FACULTY OF MEDICINE AND HEALTH SCIENCES

INCONTINENCE-ASSOCIATED DERMATITIS (IAD):

THE DEVELOPMENT AND VALIDATION OF MEASUREMENT INSTRUMENTS

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It is not the mountain we conquer, but ourselves.

– Sir Edmund Hillary

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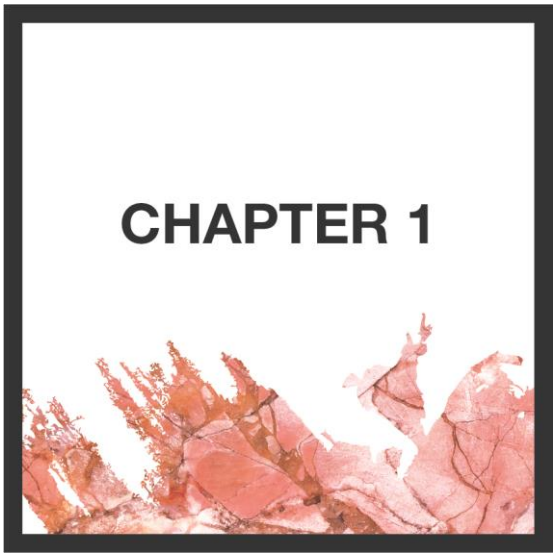
TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CMS	Centers for Medicare & Medicaid Services
COF	Coefficient of friction
COS	Core Outcome Set
CONSIDER	Core Outcome Set in IAD Research
COMET	Core Outcome Measures in Effectiveness Trials Initiative
COSMIN	Consensus-based Standards for the selection of health Measurement Instruments
CSG-COUSIN	The Cochrane Skin Group - Core Outcome Set Initiative
GLOBIAD	Ghent Global IAD Categorisation Tool
GLOBIAD-M	Ghent Global IAD Monitoring Tool
EPUAP	European Pressure Ulcer Advisory Panel
GRADE	the Grading of Recommendations Assessment, Development and Evaluation
HOME	the Harmonizing Outcome Measures for Eczema
IAD	Incontinence-Associated Dermatitis
IADS	IAD and Its Severity Instrument
IADS-D	IAD and its Severity Instrument for darker toned skin
IADIT	Incontinence-Associated Dermatitis Intervention Tool
IADIT-D	German Incontinence-Associated Dermatitis Intervention Tool
ICD	International Classification of Diseases
ICU	Intensive Care Unit
ISC	International Steering Committee
JBI	Joanna Briggs Institute
MASD	Moisture-Associated Skin Damage
MDS	Minimum Data Set
NMF	Natural Moisturizing Factor
MRC	Medical Research Council
NANDA	North American Nursing Diagnosis Association
NATVNS	National Association for Tissue Viability Nurses
NPUAP	National Pressure Ulcer Advisory Panel

NRS	Numerical Rating Scale
OMERACT	Outcome Measures in Rheumatology
PAT	Perineal Assessment Tool
PPPIA	Pan Pacific Pressure Injury Alliance
PRO	Patient-Reported Outcome
PROM	Patient-Reported Outcome Measure
PRP	Patient Research Partner
RAI	Resident Assessment Instrument
RCT	Randomised Controlled Trial
TEWL	Transepidermal Water Loss
SPC	Statistical Process Control
WHO	World Health Organization
WOC	Wound, Ostomy, and Continence



GENERAL INTRODUCTION

Incontinence-associated dermatitis

The skin is considered the largest organ in the body, consisting of the epidermis, dermis, and the subcutis or hypodermal fat layer (Powell 2006). Apart from its sensory function, the skin has a number of important physiological roles including temperature maintenance, homeostatic regulation, immune function, and the protection from environmental exposure (Farage et al. 2008b). The epidermis is responsible to maintain skin integrity by presenting a physical and chemical barrier to microorganisms, physical insults, and toxic agents. The main barrier of the skin is located in the outermost layer of the epidermis, the stratum corneum which is continually renewed (Bouwstra et al. 2003b). The stratum corneum is commonly described as a 'bricks and mortar' structure in which the keratin-filled corneocytes formed from keratinocytes in the epidermis are the 'bricks' (Figure 1). The corneocyte layers are embedded in lipids or the 'mortar', composed primarily of ceramide, fatty acids and cholesterol, joined together with protein links (Ananthapadmanabhan et al. 2013). An essential mechanism that maintains skin hydration within the stratum corneum and leads to an effective and flexible barrier, is the natural moisturizing factor (NMF) present within corneocytes (Harding 2004). The NMF contains free amino acids, formed from filaggrin proteolysis to small, hygroscopic molecules, and other substances such as urea, lactate, and sugars (Del Rosso and Levin 2011).

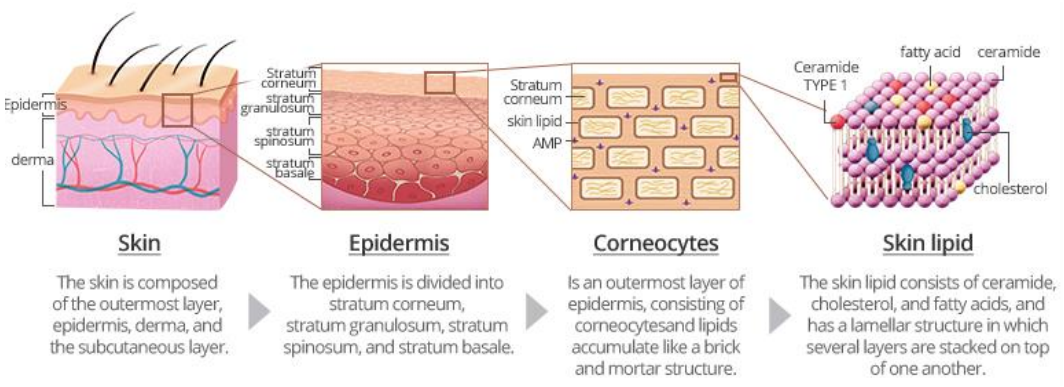


Figure 1. Structure of the skin (ZEROID 2015)

Terminology

Repeated and/or prolonged exposure of the stratum corneum to moisture such as perspiration, wound exudate, saliva, urine or faeces can cause skin damage. The skin surface is regularly exposed to urine and/or faeces in both infants and adults with incontinence. In babies and small infants, this cutaneous problem has been recognised as diaper dermatitis (Blume- Peytavi et al. 2014, Folster-Holst et al. 2011). Other widely used terms for this skin condition in early childhood are perineal, diaper, or napkin dermatitis/rash. However, this cutaneous problem not only occurs in paediatric patients but is also common in adults. In 1987, the concept

of ‘incontinence-associated dermatitis’ was first used by Anthony et al. (1987). In 2007, the concept was promoted by an international consensus panel (Gray et al. 2007). The panel defined IAD as a skin inflammation manifested as redness with or without blistering, erosion, or loss of skin barrier function that occurs as a consequence of chronically or repeated exposure of the skin to urine or faeces (Gray et al. 2007).

The World Health Organization (WHO) International Classification of Diseases, 10th Revision (ICD-10) can be defined as a system of categories to which morbid entities are assigned according to established criteria (WHO 2004). The ICD-10 version for 2016 classifies incontinence-related skin problems as ‘Diseases of the skin and subcutaneous tissue’ in subcategory ‘Dermatitis and eczema’ (WHO 2016). The ICD-10 contains codes for Diaper [napkin] Dermatitis (L22) and Irritant Contact Dermatitis (L24) but does not contain separate codes for IAD (Gray et al. 2012). Diaper [napkin] Dermatitis is a condition well known to occur early in life. As IAD occurs frequently in geriatric care settings, the use of the term “diaper rash” is not appropriate for adult persons. The Medical Subject Heading Terms (MeSH) database of the US National Library of Medicine describes incontinence-related skin problems as ‘diaper rash’. Diaper rash is defined as “a type of irritant dermatitis localised to the area in contact with a diaper and occurring most often as a reaction to prolonged contact with urine, faeces, or retained soap or detergent” (Gray et al. 2012, Medicine 2016). Currently, IAD is considered as part of a broader group of skin conditions, referred to as Moisture-Associated Skin Damage (MASD) (Gray et al. 2011). Apart from IAD, MASD includes intertriginous dermatitis, periwound moisture-associated dermatitis, and peristomal moisture-associated dermatitis (Gray et al. 2011). The term IAD is preferred, as it relates the skin damage to urine and/or faecal incontinence and not to other moisture sources such as wound exudate, perspiration or enterostomal fluids (Beeckman et al. 2015, Beeckman et al. 2016).

Aetiology and pathophysiology

A number of studies and reviews revealed a complex and multifactorial aetiology of IAD; a summary is presented in Figure 2 (Beeckman et al. 2009b). During incontinence episodes, the skin is exposed to water from urine and/or faeces. This excessive skin surface moisture results in a hyperhydration of the corneocytes and a disruption of the intercellular lipid bilayers (Bouwstra et al. 2003a, Warner et al. 2003). This process may lead to skin maceration, characterised by a whitened appearance and swelling (Ichikawa-Shigeta et al. 2014). Loss of barrier function, and permeability of the skin, makes the skin more permeable to irritants and pathogens (Foureur et al. 2006). The hyperhydration itself seems not to alter the skin surface pH (Minematsu et al. 2011), but urease transforms urea into ammonium and hence increasing the pH of the skin. The skin pH shifts from acid to neutral or to alkine pH which disrupts the acid mantle of the skin leading to a decreased stratum corneum cohesion and impaired skin barrier function (Beele et al. 2017). Faecal matter contains faecal

enzymes (proteases and lipases) which are able to break down the proteins and fat in the epidermis, especially in the stratum corneum. Moreover, the bacterial flora in the perineal area, or the skin microbiome, has been proven important in the maintenance of skin integrity (Beele et al. 2017, Bender et al. 2017). As a result, an inflammatory response of the skin occurs in response to chemical stimuli by the release of proinflammatory cytokines from keratinocytes. The main pathophysiological changes are skin barrier disruption, epidermal cellular changes and cytokine release (Jacobs et al. 2006).

The development of IAD is also related to chemical and physical irritation. Skin wetness increases the skin-support coefficient of friction (COF) and hence also the likelihood of injury from friction through contact with clothing, incontinence pads or bed linen (Adam 2008). Frequent incontinence episodes require frequent skin cleansing. The repeated use of water, skin cleansing agents, washcloths and towels leads to chemical and physical irritation. Moreover, skin care practices including drying with towel and repeated washing with water and cleanser may add to skin damage (Voegeli 2008). Also limited mobility and ability to move independently in bed and chairs cause friction and shear loads in the stratum corneum and the epidermis diminishing the strength of the epidermal barrier further (Kottner and Beeckman 2015). Often occlusive skin conditions and an impaired barrier further facilitate the infiltration of the stratum corneum by microorganisms increasing the risk of secondary skin infection (Farage et al. 2007, Foureur et al. 2006, Kottner et al. 2015).

The most common microorganisms associated with IAD are *Candida albicans*, *Escherichia coli* and *Clostridium difficile* from the gastrointestinal tract, *Pseudomonas aeruginosa* and *Staphylococcus aureus* from the perineal skin (Beeckman et al. 2009b, Campbell et al. 2017, Gray et al. 2012, Mugita et al. 2015). Few studies reported a high prevalence of cutaneous infections, between 19 and 63% (Black et al. 2011, Campbell et al. 2017, Campbell et al. 2016b, Foureur et al. 2006, Junkin and Selekof 2007).

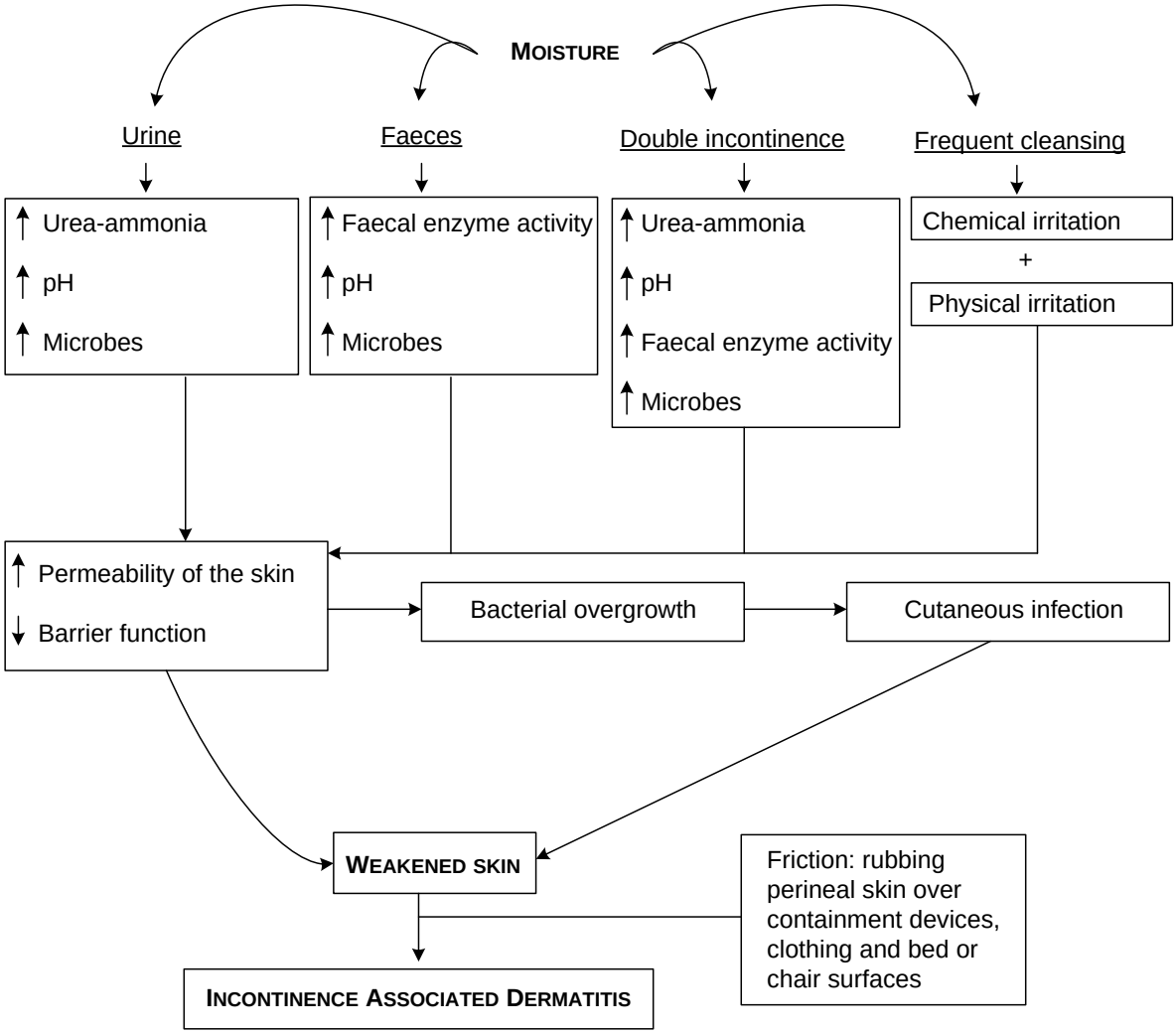


Figure 2. Aetiology of incontinence-associated dermatitis (Beeckman et al. 2009b)

Risk factors

The presence of incontinence is inherently associated with an increased risk for IAD development. Although urinary and/or faecal incontinence is a prerequisite, not all incontinent adults develop an IAD lesion. A number of contributing factors have been studied, but the current knowledge on IAD risk factors in adults is minimal. The type of incontinence has been associated with IAD development: liquid faeces is most irritating, followed by double incontinence, faecal incontinence and urinary incontinence (Bliss et al. 2006a, Campbell et al. 2016b, Gray et al. 2012, Kottner et al. 2014). IAD seems to be more common in older patients as the aging process is associated with a decreased cell replacement in the skin, a thinning epidermis, and a compromised barrier function and mechanical protection (Beeckman 2017). An elderly and acute/intensive care population is at high risk for IAD development as they are often characterised by a compromised health status (e.g. multimorbidity), poor skin condition, and a poor nutritional status (Bliss et al. 2006a, Bliss et al. 2011, Kottner et al. 2014, Van

Damme et al. 2018, Van Damme et al. 2017). A higher care dependency, restricted mobility and activity, risk of friction and shear, restricted cognitive awareness have been associated with IAD prevalence (Bliss et al. 2006a, Bliss et al. 2011, Junkin and Selekof 2007, Kottner et al. 2014). A study in Intensive Care Unit (ICU) patients with faecal incontinence revealed that the use of vasoactive agent, sensory ability, friction force, and shear force are the risk factors of IAD occurrence (Ma et al. 2017).

Impact

In addition to the pathophysiological consequences of IAD, both incontinence and the associated skin breakdown have a considerable impact on the physical and emotional health of the patient (Farage et al. 2008a, Newman et al. 2007, Sibbald et al. 2003). The development of IAD can result in an undue burden of care, loss of independence, disruption in activities and/or sleep, and reduced quality of life, worsening with frequency and quantity of soiling (Beeckman et al. 2015, Van Damme et al. 2015). Patients with IAD may experience discomfort because of pain, itching, burning or tingling in the affected areas (Van Damme et al. 2015). Little is known about the economical impact of IAD as large scale economic evaluations about the skin condition are lacking (Gray et al. 2007, Lichterfeld-Kottner et al. 2017).

To conclude, 'incontinence-associated dermatitis' (IAD) is the accepted term for skin damage caused by exposure to urine and/or faeces. A small but growing body of evidence provides insight into the definition, aetiology and pathophysiology of IAD. To date, there is no ICD coding for IAD in adults.

Prevalence and incidence

Both prevalence and the incidence are used to describe how often a disease occurs in a population. The prevalence reflects the number of existing cases of a disease at a certain point in time. It provides insight into the magnitude of the problem at a given point in time, and may be an aid in planning for health resources and facilities as it reflects the burden, such as monetary costs, life expectancy, and the morbidity of a disease in a certain population (Noordzij et al. 2010). If data are collected about preventive measures or treatment, the compliance with prevention and treatment protocols can be examined. The incidence reflects the number of new cases of a disease and can be reported as a risk or as an incidence rate. The risk is the probability that a person within a population will develop a given disease, over a specified follow-up period, which can be interpreted as an estimation of the risk of disease in an individual subject. The incidence rate can be calculated by dividing the number of subjects developing a disease by the total time at risk for all people to get the disease. For both measures, one assumes for the calculation that all subjects are free of the disease of interest at the start of the study. The incidence can also be used to gain insight into the causation of the disease and to evaluate the effectiveness of preventive measures and treatment both in research and clinical practice (Defloor et al. 2005a, Noordzij et al. 2010). To date, a number of studies have examined the prevalence and incidence of IAD (Tables 1 and 2).

Prevalence of IAD

Overall, the prevalence of IAD is estimated between 4.3% and 53.6% with the highest in acute care settings (Table 1). The studies vary by setting, country, population, and methodology. The seven large multicentre studies reported an IAD prevalence between 4.3% and 45.7%, measured in a sample ranging from 2492 to 59558 patients. Eight small-scale, often single-centre studies reported an IAD prevalence between 8% and 53.6% in a sample ranging from 11 to 198 patients. Bliss et al. (2006) and Defloor et al. (2008) examined a population of both continent and incontinent patients, reporting an IAD prevalence of 5.7% (Bliss et al. 2006a, Defloor et al. 2008). Compared to most studies, the largest study used the database of Minimum Data Set records from nursing homes across the US but without the availability of an assessment item identifying perineal dermatitis (Bliss et al. 2006a, Savik et al. 2005). Two studies included both adult and paediatric patients (Junkin et al. 2005, Junkin and Selekof 2007). Defloor et al. (2008) reported a prevalence of 5.7% in 19964 patients with and without incontinence in 84 general hospitals (Defloor et al. 2008). Since then, there is no national IAD registration in Belgium (Van Eenoo et al. 2012). Since 2012, the prevalence of IAD is assessed annually in German hospitals and nursing homes using the German IAD Intervention Tool (IADIT-D) (Steininger et al. 2012). Kottner & Lahmann (2012) reported a prevalence of 4.4% in 2386 incontinent nursing home

residents and 12% in 317 hospitalised patients (Lahmann et al. 2012). Boronat-Garrido et al. (2016) combined data of three annual cross-sectional multicentre studies in German nursing homes (2012, 2013 and 2014), resulting in a prevalence of 5.2% in 3406 incontinent residents (Boronat-Garrido et al. 2016). Kottner et al. (2014) reported an overall prevalence of 6.1% in 3713 German and Austrian hospitalised patients (academic, general and geriatric hospitals) and residents of nursing and care homes (Kottner et al. 2014). More recently, Gray and Giuliano (2017) found a prevalence of 45.7% in 2492 incontinent patients from 189 acute care facilities in the US (Gray and Giuliano 2017), and a national audit in Wales reported a prevalence of 4.3% in 8365 hospitalised patients (Clark et al. 2017).

Table 1. Prevalence of incontinence-associated dermatitis

Author	**Country, Healthcare setting**	**Incontinence type***	**IAD prevalence** *Numerator/denominator (%)*
Junkin et al. (2005)	USA, Acute and critical care (3 hospitals)	Urinary and faecal incontinence (children and adults)	NR/198 (27%)
Bliss et al. (2006a)	USA, Long-term care (555 nursing homes)	Continent and incontinent (urinary and faecal)	3405/59558 (5.7%)
Junkin and Selekof (2007)	USA, Acute and critical care (1 teaching and 1 community hospital)	Urinary and faecal incontinence (children and adults)	24/120 (20%)
Defloor et al. (2008)	Belgium, Acute and critical care (84 general hospitals)	Continent and incontinent (urinary and faecal)	1131/19964 (5.7%)
Beeckman et al. (2011)	Belgium, Long-term care (4 nursing homes)	Urinary and faecal incontinence	NR/141 patients (22.6%)
Long et al. (2012)	USA, Long-term acute care (1 hospital)	Continent (NR) and incontinent (urinary and faecal)	39/171 (22.8%)
Lahmann et al. (2012)	Germany, Acute and long-term care (47 nursing homes and 7 hospitals)	Urinary and faecal incontinence	Overall: 144/2703 (5.3%) Nursing home: 106/2386 (4.4%) Hospitals: 38/317 (12%)
Bohnenkamp et al. (2013)	USA Critical care (1 hospital)	Urinary and faecal incontinence	Before 9/11 (8%) After 1/11 (9%)
Kottner et al. (2014)	The Netherlands and Austria, Acute, long-term and home care (Care homes, nursing home, home care, academic,	Urinary and faecal incontinence	226/3713 (6.1%) Austria: 56/1289 (4.3%) NL: 170/2424 (7.0%)

	general and geriatric hospital)		
Conley et al. (2014)	USA, Critical care (1 hospital)	Urinary and faecal incontinence (including catheters)	I = NR/55 (49.1%) C = NR/44 (53.6%) *IAD at baseline*
Campbell et al. (2016b)	Australia, Acute and critical care (1 teaching hospital)	Urinary and faecal incontinence	38/91 (41.8%)
Boronat-Garrido et al. (2016)	Germany, Long-term care (78 nursing homes)	Urinary and faecal incontinence	207/3406 (5.2%)
Campbell et al. (2017)	Australia, Acute care (1 teaching hospital)	Urinary and faecal incontinence	22/53 (41%)
Gray and Giuliano (2017)	USA, Acute care (189 hospitals)	Urinary and faecal incontinence	1140/2492 (45.7%)
Clark et al. (2017)	Wales (UK), Acute and community hospitals (66 hospitals)	Continent and incontinent patients	362/8365 (4.3%)

NR, Not Reported. *Incontinence type of study sample

Incidence of IAD

In line with the studies reporting on IAD prevalence, varying sample sizes, settings, and time to follow-up are reported in IAD incidence studies (Table 2). Eleven studies reported incidence figures of IAD varying from 3.4% to 50.0%, measured in a sample ranging from 8 to 10713 patients. Whilst some studies did not report the time to follow-up period (Bliss et al. 2011, Brunner et al. 2012, Long et al. 2012, Ma et al. 2017), others lack specificity by reporting a time period 'until discharge' (Hall and Clark 2015) or '< 14 days' (Driver 2007). Most studies included patients with urinary and/or faecal incontinence, but four only included patients with faecal incontinence (Bliss et al. 2011, Coyer et al. 2017, Driver 2007, Ma et al. 2017).

Other measures have been used to assess the presence of IAD in a specific population. Bliss et al. (2008) reported a history of IAD in 52% of 188 community-living persons using self-report (Bliss et al. 2008). The same method was applied by Rohwer et al. (2013) reporting a prevalence of 52.5% in 189 community-living persons with faecal or double incontinence (Rohwer et al. 2013). A survey completed by ICU nurses from four countries (Germany, Spain, Italy, and UK) reported an estimated proportion of 26% of faecal incontinent patients with diarrhoea having IAD (Bayon et al. 2012).

To date, epidemiological data for IAD that are internationally comparable are missing. Variability in reported prevalence and incidence rates may be attributable to differences in procedures and tools to collected data, the selection and calculation of IAD measures (incidence and prevalence), and the lack of coding of this particular skin condition in the International Statistical Classification of Diseases and Related health Problems (ICD). Moreover, IAD epidemiology is challenging as the denominator should be incontinent subjects only. This

requires a clear understanding of who is incontinent to define the target population. Finally, the wide variation may be explained by the lack of diagnostic criteria to differentiate IAD from other skin conditions such as superficial pressure ulcers (Beeckman et al. 2007).

Table 2. Incidence of incontinence-associated dermatitis

Author	**Country, Healthcare setting**	**Incontinence type***	**IAD incidence** *Numerator/denominator (%)*
Lyder et al. (1992)	USA, Geriatric psychiatry (1 hospital)	Urinary and faecal incontinence	(1) 3/13 (23%) (2) 2/8 (25%) Time period: 4 weeks
Driver (2007)	USA, Acute care (1 hospital)	Faecal incontinence	(1) 8/16 (50.0%) (2) 3/16 (19.0%) Time period: (1) < 14 days, (2) > 14 days
Bliss et al. (2007), Bliss et al. (2006b)	USA, Long-term care (16 nursing homes)	Urinary and faecal incontinence	33/981 (3.4%) Time period: 6 weeks
Bliss et al. (2011)	USA, Critical care (1 hospital)	Faecal incontinence	16/45 (36%) Time period: not reported *(stay in the critical care unit: median time to onset of 4 days)*
Long et al. (2012)	USA, Long-term acute care (1 hospital)	Continent (NR) and incontinent (urinary and faecal)	10/132 (7.6%) Time period: not reported [Duration of stay (medium time to onset 13.5 days)]
Brunner et al. (2012)	USA, Critical and acute care (1 hospital)	Urinary and faecal incontinence	16/64 (25.0%) Time period: not reported
Hall and Clark (2015)	USA, Acute care (1 hospital)	Urinary and faecal incontinence	5/17 (29.4%) Time period: until discharge or up to 14 days
Bliss et al. (2017)	USA, Long-term care (448 nursing homes)	Urinary and faecal incontinence	NR/10713 (5.5%) Time period: "89% within 14 days of the occurrence of incontinence"
Coyer et al. (2017)	Australia Critical care (1 hospital)	Faecal incontinence	(1) Before 21/66 (32%) (2) After 12/80 (15%) Time period: (1) 733 days, (2) 768 days
Ma et al. (2017)	China Critical care (1 hospital)	Faecal incontinence	30/104 (28.9%) Time period: not reported *(formative period of IAD: 1 – 13 days*
Van Damme et al. (2017)	Belgium Long term care (11 nursing homes)	Urinary and faecal incontinence	96/320 (30%) Time period: one month

NR, Not Reported. *Incontinence type of study sample

Differential diagnosis

Clinicians often experience difficulties to correctly distinguish IAD from pressure ulcers (Beeckman et al. 2007, Beeckman et al. 2010, Defloor and Schoonhoven 2004, Mahoney et al. 2011). A pressure ulcer is defined by the National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP) as a "localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear" (NPUAP et al. 2014). The severity of pressure ulcers varies from non-blanchable erythema of the intact skin to tissue destruction involving skin, subcutaneous fat, muscle and bone. IAD and pressure ulcers have different aetiologies but may co-exist: IAD is a 'top down' injury, while pressure ulcers are considered to be 'bottom up' injuries, where damage is initiated by changes within soft tissues below and within the skin (Defloor et al. 2005b). The pathophysiological and histopathological differences between IAD and PU are largely understudied. In 2007, Houwing et al. performed 14 skin biopsies and concluded that an ischemic and irritation pattern emerged, in both PU and IAD. However, the pattern of irritation appeared to be more associated with lesions that clinically fitted the description of IAD (Houwing et al. 2007).

For the 2014 international pressure ulcer guideline development process, the Pan Pacific Pressure Injury Alliance (PPPIA) has joined the NPUAP and EPUAP. The NPUAP/EPUAP/PPIA developed a common international classification system for pressure ulcers consisting of six categories/grades, ranging from non-blanchable erythema to full thickness tissue loss, unstageable, and suspected deep tissue injury (Table 3) (NPUAP et al. 2014). Pressure ulcers are considered preventable, but are still a common problem in healthcare settings. To gain insight into the prevalence of pressure ulcers, Vanderwee et al. (2007) proposed a data collection form and methodology. The form includes risk assessment, skin observation to assess the location and severity of existing pressure ulcers, and provides insight into the (adequacy of) preventive measures (Vanderwee et al. 2007). The methodology was pilot tested in a sample of 5947 patients from five European countries. A pressure ulcer prevalence of 18.1% was reported for grade 1–4, and 10.5% when grade 1 ulcers were excluded. Pressure ulcers most often develop over the sacrum, ischial tuberosities, trochanters, femoral condyles, malleoli, and heels (Vanderwee et al. 2007). Since 2008, many international studies have been published using the EPUAP pressure ulcer prevalence survey minimum data set such as Ireland, Sweden, Jordan, France and Wales (Barrois et al. 2008, Gunningberg et al. 2013, James et al. 2010, Moore and Cowman 2012, Tubaishat et al. 2011). A large-scale Belgian prevalence study in 2008 (n = 19968) reported a pressure ulcer prevalence of 12.1% in hospitals (Vanderwee et al. 2011). In line with the pressure ulcer classification system and methodology for prevalence measurements, standardisation in the assessment and epidemiological research of IAD using a valid and reliable international classification tool is recommended (Beeckman et al. 2007).

Based on the EPUAP approach, algorithms for the adequacy of preventive interventions were developed and assessed in an Belgian prevalence survey including 19968 patients (Vanderwee et al. 2011). A similar uniform data collection instrument and methodology to gain insight into the adequacy of management of IAD in various healthcare settings is lacking. The use of such an instrument can lead to better benchmarking of quality of care (Defloor et al. 2005a).

To conclude, there are only a few large-scale studies reporting a wide variety in epidemiological data about IAD. The use of various IAD definitions, differing patient groups, and methods and tools for data collection complicates the comparability. The lack of an internationally used classification system, ICD coding, and standardised method for epidemiological IAD research contributes to this variability. The development of an international classification system and uniform methodology to measure the prevalence would be useful to enhance the quality and comparability of epidemiological data across different healthcare settings and countries. Chapter 4 will address the need for an international IAD classification instrument, whereas chapter 6 will address the need for a uniform methodology for epidemiological IAD research.

Table 3. Pressure Ulcer Classification (NPUAP et al. 2014)

Category/Stage I Nonblanchable Erythema	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" individuals (a heralding sign of risk).
Category/Stage II Partial Thickness Skin Loss	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.* This category should not be used to describe skin tears, tape burns, incontinence-associated dermatitis, maceration or excoriation. **Bruising indicates suspected deep tissue injury.*
Category/Stage III Full Thickness Skin Loss	Full thickness skin loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunnelling. The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.
Category/Stage IV Full Thickness Tissue Loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunnelling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/muscle is visible or directly palpable.
Unstageable: Depth Unknown	Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore Category/Stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as 'the body's natural (biological) cover' and should not be removed.
Suspected Deep Tissue Injury: Depth Unknown	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Classification of IAD

The diagnosis and classification of IAD are based on clinical observation and visual inspection of the affected area. Despite the progress in the development of technologic aids to early diagnosis, clinicians currently must rely on visual and palpatory assessment of the skin to determine aetiology (Doughty et al. 2012, Gray et al. 2012). IAD observation is complex and different stages of severity are described. The distribution of the affected skin depends on the extent of skin surface contact with the irritant. Most often, signs of IAD are located around the anal cleft, extending to the perianal and sacrococcygeal areas, the posterior thighs and buttocks (Gray et al. 2007).

Signs and symptoms

Excessive moisture often presents first as maceration, the presence of a whitened appearance and slight swelling (Ichikawa-Shigeta et al. 2014, Kottner and Beeckman 2015). In early stages, the skin is characterised by erythema but with an intact epidermis. In patients with light skin tones, early signs of IAD are erythema, ranging from pink to red, maceration and slight oedema of the surrounding skin. In patients with darker skin tones, erythema can present paler, darker, purple, dark red or yellow (Bliss et al. 2014). Palpation may reveal induration, or firmness of the area as compared to surrounding tissue (Junkin and Selekof 2008). The appearance of a glossy, shiny appearance of the skin has been associated with a reduced perianal skin barrier function in geriatric patients (Nakagami et al. 2006). Additionally, the presence of papules, pustules, vesicles, and bullae have been reported (Gray et al. 2012). Intact vesicles or bullae are not often observed as even the smallest trauma and/or friction causes skin breakdown, resulting in superficial erosions surrounded with erythema (Beele et al. 2017, Campbell et al. 2016b). The epidermis may be damaged to varying depths; in some cases, the entire epidermis may be eroded exposing a moist, weeping dermis (Gray et al. 2012, Ichikawa-Shigeta et al. 2014). As the skin barrier function is compromised, a number of clinical signs may suggest colonisation or infection with microorganisms from the nearby environment (Foureur et al. 2006). A clinical sign suggesting a secondary skin infection by *Candida albicans* is the presence of white pustules surrounding the open lesion, also defined as 'satellite lesions' (Black et al. 2011, Campbell et al. 2017, Junkin and Selekof 2007). The presence of excessive or purulent exudate and/or discolouration of the wound bed may suggest a secondary infection by bacteria such as *Pseudomonas aeruginosa* (Beele et al. 2017, Gray et al. 2012, Mugita et al. 2015). A patient may report burning, itching, tingling or pain (Junkin and Selekof 2008).

Differential diagnosis

In the diagnosis and classification of IAD, it is important to distinguish IAD from other skin diseases in the perianal region. Contact dermatitis from textiles, compounds or skin products should be considered, as well as lesions due to infections such as herpes simplex or perspiration (e.g. intertrigo) (Beele et al. 2017, Bender et al. 2017). However, as previously discussed, the most important differential diagnosis is with pressure ulcers as clinicians often experience difficulties to correctly distinguish IAD from pressure ulcers (Beeckman et al. 2007, Beeckman et al. 2010, Defloor and Schoonhoven 2004, Defloor et al. 2005b, Mahoney et al. 2011). Differential diagnoses might be challenging, because of multiple co-existing risk factors and a similar clinical picture (mainly erythema or up to the level of partial thickness loss). Moreover, several studies and systematic reviews with meta-analyses found incontinence and IAD to be risk factors for pressure ulcer development (Beeckman et al. 2014, Demarre et al. 2012, Demarre et al. 2015, Gray and Giuliano 2017). To aid correct differentiation between pressure ulcers and IAD, the PuClas educational e-learning tool (currently version 4, http://puclas4.ucvvgent.be) was developed, based on the EPUAP statement (Beeckman et al. 2010, Defloor et al. 2005b). A summary of the PuClas guideline on differentiation between IAD and pressure ulcers is provided in table 4.

Table 4. Pressure ulcer classification and IAD differentiation

Parameter	Incontinence-associated dermatitis	Pressure ulcers
History	Urinary and/or faecal incontinence	Exposure to pressure and/or shear
Location	Affects perineum, perigenital area, buttocks, gluteal fold, medial and posterior aspects of upper thighs, lower back, and IAD may occur over a bony prominence	Usually over a bony prominence or associated with location of a medical device
Shape	Diffuse, different superficial spots are more likely to be IAD, may be blotchy or present as a kissing ulcer (copy lesion)	If the lesion is limited to one spot, it is likely to be a pressure ulcer
Edges	Diffuse or irregular edges	Distinct edges or margins
Depth	Intact skin with erythema (blanchable or non-blanchable), with or without superficial, partial-thickness skin loss	Varies from intact skin with non-blanchable erythema to full-thickness skin loss
Colour	Blanchable or non blanchable erythema Pink or white surrounding skin due to maceration	If redness is non-blanchable, this is most likely a pressure ulcer grade I
Necrosis	No necrosis	A black necrotic scab on a bony prominence is a pressure ulcer grade III or IV. If there is no or limited muscular mass underlying the necrosis, the lesion is a pressure ulcer grade IV

Adapted from Beeckman et al. (2010) and Defloor et al. (2005) (Beeckman et al. 2010, Defloor et al. 2005b)

Correct pressure ulcer classification is of utmost importance in terms of quality measurements, reimbursement, and in the legal context (Gunningberg and Stotts 2008, Heinemann et al. 2003, Van den Heede et al. 2007). Correct assessment and diagnosis of IAD is important and necessary to ensure that a patient receives the appropriate treatment, documentation is accurate, and regarding quality reporting and correct reimbursement (Junkin and Selekof 2008).

IAD assessment instruments

During the last two decades, a number of IAD classification tools have been developed. Psychometric characteristics have been investigated for some (Table 5). To date, ten IAD-related instruments have been developed for single or multiple purposes. Three were developed for IAD risk assessment (Junkin and Selekof 2008, Nix 2002, Steininger et al. 2012), nine for describing the severity of IAD (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008, Long et al. 2012, Lutz et al. 1996, Scotland 2008, Steininger et al. 2012), and two instruments for the classification and treatment of IAD (Junkin and Selekof 2008, Scotland 2008). Five of these IAD assessment instruments were designed for describing the severity of IAD and its monitoring over time (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Long et al. 2012, Lutz et al. 1996).

The presence of erythema and skin loss is a symptom covered by all IAD assessment tools, although the definitions and measurement methods differ. The Perineal Dermatitis Grading Scale categorises erythema as mild to severe erythema, whereas the IAD and its Severity Instrument (IADS) provides pictures ranging from no redness, to pink and red (Borchert et al. 2010, Brown 1993). A number of instruments assess the size of the IAD lesion, either via body locations (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Lutz et al. 1996) or an estimation of the surface area (Brown 1993, Lutz et al. 1996). The assessment of clinical signs of infection is mainly limited to the presence of a fungal infection, defined as 'fungal-appearing rash' (Bliss et al. 2014, Borchert et al. 2010, Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008) or 'candidiasis' (Nix 2002, Scotland 2008). Few studies assess the burden and physical discomfort of IAD, caused by the related pain or itching (Brown 1993, Junkin and Selekof 2008, Long et al. 2012, Steininger et al. 2012). The instruments use different systems to provide a global assessment. Five instruments propose a global assessment and categorise IAD as mild, moderate or severe (Bliss et al. 2014, Borchert et al. 2010, Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008, Lutz et al. 1996, Scotland 2008, Steininger et al. 2012), whereas the others use a (cumulative) scoring system to delineate the severity or risk on a continuum or dimension (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Lutz et al. 1996, Nix 2002).

Table 5. Overview IAD assessment instruments

Author and Country	Instrument	Items	Type *	Psychometric testing
Brown (1993) USA	Perineal Dermatitis Grading Scale	▪ Skin colour (severity of erythema) ▪ Skin integrity (incl. bullae, vesicles, swollen/raised areas, crusted or scaling, ▪ Area of affected area ▪ Patient symptoms	Severity Monitoring	No studies found
Lutz et al. (1996) USA	IAD Skin Condition Assessment Tool	▪ Area of skin breakdown (small – large) ▪ Skin redness (mild – severe) ▪ Erosion (mild – extreme; incl. exudation)	Severity Monitoring	*Inter-observer reliability* of skin observation between the researcher and the nurses: Cohen's k = 0.81; 95% CI 0.69-0.87 Beeckman et al. (2011)
Nix (2002) USA	Perineal Assessment Tool (PAT)	▪ Type and intensity of irritant ▪ Duration of irritant (linen/ pad changes) ▪ Perineal skin condition (skin integrity; incl. candidiasis) ▪ Contributing factors (e.g. antibiotics, tube feeding)	Risk	*Content validity* using 102 nursing specialists (WOC) from 31 states. *Inter-rater reliability* of assessing 20 long-term care patients between 2 raters (WOC and staff nurse): r = 0.970; 95% CI, 0.923-0.988; p < 0.001
Junkin and Selekof (2008) USA	Incontinence-associated dermatitis Intervention tool (IADIT)	Definition and intervention for 5 categories ▪ High risk ▪ Early IAD ▪ Moderate IAD ▪ Severe IAD ▪ Fungal-appearing rash	Risk Severity Intervention	No studies found
Scotland (2008) Scotland (UK)	Skin Excoriation Tool for Incontinent Patients	Definition and intervention for 4 categories ▪ Healthy skin ▪ Mild excoriation ▪ Moderate excoriation (incl. < 50% broken skin, oozing and/or bleeding) ▪ Severe excoriation (incl. > 50% broken skin, oozing and/or bleeding)	Severity Intervention	No studies found

Borchert et al. (2010) USA	IAD and its Severity Instrument (IADS)	IAD rated in 13 locations, scored on a 4-point scale: ▪ Pink in colour ▪ Red without rash or skin loss ▪ Fungal rash ▪ Any degree of skin loss	Severity Monitoring	*Content and face validity* using 247 WOC nurses. *Criterion validity* between staff nurses (n=347) and WOC nurses (n=3) (ICC=0.98; p=0.006) and between the WOC nurses (ICC=0.91; p=0.008). *Inter-rater reliability* was obtained in three groups (nurses' assistants, staff nurses and WOC nurses): no statistical difference between the 4 cases
Steininger et al. (2012) Austria	German Incontinence-Associated Dermatitis Intervention Tool (IADIT-D) Based on Junkin and Selekof (2008)	Definition for 5 categories ▪ Hochrisiko ▪ Beginnende IAD ▪ Mässige IAD ▪ Schwere IAD ▪ Pilzartig erscheinender ausschlag	Risk Severity Intervention	*Content validity* using 46 experts (2-round Delphi procedure) Steininger et al. (2012) *Inter-rater reliability* of assessing 381 nursing home residents between 2 independent registered nurses: 84%, κ=0.70, AC1=0.83 Braunschmidt et al. (2013)
Long et al. (2012) USA	Hospital survey on Incontinence and Perineal Injury Based on Brown (1993)	Assessment of 5 areas ▪ Skin colour (severity of erythema) ▪ Skin integrity (incl. bullae, vesicles, swollen/raised areas, crusted or scaling) ▪ Patient symptoms (incl. nonverbal/comatose)	Severity Monitoring	No studies found
Bliss et al. (2014) **USA**	IAD and its Severity Instrument for darker toned skin (IADS-D) Based on Borchert et al. (2010)	IAD rated in 13 locations, scored on a 4-point scale for light-, medium- and dark-toned skin ▪ Pink in colour ▪ Red without rash or skin loss ▪ Fungal rash ▪ Any degree of skin loss	Severity Monitoring	*Face and content validity* using 4 WOC nurse consultants and 2 WOC nurse clinical experts. *Criterion validity* ICC = 0.90 *Inter-rater reliability* ICC = 0.99 using photo cases assessed by 266 WOC conference attendees
Clarke-O'Neill et al. (2015c) UK	UCL/SCA tool	Overall severity rating (none, mild, moderate, severe) ▪ Description of skin appearance / permanent or temporary marks ▪ Severity of erythema (most severe area only), blanchable / non-blanchable erythema, wound classification (using EPUAP)	Severity	No studies found

WOC: Wound, Ostomy, and Continence; NATVNS: National Association for Tissue Viability Nurses. * Four types of instruments: Severity, to describe the level of severity based on the observed symptoms; Monitoring, to describe the change in IAD status over time; Risk, to describe the risk of developing IAD; Intervention, the level of severity is associated with intervention options.

Psychometric properties

An ideal instrument should measure IAD consistently and accurately (Streiner and Kottner 2014). Both the reliability and the validity of an instrument are criteria for assessing its quality (Polit 2010). Validity is defined as the degree to which an instrument measures what it is supposed to measure and can be divided into content validity, criterion-related validity, and construct validity (Kimberlin and Winterstein 2008, Polit 2010). Reliability estimates evaluate the stability of measures ('test-retest reliability'), internal consistency of measurement instruments, and the interrater reliability of instrument scores (Kimberlin and Winterstein 2008).

Some studies have reported on the psychometric properties of five IAD assessment instruments (Table 5). Content validity was assessed in four instruments using experts (Bliss et al. 2014, Borchert et al. 2010, Nix 2002, Steininger et al. 2012). Psychometric properties of five instruments were tested through the assessment of patients (Braunschmidt et al. 2013, Nix 2002) or photographs (Beeckman et al. 2011, Bliss et al. 2014, Borchert et al. 2010). Overall, the reliability coefficients are high and content validation has been performed. In 2015, a feasibility study tested three existing IAD assessment instruments in twelve incontinent residents from two nursing homes (Clarke-O'Neill et al. 2015a). The authors concluded that the existing instruments were too time-consuming and linguistically complex for use in routine clinical practice in nursing homes. The authors suggested to use a simple classification tool, supported by photographs illustrating the severity of each category (Clarke-O'Neill et al. 2015a). There is a need for a simplified tool that is clearly linked to the level and severity of the skin injury.

Classification aims to assess the severity of IAD at one point in time. However, from a clinical perspective it is important assess the change in IAD status over time to evaluate and tailor IAD management. In the observation and monitoring of IAD healing, the use of a valid assessment instrument is important for both clinical practice and clinical research.

To conclude, the diagnosis and classification of IAD depends on clinical observation and visual inspection. Although several assessment instruments are available, there is no internationally, easy to use, feasible instrument to categorise and monitor IAD in routine clinical practice and research. Chapter 4 will address the need for an international IAD classification instrument. Chapter 5 will address the need for an IAD monitoring instrument.

IAD prevention and treatment

The exposure of the skin to urine or faeces constitutes the primary risk factor for IAD. Therefore, the goal of any intervention for IAD prevention and treatment is to eliminate or minimise skin contact with the irritant (Bender et al. 2017). The two key strategies are to manage incontinence and to implement a structured skin care regimen to maintain or restore skin barrier, skin integrity and health (Beele et al. 2017).

Incontinence management

Incontinence management includes the evaluation of the bladder and kidney function regarding urinary incontinence, and that of the intestine and colon in the case of faecal incontinence (Beele et al. 2017). Whenever possible, the cause of the incontinence should be identified and eliminated, and treatment options examined (Wishin et al. 2008). If treatment is not possible, it is recommended to use suitable incontinence products and implement behavioural interventions. Incontinence products such as briefs and liners should be chosen carefully, depending on the population. Preferably using smooth and breathable materials with maximum absorption capacity, as occlusive conditions between the incontinence product and the skin in combination with incontinence may exaggerate the risk and the severity of IAD (Muller and McInnis 2013). Bed linens and occlusive faecal containment products should be changed frequently to minimise exposure to both moisture and faeces, a time-consuming process that may interfere with other important nursing tasks (Foureur et al. 2006, Wishin et al. 2008). In specific situations, indwelling urinary catheters, faecal management systems, or pouches might provide a solution in severe forms of urinary or faecal incontinence in high-risk patients (Coyer and Campbell 2017, Morris 2011). Behavioural interventions include nutritional and fluid management, mobility enhancement, and different toileting techniques (Wishin et al. 2008). These are relevant to all patient populations as evidence suggests that structured toileting and exercise interventions can improve incontinence and skin status in elderly nursing home residents (Bates-Jensen et al. 2003). It is recommended to re-assess the type and frequency of incontinence on regular basis, to tailor incontinence management and estimate the risk for skin lesions such as IAD.

Structured skin care regimen

The second key strategy is the implementation of a structured skin care regimen, which comprises a thorough skin assessment, correct differential diagnosis, gentle cleansing, and the application of a leave-on product (Gray et al. 2012).

Skin assessment includes the clinical observation of signs of IAD via visual inspection of the skin areas that are being exposed to urine and/or faeces (Abrams et al. 2017, Gray et al. 2011). It is recommended to assess

the skin of all patients with urinary and/or faecal incontinence on a daily basis. If symptoms of IAD are observed, a correct differential diagnosis is crucial for appropriate treatment, accurate documentation and quality reporting (Junkin and Selekof 2008). Recognising the condition and distinguishing it from other skin lesions such as superficial pressure ulcers are most common (Beeckman et al. 2009b, Beeckman et al. 2014, Defloor and Schoonhoven 2004, Vanderwee et al. 2011). If the aetiology of erythema is not clear, a standard bundle of interventions for the management of both IAD and pressure ulcer prevention should be implemented and reviewed to assess the anticipated response (Beeckman et al. 2015).

Gentle cleansing

Prevention and treatment of IAD includes gentle skin cleansing and the application of topical leave-on products for protection and promotion of healing (Kottner and Beeckman 2015). Although a number of studies about prevention and treatment of IAD have been performed, the current knowledge is limited. A recent Cochrane review of skin care interventions for the prevention and treatment of IAD in adults included only 13 trials in a qualitative synthesis (Beeckman et al. 2016). The overall quality of the trials was low, with small sample sizes and short follow-up periods. More recently, a Joanna Briggs Institute (JBI) systematic review on the effectiveness of topical skin products in the treatment and prevention of IAD was performed (Pather et al. 2017). Of the 10 studies included in this review, five focused on both cost-effectiveness and clinical effectiveness while the other studies focused solely on clinical benefits. Current recommendations about IAD management including gentle cleansing and the application of leave-on products are based on a limited number of clinical trials and best practices. Strict distinctions between IAD prevention and treatment have not been made so far.

Effective cleansers remove organic matter rapidly and thoroughly from the surface, and reduce the odour (Nix 2000). Traditional washing with water and alkaline soap should be avoided as it will change the barrier and increase skin pH (Beele et al. 2017, Kuehl et al. 2003). As the product itself can become an irritant to the skin, skin cleansers containing non-ionic surfactants reflecting the pH-range of the acid mantle of healthy skin are preferred because of their gentleness (Kuehl et al. 2003, Nix 2000). Although there is insufficient evidence showing the superiority of certain cleansing products, cleansers and washcloths containing low-irritating surfactants, emollients and/or dimethicone are skin barrier protective in contrast to standard care (Beeckman et al. 2016). Excessive cleansing can cause skin dryness and skin irritation, but also influence the pH and hence the bacterial flora (Ananthapadmanabhan et al. 2013, Beele et al. 2017, Voegeli 2008). Drying the skin by rubbing causes additional friction, and should be avoided (Voegeli 2008). An optimal balance must be found

between removing irritants and preventing additional irritation due to frequent cleansing. Therefore, it is recommended to cleanse daily and after every episode of faecal incontinence (Kottner and Beeckman 2015).

Leave-on products

Leave-on products are defined by the EU cosmetics directive and was adopted by the authors of the Cochrane review as "moisturisers, skin protectants/barriers, and other functions, whether combined or not into one product" (Beeckman et al. 2016). Leave-on products are used for both prevention, as a barrier between the stratum corneum and the irritant, and treatment, to promote healing and allow the skin to recover (Beeckman et al. 2016). They aim to repair or augment the skin's barrier, retain and/or increase its water content, and restore or improve the intercellular lipid structure (Beeckman 2017). A skin barrier product aims to prevent skin breakdown by providing an impermeable or semi-permeable barrier on the skin (Beeckman et al. 2009b, Beeckman et al. 2016, Kottner and Beeckman 2015). Different types of skin protectant ingredients, such as petrolatum and dimethicone, and different types of products, such as creams and lotions are available (Beeckman 2017, Beele et al. 2017). As it is always the total formulation and the usage (e.g. amount applied) that shows a certain effect, determining the relative performance of an individual product is difficult (Beeckman et al. 2016, Doughty et al. 2012). Both systematic reviews concluded that the application of leave-on products seem to be more effective (Beeckman et al. 2016, Pather et al. 2017). However, the current available evidence does not support the superior performance of one leave-on product in IAD care compared to another. As evidence is limited, some general recommendations are made. Skin protectants should be applied regularly and in a gentle way to avoid friction, in the appropriate quantity, ideally before the exposure, and applied to all skin areas coming into contact with urine and/or faeces (Beele et al. 2017, Kottner and Beeckman 2015).

IAD treatment

When an IAD lesion is present and the skin barrier is compromised, IAD treatment should reduce inflammation, promote healing and reepithelialisation. All interventions listed above including incontinence management and preventive measures are applicable for treatment as well. A leave-on product is also to be used to treat mild irritant contact dermatitis. In severe IAD cases, dressings may be used temporally to promote healing (Kottner and Beeckman 2015). In case of secondary skin infection, such as a *Candida albicans* infection, an antimicrobial (antifungal) treatment should be used as a first-line therapy (Gray et al. 2012). It is recommended to treat the infection if present. The superimposed infection may alter the loco-regional clinical picture depending on the type of microorganism (bacteria, fungus or yeasts). Wound swabs are indicated to confirm the infection and/or identify the micro-organism involved to target the treatment (Beele et al. 2017).

Core Outcome Set

Although a number of studies about prevention and treatment of IAD have been performed, the current evidence on the effects of interventions for preventing and treating IAD in adults is limited. The Cochrane systematic review (Beeckman et al. 2016) included 13 trials with 1316 participants, the JBI systematic review included 10 studies with a total of 804 participants (Pather et al. 2017). The overall quality of the trials was low to moderate, with small sample sizes, short follow-up periods and few studies utilising randomisation, blinding or product allocation concealment. Due to the various outcomes, the reviewers could only perform a Grading of Recommendations Assessment, Development and Evaluation (GRADE) (Guyatt et al. 2011) assessment of the quality of evidence for two of the primary outcomes of this review: 'number of participants with IAD (new)' and 'number of participants with IAD (residual, i.e. not healed)' (Beeckman et al. 2016). Consequently, *Summary of Findings* tables in Cochrane reviews are often empty. Moreover, in both systematic reviews, meta-analysis of the extracted results was not possible due to the heterogeneity of comparators, measurement tools, and non-comparable outcomes.

The lack of comparability between studies about efficacy and (cost-)effectiveness of products and procedures complicates standardisation of IAD management (Beeckman et al. 2016). These issues may be reduced by adopting a Core Outcome Set (COS). 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). Outcomes measured in RCTs need to be useful and relevant to a range of stakeholders including patients, clinicians, policymakers and regulatory bodies (Keeley et al. 2016). Outcomes are often identified, chosen and specified a priori by a trial management team (traditionally including only researchers and clinicians), sometimes with input from patients and the public (Gargon et al. 2014). However, a COS does not limit researchers to choose additional outcomes and measurements (Schmitt et al. 2014). Using identical outcomes across trials allows comparability of results enhancing the value of evidence synthesis and reducing the risk of outcome reporting bias (Williamson et al. 2012b).

The need for standardisation of outcomes dates back to the work of the World Health Organization (WHO) in the 1970s relating to cancer trials (Miller et al. 1981). Representatives from groups doing trials in cancer developed the WHO Handbook of guidelines recommending the minimum requirements for data collection in cancer trials (WHO 1979). In the 1980s, it became clear that rheumatologists varied considerably in the way they use clinical measures to make judgments about the efficiency of treatment. Since then, the Outcome Measures in Rheumatology (OMERACT) initiative has been one of the most extensive collaborations relating to outcome standardisation (Boers et al. 2014a). Currently, the domains where a COS has been developed are

expanding to other fields such as neurology, heart and circulation, dentistry and oral health, gynaecology, neonatal care (Gargon et al. 2014). However, these COS are related to the field of medicine whereas a COS relevant for nursing research is non-existent.

To conclude, managing IAD is an important challenge for healthcare professionals. Given the magnitude of the problem, timely, adequate and targeted prevention and treatment are essential. Therefore, standardisation in research methods to evaluate effectiveness in a valid and reliable way, to enhance comparability between trials and to allow statistical pooling of results is needed. Chapters 2 and 3 will address the need for a Core Outcome Set in IAD research.

Outline and research questions

This dissertation aims to contribute to the standardisation in language, outcome definition and methods for epidemiological and clinical IAD research. Four areas for improvement were identified: the low comparability between clinical trials due to heterogeneity in measurement tools and outcomes, varying prevalence and incidence estimates indicated the lack of an internationally used IAD classification system and the lack of a standardised method for epidemiological IAD research, and the lack of an instrument to monitor the change in IAD status over time.

Therefore, the aims of this thesis were first to develop outcome domains for clinical incontinence-associated dermatitis research (Chapters 2 and 3). Second, to develop and psychometrically evaluate a tool to categorise the severity of incontinence-associated dermatitis (Chapter 4). Third, to develop and psychometrically evaluate a tool to monitor healing of incontinence-associated dermatitis (Chapter 5). Fourth and final, to develop, psychometrically evaluate, and pilot test an instrument to assess IAD prevalence and adequacy of IAD management in healthcare settings (Chapter 6).

These objectives lead to four research questions:

1. Which set of core outcome domains should be assessed and reported in IAD clinical trials involving adults with IAD or at risk of IAD, independently from any geographical location or skin colour?
2. What is the content validity, agreement and reliability of a new instrument to assess the severity of IAD in patients with urinary and/or faecal incontinence?
3. How can the IAD status in patients diagnosed with IAD be monitored over time in a valid and reliable way?
4. What is the content validity, agreement and reliability of a new instrument to assess the prevalence in patients with urinary and/or faecal incontinence and the adequacy of IAD management at organisational level?

Chapter 2 focuses on the methodology of the Core Outcome Set in IAD Research (CONSIDER) project. In chapter 3, the results of the development of the core set of outcome domains is presented.

Chapters 4 and 5 address the need for internationally, easy to use, valid and reliable instruments for IAD categorisation and monitoring. Chapter 4 reports the design and psychometric evaluation of the Ghent Global IAD Categorisation Tool (GLOBIAD). The design and psychometric evaluation of the Ghent Global IAD Monitoring Tool (GLOBIAD-M) in an acute care setting is presented in chapter 5.

An instrument and methodology for epidemiological IAD research is lacking. In line with the pressure ulcer methodology for epidemiological research, a Minimum Data Set for IAD and methodology for epidemiological

IAD research was developed and tested in nursing home population. The results of the development of this instrument and empirical evidence supporting the validity are presented in chapter 6.

Finally, chapter 7 provides a general discussion of the findings, methodological considerations, and future perspectives for clinical practice, policy, education, and research.

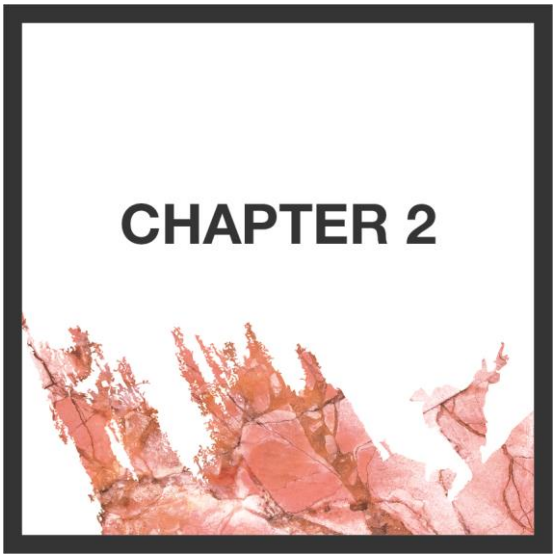
A brief overview of the addressed gap, the developed instruments, and the methods employed in each study are presented in Table 6, and described in more detail in the subsequent chapters.

Table 6. Overview of studies and methods in each chapter of this dissertation

Addressed gap	Development of	Methods
Low comparability between clinical trials due to heterogeneity in measurement tools and outcomes	Core Outcome Set in IAD research (CONSIDER) project study protocol (chapter 2) Core set of outcome domains (chapter 3)	<u>Development and international consensus study</u> ▪ Generating a list of outcomes via systematic literature review, patient interviews and expert consultation ▪ Multidisciplinary consensus study using the Delphi procedure with a group of 57 panellists from 17 countries
No internationally used, valid and reliable IAD classification system	GLOBIAD – Ghent Global IAD Categorisation Tool (chapter 4)	<u>Psychometric instrument development and validation study</u> ▪ Content validation using a three-round Delphi procedure with 34 experts from 13 countries ▪ Psychometric evaluation with 823 health professionals from 30 countries
No easy to use, valid and reliable instrument to monitor the change in IAD status over time	GLOBIAD-M – Ghent Global IAD Monitoring Tool (chapter 5)	<u>Psychometric instrument development and validation study</u> ▪ Content validation by experts, based on the GLOBIAD development ▪ Psychometric evaluation using 36 observations of 9 hospitalised patients with IAD
Varying prevalence and incidence estimates due to the lack of a standardised method for epidemiological IAD research	Minimum Data Set for IAD (chapter 6)	<u>Instrument development and pilot test in nursing homes</u> ▪ Development and content validation with experts and nurses from 3 nursing homes ▪ Reliability study and pilot test in 108 residents from 3 nursing homes

Chapter based on:

VAN DEN BUSSCHE K., DE MEYER D., VAN DAMME N., KOTTNER J. & BEECKMAN D. (2017) CONSIDER – Core Outcome Set in IAD Research: study protocol for establishing a core set of outcomes and measurements in incontinence-associated dermatitis research. *Journal of Advanced Nursing,* **73**(10), 2473–2483.



CONSIDER – Core Outcome Set in IAD Research: study protocol for establishing a core set of outcomes and measurements in incontinence-associated dermatitis research

ABSTRACT

Aim. This study protocol describes the methodology for the development of a core set of outcomes and a core set of measurements for incontinence-associated dermatitis.

Background. Incontinence is a widespread disorder with an important impact on quality of life. One of the most common complications is incontinence-associated dermatitis, resulting from chemical and physical irritation of the skin barrier, triggering inflammation and skin damage. Managing incontinence-associated dermatitis is an important challenge for nurses. Several interventions have been assessed in clinical trials, but heterogeneity in study outcomes complicates the comparability and standardisation. To overcome this challenge, the development of a core outcome set, a minimum set of outcomes and measurements to be assessed in clinical research, is needed.

Design. A project team, International Steering Committee and panelists will be involved to guide the development of the core outcome set. The framework of the Harmonizing Outcomes Measures for Eczema roadmap endorsed by Cochrane Skin Group Core Outcomes Set Initiative, is used to inform the project design.

Methods. A systematic literature review, interviews to integrate the patients' perspective and a consensus study with healthcare researchers and providers using the Delphi procedure will be performed. The project was approved by the Ethics review Committee (April, 2016).

Discussion. This is the first project that will identify a core outcome set of outcomes and measurements for incontinence-associated dermatitis research. A core outcome set will reduce possible reporting bias, allow results comparisons and statistical pooling across trials and strengthen evidence based practice and decision making.

Registration. This project has been registered in the Core Outcome Measures in Effectiveness Trials (COMET) database and is part of the Cochrane Skin Group Core Outcomes Set Initiative (CSG-COUSIN).

Keywords. Clinical nursing research, Core outcome set, Domains, Incontinence-associated dermatitis, Measurement instruments, Nursing, Outcome assessment, Outcomes, Outcomes research

Why this study or review is needed

- Incontinence and the related complications such as incontinence-associated dermatitis are a burden for patients and their caregivers. Adequate prevention and treatment of incontinence-associated dermatitis are essential and recommended.
- Many leave-on products are available, but the studies on the efficacy and (cost-) effectiveness are difficult to compare because of the great variety in used outcomes and their measurements.
- To date, there is no consensus on which outcomes to measure in clinical effectiveness trials in incontinence-associated dermatitis research.

INTRODUCTION

Incontinence-associated dermatitis (IAD) is an inflammation of the skin that occurs when urine or stool comes into contact with perineal or perigenital skin (Gray *et al.* 2007). IAD affects all age groups and all healthcare settings but is mainly present in early childhood and old age (Farage *et al.* 2007, Folster-Holst *et al.* 2011). Other widely used terms for this skin condition in early childhood are perineal, diaper, or napkin dermatitis/rash. The term IAD is regarded as being more appropriate to be used in adults and this concept is increasingly recognised in clinical practice and research. The exact etiology of IAD is unclear but it is assumed that the interaction between increased skin surface wetness, increased skin surface pH, increased microbial loads, fecal proteases and lipases and mechanical factors like friction, weaken and damage the epidermal barrier leading to inflammation to full thickness wounds. Fungal infections are often associated with IAD (Farage *et al.* 2007).

Background

Prevention and treatment of IAD includes gentle skin cleansing and the application of topical leave-on products for protection and promotion of healing (e.g. 'barrier products') (Kottner and Beeckman 2015). Although numerous studies about prevention and treatment of IAD have been performed, the current knowledge is limited. One reason is the use of many different and sometimes ill-defined outcome parameters in clinical studies. The Cochrane review of skin care interventions (different topical skin care products, structured and unstructured skin care procedures and different methods and frequencies of application of topical skin care products) in the prevention and treatment of IAD in adults revealed a variety in reported outcomes (Beeckman et al. 2016). Comparing data and pooling results of clinical trials to be used in evidence based healthcare, can only be conducted if outcomes are comparable. Therefore a Core Outcome Set (COS) in IAD research needs to be developed.

A COS is a consensus-derived minimum set of outcomes to be assessed in clinical research. The agreed standardised set of outcomes should be measured and reported in all trials for a specific clinical area. However, a COS does not limit researchers to choose additional outcomes and measurements (Schmitt *et al.* 2014). Using identical outcomes across trials allows comparisons of results enhancing the value of evidence synthesis and reducing the risk of outcome reporting bias (Williamson et al. 2012b). A COS consists of two different levels, namely a core set of outcomes and a core set of measurements. Where a core set of outcomes will refer to 'what' to measure, a core set of measurements will refer to 'how' to measure (Prinsen et al. 2014, Schmitt et al. 2014). Each core set of outcomes must have at least one measurement instrument. Measurement instruments must be valid and reliable (Streiner and Kottner 2014). To reduce a perceived confusion in

terminology across disciplines (e.g. psychology, medicine) the Outcome Measures in Rheumatology (OMERACT) group proposed three concepts: truthful, discriminative and feasible (Boers *et al.* 1998). 'Truthful' means that the outcome measurement captures what it intends to and thus corresponds to the measurement property validity. 'Discriminative' means that the outcome measurement discriminates between disease states in a reliable way and therefore corresponds to the measurement criteria of 'reliability' and 'sensitivity to change'. 'Feasible' captures important aspects of outcome measurements beyond the classic psychometric properties such as interpretability, cost, availability, time requirements and practicability and depends on the setting (Boers *et al.* 2014b).

First formal methodological approaches for COS development have been published. More than twenty years ago the OMERACT was launched at a conference as a formal way to develop and discuss core outcomes in the specific health area of rheumatology (Clarke 2007). Since 1992 core sets for many rheumatologic conditions were developed, where patients were actively involved since 2002 (Boers *et al.* 2014b). The Harmonizing Outcome Measures for Eczema (HOME) project was founded in 2008 and developed a roadmap for the development and implementation of a COS for atopic eczema (Schmitt *et al.* 2014). The Core Outcome Measures in Effectiveness Trials (COMET) initiative was launched in 2010 to bring together researchers who are interested in the development and application of agreed standardised sets of outcomes COMET (COMET 2016a). The aim of COMET is threefold, namely (1) to collect relevant resources; (2) to facilitate the exchange of ideas and information and (3) to foster methodological research. Therefore, a searchable database of complete and ongoing projects in core outcome set development was established, next to a repository for project protocols. The COMET initiative also foresees in guidance on (1) developing and reporting core outcome sets, (2) integrating patient reported outcomes into core outcome sets and (3) obtaining funding to develop core outcome sets (COMET 2016a). Regarding skin related health domains, the international Cochrane Skin Group initiated the Core Outcomes Set Initiative (CSG-COUSIN) in 2014. It is considered as a research group, open for everyone interested in outcomes research and evidence-based dermatology to develop and implement core outcome sets (CSG-COUSIN 2016a).

During the development of a core set of outcomes and measurements, participation of stakeholders throughout the whole process is of utmost importance. The involvement of stakeholders can increase the number of ideas and perspectives, establish credibility, ensure relevance and meaning to different groups, identify concerns, barriers and controversies that would not have otherwise been considered, increasing transparency and dissemination (Boers *et al.* 2014a).

Irrespectively from the health domain or construct, the development and use of a COS is appropriate and highly recommended. Gargon *et al.* (2014) identified 198 published and ongoing COS development studies covering various areas of health, most commonly cancer, rheumatology, neurology, heart and circulation and dentistry and oral health (Gargon *et al.* 2014). This review shows that there has been a rapid increase in the development of COS over recent years. Despite the wide range of health areas, there are significant gaps in certain health areas providing future opportunities for COS developers. CONSIDER project is the first to develop a COS in the area of IAD.

THE STUDY

Aims

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

Methods

The project consists of several phases and steps including different research methods (scoping review and consensus study using Delphi procedure). The COS for IAD research project will consist of two levels, namely a core set of outcomes and a core set of measurements. Figure 1 shows an overview of the COS development and the phases and steps that will be completed.

Phase 1: Background, preparation and process

In this project several groups will be involved (Figure 2). The project team will establish the methods and will take final decisions. The International Steering Committee and panelists will guide the development of the COS. The separate category of 'both healthcare researcher and provider' in the group of panelists will be made because they might bring a perspective on core outcomes that may differ from that of people who perform only one of the two jobs. At least 100 experts will be invited to have a minimum of 80 experts completing all phases of the Delphi procedures, taking into account a response rate of 80%. In this project, more than one representative from each of following stakeholder groups will be involved: patients, healthcare researchers, healthcare providers and healthcare researchers who are also healthcare providers (Boers *et al.* 2014a). Stakeholders will be represented from at least three continents.

Phase 2: Developing of a core set of outcomes for IAD research

For the development of the core set of outcomes for IAD research two steps need to be completed: (1) the identification of existing outcomes and (2) a consensus study using Delphi procedure.

Step 1: Identification of existing outcomes

A list of outcomes will be generated based on a literature review, consultation of the International Steering Committee and patients (see Figure 3).

A systematic literature review will be conducted using a sensitive search filter to identify all possible outcomes, including rare endpoints and the patients' perspective (e.g. qualitative studies) (Williamson et al. 2012b). The search filter will cover the concept of IAD broadly (synonyms, incontinence- and dermatology related terms) and will be applied in the Cochrane Library, Pubmed, Web of Science and the Cumulative Index to Nursing & Allied Health Literature (CINAHL). References of studies included in the review will also be screened. All study designs (systematic and narrative reviews with or without meta-analyses, clinical trials, case series and qualitative research) will be included. There will be no restriction regarding the year of publication. Two reviewers will independently assess all records obtained. Studies focusing on adults aged ≥18 years with IAD or at risk, from any geographical location or skin colour will be included. Studies will be excluded based on following criteria: children, healthy volunteers and studies in languages other than English, French, German and Dutch. All outcomes will be extracted by one author and 10% by a second author after which the inter-rater agreement will be assessed. The exact actual wording of each obtained outcome and, if possible, the definition of the outcome, will be extracted in tables.

The International Steering Committee will be consulted to brainstorm about possible outcomes and existing conceptual frameworks. Next, 4 - 5 patients will be interviewed with the purpose of obtaining outcomes relevant for patients with IAD. The patients will be recruited via the wound network of the university hospital and incontinence patient associations. Final, outcomes will be classified into domains by the project team and reported back to the International Steering Committee which will result in a draft core set of outcomes.

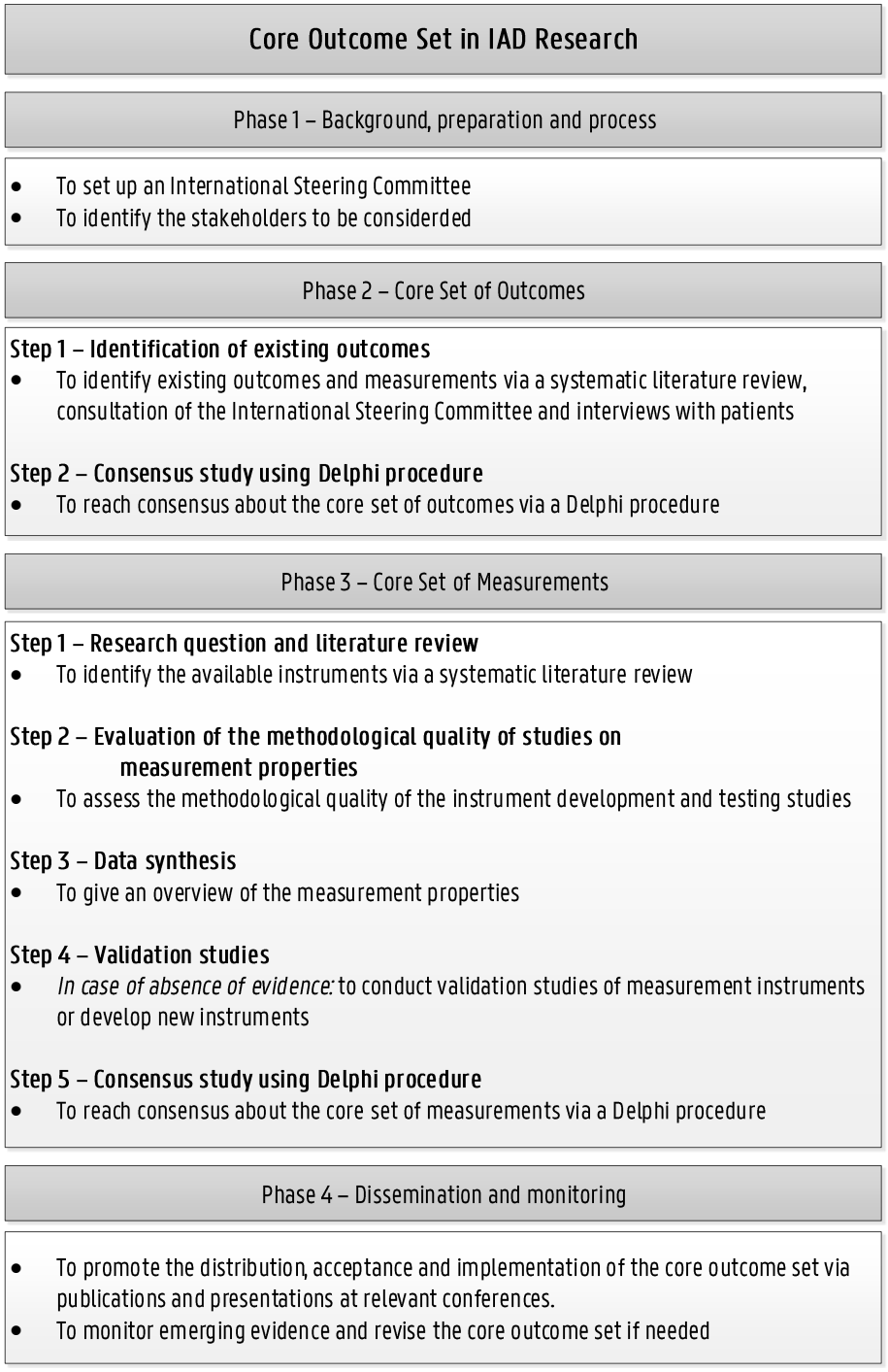


Figure 1 Project phases and steps

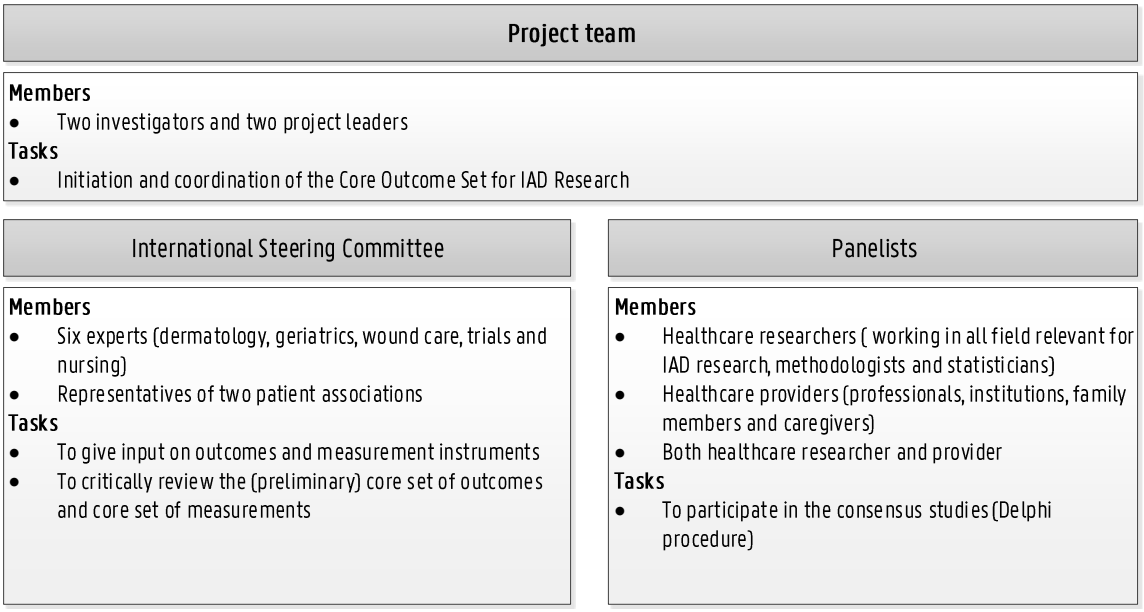


Figure 2 Project organisation

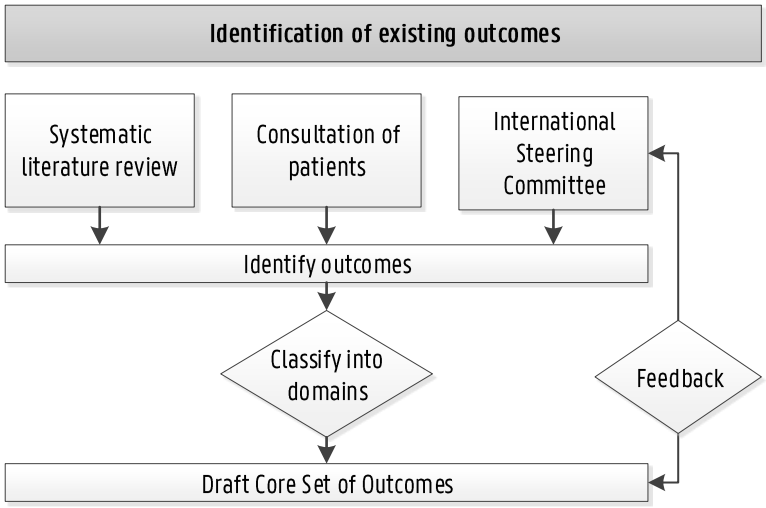


Figure 3 Identification of existing outcomes

Step 2: Consensus study using Delphi procedure

The draft core set of outcomes will be submitted to the panelists (see Figure 2), using a Delphi procedure (Figure 4). The Delphi procedure has two objectives: (1) to obtain consensus about a core set of outcomes and (2) to select those domains considered most important for which outcome measurements will be searched. An overview of the aims of the Delphi procedure per round can be found in Figure 5.

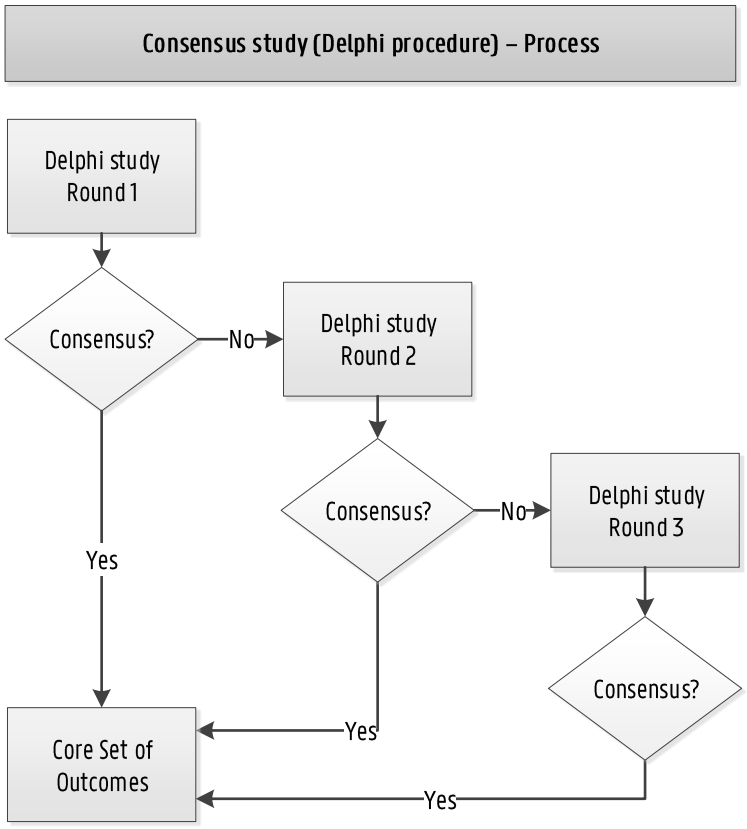


Figure 4 Flowchart process consensus study using Delphi procedure

The draft core set of outcomes will be presented to the panelists via an online survey. In this way, equal influence is given to all participants and it avoids an individual participant being influenced by the opinions of any other participant (Sinha *et al* 2011). At the start of the procedure, panelists will be reminded of the importance of completing the procedure and that anonymity will be assured. An email reminder will be send to stimulate completion of the survey. Non-responders who did not explicitly express their desire to opt-out, will be invited to participate in the following rounds (Sinha *et al* 2011).

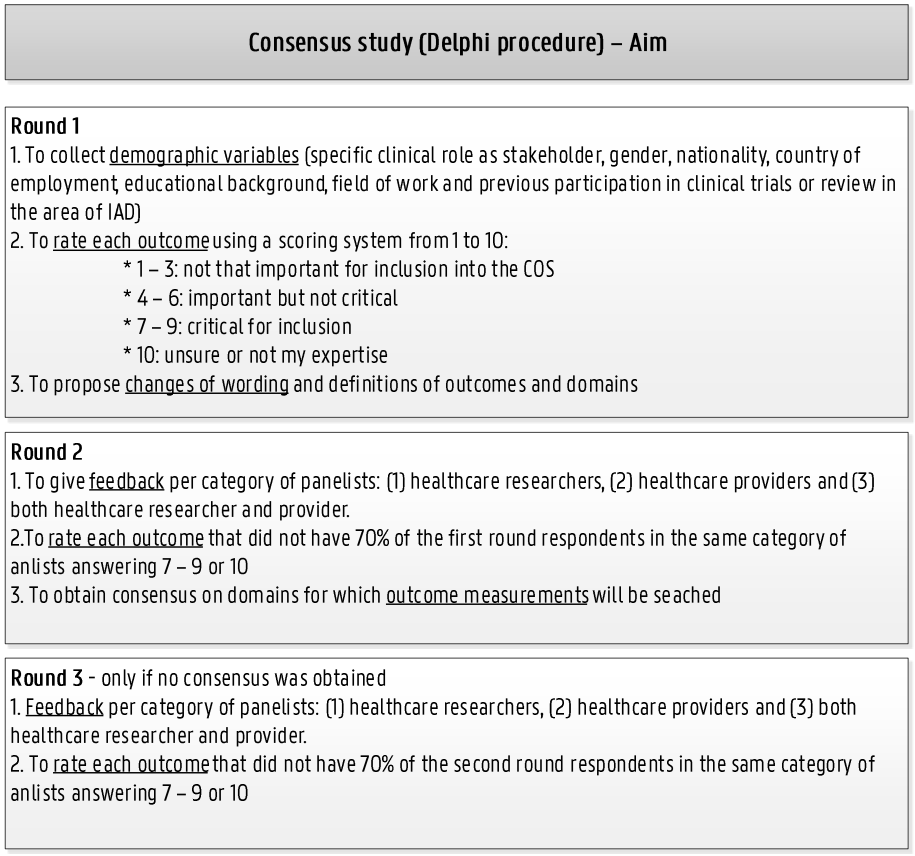


Figure 5 Aim consensus study using Delphi procedure

Phase 3: developing a core set of measurements for IAD research

For the development of the core set of measurements for IAD research five steps need to be completed (see Figure 1).

Step 1: Research question and literature review

The systematic literature review performed for the development of the core set of outcomes will identify instruments to measure the domain. If no instrument is available, a second search will be performed.

Step 2: Evaluation of the methodological quality of studies on measurement properties

The methodological quality of the instrument development and testing studies will be appraised. Therefore an additional systematic review will be carried out using a specific search filter in the following databases: the Cochrane Library, Pubmed, Web of Science and the Cumulative Index to Nursing & Allied Health Literature (CINAHL). References of studies included in the review will also be screened. An overview of the focus and the inclusion and exclusion criteria concerning the literature review can be found in Figure 6. The title and abstract

of the studies will be screened independently on the inclusion criteria by two reviewers. In case of different opinions, the two reviewers will make a decision based on discussion of the full text papers. The reason for exclusion will be documented. All discrepancies will be resolved by consensus or with a third reviewer (a member of the project team). Data extraction using data extraction tables will be performed by one author and 10% by a second author after which the inter-rater agreement will be assessed.

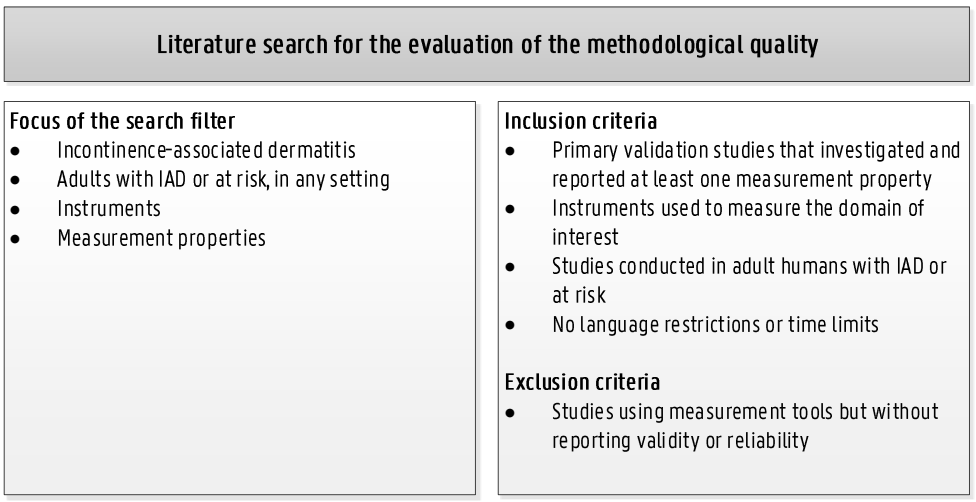


Figure 6 Literature search for the evaluation of the methodological quality

The methodological quality of studies on measurement properties will be assessed using the COSMIN checklist (Mokkink *et al.* 2013). This checklist includes 12 boxes and aims to: to evaluate general requirements (n=2), to evaluate the quality of the assessment of different measurement properties (reliability, validity and responsiveness) (n=9) and to evaluate the quality of a study on interpretability of a health-related patient-reported outcome (n=1). The methodological assessment of the included studies will be performed by two reviewers independently, resolving differences by consensus or with a third reviewer (a member of the project team).

Step 3: Data synthesis

For studies with excellent or good methodological quality, a detailed overview of measurement properties will be given using the COSMIN checklist in combination with criteria for good measurement properties developed by Terwee (2011). Aspects that will be extracted per measurement instrument (see Figure 7) are (1) the general characteristics of the instrument, (2) the characteristics of the study populations where the

measurement properties were assessed, (3) the results of the measurement properties of the instrument and (4) evidence on the feasibility of the instrument.

The final result, a core set of measurements, will be a selection of instruments that have proven to be truthful, discriminative and feasible (Boers *et al.* 2014b).

Step 4: Validation studies of measurement instruments or development of new instruments

A consensus discussion and voting with the International Steering Committee will be organised to determine what validation studies should be conducted in case of absence of evidence. For core outcomes without valid core outcome measurement instruments, new instruments should be developed in further research.

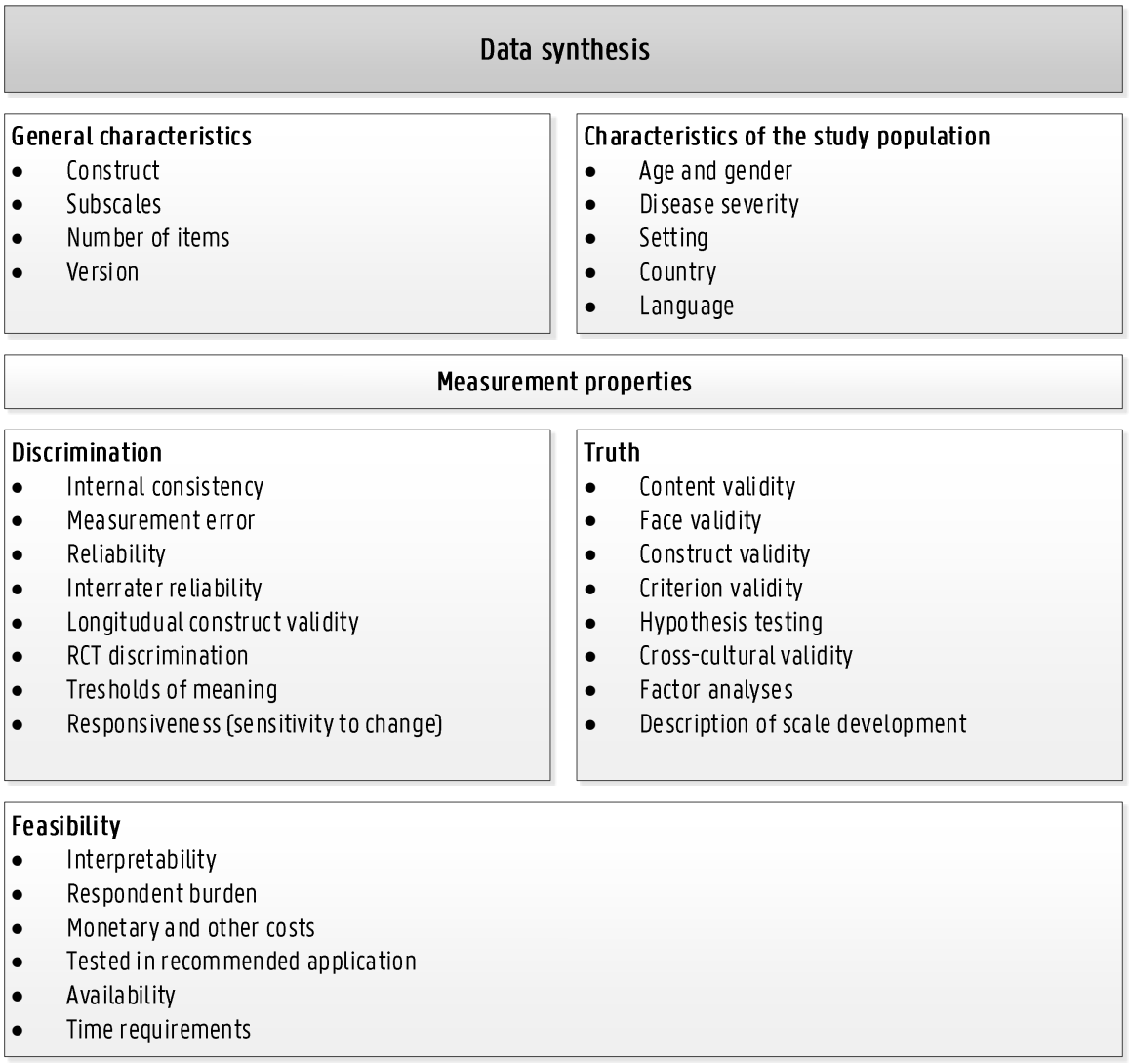


Figure 7 Data synthesis

Step 5: Consensus study using Delphi procedure

The draft core set of measurements for IAD research will be discussed in consultation with the International Steering Committee. They will be asked to concentrate on the clinical, patient-important and sensibility aspects of the instruments. Furthermore, they will be asked to complete the draft with possible missing instruments. The project team will adjust the list of core measurements, taking into account the input of the International Steering Committee. Next, a consensus with the panellists (see Figure 2) will be obtained via a Delphi procedure similar to the consensus study in the development of the core set of outcomes (Figure 4 & 5). The consensus study aims to obtain consensus about a core set of valid and reliable measurements. The previous steps, including the systematic review of measurement properties, will be used to inform the consensus process whether or not the individual outcome measurement instruments are suitable to assess the chosen core outcome.

Phase 4: Dissemination and monitoring

The distribution, acceptance and implementation of the core set of outcomes and measurements will be promoted via international publications and presentations at relevant conferences. The emerging evidence will be monitored with the aim to revise the core set of measurements if needed.

Ethical considerations

Research Ethics Committee approval was obtained by the Ethics review Committee (April, 2016). All individual participation will be voluntarily sought following the presentation of written information about the theoretical purposes of the study and how participation will strengthen clinical decision making, contributing to patient-centered healthcare and improved methodology of IAD research. Written informed consent will be obtained from all voluntary participants. Participants' information will be kept anonymous and confidential. Participants will be free to withdraw from the study at any point in time.

Validity and reliability / Rigour

Several aspects will be considered to assure the validity and reliability of this project. First, two researchers will carry out the entire project where some of the steps will be performed independently (e.g. screening of literature). Second, the perspective of all relevant stakeholders such as patients and their carers, healthcare providers, healthcare researchers will be included throughout the whole process of this project. Final, the members of the project team and International Steering Committee are all experts who have published extensively in the field of IAD.

DISCUSSION

Although numerous studies about prevention and treatment of IAD have been performed, there is a pronounced heterogeneity and a low comparability between studies. This is also related to the use of many different and sometimes ill-defined outcome parameters in clinical studies. This results in the difficulty to compare and pool the results and thus is unhelpful in clinical decision making. In this project, a core set of outcomes relevant for patients and their clinicians will be developed to be used in clinical IAD research. The use of a COS in clinical trials will decrease outcome reporting bias and allow comparisons across trials. The core set of measurement instruments will further enhance the validity and reliability of the used outcomes and the comparability. This would enhance interpreting the observed effects and strengthen informed decision making about treatment and evidence-based healthcare decisions. The strength of this project is the international input of relevant experts to enhance to generalizability of the core outcome set and the patient involvement. CONSIDER project is embedded in the CSG-COUSIN, a working group in the international Cochrane Skin Group (CSG-COUSIN 2016b).

Limitations

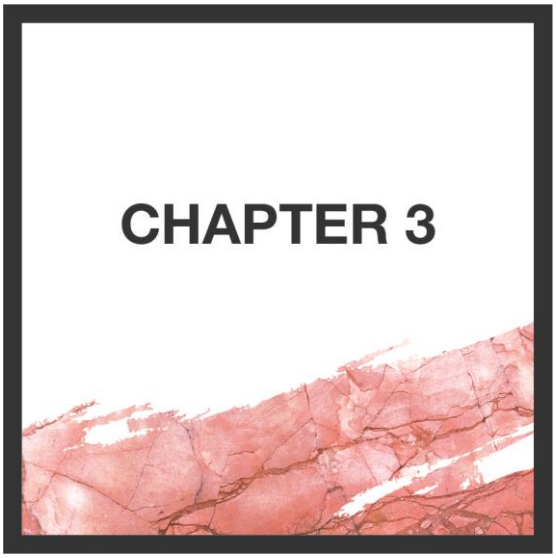
Few methodological guidelines are available, resulting in the absence of a reference standard to develop a COS. Different core outcome sets for specific pathologies have been developed, but many details are still unclear. In general it is agreed that the input of relevant stakeholders is crucial in the development of a COS. Therefore, international experts will be involved throughout this whole process. The condition that the stakeholder must be capable to communicate in English through Skype or e-mail could create bias. Since patients with IAD or at risk are mainly from an older population, it could be difficult to communicate adequately with them. This would possible lead to missing information.

CONCLUSION

IAD is a burden for patients and their caregivers. Prevention and treatment of IAD are essential but often expensive. Many skin care products and procedures are available, but the studies on the efficacy and (cost-) effectiveness have been difficult to compare because of the heterogeneity in used outcome measurements. A COS, a consensus-derived minimum set of outcomes and measurements, used in clinical IAD research would improve clinical research, clinical practice and patient outcome. The use of a COS would standardise outcomes, enhance comparison between trials, diminish outcome reporting bias and enhance clinical informed decision making.

Chapter based on:

VAN DEN BUSSCHE K., KOTTNER J., BEELE, H., DE MEYER D., DUNK AM., ERSSER S., LANGE T., PETROVIC M., SCHOONHOVEN L., SMET S., VAN DAMME N., VERHAEGHE S., VAN HECKE A. & BEECKMAN D. (2018) Core Outcome Domains in incontinence-associated dermatitis research. *Journal of Advanced Nursing* [ePub ahead of print]



Core Outcome Set in IAD 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 and 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, IAD-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

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 characterised 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. 2009a, 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 of 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 standardisation 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 emphasise 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 and 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.

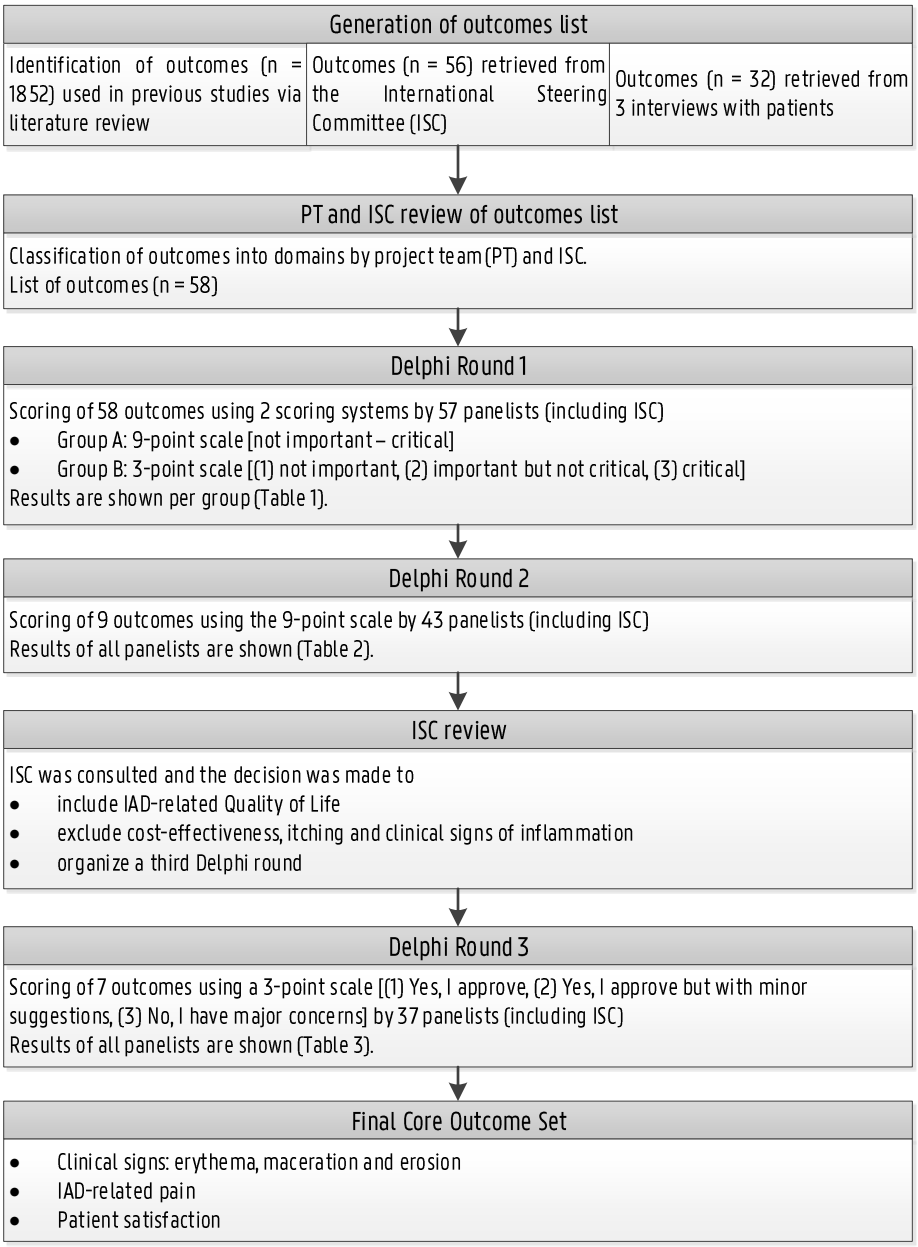


Figure 1. COS domain development process

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. The ISC received information regarding the study objectives and two questions to be discussed during the individual face-to-face meeting with one of the researchers (KV) in advance: (1) 'which outcomes would you define when designing a clinical study to test interventions to prevent and/or treat IAD?', and (2) 'which outcomes are you most interested in when reading research about the prevention and/or treatment of IAD?'. 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. The unstructured interviews conducted by one of the researchers (KV) gave in-depth information on individual values, beliefs and outcomes of importance for these groups. Following data was collected for each patient: age, status of incontinence, and history of IAD.

A 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. A detailed description of the search strategy can be found in Appendix 1.

The project team discussed outcomes addressing similar concepts and classified these using the OMERACT framework (Boers et al. 2014a). The origin of the outcome was not taken into account when restructuring the long lists of outcomes according to the OMERACT framework. 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 within 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 summarise the demographic characteristics and the responses of the panellists for each Delphi round.

After the last round the 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 in which participation will strengthen clinical decision-making, contribute to patient-centered healthcare, 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 experts who have published extensively 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 2. Socio-demographic characteristics, disciplines of expertise and experience of the panellists (presented per group and per round), can be found in Table 1.

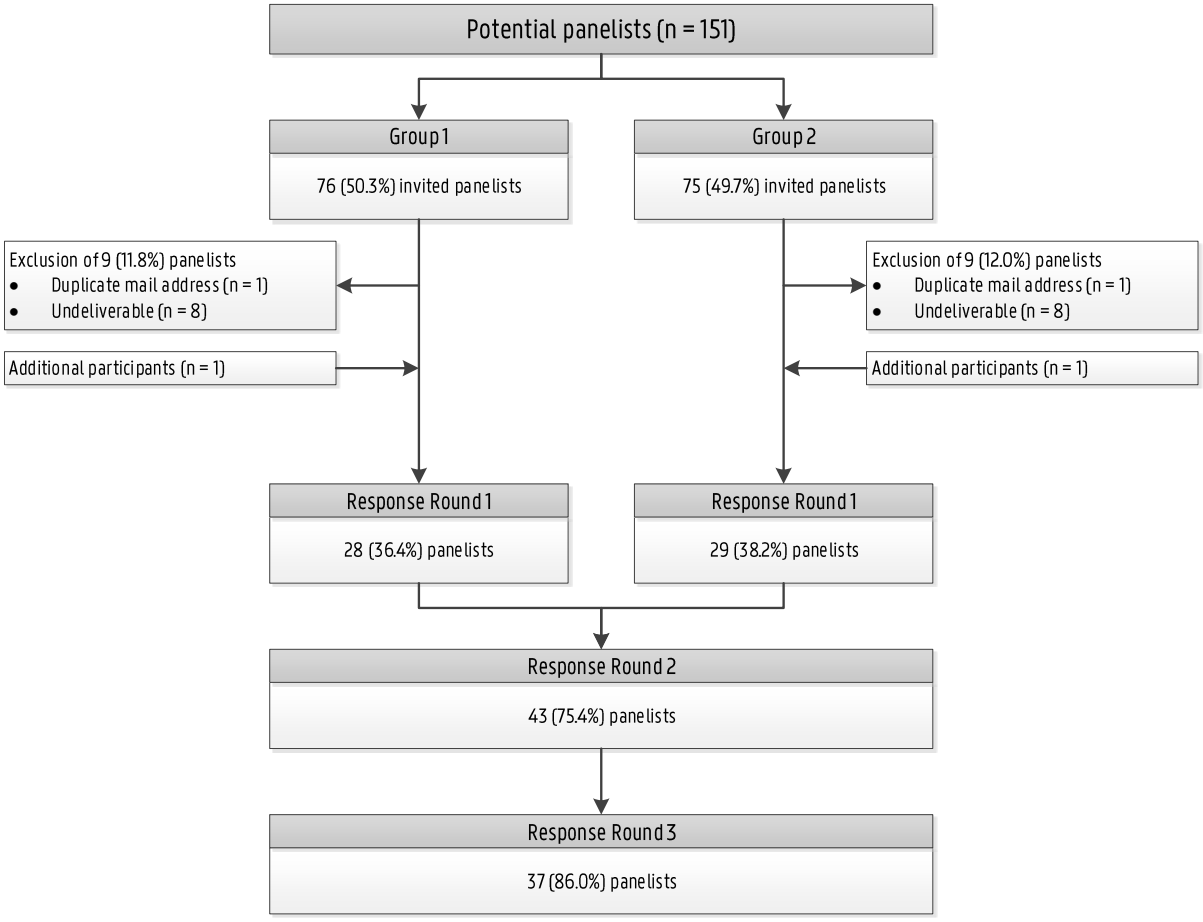


Figure 2. Flowchart of participation rate per round

Table 1. Characteristics of the panelists per round of the Delphi study

	Round 1		Round 2	Round 3
	Group 1[†]	Group 2[‡]		
n (%)	n = 28	n = 29	n = 43	n = 37
Country				
Australia	3 (10.7)	1 (3.4)	3 (7)	3 (8.1)
Austria	2 (7.1)	4 (13.8)	5 (11.6)	5 (13.5)
Belgium	8 (28.6)	4 (13.8)	10 (23.3)	6 (16.2)
Canada	1 (3.6)	0 (0.0)	1 (2.3)	1 (2.7)
Chile	0 (0.0)	1 (3.4)	1 (2.3)	1 (2.7)
Czech Republic	0 (0.0)	1 (3.4)	1 (2.3)	1 (2.7)
France	0 (0.0)	1 (3.4)	1 (2.3)	0 (0.0)
Italy	1 (3.6)	0 (0.0)	1 (2.3)	1 (2.7)
Germany	0 (0.0)	1 (3.4)	1 (2.3)	1 (2.7)
Norway	0 (0.0)	1 (3.4)	1 (2.3)	1 (2.7)
South Africa	2 (7.1)	0 (0.0)	2 (4.7)	2 (5.4)
Spain	0 (0.0)	1 (3.4)	1 (2.3)	1 (2.7)
Sweden	1 (3.6)	2 (6.9)	2 (4.7)	2 (5.4)
Thailand	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Turkey	1 (3.6)	0 (0.0)	1 (2.3)	1 (2.7)
United Kingdom	5 (17.9)	4 (13.8)	6 (14.0)	5 (13.5)
United States	3 (10.7)	8 (27.6)	6 (14.0)	6 (16.2)
Sex				
Female	21 (75)	21 (72.4)	31 (72.1)	27 (73.0)
Age				
mean (SD) years	50.0 (8.7)	50.7 (8.2)	49.7 (8.8)	49.6 (8.9)
Education				
High school	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
College degree	1 (3.6)	1 (3.4)	2 (4.7)	2 (5.4)
Bachelor degree	6 (21.4)	2 (6.9)	7 (16.3)	5 (13.5)
Master degree	9 (32.1)	9 (31.0)	10 (23.3)	10 (27.0)
Doctoral degree	11 (39.3)	15 (51.7)	23 (53.5)	19 (51.4)
Other	0 (0.0)	2 (6.9)	1 (2.3)	1 (2.7)
Current work setting				
Local hospital	4 (14.3)	2 (6.9)	2 (4.7)	1 (2.7)
Teaching / university hospital	10 (35.7)	13 (44.8)	20 (46.5)	18 (48.6)
Community care	1 (3.6)	0 (0.0)	1 (2.3)	1 (2.7)
Education	5 (17.9)	4 (13.8)	6 (14.0)	6 (16.2)
Clinical research	1 (3.6)	2 (6.9)	3 (7.0)	3 (8.1)
Industry / commercial	5 (17.9)	4 (13.8)	7 (16.3)	5 (13.5)
Other	0 (0.0)	2 (6.9)	1 (2.3)	1 (2.7)
Missing	2 (7.1)	0 (6.9)	3 (7.0)	2 (5.4)

Role §				
Clinician (nurse)	14 (50)	15 (51.7)	20 (46.5)	18 (48.6)
Clinician (medical doctor)	2 (7.1)	2 (6.9)	4 (9.3)	2 (5.4)
Clinician (other)	0 (0.0)	2 (6.9)	2 (4.7)	1 (2.7)
Clinical researchers	6 (21.4)	9 (31)	12 (27.9)	13 (35.1)
Educator	14 (50)	18 (62.1)	27 (62.8)	26 (7.03
Research and development	12 (42.9)	13 (44.8)	20 (46.5)	17 (45.9)
Industry	3 (10.7)	1 (3.4)	4 (9.3)	3 (8.1)
Other	2 (7.1)	2 (6.9)	2 (4.7)	2 (5.4)
Field of work §				
General medicine	2 (7.1)	2 (6.9)	2 (4.7)	2 (5.4)
Nursing	15 (53.6)	21 (72.4)	28 (65.1)	27 (73.0)
Dermatology	4 (14.3)	6 (20.7)	9 (20.9)	5 (13.5)
Wound care	17 (60.7)	18 (62.1)	26 (60.5)	21 (56.8)
Psychology	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Geriatrics	4 (14.3)	4 (13.8)	5 (11.6)	5 (13.5)
Education	9 (32.1)	16 (55.2)	21 (48.8)	20 (54.1)
Methodology / statistics	2 (7.1)	2 (6.9)	3 (7.0)	2 (5.4)
Intensive care	5 (17.9)	5 (17.2)	6 (14.0)	6 (16.2)
Long-term care	1 (3.6)	4 (13.8)	3 (7.0)	3 (8.1)
Rehabilitation Care	0 (0.0)	2 (6.9)	2 (4.7)	1 (2.7)
Other	3 (10.7)	6 (20.7)	5 (11.6)	3 (8.1)
Professional experience				
mean (SD) years	26.1 (10.2)	25.31 (9.6)	25.6 (10.0)	25.6 (10.4)
IAD-related activities §				
Clinical trial	8 (28.6)	10 (34.5)	16 (37.2)	14 (37.8)
Quality improvement project	12 (42.9)	19 (65.5)	24 (55.8)	21 (56.8)
Education	17 (60.7)	22 (75.9)	31 (72.1)	29 (78.4)
Other	8 (28.6)	9 (31.0)	10 (23.3)	7 (18.9)
IAD publication				
Yes	11 (39.3)	18 (62.1)	24 (55.8)	23 (62.2)
No	17 (60.7)	11 (37.9)	19 (44.2)	14 (37.8)
Direct patient care				
Yes	17 (60.7)	19 (65.5)	27 (62.8)	24 (64.9)
No	11 (39.3)	10 (34.5)	16 (37.2)	13 (35.1)

IAD, incontinence-associated dermatitis; SD, standard deviation; Education, highest degree; IAD publication, if the panelist has published IAD-related articles. † 3-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]. ǂ 9-point scale [from 'not important for inclusion' to 'critical, should be included in a COS for IAD']. § Multiple answers possible.

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 3. 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.

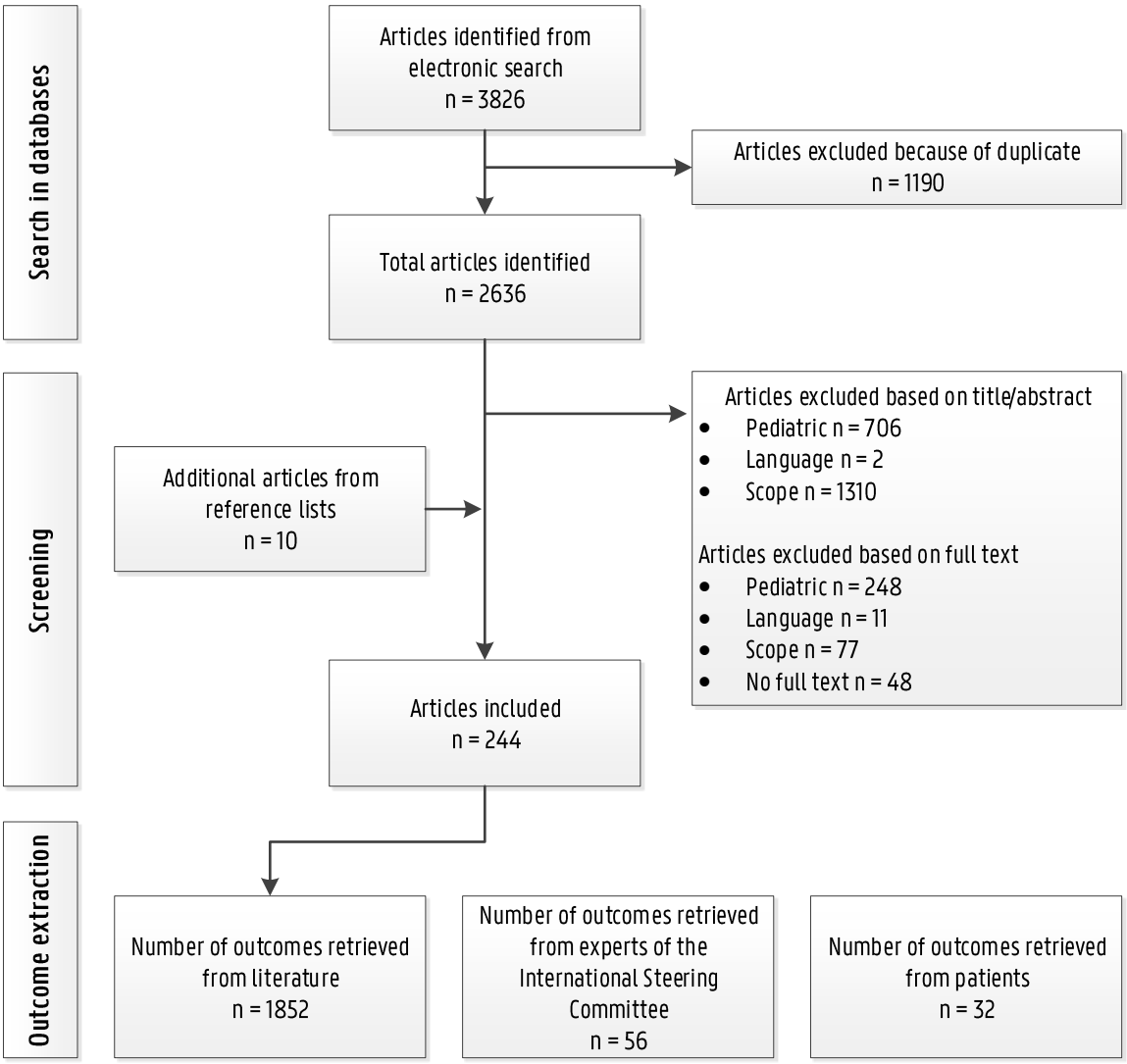


Figure 3. Results of search strategy and outcome extraction

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/economical impact', and 40 in 'pathophysiological manifestations'. The list used at the start of the Delphi study is presented in Table 2.

Table 2. Draft core set of outcomes – Delphi round 1

Core Area	Domain	Examples
Life Impact		
	Burden of care from caregiver's perspective	
	Burden of care from patient perspective	
	Health-related Quality of Life	
	Independence (IAD related)	
	Pain	How much a patient hurts at the affected area, magnitude of the pain experience, frequency of pain, pain quality
	Physical comfort	
	Physical functioning	
	Physical well-being	
	Psychological impact of the disease	Anxiety, depression, stress, embarrassment, dignity, ignorance resulting in unrest and panic, sense of dependency, dysfunctional beliefs, negative thoughts, cognitive biases
	Quality of Life (general)	
	Quality of Life (IAD related)	
	Satisfaction with intervention from by caregiver's perspective	Acceptability, preference, amount of patient handling, patient care load, staff time
	Satisfaction with intervention from patient perspective	Satisfaction, acceptability, appreciation, tolerance, benefit, preference, feeling refreshed afterwards, confidence in dressing's effectiveness, understandability, comfort
	Self-reported symptoms	Itching/pruritus, stinging, tenderness of intact skin, tightness, tingling or burning, pain
	Sleep (IAD related)	Sleep disturbance
Resource use/ economical impact		
	Caregivers' work productivity	Caregivers' time to perform the intervention
	Cost-effectiveness	
	Costs	Direct costs, indirect costs, visits for primary and secondary care, laboratory tests, days of admission to a hospital, medications, skin care products,...
Pathophysiological manifestations		
	Bleeding	
	Bullae	Blisters
	Clinical characteristics of skin surrounding IAD area assessed by caregiver	Erythema or maceration

Clinical signs of inflammation / colonisation / infection of IAD area assessed by caregiver	Satellite lesions, a white scaling of the skin, discolouration, maceration, shiny appearance, swelling, inflammatory response, oedema, (purulent) exudate, shiny appearance, slough present in the wound bed (yellow/brown/greyish), rubor, calor, dolor, tumor
Cracking	Cracks, fissures
Crusting	
Denudation	Denudement, loss of superficial skin layers
Desquamation	
Discolouration	
Dryness	Xerosis
Erosion	
Erythema	Blanchable erythema, change in erythema, changes in the red components of colour, non-exuding infiltrated erythema, red skin, redness
Excoriation	
Exudate	Exudation, exuding infiltrated erythema, infiltrated erythema (dry or exuding), serous exudate
Glossy/shiny appearance	
Infection confirmed by culture	
Lichenification	
Maceration	
Macules	
Maculopapular rash	
Necrosis	
Nodules	
Oedema	Edema
Oozing	
Papules	
Pigmentation	Hyperpigmentation, hypopigmentation
Purulent exudate	
Pustules	
Roughness	
Satellite lesions	
Scabbing	
Scaling	Scales, flaky appearance
Scratch marks	Scratching
Shiny appearance	
Skin barrier properties	Transepidermal water loss, stratum corneum hydration, pH, or others
Skin loss	
Slough present in the wound bed (yellow/brown/greyish)	
Swelling	
Vesicles	Blisters
White scaling	

IAD, incontinence-associated dermatitis.

Delphi round 1

The first round was performed between April 7 to May 7, 2017. The results are presented in Table 3. 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 emphasised 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' within 'IAD-related Quality of Life' because of overlap, (3) incorporate symptoms such as 'burning' and 'stinging' (as part of 'self-reported symptoms') within 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' within '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.

Table 3. Ratings of 58 outcome domains in the first Delphi round – 57 panellists

Core Area and Domain	Group 1[†] n = 28				Group 2[‡] n = 29				Result[¶]
N (%)	Not important	Important	Critical	Don't know[§]	Not important	Important	Critical	Don't know[§]	in or out
Life Impact									
Burden of care from caregiver's perspective	1 (3.8)	13 (50.0)	12 (46.2)	2	2 (6.8)	4 (13.7)	23 (79.3)	0	Out
Burden of care from patient perspective	0 (0)	4 (14.8)	23 (85.2)	1	2 (7.4)	1 (3.7)	24 (88.8)	0	In
Health-related Quality of Life	2 (7.1)	7 (25.0)	19 (67.9)	0	3 (10.3)	1 (3.4)	25 (86.2)	0	Out
Independence (IAD related)	3 (11.1)	11 (40.7)	13 (48.1)	1	1 (3.7)	7 (25.9)	19 (70.3)	2	Out
Pain	0 (0)	4 (14.8)	23 (85.2)	1	1 (3.4)	0 (0)	28 (96.6)	0	In
Physical comfort	0 (0)	7 (25.0)	21 (75.0)	0	2 (7.1)	3 (10.7)	23 (82,2)	1	In
Physical functioning	4 (14.3)	8 (28.6)	16 (57.1)	0	3 (10.8)	8 (28.5)	17 (60.7)	1	Out
Physical well-being	3 (11.5)	9 (34.6)	14 (53.8)	2	3 (10.2)	10 (34.4)	16 (55.1)	0	Out
Psychological impact of the disease	2 (7.1)	9 (32.1)	17 (60.7)	0	2 (6.9)	8 (27.6)	19 (65.5)	0	Out
Quality of Life (general)	5 (17.9)	10 (35.7)	13 (46.4)	0	4 (13.8)	9 (31)	14 (48.3)	2	Out
Quality of Life (IAD related)	3 (11.1)	3 (11.1)	21 (77.8)	1	1 (3.6)	2 (7.2)	25 (89.3)	1	In
Satisfaction with intervention from by caregiver's perspective	3 (11.1)	12 (44.4)	12 (44.4)	1	3 (10.8)	3 (10.8)	22 (78.6)	1	Out
Satisfaction with intervention from patient perspective	1 (3.7)	7 (25.9)	19 (70.4)	1	2 (7.2)	1 (3.6)	25 (89.2)	1	In
Self-reported symptoms	1 (3.6)	6 (21.4)	21 (75.0)	0	0 (0)	1 (6.8)	27 (93.1)	0	In
Sleep (IAD related)	4 (14.3)	13 (46.4)	11 (39.3)	0	3 (10.8)	7 (25)	18 (64.3)	1	Out
Resource use /economical impact									
Caregivers' work productivity	4 (16.0)	13 (52.0)	8 (32.0)	2	4 (14.3)	8 (32.2)	15 (53.5)	1	Out
Cost-effectiveness	0 (0.0)	19 (29.6)	27 (70.4)	1	2 (7.4)	4 (14.8)	21 (77.8)	2	In
Costs	2 (7.4)	9 (33.3)	16 (59.3)	1	3 (10.3)	7 (24.1)	19 (65.4)	0	Out
Pathophysiological manifestations									
Bleeding	6 (24.0)	7 (28.0)	12 (48.0)	1	4 (14.8)	5 (18.5)	18 (66.6)	1	Out

Bullae	5 (20.0)	7 (28.0)	13 (52.0)	1	2 (8.4)	5 (20.8)	17 (70.8)	4	Out
Clinical characteristics of skin surrounding IAD area assessed by caregiver	1 (3.8)	8 (30.8)	17 (65.4)	2	1 (4.0)	5 (20.0)	19 (76)	3	Out
Clinical signs of inflammation / colonisation / infection of IAD area assessed by caregiver	0 (0.0)	6 (23.1)	20 (76.9)	2	2 (7.6)	2 (11.5)	21 (80.8)	2	In
Cracking	5 (19.2)	12 (43.2)	9 (34.6)	2	3 (12.0)	5 (20.0)	17 (68.0)	3	Out
Crusting	7 (26.9)	10 (38.5)	9 (34.6)	2	4 (15.4)	6 (16.0)	16 (61.5)	2	Out
Denudation	2 (8.0)	4 (16.0)	19 (76.0)	1	2 (7.6)	1 (3.8)	23 (88.4)	2	In
Desquamation	6 (24.0)	8 (32.0)	11 (44.0)	2	4 (15.3)	2 (7.7)	17 (65.4)	2	Out
Discolouration	5 (19.2)	7 (26.9)	14 (53.8)	0	2 (8.4)	5 (20.9	17 (70.8)	4	Out
Dryness	5 (19.2)	11 (42.3)	10 (38.5)	0	4 (16.0)	5 (20.0)	16 (64.0)	3	Out
Erosion	1 (4.0)	6 (24.0)	18 (72.0)	1	4 (16.0)	2 (8.0)	19 (76.0)	3	In
Erythema	1 (3.8)	3 (11.5)	22 (84.6)	0	1 (4.0)	2 (8.0)	22 (88.0)	3	In
Excoriation	5 (20.8)	7 (29.2)	12 (50.0)	2	5 (20.0)	6 (24.0)	14 (56.0)	3	Out
Exudate	4 (15.4)	7 (26.9)	15 (57.7)	0	2 (7.6)	5 (19.2)	19 (73.1)	2	Out
Glossy/shiny appearance	5 (19.2)	10 (38.5)	11 (42.3)	0	2 (6.8)	4 (13.7)	20 (68.9)	2	Out
Infection confirmed by culture	4 (16.0)	7 (28.0)	14 (56.0)	1	5 (19.1)	5 (19.2)	16 (61.6)	2	Out
Lichenification	9 (40.9)	11 (50.0)	2 (9.1)	4	7 (26.9)	8 (30.7)	11 (42.3)	2	Out
Maceration	1 (3.8)	4 (15.4)	21 (80.8)	0	1 (3.8)	4 (15.4)	21 (80.8)	2	In
Macules	7 (33.3)	10 (47.6)	4 (19.0)	4	5 (20.0)	9 (36.0)	11 (44.0)	3	Out
Maculopapular rash	4 (18.2)	10 (45.5)	8 (36.4)	4	3 (12.5)	6 (25.0)	15 (62.5)	4	Out
Necrosis	9 (37.5)	7 (29.2)	8 (33.3)	2	6 (25)	6 (25)	12 (49.9)	4	Out
Nodules	10 (43.5)	12 (52.2)	1 (4.3)	3	12 (50.0)	8 (33.3)	4 (16.7)	4	Out
Oedema	5 (19.2)	13 (50.0)	8 (30.8)	0	4 (16.0)	5 (20.0)	16.0 (64.0)	3	Out
Oozing	7 (29.2)	11 (45.8)	6 (25.0)	2	5 (21.7)	5 (21.7)	13 (56.4)	5	Out
Papules	10 (41.7)	10 (41.7)	4 (16.7)	2	5 (20.0)	4 (16.0)	16 (64.0)	3	Out
Pigmentation	10 (38.5)	13 (50.0)	3 (11.5)	0	3 (12.5)	11 (45.8)	10 (41.7)	4	Out
Purulent exudate	9 (34.6)	8 (30.8)	9 (34.6)	0	5 (20.0)	8 (32.0)	12 (48.0)	3	Out
Pustules	10 (38.5)	6 (23.1)	10 (38.5)	0	3 (12.0)	3 (12.0)	19 (76.0)	3	Out

Roughness	12 (48.0)	11 (44.0)	2 (8.0)	1	9 (36.0)	9 (36.0)	7 (28.0)	3	Out
Satellite lesions	2 (7.7)	8 (30.8)	16 (61.5)	0	1 (3.8)	3 (11.4)	22 (84.6)	2	Out
Scabbing	10 (40.0)	12 (48.0)	3 (12.0)	1	4 (16.7)	9 (37.5)	11 (45.8)	4	Out
Scaling	10 (40.0)	10 (40.0)	5 (20.0)	1	4 (16.0)	9 (44.0)	12 (48.0)	3	Out
Scratch marks	10 (38.5)	12 (46.2)	4 (15.4)	0	7 (26.9)	11 (42.2)	8 (30.7)	2	Out
Shiny appearance	6 (23.1)	12 (46.2)	8 (30.8)	0	4 (15.3)	6 (23.1)	16 (61.5)	2	Out
Skin barrier properties	4 (16.0)	8 (32.0)	13 (52.0)	1	4 (16.7)	1 (4.2)	19 (79.1)	4	Out
Skin loss	1 (3.8)	4 (15.4)	21 (80.8)	0	1 (4.0)	2 (8.0)	22 (88.0)	3	In
Slough present in the wound bed (yellow / brown / greyish)	7 (26.9)	11 (42.3)	8 (30.8)	0	5 (19.2)	6 (23.0)	15 (57.7)	2	Out
Swelling	7 (26.9)	9 (34.6)	10 (38.5)	0	5 (20.3)	6 (25.0)	13 (54.2)	4	Out
Vesicles	4 (16.0)	10 (40.0)	11 (44.0)	1	4 (16.0)	5 (20.0)	16 (64.0)	3	Out
White scaling	7 (33.3)	12 (571)	2 (9.5)	5	10 (45.4)	3 (13.6)	9 (41.9)	6	Out

IAD, incontinence-associated dermatitis. † 3-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]. ‡ 9-point scale [from 'not important for inclusion' to 'critical, should be included in a COS for IAD']. § Don't know: 'I can't rate the importance of the outcome because I don't know the outcome'. ¶ 70% of panelists in both groups rate the outcome as 'critical for inclusion'.

Delphi round 2

The second round was performed between June 20 to July 4, 2017. The results are presented in Table 4. 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', 'maceration', and 'pain'). After point-by-point discussion of both the quantitative and the additional remarks of the panelists with the project team, it was decided to consult the ISC.

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 summarise 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 (1) exclude 'cost-effectiveness and 'pain', (2) include 'IAD-related Quality of Life', (3) change the outcome 'clinical signs of inflammation' to 'erythema' due to the overlap with the included domains 'pain' and 'maceration', and (4) 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 28 to September 10, 2017. The ratings of the seven outcome domains are presented in Table 5. 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'.

Table 4. Ratings of 9 outcome domains in the second Delphi round – 43 panellists

Outcome domain and definition	*n (%)*	Not important*	Important	Critical	Result‡
1. Clinical signs of inflammation **Clinical signs of inflammation** is defined as the presence of dolor (pain), rubor (erythema), calor (warmth), tumor (edema/swelling), and function lesa (disturbed skin barrier) (Schultz et al. 2003).		1 (2.3)	3 (7.0)	39 (90.8)	In
2. Clinical signs of infection **Clinical signs of infection** is defined as the presence of nonhealing, pain, increased wound size, warmth, white scaling of the skin (suggesting a fungal infection), satellite lesions (pustules surrounding the lesion, suggesting a *Candida albicans* fungal infection), slough visible in the wound bed (yellow/brown/greyish), a green appearance within the wound bed (suggesting a bacterial infection with *Pseudomonas aeruginosa*), increased exudate levels, purulent exudate (pus), or a shiny appearance of the wound bed due to the presence of replicating microorganisms within the wound and the presence of injury to the host (adapted from Schultz et al., 2003).		3 (6.9)	3 (6.9)	37 (86.1)	In
3. Cost-effectiveness **Cost-effectiveness** is defined as the ratio of the cost of the intervention to the health effects of the intervention (Gold 1996).		2 (4.6)	14 (32.7)	27 (62.8)	Out
4. Erosion **Erosion** is defined as the loss of either a portion or the entire epidermis (Nast et al. 2016).		1 (2.3)	3 (7.0)	39 (90.7)	In
5. IAD-related Quality of Life **IAD-related Quality of Life** is defined as physical, material, social, and emotional wellbeing and comfort compromised by the presence of IAD and its associated care by (in)formal caregivers (Felce and Perry 1995).		1 (2.3)	13 (30.3)	29 (67.5)	Out
6. Itching **Itching** is defined as the unpleasant cutaneous sensation which provokes the desire to scratch (Ständer et al. 2007).		5 (11.7)	13 (30.3)	25 (58.2)	Out
7. Maceration **Maceration** is defined as the softening and subsequent breakdown of skin characterised by a whitened appearance and		3 (7.0)	3 (6.9)	37 (86.1)	In

swelling caused by prolonged exposure to moisture (Ichikawa-Shigeta et al. 2014, Mugita et al. 2015).				
8. Pain **Pain** is defined as the magnitude and frequency of how much a patient hurts at the affected area. Pain can be expressed by the patient as stinging, tingling of burning.	0 (0.0)	5 (11.7)	38 (88.4)	In
9. Patient satisfaction **Patient satisfaction** is defined as the degree to which the individual regards the healthcare service or product (the intervention) or the manner in which it is delivered by the provider as useful, effective, or beneficial [NCBI MeSH term definition, (Medicine 2016)]	3 (7.0)	6 (13.9)	34 (79.1)	In

IAD, incontinence-associated dermatitis. † 9-point scale [from 'not important for inclusion' to 'critical, should be included in a COS for IAD']. ‡ 70% of panelists rate the outcome as 'critical for inclusion'.

Table 5. Ratings of 7 outcome domains in the third Delphi round – 37 panellists

Outcome domain and definition	*n(%)*	Yes, I approve	Yes, I approve but with minor suggestions	No, I have major concerns	Result
1. Erythema **Erythema** is defined as redness of the skin. A variety of tones of redness may be present. In patients with darker skin tones, the skin may be paler or darker than their normal skin colour, or purple.		34 (91.9)	3 (8.1)	0 (0.0)	In
2. Erosion **Erosion** is defined as the loss of either a portion or either the entire epidermis (Nast et al. 2016).		32 (86.5)	5 (13.5)	0 (0.0)	In
3. Maceration **Maceration** of the skin is defined as the softening of the epidermis and dermis characterised by a whitened appearance and swelling caused by prolonged exposure to urine and faeces (Ichikawa-Shigeta et al. 2014, Mugita et al. 2015).		27 (73.0)	9 (24.3)	1 (2.7)	In
4. IAD related pain **IAD related pain** is defined as a symptom that is subjectively expressed by the patient. It composes of both the magnitude and the frequency of how much at the affected area hurts. Pain can be expressed as non-verbal sounds (e.g. crying), vocal complaints of pain (e.g. that hurts), facial expressions (e.g. grimaces), protective body movements or postures (e.g. bracing).		29 (78.4)	8 (21.6)	0 (0.0)	In
5. Major colonization and infection of IAD **Major colonization and infection of IAD** can manifest both loco-regional and/or systemically: ▪ *Loco-regional signs of major colonization of IAD* are (increased) malodor, increased wound size, increased exudate levels, purulent exudate (pus), slough visible in the wound bed (yellow/brown/greyish/green), and shiny appearance of the wound bed (friable granulation tissue). ▪ *Loco-regional signs of microbiological infection of IAD* are rubor (redness), calor (increased localised warmth), dolor (increased and excessive level pain), and tumor (increased edema/swelling). ▪ *Loco-regional signs of bacterial infection of IAD* include (increased) malodor, increased wound size, increased exudate levels, purulent exudate (pus), slough visible in		20 (54.1)	11 (29.7)	6 (16.2)	Out

the wound bed (yellow/brown/greyish/green), and shiny appearance of the wound bed (friable granulation tissue). ▪ *Loco-regional signs of fungal infection of IAD* are white scaling on the edge of the lesion, and satellite lesions (pustules surrounding the lesion). ▪ *Signs of systemic infection related to the presence of IAD* may include fever, malaise, tachycardia, and hypotension.				
6. IAD related Quality of Life **IAD related Quality of Life** is defined as the degree of physical, material, social, and emotional wellbeing and comfort compromised by the presence of IAD and its associated care by (in)formal caregivers (Felce and Perry 1995).	30 (81.1)	3 (8.1)	4 (10.8)	Out
7. Patient satisfaction **Patient satisfaction** is defined as the degree to which the individual regards the intervention (e.g. service, product, program) or the procedure in which it is delivered as useful, effective, or beneficial [NCBI MeSH term definition, (Medicine 2016)]	33 (89.2)	3 (8.1)	1 (2.7)	In

IAD, incontinence-associated dermatitis.

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 in which 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 a number of IAD assessment instruments, but no data was found for the domain 'pain due to IAD' within the (quasi-)RCTs included in a recent Cochrane review of 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 within 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 / economical 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 economical 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 within 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 a number of 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 a number of 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.

Chapter based on:

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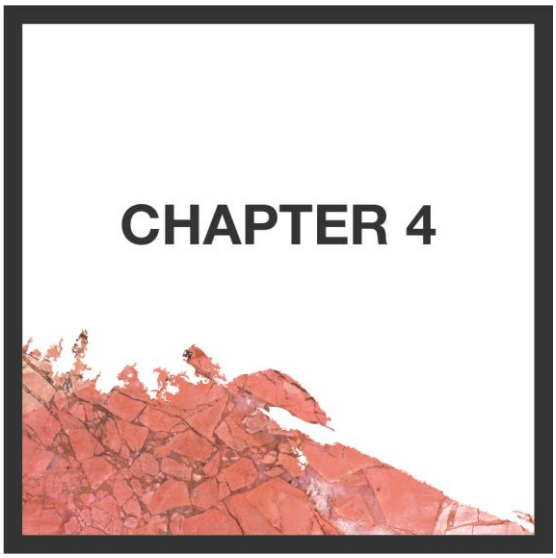


Towards an international language for incontinence-associated dermatitis (IAD): the design and evaluation of psychometric properties of the Ghent Global IAD Categorisation Tool (GLOBIAD) in 30 countries

ABSTRACT

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.

Keywords. Classification, Incontinence-associated dermatitis, Instrument, Reliability, Validity

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.

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 (Blume- Peytavi et al. 2014). This cutaneous problem not only occurs in paediatric patients but is also common in adults that is widely accepted as incontinence-associated dermatitis (IAD) (Gray et al. 2007). 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 (Gray et al. 2012). The aetiology of IAD is complex and multifactorial (Beeckman et al. 2009a). 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 (Mugita et al. 2015). Therefore, the skin is more permeable to irritants and pathogens (Foureur et al. 2006). 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 (Beeckman et al. 2009a, Campbell et al. 2017, Gray et al. 2012, Mugita et al. 2015).

The epidemiology of IAD varies across different countries, healthcare 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% (Gray et al. 2012, Van Damme et al. 2017). 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 (Beeckman et al. 2007). 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 recommended (Beeckman et al. 2007).

A recent Cochrane review revealed a substantial heterogeneity of reported outcomes and instruments in IAD research (Beeckman et al. 2016). To date, ten IAD-related instruments have been developed (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008, Long et al. 2012, Lutz et al. 1996, Nix 2002, Scotland 2008, Steininger et al. 2012) of which three were developed for IAD risk assessment (Junkin and Selekof 2008, Nix 2002, Steininger et al. 2012), nine for describing the severity of IAD (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008, Long et al. 2012, Lutz et al. 1996, Scotland 2008, Steininger et al. 2012), and two instruments for the classification and treatment of IAD (Junkin and Selekof 2008, Scotland 2008). Five instruments propose global assessment

and categorise IAD as mild, moderate or severe (Bliss et al. 2014, Borchert et al. 2010, Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008, Lutz et al. 1996, Scotland 2008, Steininger et al. 2012), whereas the others use a (cumulative) scoring system to delineate the severity or risk on a continuum or dimension (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Lutz et al. 1996, Nix 2002). Four instruments assess patient-specific symptoms such as pain and burning (Brown 1993, Junkin and Selekof 2008, Long et al. 2012, Steininger et al. 2012). An ideal instrument should measure IAD consistently and accurately (Streiner and Kottner 2014). Content validity was only assessed in four instruments using experts (Bliss et al. 2014, Borchert et al. 2010, Nix 2002, Steininger et al. 2012). Psychometric properties of five instruments were tested through the assessment of patients (Beeckman et al. 2011, Braunschmidt et al. 2013, Nix 2002) or photographs (Bliss et al. 2014, Borchert et al. 2010). In addition, several instruments (Brown 1993, Clarke-O'Neill et al. 2015b, Lutz et al. 1996) were found to be time-consuming and complex for use in clinical practice (Clarke-O'Neill et al. 2015a).

Therefore, in 2015 an international expert panel proposed a simplified IAD severity categorisation tool (Beeckman et al. 2015). 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) (Beeckman et al. 2015). 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 1. 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 (R Development Core Team 2017) using the function CI4Cats in the kappaSize R-library (version 1.1) (Rotondi 2013, Rotondi and Donner 2012) 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 (Defloor and Schoonhoven 2004)], 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).

Table 1. Classification of the photographs based on the assessment of two experts

Category		Number of photographs [a]
1A	Persistent redness without clinical signs of infection	9
1B	Persistent redness with clinical signs of infection	5
2A	Skin loss without clinical signs of infection	12
2B	Skin loss with clinical signs of infection	8
	Total	34

[a] The set of 34 photographs used in both step 1 and step 2 are identical.

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 2,5th and 97,5th 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 (Fleiss 1971). 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) (Landis and Koch 1977). All measures were calculated in R, version 3.4.1 (R Development Core Team 2017). 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 1. An overview of the instrument design process is presented in Figure 2.

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 (Nast et al. 2016). 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.

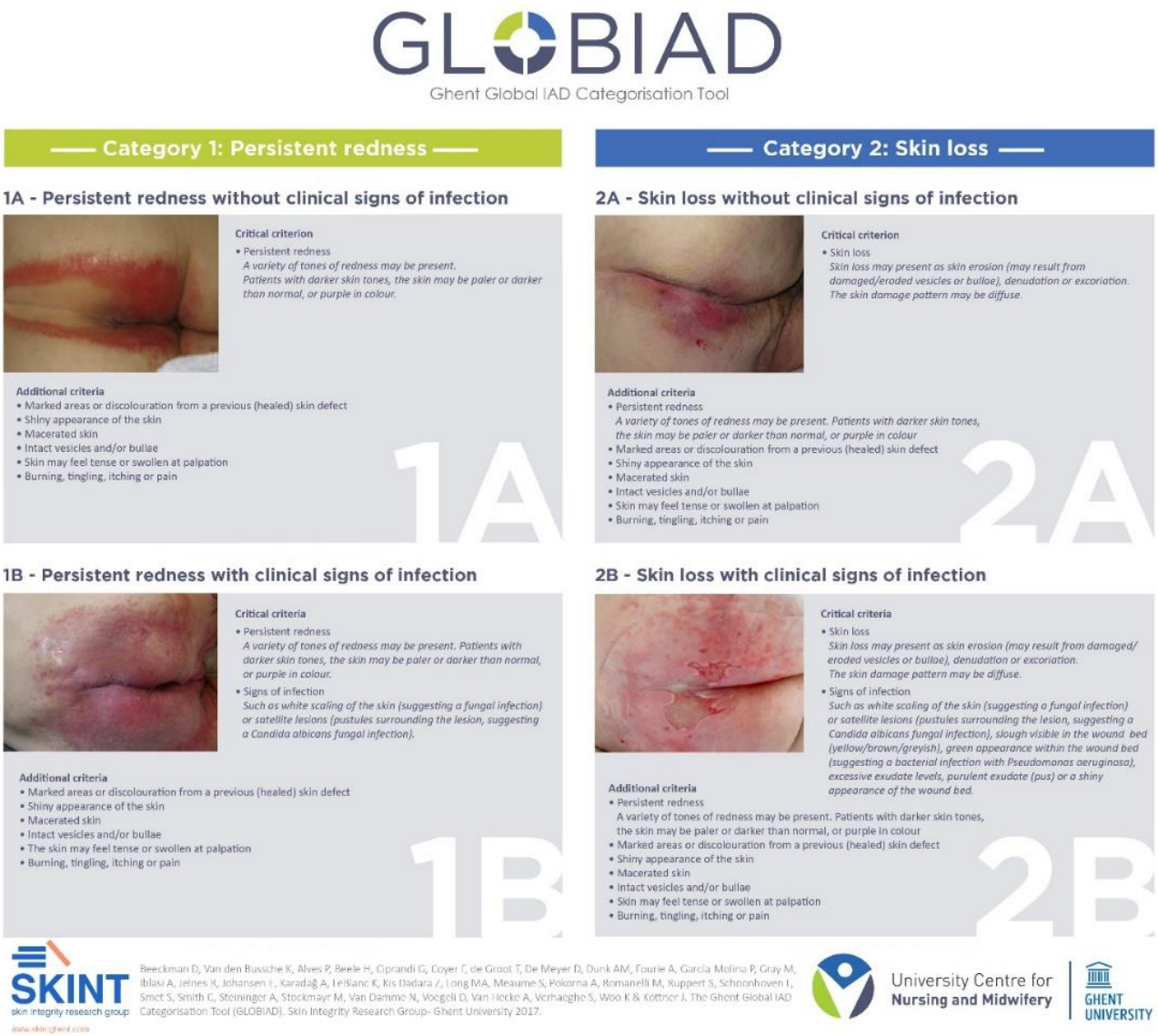


Figure 1. The Ghent Global IAD Categorisation Tool

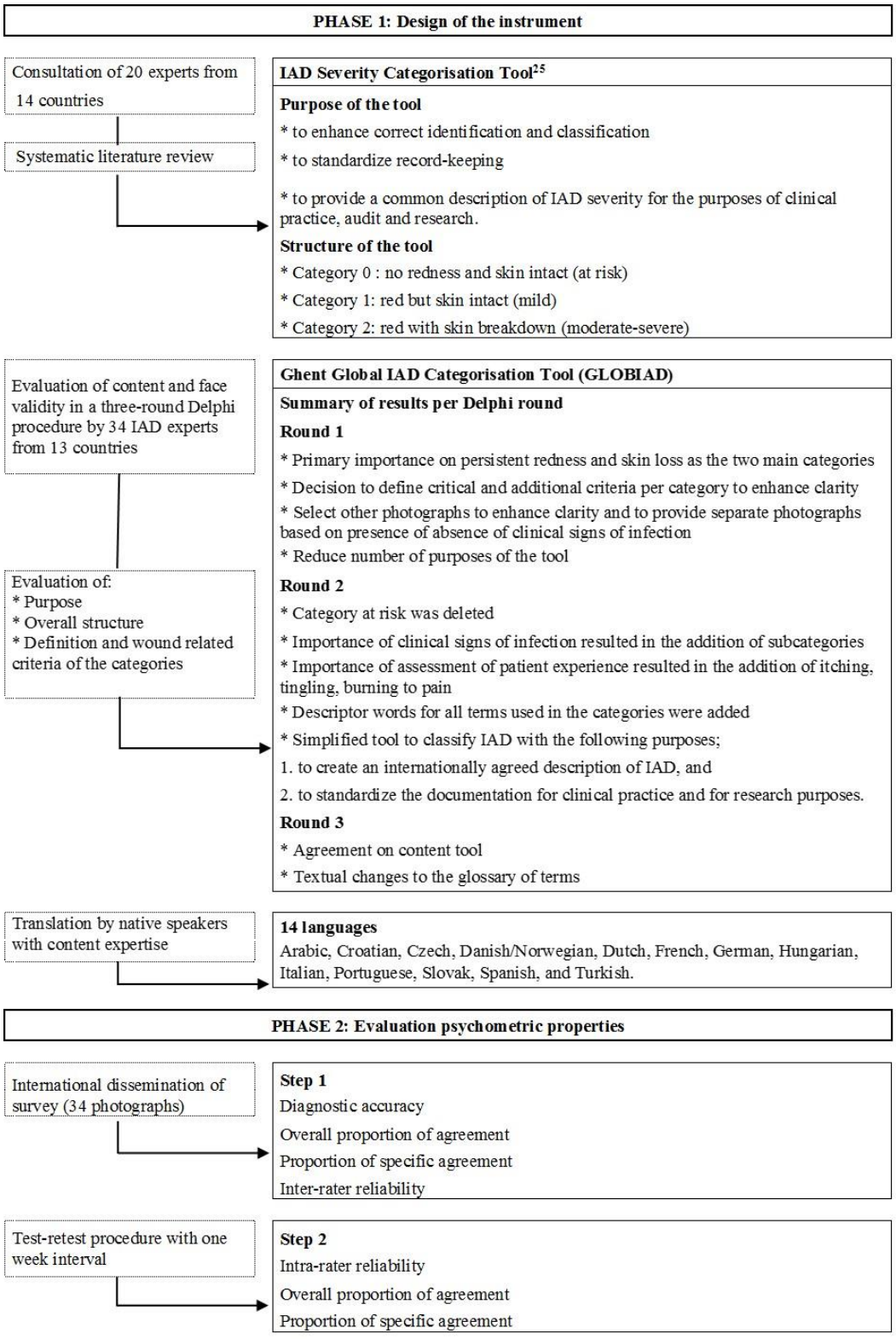


Figure 2. Process of design and evaluation of psychometric properties

General characteristics of the participants

A total of 823 participants (84.6% female) completed the first step and 463 completed the second step (Table 2).

Table 2. Characteristics of the participants

	Step 1		Step 2	
n	823		463	
	n	%	n	%
Sex				
Female	696	84.6	383	82.7
Age				
Mean (SD) in years	40.9	12.0	43.0	11.4
Age				
< 30 years	174	21.2	66	14.3
30 - 39 years	202	24.6	113	24.5
40 - 49 years	197	24.0	126	27.3
≥ 50 years	249	30.3	157	34.0
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
Work experience in healthcare				
< 5 years	130	15.8	51	11.0
5 - 10 years	122	14.8	55	11.9
10 - 20 years	196	23.8	115	24.8
> 20 years	375	45.6	242	52.3
Current work setting				
Local hospital	277	33.7	134	28.9
Teaching / university hospital	241	29.3	151	32.6
Magnet hospital	13	1.6	9	1.9
Nursing home	53	6.4	34	7.3
Community care	89	10.8	51	11.0
Education	76	9.2	41	8.9
Clinical research	14	1.7	12	2.6

Industry / commercial	6	0.7	5	1.1
No work / student	20	2.4	8	1.7
Other	32	3.9	17	3.7
Missing	2	0.2	1	0.2
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
Observation of IAD in practice [c]				
none	134	16.3	77	16.6
< 5 times a week	514	62.5	285	61.6
5 - 10 times a week	141	17.1	78	16.8
> 10 times a week	34	4.1	23	5.0
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
Country of work				
Australia	22	2.7	12	2.6
Austria	63	7.7	46	9.9
Belgium	115	14.0	74	16.0
Brazil	3	0.4	3	0.6
Canada	33	4.0	18	3.9
China	1	0.1	0	0.0
Croatia	14	1.7	9	1.9
Cyprus	1	0.1	1	0.2
Czech Republic	81	9.8	53	11.4
Denmark	19	2.3	14	3.0
France	9	1.1	6	1.3
Germany	26	3.2	16	3.5
Greece	1	0.1	0	0.0
Hungary	21	2.6	9	1.9
Ireland	1	0.1	0	0.0

Italy	12	1.5	5	1.1
México	1	0.1	0	0.0
the Netherlands	59	7.2	43	9.3
Norway	12	1.5	5	1.1
Poland	1	0.1	0	0.0
Portugal	32	3.9	18	3.9
Saudi Arabia	32	3.9	3	0.6
Serbia	1	0.1	1	0.2
Slovakia	71	8.6	24	5.2
Spain	71	8.6	41	8.9
Sweden	1	0.1	1	0.2
Switzerland	4	0.5	4	0.9
Turkey	59	7.2	24	5.2
United Kingdom	20	2.4	9	1.9
United States of America	37	4.5	24	5.2

[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 recognised 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.

Diagnostic accuracy and agreement

The diagnostic accuracy and agreement between participants and the reference standard is presented in Table 3. 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.

Table 3. 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.

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 4). 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 5). 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.

Table 4. 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 5. 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.

DISCUSSION

IAD is highly prevalent among individuals with urinary and/or faecal incontinence (Gray et al. 2012). The heterogeneity of reported outcomes and instruments point towards a need for standardised classification (Beeckman et al. 2016). 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 (Beeckman et al. 2009a, Gray et al. 2012, Mugita et al. 2015). The presence of erythema and skin loss is also consistently reflected in all available IAD assessment tools (Bliss et al. 2014, Borchert et al. 2010, Brown 1993,

Clarke-O'Neill et al. 2015b, Junkin and Selekof 2008, Long et al. 2012, Lutz et al. 1996, Nix 2002, Scotland 2008, Steininger et al. 2012). 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%) (Black et al. 2011, Campbell et al. 2017, Campbell et al. 2016b, Foureur et al. 2006, Junkin and Selekof 2007). 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 (Schultz et al. 2003) 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 (Cefalu et al. 2017, Schultz et al. 2003). However, this technique is time-consuming, expensive, and of limited accuracy (Bowler et al. 2001). Correct and early detection of clinical signs of infection by the health professional is crucial in the management of IAD (Bowler et al. 2001, Posnett et al. 2009). Inadequate treatment can cause delayed wound healing, prolonged hospitalisation, and an increase in costs (Sen et al. 2009).

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 (Kottner et al. 2011).

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 1) influences the reliability estimates (Kottner et al. 2011). Because the number of images with clinical signs of infection were lower (based on an estimated prevalence in clinical

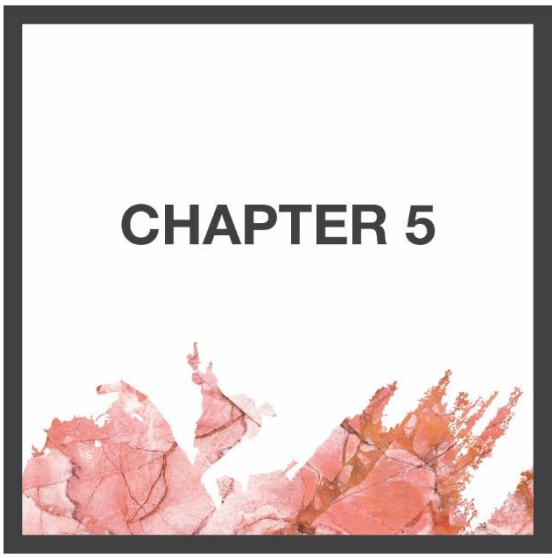
practice), sensitivity and specificity, and reliability may have been affected. In addition, there were only two images of darkly pigmented skin. This may limit the applicability of the results to all skin phototypes. Translations were done by native speakers with extensive content experience in the field of IAD but back-translation was not performed (Maneesriwongul and Dixon 2004).

IAD as well as pressure ulcers are frequently classified incorrectly (Beeckman et al. 2007, Beeckman et al. 2010, Defloor and Schoonhoven 2004). 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. Correct scoring and the reliability of IAD assessment will enhance when sufficient and adequate education and training is provided (Beeckman et al. 2010). The GLOBIAD was developed as a simple, easy and time-saving instrument that can easily be implemented by educators (Clarke-O'Neill et al. 2015a). 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.

Chapter based on:

VAN DEN BUSSCHE K., VERHAEGHE S., VAN HECKE A. & BEECKMAN D. (2018) The Ghent Global IAD Monitoring Tool (GLOBIAD-M) to monitor the healing of incontinence-associated dermatitis (IAD): design and reliability study. *International Wound Journal, 1-10.* [ePub ahead of print]



The Ghent Global IAD Monitoring Tool (GLOBIAD-M) to monitor the healing of incontinence-associated dermatitis (IAD): design and reliability study

ABSTRACT

Aim. The aim of this study was to design and evaluate the reliability of the Ghent Global incontinence-associated dermatitis (IAD) Monitoring Tool (GLOBIAD-M).

Methods. The tool was designed based on the internationally validated Ghent Global IAD Categorisation Tool (GLOBIAD). After designing and validation by experts, one trained researcher carried out 36 observations of nine patients affected with IAD. Photographs of the IAD lesions were independently assessed by a second trained researcher. Measures for inter-rater agreement (p_o) and reliability [Cohen's Kappa (κ) and intra-class correlation coefficients (ICC)] were analysed.

Results. The p_o ranged between 0.86 for the item 'maceration' to 0.97 for the item 'clinical signs of infection'. The κ for the item 'GLOBIAD classification' was 0.61 [95% confidence interval (CI) 0.28–0.95] and 0.72 (95% CI 0.50–0.95) for 'maceration'. The lowest κ was found for the item 'oedema' (0.27; 95% CI -0.24–0.79). The ICC of the item 'redness' was 0.83 (95% CI 0.69–0.91) and 0.87 (95% CI 0.76–0.93) for 'skin loss'. The inter-rater agreement and reliability of the GLOBIAD-M appears to be good for the assessment of photographs by experts.

Conclusion. This tool could support clinical decision-making for IAD treatment. Further validation with clinicians is however needed.

Keywords. Assessment, Healing, Incontinence-associated dermatitis, Instrument, Monitoring

Key messages

- The GLOBIAD-M builds on the internationally validated Ghent Global IAD Categorisation Tool (GLOBIAD) and includes an observation document and a dashboard to allow the monitoring of change in incontinence-associated dermatitis (IAD) status over time.
- Thirty-six independent assessments of nine hospitalised patients affected with IAD (over a period of 7 days) by two trained researchers revealed good inter-rater agreement and reliability properties.
- The inter-rater reliability of the item 'oedema' was lower compared to the items 'classification according to the GLOBIAD', 'redness', 'skin loss', 'maceration', and 'clinical signs of infection'.

INTRODUCTION

The prevalence of incontinent individuals across different countries and care settings is high (55% to 84%) (Kottner and Beeckman 2015). One of the most prevalent skin conditions associated with incontinence is incontinence-associated dermatitis (IAD) (Gray et al. 2012). IAD is a specific type of irritant contact dermatitis characterised by redness, but in some cases swelling, vesicles or bullae, skin loss, and/or cutaneous skin infection are present (Gray et al. 2012). Managing IAD is an important challenge for healthcare professionals. The application of mild skin cleansers immediately after soiling, and protective and caring leave-on products as part of a structured skin care regimen are recommended for prevention and treatment (Beeckman et al. 2015). However, the lack of comparability between studies about efficacy and (cost-)effectiveness of products and procedures complicates standardisation of IAD management (Beeckman et al. 2016). Recognising the condition and distinguishing it from other skin lesions such as superficial pressure ulcers add to the complexity of managing the condition in practice (Beeckman et al. 2009b, Beeckman et al. 2014, Defloor and Schoonhoven 2004, Vanderwee et al. 2011).

IAD is more common in older patients as the aging process is associated with a decreased cell replacement in the skin, compromised barrier function and mechanical protection, and delayed wound healing (Beeckman 2017). Although its acute nature, IAD can become a chronic progressive wound under certain conditions [such as a secondary *Candida albicans* skin infection (Campbell et al. 2017)]. Little is known about the time to healing of IAD. Bliss et al. (2011) reported a median time to IAD healing of 11 days (range, 1 – 19 days) in critically ill adults in the intensive care unit (ICU) (Bliss et al. 2011). A randomised controlled trial including 142 hospitalised patients reported a percentage of completely healed between 9.6% and 21.7% within the study follow-up period of six days (Buckley et al. 2014). Long et al. (2011) reported a median time to healing of 9 days (range, 2 – 39 days) in 22 patients with IAD in a long-term acute care facility setting (Long et al. 2012). International recommendations state that there should be visible improvement of the skin condition and reduction in pain in two to four days following the implementation of a skin care regimen, with resolution within two to three weeks (Beeckman et al. 2015). Inadequate treatment can cause prolonged discomfort and pain, delayed wound healing, prolonged hospitalisation, and an increase of costs (Sen et al. 2009, Van Damme et al. 2015).

Timely, adequate and targeted prevention and treatment are essential. Therefore, the use of a valid and reliable instrument to clinically assess IAD based on visual inspection by trained healthcare professionals is crucial. To date, five IAD assessment instruments have been developed and disseminated for the purpose of describing the severity of IAD and its monitoring over time (Bliss et al. 2014, Borchert et al. 2010, Brown 1993,

Long et al. 2012, Lutz et al. 1996). All instruments assess the size of the IAD lesion, either via body locations (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Lutz et al. 1996) or an estimation of the surface area (Brown 1993, Lutz et al. 1996). To monitor the healing over time, four instruments use a (cumulative) scoring system (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Lutz et al. 1996). Two instruments assess patient-specific symptoms such as pain and burning (Brown 1993, Long et al. 2012). Content validity was only assessed in two instruments by experts (Bliss et al. 2014, Borchert et al. 2010). Psychometric properties of three instruments were tested by assessing photographs to analyse the inter-rater reliability, whereas none used multiple photographs of the same IAD lesion (Beeckman et al. 2011, Bliss et al. 2014, Borchert et al. 2010). Moreover, a feasibility study in twelve incontinent residents in two nursing homes concluded that three existing IAD assessment instruments too time-consuming and (linguistically) too complex for use in routine clinical practice (Clarke-O'Neill et al. 2015a). In the observation and monitoring of IAD healing, the use of a valid assessment instrument is important for both clinical practice and clinical research. The recently developed core outcome set (COS) for IAD research, a minimum set of outcomes to be measured and reported in all IAD trials, recommends to assess the outcome domains redness, skin loss, maceration, IAD-related pain, and patient satisfaction (Van den Bussche et al. 2018).

To date, there is no internationally, easy to use, valid and reliable instrument to monitor the healing of IAD in routine clinical practice and research. In 2017, an important step towards an international language of IAD was the design and international validation of the Ghent Global IAD Categorisation Tool (GLOBIAD) (Beeckman et al. 2018). The GLOBIAD categorises IAD based on the severity of the skin lesion and distinguishes between the presence of persistent redness [category (cat.) 1] and the presence of skin loss (cat. 2), both subdivided based on the absence (cat. A) and presence (cat. B) of clinical signs of infection (Beeckman et al. 2018). Content and face validity of the GLOBIAD were established after a three-round Delphi procedure with an international panel of experts from 13 countries. The validation process of the GLOBIAD has been published elsewhere (Beeckman et al. 2018). The overall inter-rater agreement (p_0) was 0.55 [95% confidence interval (CI) 0.55-0.56] and the overall inter-rater reliability [Fleiss kappa (κ)] was 0.41 (95% CI 0.41-0.41) when health professionals apply this tool based on the presented images. Highest inter-rater agreement values were achieved for differentiating between erythematous skin (cat. 1) and skin loss (cat. 2) [$\kappa = 0.65$ (95% CI 0.65-0.65), $p_0 = 0.86$].

However, this classification was not developed to monitor the change in IAD status over time. The aim of this study was to design and assess the reliability of a tool to monitor the change in IAD status over time.

METHODS

A two-phase instrument design and reliability study was conducted.

Phase 1 – Instrument design

Methods

The GLOBIAD and COS were used to design the Ghent Global IAD Monitoring Tool (GLOBIAD-M) (Figure 1) (Beeckman et al. 2018, Van den Bussche et al. 2018). Content and face validity of the GLOBIAD were established after a three-round Delphi procedure with an international panel of experts from 13 countries. The validation process of the GLOBIAD has been published elsewhere (Beeckman et al. 2018). The GLOBIAD consists of multiple items classified as critical or additional criteria within each of the four categories. For the development of the GLOBIAD-M, the Skin Integrity Research Group (SKINT) at Ghent University (Belgium) reviewed and discussed each item extensively to be included (yes/no) in the GLOBIAD-M.

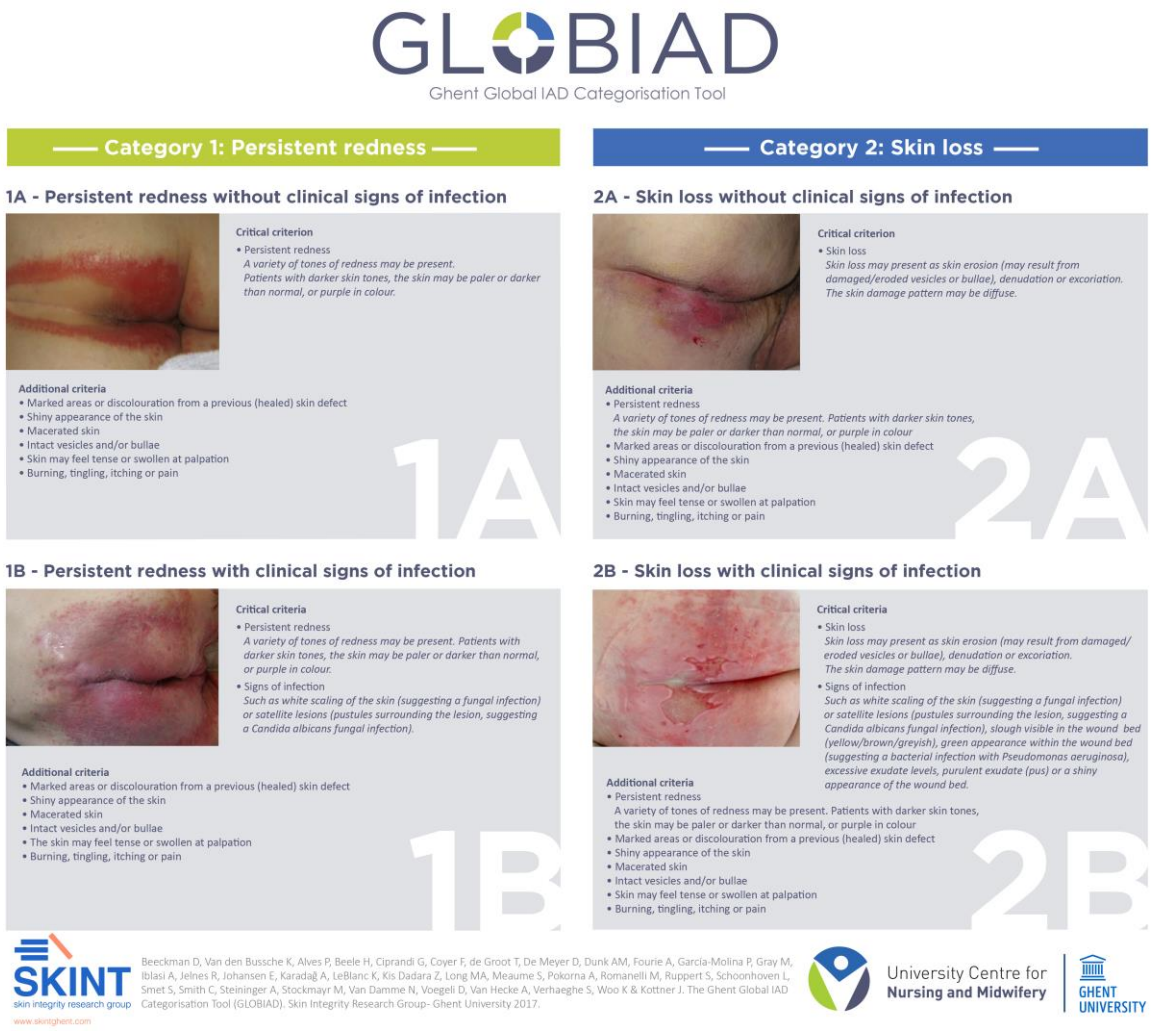


Figure 1. the Ghent Global IAD Categorisation Tool (GLOBIAD)

Results

The tool that emerged after expert review is displayed in Figures 2 and 3. The overview of the instrument design is presented in Table 1. The GLOBIAD-M includes an observation document and a dashboard to allow the monitoring of the healing of IAD.

The observation document (one page) includes four data categories: general data, IAD categorisation (based on the GLOBIAD), observation of IAD and the surrounding skin, and patient's experience. The first category, general data, contains the date, patient identification number, and nurse initials. The second category relates to the categorisation of the IAD according to the GLOBIAD classification system (Beeckman et al. 2018). The third category includes nine items related to IAD and surrounding skin that need to be assessed. The items 'redness' and 'skin loss' are scored on a grid to automatically calculate the surface area (as a percentage). Next, the presence of 'oedema', 'maceration', and 'clinical signs of infections' (such as satellite lesions) are to be documented. The last category consists of IAD-related 'itching', 'tingling', 'burning', and 'pain'. The intensity of the IAD-related pain is assessed using the Numerical Rating Scale (NRS) (Williamson and Hoggart 2005).

To monitor the change in IAD status over time, the dashboard comprises a graph and colour-grading system. Red represents the presence of the item and green the absence. To illustrate the GLOBIAD-M, the daily observation document and dashboard of one patient is presented in Figure 4.

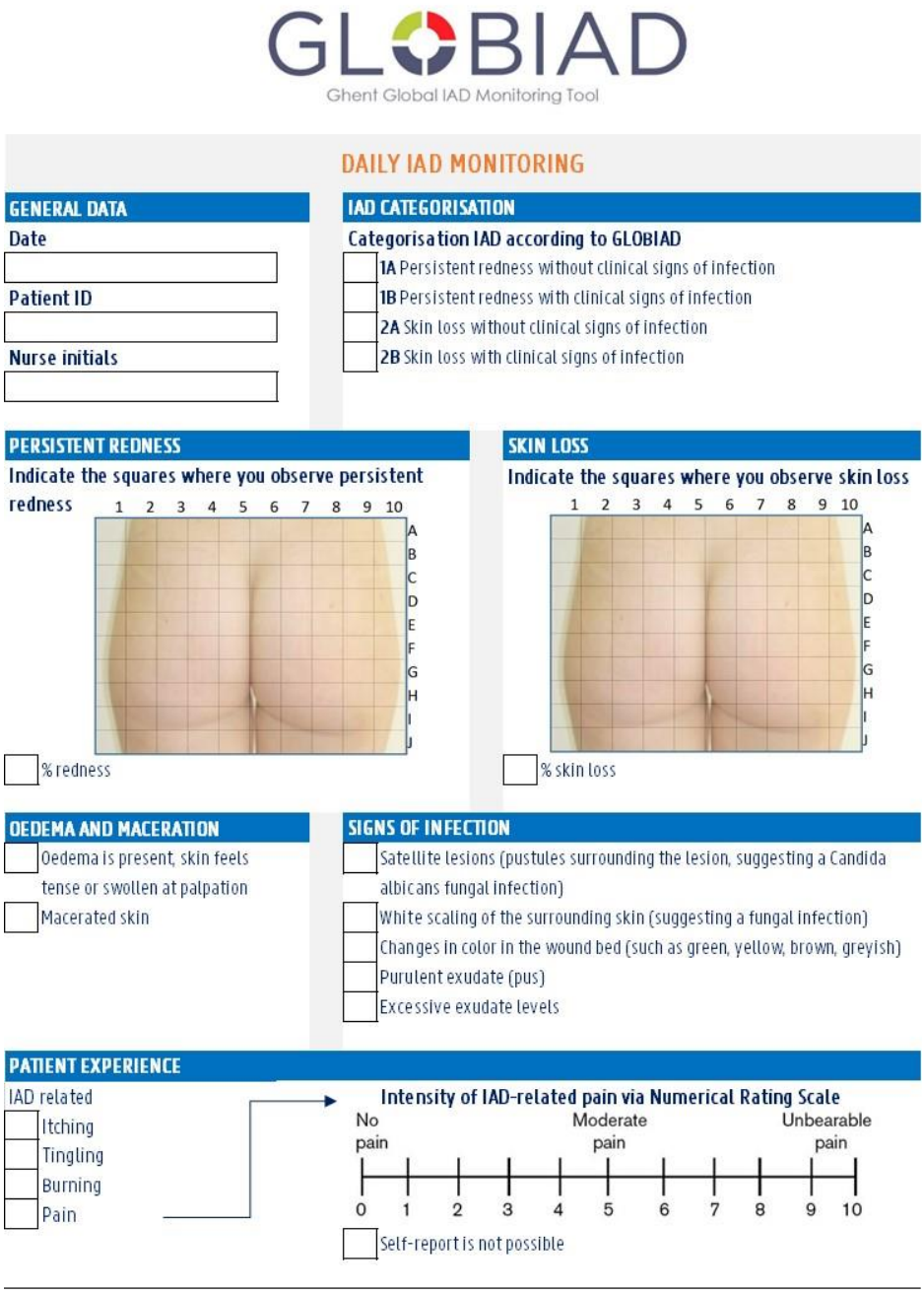
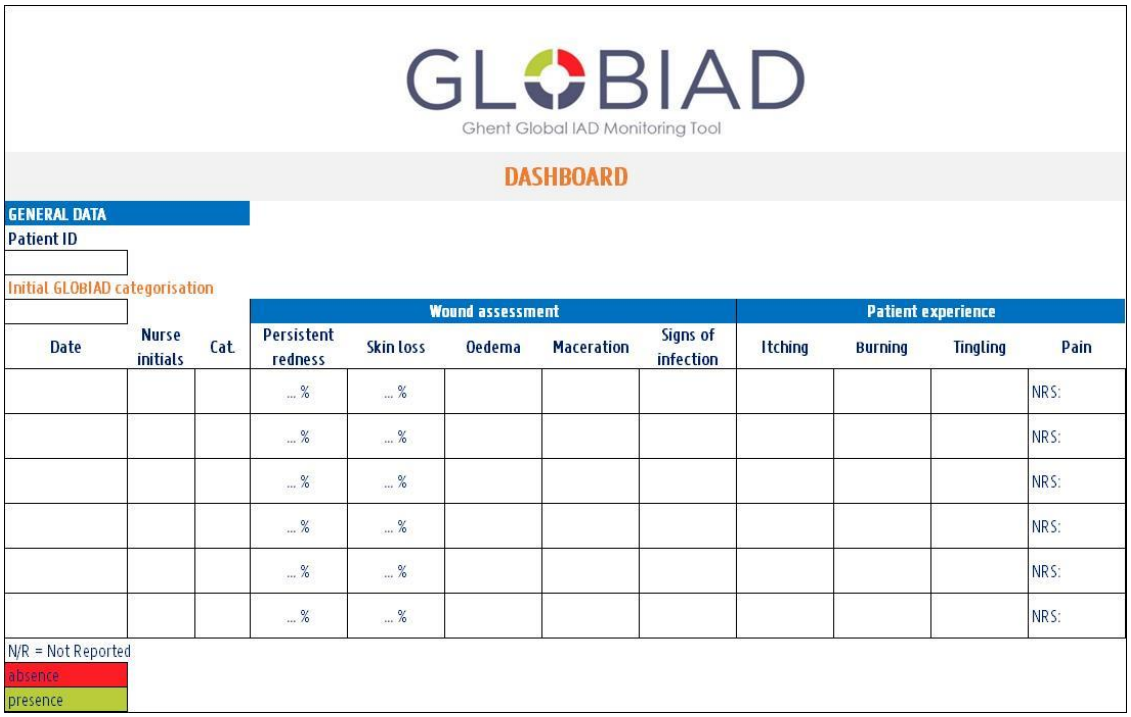


Figure 2. the Ghent Global IAD Monitoring Tool (GLOBIAD-M) – daily observation document



GLOBIAD

Ghent Global IAD Monitoring Tool

DASHBOARD

GENERAL DATA

Patient ID

Initial GLOBIAD categorisation

			Wound assessment					Patient experience			
Date	Nurse initials	Cat.	Persistent redness	Skin loss	Oedema	Maceration	Signs of infection	Itching	Burning	Tingling	Pain
			... %	... %							NRS:
			... %	... %							NRS:
			... %	... %							NRS:
			... %	... %							NRS:
			... %	... %							NRS:
			... %	... %							NRS:

N/R = Not Reported

absence

presence

Figure 3. the Ghent Global IAD Monitoring Tool (GLOBIAD-M) – dashboard

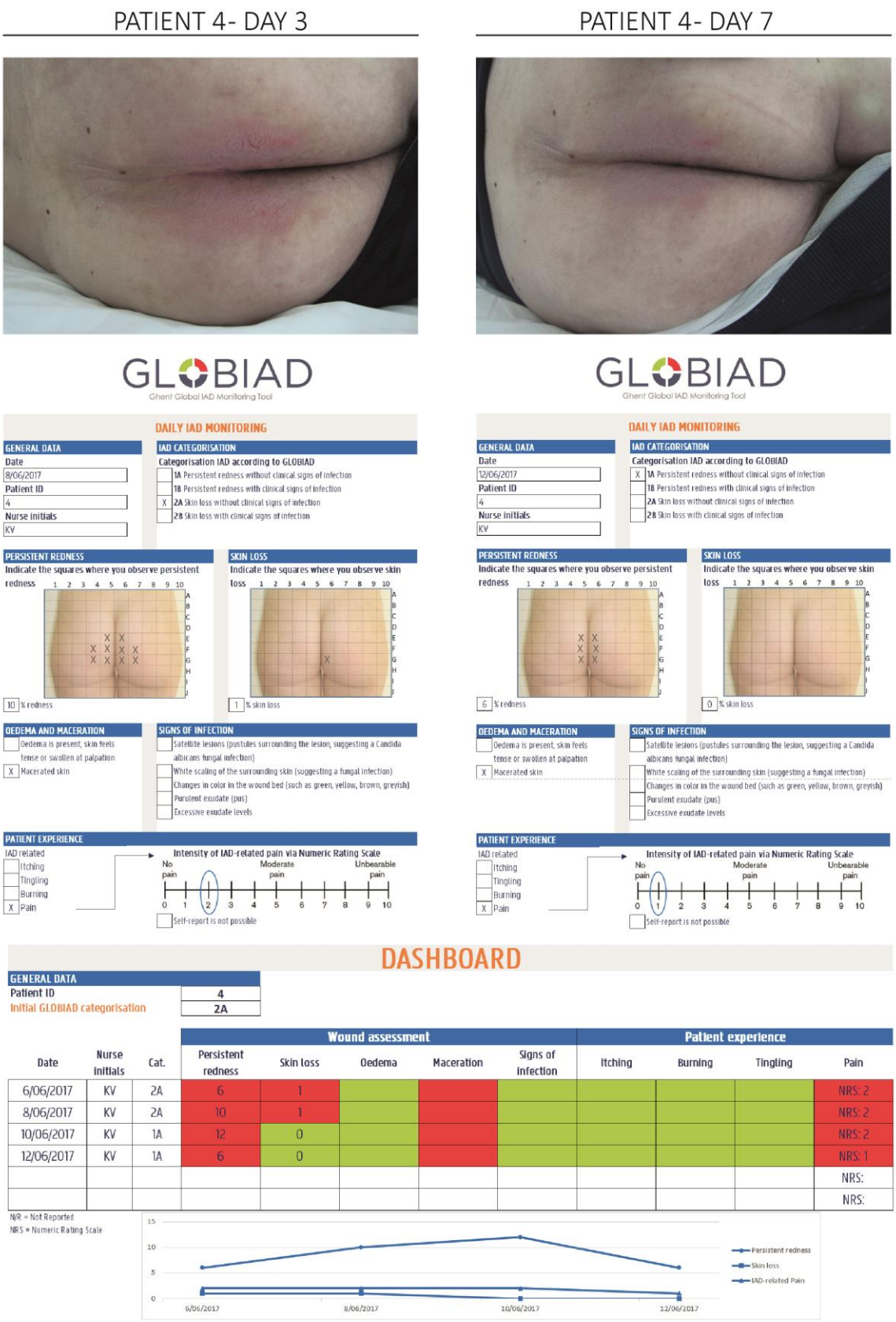


Figure 4. Example GLOBIAD-M daily observation document and dashboard (patient 4)

Table 1. GLOBIAD-M instrument design

GLOBIAD items	Decision	Outcome
Critical criteria		
Persistent redness	Inclusion, surface area	Percentage[a,b] Binary (red or green)[b,c]
Skin loss	Inclusion, surface area	Percentage[a,b] Binary (red or green)[b,c]
Signs of infection	Summary on dashboard	Binary (red or green)[b,d]
White scaling of the skin	Included identically	Binary (yes or no)[a]
Satellite lesions	Included identically	Binary (yes or no)[a]
Slough visible in the wound bed (yellow/brown/greyish)	Included as new item *"Changes in color in the wound bed (such as green, yellow, brown, greyish)"*	Binary (yes or no)[a]
Green appearance within the wound bed	Included as new item *"Changes in color in the wound bed (such as green, yellow, brown, greyish)"*	Binary (yes or no)[a]
Excessive exudate levels	Included identically	Binary (yes or no)[a]
Purulent exudate levels	Included identically	Binary (yes or no)[a]
Shiny appearance of the wound bed	Included as new item *"Changes in color in the wound bed (such as green, yellow, brown, greyish)"*	Binary (yes or no)[a]
Additional criteria		
Marked areas or discolouration from a previous (healed) skin defect	Not primarily relevant to IAD healing	/
Shiny appearance of the skin	Incorporated in new item "Changes in color in the wound bed (such as green, yellow, brown, greyish)	Binary (yes or no)[a]
Macerated skin	Included identically	Binary (yes or no)[a] Binary (red or green)[b]
Intact vesicles and bullae	Not primarily relevant to IAD healing	/
The skin may feel tense or swollen at palpation	Changed to "Oedema is present, skin may feel tense or swollen at palpation"	Binary (yes or no)[a] Binary (red or green)[b]
Burning, tingling, itching or pain	Incorporated identically Two items were added:	Binary (yes or no)[a] Binary (red or green)[b]
	1. 'Self-report is not possible'	Binary (yes or no)[b] Not reported (N/R)[b]
	2. NRS pain scale: to quantify the intensity of IAD-related pain	Number from 0 – 10[a,b]

NRS: numerical rating scale. [a] Displayed on daily observation document. [b] Displayed on dashboard, red indicates the presence, and green the absence. [c] Red if ≥ 1% redness or skin loss is present. [d] Red if ≥ 1 clinical signs of infection is present.

Phase 2 – Reliability testing

Setting and participants

The study was conducted in one large general hospital in Belgium. All patients meeting the criteria for inclusion were eligible for participation. Inclusion criteria were: (1) being ≥ 18 years, (2) IAD present, (3) expected to have an additional length of stay of a minimum of seven days, and (4) written informed consent by the patient or his/her representative including explicit consent to take photographs of the IAD.

Data collection

The researcher was notified by the clinical nurse specialist in wound care about patients with an IAD diagnosis that potentially could be included (and thus meeting the inclusion criteria). The researcher re-assessed the eligibility criteria and obtained oral and written consent from the patient or his/her representative. The GLOBIAD-M was completed on day 1, day 3, day 5, and day 7 by observation of the patient's skin and the assessment of several symptoms such as itching and pain. At the same time, a photograph of the IAD lesion was taken with a Canon EOS 60D with lens EFS 17-85mm in the most comfortable position for the patient (lying on the preferred side or standing). To examine the degree of inter-rater agreement, a second IAD expert independently categorised the IAD lesion (data category 2) and assessed the surrounding skin items (data category 3) for each photograph. If no data from four consecutive observation points could be obtained, the data was deleted and a new patient was included. The aim was a sample of ten patients with complete data.

Ethical considerations

The study was performed according to the ethical guidelines of the 1975 Declaration of Helsinki and approved by the Ethics Review Committee of Ghent University Hospital and the Ethics Review Committee of AZ Sint-Lucas Ghent (B670201732140). Written and oral informed consent were obtained from all participating patients or their legal representatives.

Statistical analysis

To examine the degree of inter-rater agreement, photographs of the IAD lesions were independently assessed by a second IAD expert. The number of patients (n = 9) were based on similar studies ranging from four and nine photo cases (Bliss et al. 2014, Borchert et al. 2010). However, these studies did not monitor each IAD lesion multiple times. The overall percentage of agreement (p_0) and Cohen's kappa (κ) were calculated for ordinal data. The p_0 is the ratio of exact agreement between the raters to the total number of all ratings. The coefficient κ indicates whether observed agreement is higher than or equal to chance agreement. 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) (Landis and Koch 1977).

Intraclass correlation coefficient (ICC) was calculated to determine the inter-rater reliability for the items 'redness' and 'skin loss'. ICC estimates and their 95% confident intervals (CI) were calculated based on single rating [model ICC(2,1)] (Shrout and Fleiss 1979). The underlying statistical model is a consistency two-way random effects model in which the systematic variability between raters is included. In order to gain a detailed insight into the actual level of agreement of the calculated inter-rater reliability coefficients for the variables 'redness' and 'skin loss', the range of occurred differences between raters was calculated. Additionally, the differences between raters were plotted against their mean score to explicitly show the range and number of disagreements (Bland and Altman 1999). The 95% limits of agreement were calculated, as proposed by Bland and Altman (Bland and Altman 1999). All statistical analyses were performed using SPSS statistical package version 24 (SPSS, Inc., Chicago, IL, USA).

RESULTS

General characteristics of the participants

A total of thirteen incontinent patients were enrolled in the study of which three patients dropped out [due to discharge (n = 2) and death (n = 1)]. Data collection was complete for a total of nine patients (two males, median age 78 years) mainly admitted to a geriatric or rehabilitation ward (Table 2). The IAD treatment consisted of the same type of leave-on product for all patients, a combination of a moisturiser and a skin protectant. None of the IAD lesions healed during study follow-up period.

Table 2. Key demographic characteristics of the hospitalised patients

ID	Age, y	Sex	Mobility†	Friction and shear†	Diarrhea*	Initial GLOBIAD	Ward type
1	77	F	Very limited	Potential problem	No	2A	Nephrology
2	75	F	Very limited	Potential problem	No	2A	Rehabilitation neurology
3	78	F	Very limited	Actual problem	No	2A	Geriatrics
4	64	M	Slightly limited	No apparent problem	Yes	2A	Rehabilitation chronic
5	89	F	Slightly limited	Potential problem	No	1A	Geriatrics
6	77	F	Very limited	Potential problem	No	2B	Geriatrics
7	85	F	Completely immobile	Potential problem	Yes	2A	Rehabilitation neurology
8	82	F	Very limited	Potential problem	Yes	2A	Geriatrics
9	84	M	Slightly limited	Potential problem	No	2A	Geriatrics

F, Female; M, Male; 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. * present at day 1 or in past 5 days. † Braden Risk Assessment subscales 'Mobility' and 'Friction and Shear'

Inter-rater reliability

The inter-rater reliability coefficients κ, $p_{o,}$ ICC(2,1) for each assessment item of the GLOBIAD-M tool are presented in Table 3. All 36 observations were rated, there were no missing values. The κ-values for items 'GLOBIAD' and 'maceration' were "substantial" [respectively 0.61 (95% CI 0.28–0.95) and 0.72 (95% CI 0.50–0.95)]. For the item 'clinical signs of infection', there was no κ calculated because the ratings were almost identical (p_o = 0.97). The lowest exact agreement was found for the item 'maceration'. The lowest inter-rater reliability coefficient was found for the item 'oedema' (0.27, 95% CI -0.24–0.79) which can be labelled as "fair".

High ICC(2,1)-values were found for the items 'redness' and 'skin loss', respectively 0.83 (95% CI 0.69–0.91) and 0.87 (95% CI 0.76–0.93). Figure 5 shows the distribution and the amount of rater differences against their average scores for the total sample (n = 36). The size of the circles indicate the frequency of similar values. The 95% limits of agreement correspond to the interval -8.41–4.8 for redness and -1.55–1.89 for skin loss. Most differences were found within this interval

Table 3. Inter-rater agreement and reliability coefficients – 2 raters

Items GLOBIAD-M dasboard	Kappa (95% CI)	p_0
GLOBIAD	0.61 (0.28-0.95)	0.89
Oedema	0.27 (-0.24-0.79)	0.89
Maceration	0.72 (0.50-0.95)	0.86
Signs of infection	– *	0.97
	ICC(2,1) (95% CI)	**Range difference†**
Redness, %	0.83 (0.69-0.91)	0 - 9%
Skin loss, %	0.87 (0.76-0.93)	0 - 3%

Based on the assessment of 36 photographs by 2 raters. 95% CI, 95% confidence interval; p_0, percentage overall agreement. * Not calculated, almost identical ratings, the variance of this rating is 0. † Difference between rater 1 and rater 2 (range).

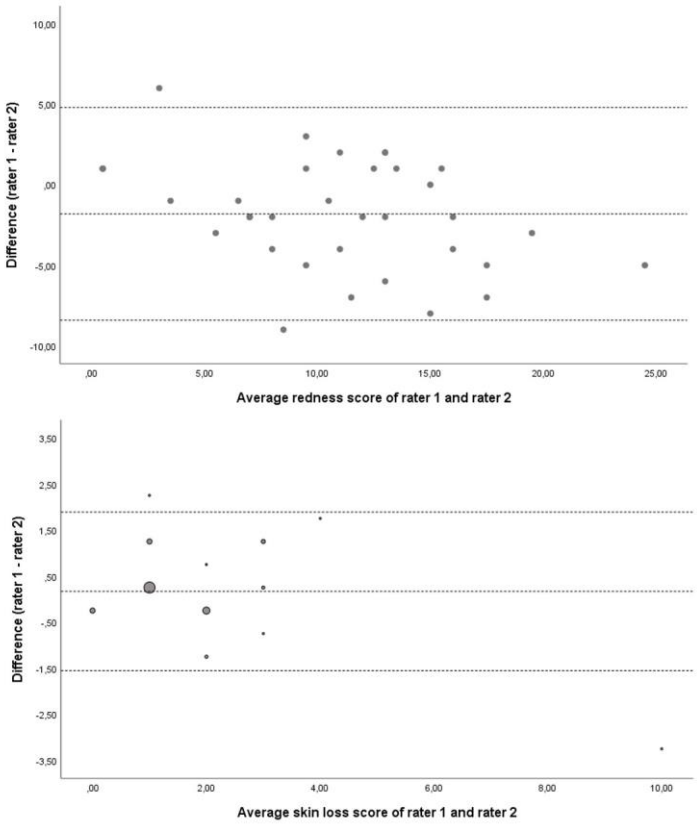


Figure 5. Bland-Altman plots of differences between raters and average scores measured by rater 1 and rater 2

DISCUSSION

The aim of this study was to design a tool to monitor the change in IAD status over time (GLOBIAD-M) and at the same time evaluate the reliability of the GLOBIAD-M. Content and face validity were established by an international expert panel during the validation of the GLOBIAD tool (Beeckman et al. 2018). In this study, the SKINT research group determined the relevance and feasibility of the items resulting in an instrument with content and face validity.

The GLOBIAD-M daily observation document includes four IAD and surrounding skin assessment items and patient experiences such as itching and pain. Compared to other instruments, Brown and Long et al. included the assessment of patient symptoms (tingling, itching, burning, pain) whereas the other instruments did not (Bliss et al. 2014, Borchert et al. 2010, Lutz et al. 1996). However, the assessment of IAD-related patient symptoms such as pain proved to be of critical importance in both the GLOBIAD as the COS for IAD research (Beeckman et al. 2018, Van den Bussche et al. 2018).

In this study, the agreement and reliability of the GLOBIAD-M was examined in a sample of 36 photographs of nine patients. The estimates indicate a high degree of inter-rater reliability for the assessment of 'redness', 'skin loss', 'maceration', and 'clinical signs of infection'. The assessment of 'oedema' seemed more difficult. This may be due to the assessment of photographs by the second rater. The GLOBIAD defined oedema as 'the skin may feel tense or swollen at palpation' which consequently should be assessed by palpating the skin. Oedema, defined as the presence of 'swollen/raised areas', was included in two other tools which were not psychometrically tested (Brown 1993, Long et al. 2012). If further validation points towards the same results, it is recommended to delete this item.

The assessment of the surface area of IAD is in line with other assessment instruments although different methods are used. The instruments developed by Brown (Brown 1993) and adapted by Long et al. (Long et al. 2012), Borchert et al. (Borchert et al. 2010), and Bliss et al. (Bliss et al. 2014) assesses different skin items for respectively five (buttocks, coccyx, rectal area, scrotum/perineum, and upper thighs) or 13 body areas. The assessment of large body areas could possibly impede the assessment of the surface area since slight healing will not be noticed. Additionally, Brown includes the size of the lesion by reporting the length and width (in cm) for the left and right side for each of the five body areas (Brown 1993). The instrument of Kennedy & Lutz assesses the estimated area of skin breakdown using a four-point scale [no area, small area (≤ 20 cm^2), moderate area (20-50 cm^2), and large area (> 50cm^2)] (Lutz et al. 1996). This method could pose difficulties since IAD is often characterised by an irregular shape.

In this study, healing was visualised through a dashboard comprising a graph and colour-grading system. This is in contrast with other IAD monitoring instruments which use a (cumulative) scoring system (Bliss et al. 2014, Borchert et al. 2010, Brown 1993, Lutz et al. 1996) or no scoring system (Long et al. 2012). The use of a scoring system was not preferred since epidemiological data indicating a relation between scores and time to healing is lacking. The GLOBIAD-M reflects more accurately the items on which the wound improves or deteriorates.

The small sample size is acknowledged as a limitation of this study which may mean it lacks power, furthermore follow-up over a longer period was not possible which meant that patients were not monitored after discharge. However, our sample size (36 observations) is comparable or larger compared to other similar studies ranging from four and nine photo cases (Bliss et al. 2014, Borchert et al. 2010). Another limitation is the use of photographs which provides a two-dimensional perspective only. Another consideration is that the surface area of redness and skin loss were estimated by visual observation. Future research could consider the use of an electronic scanning device to assess and monitor IAD (Ahn 2008). In this study, the reliability was assessed by two researchers. Further psychometric evaluation with clinicians in clinical practice is recommended with specific attention to the item 'oedema'.

In this study, time to healing of IAD was not calculated since no complete healing was achieved before discharge. In addition, patients should be monitored over a longer period of time to gain insight into the complete healing of the IAD. In line with our findings, Bliss et al. reported that most patients were discharged from the ICU before IAD healed and that hospital-wide adoption of a defined skin care regimen seems advisable to ensure timely healing of IAD (Bliss et al. 2011). Routine use of an instrument to monitor the magnitude of change in skin damage over time, could result in more tailored and adequate treatment. Since the psychometric evaluation of the GLOBIAD indicated that reliability was associated with level of education and expertise, training remains an important tool for improving the classification, monitoring, prevention and treatment of IAD (Beeckman et al. 2010, Beeckman et al. 2018).

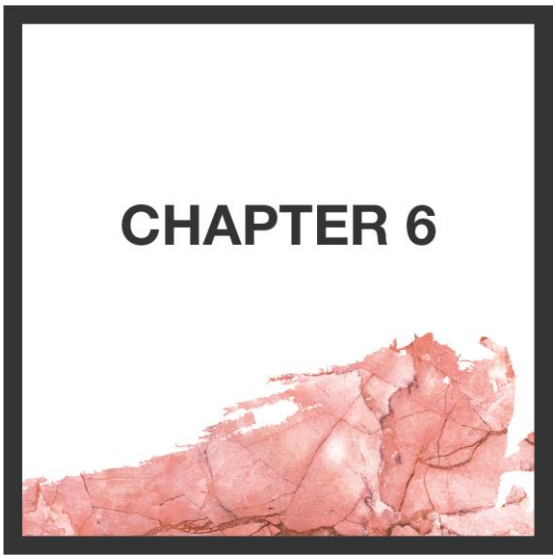
This tool could be used in clinical research as it is largely in line with the recent developed COS for IAD research which consist of the following critical outcomes for IAD research: 'erythema', 'maceration', 'erosion', and 'IAD-related pain' (Van den Bussche et al. 2018). The outcome 'patient satisfaction' was not embedded in the GLOBIAD-M since this is out of scope.

To conclude, the inter-rater agreement and reliability of the GLOBIAD-M is high when experts in the assessment of IAD apply this tool based on a set of images. The GLOBIAD-M could guide clinical decision-

making for treatment of patients with IAD as it can indicate a stagnation or deterioration of the wound healing. Further validation in clinical practice with clinicians is however needed.

Chapter based on:

VAN DEN BUSSCHE K., VERHAEGHE S., VAN HECKE A. & BEECKMAN D. (2018) Minimum Data Set for incontinence-associated dermatitis in adults: design and pilot study in nursing home residents. *Journal of Tissue Viability* [Under Review]



Minimum Data Set for incontinence-associated dermatitis in adults (MDS-IAD): design and pilot study in nursing home residents

ABSTRACT

Aim. The aim of this study was to develop a Minimum Data Set for Incontinence-Associated Dermatitis (MDS-IAD), to psychometrically evaluate and pilot test the instrument in nursing homes. Comparable to the MDS for pressure ulcers, the MDS-IAD aims to collect epidemiological data and evaluate the quality of care.

Methods. After designing and content/face validation by experts and clinicians, staff nurses assessed 108 residents (75.9% female, 77.8% double incontinent) in a convenience sample of five wards. A second nurse independently assessed fifteen residents to calculate inter-rater agreement (p_o) and reliability [Cohen's Kappa (κ)].

Results. The κ-value for 'urinary incontinence' was 0.68 [95% confidence interval (CI) 0.37-0.99] and 0.55 (95% CI 0.27-0.82) for 'faecal incontinence'. The p_o for severity categorisation according to the Ghent Global IAD Categorisation Tool (GLOBIAD) was 0.60. IAD was diagnosed in 21.3% of the residents. IAD management mainly involved the application of a leave-on product (66.7%), no-rinse foams (49.1%), toilet paper (47.9%), and water and cleanser (38.8%). Fully adequate prevention or treatment was provided to respectively 3.6% and 8.7% of the residents.

Conclusion. This instrument provides valuable insights in IAD prevalence at organisational level, will allow benchmarking between organisations, and will support policy makers. Future testing in other healthcare settings is recommended.

Keywords. Incontinence-associated dermatitis, Minimum data set, Nursing home, Prevalence, Reliability

Key messages

- The variation in epidemiological data (such as incidence and prevalence) of incontinence-associated dermatitis (IAD) across different countries, healthcare settings and patient populations can partly be explained by the lack of an internationally standardised tool and procedure to collect the data.
- No tool existed to assess the adequacy of IAD prevention and treatment practices at organisational level.
- A Minimum Data Set for IAD (MDS-IAD) to collect epidemiological data and to evaluate the quality of care at organisational level was developed rigorously by future users (researchers and clinicians).
- The low inter-rater agreement and reliability estimates indicate the need for education and further testing.

INTRODUCTION

Prolonged and repeated exposures of the skin to urine and/or faeces can cause incontinence-associated dermatitis (IAD). IAD is a specific type of irritant contact dermatitis characterised by erythema and oedema of the peri-anal and/or genital skin. In some cases, swelling, vesicles or bullae, skin loss, and/or cutaneous skin infection are present (Gray et al. 2012). Patients with IAD may experience physical discomfort because of pain, itching, burning or tingling (Van Damme et al. 2015). In addition, 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). Effective strategies for IAD prevention and treatment include the promotion of continence to limit and/or reduce exposure of the skin to urine and stool, the use of mild skin cleansers immediately after soiling, and the application of protective and caring leave-on products as part of a structured skin care regimen (Beele et al. 2017). Despite the growing body of evidence, standardisation of IAD management is challenging due to the lack of comparability between studies about the efficacy and (cost-)effectiveness of products and procedures (Beeckman et al. 2016, Pather et al. 2017).

To gain insight into the size of the problem, prevalence and incidence are the most common measures. Prevalence is the percentage of persons with IAD as a proportion of the entire patient population with incontinence, measured at a specific point in time (Defloor et al. 2005a). The incidence reflects the number of new cases of a disease and can be reported as a risk or as an incidence rate (Noordzij et al. 2010). To date, epidemiological data for IAD that are internationally comparable are missing. Seven large multicentre studies have reported data on IAD prevalence. Bliss et al. (2006) found a prevalence of 5.7% in continent and incontinent residents in US nursing homes, using a Minimum Data Set (Bliss et al. 2006a). Defloor et al. (2011) reported a prevalence of 5.7% in 19964 Belgian hospitalised patients with and without incontinence (Defloor et al. 2008). Since 2012, the prevalence of IAD is assessed annually in German hospitals and nursing homes using the German IAD Intervention Tool (IADIT-D) (Steininger et al. 2012). Kottner & Lahmann (2012) found a prevalence of 4.4% in 2386 incontinent nursing home residents and 12% in 317 hospitalised patients. Boronat-Garrido et al. (2016) combined data of three annual cross-sectional multicentre studies in German nursing homes (2012, 2013 and 2014), resulting in a prevalence of 5.2% in 3406 incontinent residents (Boronat-Garrido et al. 2016). Kottner et al. (2014) reported an overall prevalence of 6.1% in 3713 German and Austrian hospitalised patients (academic, general and geriatric hospitals) and residents of nursing and care homes (Kottner et al. 2014). More recently, Gray and Giuliano (2017) found a prevalence of 45.7% in 2492 incontinent patients in acute care facilities in the US (Gray and Giuliano 2017), and a national audit in Wales reported a prevalence of 4.3% in 8365 hospitalised patients (Clark et al. 2017).

Whereas certain patient populations may be more vulnerable to IAD, wide variations in the prevalence of IAD might be explained by the lack of coding of this particular skin condition in the International Statistical Classification of Diseases and Related health Problems (ICD), the lack of diagnostic criteria to differentiate IAD from other skin conditions (such as superficial pressure ulcers), and the differences in procedures and tools to collect data (Beeckman et al. 2007).

In 2017, an important step towards an international and uniform language of IAD was the design and international validation of the Ghent Global IAD Categorisation Tool (GLOBIAD) (Beeckman et al. 2018). The GLOBIAD categorises IAD based on the severity of the skin lesion and distinguishes between the presence of persistent redness [category (Cat.) 1] and the presence of skin loss (Cat. 2), both subdivided based on the absence (Cat. A) and presence (Cat. B) of clinical signs of infection (Beeckman et al. 2018). Content and face validity of the GLOBIAD was supported in a three-round Delphi procedure with an international panel of experts from 13 countries. The results of the psychometric evaluation of the GLOBIAD in 823 health professionals from 30 countries are published elsewhere (Beeckman et al. 2018).

In line with the European Pressure Ulcer Advisory Panel (EPUAP) pressure ulcer methodology for the collection of pressure ulcer prevalence data, the systematic assessment of IAD prevalence data using a valid and reliable minimum data set (MDS) is needed (Vanderwee et al. 2007). The MDS for pressure ulcers includes risk assessment, skin observation to assess the location and severity of existing pressure ulcers, and provides insight into the (adequacy of) preventive measures (Vanderwee et al. 2007). The EPUAP approach includes the independent assessment of the skin of each patient by two qualified nurses, leading to a report of the number of patients with pressure ulcers (Defloor et al. 2005a). Based on the EPUAP approach, algorithms for the adequacy of preventive interventions were developed and assessed in an Belgian prevalence survey including 19968 patients (Vanderwee et al. 2011). A similar uniform data collection instrument and methodology to gain insight into epidemiological data and adequacy of management of IAD in various healthcare settings is lacking. The use of a MDS can lead to better insights in the epidemiology of IAD, can enhance the comparability of research, and can lead to better benchmarking of quality of care (Defloor et al. 2005a).

The aim of this study was to develop a minimum data set for IAD (MDS-IAD) in adults and to psychometrically evaluate and pilot test the instrument in nursing home population.

METHODS

A two-phase instrument design and psychometric evaluation and pilot study was conducted.

Phase 1 – Instrument design and content validation

The aim of this phase was (1) to establish consensus on the content and face validity of the tool through meetings with future users (researchers and clinicians), and (2) to develop algorithms to assess the adequacy of IAD prevention and treatment.

Methods

The GLOBIAD (Beeckman et al. 2018), a Cochrane review of IAD prevention and treatment (Beeckman et al. 2016), the US Centers for Medicare & Medicaid Services (CMS) Resident Assessment Instrument (RAI) 3.0 (Saliba and Buchanan 2008, Services 2015), and the European Pressure Ulcer Advisory Panel (EPUAP) MDS were used to design the MDS-IAD (Vanderwee et al. 2007). For the development of the MDS-IAD, the Skin Integrity Research Group (SKINT) at Ghent University (Belgium) and clinicians of nursing homes reviewed and discussed each item extensively to be included in the tool. The criteria for the inclusion of the items were (1) the importance and relevance to the topic, (2) the applicability for all patients with incontinence [including patients with dementia or admitted to an intensive care unit (ICU)], and (3) feasible and easy to complete by clinicians and researchers. The rationale of the inclusion of items in the MDS, the instrument design and the data collection procedure are presented in Tables 1 and 2.

Results

The tool that emerged after review by experts and clinicians is displayed in Figure 1. The MDS-IAD (one page) consists of five categories of data: (1) administrative data, (2) patient data, (3) incontinence data, (4) IAD categorisation according to GLOBIAD, and (5) data about IAD prevention and treatment practices present at the day of observation. Incontinence was defined as the involuntary loss of urine and/or stool. An individual was considered continent when an indwelling catheter or stoma was present.

The algorithms to assess the adequacy of IAD prevention and treatment were constructed based on the available evidence (Beeckman et al. 2016, Beele et al. 2017). The algorithm took into account: (1) the use of appropriate skin cleansing after an incontinence episode, (2) the application of a leave-on product, (3) the use of an antimicrobial product only when necessary, and (4) the presence of a tailored toileting program. Figure 2 presents the adequacy of IAD prevention and treatment based on the algorithms. The algorithms for individuals with urinary and/or faecal incontinence but with intact skin consist of the following categories: (1)

complete and correct prevention: appropriate skin cleansing, use of a leave-on product, no use of an antimicrobial agent, and the presence of a tailored toileting program; (2) incomplete prevention: one of the criteria above is missing (such as the lack of a tailored toileting program); (3) incorrect prevention: the use of an antimicrobial agent; (4) no prevention: no appropriate skin cleansing, no leave-on product, and no tailored toileting program. The algorithms for individuals with urinary and/or faecal incontinence and diagnosed with IAD consist of the following categories: (1) complete and correct treatment: appropriate skin cleansing, use of a leave-on product, use of an antimicrobial agent if IAD Cat. B, and the presence of a tailored toileting program; (2) incomplete treatment: one of the criteria above is missing (such as the lack of a leave-on product); (3) incorrect treatment: the use of an antimicrobial agent if IAD Cat. A; (4) no treatment: no appropriate skin cleansing, no leave-on product, and no tailored toileting program.

Table 1. Rationale data collection instrument

Item	Rationale
Administrative and patient data ▪ Date ▪ Country ▪ Setting and discipline ▪ Sex and year of birth	To allow comparisons across countries, setting and disciplines (Vanderwee et al. 2007, Vanderwee et al. 2011) ▪ Following disciplines were constructed: medical (non-surgical), surgical, ICU, rehabilitation, and geriatrics
Incontinence The involuntary loss of urine and/or stool. Not incontinent if an indwelling catheter, FMS or stoma is present.	To define the target population necessary to obtain a correct prevalence calculation (Defloor et al. 2005a) ▪ Catheters are excluded as the skin is not exposed to the irritant ▪ UI, FI and diarrhoea were separated due to different risk for IAD (Bliss et al. 2006a, Bliss et al. 2011, Junkin and Selekof 2007, Kottner et al. 2014) ▪ Definitions according to the CMS RAI 3.0 (Saliba and Buchanan 2008, Services 2015)
Urinary incontinence	During a 7-day look-back period [any amount of urine (day or night)] ▪ Occasionally: < 7 episodes ▪ Frequently: ≥ 7 episodes but at least 1 continent void ▪ Always: no continent voids
Faecal incontinence	During a 7-day look-back period [any amount of stool (day or night)] ▪ Occasionally: 1 episode ▪ Frequently: > 1 episode but had at least 1 continent bowel movement ▪ Always: no continent bowel movements
Diarrhoea	During a 7-day look-back period ▪ Liquid stool or diarrhoea increases the risk for IAD (Bliss et al. 2011, Van Damme et al. 2018) ▪ Present if type 6 or 7, according to the Bristol Stool Chart (Lewis and Heaton 1997)
IAD categorisation ▪ Categorisation ▪ Facility-acquired ▪ Confirm infection ▪ Location	To obtain a valid and reliable skin observation ▪ Categorisation according to the 2017 developed and validated GLOBIAD (Beeckman et al. 2018) ▪ Confirmation of diagnosis of the clinical signs of infection if IAD Cat. B (Beele et al. 2017, Van den Bussche et al. 2018)
Management of the peri-anal region ▪ Cleansing ▪ Leave-on product ▪ Anti-microbial agent ▪ Incontinence products ▪ Toileting programs	To gain insight into the current IAD prevention and treatment practices ▪ Only products and procedures present at the day of observation ▪ Cleansing products groups according to the Cochrane review and clinician's input (Beeckman et al. 2016) ▪ Beneficial effects of a leave-on product (moisturiser, protectant or combination) (Beeckman et al. 2016) ▪ Not using diapers increases the risk of IAD (Van Damme et al. 2018) ▪ A toileting program benefits incontinence and skin status (Bates-Jensen et al. 2003), if appropriate and tailored (Abrams et al. 2017)

IAD, incontinence-associated dermatitis; CMS, US Centers for Medicare & Medicaid Services; RAI, Resident Assessment Instrument; GLOBIAD, Ghent Global IAD Categorisation Tool; FMS, Faecal Management System, UI, urinary incontinence; FI, faecal incontinence; ICU, Intensive Care Unit.

Table 2. Data collection procedure and rationale

Procedure *	**Rationale**
Training ▪ All participating nurses ▪ Before data collection	To improve correct IAD diagnosis, classification and documentation, including ▪ theoretical training (such as pathophysiology, classification, clinical signs of infection) preferably using PuClas (Beeckman et al. 2010) ▪ the use of the data collection instrument ▪ the data collection procedure (Beeckman et al. 2018, Vanderwee et al. 2007)
Determine target population ▪ Assess all individuals with urinary and/or faecal incontinence	To define the target population necessary to obtain a correct prevalence calculation (Defloor et al. 2005a) ▪ Numerator: the number of individuals diagnosed with IAD ▪ Denominator: the number of incontinent individuals
Data collection instrument (Figure 1)	
Complete items administrative data, patient data and incontinence data	To gain insight into the population, and allow comparisons across countries, setting and disciplines (Vanderwee et al. 2007, Vanderwee et al. 2011)
Perform skin observation ▪ Assessment of peri-anal skin ▪ Independent by 2 nurses: one ward nurse and one non-ward nurse ▪ On the same day ▪ Complete item 'IAD categorisation'	To enhance validity and reliability of the skin observation and prevalence calculation (Noordzij et al. 2010) ▪ The ward nurse can provide relevant background information about individual patients. If there is disagreement, the opinion of the non-ward nurse should be decisive ▪ The assessment should be performed on a predefined day to minimise bias
Complete item management peri-anal region	To gain insight into the adequacy of IAD prevention and treatment practices ▪ Record only products and procedures used at the day of skin observation

IAD, incontinence-associated dermatitis; PuClas, the PuClas educational e-learning tool (currently version 4, http://puclas4.ucvvgent.be) (Beeckman et al. 2010, Defloor et al. 2005b). * Procedure based on the European Pressure Ulcer Advisory Panel (EPUAP) methodology for the collection of pressure ulcer prevalence data (Vanderwee et al. 2007)

Minimum Data Set IAD

SKINT skin integrity research group www.skintghent.com

GHENT UNIVERSITY

ADMINISTRATIVE DATA

Date

Country

Setting

- ☐ Teaching hospital
- ☐ General hospital
- ☐ Nursing home
- ☐ Home care

Discipline (hospital only)

PATIENT DATA

Year of birth

Gender

- ☐ Female
- ☐ Male

INCONTINENCE

Urinary incontinence

- ☐ Not incontinent
- ☐ Occassionally incontinent
- ☐ Frequently incontinent
- ☐ Always incontinent

Faecal incontinence

- ☐ Not incontinent
- ☐ Occassionally incontinent
- ☐ Frequently incontinent
- ☐ Always incontinent

Diarrhoea

- ☐ No
- ☐ Yes

Start date: ..... / ..... / 20....

Stop date: ..... / ..... / 20....

IAD CATEGORISATION

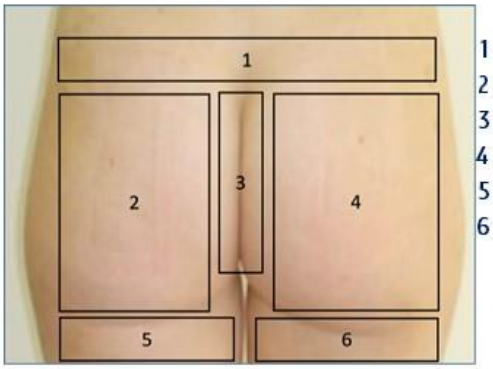
Do you observe IAD?

- ☐ No
- ☐ Yes

→ **Facility-acquired?**

- ☐ No
- ☐ Yes

Location IAD



- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

Categorisation IAD according to GLOBIAD

- ☐ **1A** Persistent redness without clinical signs of infection
- ☐ **1B** Persistent redness with clinical signs of infection
- ☐ **2A** Skin loss without clinical signs of infection
- ☐ **2B** Skin loss with clinical signs of infection

☐ Infection confirmed by wound culture

MANAGEMENT OF PERI-ANAL REGION

The skin is cleansed after an episode of incontinence with...

- ☐ Toilet paper
- ☐ Water and cleanser
- ☐ Water and oil
- ☐ No-rinse skin cleansers
- ☐ Cleansing foam
- ☐ Single-use disposable bathing wipes

After cleansing, do you use a leave-on product?

- ☐ Yes
- ☐ No

Do you use an anti-microbial agent?

- ☐ Yes
- ☐ Yes, on prescription
- ☐ No

Which incontinence products are used?

- ☐ Pads / briefs / liners
- ☐ Pull-up pants
- ☐ Underpads

Toileting programs

- ☐ Urinary toileting program since: ...../...../20..
- ☐ Bowel toileting program since: ...../...../20..

Van den Bussche K. & Beeckman D. (2017) Minimum Data Set IAD - Skin Integrity Research Group, University Centre for Nursing and Midwifery, Ghent University

Figure 1. Minimum Data Set for Incontinence-Associated Dermatitis

Phase 2 – Psychometric evaluation and pilot study

The aim of this phase was (1) to pilot test the MDS-IAD in nursing home residents to gain insight into the prevalence and adequacy of IAD prevention and treatment, and (2) to examine the inter-rater agreement and reliability of the instrument. Therefore, the first step was the Dutch translation of the MDS-IAD by the experts of the SKINT research group at Ghent University (Belgium).

Setting and participants

The pilot study was carried out in a convenience sample of three nursing homes in Belgium. All residents meeting the criteria for inclusion were eligible for participation. Inclusion criteria were: (1) present at the day of the data collection, (2) incontinent for urine and/or faeces, and (3) written informed consent by the patient or his/her representative.

Data collection procedure

In each nursing home, informal meetings with the senior nurses were conducted before and after the data collection. The aim was (1) to review and validate the Dutch language version of the MDS-IAD and provide information about the data collection procedures, and (2) to check the feasibility of the completion of the data collection instrument. The data collection instrument was provided on paper and distributed to the nursing homes. An instruction manual was provided (in Dutch) containing information about the data collection procedure and about how to score the MDS-IAD items. The nursing homes could decide the date of data collection and the number of participating wards depending on the staff availability. The procedure is presented in Table 2. To examine the degree of inter-rater agreement and reliability, residents of one ward were independently assessed by a second nurse. Identical data collection sheets were used by both nurses, but with the addition of a coded identification number to allow comparison between the nurses at patient level. In general, the nurses found the data collection instrument easy to complete. Only minor changes were made to the Dutch language version of the MDS-IAD. Nurses of one ward reported an average time for completion of 3.4 minutes per resident (35 residents in 2 hours).

Ethical approval

The study was performed conform to the ethical guidelines of the 1975 Declaration of Helsinki and approved by the Ethics Review Committee of Ghent University Hospital (B670201732240). Written and oral informed consent was obtained from all participating nursing home residents or their legal representatives.

Statistical analysis

All data of the residents including demographic variables were described using frequency distributions. To evaluate the adequacy of management, the surveyed residents were divided into two groups: those without IAD but at risk, and those with IAD. To examine the degree of inter-rater agreement, all eligible residents of one ward were independently assessed by a second nurse. Two MDS-IAD were completed per resident, including both the observation of the skin and the assessment of strategies for IAD prevention and treatment present at the day of observation. The overall percentage of agreement (p_0) and Cohen's kappa (κ) were calculated for ordinal data. The p_0 is the ratio of exact agreement between the raters to the total number of all ratings. The coefficient κ indicates reliability. 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) (Landis and Koch 1977). All statistical analyses were performed using SPSS statistical package version 24 (SPSS, Inc., Chicago, IL, USA).

RESULTS

General characteristics of the participants

A total of 108 incontinent residents [75.9% female, mean age 85.7 years (SD 9.4)] were assessed in five wards from three nursing homes. The majority of the residents were incontinent for both urine and faeces (77.8%) whereas the other residents were urinary incontinent only (22.2%). Table 3 provides an overview of the sample characteristics.

Table 3. Characteristics of residents (n = 108)

	Residents n (%)
Gender	
Male	26 (24.1)
Female	82 (75.9)
Age	
< 70 years	4 (3.7)
70 - 79 years	12 (11.0)
80 - 89 years	57 (52.3)
≥ 90 years	36 (33.0)
Urinary incontinence	
Not	3 (2.8)
Occasionally	29 (26.9)
Frequently	27 (25.0)
Always	49 (45.4)
Faecal incontinence	
Not	22 (20.4)
Occasionally	21 (19.4)
Frequently	24 (22.2)
Always	41 (38.0)
Double incontinent	83 (76.9)
Diarrhoea present *	3 (2.8)

* during a 7-day look-back period

IAD prevalence

First, the MDS-IAD generates data on IAD prevalence. In this pilot study, IAD was present in 23 (21.3%) of the examined participants, of which 20 were categorised as IAD Cat. 1A (87.0%), none as IAD Cat. 1B (0.0%), two as IAD Cat. 2A (8.7%), and one as IAD Cat. 2B (4.3%) (Table 4). The majority of the IAD were facility-acquired (73.9%) and located in the gluteal fold and peri-anal skin (69.6%), and the right and left buttock (respectively 65.2 and 60.9%).

Table 4. IAD prevalence and management of the surveyed residents (n = 108)

	Residents n (%)
IAD present	23 (21.3)
cat. 1A	20 (87.0)
cat. 1B	0 (0.0)
cat. 2A	2 (8.7)
cat. 2B	1 (4.3)
Facility-acquired IAD	17 (73.9)
Location IAD *	
Lower back	3 (13.0)
Left buttock	14 (60.9)
Gluteal fold and perianal skin	16 (69.6)
Right buttock	15 (65.2)
Left posterior thigh	2 (8.7)
Right posterior thigh	2 (8.7)
Infection confirmed by wound culture	0 (0.0)
Cleansing after incontinence episode *	
Toilet paper †	35 (47.9)
Water and cleanser	42 (38.9)
Water and oil	1 (0.9)
No-rinse skin cleansers	7 (6.5)
Cleansing foam	53 (49.1)
Single-use disposable bathing wipes	1 (0.9)
Leave-on product after cleansing	72 (66.7)
Application of anti-microbial agent	0 (0.0)
Use of briefs and underpads	
Pad / brief / diaper	101 (93.5)
Underpads	37 (34.3)
Toileting programs	
Urinary toileting program	17 (15.9)
Bowel toileting program	27 (25.0)

1A, persistent redness without clinical signs of infection; 1B, persistent redness with clinical signs of infection; 2A, skin loss without clinical signs of infection; 2B, skin loss with clinical signs of infection. * multiple answers possible. † Data available for 73 (67.6) residents

Assessment of IAD prevention and management practice

Second, the MDS-IAD provides insight into the current IAD prevention and treatment practices. The management of the peri-anal region, such as the use of cleansing and leave-on products, is presented in Table 4. Perineal skin cleansing mainly involved the use of no-rinse foams (49.1%), toilet paper (47.9%), and water and cleanser (38.8%). A leave-on product was applied in 66.7% of the residents. A final indicator was developed from the data collected during the survey to mark the allocation of 'adequate' IAD management. Figure 2

presents the adequacy of IAD prevention and treatment based on the algorithms. Complete and correct prevention and treatment was provided to respectively 3.6% and 8.7% of the residents. Most of the patients received incomplete IAD prevention (70.2%) mainly due to the absence of a tailored toileting program, followed by inadequate skin cleansing (such as the use of toilet paper, and water and cleanser). When the presence of a tailored toileting program was not taken into account, 37.6% of the residents received complete and correct prevention, 30.6% incomplete prevention, and 31.8% no prevention. Complete and correct treatment was present in 39.1%, incomplete treatment in 56.5%, and incorrect treatment in 4.3% of the residents diagnosed with IAD.

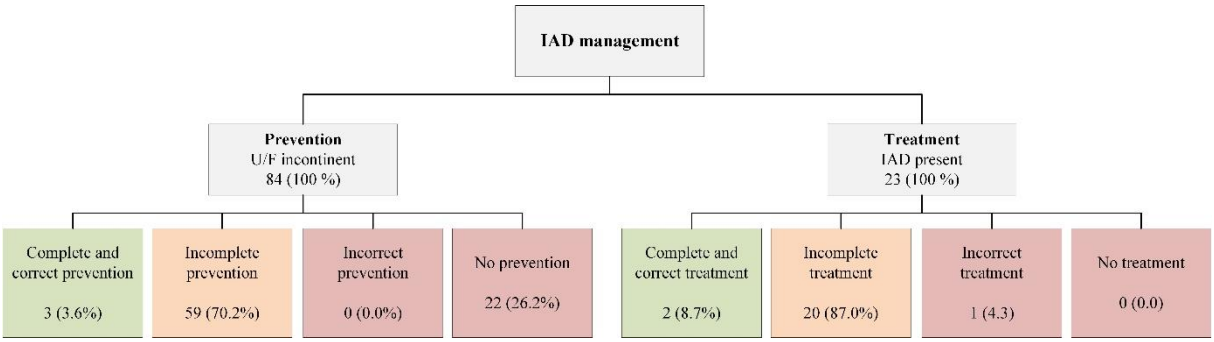


Figure 2. Adequacy IAD prevention and treatment

Inter-rater reliability

The inter-rater agreement and reliability coefficients κ and p_0 for each assessment item of the MDS-IAD are presented in Table 5. Two ward nurses independently assessed fifteen residents. The κ-value for the item 'urinary incontinence' was "substantial [0.68 (95% CI 0.37-0.99)] and "moderate" for 'faecal incontinence' [0.55 (95% CI 0.27-0.82)]. "Poor" to "moderate" κ-values were found for the items 'toilet paper', 'cleansing foam', 'leave-on product' and 'water and cleanser', ranging from κ = -0.25 (95% CI -0.54-0.04) to κ = 0.53 (95% CI 0.06-0.99)] . There was no κ calculated for a number of items because of almost identical ratings (range p_0 = 0.60 –1). The p_0 for the categorisation according to the GLOBIAD was 0.60.

Table 5. Inter-rater agreement and reliability coefficients – 2 raters

MDS item	Kappa (95% CI)	p_0
Incontinence		
Urinary	0.68 (0.37-0.99)	0.87
Faecal	0.55 (0.27-0.82)	0.67
Diarrhoea	– *	0.93
IAD present	0.50 (0.14-0.86)	0.73
Facility-acquired	– *	1
GLOBIAD	– *	0.60
Cleansing		
Toilet paper	-0.12 (-0.32-0.08)	0.67
Water and cleanser	0.53 (0.06-0.99)	0.8
Water and oil	– *	1
No-rinse skin cleansers	– *	0.93
Cleansing foam	-0.25 (-0.54-0.04)	0.47
Single-use disposable bathing wipes	– *	1
Leave-on product	0.10 (-0.41-0.61)	0.60
Anti-microbial product	– *	0.93
Incontinence products		
Pad / brief / diaper	– *	1
Underpads	– *	0.93
Toileting programs	– *	1

Based on the assessment of 15 residents by 2 raters. 95% CI, 95% confidence interval; p_0, percentage overall agreement. MDS, Minimum Data Set. * Not calculated, the variance of this rating is 0 due to almost identical ratings.

DISCUSSION

IAD is prevalent among adults with urinary and/or faecal incontinence across different healthcare settings. To date, no uniform data collection instrument or methodology for epidemiological IAD research and the assessment of the adequacy of IAD management at organisational level is available. The aim of this study was to develop a MDS-IAD, and to psychometrically evaluate and pilot test the data collection instrument in a nursing home setting. The Cochrane review, the recently developed Core Outcome Set in IAD and GLOBIAD by the SKINT research group were used to design the MDS-IAD (Beeckman et al. 2016, Beeckman et al. 2018, Van den Bussche et al. 2018). The content and feasibility of the items were determined by the SKINT research group and staff nurses of the participating wards, resulting in an instrument with content and face validity.

The MDS-IAD consists of five categories of data including general and patient data, the incontinence and skin status, and the management of the peri-anal region. The MDS-IAD is in line with the EPUAP MDS for pressure ulcers except the assessment of risk factors (Vanderwee et al. 2007). Risk assessment was not included as a

separate item as all individuals with urinary and/or faecal incontinence are considered at risk. In this study, incontinence was defined as the involuntary loss of urine and/or stool. An individual was not incontinent when an indwelling catheter or stoma was present. The frequency of incontinence was defined according to the validated US CMS RAI 3.0 (Saliba and Buchanan 2008, Services 2015). The skin status was assessed using the recently developed and psychometrically tested GLOBIAD (Beeckman et al. 2018). The proposed procedure is based on the widely used EPUAP approach for the collection of prevalence data which includes the independent assessment of the skin of each patient by two qualified nurses (Defloor et al. 2005a, Vanderwee et al. 2007). Moreover, this method can be used for the evaluation of quality improvement projects as it provides insight into the adequacy of IAD prevention (Vanderwee et al. 2011).

In this pilot survey, the overall prevalence of IAD was 21.3% in a sample of incontinent nursing home residents. This result is comparable to a study of Long et al. (2012) reporting an IAD prevalence of 22.8% in 171 long-term acute care patients (Long et al. 2012). Compared to larger studies, the prevalence was much higher. The variance in prevalence data between large prevalence studies could be explained by the underestimation of IAD in larger prevalence studies as they could be confused with superficial pressure ulcers (Beeckman et al. 2007), and the use of different methods. Bliss et al. (2006) and Defloor et al. (2011) reported the prevalence of IAD in a sample of incontinent and continent patients (Bliss et al. 2006a, Defloor et al. 2008). Boronat-Garrido et al. (2016) used the IADIT-D tool to categorise IAD (Boronat-Garrido et al. 2016), whereas Gray & Giuliano (2017) ranked IAD as mild, moderate or severe without using a specific instrument (Gray and Giuliano 2017). Moreover, some large studies were not intended for the purpose of assessing specifically IAD. Bliss et al. (2006) used the database of MDS records from nursing homes across the US but without the availability of an assessment item identifying perineal dermatitis (Bliss et al. 2006a, Savik et al. 2005). The MDS-IAD allows the calculation of IAD prevalence in healthcare settings using the number of individuals diagnosed with IAD as the numerator, and the number of incontinent individuals as denominator (Defloor et al. 2005a). To date, there is no internationally consented definition of the target population. Future research should look into the definition of incontinence for IAD purposes. The MDS-IAD nor the GLOBIAD are intended to instruct on differential diagnosis with pressure ulcers. To aid correct differentiation between pressure ulcers and IAD, the PuClas educational e-learning tool (currently version 4, http://puclas4.ucvvgent.be) was developed based on the EPUAP statement on pressure ulcer prevalence and incidence monitoring (Beeckman et al. 2010, Defloor et al. 2005b).

This study aimed to assess the adequacy of IAD management. Therefore, the participants were divided based on the presence of absence of IAD. The vast majority of participants did not receive adequate IAD prevention or treatment. A possible explanation could be limited staffing as it has been associated with poor skin care,

but this was not within the scope of this study (Schnelle et al. 2004). Few studies have specifically examined skin care practices in healthcare settings. Two large German studies in the home care and nursing home setting, identified a large heterogeneity in cleansing and skin care products used (Kottner et al. 2015, Kottner et al. 2013a). Preventive interventions are important since they have shown to be the strongest protective factor against the development of IAD (Bliss et al. 2017). The absence of a tailored toileting program had a major impact on the assessment of quality of care. It is recommended to consider tailored toileting programs for all patients with incontinence as evidence suggests that structured toileting and exercise interventions can improve incontinence and skin status in nursing home residents (Bates-Jensen et al. 2003). All nursing home nurses reported the presence of several timed 'toileting rounds' as general continence management for all residents, both incontinent as continent. Timed voiding is considered a passive toileting programme and there is insufficient evidence if timed voiding reduces urinary incontinence in frail older persons (Abrams et al. 2017).

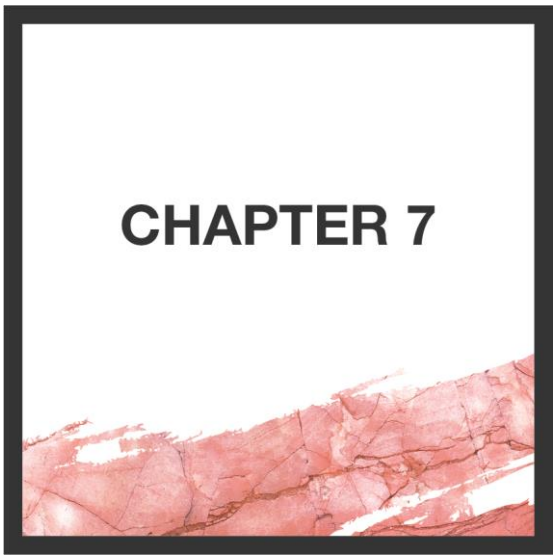
In this study, the agreement and reliability of the MDS-IAD was examined in a sample of 15 residents from one nursing home ward. The estimates indicate a low degree of inter-rater reliability for the assessment of cleansing products. This may reflect the current nursing practice and the lack of standardised language and skin care protocols in nursing homes (Kottner et al. 2013c). A large number of reliability estimates could not be calculated due to identical ratings of both nurses. Since the psychometric evaluation of the GLOBIAD indicated that reliability was associated with level of education and expertise, training remains an important tool for improving the classification, monitoring, prevention and treatment of IAD (Beeckman et al. 2010, Beeckman et al. 2018).

This study reports on the development of the first MDS-IAD based on state of the art evidence, consultation with future users (experts and clinicians), and a pilot test in nursing homes. This study had limitations. The study did not recruit a representative sample of nursing homes, as the participation was voluntary. Consequently, caution in interpreting the results of the pilot test is warranted. This study used a considerably smaller sample of residents compared to other studies. Vanderwee et al. (2007) included the assessment of 225 patients in five countries (ranging from 16 to 113 patients per country) in the inter-rater reliability study. Although the heterogeneity among patients with incontinence in different settings (such as ICU and nursing homes) was taken into account when designing the MDS-IAD, future research should test the MDS-IAD and methodology in other healthcare settings, including a powered psychometric evaluation. Translations were done by experts in the field of IAD before the validation process with staff nurses of nursing homes, but back-translation was not performed (Maneesriwongul and Dixon 2004). Next, the lack of IAD guidelines, internationally agreed recommendations, and knowledge on current applied products are a limitation in the

development of algorithms. One large prevalence study reported the problem of missing data (Gray and Giuliano 2017). Therefore, it is recommended to develop an electronic system for data collection with mandatory fields to avoid missing data.

As pressure ulcers are considered avoidable and linked to the quality of care, many countries frequently measure pressure ulcer prevalence as a quality indicator. Van Dishoeck et al. (2016) found that the development of pressure ulcers or IAD was associated with the quality of the preventive care process, reflecting the quality of care (Dishoeck et al. 2016). An accurate differentiation between a pressure ulcer and IAD is important for adequate documentation and benchmarking quality of care (Beeckman et al. 2011). Therefore, it could be useful to perform prevalence surveys of pressure ulcers simultaneous with IAD, as suggested by Campbell et al. (2016) (Campbell et al. 2016a).

To conclude, the execution of this pilot survey provided valuable insights for future studies and practice. The MDS-IAD aims to measure IAD prevalence in incontinent individuals and assess the adequacy of IAD management, for benchmarking and comparing between different healthcare settings and countries, to support policy makers in their decision making process and incontinence/skin care budget allocation, and to evaluate quality improvement projects. Training will be important to improve correct classification and reliability of the MDS-IAD. Future testing in other healthcare settings is recommended. The IAD prevalence and strategies for IAD prevention and treatment used in practice should be re-evaluated on a regular basis.



GENERAL DISCUSSION

Introduction

Incontinence-associated dermatitis (IAD) was defined in 2007 as "an inflammation of the skin that occurs when urine or stool comes into contact with perineal or perigenital skin" (Gray et al. 2007). The application of various methods and tools for data collection resulted in varying prevalence and incidence estimates. The lack of an internationally adopted classification system, ICD coding, and standardised method to collect epidemiological data importantly contributed to this variability. Despite the growing evidence base, the limited evidence about the effectiveness of products and procedures for IAD management still poses a challenge for clinicians (Beeckman et al. 2016, Pather et al. 2017). Inadequate IAD prevention and treatment increase burden for patients, caregivers, and society (Sen et al. 2009, Van Damme et al. 2015).

A standardisation of language, outcome definition and methods for IAD research are needed. This thesis reports on the development of a core set of outcome domains for IAD research to standardise outcomes in IAD research. Different studies were conducted to develop tools to (1) categorise the severity of IAD, (2) monitor healing of IAD, and (3) assess IAD prevalence and adequacy of prevention and treatment. The aim of this chapter is to discuss the key challenges, opportunities, recommendations and future perspectives for research, clinical practice, education, and policy. The contributions of this thesis and future challenges are discussed in three sections: (1) core outcome set in IAD research, (2) IAD classification and monitoring, and (3) Minimum Data Set for IAD.

Core Outcome Set in IAD research

As there was no agreed standardised set of outcomes for clinical trials in the field of IAD, this thesis started by answering the first research question: which set of core outcome domains should be assessed and reported in IAD clinical trials involving adults with IAD or at risk of IAD, independently from any geographical location or skin colour? (chapter 3). An international and multidisciplinary consensus method study resulted in five critical outcome domains: erythema, maceration, erosion, IAD-related pain, and patient satisfaction.

The highest level of consensus was reached for the domains concerning clinical signs of IAD: erythema, maceration, and erosion. These outcome domains are highly relevant and critical elements of the clinical picture of IAD (Gray et al. 2012, Mugita et al. 2015). First, excessive skin surface moisture during incontinence episodes results in maceration of the skin, often described as the presence of a whitened appearance and slight swelling (Ichikawa-Shigeta et al. 2014, Kottner and Beeckman 2015). Although maceration is frequently part of an IAD definition, it is not reflected in the IAD assessment instruments. Limited research is available

on the physiological and appearance characteristics of skin maceration caused by urine and/or faeces. Ichikawa-Shigeta et al. (2014) described macerated skin surface as "not smooth, but laced with multiple networks of fin rooves called sulci cutis" (Ichikawa-Shigeta et al. 2014). Two studies with healthy volunteers and elderly women with incontinence reported on possible non-invasive proxy measures for maceration (Ichikawa-Shigeta et al. 2014, Minematsu et al. 2011). Higher levels of transepidermal water loss (TEWL) which evaluates the skin barrier function, and higher levels of skin hydration were found in the macerated skin compared to the control skin (Ichikawa-Shigeta et al. 2014, Minematsu et al. 2011). To date, the diagnosis of maceration by practicing clinicians relies on visual inspection of the skin.

The second phase in the development of IAD is an inflammatory response characterised by erythema but with an intact epidermis (Gray et al. 2007). Erythema is inextricably linked with IAD and this is reflected in all existing IAD assessment instruments. The assessment of erythema is based on visual inspection of the degree of severity using categories such as mild, moderate, severe (Brown 1993, Long et al. 2012, Lutz et al. 1996), or the use of redness colour charts (Bliss et al. 2014, Borchert et al. 2010). Other methods that provide an objective measure of erythema have been used in studies such as the Lovibond Tintometer (Anthony et al. 1987) or the Diastron Erythema Meter (Byers et al. 1995, Fader et al. 2003). To date, these instruments have limited use for clinical practice.

Thirdly, in some cases IAD will evolve to an erosion of the skin. The epidermis may be damaged; in some cases, the entire epidermis may be eroded exposing a moist, weeping dermis (Gray et al. 2012, Ichikawa-Shigeta et al. 2014). Erosion is often part of assessment instruments, with variation in wording such as skin integrity, skin breakdown or excoriation (Brown 1993, Lutz et al. 1996, Scotland 2008). Currently, the presence of erosion is assessed via visual inspection of the skin.

IAD-related pain and patient satisfaction reached a high level of consensus for inclusion in the core domain set. Pain is a key characteristic of IAD occurring especially during touch and skin cleansing activities (Kottner and Beeckman 2015, Van Damme et al. 2015). Several patient symptoms such as pain and burning are included in a number of IAD assessment instruments (Brown 1993, Junkin and Selekof 2008, Long et al. 2012). However, the Cochrane review of interventions related to IAD prevention and treatment found no data for the domain 'pain due to IAD' within the included (quasi-) Randomised Controlled Trials (RCTs) (Beeckman et al. 2016). A variety of methods can be applied to assess pain and pain levels. Adults with incontinence who are able to report about pain levels, can use instruments such as the numeric rating scale (Williamson and Hoggart 2005). Appropriate methods should be applied in patients who do not have capacity to provide feedback (e.g. due to cognitive or conscious state). Tools for assessing pain in nonverbal older adults have been developed such as

the Discomfort Behavior Scale (DBS) and the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) (Herr 2011, Kim et al. 2017).

Patient satisfaction refers to the degree to which the individual regards the intervention or the procedure in which it is delivered as useful, effective, or beneficial (NCBI MeSH term definition)(Medicine 2016). The Cochrane review of interventions for IAD prevention and treatment did not reported the a priori defined primary outcome "number of participants not satisfied with treatment" (Beeckman et al. 2016). A clinical trial reporting the effects of 'washing without water' measured resident satisfaction with a questionnaire containing items on perceived discomfort, pain and overall satisfaction completed by the residents or their legal representatives (Schoonhoven et al. 2015). Within a clinical trial studying the effects of an absorbent product, community-living people with faecal in continence rated their overall satisfaction on a 4-point scale from very satisfied to very dissatisfied (Bliss and Savik 2008).

Although we recommend future trial developers to include these five outcome domains when designing clinical trials in the field of IAD, this does not imply that outcomes in a particular trial should be restricted to those. There is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well (Boers et al. 2014a, Williamson et al. 2017). Following outcomes were considered important but not critical for inclusion in the core set of outcome domains, and can be considered by future trial developers besides the recommended aforementioned five domains: cost-effectiveness, IAD-related Quality of Life, and major colonization and infection.

Nursing research aims to guide nursing practice and to improve the health and quality of life of patients. The importance of clinical trials contributing to evidence-based knowledge, practice and informed clinical decision making is acknowledged in health and nursing science (Polit 2010). Since trial designs are of varying methodological quality and populations, interventions, and outcomes are not comparable, the development and use of a COS relevant to nursing practice is appropriate and highly recommended. Existing frameworks such as the North American Nursing Diagnosis Association (NANDA) lack specificity to guide future trial developers when designing effectiveness trials. In the NANDA, the diagnoses '(risk for) impaired skin integrity' and 'risk for pressure ulcer' are present but not the diagnosis of IAD (NANDA 2014). We encourage researchers and advocates from other fields to pursue the development of a COS. A COS represents the minimum that should be reported in clinical trials, but are also considered suitable for use in clinical audit or research other than randomised trials (Williamson et al. 2017).

Methodological strengths and limitations

This study was the first to obtain consensus on a set of core outcome domains to be assessed and reported in IAD clinical trials. The international and multidisciplinary approach is a major strength of this study. However, it is important to emphasise some methodological considerations when adopting a core set of outcome domains.

The frameworks for COS development emphasise the importance of involving relevant stakeholders throughout the entire process ensuring multiple perspectives (Boers et al. 2014a, Schmitt et al. 2014, Williamson et al. 2017). The perspective of patients living with the health condition is also considered essential as they are 'experts by experience' (Williamson et al. 2012b, Young and Bagley 2016). Since 2002, the OMERACT initiative has been involving patient research partners (PRP's) for the development of COS in the field of rheumatology. OMERACT defines PRPs as "persons with a relevant disease who operate as active research team members on an equal basis with professional researchers, adding to benefit of their experiential knowledge to a research project" (Boers et al. 2014a). We aimed to involve all stakeholder perspectives but patients were underrepresented compared to COS studies in other fields (Boers et al. 2014a). The acute nature of the condition and the care-dependent population (elderly and ICU patients) restricted the participation of patients. In our project, patient involvement was crucial for domain identification. Although patient views were considered, they were not included as real PRP's.

The COS development frameworks provide guidance for the involvement of patients as research partners, but there is uncertainty on how best to ensure meaningful patient involvement (Kottner et al. 2017). Within the COMET Initiative, the People and Patient Participation, Involvement and Engagement (PoPPIE) working group provide recommendations such as the development of strong links with patient organisations (COMET 2016b, Young and Bagley 2016). In our study, the patients were recruited via patient organisations. Our concern, as well as the concern of other COS projects as part of the CSG-COUSIN, is whether involved patients are sufficiently representative for a whole patient group (Kottner et al. 2017).

Although the methods of our COS project was guided by COMET, OMERACT, and the HOME roadmap, details regarding outcome selection and consensus methods were vague (Boers et al. 2014b, Schmitt et al. 2014, Sinha et al. 2011, Williamson et al. 2017, Williamson et al. 2012b). To date, there is no evidence to suggest whether the different approaches regarding methods for consensus and scoring systems impact on the final COS. A review published in 2014 identified 198 published and ongoing COS development studies covering various areas of health, most commonly cancer, rheumatology, neurology, heart and circulation, and dentistry and oral health (Gargon *et al.* 2014). The review reported a variety of methods which have been used to select

outcomes for the COS including systematic review, semi-structured or unstructured group discussion, the Delphi Technique, and consensus development conferences (Gargon *et al.* 2014).

In our study, we used both systematic literature review methods and interviews with stakeholders to inform the subsequent consensus study using Delphi procedure. Neither there is a reference standard for conducting Delphi methods and for consensus definitions. Two methodological studies concerning the use of Delphi studies during COS development were published. A systematic review on how consensus is operationalised in Delphi studies reported a large variety in methods; consensus was not always specified a priori (with a threshold value), definitions of consensus varied widely, and were poorly reported (Diamond et al. 2014). A study of Brookes et al. (2015) reported that the type of feedback presented did impact on the subsequent scoring of items and the items subsequently retained at the end of the Delphi process (Brookes et al. 2016). None of the described studies provided guidance on the scoring system.

Currently, the nine-point scale is most often used in COS studies to measure agreement between Delphi study participants (Williamson et al. 2017). The decision rules, mainly based on cut-offs, during the Delphi rounds are 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. For the purpose of the development of the core set of outcome domains, the domains rated critical in both groups were included in the second round. Further research will explore whether these different scoring systems would lead to different outcome selection.

Future perspectives

Two future perspectives will be discussed. First, the development and implementation of a COS in clinical research may contribute to evidence synthesis via systematic reviews including meta-analysis and the development of clinical practice guidelines. Second, future work will be needed to establish instruments to measure the defined domains in a valid and reliable way.

COS for evidence synthesis and development of guidelines

The use of the core set of outcome domains will benefit IAD research. First, the use of the core set of outcome domains will lead to better, more efficient and relevant research regarding both IAD prevention and treatment (Williamson et al. 2012a). Second, standardisation of outcomes will lead to better evidence summary in a next Cochrane review. A more qualitative and comparable evidence base will facilitate data synthesis in systematic

reviews and enable meta-analysis to include data from relevant studies (Higgins and Green 2005). Third, the core set of outcome domains will allow the development of guidelines. To date, the dissemination of knowledge regarding IAD appears scattered and via several sources, such as overviews of knowledge combining research findings and expert opinion, consensus or best practice documents (Beeckman 2017, Beeckman et al. 2015, Gray et al. 2012, Kottner and Beeckman 2015). In line with the domain of pressure ulcers, it is recommended to develop clinical practice guidelines (NPUAP et al. 2014, Steinberg et al. 2011). Multidisciplinary development with all stakeholders such as nurses, continence care specialists, tissue viability team, dermatologists, and patients on both international and national level is recommended (Werner et al. 2016). The implementation of these guidelines will be important for improving the quality of care for patients with incontinence.

Core Set of Measurements

The core set of outcome domains for IAD research includes "what" should be measured, future research will address "how" these outcome domains should be measured in a valid and reliable way (Prinsen et al. 2014). A variety of definitions, measurement instruments or devices are used to measure similar outcomes. Evidence synthesis is further hampered by incomparable scores from different instruments and variability in the quality (reliability and validity) of measures used (Williamson et al. 2017).

Although the outcome domains patient satisfaction and IAD-related pain emerged as critically important to measure and report in clinical trials, few clinical trials have measured these outcomes (Beeckman et al. 2016). The most appropriate way to measure these patient-reported outcomes (PRO), patient-reported outcome measures (PROMs), should be investigated (Macefield et al. 2014). Patient satisfaction is considered a patient-reported experience measure (PREM) which captures information about the healthcare experience as perceived by the patient (Breckenridge et al. 2015). Moreover, panellists in our consensus study indicated the importance of the capacity of patients to provide feedback (e.g. due to cognitive or conscious state) for the choice of instruments.

A number of frameworks provide guidance for the selection of measurement instruments. A joint initiative between COMET and Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) developed a guideline on how to select outcome measurement instruments for outcomes included in a COS (Mokkink et al. 2016, Prinsen et al. 2014). The COSMIN standards were originally developed for evaluating the quality of studies on the measurement properties of PROMs (Mokkink et al. 2016). The COSMIN initiative collates systematic reviews of measurement properties of available measurement instruments that intend to measure (aspects of) health status or (health-related) quality of life. COSMIN has also developed a

checklist about which measurement properties are important and standards for how to evaluate their measurement properties including the evaluation of the different measurement properties (such as reliability, validity, and responsiveness) (Mokkink et al. 2009). The COSMIN checklist will facilitate the selection of the most appropriate PROM amongst competing instruments (Williamson et al. 2017).

The framework of the HOME roadmap endorsed by CSG-COUSIN, the OMERACT Filter, and the joint initiative between COMET and COSMIN were used to inform the project design of the Core Set of Measurements for IAD research (chapter 2). First, the research question will be determined and the available instruments will be identified via a systematic literature review. Next, the methodological quality of the instrument development and testing studies will be assessed using the COSMIN checklist. Third, an overview of the measurement properties will be given using the COSMIN checklist and the criteria for good measurement properties developed by Terwee (2011). The final result, a core set of measurements, will be a selection of instruments that have proven to be truthful (e.g. content validity, construct validity), discriminative (e.g. internal consistency, reliability) and feasible (e.g. interpretability, availability) (Boers *et al.* 2014b). Fourth, validation studies should be conducted or new instrument developed if there is an absence of evidence. Final, a consensus study will be organised to reach consensus about the core set of measurements.

To conclude, we recommend future trial developers to consider the application of a Core Outcome Set when designing trials in the field of IAD. As with the uptake of guidelines for the reporting of different types of research study, such as Consolidated Standards of Reporting Trials (CONSORT) for randomised trials, the next step will be the active encouragement by journals to apply a COS in research studies (Williamson et al. 2017). Schmitt et al. (2014) reported that the majority of the coordinating editors of the Cochrane Review Groups indicated that a COS for effectiveness trials should be used routinely for a *Summary of Finding* table in their Cochrane Reviews. Funding bodies are increasingly asking for COSs to be included in the trial funding applications (Schmitt et al. 2014).

IAD classification and monitoring

Classification is defined as 'an exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose' (ISO 2003). Classification of wounds such as pressure ulcers is an essential and integral part of clinical practice and research to ensure consistent and accurate wound categorisation as a means to guide clinical treatment and to aid diagnosis coding for accurate communication and reimbursement (Defloor et al. 2006, NPUAP et al. 2014, Weller et al. 2017). The ICD-10 is used to translate diagnoses of diseases and other health problems from words into an alphanumeric code, which permits analysis, sharing and comparison of the data (Patel et al. 2017, WHO 2016). The purpose of the ICD-10 is to authorise the systematic recording, analysis, interpretation and comparison of mortality and morbidity data collected in different countries or areas, and at different times (WHO 2004). Registration and coding of diagnoses based on standardised definitions allow consistent data for different purposes, such as determining the needs of hospitals, the organization of the financing of the hospitals, to support health policy, and providing data for local, national and international scientific studies (FOD 2017).

To date, there is no separate code for IAD in the ICD-10 (Gray et al. 2012, WHO 2016) and existing IAD assessment instruments have limitations regarding complexity and feasibility for routine clinical practice (Clarke-O'Neill et al. 2015a). Therefore, an international project, comparable to the pressure ulcer classification system (NPUAP et al. 2014), was set up to generate a new IAD classification instrument, the Ghent Global IAD Categorisation tool (GLOBIAD), to work towards a uniform language for IAD (chapter 4). This chapter answered the second research question: what is the content validity, agreement and reliability of a new instrument to assess the severity of IAD in patients with urinary and/or faecal incontinence? The experts agreed on a two-fold purpose: to create an internationally agreed description of IAD, and to standardise the documentation for clinical practice and for research purposes. In line with the recommendations of Clarke-O'Neill et al. (2015), the GLOBIAD is easy to complete and comprises photographs illustrating the different severity levels for each of the four categories (Clarke-O'Neill et al. 2015a). Moreover, existing instruments could be mapped to the GLOBIAD. For instance, the category "early IAD" of the incontinence-associated dermatitis Intervention tool (IADIT) could be mapped to GLOBIAD Cat. 1, and the categories "moderate IAD" and "severe IAD" to GLOBIAD Cat. 2 (Junkin and Selekof 2008)

Next to the classification of wounds, clinicians need instruments that are sensitive to wound changes over time to assure timely, adequate and targeted prevention and treatment (Arndt and Kelechi 2014). Instruments that allow assessment of wound healing should help to enhance communication among clinicians by defining a common language and standardising assessment of wound characteristics (Pillen et al. 2009). The GLOBIAD

was developed for IAD severity categorisation but not to monitor the change in IAD status over time. To address this need, a two-phase instrument design and reliability study was conducted, resulting in the Ghent Global IAD Monitoring Tool (GLOBIAD-M) (chapter 5). This chapter answered the third research question: how can the IAD status in patients diagnosed with IAD be monitored over time in a valid and reliable way?

Each item of the GLOBIAD was reviewed and discussed extensively before inclusion in the GLOBIAD-M. The single-page GLOBIAD-M consists of general data, IAD categorisation according to the GLOBIAD to allow incidence measurements, nine IAD and surrounding skin assessment items (such as maceration and purulent exudate), and the assessment of patient-related symptoms such as itching and pain. A dashboard with a graph and colour-grading system allows the monitoring of the change in IAD status over time. The GLOBIAD-M may guide clinical decision-making for treatment of patients with IAD as it can indicate a stagnation or deterioration of the wound healing process.

Methodological strengths and limitations

The particular strength of this study is the sound content and face validity resulting from structured input and feedback of international experts in the field of IAD from 13 countries, and the psychometric evaluation of the instrument in a large sample of health professionals from 30 countries. However, there are some important methodological considerations when adopting the GLOBIAD.

The psychometric evaluation in an international sample of healthcare professionals indicated the complexity of assessing the presence or absence of clinical signs of infection. This study used photographs of IAD lesions to evaluate the psychometric properties of the GLOBIAD. The use of photographs provides a two-dimensional perspective only and important clinical signs of infection like warmth, swelling, pain, and itching are not detectable. Although the use of photographs has some limitations, it increases feasibility as it allows repeated assessments in a large international sample of healthcare professionals. It is important to consider that diagnostic accuracy and reliability estimates are influenced by the characteristics of the set of photographs (Kottner et al. 2011). In this study, the number of images with clinical signs of infection were lower and only two images of darkly pigmented skin were included. The latter may limit the applicability of the results to all skin phototypes. The use of patient cases, in which more complex information is provided, is recommended for future research. When using photographs in future research, it is recommended to consider an identical number of photographs per category.

The heterogeneous sample of healthcare professionals allowed the comparison of results between groups. In this study, more experienced and higher educated clinicians classified the IAD lesions in a more correct and reliable way. Training and education will be important for improving the classification of IAD, as classification

requires a profound knowledge and clear understanding of the pathophysiology, signs and symptoms (Beeckman et al. 2010, Defloor et al. 2005b). Basic nursing and post-qualification education are to be encouraged to implement IAD classification, prevention and treatment within their curricula to improve both knowledge and attitudes about IAD and its management. Specific attention should be given to recognising clinical signs of infection. The development of methods to teach IAD classification is recommended. Further research should focus on the effectiveness of education on classification skills.

For the purpose of the psychometric evaluation, the GLOBIAD was translated into 14 languages [Arabic, Croatian, Czech, Danish/Norwegian, Dutch, English, French, German, Hungarian, Italian, Portuguese, Slovak, Spanish, and Turkish] of the 30 participating countries by native speakers with extensive content expertise. Clinicians and researchers can implement the GLOBIAD in their own language. However, to achieve different language versions of an English instrument that are conceptually equivalent in each of the target countries, the WHO proposed the forward-translations and back-translations (WHO 2018a). In our study, back-translation was not performed. To aid global dissemination, the availability in other languages should be extended in the future. Any translation or modification should be carried out in accordance to the methods outlined by the WHO (WHO 2018a).

Clinicians and policy-makers should take into account some considerations when implementing the GLOBIAD-M instrument. The psychometric properties of the GLOBIAD-M were tested in a sample of hospitalised patients with trained researchers, and not with bedside nurses. The same instrument, used in a different setting or with different subjects, may demonstrate variation in agreement and reliability (Cook and Beckman 2006). Therefore, future research is needed to evaluate the feasibility and reliability of the instrument in clinical nursing practice. In our study, complete healing of the IAD lesions was not achieved before discharge. In future research, patients should be monitored over a longer period of time to gain insight into the factors that compromises or contributes to the complete healing of the IAD.

Future perspectives

Towards an international language for IAD

Our studies have contributed considerably to the awareness of IAD among clinicians and researchers. As a result of the increasing attention towards IAD, efforts are ongoing to add IAD as an index term for irritant contact dermatitis due to incontinence in the WHO ICD 11th Revision (WHO 2017). This version is expected to be available in 2018. A proposal is made to change the index terms as follows: (1) *Primary irritant napkin dermatitis*: "A type of irritant dermatitis seen in infants and young children localised to the area in contact with a napkin (diaper) and occurring most often as a reaction to prolonged contact with urine, faeces, or

retained soap or detergent" (inclusions nappy rash, diaper rash) [EH80.10], and (2) *Irritant contact dermatitis due to incontinence*: "Irritant contact dermatitis from prolonged contact with urine or faeces as a result of incontinence" including the term incontinence-associated dermatitis [EK42.22]. In the future, healthcare organisations, governments, and researchers will be able to implement the new codes within clinical practice and for research purposes. The ICD code will permit the systematic recording analysis, interpretation and comparison of IAD data collected in different countries or areas and at different times. Consistent terminology for IAD will facilitate the comparability of research worldwide.

Development and implementation of IAD management in electronic health records

At individual patient level, categorisation of the severity of IAD according to the GLOBIAD tool should be considered. Upon IAD diagnosis, the GLOBIAD-M could be used to monitor IAD over time on a regular basis to evaluate the effectiveness of treatment strategies. Future research is however needed to evaluate the feasibility and reliability of the instrument used by nurses in clinical practice.

In line with the increasing attention for digitalising healthcare organisations, it is recommended to include the GLOBIAD within the electronic health record, a systematised longitudinal collection of electronic health information about individual patients in a digital format (Gunter and Terry 2005). Moreover, it is recommended to develop and implement a computer-based clinical decision support system for IAD management in healthcare settings, which provides clinicians with patient-specific assessments or recommendations to aid clinical decision making (Musen et al. 2014). Such systems showed to improve prescribing practices, enhance the delivery of preventive care services, and improve adherence to recommended care standards (Kawamoto et al. 2005). Kawamoto et al. (2005) reported several features that were closely correlated with decision support systems' ability to improve patient care significantly: (1) provide decision support automatically as part of clinician workflow, (2) deliver decision support at the time and location of decision making, (3) provide actionable recommendations, and (4) use a computer to generate the decision support (Kawamoto et al. 2005).

Because of the lack of (high quality) evidence regarding IAD treatment and prevention, best practice should be used to develop a care protocol (Beeckman et al. 2016, Pather et al. 2017). Beele et al. (2017) published a ready to use and practical protocol used within a Belgian university hospital based on best practices (Beele et al. 2017). It would be interesting to link this protocol to a computer-based clinical decision support system. The presence of incontinence is inherently associated with an increased risk for IAD development. Therefore, it is recommended to assess the continence status of the patient on admission. If the patient is urinary and/or faecal incontinent, an appropriate IAD prevention protocol to minimise exposure to urine and stool, including

a number of incontinence management recommendations, and to protect the skin should be given. Although risk assessment tools have been developed (Junkin and Selekof 2008, Nix 2002, Steininger et al. 2012), its usefulness in clinical practice has not been established. Quantifying IAD risk with assessment tools is not recommended as the predictive value of risk assessment scales varies per setting (Beeckman et al. 2013, Defloor and Grypdonck 2005). However, knowledge and awareness of key risk factors for IAD combined with skin assessment on admission and at regular intervals is needed.

Patients with faecal incontinence and/or urinary incontinence are at higher risk of developing IAD than those with urinary incontinence alone (Bliss et al. 2006a, Kottner et al. 2014). Currently, nurses record important physiological parameters such as blood pressure and pulse, but also the time, amount and the type of defaecation on a daily basis. If liquid stool or diarrhoea (type 6 and 7), which increases the risk for IAD (Bliss et al. 2011, Van Damme et al. 2018) is reported, tailored recommendations should be presented to the nurse including increased skin assessment, appropriate skin cleansing and protection. Other identified risk factors are non-use of diaper, poor skin condition due to aging and diabetes, limited tissue oxygen supply due to fever, low oxygen saturation and smoking, friction and shear, and occlusive skin cleansing practices (Bliss et al. 2006a, Bliss et al. 2011, Junkin and Selekof 2007, Kottner et al. 2014, Van Damme et al. 2018, Van Damme et al. 2017).

The skin status of all patients with faecal and/or urinary incontinence should be assessed daily for signs of IAD, and consequently classified according to the GLOBIAD. If an IAD lesion is present, recommendations regarding treatment should be given and the affected area should be monitored using the GLOBIAD-M. It will be important to design implementation strategies that take into account the observed barriers and facilitators at the level of the patient, health professional, team, and organisation (Grol and Wensing 2004).

Minimum Data Set for IAD

The WHO defines quality of care as "the extent to which healthcare services provided to individuals and patient populations improve desired health outcomes" (WHO 2018b). In order to achieve this, healthcare must be safe, effective, timely, efficient, equitable and people-centred. Growing demand for healthcare, rising costs, constrained resources, and evidence of variations in clinical practice have increased interest in measuring and improving the quality of healthcare in many countries of the world (Campbell et al. 2000). The continuous measurement of healthcare quality is an essential aspect for the establishment of a high quality of care. Quality indicators are used to measure structures, processes, and outcomes to monitor effectiveness, protect patient safety, inform decision-making and ensure value for money, among many other purposes (Nolte 2012). Key criteria of indicators are its validity, reliability, and sensitivity to change. Depending on the context and purpose of measurement, the range of indicator attributes may be broadened to allow for appropriate conclusions such as effective, comparable, repeatable, and interpretable (Nolte 2012).

Currently, prevalence and incidence rates are used as outcome indicators as they refer to the effects of care on patients' health status (Donabedian 1997). Outcome measures focus the attention of policy makers on whether systems are achieving the desired goals and towards the patient (Nolte 2012). Outcome indicators are more relevant on national and system level, because they tend to reflect the inter-play of a range of factors, some of which directly related to healthcare. To date, epidemiological data for IAD that are internationally comparable are missing. Variability in reported prevalence and incidence rates may be attributable to differences in procedures and tools to collected data, the selection and calculation of IAD measures (incidence and prevalence), and the lack of ICD coding of this particular skin condition. To improve data collection, we developed a uniform data collection instrument and methodology (chapter 6). This chapter answered the fourth and last research question: what is the content validity, agreement and reliability of a new instrument to assess the prevalence of IAD in patients with urinary and/or faecal incontinence and the adequacy of IAD management at organisational level?

Healthcare organisations are recommended to use the MDS-IAD to gain insight into the prevalence and incidence of IAD. The MDS-IAD allows the calculation of IAD prevalence in healthcare settings using the number of individuals diagnosed with IAD as the numerator, and the number of incontinent individuals as denominator (Defloor et al. 2005a). To calculate the IAD incidence, the numerator should be the number of incontinent patients with newly acquired IAD and the denominator the number of incontinent patients admitted over a defined period of time. Incidence density has been considered the best quality measure in relation to pressure ulcer prevention, which allows comparison between settings of all sizes. To calculate the incidence density,

the numerator should be the number of patients admitted to a hospital who develop a new IAD lesion divided by 1000 patient days (Weller et al. 2017).

The MDS-IAD allows the measurement of IAD prevalence, which reflects the burden of IAD in a certain population. However, there is no internationally consented definition of the target population. For example, some studies included both adult and paediatric patients (Junkin et al. 2005, Junkin and Selekof 2007). Defining the population to be surveyed is a fundamental step in planning a prevalence or incidence study (Baharestani et al. 2009). The nature of this population will have a profound effect on the findings. Therefore, both the care setting and the inclusion and exclusion criteria such as patient characteristics should be specified clearly. We recommend assessing all patients with urinary and/or faecal incontinence because the presence of incontinence is inherently associated with an increased risk for IAD development.

To date, IAD epidemiological research is often restricted to a one-time measurement (Bohnenkamp et al. 2013, Campbell et al. 2016b, Long et al. 2012). Continuous measurements of IAD prevalence has been implemented annually since 2012 in German hospitals and nursing homes (Boronat-Garrido et al. 2016, Lahmann et al. 2012). The largest prevalence study used the US Centers for Medicare & Medicaid Services (CMS) Resident Assessment Instrument – Minimum Data Set (RAI-MDS) 3.0 database of nursing home records (Bliss et al. 2006a). The RAI-MDS is designed to collect the minimum amount of data to guide care planning and monitoring for residents in long-term care settings on admission and periodically, within specific guidelines and time frames (Hutchinson et al. 2010, Saliba and Buchanan 2008, Services 2015). The chapter M assesses the skin condition, mainly focusing on pressure ulcers. Although there is no code for IAD, Bliss et al. (2006) used the CMS MDS for research purposes (Bliss et al. 2006a, Savik et al. 2005). In Flanders (Belgium), there is a similar minimum data set for nursing homes which includes the assessment of pressure ulcers (Vlaanderen 2018). At federal level, hospitals are supported to assess outcome, process and structure indicators regarding malnutrition and pressure ulcers (FRKVA 2017). The inclusion of the MDS-IAD within those existing minimum data sets could prove useful in the future.

Methodological strengths and limitations

This study reported the development of the first Minimum Data Set for IAD. The development based on state of the art evidence, consultation with future users, and a pilot test in nursing homes are the major strengths of this study. However, clinicians and policy-makers should take into account some considerations when implementing the MDS-IAD instrument.

Although the data collection instrument was considered easy to complete and feasible by the participating nurses, the psychometric evaluation indicated low to moderate agreement and reliability estimates. Future

research should evaluate the psychometric properties when receiving tailored education. The MDS-IAD is developed in line with the EPUAP approach (Vanderwee et al. 2007), but it was only psychometrically tested in a nursing home setting. Similar to the GLOBIAD-M, the same instrument used in a different setting or with different subjects may demonstrate variation in reliability (Cook and Beckman 2006). Further research is however needed to evaluate the reliability of the instrument in other healthcare settings. The issues mentioned previously regarding the GLOBIAD should be considered, as the GLOBIAD served as a basis for the development of the MDS-IAD.

To date, the diagnosis and classification of IAD are based on clinical observation and visual inspection of the affected area. Differences in assessor's knowledge and skills in using the MDS-IAD may affect the outcome. Despite the progress in the development of technological aids to early diagnosis, clinicians currently must rely on visual and palpatory assessment of the skin to determine aetiology (Doughty et al. 2012, Gray et al. 2012). Future research should focus on valid and reliable bedside technologies for clinical practice to assess core outcomes. In a research setting, TEWL has been used to measure the skin barrier function as potential parameter for diagnosing or predicting IAD (Kottner et al. 2013b). TEWL is a measure of passive water loss through the skin. To date, TEWL measurements are too complicated to use outside of the research setting and interpretation is difficult. Further research should focus on adaptation of this technique (and other skin parameters) to aid diagnosis and their advantages over standard clinical assessment (Beeckman et al. 2015).

Finally, the MDS-IAD consists of clinical algorithms indicating the adequacy of management, based on the most recent evidence. Although there is growing evidence base, the algorithms should be interpreted with caution due to the limited evidence about products and procedures for IAD management and the lack of (international) guidelines (Beeckman et al. 2016, Pather et al. 2017). It will be important to re-evaluate the content of the MDS-IAD each time the evidence about IAD prevention changes. As systematic literature reviews should be updated regularly, new emerged evidence from these review can be used to evaluate the content of the tool (Garner et al. 2016).

Future perspectives

Systematic assessment and international benchmarking of quality of care

The MDS-IAD may be used for benchmarking and comparing between different healthcare settings and countries, to support policy makers in their decision making process and incontinence/skin care budget allocation, and to evaluate quality improvement projects (Defloor et al. 2005a). There is growing interest in the systematic assessment and international benchmarking of quality of care provided in different healthcare systems (Nolte 2012). Benchmarking is considered a method for continuous quality improvement in health

and involves regularly comparing indicators (structure, activities, process and outcomes), identifying differences in outcomes through inter-organisational visits, seeking out new approaches in order to make improvements that will have the greatest impact on outcomes, and monitoring indicators (Ettorchi-Tardy et al. 2012).

However, a number of conditions should be considered for successful benchmarking (Ettorchi-Tardy et al. 2012). First, accurate collection of indicator data relies on the knowledge and skills of the assessor (Weller et al. 2017). As classification has proved to be difficult in our and previous studies, observers should be trained thoroughly (Beeckman et al. 2007, Mahoney et al. 2011). Second, the methodology of monitoring relevant indicators influences the accuracy of data collection. Therefore, the proposed MDS-IAD data collection instrument and procedure should be used to monitor all patients with urinary and/or faecal incontinence. Future work should look into the adjustment of the reported measures to certain risk factors that are outside of the control of an institution including advanced age, care dependency, and restricted mobility and activity (Bliss et al. 2006a, Bliss et al. 2011, Junkin and Selekof 2007, Kottner et al. 2014). Third, IAD could be integrated as routine data in healthcare organisations, alongside the reporting of pressure ulcers. Therefore, IAD should be implemented in electronic patient records. The use of routine data for quality measurement has many advantages as data are readily available, data that can be used retrospectively and is available over longer time periods (Nolte 2012). However, routine data sets are frequently incomplete and inaccurate (Davies 2005). A large study demonstrated discrepancies between the assessment of pressure ulcers by trained nurses and the standard recording in the administrative data (Backman et al. 2016). On an (inter)national level, it is recommended to include IAD within (inter)national quality measurements such as the Dutch national prevalence surveys and the US CMS Minimum Data Set (Bours et al. 2002, Saliba and Buchanan 2008, Services 2015). Future work can facilitate the assessment of this outcome such as performing prevalence surveys of IAD simultaneous with pressure ulcers (Campbell et al. 2016a).

Development and evaluation of complex interventions

Benchmarking will inform the need for further interventions. Researchers are encouraged to consult the Medical Research Council (MRC) Framework when developing and evaluating complex interventions (Craig et al. 2008). Interventions related to IAD prevention and treatment may be considered as complex interventions as a range of healthcare providers are involved, management needs ongoing and multiple components (e.g. incontinence management, daily cleansing and application barrier product), and the extensive target group depending on the setting (e.g. all elderly in a nursing home facility) (Craig et al. 2013, Hawe et al. 2004). It is recommended to evaluate the new interventions and strategies regularly using a pretest-posttest design or

statistical process control (SPC). SPC helps to decide whether data comes from stable processes or whether real changes took place (Neuhauser et al. 2011).

Structure, process and outcome indicators

This study mainly focussed on outcome indicators such as the prevalence and incidence of IAD. Future work should also focus on the development and validation of structure, process, and outcome indicators which could be used to assess the quality of care for patients with incontinence (Donabedian 1997). A structure indicator could be the availability of a skin care protocol in the healthcare setting, preferably based on international evidence-based guidelines. The staffing and nurse-to-patient ratio could be a second structure indicator for quality of care. As adequate skin and wound care is the responsibility of a wide range of caregivers, IAD prevention and treatment requires a multidisciplinary approach including tissue viability team and continence care specialists. The availability of higher educated staff could pose a problem in some settings, such as nursing homes. A process indicator could be the presence of regular and adequate skin assessments of all individuals with incontinence performed by nurses. Second, the use of adequate IAD prevention and treatment strategies, including incontinence management and a structured skin care regimen could be evaluated. The MDS-IAD can be used to assess adequacy of current preventive and treatment practices at an organisational level.

Conclusion

Research on 'incontinence-associated dermatitis' is expanding, both in depth and width. The last decade, IAD as a concept has increasingly been more accepted and recognised in clinical practice and research globally. There was a clear need for a standardisation in language, outcome definition, and methods for epidemiological and clinical IAD research. The research on the development and psychometric evaluation of four instruments contributed to finding answers for this need. First, consider the application of the core set of outcome domains for IAD research (chapter 3) when designing effectiveness trials in the field of IAD. Second, consider the application of the Ghent Global IAD Categorisation Tool (GLOBIAD; chapter 4) to classify IAD in clinical practice and for research purposes. Third, upon IAD diagnosis, consider the Ghent Global IAD Monitoring Tool (GLOBIAD-M; chapter 5) to evaluate the effectiveness of treatment strategies. Fourth, consider the Minimum Data Set for IAD (MDS-IAD; chapter 6) to gain insight in prevalence and incidence of IAD in incontinent individuals and to assess the adequacy of IAD prevention and treatment practice.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APPENDIX

Appendix 1: search strategy CONSIDER project

Aim

The aim of this broad IAD-COS search strategy was to include all studies on (1) adults at risk for or with IAD from any geographical location or skin colour, and (2) any kind of quantification and characterization (including nominal yes/no) of IAD related traits, states, or characteristics.

Search strategy

A two-step search strategy was used to identify all relevant literature. First, four electronic databases were automatically searched: Medline (Pubmed interface), the Cochrane Library, Web of Science, and the Cumulative Index to Nursing & Allied Health Literature (CINAHL). The search was carried out using a sensitive search filter to identify all possible outcomes, including rare endpoints and the patients' perspective (e.g. qualitative studies) (Williamson et al. 2012b). The search filter covered the domain of IAD broadly (synonyms, incontinence- and dermatology related terms), see below. Second, a hand search through the reference lists of the studies included in the review was also performed.

Following inclusion criteria were applied:

- All study designs (systematic and narrative reviews with or without meta-analyses, clinical trials, case series as well as qualitative research)
- There was no restriction on the year of publication.
- Studies focusing on adults aged >18 years with IAD or at risk, from any geographical location or skin colour

Studies will be excluded based on following criteria:

- Children, healthy volunteers
- Studies in languages other than English, French, German and Dutch

Two reviewers independently assessed all records obtained (KV, DD). First, titles and abstracts of the retrieved records were screened. The full text of all potentially relevant were retrieved and further checked for inclusion. Disagreements about inclusion or exclusion were discussed until consensus was reached. If necessary, advice from a third reviewer will was sought (DB).

Key words

As an example, the key words for the Medline database (PUBMED interface) are presented below. This search string was adjusted according to the specifications of the other three databases.

Concept 1A

("diaper rash" [MeSH] OR "Incontinence-associated dermatitis" [Title/Abstract] OR "diaper dermatitis" [Title/Abstract] OR "diaper erythema" [Title/Abstract] OR "diaper rash" [Title/Abstract] OR "napkin dermatitis" [Title/Abstract] OR "napkin rash" [Title/Abstract] OR "nappy dermatitis" [Title/Abstract] OR "nappy rash" [Title/Abstract] OR "perineal dermatitis" [Title/Abstract] OR "perineal erythema" [Title/Abstract] OR "perineal rash" [Title/Abstract])

Concept 2B

(moist*wound* [Title/Abstract] OR "moist wound"[Title/abstract] OR "moist skin" [Title/Abstract] OR dermatitis [Title/Abstract] OR sore* [Title/Abstract] Or ulcer* [Title/Abstract] OR damage [Title/Abstract] OR injur* [Title/Abstract] OR lesion* [Title/Abstract] OR skin [Title/Abstract] OR "skin integrity" [Title/Abstract] OR "skin inflammation" [Title/Abstract] OR "contact dermatitis" [Title/Abstract] OR "irritant dermatitis" [Title/Abstract] OR Erythema [Title/Abstract] OR Skin macerat* [Title/Abstract] OR "skin wetness" [Title/Abstract])

Concept 2C

("urinary incontinence"[MeSH Terms] OR "fecal incontinence"[MeSH Terms] OR "urinary incontinence"[Title/Abstract] OR "fecal incontinence"[Title/Abstract] OR incontinen*[Title/Abstract])

Concept 2D

(perineal[Text Word] OR perirect*[Text Word] OR perianal[Text Word] OR intergluteal[Text Word] OR inguinal[Text Word] OR perineum[Text Word] OR buttock[Text Word] OR thigh*[Text Word])

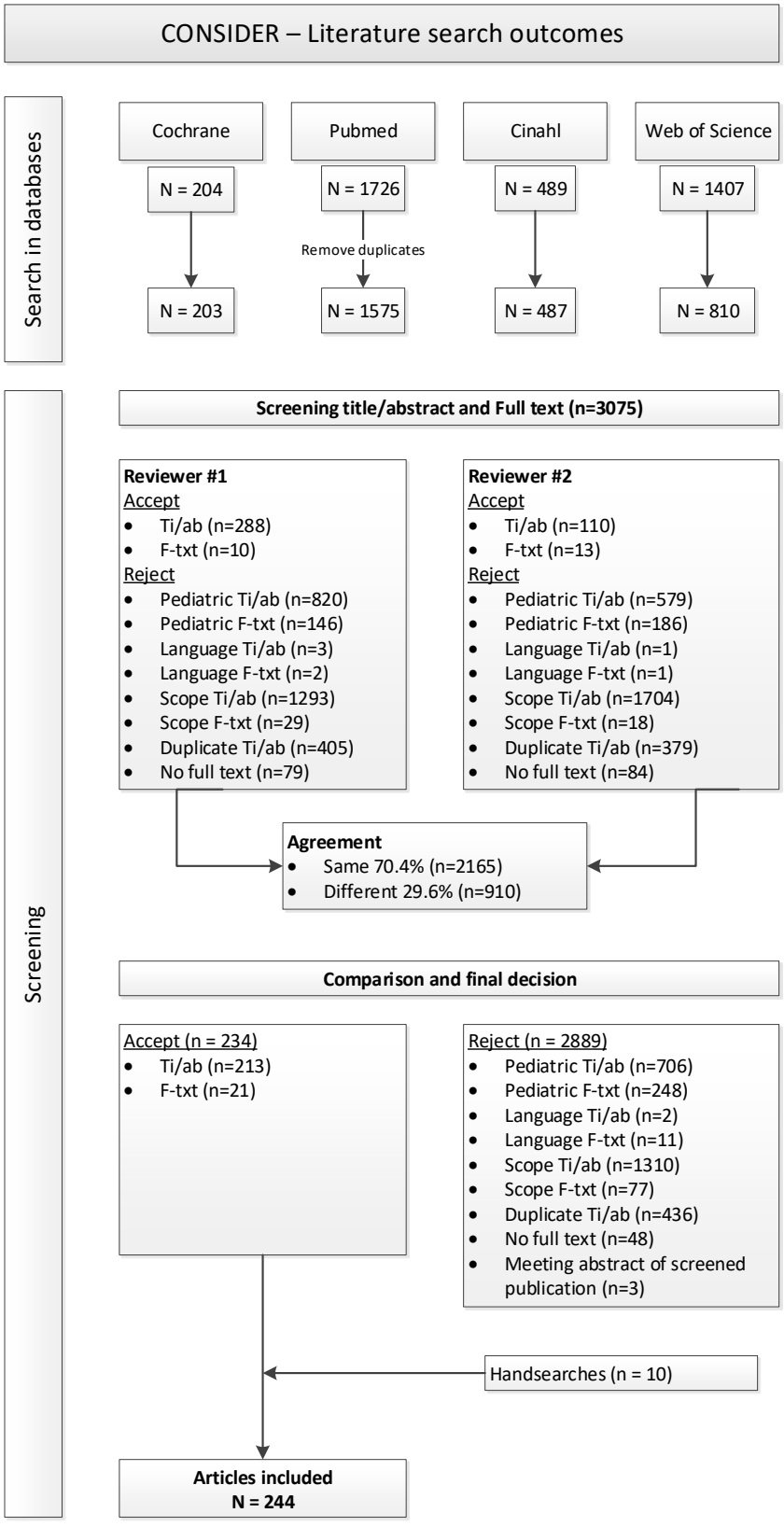
(Concept 1A) OR (Concept 2B AND 2C AND 2D)

("diaper rash" [MeSH] OR "Incontinence-associated dermatitis" [Title/Abstract] OR "diaper dermatitis" [Title/Abstract] OR "diaper erythema" [Title/Abstract] OR "diaper rash" [Title/Abstract] OR "napkin dermatitis" [Title/Abstract] OR "napkin rash" [Title/Abstract] OR "nappy dermatitis" [Title/Abstract] OR "nappy rash" [Title/Abstract] OR "perineal dermatitis" [Title/Abstract] OR "perineal erythema" [Title/Abstract] OR "perineal rash" [Title/Abstract]) OR ((moist*wound* [Title/Abstract] OR "moist wound"[Title/abstract] OR "moist skin" [Title/Abstract] OR dermatitis [Title/Abstract] OR sore* [Title/Abstract] Or ulcer* [Title/Abstract] OR damage

[Title/Abstract] OR injur* [Title/Abstract] OR lesion* [Title/Abstract] OR skin [Title/Abstract] OR “skin integrity” [Title/Abstract] OR "skin inflammation" [Title/Abstract] OR “contact dermatitis” [Title/Abstract] OR “irritant dermatitis” [Title/Abstract] OR Erythema [Title/Abstract] OR Skin macerat* [Title/Abstract] OR “skin wetness” [Title/Abstract]) AND (“urinary incontinence”[MeSH Terms] OR “fecal incontinence”[MeSH Terms] OR “urinary incontinence”[Title/Abstract] OR “fecal incontinence”[Title/Abstract] OR incontinen*[Title/Abstract]) AND (perineal[Text Word] OR perirect*[Text Word] OR perianal[Text Word] OR intergluteal[Text Word] OR inguinal[Text Word] OR perineum[Text Word] OR buttock[Text Word] OR thigh*[Text Word]))

Overview Search Results

The search in all databases was performed on April 12, 2016.



SUMMARY

Today, the concept of incontinence-associated dermatitis (IAD) is widely accepted as “an inflammation of the skin that occurs when urine or stool comes into contact with perineal or perigenital skin”. A growing body of research provides insight into the epidemiology, aetiology, and pathophysiology of IAD. To date, epidemiological data for IAD that are internationally comparable are missing. Variability in reported prevalence and incidence rates may be attributable to differences in IAD definitions, procedures and tools for data collection. Although there is growing evidence base, the limited empirical and clinical evidence about products and procedures for IAD management poses a challenge for clinicians when preventing and treating IAD. Several interventions have been assessed in clinical trials, but the use of many different and sometimes ill-defined outcome parameters complicate the comparability and standardisation. The need for a standardisation in language, outcome definition and methods for epidemiological and clinical IAD research was addressed in this doctoral dissertation.

The first aim of this thesis was to develop a core set of outcome domains for clinical IAD research. The second aim was to develop and psychometrically evaluate a tool to categorise the severity of IAD. The third aim was to develop and psychometrically evaluate a tool to monitor healing of IAD. The fourth aim was to develop, psychometrically evaluate and pilot test an instrument to assess IAD prevalence and adequacy of IAD management in healthcare settings.

The first study included the development of a core set of outcome domains, a consensus-derived minimum set of outcomes to be measured and reported in clinical IAD research. A systematic literature review, consultation with experts, and patient interviews resulted in 1852 extracted outcomes, combined to a list of 58 outcome domains. The subsequent three-round Delphi procedure with 57 international panelists from 17 countries resulted in a list of five critical outcomes: erythema, maceration, erosion, IAD-related pain, and patient satisfaction. Three important but not critical outcomes were cost-effectiveness, IAD-related Quality of Life, and major colonization and infection.

Second, a two-phase psychometric instrument development and validation study resulted in the Ghent Global IAD Categorisation Tool (GLOBIAD). An international panel of 34 experts agreed on a two-fold purpose: to create an internationally agreed description of IAD, and to standardise the documentation for clinical practice and for research purposes. The GLOBIAD consists of two main categories: the presence of persistent redness (Cat. 1) and the presence of skin loss (Cat. 2). Both categories are subdivided based on the absence (Cat. A) or presence (Cat. B) of clinical signs of infection. The psychometric properties of the GLOBIAD were evaluated in a sample of 823 healthcare professionals in 30 countries. Results showed higher accuracy, agreement and

reliability estimates for differentiating between intact skin (IAD Cat. 1) and skin loss (IAD Cat. 2). Identifying clinical signs of infection was prone to error.

In a third study, the GLOBIAD was used to design the Ghent Global IAD Monitoring tool (GLOBIAD-M), an instrument to monitor the change in IAD status over time. The one-page GLOBIAD-M consists of general data, IAD categorisation according to the GLOBIAD to allow incidence measurements, nine IAD and surrounding skin assessment items, and the assessment of patient-related symptoms such as pain. A dashboard with a graph and colour-grading system allows the monitoring of the change in IAD status over time. The psychometric properties of the GLOBIAD-M were evaluated by two trained researchers in a sample of hospitalised patients affected with IAD over a period of seven days. Thirty-six independent assessments of nine patients revealed good inter-rater agreement and reliability properties.

The fourth and final study included the development and psychometric evaluation of the Minimum Data Set for IAD (MDS-IAD), an instrument to collect epidemiological data, and to assess the adequacy of IAD prevention and treatment practices at organisational level. The instrument that emerged after content and face validation by experts and clinicians consists of five categories of data: administrative and patient data, data on incontinence and skin status (categorisation according to the GLOBIAD), and the management of IAD. The psychometric properties of the MDS-IAD were evaluated by two nurses in a sample of 15 nursing home residents. Results showed poor to moderate agreement and reliability coefficients when residents were assessed using the MDS-IAD by nurses. Results of a pilot study in 108 residents of three nursing homes indicated an IAD prevalence of 21.3%. Fully adequate IAD prevention or treatment was provided to respectively 3.6% and 8.7% of the residents.

SAMENVATTING

Incontinentie-geassocieerde dermatitis (IAD) wordt gedefinieerd als “een inflammatie van de huid die optreedt wanneer urine of stoelgang in contact komt met de perineale of genitale huid”. Een groeiend aantal studies geeft inzicht in de epidemiologie, etiologie en pathofysiologie van IAD, maar tot op heden ontbreken internationaal vergelijkbare epidemiologische gegevens. De variabiliteit in gerapporteerde prevalentie- en incidentiecijfers kan te wijten zijn aan het gebruik van verschillende definities, procedures en instrumenten voor dataverzameling. Ondanks de groeiende kennis vormt de beperkte empirische en klinische evidentie over producten en procedures een uitdaging voor clinici in de preventie en behandeling van IAD. Verschillende huidverzorgingsproducten en procedures werden reeds getest in klinische studies, maar het gebruik van een groot aantal verschillende en soms slecht gedefinieerde uitkomstmaten bemoeilijkt de vergelijkbaarheid en standaardisatie van de resultaten. De nood aan standaardisatie in taal, definitie van uitkomstmaten en methoden voor epidemiologisch en klinisch IAD onderzoek werden behandeld in dit proefschrift.

Het eerste doel van dit proefschrift was de ontwikkeling van een *core outcome set* voor klinisch IAD onderzoek. Het tweede doel was de ontwikkeling en psychometrische evaluatie van een instrument dat de ernst van IAD categoriseert. Het derde doel was de ontwikkeling en psychometrische evaluatie van een instrument dat de genezing van IAD monitort. Het vierde en laatste doel van dit proefschrift was de ontwikkeling, psychometrische evaluatie en piloottest van een instrument dat de prevalentie van IAD en de adequaatheid van IAD preventie en behandeling in kaart brengt.

De eerste studie omvatte de ontwikkeling van een *core outcome set*, een lijst van uitkomstmaten die minimaal gemeten en gerapporteerd dienen te worden in klinisch IAD onderzoek. Een systematisch literatuuronderzoek, overleg met experten en interviews met patiënten resulteerde in 1852 geëxtraheerde uitkomstmaten die werden gecombineerd tot een lijst van 58 domeinen. De daaropvolgende Delphi procedure met 57 internationale panelleden uit 17 landen resulteerde in een lijst van vijf cruciale domeinen: roodheid, maceratie, erosie, IAD-gerelateerde pijn en patiëntentevredenheid. Drie domeinen werden als belangrijk maar niet cruciaal geacht: kosteneffectiviteit, IAD-gerelateerde kwaliteit van leven en kritische kolonisatie en infectie.

De tweede studie, een tweeledige psychometrische instrumentontwikkeling en -validatie studie, resulteerde in de ontwikkeling van de Ghent Global IAD Categorisation Tool (GLOBIAD). Een internationaal panel van 34 experten kwam tot een tweevoudig doel van de GLOBIAD: het bekomen van een internationaal overeengekomen beschrijving van IAD, en de standaardisatie van de documentatie voor klinische praktijk en onderzoek. De GLOBIAD bestaat uit twee hoofdcategorieën: de aanwezigheid van aanhoudende roodheid (Cat. 1) en de aanwezigheid van ontvelling (Cat. 2). Beide categorieën worden opgedeeld op basis van de afwezigheid (Cat. A) en de aanwezigheid (Cat B.) van klinische tekenen van infectie. De psychometrische

eigenschappen werden geëvalueerd in een steekproef van 823 zorgverleners uit 30 landen. Het differentiëren van intacte huid (IAD Cat. 1) versus ontvelling (IAD Cat. 2) resulteerde in een hoge nauwkeurigheid, overeenstemming en betrouwbaarheid. Bij het identificeren van klinische tekenen van infectie (IAD Cat. A versus B) verhoogt het risico op fouten.

In een derde onderzoek werd de GLOBIAD gebruikt om de Ghent Global IAD Monitoring Tool (GLOBIAD-M) te ontwikkelen, een instrument dat verandering in status van het IAD letsel over de tijd heen opvolgt. De GLOBIAD-M bestaat uit één pagina en omvat algemene gegevens, categorisering van IAD aan de hand van de GLOBIAD om incidentiemetingen toe te laten, negen items om de kenmerken van het IAD letsel en de omliggende huid te beoordelen, en de beoordeling van patiëntgerelateerde symptomen zoals pijn. Een dashboard met een grafiek en systeem op basis van kleuren maakt het mogelijk om de status van het IAD letsel over de tijd heen op te volgen. De psychometrische eigenschappen van de GLOBIAD-M werden geëvalueerd door twee getrainde onderzoekers in een steekproef van gehospitaliseerde patiënten gediagnostiseerd met IAD. Zessendertig onafhankelijke huidbeoordelingen van negen patiënten resulteerde in goede inter-beoordelaarsbetrouwbaarheid.

De vierde en laatste studie omvatte de ontwikkeling en psychometrische evaluatie van de Minimum Data Set voor IAD (MDS-IAD), een instrument om epidemiologische gegevens te verzamelen en om de adequaatheid van IAD preventie en behandeling op organisatieniveau in kaart te brengen. De inhoud van het instrument werd gevalideerd door experten en zorgverleners en bevat vijf categorieën: administratieve en patiënt gerelateerde gegevens, gegevens over de incontinentie en huidstatus (categorisatie volgens de GLOBIAD), en IAD preventie en behandeling. De psychometrische eigenschappen van de MDS-IAD werden geëvalueerd door twee verpleegkundigen in een steekproef van 15 bewoners van een woonzorgcentrum. De resultaten toonden lage tot matige overeenstemming en betrouwbaarheid wanneer de bewoners door verpleegkundigen beoordeeld werden met behulp van de MDS-IAD. Resultaten van een pilootstudie bij 108 bewoners uit drie woonzorgcentra resulteerde in een IAD prevalentie van 21.3%. Volledig adequate IAD preventie en behandeling was aanwezig in respectievelijk 3.6% en 8.7% van de bewoners.

CURRICULUM VITAE

PERSONAL DATA

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EDUCATION

2012 – 2013 Specific Teacher Training Program, Academic Teacher Education in Health Science, Faculty of Psychology and Educational Sciences, Ghent University

2010 – 2012 Master of Science in Nursing and Midwifery, Faculty of Medicine and Health Sciences, Ghent University

2007 – 2010 Bachelor of Nursing, option pediatric nursing, KATHO Roeselare

2001 – 2007 Human sciences, Onze-Lieve-Vrouwecollege Oostende

WORK EXPERIENCE

2015 – PhD student, University Centre for Nursing & Midwifery, Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University

2013 – 2015 Scientific staff, unit Nutrition and Food Safety, Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University

- European FP7 I.Family project (www.ifamilystudy.eu)
- Beweging, Roken en Nutritie-project (BRON) – Stichting tegen Kanker
- Drink, Eet & Plas op School study (DEPS) – Spadel

2008 – 2012 Interim and summer jobs as a nurse assistant and registered nurse, various healthcare institutions

SPECIFIC TRAINING

2015 – 2018 Doctoral Schools Training Program, Life Sciences and Medicine, Ghent University

- Advanced Pressure Ulcer Prevention and Treatment Masterclass, EPUAP
- Advanced Academic English: Writing Skills, Ghent University
- Personal Effectiveness, Ghent University
- Leadership Foundation Course, Ghent University
- Argumentation and debating techniques, Summer School 'Let's Talk Science'
- High impact presentation challenges, Summer School 'Let's Talk Science'

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PRESENTATIONS

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Poster presentations

Beeckman, D., **Van den Bussche, K.** The IAD Wound Observation Tool: development and international validation of a tool to monitor the healing of Incontinence-Associated Dermatitis (IAD). *CARE4, Abstracts*. Poster presentation at the CARE4: 2nd International Scientific Nursing and Midwifery congress, Antwerp, Belgium

De Meyer, D., **Van den Bussche, K.,** Van Damme, N., Kotter, J., Beeckman, D. CONSIDER – Core Outcome Set in IAD Research: development of a core set of outcomes and measurements in Incontinence-Associated Dermatitis research. *CARE4, Abstracts*. Poster presentation at the CARE4: 2nd International Scientific Nursing and Midwifery congress, Antwerp, Belgium

AWARDS

April 2018	Prijs Magda Dierendonck 2017, kwantitatief onderzoek, Ghent University Hospital, Ghent, Belgium
	De classificatie van incontinentie-geassocieerde dermatitis (IAD): Ontwikkeling en psychometrische validering van de Ghent Global IAD Categorisation Tool (GLOBIAD) in 30 landen
September 2017	EPUAP & 3M Pressure Ulcer and IAD Innovation Award, 19th Annual Meeting of EPUAP 2017, Belfast, Northern Ireland
	Oral presentation: *"The Ghent Global IAD Categorisation Tool (GLOBIAD) for incontinence-associated dermatitis: international development and reliability study"*
September 2015	Student free paper award: Clinical science, 18th Annual Meeting of EPUAP 2015, Ghent, Belgium
	Oral presentation: *"Development and validation of an instrument to monitor the healing of incontinence-associated dermatitis"*

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Karen Van den Bussche

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