The International Consortium for Health Outcome Measurement (ICHOM) Set of
Outcomes that Matter to People Living with Inflammatory Arthritis

Consensus from an international Working Group

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Background

The implementation of value based healthcare (VBHC) in inflammatory arthritis (IA) requires a standardized set of modifiable outcomes and risk-adjustment variables that is feasible to implement worldwide.

Methods

The International Consortium for Health Outcomes Measurement (ICHOM) assembled a multidisciplinary working group, consisting of 24 experts from six continents, including six patient representatives, to develop a Standard Set of outcomes for IA. The process followed a structured approach using a modified Delphi process to reach consensus on 1) conditions covered by the set, 2) outcome domains, 3) outcome measures, 4) risk-adjustment variables. Consensus on decision areas two to four were supported by systematic literature reviews and consultation of experts.

Results

The ICHOM IA Standard Set covers patients with rheumatoid arthritis (RA), axial spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis (JIA). We recommend that the following outcomes be collected at least annually: pain, fatigue, activity limitations, overall physical and mental health impact, work/school/housework ability and productivity, disease activity, and serious adverse events. Validated
measures for patient-reported outcomes were endorsed, and linked to common reporting metrics. Age, sex at birth, educational level, smoking status, comorbidities, time since diagnosis, and rheumatoid factor and anti-citrullinated protein antibody lab testing for RA and JIA should be collected as risk-adjustment variables.

Conclusion

We present the ICHOM IA Standard Set of outcomes that enables healthcare providers to implement the value based healthcare framework and enable comparison of outcomes important to patients with IA.

Significance & Innovation

- Standards for measuring and comparing treatment outcomes that matter to patients with inflammatory arthritis that are globally implementable are currently lacking
- We used a modified Delphi procedure and systematic reviews of the literature to develop a Standard Set of Outcomes that matter to patients with inflammatory arthritis
- The patient reported outcome measures we recommend for measuring pain, activity limitations, fatigue and assessment of overall emotional and physical health impact were linked to a common Item response theory based common metric, so that users of the set can select their preferred instrument for measuring these outcomes

Introduction

The inflammatory arthritides are a group of systemic, immune mediated rheumatic conditions, characterized by synovitis or inflammation of periarticular tissues and joint damage. The lifetime risk of adult onset inflammatory arthritis (IA) has been estimated to be about 6% of the population in the United States (1). The availability of strategies to diagnose the diseases earlier,
and the availability of biological and targeted small molecule therapies, in combination with early, tight controlled treatment strategies have led to relevant improvements in outcomes for many patients over the last decades (2,3). However, these improvements have also resulted in an increased financial burden on healthcare systems (4,5).

The prevalence and case recognition of IA is expected to rise further over the next decade, particularly in less economically developed countries (6). Hence it will be increasingly important to optimize care and allocate available resources efficiently to improve or maintain quality of care. Value Based Healthcare (VBHC) is a framework for improving the quality and efficiency of healthcare, in which improving value for the patient is the central concept (7). Value is defined as the patient outcomes achieved, relative to financial costs for obtaining those outcomes. Within this framework, value can be increased by improving patient outcomes or by delivering the same outcomes at a lower cost. Public reporting of patient outcomes by healthcare providers is proposed as a mechanism that will accelerate identification and adoption of high value care, through shared learning and promoting benchmarking of outcomes that matter to patients.

In order for outcomes to be comparable between different healthcare providers, exact definitions for each relevant outcome are required. The outcomes need to be feasible to collected in a variety of healthcare systems and a set of relevant risk-adjustment variables should be included to ensure risk-adjusted comparisons of outcomes between providers that serve different patient populations. The International Consortium for Health Outcomes Measurement (ICHOM) initiative is working toward the global implementation of VBHC by developing Standard Sets of patient outcomes for a range of medical conditions (8). These standards are intended to be implemented in routine clinical practice and therefore complement earlier core sets and reporting standards intended for clinical research, including the work of the Outcome Measures in Rheumatology (OMERACT) group (10).
The ICHOM process is grounded in a conceptual framework which distinguishes three hierarchically ordered tiers of outcome: health status achieved/retained, the process of recovery and sustainability of health (9). To select the most relevant outcomes, outcome measures and risk adjustment variable for particular conditions, various stakeholders including patients, physicians, policy makers and outcome experts are engaged in a consensus building process that is supported by a systematic evaluation of the available evidence base, including critical evaluation of available instruments and evidence supporting their measurement properties.

To further encourage the adoption and implementation of VBHC in rheumatology, we set out to develop a globally applicable set of outcome measures that reflect outcomes that matter to patients with IA, for providers to track in their clinical practice.

**Methods**

**Working group**

A working group of outcome experts (n = 24) was convened by ICHOM. Working group members were carefully selected to ensure representation of relevant professional disciplines, different geographic areas, and the patient perspective. The working group included patient representatives (n = 6), registry leaders, and members with a professional background in: adult and pediatric rheumatology; nursing; epidemiology; psychology; rehabilitation medicine; physiotherapy; and psychometrics. Working group members of all 6 inhabited continents were included. The efforts of the working group were guided and facilitated by a core project team.

**Working group process**

A modified Delphi approach was used that has been developed by ICHOM and was previously applied by ICHOM to develop standards for a number of other conditions (10,11,20–26,12–19). The process involved reaching consensus in four major decision areas 1) which IA conditions
and treatments to include in the Standard Set, 2) a minimally sufficient set of outcomes relevant for each of the conditions, 3) standardized definitions and time points for assessing these outcomes, and 4) standardized definitions for risk-adjustment variables to ensure fair comparisons between healthcare providers who wish to implement the set. Each decision area was discussed during a dedicated videoconference. A list of potentially relevant items (i.e. conditions/domains/time points/risk-adjustment variables) to be included in the Standard Set, along with supporting evidence (see below), was prepared by the project team preceding each meeting. These items were identified in a series of systematic literature reviews and/or consultation with external experts on the topic under consideration. A summary of the preparatory work was provided to working group members preceding each videoconference. During each meeting, the items were discussed and expanded on or revised based on the input of the working group. Following each videoconference, the project team circulated a summary of the discussions and a survey asking working group members to provide feedback and vote on each item considered for inclusion in the Standard Set. For voting during the final survey, a 9-point Likert scale ranging from 1 – “not recommended” to 9 – “essential to have” was used. Items were included in the Standard Set if rated ≥ 7 by at least 70% of the working group or excluded if rated ≤ 3 by at least 70% of the working group. In other cases, the result was considered inconclusive and the item was discussed again during the following videoconference. The conduct and reporting of the Delphi process followed reporting guidelines for core outcome set development using the Delphi approach (see supplemental file 1) (27).

Pre-selection of relevant patient outcome domains

Preceding the videoconference on ‘selection of outcome domains’, two separate systematic literature reviews were performed in December 2016 in the PubMed database to identify outcomes relevant to patients for the included conditions, that were modifiable in principle and feasible to implement. In the first search we used the “Cochrane Highly Sensitive Search Strategy
for identifying randomized trials” (28) to identify 25 recent randomized trials in each of the conditions included in the Standard Set. For each randomized trial, we checked the relevant online repositories and conducted a second PubMed search using the name of each trial and trial registration number to find additional publications on the same study. All outcomes assessed in each trial were extracted. Reports on randomized trials in languages other than English were excluded. In the second search we identified reports on qualitative studies in which patients with one of the relevant conditions were asked about the most important outcomes of their disease. We included only papers in which an open-ended question format was used, to prevent investigator-imposed biases on the list of patient-generated outcome domains. All outcome domains considered important by patients were extracted from each paper by two reviewers independently. Disagreements were resolved during a consensus meeting with a third referee present. Previously published core set recommendations for outcome measurement in randomized trials were also consulted, as was the EULAR standardized dataset for observational research (29–33). Finally, two patient advisory group sessions with IA patients from the Netherlands and the USA were organized by the project team to serve as a check on the comprehensiveness of the list of identified patient outcomes. The patient advisory group protocol was exempt from ethical review by the Chesapeake Institutional Review Board.

Pre-selection of Outcome measures

All outcome measures used in any randomized trial identified in the initial systematic review, recommended for inclusion by working group members or previously endorsed by relevant consensus statements, were considered for inclusion. The instruments were reviewed with respect to: outcome domains, evidence supporting psychometric properties, feasibility, licensing fees, and degree to which they were established in the field. To support this process, a systematic literature review was performed in May 2017 to identify papers reporting on the measurement properties of 26 potentially relevant Patient-reported outcome measures (PROMs). The
methodological quality of the 159 identified papers was assessed using the COSMIN checklist (34). The studies that were of high methodological quality were then used to rate the measurement properties of the 26 PROMs, using quality criteria proposed by Terwee et al. and ISOQOL (35,36). Understandability, cost and time to complete were all assessed to determine the feasibility of implementing specific PROMs. The Flesch-Kincaid grade level was calculated for the English language version of each PROM (37), information about fees payable for use of the instrument was retrieved from the copyright owner’s website when applicable, and information on time to complete was retrieved from a previous series of reviews (38).

**Pre-selection of risk-adjustment variables**

A preliminary list of risk-adjustment variables was extracted from published reviews on risk factors and validated risk models. Previously published ICHOM Standard Sets were reviewed for definitions of demographic and socioeconomic variables.

**External validation by health professionals and patient experts**

After proceeding through all the Delphi rounds, the preliminary Standard Set was made available and sent to various stakeholders for review via www.ichom.org. A patient survey was distributed via national patient organizations and the networks of the project team and working group members. Patients were asked to rate the importance of each outcome using a 9-point Likert scale ranging from “1 = not at all relevant” to ”9 = essential” and were given the opportunity to suggest additional outcomes. Health professionals were recruited via the professional networks of the working group members and project team. Health professionals were asked to rate the relevance of each domain, provide feedback on feasibility of implementation of the Standard Set in clinical practice, and rate the appropriateness of the risk-adjustment variables and time points for assessment.

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Results

Scope

At the start, it was recognized by the working group that the same treatment goals and longitudinal outcomes (pain, physical function, fatigue) are relevant to most types of IA. The ICHOM IA Standard Set was therefore designed to evaluate treatment outcomes of patients with rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA), as well as juvenile idiopathic arthritis (JIA) and applies to all treatments for these conditions, including medication, surgery, and physical and occupational therapies. All working group members voted to include RA, axSpA and PsA, and 82% voted to include JIA. The inclusion of gout (59% voted to include initially), connective tissue diseases (41%) and vasculitis (36%) was also considered, especially as few outcome recommendations are available for the latter two conditions. However, after revisiting this topic at a subsequent meeting it was decided that their inclusion might lead to a generic set of outcomes, which might insufficiently capture the outcomes that matter to patients with individual conditions due to the variety of disease manifestations and disease courses.

Outcome domains

Twenty-four outcome domains were initially identified in the 130 randomized trial reports and 28 qualitative studies that were identified in the systematic literature reviews (references are available on request from the corresponding author). This list was expanded upon and refined several times based on group discussions with working group members. The final consolidated list of outcomes is presented in table 1, together with a summary of both systematic reviews and the final voting results. The list of outcome domains assessed in randomized trials and their rank ordering reflects a preference in trials for clinical measures of disease manifestations and patient-reported outcomes of symptoms and their direct impact on functioning. The list and rank
ordering of patient-generated outcome domains on the other hand somewhat deemphasized the importance of outcome measures that reflect the pathophysiology of the specific disease and included a wider variety of outcomes that reflect the different ways arthritis impacts the daily lives of patients. Besides PROMs of symptoms and basic functioning, the patient-generated list also included more generic outcomes such as overall psychological wellbeing and participation restrictions. To characterize the core symptoms and their direct effect on functioning from the patient perspective, the working group recommends that providers assess pain, fatigue, and activity limitations (i.e. physical function). These were the most frequently used outcome domains in randomized trials and were reported as important by patients in almost all of the reviewed qualitative studies. They were also the most frequently endorsed domains in the individual core sets for randomized trials of the respective conditions. To assess impact of IA on the daily lives of patients more broadly, the working group recommends an assessment of overall emotional and physical health impact, and work/school/housework productivity. Participation restrictions other than work or school productivity were also considered important. However, this domain was eventually excluded because of significant overlap with other included domains and because experience with available measurement instruments is currently limited.

Assessments of inflammatory disease activity and therapeutic response are further recommended as measures of disease control, because the absence of signs and symptoms of disease is the primary treatment target for IA and disease activity was considered the main determinant of overall impact of disease. Finally, adverse events should be recorded as a measure of disutility of care.
Outcome measures

The list of recommended patient-reported outcome measures (PROMs) is presented in table 2. Supplemental file 2 provides an overview of characteristics and ratings assigned to the measurement properties of these PROMs and includes an overview of the criteria used for assigning ratings.

The Working Group agreed that a key property was feasibility in different settings globally. Therefore, instruments with a large number of items, or that cannot be hand-scored were avoided. All endorsed PROMs are available in multiple languages and for each outcome domain, at least one PROM is recommended that was judged to-have sufficient evidence supporting its measurement properties, based on the results of the systematic review. On the other hand, some instruments were included that do not (yet) meet psychometric standards of the COSMIN checklist. Several PROMIS measures were included so that experience with innovative Item Response Theory (IRT) based measures can accumulate. The rheumatoid- and psoriatic-arthritis impact of disease scores (RAID and PSAID) and ASAS Health index were recommended because these are patient/ICF-derived composite scores assessing the important domains of impact of RA and PSA, and AxSpA respectively. Supplemental file 3 provides an overview of the various measures that are recommended by the clinical guidelines issued by various national and international rheumatology societies. For each of the ICHOM outcome domains, the endorsed outcome measures are congruent with the various guidelines. Users of the Standard Set may select preferred instruments to assess each outcome from the list of endorsed PROMs presented in table 2. The shortest recommended combination of PROMs to assess all outcome domains is NRS/VAS to measure fatigue, overall emotional and physical health impact, and pain; the Work Productivity and Activity Impairment questionnaire (WPAI) to measure work/school/housework ability and productivity, and the Health Assessment Questionnaire II (HAQ-II) to measure activity limitations. This combination of PROMs is free
to use for all users and totals 19 questions, which most patients should be able to fill out in 5 minutes. The endorsed PROMs of pain, fatigue, overall wellbeing and activity limitations have been linked to a common reporting metric, such that outcomes can be compared between providers that have used different instruments (39). Linked scores for benchmarking outcomes using any of the recommended instruments of the Standard Set can be obtained from www.tihealthcare.nl/en/expertise/common-metrics.

To track disease activity and therapeutic response, it is proposed that major evidence-based guidelines are followed (40,41). Patients and healthcare providers should specify target disease activity levels for individual patients (preferably remission; if not, feasible low disease activity) and assess at each visit whether or not this target was achieved. Disease activity should be monitored using a validated and internationally recognized clinical composite score.

Risk-adjustment variables

Most risk-adjustment variables included in the set (table 3) apply to all patients and care was taken to include risk-adjustment variables that are relevant and applicable in a variety of healthcare systems. Year of birth and sex were included as demographic variables. Educational level was ultimately chosen as the only indirect measure of social economic status (SES). Other SES-related variables were considered important, but difficult to collect, due to restrictions on recording race/ethnicity in some countries, area-based measure of SES possibly not being available for each country, and patients potentially feeling reluctant to report on their income/wealth. For baseline status indicators, we included smoking status, comorbidities, diagnosis, time since diagnosis, and rheumatoid factor and ACPA for RA and JIA. HLA B27 was excluded since it is not routinely collected in healthcare system. Comorbidities should be assessed using the Rheumatic Disease Comorbidities Index (42), modified to include central
sensitization to pain (e.g. fibromyalgia) and obesity. To avoid misclassification of early symptoms that may or may not reflect those specific to the IA diagnosis of interest we elected to include time since diagnosis rather than time since symptom onset.

**Data collection time points**

To allow meaningful outcomes comparisons between healthcare providers, we recommend all risk-adjustment variables to be collected at the first assessment. All PROMs and clinical measures should also be collected at the first assessment and annually thereafter. In instances of active disease, we recommend that the patient’s disease activity status is recorded again at least every six months, but likely more frequently, at the discretion of the patient and their healthcare provider. Adverse events should be collected at each assessment point after baseline. A reference guide with detailed instructions for implementation and exact definitions for all the data elements can be downloaded from www.ICHOM.org. Finally, we stress that these recommendations are intended only for quality improvement purposes and should not be understood as more than minimally acceptable clinical guidelines in patients with established disease. Especially in patients with early disease, more frequent monitoring may be required.

**Open review**

Eighty-three healthcare professionals, the majority of which (95%) were clinician/researchers, and 630 people living with IA from the United States, France, Argentina, the Netherlands and Brazil reviewed the Standard Set. All outcomes included in the ICHOM IA set were considered very relevant by patients and healthcare professionals (figure 1). Similar to the results of the systematic reviews for identifying outcome domains, patients considered clinical measures slightly less relevant compared with the patient-reported outcomes. A large majority of patients (81.3%) felt that the set comprehensively covers all the relevant outcome domains of their disease.
disease. The healthcare professionals predominantly shared this view. Only three outcomes were suggested to be missing by more than 1 reviewer: financial impact (n=2), joint damage (n=2) and patient satisfaction (n=3). Psychological wellbeing (12.6%) and participation restrictions (5.4%) were the only outcomes that were reported as missing from the set by >2% of patient reviewers (supplemental file 2). The included risk-adjustment variables were rated very relevant by 91.8% of health professionals.

**Discussion**

We present a Standard Set of outcomes for IA that healthcare providers worldwide can use in routine clinical care to help quantify the value provided for patients in different centers, countries and healthcare systems. This Standard Set was developed through consensus of an international working group with expertise across a range of disciplines relevant to outcome assessment and care for patients with IA. We used a multiple methods approach, in which extensive patient input as well as published qualitative and quantitative data were used to develop a minimally sufficient set of outcomes that we believe represents outcomes that matter to patients with IA. We also proposed time points for data collection and relevant risk-adjustment variables to enable comparisons between providers with different patient populations. Feasibility of implementation in different healthcare systems was a central priority. Therefore, we included PROMs that are not only widely accepted measures of the respective domains but that are also available in multiple translations, and for each outcome there is at least one PROM free to use. However, for the use of several instruments: PedsQL, SF-6D, FACIT and EQ-5D license fees may apply. PROMIS has also introduced financial charges for the use of some of their products, including their computerized adaptive tests. Using the PROMIS Assessment Centre platform will incur a $5000 USD charge per study per year.
One of the challenges faced with international standardization of patient outcomes data collection is that a variety of well validated and frequently used PROMs are typically available to assess the different patient outcomes. The working group for the ICHOM Depression & Anxiety and Chronic Kidney Disease Standard Sets previously responded to this by endorsing PROMs that can be mapped to the PROMIS metric, using resources provided by the PROMIS PROsetta project (43,44). This way, users of these sets use one PROM for each domain, but results can be scored on the PROMS metric. In the work on the ICHOM IA Standard Set presented here, this is taken one step further again by linking multiple PROMs to an IRT based common reporting metric (45). This makes it easier for new or ongoing data collection initiatives to contribute their data since it allows users of the ICHOM IA set to choose one instrument from a number of alternatives for each domain. Provided one of the endorsed instruments presented in table 2 is collected, outcomes can be compared with other healthcare providers that use the ICHOM Standard Set. For example, outcomes assessed using the VAS fatigue scale can be directly compared with outcomes of a different group of patients assessed using FACIT fatigue. In principle, PROMs could be added to and removed from the list of endorsed instruments, without affecting comparability of the outcomes. The ICHOM list of recommended PROMS overlaps significantly with current clinical guidelines. Moreover, the results of two systematic reviews of various national RA patients registries show that the majority of the PROMs that are currently collected in the reviewed registries are also included in the ICHOM IA Standard Set. The IRT approach also allows each of the ICHOM IA outcomes to be assessed using computerized adaptive tests, which would help achieve optimally precise scores with minimal numbers of questions (46,47).

Since the Standard Set is intended to reflect outcomes that are important to patients, the extensive input from patients is a strength of this work. We included 6 patient representatives in the working group, derived the list of outcomes from published qualitative studies in which
patients reported outcomes that matter to them, organized two patient advisory group sessions with patients that were not included in the working group to review the final list of outcomes to be voted on by working group members, and 630 patients from various countries reviewed the final version of the Standard Set. The inclusion of working group members with diverse geographic and professional backgrounds is also a strength. We do however acknowledge that different results might have been obtained had other working group members been selected. We also realize that it may prove challenging to collect all the requested information for all healthcare providers at all time points. In particular, inflammatory disease activity may prove logistically challenging to track in some healthcare systems, as it requires clinical assessment of joint involvement and, in some cases, laboratory assessments. In such situations, we would encourage users of the set to at least monitor the PROMs. All patient-reported outcomes can be collected using a minimum of 20 items, which could be further reduced using computerized adaptive testing or targeted short forms. We finally acknowledge that the value of the ICHOM IA Standard Set has not yet been proven in practice. ICHOM aims to partner with a number of interested institutions to pilot-test the Standard Set. Furthermore, a steering committee has been established that will periodically review the Standard Set, including lessons learnt from the pilot phase and other applications of the Standard Set. This will include but will not be limited to reviewing: PROMs that are endorsed in the IA Standard Set PROMS; how easy these PROMS are to access and monitor; and outcomes related to personal goals that individual patients identify.

In summary, we propose a Standard Set of outcomes for patients with IA that providers of care for patients with IA can track to facilitate the global reporting of outcome data and shared learning. A detailed reference guide is available at www.ichom.org.
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based+competition+on+results&ots=VZv7MiemdE&sig=dSk0YaJd-79YCl9hjH2-OzFFkLU.


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Table 1 Final list of outcomes considered for inclusion in ICHOM IA set

<table>
<thead>
<tr>
<th>Outcome</th>
<th>qualitative studies in which outcome was reported as important disease outcome</th>
<th>Number of IA conditions for which outcome is included in clinical trial core set</th>
<th>Number of IA conditions for which outcome was measured in ≥1 clinical trial, but not in core set</th>
<th>Percentage of working group members voted for inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>27 (96%)</td>
<td>3</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>Physical function</td>
<td>20 (93%)</td>
<td>4</td>
<td>n/a</td>
<td>100%</td>
</tr>
<tr>
<td>Adverse events</td>
<td>11 (39%)</td>
<td>0</td>
<td>4</td>
<td>95%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>23 (82%)</td>
<td>2</td>
<td>2</td>
<td>90%</td>
</tr>
<tr>
<td>Work/school ability and productivity</td>
<td>14 (50%)</td>
<td>0</td>
<td>3</td>
<td>90%</td>
</tr>
<tr>
<td>Overall physical and mental Health Impact</td>
<td>n/a</td>
<td>4</td>
<td>n/a</td>
<td>86%</td>
</tr>
<tr>
<td>Inflammatory disease activity</td>
<td>6 (21%)</td>
<td>4</td>
<td>n/a</td>
<td>84%</td>
</tr>
<tr>
<td>Participation restrictions</td>
<td>18 (64%)</td>
<td>0</td>
<td>0</td>
<td>53%</td>
</tr>
<tr>
<td>Joint damage</td>
<td>7 (29%)</td>
<td>2</td>
<td>1</td>
<td>45%</td>
</tr>
<tr>
<td>Mortality</td>
<td>1 (4%)</td>
<td>0</td>
<td>0</td>
<td>40%</td>
</tr>
<tr>
<td>Psychological wellbeing</td>
<td>22 (79%)</td>
<td>0</td>
<td>0</td>
<td>35%</td>
</tr>
<tr>
<td>Sleep</td>
<td>10 (36%)</td>
<td>0</td>
<td>2</td>
<td>35%</td>
</tr>
<tr>
<td>Coping &amp; Self-Management</td>
<td>16 (57%)</td>
<td>0</td>
<td>0</td>
<td>23%</td>
</tr>
<tr>
<td>Financial impact</td>
<td>3 (11%)</td>
<td>0</td>
<td>0</td>
<td>25%</td>
</tr>
<tr>
<td>Joint stiffness</td>
<td>15 (54%)</td>
<td>0</td>
<td>4</td>
<td>20%</td>
</tr>
<tr>
<td>Joint range of motion</td>
<td>0 (0%)</td>
<td>1</td>
<td>0</td>
<td>15%</td>
</tr>
<tr>
<td>Physical appearance</td>
<td>7 (25%)</td>
<td>0</td>
<td>0</td>
<td>10%</td>
</tr>
<tr>
<td>Sexual functioning</td>
<td>8 (25%)</td>
<td>0</td>
<td>0</td>
<td>10%</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>5 (18%)</td>
<td>0</td>
<td>0</td>
<td>3%</td>
</tr>
<tr>
<td>Fever</td>
<td>0 (0%)</td>
<td>0</td>
<td>1</td>
<td>0%</td>
</tr>
</tbody>
</table>

IA = Inflammatory Arthritis

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Table 2. Overview of measures used for assessing Patient-reported outcomes included in TOGEM LA Standard Set

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Construct Validity</th>
<th>Reliability</th>
<th>Responsiveness</th>
<th>Pain</th>
<th>Visual Analog Scale (VAS)</th>
<th>Physical Function (Pf)</th>
<th>Health Status (HS)</th>
<th>Physical Function (PF-1)</th>
<th>Role Function (RF)</th>
<th>Work/School/Home/Academic Ability and productivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Fatigue</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++ (PROMIS Short Form v1.0, Fatigue SF-12)</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Activity limitations</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++ (PROMIS Short Form v1.0, Physical Function SF-12)</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Health impact</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Work/school/home/academic ability and productivity</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

**Notes:** ++ = favorable properties according to >1 study with good methodological quality; + = favorable properties according to 1 study with good methodological quality; ++ = unfavorable properties according to >1 study with good methodological quality; + = unfavorable properties according to 1 study with good methodological quality. *Including EQ-SD 2 for pediatric patients. ** Instrument is intended for pediatric patient. ** Estimated using the Kendall Grade level statistic. NEQ = Numerical rating scale; VAS = Visual Analog Scale; SF-12 Medical outcome study short form 12; PROMIS-Q = Patient-reported outcome measurement information system; SF-36 = Medical outcome study short form 36; PROMIS = Pediatric Quality of Life Inventory; IBSAP-FD = Index of Rheumatoid Arthritis Functional Impairment Questionnaire; FACT-F = Functional Assessment of Chronic Illness Fatigue; PRF = Health Assessment Questionnaire Disability Index; NHAQ = National Health Assessment Questionnaire Disability Index; C-HAQ = Childhood Health Assessment Questionnaire Disability Index; IJAMAR = The Japanese Arthritis Multidimensional Assessment Report; EQ-SD = EuroQol 5 dimensions; SF-12 Medical outcome study short form 12; PaAD = Pediatric Arthritis Impact of Disease; RAID = Rheumatoid Arthritis Impact of Disease; WPAI = Work Productivity and Activity Impairment Questionnaire.
Table 3: Case-mix variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition and response options</th>
<th>Timing*</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGE</td>
<td>Year of birth</td>
<td>Baseline</td>
<td>Patient</td>
</tr>
<tr>
<td>SEX</td>
<td>Sex at birth</td>
<td>Baseline</td>
<td>Patient</td>
</tr>
<tr>
<td>SMOKING STATUS</td>
<td>Never / former / current</td>
<td>Baseline</td>
<td>Patient</td>
</tr>
<tr>
<td>LEVEL OF EDUCATION</td>
<td>Highest attained education, IED classification (more, primary, secondary/tertiary)</td>
<td>Baseline</td>
<td>Patient</td>
</tr>
<tr>
<td>COMORBIDITIES</td>
<td>Present / Absent / Unknown. Chronic lung disease, myocardial infarction, other heart disease, stroke, hypertension, diabetes, fracture, depression, ulcer or stomach problem, cancer, renal-replacement therapy, obesity (i.e., body mass index &gt; 30)</td>
<td>Baseline and annually</td>
<td>Clinical</td>
</tr>
<tr>
<td>DIAGNOSIS</td>
<td>Physician reported diagnosis, RA / SpA / PsA / JIA</td>
<td>Baseline</td>
<td>Clinical</td>
</tr>
<tr>
<td>DISEASE DURATION</td>
<td>Year of diagnosis</td>
<td>Baseline</td>
<td>Clinical</td>
</tr>
<tr>
<td>IMMUNOLOGICAL*</td>
<td>Rheumatoid factor and ACPA positivity (yes/no)</td>
<td>Baseline</td>
<td>Clinical</td>
</tr>
</tbody>
</table>

*only for RA and JIA. ISID = institute for the Study of Infection and Human Development; RA = Rheumatoid arthritis; ankylosing spondylitis; PsA = Psoriatic Arthritis; juvenile idiopathic arthritis; ACPA = anti-cyclic citrullinated protein antibody
**Baseline = defined as first measurement for this patient.
Figure 1. Relevance of outcomes included in ICHOM IA set according to patient and health professional open review.

WSHPA = Work/School/household productivity and ability.