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

Table 3. Ratings of 7 outcome domains in the third Delphi round – 37 panellists

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| --- | --- | --- | --- | --- | --- |
| **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 |
| 1. **Erosion**   **Erosion** is defined as the loss of either a portion or either the entire epidermis (Nast et al., 2015). | | 32 (86.5) | 5 (13.5) | 0 (0.0) | In |
| 1. **Maceration**   **Maceration** of the skin is defined as the softening of the epidermis and dermis characterized by a whitened appearance and swelling caused by prolonged exposure to urine and feces (Ichikawa-Shigeta et al. 2014; Mugita et al., 2015). | | 27 (73.0) | 9 (24.3) | 1 (2.7) | In |
| 1. **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 |
| 1. **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 localized 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 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. | | 20 (54.1) | 11 (29.7) | 6 (16.2) | Out |
| 1. **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 |
| 1. **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 (based on NCBI MeSH term definition). | | 33 (89.2) | 3 (8.1) | 1 (2.7) | In |
| IAD, incontinence-associated dermatitis. | | | | | |