S *et al.* Human skin wounds: a major and snowballing threat to public health and the economy. *Wound Repair and Regeneration* 2009; **17**: 763-71.
41 Kottner J, Audigé L, Brorson S *et al.* Guidelines for reporting reliability and agreement studies (GRRAS) were proposed. *International journal of nursing studies* 2011; **48**: 661-71.
42 Maneesriwongul W, Dixon JK. Instrument translation process: a methods review. *Journal of advanced nursing* 2004; **48**: 175-86.
43 Beeckman D, Schoonhoven L, Fletcher J *et al.* Pressure ulcers and incontinence-associated dermatitis: effectiveness of the Pressure Ulcer Classification education tool on classification by nurses. *Quality & Safety in Health Care* 2010; **19**: e3.1-e3.4.

SUPPORTING INFORMATION

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

Table S1. Classification of the photographs based on the assessment of two experts

Table S2. Supplementary characteristics of the participants

Figure S1. The Ghent Global IAD Categorisation Tool (GLOBIAD)

FIGURE LEGENDS

Fig 1. Process of design and evaluation of psychometric properties

Fig 2. Category 1A. Persistent redness without clinical signs of infection

Table 1. Characteristics of the participants

	Step 1		Step 2	
n	823		463	
	n	%	n	%
Gender				
Female	696	84.6	383	82.7
Age				
Mean (SD) in years	40.9	12.0	43.0	11.4
Role				
Student Nurse	63	7.7	28	6.0
Nurse assistant	53	6.4	15	3.2
Nurse	327	39.7	172	37.1
Head nurse	25	3.0	15	3.2
Nurse specialist	264	32.1	175	37.8
Educator	37	4.5	22	4.8
Researcher	15	1.8	12	2.6
Other	33	4.0	19	4.1
Missing	5	0.7	5	1.1
Education				
Undergraduate	228	27.7	117	25.3
Bachelor's degree	381	46.3	207	44.7
Master's degree	166	20.2	10	23.5
Doctoral degree	39	4.7	25	5.4
Other / unknown	9	1.1	5	1.1
Expertise in IAD [a]				
Novice	117	14.2	55	11.9
Advanced Beginner	147	17.9	61	13.2
Competent	231	28.1	136	29.4
Proficient	180	21.9	114	24.6
Expert	148	18.0	97	21.0
Wound care module [b]				
Completed	368	44.7	227	49
Language [d]				
Arabic	5	0.6	0	0.0
Croatian	14	1.7	9	1.9
Czech	82	10.0	55	11.9
Danish / Norwegian	29	3.5	18	3.9
Dutch	170	20.7	114	24.6
English	159	19.3	77	16.6
French	12	1.5	8	1.7
German	87	10.6	61	13.2
Hungarian	21	2.6	9	1.9
Italian	12	1.5	5	1.1
Portuguese	30	3.7	17	3.7
Slovak	69	8.4	22	4.8
Spanish	74	9.0	43	9.3
Turkish	59	7.2	25	5.4

[a] Expertise in relation to the assessment and management of IAD (based on the levels of proficiency defined by Patricia Benner). [b] Completion of a recognized wound care module. [c] Estimated number of observed IAD in practice (average a week). [d] Language in which the GLOBIAD and the online survey were translated.

Table 2. Diagnostic accuracy and agreement with reference standard – 823 raters

	mean (95% CI)	median (IQR)	2.5th and 97.5th percentile
Cat. 1A vs 1B vs 2A vs 2B			
p_o [a]	0.55 (0.55-0.56)	0.56 (0.47-0.62)	0.35-0.74
$p_{cat.1A}$ [b]	0.72 (0.71-0.73)	0.73 (0.67-0.78)	0.49-0.89
$p_{cat.1B}$ [b]	0.47 (0.45-0.48)	0.46 (0.33-0.61)	0.00-0.83
$p_{cat.2A}$ [b]	0.50 (0.48-0.51)	0.50 (0.40-0.61)	0.13-0.77
$p_{cat.2B}$ [b]	0.47 (0.46-0.48)	0.47 (0.38-0.57)	0.22-0.74
Cat. 1 vs 2			
p_o [a]	0.86 (0.86-0.87)	0.88 (0.82-0.91)	0.71-0.97
$p_{cat.1}$ [b]	0.85 (0.84-0.85)	0.86 (0.81-0.90)	0.69-0.96
$p_{cat.2}$ [b]	0.88 (0.87-0.88)	0.89 (0.84-0.92)	0.71-0.97
Sensitivity	0.90 (0.89-0.91)	0.93 (0.86-1.00)	0.64-1.00
Specificity	0.84 (0.83-0.85)	0.85 (0.80-0.90)	0.60-1.00
Cat. A vs B			
p_o [a]	0.64 (0.64-0.65)	0.65 (0.59-0.71)	0.47-0.82
$p_{cat.A}$ [b]	0.69 (0.68-0.69)	0.69 (0.63-0.75)	0.48-0.85
$p_{cat.B}$ [b]	0.57 (0.57-0.58)	0.58 (0.48-0.67)	0.33-0.80
Sensitivity	0.64 (0.64-0.65)	0.67 (0.57-0.71)	0.38-0.86
Specificity	0.64 (0.63-0.66)	0.62 (0.54-0.77)	0.31-0.92

Cat. 1A, persistent redness without clinical signs of infection; Cat. 1B, persistent redness with clinical signs of infection; Cat. 2A, skin loss without clinical signs of infection; Cat. 2B, skin loss with clinical signs of infection; Cat. 1, persistent redness; Cat. 2, skin loss; Cat. A, absence of clinical signs of infection; Cat. B, presence of clinical signs of infection; IQR, interquartile range; 95% CI, 95% confidence interval. [a] Overall proportion of agreement. [b] Proportion of specific agreement.

Table 3. Inter-rater reliability

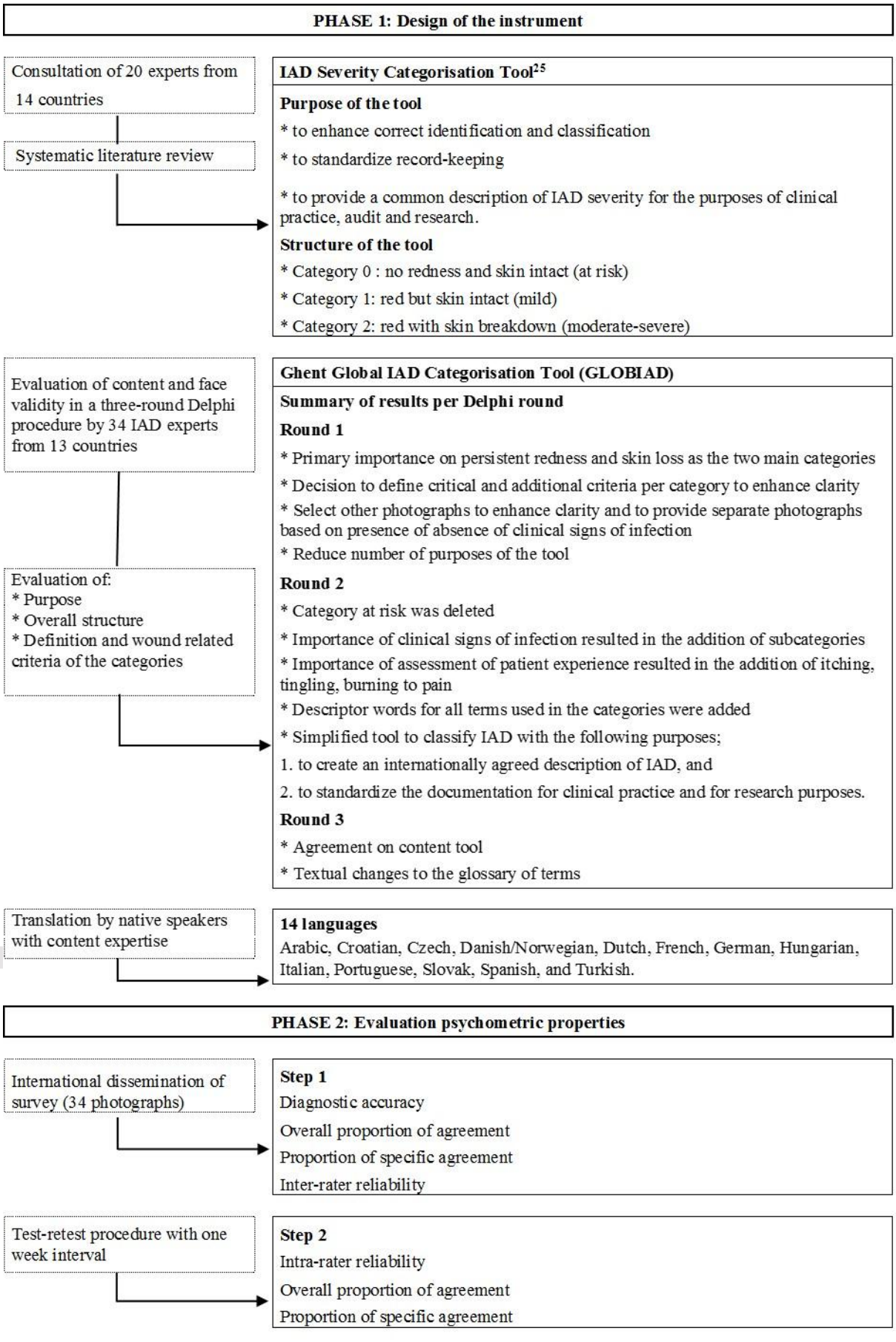
	cat. 1A vs 1B vs 2A vs 2B	cat. 1 vs 2	cat. A vs B
	κ (95% CI)	*κ (95% CI)*	*κ (95% CI)*
Total sample n = 823	0.41 (0.41-0.41)	0.65 (0.65-0.65)	0.32 (0.32-0.32)
Novice n = 117	0.40 (0.40-0.40)	0.61 (0.61-0.62)	0.32 (0.31-0.32)
Advanced Beginner n = 147	0.41 (0.40-0.41)	0.62 (0.62-0.62)	0.31 (0.31-0.31)
Competent n = 231	0.41 (0.41-0.41)	0.65 (0.65-0.65)	0.33 (0.32-0.33)
Proficient n = 180	0.44 (0.43-0.44)	0.68 (0.68-0.69)	0.34 (0.34-0.34)
Expert n = 148	0.44 (0.43-0.44)	0.68 (0.68-0.69)	0.36 (0.35-0.36)
Undergraduate n = 228	0.40 (0.40-0.40)	0.63 (0.63-0.64)	0.31 (0.31-0.31)
Bachelor' degree n = 381	0.42 (0.41-0.42)	0.65 (0.65-0.65)	0.33 (0.32-0.33)
Master' degree n = 166	0.41 (0.41-0.41)	0.66 (0.66-0.67)	0.32 (0.32-0.32)
Doctoral degree n = 39	0.43 (0.42-0.44)	0.66 (0.65-0.68)	0.33 (0.32-0.35)
Wound care module			
Not completed n = 456	0.41 (0.41-0.41)	0.63 (0.63-0.63)	0.32 (0.32-0.32)
Completed n = 368	0.42 (0.42-0.42)	0.68 (0.68-0.68)	0.33 (0.33-0.33)

Cat. 1A, persistent redness without clinical signs of infection; Cat. 1B, persistent redness with clinical signs of infection; Cat. 2A, skin loss without clinical signs of infection; Cat. 2B, skin loss with clinical signs of infection; Cat. 1, persistent redness; Cat. 2, skin loss; Cat. A, absence of clinical signs of infection; Cat. B, presence of clinical signs of infection; κ, Fleiss Kappa coefficient; 95% CI, 95% confidence interval.

Table 4. Intra-rater reliability and agreement – 463 raters

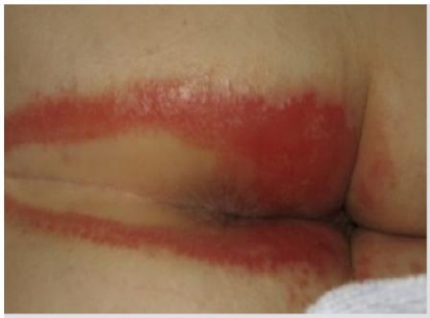
	mean (95% CI)	median (IQR)	2.5th and 97.5th percentile
Cat. 1A vs 1B vs 2A vs 2B			
κ [a]	0.61 (0.59-0.62)	0.60 (0.51-0.71)	0.33-0.84
p_o [b]	0.71 (0.70-0.72)	0.71 (0.65-0.79)	0.47-0.88
$p_{cat.1A}$ [c]	0.77 (0.76-0.78)	0.80 (0.71-0.86)	0.50-0.95
$p_{cat.1B}$ [c]	0.60 (0.58-0.62)	0.63 (0.46-0.77)	0.00-0.93
$p_{cat.2A}$ [c]	0.62 (0.60-0.63)	0.63 (0.50-0.74)	0.22-0.91
$p_{cat.2B}$ [c]	0.74 (0.73-0.75)	0.77 (0.67-0.83)	0.43-0.96
Cat. 1 vs 2			
κ [a]	0.76 (0.75-0.77)	0.76 (0.69-0.87)	0.47-0.94
p_o [b]	0.88 (0.88-0.89)	0.88 (0.85-0.94)	0.74-0.97
$p_{cat.1}$ [c]	0.87 (0.86-0.87)	0.88 (0.82-0.92)	0.69-0.97
$p_{cat.2}$ [c]	0.89 (0.88-0.90)	0.90 (0.86-0.94)	0.72-0.98
Cat. A vs B			
κ [a]	0.56 (0.54-0.58)	0.58 (0.43-0.70)	0.19-0.88
p_o [b]	0.79 (0.78-0.79)	0.79 (0.74-0.85)	0.59-0.94
$p_{cat.A}$ [c]	0.79 (0.78-0.80)	0.80 (0.73-0.86)	0.58-0.94
$p_{cat.B}$ [c]	0.77 (0.76-0.78)	0.78 (0.71-0.85)	0.52-0.94

Cat. 1A, persistent redness without clinical signs of infection; Cat. 1B, persistent redness with clinical signs of infection; Cat. 2A, skin loss without clinical signs of infection; Cat. 2B, skin loss with clinical signs of infection; Cat. 1, persistent redness; Cat. 2, skin loss; Cat. A, absence of clinical signs of infection; Cat. B, presence of clinical signs of infection. [a] κ, Cohen's Kappa coefficient. [b] Overall proportion of agreement. [c] Proportion of specific agreement.



Category 1: Persistent redness

1A - Persistent redness without clinical signs of infection



Critical criterion

- Persistent redness
  A variety of tones of redness may be present.
  Patients with darker skin tones, the skin may be paler or darker than normal, or purple in colour.

Additional criteria

- Marked areas or discolouration from a previous (healed) skin defect
- Shiny appearance of the skin
- Macerated skin
- Intact vesicles and/or bullae
- Skin may feel tense or swollen at palpation
- Burning, tingling, itching or pain

1A