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

Table 1. Ratings of 58 outcome domains in the first Delphi round – 57 panellists

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| --- | --- | --- | --- |
| **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’. |