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

Table 2. 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 |
| 1. **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 |
| 1. **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 |
| 1. **Erosion**

**Erosion** is defined as the loss of either a portion or the entire epidermis (Nast et al., 2015). | 1 (2.3) | 3 (7.0) | 39 (90.7) | In |
| 1. **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 |
| 1. **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 |
| 1. **Maceration**

**Maceration** is defined as the softening and subsequent breakdown of skin characterized by a whitened appearance and swelling caused by prolonged exposure to moisture (Ichikawa-Shigeta et al. 2014; Mugita et al., 2015). | 3 (7.0) | 3 (6.9) | 37 (86.1) | In |
| 1. **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 |
| 1. **Patient satisfaction**

**Patient satisfaction** is defined as the degree to which the individual regards the health care 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). | 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’. |