



## **A Cochrane Review on Incontinence – Associated Dermatitis (IAD) for Making the Case for Core Outcome Sets in Clinical Trials in Wound Care**

**Prof. Dimitri Beeckman**

**University Centre for Nursing and Midwifery, Ghent University, Belgium**

*(Research team includes Dimitri Beeckman, Jan Kottner, Karen Van den Bussche, Dorien De Meyer, Nele Van Damme, Toni Lange)*

### IAD Background

- IAD = Part of a broader group of skin conditions, referred to as Moisture-Associated Skin Damage (MASD)
- Skin inflammation manifested as redness with or without blistering, erosion, or loss of the skin barrier function that occurs as a consequence of chronic or repeated exposure of the skin to urine or feces
- WHO International Classification of Diseases (ICD-10): coding for diaper dermatitis but no separate coding for IAD
- Efforts are ongoing to add Incontinence-associated dermatitis as an index term for irritant contact dermatitis due to incontinence (EQ72.83 ) in the new ICD-11 coding

### Generally adopted recommendations

Management of incontinence to avoid or minimize contact from the skin with urine/feces

#### **Structured skin care regiment:**

- Skin cleansing: remove irritants, debris, microorganisms
- Skin moisturizing: to repair or increase the integrity of the skin barrier
- Skin protecting: to avoid or minimize contact of the skin with urine/feces

Discussions of IAD started 10 years ago. In the past few years, progress has been made in bringing IAD into realm of evidence-based medicine:

2015: best practice document by international expert panel was introduced

2016: Cochrane Systematic Review



2017: Core Outcome Set for IAD clinical trials

## IAD Cochrane Review

Objective of the Cochrane Review: to assess the effectiveness of various products and procedures to prevent and treat incontinence-associated dermatitis in adults.

Study selection process/criteria:

- Randomised/quasi randomised trials
- Skin care products (cleansers, moisturizers, protectants) or procedures
- Prevention and/or treatment of IAD
- Adults in any health care setting (male or female, over 18 years, with and without IAD)
- Electronic databases, handsearching, contacts with experts and authors

### Primary outcomes:

- Percentage of participants with IAD (residual)
- Percentage of participants with new IAD
- Percentage of participants not satisfied with treatment

### Secondary outcomes:

- % participants with pain due to IAD
- % participants with pain due to skin care product/procedure
- Surface affected by IAD (size of lesion)
- % participants with IAD not improved
- % participants not complying/discontinuing treatment
- QOL (condition specific, generic, psycho-social)
- Cost of products, staff time, cost-effectiveness
- Adverse reaction due to skin care product or procedure
- Normal flora disruption
- Toxicity

Started with screening – 4081 records by 2-5 independent researchers

Used the Cochrane Risk of Bias tool and also did a GRADE Assessment

Ended up with 36 full text articles for assessment for eligibility, 13 of which were included in the qualitative synthesis (accounted for 1,295 patients), all low to moderate quality



### Results:

Evidence in 2 trials (low to moderate quality) that using soap and water performed POORLY in the prevention and treatment of IAD

First trial indicated that use of a skin cleanser might be more effective than soap and water (low quality evidence)

Second trial indicated that a structured skin care procedure, being a washcloth with cleansing, moisturizing, protecting properties, would be more effective than soap and water (moderate quality evidence)

Findings from other trials (all low to very low quality) suggested that applying a leave-on product (moisturizer, skin protectant or a combo) might be more effective than not applying a leave-on product

No trial reported on the third primary outcome (number of participants not satisfied with treatment) or on adverse effects.

## Outcome of Cochrane Review

There is very little evidence on the effects of interventions for preventing and treating IAD in adults.

**High quality confirmatory trials are required!**

**Recommendation:** development of a core outcome set, including validated measurement tools, in order to increase the comparability of trial results.

## Background on Core Outcome Sets

A COS (core outcome set) is a consensus derived set of outcomes to be assessed, measured and reported in all trials for a specific clinical area.

The aim is to reduce reporting bias, allow results comparisons and statistical pooling and strengthen evidence-based practice and decision-making.

2 levels:

Which outcome should be measured and reported?

How should the selected outcomes be reported?



#### **4 Phases of Core Outcome Set Development Process:**

1. Background, preparation and process
2. Core set of outcomes
3. Core set of measurement instruments
4. Dissemination and implementation

## IAD Core Outcome Set Process

### **1. Background, preparation and process**

- international steering committee: 6 experts in dermatology, geriatrics, wound care, trials and nursing, and reps of 2 patient associations
- panelists from at least 3 continents including clinicians, researchers and educators
- develop scope and applicability
- approval from ethical review committee

### **2. Core set of outcomes**

Identification of existing outcomes and measurements via:

- systematic literature review
- consultation with the international steering committee
- interviews with patients

A literature review of 246 relevant studies, 3 interviews with patients and 6 experts consulted resulted in a long list of outcomes (over 1900!)

The longlist was narrowed to a shortlist of 58 outcomes in 3 core domains:

- life impact
- resource use/economical impact
- pathophysiological manifestations

Next came a Delphi study in which 57 panelists from 16 countries gave feedback on the 58 outcomes on the shortlist. General feedback included:

- overlap between outcomes
- (im)possibility for patients (e.g. dementia, ICU) to provide information (such as pain levels)
- need for more detailed definitions of outcomes



13 outcomes rated critical for inclusion, combined to 9 outcomes:

1. Clinical signs of inflammation
2. Clinical signs of infection
3. Cost-effectiveness
4. Erosion
5. IAD-related Quality of Life
6. Itching
7. Maceration
8. Pain
9. Patient satisfaction

### **3. Core set of measurement instruments**

- Identification of available instruments via a literature review
- Evaluation of the methodological quality of studies on measurement properties
- Overview of the measurement properties (validity and reliability)
- Consensus study using a Delphi procedure

### **4. Dissemination and implementation**

- Dissemination and implementation of the COS via publications and presentations
- Monitoring emerging evidence and revision of COS if appropriate

Application of a COS in wound care and IAD clinical trials will contribute to:

- Comparability between trials
- Reliability and validity of outcomes
- Patient-centered care
- Informed decision-making

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