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Only the best instruments should be used to measure core outcomes

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The development and use of Core Outcome Sets (COS) is increasingly recognized as an important aspect to improve the quality and usefulness of clinical trial evidence. In dermatology, several COS have been published or are under development.[1] The Cochrane Skin-Core Outcome Set Initiative (CS-COUSIN, http://cs-cousin.org/) supports the development of COS in dermatology and offers guidance and support for COS development groups. Currently, 21 COS groups are affiliated with CS-COUSIN, among them the Acne Core Outcomes Research Network (ACORN). In COS development, the selection and prioritization of critical outcome domains is a crucial first step which is followed by the selection of outcome measurement instruments (OMIs) per domain. Guidance on how to best select core outcome domains is available to support this complex and challenging process.[2] However, the appropriate selection of OMIs is at least as challenging as selecting core domains.[3]

The ACORN group identified seven core outcome domains[4] and is now in a position to proceed with OMI selection. In this issue of the *BJD*, van Zuuren *et al.* present their comprehensive and high-quality systematic review, which was conducted to identify and appraise OMIs for measuring the core outcome domain 'satisfaction with acne treatment'.[5] After searching several databases and other sources using state-of-the-art methods, they were able to identify only one single instrument that could potentially measure the domain of interest. In addition, only the content validity of this instrument could be evaluated, because there is no evidence about other measurement properties such as reliability, agreement and many more.[3] Finally, the methodological quality of content validation was rated as insufficient and the overall quality of evidence as very low. Another striking finding of this review was that nearly 200 studies were identified, in which treatment satisfaction was measured with various noncomparable instruments with unknown measurement properties.[5] What does this mean for clinical acne research and beyond?

1 Although substantial progress has been made in developing and publishing core outcome domains for many dermatological diseases,[1] there is still a long way to go. The findings from van Zuuren *et al.*[5] are comparable to many other areas where many different OMIs are used for similar outcome domains with insufficient or unknown measurement properties.[6–8] Having identified core domains is critical, but is only one step towards a complete COS.

2 In addition to efforts to select and to define core outcome domains according to the highest methodological standards, the same attention must be paid to identify and to develop OMIs. The joint COSMIN and COMET guidance on how to best select OMIs per core domain[3] should be followed as van Zuuren *et al.*[5] did. Evidence indicates that the methodological quality of OMI selection can be improved when following guidance.[9] Although primarily designed for patient-reported outcome measures these standards can be also used for other types of OMIs with adaptations.

3 Even if OMIs have been selected according to state-of-the-art methods, aspects such as the time of measurements or the methods of aggregation of obtained estimates should also be standardized to enable statistical pooling of clinical trial outcomes,[8] which is the ultimate goal of COS.

4 Review results indicate another challenge: What shall guideline developers and systematic reviewers do with all these older studies with noncomparable instruments that may overestimate, underestimate or even miss treatment effects?

In the last decade substantial advances have been made in COS development in dermatology. High-quality empirical evidence is needed to support OMI development and selection to achieve the overall goal to make trial results comparable and to reduce research waste.[10] The current example of ACORN and the review published in this issue of the *BJD* illustrate that COS development and eventually COS implementation is a long journey, that can succeed only with endurance, strong international cooperation and methodological rigour.

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Silicone adhesive multilayered foam dressings for pressure ulcer prevention

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Despite considerable attention of local facilities and clinicians on the prevention of pressure ulcers/injuries (PUs), and the publication of recent international guidelines for prevention,[1] the burden of facility- or hospital-acquired PUs remains high.[2,3] The use of silicone adhesive multilayered foam dressings, standardly used to cover postsurgical incisions or other skin injuries, is a relatively new intervention for PU prevention. In the PU prevention sphere such dressings are used to ameliorate the mechanical load forces from support surfaces to tissues over bony prominences.[4] This concept has captured international attention to the extent where this practice is now commonly adopted in a range of clinical settings from residential care to high-acuity areas such as intensive care units. A recent systematic review and meta-analysis provided moderate evidence for the effectiveness of prophylactic silicone multilayered foam dressings on the sacral area.[5] However, the studies included in that review were notably conducted only in single-site settings.[5]

In this issue of the *BJD*, Beeckman *et al.*[6] present data from the first large, robust, pragmatic multicentre trial comparing the application of prophylactic silicone foam dressings (two dressings from different manufacturers). Block randomization was used to allocate patients into either a group using the silicone multilayered foam dressing and standard PU prevention practices, or a group using standard PU prevention practices alone, to assess the incidence of PUs of stage 2 or worse. Among the 1605 patients included in the intention-to-treat analyses, patients in the treatment group showed a 36% risk reduction of developing a new PU compared with patients in the standard care group. There were fewer PUs of stage 2 or worse occurring on the sacrum in the treatment group (4·8% vs. 2·8%). Importantly, this study includes patients recruited from different sites and disciplines, and where silicone multilayered foam dressings were applied to different anatomical sites. Interestingly, the authors report that no statistically significant difference was seen when dressings were applied to the heels.[6] This is consistent with findings from previous studies.[5]

Prophylactic dressings may be efficacious but, as Beeckman *et al.* note,[6] they are not a standalone intervention. I concur with the authors that conjectural risk exists for clinicians to feel over-reliance or 'false security' when using the dressings, resulting in standard PU prevention practices being overlooked. Fortunately, this hypothetical was not reported in the study of Beeckman *et al.*[6] or in other studies.[2,5] Prophylactic silicone multilayered foam dressings should be incorporated into standardized PU prevention regimens or bundles that align with international best practice guidelines.[1] Such a bundle would incorporate the five key elements of (i) PU risk assessment, (ii) a structured and regular skin assessment, (iii) turning, repositioning and mobilization on an individualized schedule, (iv) reduction of pressure, friction and shear forces including the application of prophylactic silicone multilayered foam dressings and (v) facilitation of adequate nutrition.[7]

In conclusion, the study by Beeckman *et al.*[6] provides robust evidence for use of dressings in conjunction with standard PU prevention practices, as recommended in the recent international PU prevention and management guidelines.[1] This study provides important data to support clinician decision making in the judicial use of prophylactic silicone multilayered foam dressings when used in addition to standardized PU prevention bundles.

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