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# Development of an international standard set of patient-centred outcome measures for overall paediatric health: a consensus process

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## ABSTRACT

**Objective** To develop an Overall Pediatric Health Standard Set (OPH-SS) of outcome measures that captures what matters to young people and their families and recognising the biopsychosocial aspects of health for all children and adolescents regardless of health condition.

**Design** A modified Delphi process.

**Setting** The International Consortium for Health Outcomes Measurement convened an international Working Group (WG) comprised of 23 international experts from 12 countries in the field of paediatrics, family medicine, psychometrics as well as patient advisors. The WG participated in 11 video-conferences, through a modified Delphi process and 9 surveys between March 2018 and January 2020 consensus was reached on a final recommended health outcome standard set. By a literature review conducted in March 2018, 1136 articles were screened for clinician and patient-reported or proxy-reported outcomes. Further, 4315 clinical trials and 12 paediatric health surveys were scanned. Between November 2019 and January 2020, the final standard set was endorsed by a patient validation (n=270) and a health professional (n=51) survey.

**Results** From a total of 63 identified outcomes, consensus was formed on a standard set of outcome measures that comprises 10 patient-reported outcomes, 5 clinician-reported measures, and 6 case-mix variables. The four developmental age-specific packages (ie, 0–5, 6–12, 13–17, 18–24 years) include either five or six measures with an average time for completion of 20 min.

**Conclusions** The OPH-SS is a starting point to drive value-based paediatric healthcare delivery from a global perspective for enhancing child and adolescent physical health and psychosocial well-being.

### What is already known on this topic?

- Value-based paediatric care needs health outcome measures that capture what matters to young people and their families.
- Comparable data on child development irrespective of health condition are rare and not always translatable across countries.
- There is a lack of an internationally accepted standard set of outcome measures that recognise the biopsychosocial aspects of health for all children and adolescents.

### What this study adds?

- A consensus-based standard set of 15 health outcome measures for all young people from birth to 24 years of age, measuring 22 domains of physical, social and mental health.
- Four developmental age-specific packages made up of either five or six measures mainly patient-reported with average time of 20 min to complete.
- A starting point to drive value-based paediatric healthcare delivery from a global perspective.

## INTRODUCTION

It is a core value of any paediatric healthcare service to ensure that when a child leaves their service, they are as physically, mentally and socially healthy as possible.[1 2] Value-based paediatric care (VBPC) requires health outcome measures to capture what matters most to young people and their families to enable this.[3]

Between March 2018 and January 2020, the International Consortium for Health Outcomes Measurement (ICHOM; www.ichom.org) convened a multidisciplinary Working Group (WG) to develop an Overall Pediatric Health Standard Set (OPH-SS). The OPH-SS comprises a minimum set of outcome measures using internationally accepted standardised measures for infants, children and adolescents regardless of health condition. Collecting and using this information consistently as a part of care delivery will position caregivers to understand determinants of child and adolescent well-being in a comprehensive way, promoting person-centred interventions and enhancing VBPC worldwide. Standardised and consistent outcomes

assessment for all young people is likely to promote future research and quality improvement collaborations, leading to benchmarking within and across organisations, and between disease types.

## METHODS

### The overall paediatric health Working Group

ICHOM established a WG of 23 international experts from eight high-income countries, three upper-middle-income countries and one lower-middle-income country (online supplemental eTable 1). The WG included experts in Pediatrics, Family Medicine and Instrument Development fields across various professional backgrounds (eg, medical doctors, occupational and physical therapists). Additionally, two patient advisors (Australia and USA) who lead patient advocacy foundations were part of the WG. A Project Team (PT) guided the WG efforts and prepared the necessary materials. The project was launched in March 2018 using an iterative process of 11 WG videoconferences and subsequent rounds of electronic surveys (online supplemental eFigure 1).

### Identifying health outcomes, health outcome measures and case-mix variables

To identify potential health outcome and corresponding outcome measures as well as case-mix variables for risk adjustment, the PT reviewed the literature and more than 4000 registered paediatric clinical trials registered in the clinical trial database (www.clinicaltrials.gov) (online supplemental eFigure 1), 12 paediatric health surveys, and the Patient-Reported Outcome Measurement Information System (PROMIS) for outcome measures used in the paediatric population. The literature review was performed in March 2018 comprising 1136 articles with 580 reviews (figure 1) (online supplemental eTable 2). First, health outcomes were identified by categorising the extracted measures from literature according to the topic/health outcome that they were considered to measure, for example, quality of life, development, mental health and communication (online supplemental eTable 3). Overall, a total of 63 health outcomes (partly overlapping) were identified (online supplemental eFigure 2 and eTables 4–7). Second, a total of 104 measures of the agreed-upon health outcomes for inclusion were systematically evaluated to meet ICHOM's tool selection criteria, for example, available free of charge, available in English, validated and reliable (online supplemental eTables 8 and 9). Third, the contents of the eligible 26 tools were mapped to the consensus-based final 22 outcomes covered by the OPH-SS (eg, the *PROMIS Pediatric Scale—Global health 7+2* is considered to measure quality of life, mood, mobility, fitness, pain and sleep). Finally, the tools were packaged along with clinician-reported measures and an ICHOM standard measure of survival, to ensure the highest outcome coverage by age range, using a minimum number of measures. Priority was given to continuity of instruments through the four OPH-SS age ranges and highest rates of outcome coverage (online supplemental eTables 10–12).

Case-mix variables identified by the literature review were extracted to enable meaningful comparisons of child and adolescent health outcomes across treatment modalities and practices (online supplemental eTable 13).

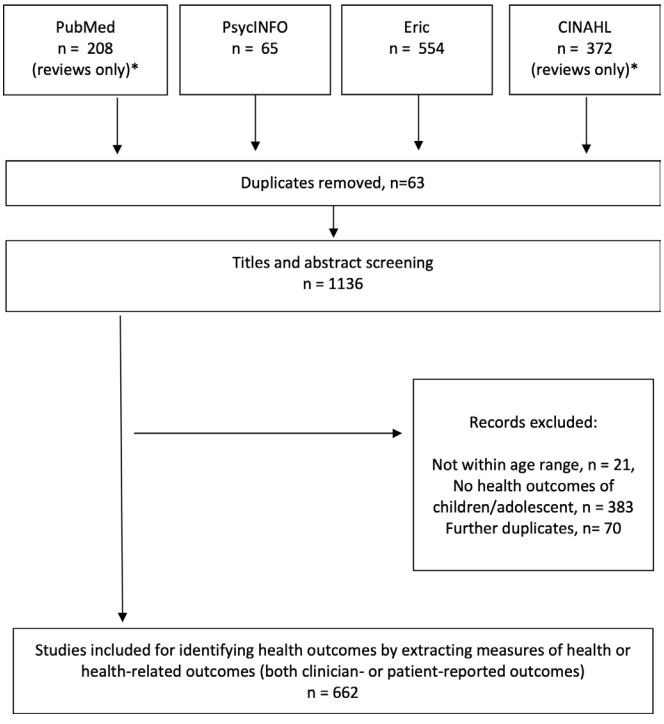


**Figure 1** The flow-diagram of the literature search, conducted in March 2018 (including peer-reviewed articles from the last 10 years). *Only reviews were included due to the otherwise tremendous amount of results (n=20 740 and n=12 751, respectively).

### Modified Delphi and consensus process

To reach consensus on health outcomes and outcome measures to be included in the OPH-SS, a modified Delphi process was employed (online supplemental eFigure 1).[4 5] To capture additional patient perspectives beyond the WG level, an online survey was trialled via hospital networks with 88 parents and caregivers in Mexico. Respondents were asked to rank the 63 identified health outcomes in accordance to the importance (on a 9-point Likert Scale) for their child/children's well-being. This list was deemed to be comprehensive by 93% of parents/caregivers and the survey results were presented to WG prior to the first Delphi round to inform outcome selection.

Following two voting rounds, only outcomes voted as 'very important' (ie, 7–9 points) by at least 80% of WG members were included. The outcomes that did not reach consensus were discussed during WG calls (2–4) in order to balance the request to develop a minimum but comprehensive standard set. In a third vote, the inconclusive outcomes were selected by a yes/no vote with a 70% cut-off for inclusion. This cut-off applied to the selection of outcome measure packages, age range and case-mix variables. The final OPH-SS was approved by all WG members.

### Consumer open review

Between November 2019 and January 2020, an electronic survey was sent to patients and professionals. While a sample of parents and caregivers of children and adolescents in Colombia, Singapore, the USA and the UK aged at least 18 years (online supplemental eTable 14) were asked to rank the importance of the preliminary OPH-SS outcomes, paediatric and/or outcome measurement professionals were asked to indicate agreement or disagreement with: the age-ranges defined by the OPH-SS, the inclusion of each of the 22 outcomes, the selected measures per outcome and age range and case-mix-variables. In both surveys, respondents had the opportunity to leave additional free text comments.

**Table 1** Overview of the included health outcomes and instruments/tools for the specific ages with agreement from health professionals and parents

| | | Age-ranges | | | | | | | | | | | | | | | | | | | | | | | | Endorsed to be important by the Consumer Open Review | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Age in years** | | **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **HP (%)** | **Parents* (%)** | |
| Health outcomes included in OPH Standard Set for the specific age-ranges as agreed on | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mental | Cognition /intelligence | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | 98 | 86 | |
| | Mood | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 91 | |
| | Mental Health | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 95 | |
| | Coping | | | | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 91 | |
| | Self-efficacy | | | | | | | | | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 86 | |
| | Self-esteem | | | | | | | | | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 90 | |
| Social | Development | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | | | | | 88 | 95 | |
| | School Attendance | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | | | | | | 77 | |
| | Communication | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 93 | |
| | HRQoL | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 91 | |
| | Social Functioning | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 92 | |
| Physical | Eating | √ | √ | √ | √ | √ | √ | | | | | | | | | | | | | | | | | | | | 92 | 91 | |
| | Hearing | √ | √ | √ | √ | √ | √ | √ | √ | | | | | | | | | | | | | | | | | | | 88 | |
| | Vision | √ | √ | √ | √ | √ | √ | √ | √ | | | | | | | | | | | | | | | | | | | 99 | |
| | Nutrition | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | | | | | | 91 | |
| | Growth | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | | | | | | | | 88 | |
| | Survival | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 88 | |
| | Mobility | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 93 | |
| | Pain-free | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 89 | |
| | Sleep | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 94 | |
| | Fitness | | | | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | | 88 | |
| | Sexual Health | | | | | | | | | | | | | | | | | | √ | √ | √ | √ | √ | √ | √ | √ | | 76 | |
| Instruments and tools included in the OPH Standard Set in order to measure the agreed-on specific health outcomes | | | | | | | | | | | | | | | | | | | | | | | | | | | **PROM** | **C** | **N** |
| CDC Milestone Checklist | | | | | | | | | | | | | | | | | | | | | | | | | | | x | x | 10–29 |
| Visual Acuity test—E-Chart | | | | | | | | | | | | | | | | | | | | | | | | | | | | x | N/A |
| Visual Acuity test—Snellen-Chart | | | | | | | | | | | | | | | | | | | | | | | | | | | | x | N/A |
| WHO Growth Charts—early years | | | | | | | | | | | | | | | | | | | | | | | | | | | | x | 6 |
| WHO Growth Charts—school age years | | | | | | | | | | | | | | | | | | | | | | | | | | | | x | 6 |
| School attendance | | | | | | | | | | | | | | | | | | | | | | | | | | | x | | 1 |
| ICHOM Standard Measure: Survival | | | | | | | | | | | | | | | | | | | | | | | | | | | | x | 3 |
| PROMIS Parent Proxy Scale—Global health | | | | | | | | | | | | | | | | | | | | | | | | | | | x | | 9 |
| PROMIS Parent Proxy short form—cognitive function | | | | | | | | | | | | | | | | | | | | | | | | | | | x | | 7 |

Continued

**Table 1** Continued

| Age in years | Age-ranges 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Endorsed to be important by the Consumer Open Review: HP (%) | Parents* (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PROMIS Pediatric Scale—global health | | | | | | | | | | | | | | | | | | | | | | | | | | x | 9 |
| NIH Toolbox—self-efficacy CAT | | | | | | | | | | | | | | | | | | | | | | | | | | x | 10 |
| PROMIS Short Form—sleep disturbance | | | | | | | | | | | | | | | | | | | | | | | | | | x | 4 |
| PROMIS Pool—sexual fct. and satisfaction-screener | | | | | | | | | | | | | | | | | | | | | | | | | | x | 3 |
| PROMIS short form—cognitive function | | | | | | | | | | | | | | | | | | | | | | | | | | x | 4 |
| AQoL-8D | | | | | | | | | | | | | | | | | | | | | | | | | | x | 35 |
| Total number of questions (n) within age-specific tool packages | 20–39 | | | | | | 25 | | | | | | | 31 | | | | | 49 | | | | | | | | |
| Time to complete (min) | 30–41 | | | | | | 24–30 | | | | | | | 26–32 | | | | | 13–23 | | | | | | | | |
| Agreement with the age-specific toolset from HP (%) | 94 | | | | | | 98 | | | | | | | 96 | | | | | 94 | | | | | | | | |

Information and definitions for all variables, data sources and recommended timeline for data collection is provided in the reference guide: https://connect.ichom.org/standard-sets/pediatric-overall-health/.
*Parents and caregivers.
√, included based on consensus, grey colour indicates that the respective health outcome is measured at this age, since it is measured by one of the instruments/tools that were agreed upon, and light grey colour indicates that the E-chart can be used as alternative to the Snellen Chart depending on what works best for the child; AQoL-8D, Assessment of Quality of Life-8 Dimensions; C, clinician reported; CDC, Centers for Disease Control and Prevention; HP, health professionals; HRQoL, health-related quality of life; ICHOM, International Consortium for Health Outcomes Measurement; N, number of questions; N/A, not applicable; NIH, National Institutes of Health; PROMIS, Patient-reported Outcomes Measurement Information System.

**Table 2** Overview of the included outcomes, measures and case-mix variables (n=6), age-range specific

| Age ranges | Outcome | Measures | Respondent |
|---|---|---|---|
| 0–5 years | Survival, HRQoL, sleep, pain, mobility, development, communication, hearing, social functioning, vision, growth, nutrition, school attendance | ICHOM Standard Measure: Survival | Clinician |
| | | CDC's Developmental Milestones Checklist (available at: https://www.cdc.gov/ncbddd/actearly/milestones/index.html) | Clinicia and patient/proxy |
| | | Visual Acuity Test—E-chart | Clinician |
| | | WHO Growth Chart (Early Years) (available at: https://www.who.int/childgrowth/standards/en/) | Clinician |
| | | School attendance | Patient/proxy |
| 6–12 years | Survival, HRQoL, sleep, pain, mobility, development communication, social functioning, vision, growth, nutrition, school attendance, cognition/intelligence, mood, mental health, coping, fitness | ICHOM Standard Measure: Survival | Clinician |
| | | PROMIS Parent Proxy Scale V.1.0—Global Health 7+2 (available at: www.healthmeasures.net) | Patient/proxy |
| | | Visual Acuity Test—Snellen-chart (E-chart where Snellen cannot be used) | Clinician |
| | | WHO Growth Chart (School-Age Years) (available at: https://www.who.int/childgrowth/standards/en/) | Clinician |
| | | School attendance | Patient/proxy |
| | | PROMIS Parent Proxy Scale V.1.0—Cognitive Function 7a (available at: www.healthmeasures.net) | |
| 13–17 years | Survival, HRQoL, sleep, pain, mobility, development, communication, social functioning, growth, nutrition, school attendance, cognition/intelligence, mood, mental health, coping, fitness, self-esteem, self-efficacy | ICHOM Standard Measure: Survival | Clinician |
| | | WHO Growth Chart (School-Age Years) (available at: https://www.who.int/childgrowth/standards/en/) | Clinician |
| | | School attendance | Patient |
| | | PROMIS Parent Proxy Scale V.1.0—Cognitive Function 7a (available at: www.healthmeasures.net) | Patient/proxy |
| | | PROMIS Pediatric Scale V.1.0—Global Health 7+2 (available at: www.healthmeasures.net) | Patient |
| | | NIH Toolbox—Self-Efficacy CAT Ages 13–17V.2.0 (available at: www.healthmeasures.net) | Patient |
| | | | Patient |
| 18–24 years | Survival, HRQoL, sleep, pain, mobility, communication, social functioning, vision, hearing cognition/intelligence, mood, mental health, coping, fitness, self-esteem, self-efficacy | ICHOM Standard Measure: Survival | Clinician |
| | | PROMIS Short Form V.1.0—Sleep Disturbance 4a (available at: www.healthmeasures.net) | Patient |
| | | PROMIS Pool V.2.0—Sexual Function and Satisfaction: Screeners (available at: www.healthmeasures.net) | Patient |
| | | PROMIS Short Form V.2.0—Cognitive Function 4a (available at: www.healthmeasures.net) | Patient |
| | | AQoL-8D (available at: http://www.aqol.com.au/choice-of-aqol-instrument/58.html) | Patient |
| Case-mix variable | | | |
| *Age* (ICHOM Standard Measure: Age) | | Patient year and month of birth. In what year and month were you born? RESPONSE: MM/YYYY | Patient/administrative |
| *Sex* (ICHOM Standard Measure) | | Biological sex of patient at birth. Please indicate your biological sex at birth. RESPONSE: male/female/unknown | Patient/administrative |
| *Diagnosis* (International Statistical Classification of Diseases and Related Health Problems (ICD)) | | Prior and current diagnosis of disease or no presence of diagnosis. Please list any prior and current conditions. RESPONSE: ICD-10 or SNOMED-CT/None | Clinician |
| *Parent education level* (ICHOM Standard Measure: Education (as defined by ISCED schooling levels)/Proxy measure for socioeconomic status on other ICHOM sets. | | Please list highest level of education of either parent. RESPONSE: None/Primary/Secondary/Tertiary | Patient and/or primary caregiver |
| *Primary caregiver* (Non-standard measure) | | Please state the primary caregiver (check all that apply). RESPONSE: Mother or Father/Other family member/Self/Other | Patient and/or primary caregiver |
| *Respondent* (Non-standard measure) | | Who is providing this information about the patient? RESPONSE: Mother or Father/Other family member/Self/Other | Patient and/or primary caregiver |

These case-mix variables are recommended for all children, with an expectation that additional variables may need to be collected to allow context-specific benchmarking in some settings during implementation.
AQoL-8D, Assessment of Quality of Life-8 Dimensions; CDC, Centers for Disease Control and Prevention; ICHOM, International Consortium for Health Outcomes Measurement; PROMIS, Patient-reported Outcomes Measurement Information System.

## Ethical considerations

For the patient validation survey, an institutional review board (IRB) exemption review was obtained for each country (online supplemental eTable14).

## RESULTS

In response to the latest debate on arbitrary age limits in paediatric care, which encourages including young adulthood, consensus was reached to include health outcome measures for newborns through 24 years of age (75%).[6–8]

## The OPH-SS: health outcomes and measures

Through the modified Delphi process, consensus was reached to include 22 outcomes in the standard set ranging across the whole spectrum of biopsychosocial health (table 1) and are measured by 15 different tools (table 2):

- Five measures that are clinician-reported and often collected routinely in clinical practice: *WHO Growth Charts—Early Years* and *School—Age Years* versions, *Visual Acuity Test—E--chart* and *Snellen-chart*, *Survival*.
- Nine measures that are patient-/parent-/proxy-reported.

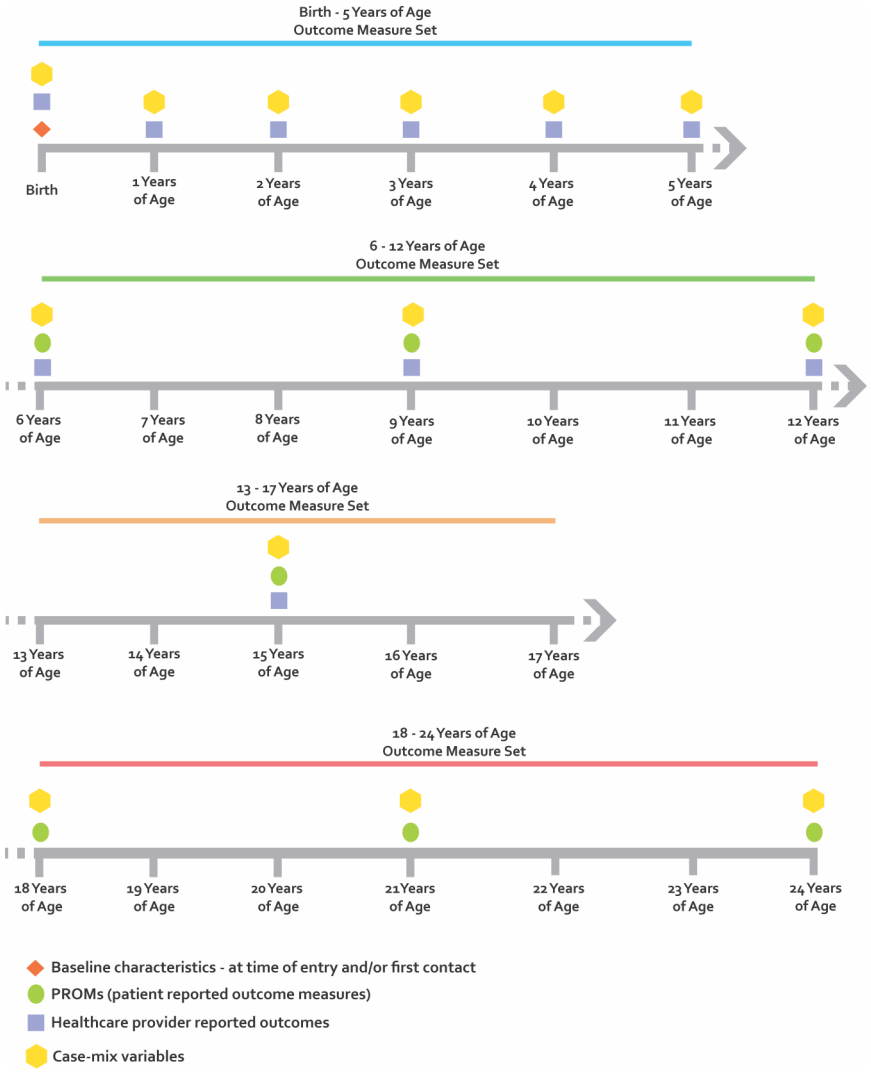


**Figure 2** Proposed timeline for collecting baseline, outcome and case-mix variables for each of the four specific developmental stage subsets.

- One that is both parent/proxy and clinician-reported, the *Centers for Disease Control and Prevention Developmental Milestone Checklist*.

The recommended age-group specific tool packages comprise between 5 and 6 instruments/measures, with 24–49 questions, taking between 15 and 40 min to complete.

## Timepoints (in years) and frequency of measurements

At a minimum, measurements should be taken at the point of transition between developmental stages as defined by on the National Institute of Child Health and Human Development Pediatric Terminology[9] (ages 6, 12, 18, 21 and where appropriate, age 24) (figure 2). The WG recommends optional annual measurements up to 5 years of age due to rapid development and then at ages 9 and 15 years. Since child and adolescent development varies independently of age, the use of the selected measures lends flexibility to an individual's development.[9] For example, if an adolescent is sexually active before the age of 18 years, a clinician could use the *PROMIS Pool v2.0- Sexual Function and Satisfaction—Screener* earlier than the age of 18 years.

## Case-mix variables

From a set of 30 case-mix variables identified (online supplemental eTable 13), 5 variables were included: age, sex, diagnosis, parent education level and primary caregiver and respondent (table 2). Since, several proxy-reported measures are included in the standard set, a sixth variable confirming the respondent (eg, mother/father, other family members, self, others) was included.

## Consumer open review

### Parents and professionals' perspectives

A total of 270 parents or caregivers of children and adolescents participated in a survey. Most respondents had one child (41%) followed by two and three children (36% and 17%, respectively) with an equal sex distribution, representing the whole age-range covered by the OPH-SS (online supplemental eTable 15). At least 86% of respondents ranked 20 of the 22 outcomes as important, with slightly fewer (76%) also deeming school attendance and sexual health as important (table 1). Almost all respondents (94%) agreed that this list captured all the important outcomes that matter most for paediatric patients.

In a concurrent survey of paediatrics health professionals from 14 countries (n=51) (online supplemental eTable 16), at least 88% or more of the respondents agreed with the proposed outcomes and case-mix variables (98% for mental and 92% for physical functioning) and over 94% agreed with the recommended measurements for each OPH-SS age-range (table 1).

**Table 3** Comments from respondents of the consumer open review survey who did not agree that the OPH-SS is complete with comments from the Working Group

| Parents (6% did not agree) | Professionals (2%–12% did not agree)* | Included in OPH-SS (Yes/No) | Answers from the Working Group | Examples of specific questions contained in the included tools |
|---|---|---|---|---|
| **Outcomes** | | | | |
| Screen time | | No | There is no standardised way to measure it yet | |
| General happiness; joy | | Yes | Included in PROMIS-General Health and AQoL-8D | How often do you feel really sad?<br>How often do you have fun with friends?<br>How often do you feel happy?<br>How often do you feel pleasure? |
| Accessibility to quality healthcare | | No | No outcome. It could be uptaken as a case-mix variable, but hard to measure in a standardised way worldwide. | |
| Social interaction with peers and parents; social well-being; social environment in family and with friends | Social interactions with family, peers and adults should be defined by its own outcome separately from general functioning and development. | Yes | Included in PROMIS-General Health and AQoL-8D.<br>We tried to reduce the amount of tools and questions to answer in order to increase the uptake and feasibility of the OPH-SS. Therefore, it is not measured by a specific social interaction instrument. | How often do you feel socially excluded or left out?<br>How often do you have fun with friends?<br>How often do your parents listen to your ideas?<br>Does your health affect your relationship with your family?<br>How satisfying are your close relationships (family and friends)?<br>How much do you enjoy your close relationships (family and friends)? How often do you feel socially isolated? |
| Treatment in school | | No | Not qualified to be included in a minimum set of health outcomes | |
| Bullying | | Yes (?) | It might be detected by questions in PROMIS-General Health and AQoL-8D | How often do you feel socially excluded or left out?<br>How often do you have fun with friends?<br>How often do you feel socially isolated? |
| Fine motor skills | | Yes | Measured by CDC's Developmental Milestones Checklist. | Makes or copies straight lines and circles; Pours, cuts with supervision, and mashes own food; Uses a fork and spoon and sometimes a table knife |
| | Lifestyle factors, including addictions, should be included in the older age ranges. | No | Not qualified to be included in a minimum set of health outcomes | |
| | Hearing should be assessed for all age ranges. | Yes/No | It is not measured by any tool only for one age range between 13 and 17 years. | |
| **Case-mix** | | | | |
| Health problems/medical condition/disease specifics | | Yes | Measured by Case-mix variable 'Diagnosis' | ICD-10 or Snomed-CT |
| Genetics | | No | Not feasible to measure worldwide, ethical aspects have to be considered | |
| | Home environment in terms of parents and access to food, healthcare and sanitation. | No | Not qualified to be included in a minimum set of health outcomes | |
| | Presence of complications during pregnancy as well as prematurity of the infant | No | Not qualified to be included in a minimum set of health outcomes | |

*For more information about agreement of completeness from health professionals, see table 1.
AQoL-8D, Assessment of Quality of Life-8 Dimensions; OPH-SS, Overall Pediatric Health Standard Set; PROMIS, Patient-Reported Outcome Measurement Information System.

Comments from both parents and professionals who did not agree are presented in table 3 with comments from the WG.

## Reference guide

In order to facilitate the adoption and implementation of the OPH-SS, a reference guide was developed by ICHOM (https://connect.ichom.org/standard-sets/pediatric-overall-health/). It provides information and definitions for all variables, data sources and a recommended timeline for data collection.

## DISCUSSION

The OPH-SS comprises 10 PROMs and 5 clinician-reported validated and reliable measures, using between 5 and 6 measurements for each of the four developmental age-stages, with an average completion time of 20 min. Ultimately, healthcare should be 'patient-centred' and put 'each patient in control of his or her own care'.[10] Therefore, the OPH-SS is recommended for routine use in clinical practice to assess health outcomes and facilitate and empower young people and parents to make shared decisions about their care, with their caregivers.[11 12]

To allow meaningful comparisons across different settings and countries, six case-mix variables addressing demographic, clinical and parental (or primary caregiver) risk factors are included. This is a multidisciplinary standard set of paediatric outcome measurements developed to measure the overall biopsychosocial health and the well-being of anyone up to 24 years of age.[8] All measures are free of licensing fees and most are available in multiple languages to reduce barriers to uptake of the standard set internationally.

For the OPH-SS to drive VBPC, widespread implementation strategies to incorporate measures in routine clinical practice and existing workflows throughout various paediatric care settings will be critical. Meaningful, relevant and actionable comparative benchmarking practices need to be developed and refined. Implementation and adoption should allow healthcare comparison across different settings and countries to facilitating local and global improvements in paediatric care delivery and promoting international cross-cultural paediatric research.

### Limitations

In order to minimise the burden of documentation and time to completion, the recommended measures cover several outcomes and comprise a minimum set of questions. The WG aimed to strike a balance between measuring each outcome using a specific instrument and risking double documentation or including instruments that measure broader concepts covering a variety of outcomes. Sum scores can be calculated for the included broader concepts (eg, quality of life, self-efficacy). While the global implementation of the OPH-SS allows further psychometric testing of the included measures for various populations, more comprehensive measures may be needed to increase validity and sensitivity for specific important outcomes. The feasibility of implementing the OPH-SS may vary between different countries and healthcare systems. As a result of varying technological access, representation from low-income countries could not be included during the consensus process diminished as the WG process progressed. The ICHOM process is iterative and a Steering Committee, comprised of former WG members, will serve as a stewarding body to ensure that the OPH-SS remains up to date with the most current evidence and is revised in line with feedback received from implementation experiences across communities.

## CONCLUSION

Based on an extensive literature review, assessment of clinical trials and registries, international patient input and paediatric expert consensus, a minimal set of 15 health outcome measures was developed. To our knowledge, this is the first set of paediatric outcome measurements not specific to any health condition but applicable to the overall biopsychosocial health and well-being of any infant, child or adolescent throughout all developmental stages from birth to 24 years of age. With the implementation of this set in daily clinical practice worldwide, care delivery teams should be increasingly accountable to promote well-being of individuals, with a subsequent understanding of the quality of care being delivered. Comprehensive evaluation of outcomes and discussion of the results with patients and parents will facilitate shared decision-making between families and their healthcare providers. Health literacy will also likely improve, ensuring that families will be sufficiently knowledgeable about the healthcare they receive, ultimately resulting in more equitable care delivery, globally. The next steps will be to implement the OPH-SS in the current clinical workflow, harmonising data collection with electronic health records and registries and developing strategies to provide the data back to clinical teams and patients, creating a meaningful process to drive value-based healthcare.

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