EDITOR'S CHOICE

A Standard Set for Outcome Measurement in Patients With Hand and Wrist Conditions: Consensus by the International Consortium for Health Outcomes Measurement Hand and Wrist Working Group

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Purpose To describe the principles, process, and results of creating the International Consortium for Health Outcomes Measurement (ICHOM) standard set for hand and wrist conditions.

Methods Following the standardized methods of ICHOM, an international working group of hand surgeons, therapists, and researchers was assembled to develop an evidence-based, patient-centered, standard set of outcome measures for patients with hand and wrist conditions. Multiple systematic reviews were performed to support our choices of outcome domains and tools for hand and wrist conditions. Fourteen video conferences were held between March 2018 and March 2020, and a modified Delphi process was used.

Results A consensus was reached on 5 measurement tracks: the thumb, finger, wrist, nerve, and severe hand trauma tracks, with a distinction between regular and extended tracks for which specific allocation criteria applied. The standard set contains a selection of outcome tools and predefined time points for outcome measurement. Additionally, we developed a hierarchy for using the tracks when there are multiple conditions, and we selected risk-adjustment, case-mix variables.

Conclusions The global implementation of the ICHOM standard set for hand and wrist conditions may facilitate value-based health care for patients with hand and wrist conditions.

Clinical relevance The ICHOM standard set for hand and wrist conditions can enable clinical decision making, quality improvement, and comparisons between treatments and health care professionals.

Key words Consensus, hand, ICHOM, outcome assessment (health care), value-based health care, wrist.

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The prevalence of hand and wrist conditions is high and likely to increase because of the aging population.[1–4] In a Dutch population-based study investigating health care and productivity costs, hand and wrist conditions ranked first in the order of the most expensive injury types, annually accounting for $740 million, followed by above-knee and lower-extremity fractures ($562 million), hip fractures ($532 million), and skull-brain injuries ($355 million).[5] Furthermore, hand and wrist injuries account for between 7% and 29% of all visits to emergency departments in the United States, the Netherlands, and Denmark, resulting in a high cost to the society.[6–11]

The value-based health care (VBHC) framework developed by Porter[12] as well as Porter and Teisberg[13] has been recognized to improve the quality of care and reduce costs. In VBHC, the value is defined as the outcomes achieved divided by the costs. A key aspect of VBHC is measuring outcomes, preferably using a condition-based "standard set" of outcome measures. A standard set recommends the use of specific outcome tools (defined as outcome measures or instruments) to measure essential outcome domains and includes predetermined time points for outcome measurement. These standard sets also include risk-adjustment, case-mix variables (eg, baseline demographics or variables describing health status). Furthermore, a standard set should apply to all types of treatment (ie, surgical or nonsurgical) and should be administered by all health care professionals (eg, hand surgeons, hand therapists, rheumatologists, etc) treating the target population, in this instance, adult patients with hand and wrist conditions. Using a standard set enables valid comparisons of outcomes across different treatments or treatment centers regionally or globally.[12,13] Additionally, it facilitates shared decision-making and benchmarking across organizations, thereby improving the quality of health care.[12,13] To implement VBHC, government organizations are endorsing the standard sets developed by the International Consortium for Health Outcome Measurement (ICHOM), which is a nonprofit organization.[14–16] The ICHOM standard sets were developed by a group of experts and patient representatives of the field, using the same standardized methods for every condition, focusing on what matters most to patients.

Although some consensus-based standard sets or large cohort registries using standardized outcome measurement systems exist in hand and wrist care, there is currently no internationally adopted system for measuring the outcomes of hand and wrist care in a standardized manner.[17–22] It remains difficult to compare outcomes across different treatments and treatment centers, both in daily clinical practice and research.[12,13] Therefore, an international, minimum standard set of outcome measures that are the most important to patients with hand and wrist conditions was developed by the ICHOM Hand and Wrist Working Group. Because we included all adult hand and wrist conditions and usually only 1 condition is included in ICHOM standard sets, an innovative approach to creating the hand and wrist conditions standard set was needed. In this article, we described the ICHOM hand and wrist standard set, including the following: (1) the scope of, and approach to, developing the hand and wrist standard set, (2) the creation of measurement tracks, (3) the identification of outcome domains and tools through systematic reviews, (4) prioritizing and defining outcome domains that capture the patient's perspective, (5) selecting outcome tools, (6) determining standardized time points for outcome measurement, (7) establishing a flowchart and track hierarchy when there are multiple conditions, (8) selecting risk-adjustment, case-mix variables, and (9) a professional open review of the standard set.

MATERIALS AND METHODS

Working group composition

An international working group was assembled—including plastic and orthopedic hand surgeons, physical and occupational hand therapists, as well as researchers—comprising 22 experts on hand and wrist conditions representing 11 countries and 4 continents. The aims of this working group were as follows: (1) to review the existing literature and practices for assessing the outcomes of treatment for hand and wrist conditions and (2) to create a standard set of measurements for evaluating hand and wrist conditions, with feasible recommendations that can be reliably implemented globally by health care providers. The selection of the working group members was based on demonstrable expertise in hand and wrist care, with the final selection aiming at capturing different geographical regions and focus areas. The efforts of the working group were guided and facilitated by a core project team (R.M.W., A.O.J.-O., A.D.T, A.J., and S.E.R.H.).

Working group process

To retain the VBHC framework and facilitate a structured process throughout the project, ICHOM standard sets are developed using the following

framing principles: (1) outcomes are defined around the medical condition, not the specialty or a procedure, (2) the standard set is a minimum set focused on outcomes that matter most to patients, (3) patients are directly involved in defining the standard set, (4) patient-reported outcome measures (PROMs) are included in every standard set to capture symptom burden, functional status, and health-related quality of life, (5) a minimum set of case-mix variables is included to facilitate meaningful comparisons, and (6) the time points and sources of data collection are clearly defined to ensure the comparability of results.

Between March 2018 and March 2020, 14 video conferences with the entire working group were scheduled. Additional break-out sessions were scheduled with a small group of representatives of the working group to generate a list of items for discussion with the entire working group. The meeting goals were to establish the scope, methods, and content of the ICHOM hand and wrist standard set, for which a 3-round structured modified Delphi process, similar to that used for previous ICHOM working groups, was followed (Fig. E1, available online on the *Journal*'s website at www.jhandsurg.org).[23–25] This Delphi process involved a structured method to achieve a consensus using a series of voting rounds to gather anonymous inputs on particular topics, with an 80% response rate as a threshold to ensure the validity of all votes.[26]

Prior to each video conference, the project team prepared and distributed a slide deck with a summary of relevant evidence from the literature and initial proposals that were shared with the working group. During these video conferences, the proposals were discussed and inputs from the working group were gathered. Following each video conference, online surveys were administered to obtain anonymous votes from the working group members, with 80% agreement as the consensus threshold. If a consensus was not reached on an item during the first voting round, this item was rediscussed during the next video conference, and a second voting round took place using the same method. If no consensus was reached after 3 rounds, the working group chair (S.E.R.H.) made the final decision. This happened once while choosing the measurement tool for thumb carpometacarpal palmar abduction.[27]

The creation of measurement tracks

Prior to identifying the outcome domains and tools, the working group faced the challenge of including all adult hand and wrist conditions (except the excluded conditions, Fig. 1) because hand and wrist conditions comprise both traumatic and nontraumatic conditions as well as multiple anatomic regions and structures. We chose to include all adult hand and wrist conditions because creating separate standard sets for every hand or wrist condition would have required a large investment of time and money and would have resulted in multiple, overlapping standard sets that would have likely confused users. Thus, the working group reached a consensus on clustering conditions into several measurement tracks, in which multiple conditions were evaluated in the same manner, using the same outcome tools and time points. Examples of the successful use of such clustering methods exist.[21,22] Conditions for which the same relevant outcome measures applied were clustered within the same track. For example, in thumb conditions, the working group agreed that the same outcome measures and time points were relevant for patients with thumb base osteoarthritis and those with ulnar collateral ligament injury of the thumb metacarpophalangeal joint. This principle led to the development of 5 tracks within the hand and wrist standard set: (1) the thumb track (includes thenar/entire ray), (2) the finger track (includes entire ray), (3) the wrist track, (4) the nerve track, and (5) the severe trauma track (Fig. 2).

Because some conditions require a large number of measurements and longer follow-up than other conditions, the working group agreed to include regular and extended forms of each track (except for the severe trauma track). A regular track comprises only basic measurements and time points for shorter follow-up, whereas an extended track includes more comprehensive measurements and time points for longer follow-up. For each track, predetermined time points for outcome measurement were established following the consensus, aiming to choose time points that maximally aligned with routine follow-up. In addition, the working group reached a consensus on track-specific criteria for the allocation of conditions to the regular or extended track, which were based on the probability of changes in health status occurring over a period longer than 6 months (regular track final time point) due to either the pathophysiology of the condition or an expected treatment effect (see Table 1 for an example of the thumb track). For allocation to the severe trauma track, a threshold of a modified hand injury scoring system score of $\geq$50 and the presence of $\geq$3 damaged structures was defined.[28,29] The modified hand injury scoring system is a validated scoring tool to quantify hand, wrist, and

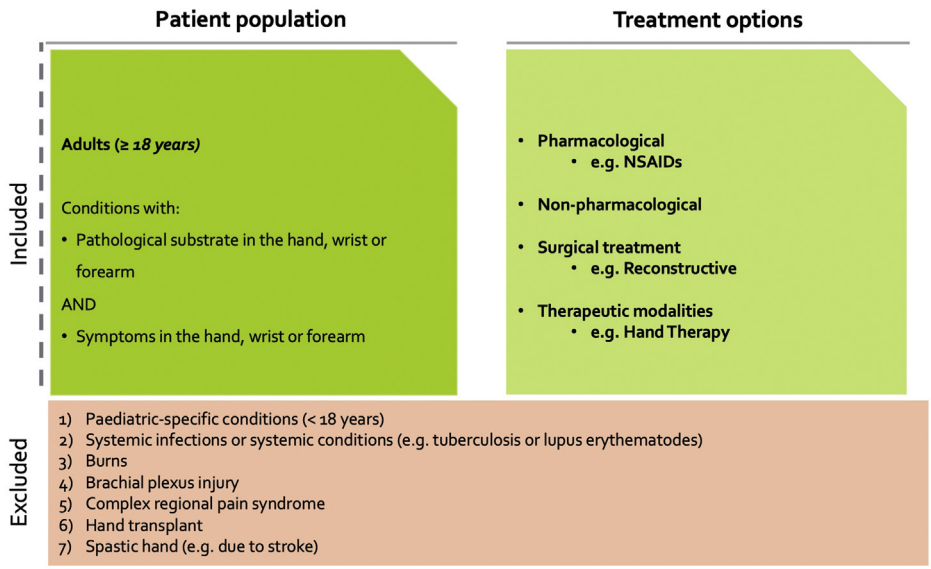

FIGURE 1: Scope of the hand-wrist standard set. Conditions were excluded if there already was an ICHOM standard set or if the condition required a specific outcome evaluation that would make it unfeasible to be included in the hand-wrist standard set. For example, these may have other relevant outcome domains, outcome tools, or follow-up algorithms.

forearm injuries, wherein scores <20 represent minor, 21−50 represent moderate, 51−100 represent severe, and >101 represent major injuries.[28,29]

Outcome domains

Systematic reviews of the literature were performed to identify all possible relevant outcome domains for patients with hand and wrist conditions as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[30] The Medical Literature Analysis and Retrieval System Online (MEDLINE) (PubMed) database was searched for relevant articles using 2 search strategies: (1) the track name (eg, "thumb") or specific conditions for the particular track (eg, thumb carpometacarpal osteoarthritis), combined with outcome or assessment terms and (2) the track name (eg, "thumb") or specific conditions for the particular track (eg, thumb carpometacarpal osteoarthritis) and randomized controlled trials. These search strategies were repeated for each track. The search strings for the thumb track are presented in Appendix E1 (available online on the *Journal's* website at www.jhandsurg.org). Articles were included if they described outcome domains, were published within the last 10 years, were written in English, and concerned adult patients with thumb conditions. Two independent reviewers (R.M.W. and A.O.J.-O.) identified and extracted all outcome domains. Disagreements in the extraction of these outcome domains were resolved in a consensus meeting. In addition to the systematic reviews, manual reference searches were performed, and outcome domains were identified based on expert opinion (discussion among the working group).

Following the modified Delphi process, the selection of outcome domains by the working group was guided by the VBHC framework, and the importance of each outcome domain was ranked on a 9-point Likert scale.[12] Subsequently, the outcome domains were classified as "essential" (ranked 7−9 by at least 80% of respondents), "nice to have" (ranked 4−6 or any range without 80% agreement), or "not recommended" (ranked 1−3 by at least 80% of respondents).The project team proposed definitions for each outcome domain using, when available, definitions recommended by the International Classification of Functioning, Disability and Health; Medical Subject Headings; professional organizations, such as the International Association for the Study of Pain; or other sources.[31−36]

Patient input on outcome domain selection

To capture patients' perception, a total of 1,060 patients with hand and wrist conditions were recruited at various treatment centers for hand surgery and hand therapy in the Netherlands and the United States following local approval by a medical ethical review committee. Informed consent was obtained. For each measurement track, a separate survey was created, and only patients fitting in this track were invited to

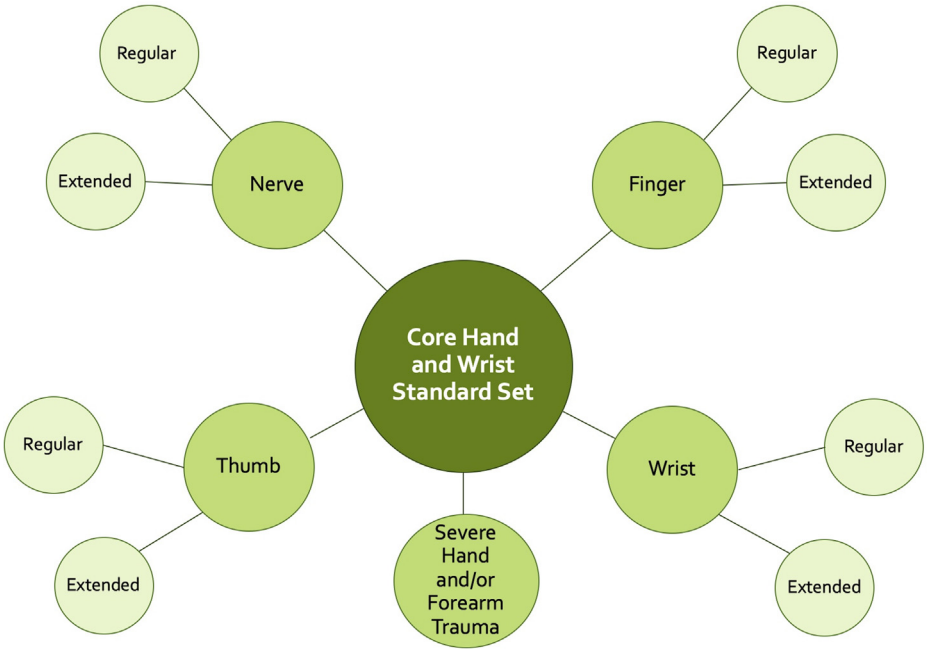

FIGURE 2: Overview of the tracks within the hand-wrist standard set. Except for the severe injury track, each track includes a regular and extended track. The regular track comprises fewer measurements and short follow-up, whereas the extended track comprises more measurements and longer follow-up.

TABLE 1. Criteria for the Allocation of Conditions to the Extended or Regular Thumb Track Based on the Probability of Changes in Health Status >6 months (Regular Track Final Time Point) due to Either the Pathophysiology of the Condition or an Expected Treatment Effect

Thumb—Regular	Thumb—Extended
Conditions in which short-term follow-up is clinically required, using basic outcome measures: - Simple fracture - Trigger digit, other tenovaginitis/(teno-) synovitis - Simple lacerations, thumb tip injury only involving the skin - Simple lesions (eg, skin, ganglion, mucous cyst, nail bed) - Symptomatic/irritating foreign material - Simple/superficial infection	Conditions in which long-term follow-up is clinically required, using comprehensive outcome measures: - Cut/lacerated or fractured structures - Lesion of tendon, ligament, or complex fracture of the bone - Bone malunion/nonunion - Amputation Joint disorders: - Osteo-, mono-, or rheumatoid arthritis - Joint laxity/instability - Joint contractures Other: - Adhesions - Dupuytren surgery - Severe/deep infection (eg, panaritium tendineum)

participate. No additional inclusion criteria were applied. These patients reviewed the identified list of outcome domains by completing an anonymous survey, which was administered to the patients online by the working group members, via ICHOM social media, and at Xpert Clinics using their routine outcome measurement system.[22] Again, the importance of each domain was ranked on a 9-point Likert scale, and the outcome domains were considered essential to patients when they were given a score of 7–9 by >80% of the respondents. It was also evaluated if the list captured the most important outcome domains, including the option to suggest additional outcomes in free text. The survey outcomes were analyzed by the project team and discussed with the working group to discuss the next steps.

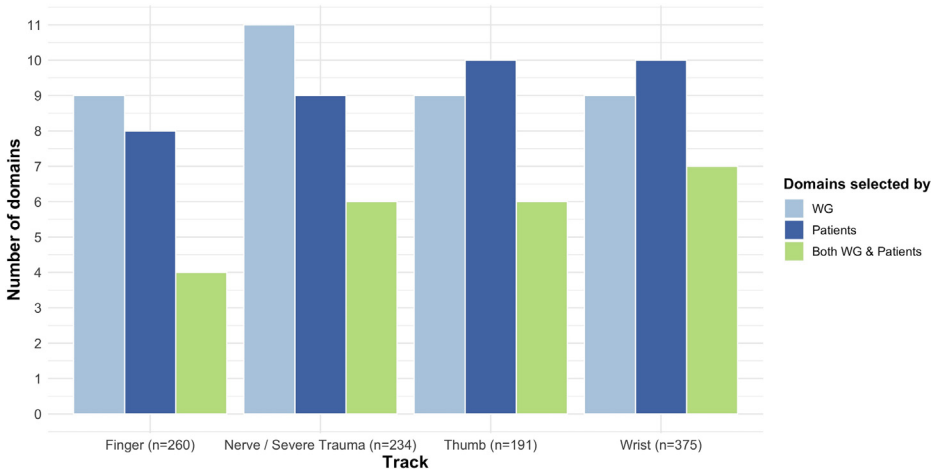

FIGURE 3: Overview of the outcome domains selected by the WG and patients and domains selected by both the WG and patients (n = 1,060). In addition, 95% of the patients indicated that we identified all relevant outcome domains. WG, working group.

Outcome tools

To identify all relevant outcome tools, additional systematic reviews were performed. First, systematic reviews were conducted for the thumb track. The following 2 search strings were used in MEDLINE (PubMed, published from 2008 onwards) to extract outcome tools: (1) outcome or assessment terms, combined with the body part region (ie, thumb) and outcome domain name (eg, "pain") and (2) track name (ie, "thumb") and tools measured in randomized controlled trials (Appendix E1). The results of the systematic reviews for the thumb were used as a basis for the other tracks, and the working group deemed additional systematic reviews necessary for specific aspects of other tracks to ensure a complete picture. Consequently, additional systematic reviews were conducted for PROMs on hand function/activities of daily living, specifically for the wrist track, patients with Dupuytren disease, and the nerve track. Furthermore, systematic reviews were performed for the following: (1) tools evaluating the range of motion specifically for the finger track, (2) tools evaluating sensibility, and (3) tools evaluating cold intolerance. All outcome tools mentioned in articles concerning the outcome domain under study were identified. Two independent reviewers (R.M.W. and A.O.J.-O.) identified and extracted the outcome tools, and disagreements in tool extraction were resolved in a consensus meeting. Manual reference searching was performed, and outcome tools were identified based on expert opinion (discussion among the working group). Subsequently, the outcome tools were reviewed by the project team and working group using standardized templates with respect to outcome domains, with evidence supporting psychometric properties, feasibility, licensing fees, and the degree to which they were established in the field. Following this, the previously described Delphi process was used to select outcome tools for the chosen outcome domains.

RESULTS

The scope and approach for the hand and wrist standard set

All the working group members agreed to the aforementioned framing principles, and there was 100% agreement on the scope of the project (Fig. 1).

Outcome domains

A total of 18 domains were identified for the thumb track of the hand and wrist standard set after screening a total of 1,195 articles, manual reference searching, and a discussion among the working group (Fig. E2, available online on the *Journal's* website at www.jhandsurg.org). Table E1 (available online on the *Journal's* website at www.jhandsurg.org) demonstrates an overview of the identified outcome domains, including their definitions. The following outcome domains were considered essential for all the tracks (both regular and extended): pain, patient-reported hand function/activities of daily living, health-related quality of life, return to work, satisfaction with treatment results, complications, and revision. In addition, grip and pinch strength, range of motion, sensibility, and cold intolerance were considered essential for specific tracks only.

For the thumb track, 191 participants completed the patient-validation survey. Figure 3 demonstrates that 6 of 9 outcome domains selected by the working group were also considered essential by >80% of the

TABLE 2. Overview of the Identified Existing Tools to Measure Outcomes That Were Considered Essential for the Hand and Wrist Standard Set*

Outcome Domain	Tools Identified
Cold intolerance	1. CISS 2. VAS 3. McCabe cold sensitivity severity scale 4. PWES
Complications	1. Method described by Rohde et al[37] 2. Method described by Vermeulen et al[38] 3. Method described by Lipira et al[39] 4. Method described by Dindo[40]
Grip and pinch strength	1. Three-jaw/palmar/tripod pinch/3-point pinch 2. Lateral/key pinch 3. Tip pinch 4. Grip strength using hand-held dynamometer 5. Grippit dynamometer 6. RET 7. Martin vigorimeter/sphygmomanometer 8. RIHM
Health-related quality of life	1. SF-12 2. SF-36 3. EuroQol EQ-5D 4. Nottingham health profile questionnaire 5. World Health Organization quality-of-life-BREF questionnaire 6. Stanford HAQ 7. Wuolle questionnaire 8. Verbal rating scale 9. PSI 10. Permanent impairment scale
Pain	1. VAS 2. NPRS 3. Troublesomeness grid questionnaire 4. Assessment of joint line tenderness 5. Pressure pain thresholds using a mechanical algometer 6. McGill pain questionnaire 7. McGill Pain Questionnaire—Short Form 8. West Haven-Yale multidimensional pain inventory 9. PROMIS Pain Interference Short Form 4/6a/6b/8 10. PROMIS scale—pain intensity 11. Brief pain inventory 12. MHQ pain subscale 13. DASH pain items 14. PRWHE pain subscale 15. AUSCAN pain subscale

(Continued)

patients. For the finger track (n = 260 survey participants), this was 4 of 9; for the wrist track (n = 375 survey participants), this was 7 of 9; and for the nerve and severe trauma tracks (n = 234 survey participants), it was 9 of 11. The additional outcome domains not yet included by the working group that were considered essential by >80% of the patients completing the survey were coping/self efficacy, performance or fine hand use, wellbeing, and reported experience with health care delivery processes. Considering all the tracks together, 95% of the respondents indicated that we identified all the relevant outcome domains most important to patients (n = 1,060).

TABLE 2. Overview of the Identified Existing Tools to Measure Outcomes That Were Considered Essential for the Hand and Wrist Standard Set* (Continued)

Outcome Domain	Tools Identified
Patient-reported hand function/activities of daily living	1. MHQ 2. Brief MHQ 3. PRWHE 4. MASS07 5. ABILHAND 6. DASH 7. QuickDASH 8. Manchester-modified or M2 DASH 9. FIHOA 10. PSFS 11. MAP-Hand 12. Cochin hand function scale/DHI 13. COPM 14. POS—hand/arm questionnaire 15. PEM 16. AUSCAN 17. MAM-36 18. UEFI 19. Levine questionnaire/ Boston Carpal Tunnel Questionnaire 20. Motor activity log 21. M-SACRAH 22. AIMS-2 23. Beursken's patient-specific approach tool (PSK) 24. URAM 25. SDSS 26. PRUNE 27. PROMIS upper-extremity function
Range of motion	1. Goniometry 2. Palmar abduction: IMD 3. Palmar abduction: pollexograph 4. Palmar abduction: AMA 5. Kapandji opposition 6. Pulp-to-palm distance/composite finger flexion 7. Total active movement 8. Cylinder grip width 9. Wire tracing 10. Visual estimation 11. Glove systems 12. Photo imaging/apps
Return to work	1. Work role functioning questionnaire 2. Work rehabilitation questionnaire 3. Questionnaire (MHQ) work performance subscale
Revision	None
Satisfaction with treatment results	1. MHQ—satisfaction with hand function subscale 2. VAS for satisfaction

(Continued)

TABLE 2. Overview of the Identified Existing Tools to Measure Outcomes That Were Considered Essential for the Hand and Wrist Standard Set* (Continued)

Outcome Domain	Tools Identified
Sensibility	1. Semmes Weinstein 2. WEST 3. Moving/static 2-point discrimination 4. Vibrometers 5. Shape-texture identification test/sensibility texture index

AIMS-2, arthritis impact measurement scales 2; AMA, American Medical Association; AUSCAN, Australian Canadian osteoarthritis hand index; BREF, abbreviated; CISS, cold intolerance symptom severity questionnaire; COPM, Canadian occupational performance measure; DASH, Disabilities of the Arm, Shoulder and Hand; DHI, Duruöz hand index; FIHOA, functional index for hand osteoarthritis; HAQ, health assessment questionnaire; IMD, inter metacarpal distance; MAM-36, manual ability measure-36; MAP-Hand, measure of activity performance of the hand; MASS07, Modern Activity Subjective Survey of 2007; MHQ, Michigan hand outcome questionnaire; M-SACRAH, modified score for the assessment and quantification of chronic rheumatoid affections of the hand; NPRS, numerical pain rating scale; PEM, patient evaluation measure; POS, patient outcomes of surgery; PRUNE, patient-rated ulnar nerve evaluation; PRWHE, patient-rated wrist/hand evaluation; PSFS, patient-specific functional scale; PSI, physical synthetic index; PWES, potential work exposure scale; QucikDASH, quick Disabilities of the Arm, Shoulder and Hand; RET, rapid exchange test; RIHM, Rotterdam intrinsic hand myometer; SDSS, Southampton Dupuytren scoring scheme; SF-12, Short Form-12; SF-36, Short Form-36; UEFI, upper-extremity functional index; URAM, Unité Rhumatologique des Affections de la Main; VAS, visual analog scale; WEST, Weinstein enhanced sensibility test.

*Not all the domains are assessed in every track.

Outcome tools and time points

After screening 2,068 articles, manual reference searching, and a discussion among the working group, a total of 90 existing outcome tools concerning the essential outcome domains were identified (Table 2, Fig. E3 [available online on the *Journal*'s website at www.jhandsurg.org]).[37–40] Of these, 5 tools that were measured across all the tracks were chosen by the working group. Furthermore, a total of 10 other tools that were measured in specific tracks only were chosen. Because no validated and feasible tools were available for hand and wrist conditions to assess return to work, satisfaction with treatment results, and complications, novel tools for these domains were developed by the working group (Appendix E2, available online on the *Journal's* website at www.jhandsurg.org). An overview of the selected outcome tools, the associated predefined time points, and the estimated time to complete are displayed in Figure 4A, B separately for each measurement track.

Track hierarchy and flowchart

Because patients with hand and wrist conditions often present with multiple conditions and because multiple tracks were created, a clear hierarchy and flowchart were needed to guide the end users of the standard set. Hence, the working group reached a consensus on a flowchart for selecting the right track (Fig. 5). This flowchart included a hierarchy of the tracks for cases with multiple conditions, meaning that in cases with multiple conditions, only the PROMs of the track with the highest hierarchy were employed. In these cases, the clinician-reported outcome measurements of the track(s) lower in hierarchy were added if these were not already used in the track higher in hierarchy. For example, for a case that was allocated to the extended thumb track and extended wrist track, only the PROMs of the extended wrist track were used, and additional clinician-reported outcome measurements of the extended thumb track were added if not already present (in this case: thumb goniometry, Kapandji score, and pinch strength). The hierarchy was not based on the severity of the conditions within the tracks but on the suitability of using the PROMs in other tracks. For example, the Patient-Rated Wrist/Hand Evaluation is feasible for use across many hand and wrist conditions, whereas the Michigan Hand Outcomes Questionnaire may be less responsive in patients with wrist conditions.[41-45]

Case-mix variables

The working group reached a consensus on recording at least the following case-mix variables at baseline: age, sex, level of education, type of work, smoking status, comorbidities, specific medical history, hand dominance, hand affected, description of treatment, and whether the consultation concerned a second opinion visit. More details on how to register these case-mix variables are available in the reference guide.[27]

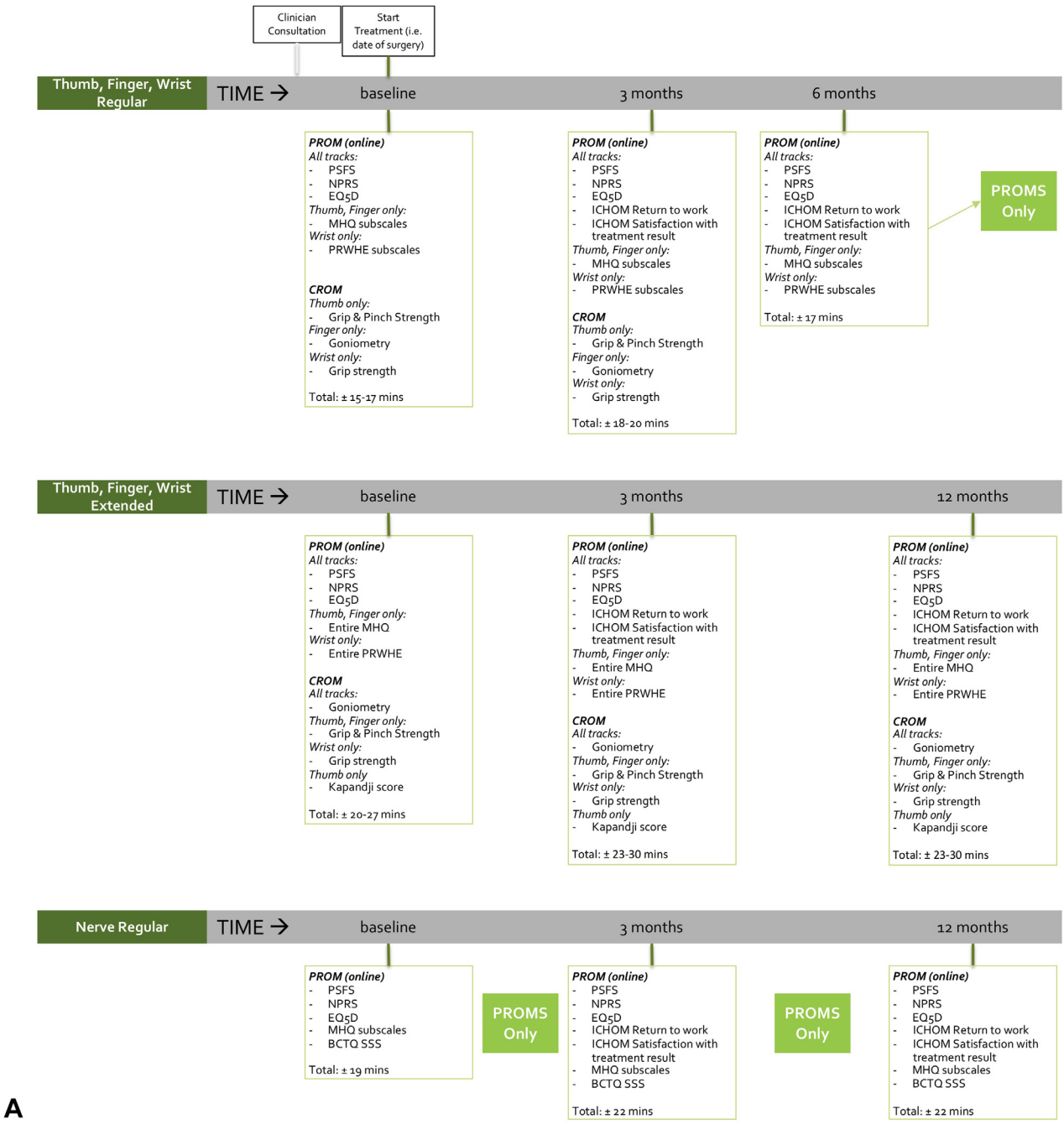

FIGURE 4: Overview of the tools measured in the ICHOM hand and wrist standard set. For each track, this figure demonstrates all measurements and associated estimated time to complete for every time point. Additionally, these figures indicate which measures are patient-reported (PROM) and which are clinician-reported (CROM). **A** Regular and extended thumb, finger, and wrist tracks and regular nerve track. **B** Extended nerve track and severe trauma track.

Professional open review

In addition to the patient-validation surveys, the entire standard set was distributed via social media, by professional organizations, and via individual approaches for review by professionals in the field of hand and wrist conditions. The participants of the professional open-review survey came from different countries (n = 32), and 46% of the participants were hand surgeons, whereas 44% were hand therapists (Table E2, available online on the *Journal's* website at www.jhandsurg.org). In this survey, 82% to 97% of the respondents agreed with the selected outcome domains, 87% to 95% agreed with the selected outcome tools, 86% to 96% agreed with the proposed time points, and 94% agreed with the proposed case-mix variables (the number of respondents

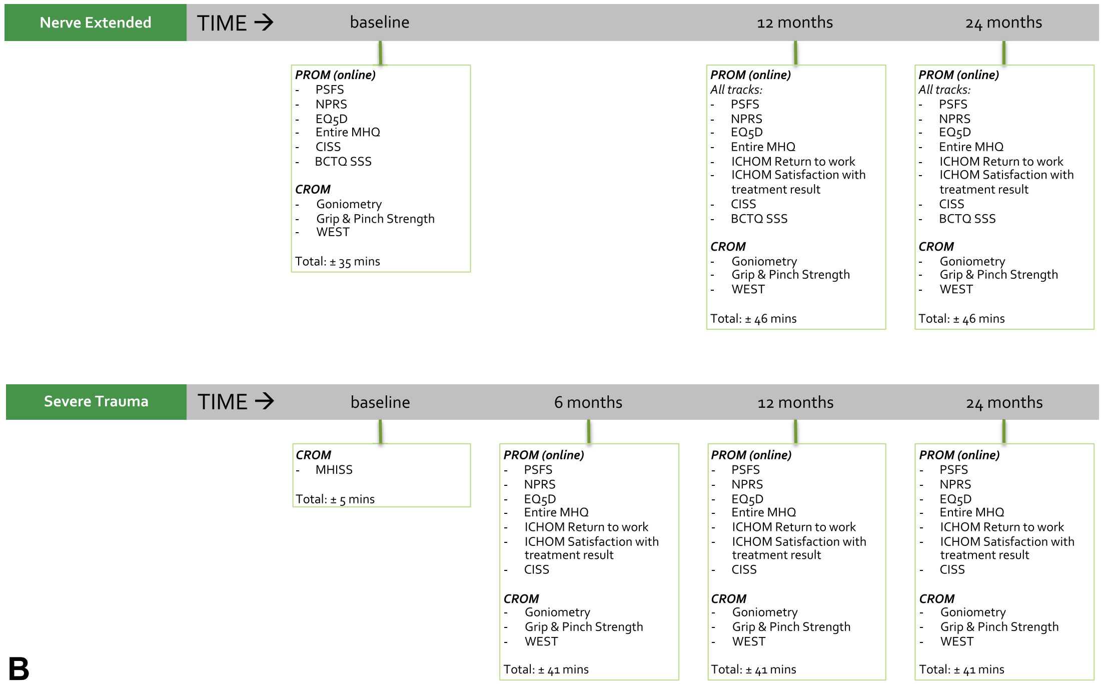

FIGURE 4: (*continued*).

ranged from 98 to 244 depending on the item and measurement track).

DISCUSSION

An international multidisciplinary working group defined a standard set of patient-centered outcome measures for patients with hand and wrist conditions, which is based on patient input, literature reviews, the assessment of registries, and an expert consensus. In this process, 5 measurement tracks were created within the ICHOM hand and wrist standard set: (1) the thumb track, (2) the finger track, (3) the wrist track, (4) the nerve track, and (5) the severe hand and/or forearm trauma track. Additionally, within the tracks, a distinction was made between regular and extended tracks, for which specific allocation criteria applied. The standard set contains a selection of outcome tools and standardized time points for outcome measurement. Furthermore, we developed a hierarchy for using the tracks when there are multiple conditions (eg, thumb base osteoarthritis and carpal tunnel syndrome), and we defined the risk-adjustment case-mix variables.

To our knowledge, our method of creating measurement tracks is innovative, in that it created an ICHOM standard set, because standard sets usually focus on 1 condition (eg, diabetes or stroke), whereas in the current standard set, many hand and wrist conditions were included. Furthermore, for the classification of conditions into the regular or extended track, we created specific criteria based on the probability of changes in health status after the regular track final time point due to either the pathophysiology of the condition or an expected treatment effect. Thus, we aimed to create general criteria for classifying conditions into the tracks without creating an unwieldy and complex system.

Although these criteria are highly specific, our proposed system should be evaluated in terms of the daily clinical care of patients with hand and wrist conditions to determine the usability and aspects needing further optimization. Future efforts should evaluate whether the use of this system is feasible in a clinical research setting, or in other words, whether it is feasible in working hand clinics. The concept of measurement tracks in daily practice may be challenging because these tracks may not fit every patient or may be too general for evaluating condition-specific issues. However, examples of successfully applying similar methods for routine outcome measurement in hand surgery clinics exist.[21,22] Additionally, the development of our system was based on inputs from experts in the field, and a 100% consensus on this approach was reached by our working group. Future implementation across

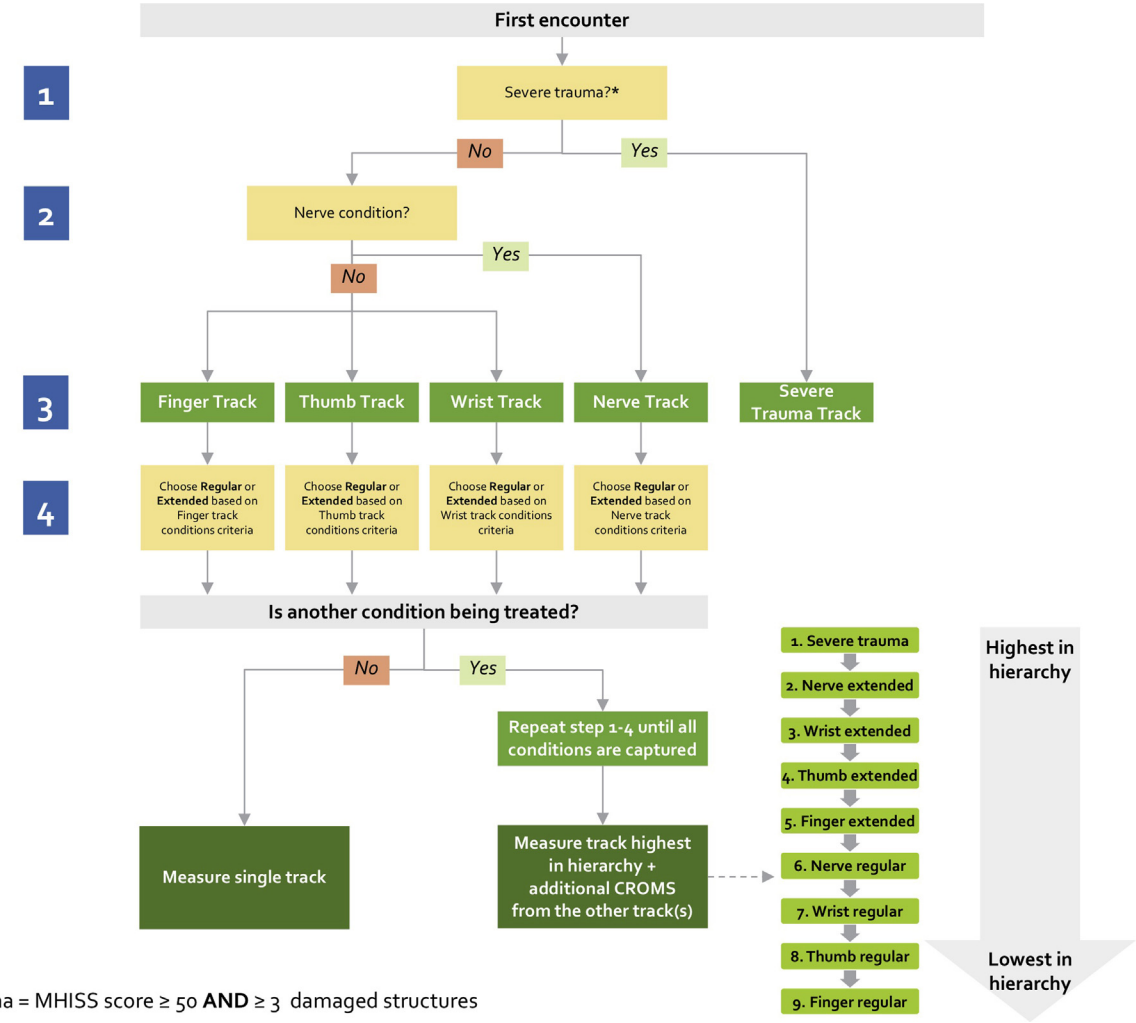

FIGURE 5: Flowchart and hierarchy for the ICHOM hand and wrist standard set. This flowchart can be used to select the right track, and it is needed in cases with multiple conditions. For a patient to be allocated to the severe trauma track, there has to be an MHISS score of ≥50 and the presence of ≥3 damaged structures. MHISS, modified hand injury scoring system.

different geographical areas is needed to investigate whether it is feasible to use the measurement tracks, including the flowchart and hierarchy, in patients with hand and wrist conditions in everyday clinical practice. Furthermore, the feasibility, validity, and reliability of the standard set and potential modifications needed for its use in clinical practice across the health care system and cultural influences need to be investigated.

Although our effort is not the first initiative to reach a consensus on a standard set for outcome measurement in patients with hand and wrist conditions, we believe that the creation of measurement tracks, which are based on similar relevant outcome domains across conditions, will be feasible for use and will facilitate global implementation.[17–20] Additionally, we used a very rigorous consensus process that has been successfully used previously for developing other ICHOM standard sets.[23–25] Furthermore, multiple professional organizations in the field have been engaged in the development of the ICHOM hand and wrist standard set, which may facilitate acceptance and encourage the adoption of the standard set.

We did not include any measures of the patient-reported outcomes measurement information system (PROMIS).[46] One of the core properties of the PROMIS measures is the integration of computer adaptive testing, which has many benefits, but may limit global usage in settings without sufficient information and communications technology infrastructure (eg, in lower- to middle-income countries). Additionally, while there is a PROMIS tool for the upper extremity, this tool was not considered specific enough by the working group for many hand or wrist conditions. This standard set reflects the current evidence of

outcome measurement tools in hand and wrist care, but novel outcome measurement techniques may be incorporated over time for the revision of this standard set when superior evidence emerges. An advantage of PROMIS tools is their feasibility, and future research should investigate how the present ICHOM hand and wrist standard set compares with PROMIS with regard to this feasibility and accuracy, ceiling effects, or other performance characteristics. Theoretically, the outcome domains we selected should remain stable over time.

As in any standard set development, a potential limitation is that it reflects the opinion of a select group of experts. However, to avoid a selection bias, we used a transparent and structured Delphi process and performed multiple systematic reviews to support our choices with evidence.[23–25]

Another theoretical limitation of this standard set is the discrepancy between the outcome domains selected by the working group and those selected by the patient representatives, meaning that coping or self efficacy, performance or fine hand use, psychological wellbeing, and reported experience with health care delivery processes were not included in the standard set but were considered essential by patients. In keeping the standard set as minimal as possible, we believe that performance or fine hand use might have been captured using a hand-specific PROM that encompasses dexterous hand use and that psychological wellbeing might have been captured within health-related quality-of-life measures. Furthermore, ICHOM standard sets do not usually include tools for reported experience with health care delivery processes because these mainly concern the process of health care delivery rather than with a health care outcome. In addition, following our framing principles, we aimed to create a minimum set, constantly weighing the necessity of including additional outcomes against the burden of assessment. Moreover, the finding that 95% of the patients indicated that we identified all relevant outcome domains and the results of the professional open-review survey give us the confidence that we captured the views of the relevant stakeholders. Hence, both the completeness and burden of this standard set should be evaluated globally from patient and clinician perspectives in the future.

An additional limitation is that we included newly developed tools for return to work, satisfaction with treatment results, and complications that have not yet undergone testing for reliability and validity. Although very similar tools have been validated or previously used in clinical research, our new tools require further investigation. Specifically for satisfaction with treatment results, doubts have previously been raised on the reliability and validity of the tools measuring this construct.[47–49] However, a recent study by De Ridder et al[50] found good-to-excellent construct validity and very high test-retest reliability of a satisfaction with treatment results questionnaire very similar to the tool currently posed.

In conclusion, we present the ICHOM hand and wrist standard set. Five measurement tracks were created within the hand and wrist standard set, comprising the thumb, wrist, finger, nerve, and severe hand and/or forearm trauma tracks. The global implementation of the ICHOM hand and wrist standard set may facilitate VBHC for patients with hand and wrist conditions.

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Appendix A

TABLE E1. Definitions of Outcome Domains, Determined Using, When Available, Definitions by the International Classification of Functioning, Disability and Health, Medical Subject Headings, or Professional Organizations Such as the International Association for the Study of Pain[1–3]

Outcome Domain	Definition
Aesthetics	The branch of philosophy dealing with the nature of the beautiful. It includes beauty, aesthetic experience, aesthetic judgment, aesthetic aspects of medicine, etc.[2]
Anxiety*	Specific mental functions related to the feeling and affective components of the processes of the mind.[1]
Cold intolerance	A collection of acquired symptoms resulting in an abnormal aversion to cold.[4]
Complications	An adverse or unexpected event arising from an intervention.[1]
Coping/self efficacy	A state of harmony between internal needs and external demands and the processes used in achieving this condition. Cognitive mechanism based on expectations or beliefs about one's ability to perform actions necessary to produce a given effect. It is also a theoretical component of behavior change in various therapeutic treatments.[2]
Costs†	Absolute, comparative, or differential costs pertaining to services, institutions, and resources.[2]
Depression*	The presence of sad, empty, or irritable mood, accompanied by somatic and cognitive changes that significantly affect the individual's capacity to function.[5]
Grip and pinch strength	Force exerted when using the index finger and the thumb. It is a test for determining maximum voluntary contraction force.[2]
Health-related quality of life	Individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, and concerns.[1]
Pain	An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[3]
Pain catastrophizing*	Cognitive and emotional processes encompassing the magnification of pain-related stimuli, feelings of helplessness, and a generally pessimistic orientation.[32]
Patient-reported hand function/activities of daily living	The performance of the basic activities of self-care, such as dressing, ambulation, or eating.[2]
Performance/fine hand use	Performing the coordinated actions of handling objects, picking up, manipulating, and releasing them using one's hand, fingers, and thumb. For example, action required to lift coins off a table or turn a dial or knob.[1]
Psychological wellbeing	Consists of positive functioning (namely autonomy), environmental mastery, personal growth, purpose in life, positive relations with others, and self-acceptance.[6]
Range of motion	Functions of the range and ease of movement of a joint.[1]
Reported experience	Reflects the patient's interactions with health care systems and the degree to which their needs are met.[7]
Return to work/daily activities	Resumption of normal work/activity routine following a hiatus or period of absence because of an injury, a disability, or other reasons.[2]
Revision	A repeat operation for the same condition in the same patient because of disease progression or recurrence or as follow-up to a failed previous surgery.[2]
Satisfaction with treatment results	The degree to which an individual regards the health care service or product or the manner in which it is delivered by the provider as useful, effective, or beneficial.[2]
Sensibility	The process by which the nature and meaning of tactile stimuli are recognized and interpreted by the brain, such as realizing the characteristics or name of an object being touched.[2]

*For patient-validation surveys, these variables are considered part of "coping/self efficacy" and "psychological wellbeing" and are not evaluated separately.

†For patient-validation surveys, "costs" are not included as a treatment outcome because the working group considers this to be too dependent on specific national financial systems.

TABLE E2. Characteristics of the Professional Open-Review Survey Participants

n = 244	
Characteristics	n (%)
Profession	
Advocacy representative	3 (1%)
General practitioner	1 (<1%)
Hand surgeon (orthopedic)	68 (28%)
Hand surgeon (plastic)	45 (18%)
Hand therapist (OT)	59 (24%)
Hand therapist (PT)	49 (20%)
Health care administration	3 (1%)
Medical doctor, other	2 (1%)
Other	1 (<1%)
Rehabilitation physician	1 (<1%)
Researcher	12 (5%)
Country of residence	
Afghanistan	1 (<1%)
Albania	2 (1%)
Andorra	1 (<1%)
Angola	1 (<1%)
Antigua and Barbuda	3 (1%)
Argentina	2 (1%)
Australia	28 (12%)
Austria	2 (1%)
Belgium	6 (3%)
Canada	3 (1%)
Denmark	2 (1%)
France	1 (<1%)
Greece	2 (1%)
India	1 (<1%)
Ireland	1 (<1%)
Israel	3 (1%)
Italy	4 (2%)
Mexico	3 (1%)
Nepal	1 (<1%)
The Netherlands	65 (27%)
New Zealand	1 (<1%)
Poland	3 (1%)
Romania	1 (<1%)
Russian Federation	1 (<1%)
South Africa	2 (1%)
Spain	14 (6%)
Sweden	3 (1%)
Switzerland	50 (21%)
Turkey	8 (3%)
Ukraine	1 (<1%)
United Kingdom and Northern Ireland	23 (9%)
The United States of America	5 (2%)

OT, occupational therapist; PT, physical therapist.

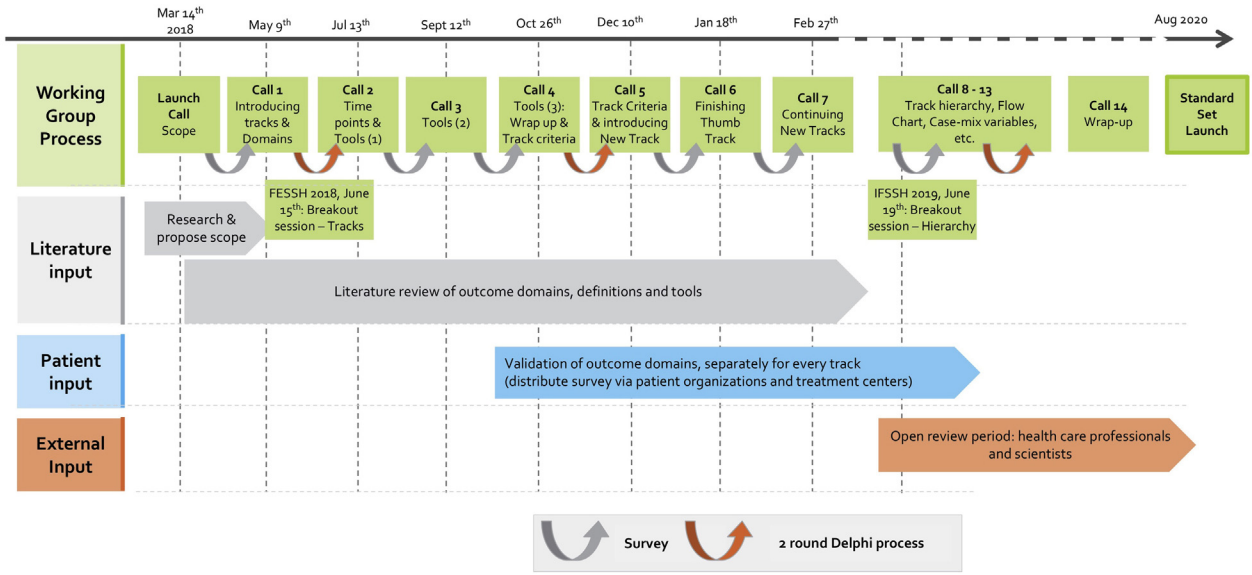


FIGURE E1: Process of the development of the ICHOM hand and wrist standard set, supported by 14 working group calls and several break-out sessions as well as literature research and patient input.

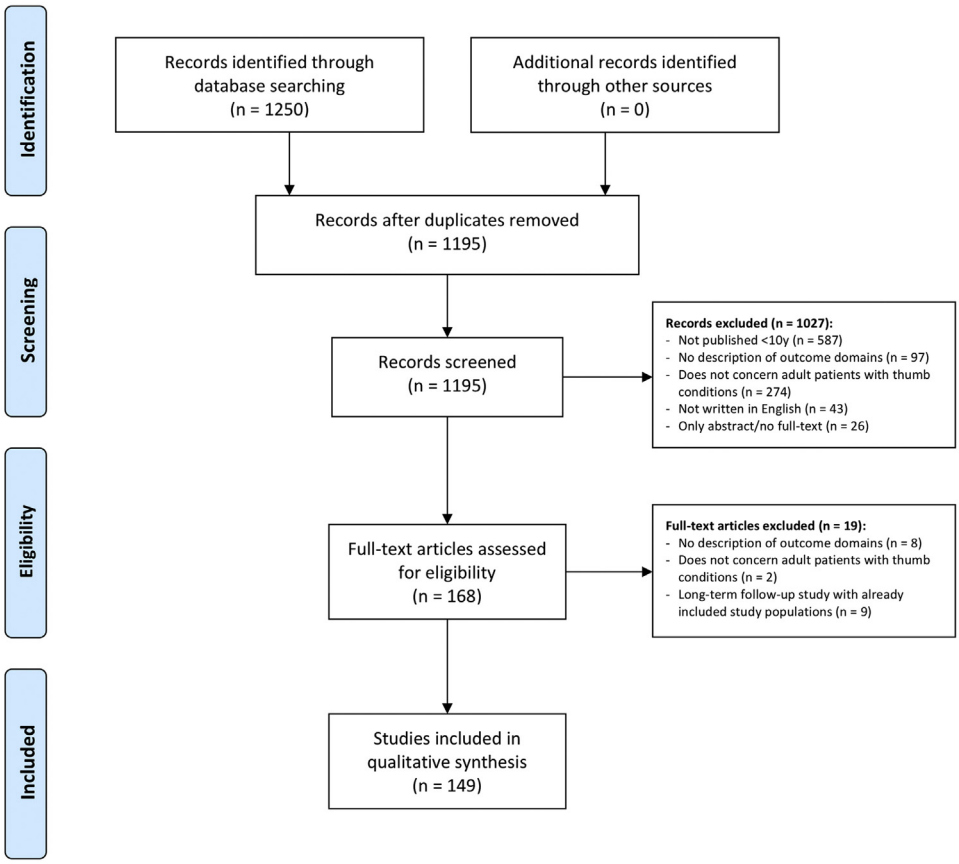


FIGURE E2: Flowchart of the systematic review of outcome domains.

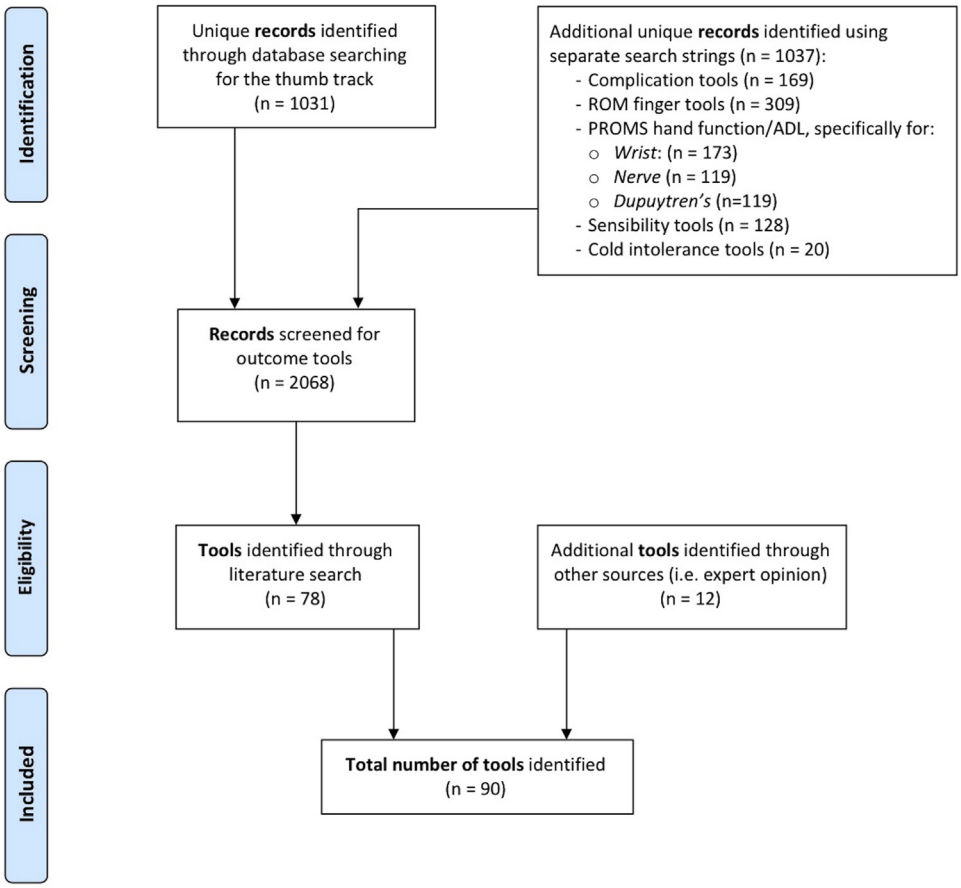


FIGURE E3: Flowchart of the systematic review of outcome tools.

Appendix E1. Final Search Strings for the Thumb Track

OUTCOME DOMAINS FOR THE THUMB TRACK (ACCESSED APRIL 17, 2018) → 1,250 HITS

Search for track name or thumb conditions and outcome/assessment terms: *Database*: MEDLINE.
Search terms (MeSH)

1. Thumb conditions (ie, CMC-1 OA)
2. Track name (ie, thumb)
3. Outcome/assessment terms (ie, patient outcome assessment)

Search string: (1 OR 2) AND 3. ((((("Thumb"[Mesh] OR CMC* OR carpometacarp* OR ("basal joint") OR ("basilar joint") OR basal OR basilar OR ("thumb base") OR ("Carpometacarpal Joints"[Mesh]) OR trapeziometacarp*) AND "Osteoarthritis"[Mesh]) OR (("Thumb"[Mesh] OR CMC* OR carpometacarp* OR ("basal joint") OR ("basilar joint") OR basal OR basilar OR ("thumb base") OR ("Carpometacarpal Joints"[Mesh]) OR trapeziometacarp*) AND "Joint Instability"[Mesh]) OR (("Thumb"[Mesh] AND Interphalangeal*) AND "Osteoarthritis"[Mesh]) OR (("Thumb"[Mesh] AND "Metacarpophalangeal Joint"[Mesh]) AND "Osteoarthritis"[Mesh]) OR (("Thumb"[Mesh] AND "Metacarpophalangeal Joint"[Mesh]) AND ("Collateral Ligaments"[Mesh] OR "Palmar Plate"[Mesh])) OR (("Thumb"[Mesh] AND "Metacarpal Bones/injuries"[Mesh])) OR (("Thumb"[Mesh] AND "Finger Phalanges/injuries"[Mesh])) OR (("Thumb"[Mesh] AND "Tendon Injuries"[Mesh])) OR (("Thumb"[Mesh] AND ("Tendon Entrapment"[Mesh] OR "Tenosynovitis"[Mesh] OR "Trigger Finger Disorder"[Mesh]))))) OR "Thumb"[Mesh]) AND ("Outcome Assessment (Health Care)"[Mesh] OR "Patient Outcome Assessment"[Mesh] OR "Treatment Outcome"[Mesh] OR "Patient Reported Outcome Measures"[Mesh] OR "Disability Evaluation"[Mesh] OR "Surveys and Questionnaires"[Mesh] OR "Psychometrics"[Mesh]))

Search for track name or thumb conditions and outcomes measured in randomized controlled trials: *Database*: MEDLINE.
Search terms (MeSH)

1. Track name (ie, thumb)

2. Thumb conditions (ie, CMC-1 OA)
3. Randomized controlled trial

Search string: (1 OR 2) AND 3. ((((("Thumb"[Mesh] OR CMC* OR carpometacarp* OR ("basal joint") OR ("basilar joint") OR basal OR basilar OR ("thumb base") OR ("Carpometacarpal Joints"[Mesh]) OR trapeziometacarp*) AND "Osteoarthritis"[Mesh]) OR (("Thumb"[Mesh] OR CMC* OR carpometacarp* OR ("basal joint") OR ("basilar joint") OR basal OR basilar OR ("thumb base") OR ("Carpometacarpal Joints") OR trapeziometacarp*) AND "Joint Instability"[Mesh]) OR (("Thumb"[Mesh] AND Interphalangeal*) AND "Osteoarthritis"[Mesh]) OR (("Thumb"[Mesh] AND "Metacarpophalangeal Joint"[Mesh]) AND "Osteoarthritis"[Mesh])

OR (("Thumb"[Mesh] AND "Metacarpophalangeal Joint"[Mesh]) AND ("Collateral Ligaments"[Mesh] OR "Palmar Plate"[Mesh])) OR (("Thumb"[Mesh] AND "Metacarpal Bones/injuries"[Mesh])) OR (("Thumb"[Mesh] AND "Finger Phalanges/injuries"[Mesh])) OR (("Thumb"[Mesh] AND "Tendon Injuries"[Mesh])) OR (("Thumb"[Mesh] AND ("Tendon Entrapment"[Mesh] OR "Tenosynovitis"[Mesh] OR "Trigger Finger Disorder"[Mesh]))) OR "Thumb"[Mesh]) AND "randomized controlled trial"[Publication Type]

OUTCOME TOOLS FOR THE THUMB TRACK (ACCESSED MAY 23, 2018) → 1,031 HITS

Search for outcome/assessment terms combined with body part region and outcome domain name: *Database*: MEDLINE.

Search terms (MeSH)

1. "Patient Reported Outcome Measures"[Mesh] OR "Outcome Assessment (Health Care)"[Mesh]
2. "Hand"[Mesh] OR "Thumb"[Mesh]
3. Outcome name (ie, "Pain"[Mesh])*Search string*: (1 OR 2) AND 3

("Patient Reported Outcome Measures"[Mesh] OR "Outcome Assessment (Health Care)"[Mesh]) AND ("Hand"[Mesh] OR "Thumb"[Mesh]) AND ("2008"[Date - Publication] : "3000"[Date - Publication]) AND ("Pain"[Mesh] OR "Activities of Daily Living"[Mesh] OR "Hand Function" OR "Range of Motion, Articular"[Mesh] OR "Hand Strength"[Mesh] OR "Pinch Strength"[Mesh] OR "Performance" OR "dexterity" OR "Fine hand use" OR "Esthetics"[Mesh] OR "Quality of Life"[Mesh] OR "Return to Work"[Mesh] OR "Mood Disorders"[Mesh] OR "Anxiety"[Mesh] OR "Anxiety Disorders"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depression"[Mesh] OR "Catastrophization"[Mesh] OR "Adaptation, Psychological"[Mesh] OR "Self Efficacy"[Mesh] OR "Reoperation"[Mesh] OR "Costs and Cost Analysis"[Mesh] OR "Patient Satisfaction"[Mesh])

Search for track name and tools measured in RCT's: *Database*: MEDLINE.

Search terms (MeSH)

1. Track name (ie, thumb)
2. "Randomized controlled trial"[Publication type]

Search string: 1 AND 2

("Thumb"[Mesh]) AND ("randomized controlled trial"[Publication Type]))

Appendix E2. Self-Designed Tools by the ICHOM Hand and Wrist Working Group

Self-designed return to work questionnaire

1. Do you normally work?
   a. Yes, in paid employment (including self-employed)
   b. Yes, in unpaid activities (e.g. parent, caregiver, volunteer work)
   c. No, not at all → you do not need to answer the following questions
2. How many hours do you normally work per week (according to your contract or if you are self-employed according to your usual routine)?

__hours a week

3. Are you currently working? This includes modified work duties or working less hours than usual. Pick the best response from below.
   a. No, due reasons other than my current hand or wrist condition (such as another health condition) → you do not need to answer the following questions
   b. No, due to the hand /wrist condition for which I am being treated
      i. How many weeks have you not been able to work or perform your usual work activities so far as a result of the hand or wrist condition for which you are being treated? → you do not need to answer the following questions

___week(s)

   c. Yes, paid employment (including self-employed)
   d. Yes, unpaid activities (e.g. parent, caregiver, volunteer work)
4. How many hours are you currently working per week?

__hours a week

5. At present, do you perform your usual work duties?
   a. Yes, I perform usual work duties
      i. How many week(s) after the start of treatment did you resume your usual work duties?
         - After__ week(s)

b.No, I perform modified work duties.

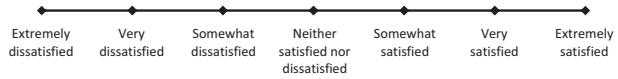
6. How many weeks after the start of treatment did you first resume work?

After __week(s)

7. How confident did you feel in your ability to return to work?
   a. Very confident
   b. Confident
   c. Moderately confident
   d. Not confident at all

Satisfaction with treatment result questionnaire

1. How satisfied are you with your treatment result so far? Please choose 1 option from below



2. Would you undergo the treatment again under similar circumstances?
   a. Yes
   b. No
3. Would you recommend this treatment to friends and family?
   a. Yes
   b. No

ICHOM COMPLICATIONS IN HAND AND WRIST CONDITIONS, MODIFIED AND DERIVED FROM CLAVIEN-DINDO 2009

Grade	Definition, to Occur Within the Final Time Point of the Relevant Track
Grade I	Any deviation from the normal treatment course without the need for surgical, endoscopic, and radiological interventions. The acceptable therapeutic regimens are as follows: extra analgesics and additional hand therapy/ splinting/ cast. This grade incudes tendinitis, scar tenderness, temporary sensory disturbances, etc. Complex regional pain syndrome is excluded from this grade (see grade III-C).
Grade II	Any deviation from the normal treatment course requiring antibiotics, steroid injections, or other pharmacological treatment not listed in grade I. It also includes wound infections and hematomas not needing anesthesia. Complex regional pain syndrome is excluded from this grade (see grade III-C).
Grade III	Any deviation from the normal treatment course requiring surgical, endoscopic, or radiological intervention. Additionally, this includes tendinitis, scar tenderness, persistent pain, etc not responding to conservative therapy, drugs, or injections.
A:	Minor surgical intervention under local anesthesia (eg, irritating K wire and suture removal subcutaneously)
B	Major surgical intervention under regional or general anesthesia (eg, repeat surgery, tenolysis, neurolysis, nerve repair or surgery for tendon rupture, breaking of plate, nonunion, and initial prosthesis failure)
C	Complex regional pain syndrome, diagnosed using Budapest* criteria, independent of the initiated treatment

*Budapest criteria:

(1) Continuing pain, which is disproportionate to any inciting event
(2) Must report at least one symptom in *three of the four* following categories:
   - *Sensory:* reports of hyperesthesia and/or allodynia
   - *Vasomotor:* reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry
   - *Sudomotor/edema:* reports of edema and/or sweating changes and/or sweating asymmetry
   - *Motor/trophic:* reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
(3) Must display at least one sign at time of evaluation in *two or more* of the following categories:
   - *Sensory:* evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement)
   - *Vasomotor:* evidence of temperature asymmetry and/or skin color changes and/or asymmetry
   - *Sudomotor/edema:* evidence of edema and/or sweating changes and/or sweating asymmetry
   - *Motor/trophic:* evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
(4) There is no other diagnosis that better explains the signs and symptoms

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