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Development of a value-based healthcare burns core set for adult burn care

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Abbreviations: BBA, British Burn Association; COSB-I, Core Outcome Set for Burn Injuries; PROM, Patient-reported outcome measure; SDM, Shared decision making; VBHC, Value-based healthcare

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ABSTRACT

Background: Value-based healthcare (VBHC) is increasingly implemented in healthcare worldwide. Transparent measurement of the outcomes most important and relevant to patients is essential in VBHC, which is supported by a core set of most important quality indicators and outcomes. Therefore, the aim of this study was to develop a VBHC-burns core set for adult burn patients.

Methods: A three-round modified national Delphi study, including 44 outcomes and 24 quality indicators, was conducted to reach consensus among Dutch patients, burn care professionals and researchers. Items were rated on a nine-point Likert scale and selected if \geq 70% in each group considered an item 'important'. Subsequently, instruments quantifying selected outcomes were identified based on a literature review and were chosen in a consensus meeting using recommendations from the Dutch consensus-based standard set and the Dutch Centre of Expertise on Health Disparities. Time assessment points were chosen to reflect the burn care and patient recovery process. Finally, the initial core set was evaluated in practice, leading to the adapted VBHC-burns core set.

Results: Twenty-seven patients, 63 burn care professionals and 23 researchers participated. Ten outcomes and four quality indicators were selected in the Delphi study, including the outcomes pain, wound healing, physical activity, self-care, independence, return to work, depression, itching, scar flexibility and return to school. Quality indicators included shared decision-making (SDM), the number of patients receiving aftercare, determination of burn depth, and assessment of active range of motion. After evaluation of its use in clinical practice, the core set included all items except SDM, which are assessed by 9 patient-reported outcome instruments or measured in clinical care. Assessment time points included are at discharge, 2 weeks, 3 months, 12 months after discharge and annually afterwards.

Conclusion: A VBHC-burns core set was developed, consisting of outcomes and quality indicators that are important to burn patients and burn care professionals. The VBHC-burns core set is now systemically monitored and analysed in Dutch burn care to improve care and patient relevant outcomes. As improving burn care and patient relevant outcomes is important worldwide, the developed VBHC-burns core set could be inspiring for other countries.

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1. Introduction

Burn injuries can have a large impact on an individual and are a major cause of morbidity worldwide [1]. Patients have to live with functional and mental consequences and returning to daily life may take a long time, impacting their quality of life [2,3]. Both the burden of burn injuries and associated healthcare costs are high [4–7]. Burns require complex, highly specialized and individualized interventions. Globally, a main issue is the large number of treatment strategies for which neither a gold standard nor consensus exists, such as the optimal timing of acute surgery for intermediate-depth burns [8]. A way to tackle these problems is by determining and systematically evaluating quality indicators and health outcomes. Quality indicators in burns have been defined as 'measurement tools based on standards of care that can be used to inform policy or strategy, improve quality of care, monitor performance, and provide consumer information to facilitate choice' by Watterson et al. [9]. A health outcome is defined as 'A change in the health status of an individual, group or population that is attributable to a planned intervention or series of interventions, regardless of whether such an intervention was intended to change health status' by the World Health Organisation [10]. In general, there is limited knowledge about patient-relevant outcomes of different treatment strategies. The value-based healthcare (VBHC) approach which learns from each patient by analysing provided care through patient-relevant outcomes to identify the best treatment strategies, addresses this issue [11]. The use of patient-relevant outcomes and quality indicators focussing on personalized care are crucial to improve complex care [12]. Its use, however, is still limited. Besides, in healthcare worldwide, there is an increasing demand to spend resources cost-efficiently [13–15]. VBHC is a strategy that maximizes value for patients, and health systems by achieving the best patient-relevant health outcomes at the lowest cost per patient [11].

In 2006, Porter and Teisberg introduced VBHC as a strategy to achieve high value for patients [11], where patient value is defined as achieved health outcomes divided by costs per patient to deliver these outcomes [11]. If the patient value improves, patients, providers, payers, and suppliers may all benefit while the financial sustainability of the healthcare system increases [16–18]. Implementation of the VBHC approach might generate a shift towards a more value-driven system by measuring and improving outcomes [19]. Embedding VBHC has led to increased patient value, cost-effective strategies, shorter hospital stay, fewer complications, improved quality of life, and decreased costs in other healthcare fields [20–22]. Potentially, these positive results can be achieved by implementing VBHC in burn care.

Outcomes and quality indicators that are important to patients are key in defining patient value. Transparently measuring and reporting patient relevant quality indicators and outcomes is essential in adopting and embedding VBHC in burn care [23]. A precondition for the implementation of VBHC is the determination of a core set of relevant outcomes and quality indicators [23,24]. The core set should cover short-and long-term health outcomes and quality indicators [16]. In tandem, healthcare costs should be evaluated. By doing so, the patient relevant outcomes can be compared against the costs in delivering these outcomes.

A VBHC-burns core set is not yet available. Therefore, the aim of this study was to define a VBHC-burns core set, including important quality indicators and outcomes. In addition, measurement instruments and assessment time points were defined to support benchmarking of outcomes included in the VBHC-burns core set.

2. Methods

We conducted a modified three-round Delphi study including patients, burn care professionals, and researchers between March and May 2022 in the Netherlands. The central Medical Ethical Committee (MEC-U, number W21.305) and the institutional review boards of the three participating hospitals (Red Cross Hospital Beverwijk, Martini Hospital Groningen, Maasstad Hospital Rotterdam) approved this study which was conducted in line with the principles of the Declaration of Helsinki. Participants provided consent by answering the survey.

2.1. Participants

Patients were invited via the patient association (Dutch Association of Burn Survivors) or via the patient panels of each burn centre. In addition, multidisciplinary burn care professionals from the three Dutch burn centres were invited to participate in the Delphi study. Burn consultants, (plastic) surgeons, intensivists, burn nurses, allied health professionals, and management were among the included professions. Researchers from the three Dutch burn centres, the Dutch burns foundation, and the Association of Dutch Burns Centres were invited to complete the Delphi survey.

2.2. Definement of Delphi items

Several preparation steps were undertaken to ultimately define the outcomes and quality indicators for the Delphi study. Insights from these preparation steps were used to provide participants with background information, helping them make informed decisions about the importance of specific outcomes or quality indicators when filling out the Delphi survey. Detailed information about the preparation steps is provided in Appendix 1. In short, the first preparation step included a patient survey on the outcomes that matter most to burn patients [25]. Items from this survey were used in the Delphi survey. Additionally, the percentage of patients indicating an item as 'very important' was included as information for participants in the Delphi study (see Appendix 2). Preparation step 2 consisted of two focus groups with patients to explore their perspectives on their care process and to identify important quality indicators to include in the Delphi study. Preparation step 3 included the review of existing registries and studies to uncover additional important items to be included in the Delphi study.

All these steps were discussed with the project team, burn care providers and patients. Based on their input and based on the three preparation steps the list of Delphi items (Appendix 3) was composed. The International Classification of Functioning Disability and Health (ICF) framework was used as guidance in this process [26,27]. The ICF categorizes health and its related domains, offering a nuanced framework to delineate the intricacies of a health condition across physiological, individual, and population levels. [27]. Impairments in body functions, body structures, activity and participation are included, as well as environmental factors. The ICF framework was employed to ensure the incorporation of all relevant domains in the Delphi study. Items were divided into outcomes and quality indicators. Outcomes were included in the Delphi study for patients, burn care providers and researcher participants. Quality indicators, with the exception of shared decision-making (SDM), were only included for burn care providers and researcher participants since these are very specific to the clinical process.

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2.3. Delphi study

SurveyMonkey was used for the three-round Delphi study. In the first electronic Delphi survey, responders were asked to anonymously score the importance of each outcome and quality indicator on a 9-point Likert scale. For each item, information from the patient survey, focus groups, and review of existing registries and studies was added to make sure that participants were able to make an informed decision. Following international recommendations, outcomes and indicators were included in the VBHC-burns outcome set if \geq 70% of participants in each group voted the outcome or indicator as critically important (score 7–9); and excluded if \geq 70% if participants in each group voted the outcome/indicator as not important (score 1–3) [28,29].

The results of Delphi survey 1 were discussed with the project team and subsequently presented anonymously to the participants in round two of the Delphi survey. Outcomes and indicators not included or excluded in Delphi survey 1 based on the aforementioned cut-off points were encompassed in Delphi survey 2. Participants were asked to thoroughly reconsider their vote, and to score the importance of each outcome and quality indicator on a 9-point Likert scale again.

Outcomes and indicators meeting neither the inclusion nor the exclusion criteria after the second Delphi survey were discussed with the project team and then presented for a final binary vote to all participants in Delphi survey 3 [29]. Both responders and non-responders to the second Delphi survey were invited for the third Delphi survey. If \geq 70% of participants in each group votes 'yes' the outcome/indicator was included in the VBHC-burns outcome set. Delphi results were discussed with the project group and if deemed necessary, additional outcomes/indicators were added to the VBHC-burns core in a consensus meeting.

2.4. VBHC-burns core set instruments and time assessment points

To select existing instruments providing measurement or quantification of the items included in the VBHC-burns core set, several sources were used. First, the overview of Dutch burn registries and studies described above included information on instruments and time points and was used to identify relevant instruments for the core set. In addition, international literature was reviewed to identify additional instruments. Second, Dutch experts were consulted to identify emergent instruments and obtain their advice regarding preferred or contemporary instruments. Third, the Dutch consensus-based standard set of generic patient-reported outcome measures (PROMs) report and accompanying recommendations were reviewed and applied [30].

Next, the project team proposed a selection of instruments which were evaluated by the Pharos institute, the Dutch Centre of Expertise on Health Disparities [31]. They tested the instruments on accessibility and comprehensibility for people with limited health literacy. This was done by a test panel consisting of consumer literacy ambassadors. In four one-on-one sessions, qualitative data on the proposed questionnaires was collected. The timing of measurement was determined based on clinical relevance and feasibility, experiences with the Burn Centre Outcome Registry the Netherlands (BORN) and on timing of PROM questionnaires in international burn care [2,32,33]. Experts were consulted on time points to best assess specific outcomes. Decisions on instruments, time assessment points, and specific time points collection for outcome were made by the project group and patient representatives in a consensus meeting; all patients who participated in the Delphi study were invited to participate. The main rationale for the choices were clinical relevance and feasibility. The defined VBHC-burns core set was implemented in the three Dutch burn centres. After approximately four months, the usability was evaluated with patients and burn care professionals. Six patients and six burn care professionals were interviewed. Their input was discussed with the project group and the VBHC-burns core set was adapted accordingly.

3. Results

A total of 49 patients, 129 burn care professionals and 29 researchers were invited, of whom 27 patients (response rate: 55.1%), 63 burn care professionals (response rate: 48.8%), and 23 researchers (response rate: 79.3%) completed the first Delphi survey. The second Delphi survey was completed by a subset of 23 patients, 44 burn care professionals, and 22 researchers. The last Delphi survey was completed by 18 patients, 40 burn care professionals, and 23 researchers.

3.1. Selection of outcomes and quality indicators

Out of the 68 items (44 outcomes and 24 quality indicators) that were included in the Delphi study, a total of 14 items, including 10 outcomes and 4 quality indicators, were included in the VBHC-burns core set (Table 1). Three of these items were selected in the first round: pain, wound healing and physical activity. The second Delphi round resulted in the inclusion of four additional items: self-care, independence, return to work and aftercare. In the final round, seven extra items were added. These items included: depression, itching, scar flexibility, return to school, SDM, active range of motion, and burn depth. The proportion of participants per group who found a specific outcome or indicator "very important" differed. Generally, the percentage was highest in patients and lowest in burn care professionals. In addition to the items selected in the Delphi process, the outcomes quality of life, self-management and post-traumatic stress symptoms were added by the project team as result of the consensus meeting.

3.2. Selection of core assessment instruments

Outcomes and the quality indicator SDM were assessed using PROMs, except for time to wound healing (the number of days until 95% re-epithelisation of the burn area) which is assessed by a clinician in practice. The initially selected PROMs were PROMIS (Patient-Reported Outcomes Measurement Information System) Global quality of life and health (PROMIS Global01 and Global02) [34], Impact of Event

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Table 1 – Delphi results for selection of items for the VBHC-burns core set.						
	Proportion of participants per group who found the outcome or indicator very important					
Item (type)	<u>Patients</u>	Burn care professionals	<u>Researchers</u>			
Included in Delphi round 1						
Wound healing (outcome)	93%	71%	87%			
Pain (outcome)	89%	79%	91%			
Physical activity (outcome)	78%	73%	83%			
Included in Delphi round 2						
Self-care (outcome)	87%	73%	73%			
Being independent (outcome)	74%	82%	86%			
Return to work (outcome)	74%	77%	77%			
Percentage of patients that received aftercare (quality		73%	91%			
indicator)						
Included in Delphi round 3						
Depression (outcome)	100%	80%	96%			
Itching (outcome)	100%	80%	70%			
Scar flexibility (outcome)	100%	80%	78%			
Shared decision making (quality indicator)	100%	73%	96%			
Return to school (outcome)	72%	80%	70%			
Percentage of patients of whom active range of		100%	83%			
motion is assessed (quality indicator)						
Burn depth determined via Laser Doppler imager		73%	96%			
between 2 and 5 days postburn (quality indicator)						

Scale-6 (IES-6) [35], EQ-5D-5L [36], self-developed item independence, PROMIS short form (SF) physical function [37], PROMIS SF pain (only asked when a patient indicated having pain on the EQ-5D-5L) [38], Numeric Rating Scale (NRS) itch [26], Partners in health scale (PIH) [39,40], PROMIS SF depression (only asked when a patient indicated experiencing anxiety/depression on the EQ-5D-5L) [41], Control Preference Scale [42], and the Patient and Observer Scar Assessment scale version 3.0 (POSAS 3.0) [43]. In addition, questions that met the recommendations from the Dutch Centre of Expertise on Health Disparities, were formulated to assess return to work/school based on the International Consortium for Health Outcomes Measurement (ICHOM) return to work items (Table 2). These PROMS were used in practice for a period of approximately three to four months. During this period 44 patients received the questionnaire of which 39 patients completed the first questionnaire. The usability and understandability were evaluated with six patients and healthcare professionals across all three Dutch burn centres.

Based on this evaluation and discussions with the project group, the Control Preference Scale was removed from the VBHC-burns core set as this instrument was found too difficult to understand by patients. In addition, the IES-6 and PIH were being refined linguistically and burn-care-specific examples were added to improve understandability. This led to the set of instruments included in the VBHC-burns core set (Table 2).

To supplement the outcome measures and the quality indicator SDM, the VBHC-burn core set includes three additional quality indicators, namely: active range of motion, defined as the extend or limit to which a body part can be moved around a fixed point; percentage of patients that received aftercare/rehabilitation; and burn depth determined using laser Doppler scanning between 2 and 5 days post burn. These three quality indicators were assessed in clinical practice and where relevant were registered in the Dutch Burn Repository (DBR) R3 [44].

3.3. Selection of assessment time points

After considering several assessments time point schedules, and trajectories, the time points at discharge, 2 weeks after discharge, 3 months post burn, 12 months post burn and annual assessment were chosen in first instance. These time points were used during a period of approximately four months and reviewed afterwards to determine outcome measure utility and relevance to clinical practice. This evaluation led to an adaptation in the reference point of the chosen assessment time points mentioned above because the timepoints linked to time of burn did not optimally match the outpatient clinic visits. Instead of post burn, the threeand twelve-month assessments were changed to after discharge. The VBHC-burns core set therefore finally consisted of the following time assessment points: at discharge (including retrospective questions), 2 weeks after discharge, 3 months after discharge and 12 months after discharge followed by an annual assessment (Fig. 1).

3.4. VBHC-burns core set

In the last step of defining the VBHC-burns core set, it was decided what items and instruments were best to assess on what time assessment points. Each item, and each instrument was carefully evaluated to find a balance that minimised patient burden and clinical utility of assessment of items. In addition, decisions were made on how to apply the quality indicators and for which indications. This resulted in the VBHC-burns core set currently being used in Dutch burn care (Fig. 1).

Table 2 – Selection of patient reported outcomes (PROs) and patient reported outcome measurements (PROMs) instruments included in the VBHC-burns core set.				
Patient reported outcomes	Patient reported outcome measurements			
Pain	EQ-5D-5 L – item pain; PROMIS SF pain 1a			
Physical activity	PROMIS SF physical function 8b			
Self-care	EQ-5D-5 L – item self-care			
Independence	Self-developed item independence			
Return to work, return to school	Adjusted ICHOM return to work/school			
Depression	EQ-5D-5 L – item anxiety/depression; PROMIS SF depression 4a			
Itching	Numeric Rating Scale itch			
Scar flexibility	Patient and observer assessment scale 3.0 (POSAS 3.0)			
Self-management	Partners in health scale (PIH)			
Quality of life	PROMIS Global01 and Global02			
Post-traumatic stress symptoms	Impact of Event scale (IES-6)			
Note BROMIS: Patient Penerted Outcomer Measurement Information System: SE: Short Form: ICHOM: International Consertium for Health				

Note. PROMIS: Patient-Reported Outcomes Measurement Information System; SF: Short Form; ICHOM: International Consortium for Health Outcomes Measurement.

4. Discussion

This study was one of the first to systematically evaluate the importance of outcomes and quality indicators for VBHC in burns with input from stakeholders. The defined VBHC-burns core set, which aims at supporting improvement of patientrelevant outcomes, includes outcomes and quality indicators that were considered most important by patients, burn care professionals and researchers. In addition, outcome assessment instruments as well as time assessment points to apply the VBHC-burns core set in practice were carefully chosen in collaboration with the stakeholders involved. The VBHCburns core set has been evaluated, adapted and is implemented in the three Dutch burn centres.

An earlier project concerning burns developed a Core Outcome Set for Burn Injuries (COSB-I) for clinical trials within burns [45]. This is an agreed standardised collection of outcomes which are recommended to be measured and reported, as a minimum, in all clinical burn trials. The aim of the COSB-I was different from the development of the VBHCburns core set; namely focussing on enhancing the quality and comparability of clinical trials, instead of supporting clinical burn care. Many outcomes are important in both

At discharge (14 items)	1-2 weeks after discharge (29-30 items)	3 months after discharge (42-47 items)	12 months after discharge (48-53 items)	24 months after discharge (36-41 items)	Annually (19-24 items)		
Quality of life: -EQ-5D-5L (retrospectively) -PROMIS Global QoL + GH (prospectively)	Quality of life: -EQ-5D-5L -PROMIS Global QoL + GH Physical functioning: -PROMIS-SF physical	Quality of life: -EQ-5D-5L -PROMIS Global QoL + GH Physical functioning: -PROMIS-SF physical	Quality of life: -EQ-5D-5L -PROMIS Global QoL + GH Physical functioning: -PROMIS-SF physical	Quality of life: -EQ-SD-SL -PROMIS Global QoL + GH <u>Physical functioning:</u> -PROMIS-SF physical	Quality of life: -EQ-SD-5L -PROMIS Global QoL + GH Physical functioning: -PROMIS-SF physical		
Independence: -Self developed item	functioning Independence: -Self developed item *Pain: -PROMIS-SF pain	functioning <u>Independence:</u> -Self developed item *Pain: -PROMIS-SF pain	functioning <u>Independence:</u> -Self developed item * <u>Pain:</u> -PROMIS-SE pain	functioning Independence: -Self developed item *Pain: -PBOMIS-SE pain	functioning <u>Independence:</u> -Self developed item * <u>Pain:</u> -PROMIS-SE pain		
		**Depression: -PROMIS-SF depression Return to work/school: -Based on ICHOM item	**Depression: -PROMIS-SF depression Return to work/school: -Based on ICHOM item	**Depression: -PROMIS-SF depression Return to work/school: -Based on ICHOM item	**Depression: -PROMIS-SF depression Return to work/school: -Based on ICHOM item		
<u>PTSS:</u> -IES-6	<u>Itch:</u> -NRS Itch <u>Self management:</u> -PIH	<u>Scar quality:</u> -POSAS v3.0 <u>PTSS:</u> -IES-6	<u>Scar quality:</u> -POSAS v3.0 <u>Self management:</u> -PIH	<u>Scar quality:</u> -POSAS v3.0			
Qutcome: time to wound healing (the number of days until 95% re-epithelisation of the burn was reached) Quality indicators: range of motion, percentage of patients that received aftercare, and burn depth determined using the Laser Doppler Imaginer between 2 and 5 days post burn.							

*Only for patients who reported pain complaints on the EQ-5D-5L

** Only for patients who reported anxiety/depression complaints on the EQ-5D-5L

GH = general health, ICHOM = International Consortium Health Outcomes Measurement, IES-6 = abbreviated Impact of Event Scale, NRS = numeric rating scale, PIH = partners in health, QoL = quality of life

Fig. 1 – Overview of outcomes, quality indicators, instruments and time assessment points included in the VBHC-burns core set. *Only for patients who reported pain complaints on the EQ-5D-5L. ** Only for patients who reported anxiety/depression complaints on the EQ-5D-5L. GH = general health, ICHOM = International Consortium Health Outcomes Measurement, IES-6 = abbreviated Impact of Event Scale, NRS = numeric rating scale, PIH = partners in health, QoL = quality of life.

clinical trials and care, which is reflected in the concurrence between COSB-I and the VBHC-burns core set, showing the international importance of these outcomes in both burn care and research. Of note, both COSB-I and the VBHC-burns core set included patients' views, showing the importance of consulting all stakeholders involved, especially patients. Some differences included the inclusion of mortality in COSB-I, and not in the VBHC-burns core set, and the inclusion of quality indicators in the VBHC-burns core set. Other important differences include the assessment instruments and time points defined for the VBHC-burns core set.

A major difficulty in comparing and benchmarking outcomes are the wide selection of both instruments and time points used internationally [2,32]. The careful selection and recommendation of assessment instruments and time points aimed at overcoming these barriers. However, this remains a challenge as clinical processes as well as cultures might differ between countries. Our evaluation showed that adhering to internationally recommended time points, such as three months after burn injury, did not always fit with clinical practice and was therefore refined to three months after discharge [32]. Another study investigated the most important outcomes for patients for pressure garment therapy for burn scars and identified eight core outcome domains [46]. Some of the outcomes identified, such as physical activity and scar flexibility, were included in our VBHC-burns core set, however, many scar related outcomes were not. The wide range of outcomes included in the VBHC-burns core set reflects the broad impact of burn injuries on patients.

The British Burn Association (BBA) has published a recommendation on instruments to use to assess and evaluate recovery following burns [47]. Interestingly, few instruments correspond to the instruments we recommended for use to assess the VBHC-burns core set. We have reviewed and considered the recommended instruments by the BBA, however, many of them were deemed to extensive for a specific item; putting a too heavy burden on our patients or were not available in Dutch. Further, we have followed the Dutch consensus-based standard set of generic patient-reported outcome measures and included many generic instead of burn-specific instruments in order to allow for comparison and benchmarking with other conditions and fields [30]. Moreover, generic instruments enable the comparison of outcomes against norm scores. Additionally, an earlier important study in the field of burns showed that a burn-specific instrument exhibited a significantly larger ceiling effect compared to a generic instrument. This suggests that the disease-specific instrument was less effective in distinguishing well among high-achieving individuals due to its limited sensitivity in accurately delineating their varying levels of performance [48]. However, it is important to note that our VBHC-burns core set incorporates not only generic assessment instruments but also burn-specific instruments ones, such as the POSAS 3.0 [43]. Some items are specific to burn injuries and are not applicable to the general population; in such cases, a disease-specific instrument is necessary. Therefore, both generic and disease-specific instruments have been selected to assess our VBHC-burns core set. This approach aligns with the recommendation of Van Beeck et al. to use both generic and disease-specific

instruments to comprehensively capture the impact of a health condition [49].

The number of VBHC core sets is steadily increasing [24,50–54]. For some conditions, VBHC core sets have been developed by the International Consortium for Health Outcome Measurement (ICHOM) [55]. As highlighted in earlier reports and reviews [55–57], many outcomes overlap between core sets and are important for a wide range of conditions [57]. However, often, different assessment instruments are applied, limiting comparison and benchmarking of outcomes, and mitigating improvements. This resulted in the current tendencies towards favouring generic instruments, and mapping outcomes [30,58–60].

4.1. VBHC-burns core set in practice

Currently, patients receive the PROMs in the form of an online questionnaire at the defined assessment time points. In cases where patients do not have an email address or access to a computer, the questionnaire can be completed by telephone interview, or on paper. When the questionnaire is completed, burn care providers and patients can see the results in a dashboard. This dashboard can be used to discuss outcomes and specific problems identified by the PROMs during a standard burn care follow-up visit in the outpatient clinic, enhancing patient-centred care and patient-relevant outcomes. The quality indicators included in the VBHC-burns core set are assessed in clinical practice and registered in the Dutch clinical burns' registry R3.

The primary aim of the VBHC-burns core set is improving patient-centered care and patient-relevant outcomes by supporting the implementation of VBHC. Although not primarily designed for research, the core set might be of added value to evaluate research questions, providing more insight in what matters most to patients. In this way, the VBHC-burns core set facilitates research and evaluating research questions.

In the present manuscript, face and content validity of the VBHC-burns core set have been examined and documented. The next important steps in the development involves assessing and evaluating the measurement properties, including establishing the reliability and validity of the assessment instruments. To guide these crucial future endeavours, we will employ the COSMIN methodology [61]. Structural validity will be assessed through psychometric techniques including Item Response Theory and Rasch analyses, while internal consistency will be examined using factor analyses. Construct validity will entail testing hypotheses concerning anticipated relationships with other established outcome measures and expected distinctions between relevant subgroups. Finally, responsiveness will be evaluated to validate longitudinal consistency. However, prior to conduction these analyses, a substantial number of burn patients (≥100 patients) must completed the VBHCburns core set at all assessment time points to ensure reliable validity assessments.

4.2. Strengths and limitations

This study includes some strengths and limitations. It is the first VBHC-burns core set that was derived through

consensus and includes outcomes and quality indicators that were considered most important to evaluate and improve patient-centered burn care. Besides, assessment instruments as well as time assessment points have been defined to support implementation of the VBHC-burns core set. A comprehensive approach was used to create the list of items that was included in the Delphi study, besides the Delphi study included relevant information on these items to support the participants of the Delphi study. Another strength is the inclusion and collaboration of relevant stakeholders. The VBHC-burns core set has been developed and evaluated with input from patients, burn care providers, and burn researchers from all three Dutch burn centres. Furthermore, advice was gathered from experts on the specific concepts included in the VBHC-burns core set. Additionally, Dutch consensus-based standard set of generic patient-reported outcome measures were reviewed and used if relevant, enabling national benchmarking [26]. Also, the instruments included were systematically evaluated by the Dutch Centre of Expertise on Health Disparities [31]. Lastly, the VBHCburns core set has been implemented in all three Dutch burn centres, evaluated in clinical practice and adapted to the experiences of patients and burn care providers.

This study has some limitations. The number of participants in the Delphi study differed between the three subgroups, with a substantial larger number of burn care professionals that participated. However, using the results of the Delphi study by subgroup minimises any bias or influence of this imbalance on the outcomes. Another limitation is that we are not aware of the characteristics of patients who participated. The participants might not have been fully representative of our burn patient population. The VBHC-burns core set included 9 outcomes that were covered by the chosen assessment instruments. The total number of questions asked on the defined time assessment points range from 14 to 53, possibly posing a too high burden on patients. Interestingly, during the evaluation, patients reported that the time needed to complete the questions was reasonable. However, the twelve months' time point, where the maximal number of questions are asked, had not yet occurred at the time of writing. A more thorough evaluation will follow and will further improve the VBHC-burns core set. To limit the patient burden, which outcomes should be assessed when was carefully considered; and consequently, not all outcomes are assessed on all time assessment points. This reduces the time to answer all questions; however, it decreases the evaluation of, for example, itching and self-management over time. Furthermore, a six-month assessment was not included to limit patient burden; however, this is a common time point in the evaluation of published burn outcomes and might therefore be considered a limitation. The questionnaire is currently only available in Dutch and some questions are considered difficult to understand by patients with a low health literacy. Those questions are being reviewed and we aim at making them easier; in addition, the option to provide an English questionnaire is being considered. Another limitation is the development of the VBHC-burns core set nationally instead of internationally. By developing it nationally we were able to follow the Dutch guidelines and include instruments to benchmark outcomes with other health fields in

the Netherlands, which could hamper international applicability. Also, the quality indicator regarding the use of the LDI to determine burn depth may not be relevant for all countries, as it is common practice in Dutch burn care but not universally adopted worldwide.

5. Conclusion

A VBHC-burns core set was developed, consisting of outcomes and quality indicators that are important to burn patients and burn care professionals. These VBHC-burns core set is now systemically monitored and analysed in Dutch burn care to improve patient-relevant outcomes. As the importance of VBHC is increasingly acknowledged in burn care worldwide, the developed VBHC-burns core set is valuable to support VBHC in burns, and could be inspiring to evaluate and improve burn care in other countries as well.

Ethics approval and consent to participate

This study was performed according to the principles of the Declaration of Helsinki (Ethics manual World Medical Association 2nd edition 2009), and approved by the Ethics Committee (MEC-U; number W21.305) and the institutional boards of the three hospitals. Participants provided consent by answering the survey.

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CRediT authorship contribution statement

IS: The conceptualization and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, project administration, funding acquisition; DvU: The conceptualization and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, project administration; PvZ: The conceptualization and design of the study, acquisition of data, analysis and interpretation of data, supervision, project administration, funding acquisition; TH, CvS, CL, LvD, FW, DE: The conceptualization and design of the study, acquisition of data, analysis and interpretation of data, revising the article critically for important intellectual content; CvdV, EB, EM, SS, AdV, MN, MvB, AP: The design of the study, acquisition of data, revising the article critically for important intellectual content, funding acquisition; SG, RvW, MvV: The design of the study, acquisition of data, revising the article critically for important intellectual content; KG, YL, AS, AW, RvG, IV, GV, HW, GB, MH, MA, MS: acquisition of data, revising the article critically for important intellectual content. All authors

approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Declaration of Competing Interest

Not applicable.

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Consent for publication

Not applicable.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.burns.2024.03.038.

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