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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

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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).

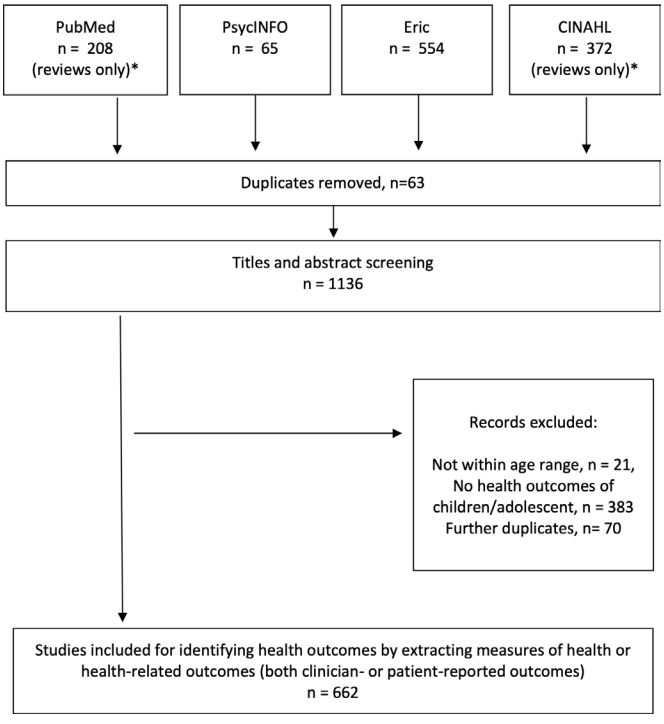

Figure 1 The flow-diagram of the literature search, conducted in March 2018 (including peer-reviewed articles from the last 10 years). *Only reviews were included due to the otherwise tremendous amount of results (n=20 740 and n=12 751, respectively).

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.

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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

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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.

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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.

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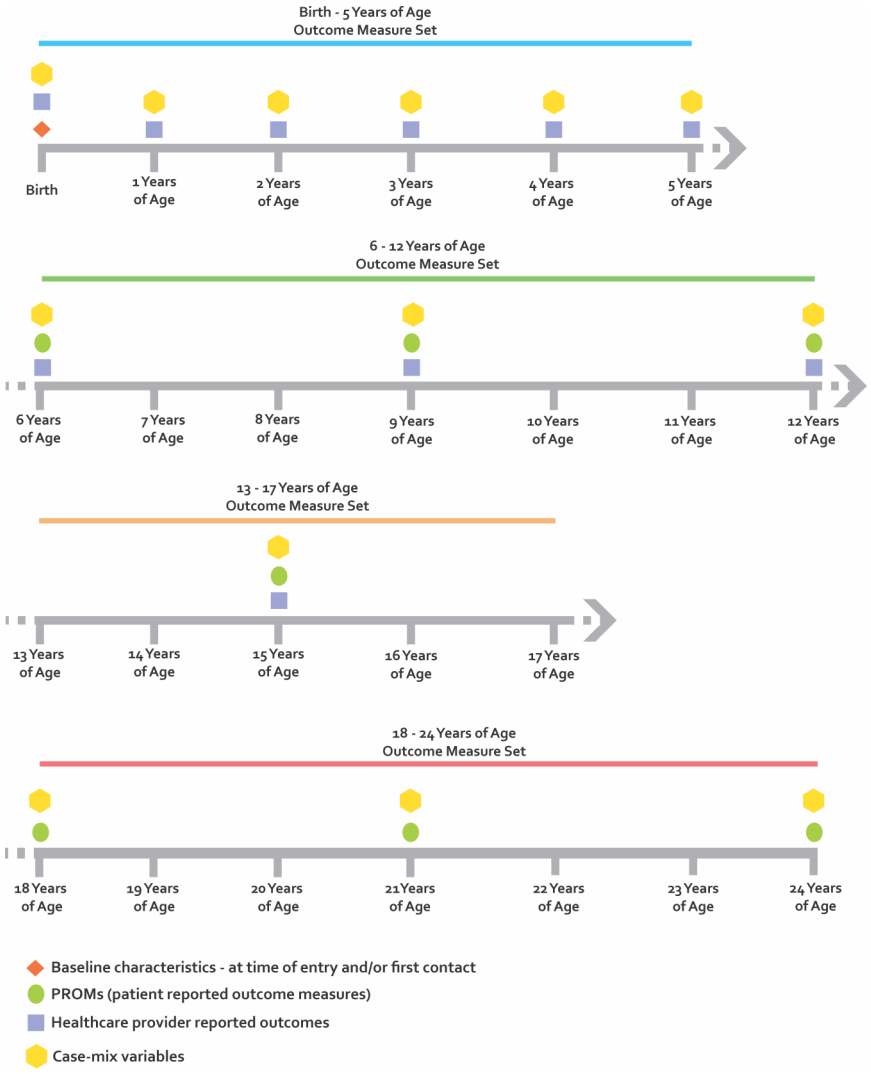

Figure 2 Proposed timeline for collecting baseline, outcome and case-mix variables for each of the four specific developmental stage subsets.

- 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).

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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? How often do you have fun with friends? How often do you feel happy? 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. 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? How often do you have fun with friends? How often do your parents listen to your ideas? Does your health affect your relationship with your family? How satisfying are your close relationships (family and friends)? 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? How often do you have fun with friends? 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.

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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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Contributors BA, as a member of the Project Team performed the literature search and analysis, prepared materials for the consensus process, drafted the manuscript and finalised it in collaboration with all authors. JR, MS, NS and SM as members of the Project Team performed analysis, prepared materials for the consensus process, revised the manuscript and approved the final version prior to submission. KJ, as Working Group Chair and member of the Project Team led the group by promoting the vision for the project and guiding the consensus building process, revised the manuscript and approved the final version prior to submission. AA-C, NB, LC, JaC, JoC, NKC, JJG-G, JH, AK, ALRT, EM, MM, MO, MO'M, JP, CRGdL, TS, CV, as members of the working group participated in discussions and consensus process, revised the manuscript and approved the final version prior to submission.

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eTable 1. Overview of Working Group members.

Name	Title(s)	Country	Income Level*	Organization
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Anne F. Klassen, DPhil	Professor of Pediatrics	Canada	High	McMaster University
Emma J. Mew, MPH	Clinical Research Project Manager	Canada	High	Child Health Evaluative Sciences, Peter Gilgan Center for Research and Learning, The Hospital for Sick Children
Martin Offringa, MD, PhD	Neonatologist; Professor of Paediatrics; Senior Scientist	Canada	High	Department of Paediatrics, The Hospital for Sick Children, University of Toronto
Nancy J. Butcher, PhD,MSc	Senior Research Associate	Canada	High	The Hospital for Sick Children Research Institute, University of Toronto
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Salman Kirmani, MBBS, MD	Associate Professor of Department of Paediatrics and Child Health	Pakistan	Lower Middle	Aga Khan University
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Albie Alvarez-Cote	Founding Member of Milagros para Niños; WG Patient Advisor	United States	High	Milagros para Niños - Boston Children's Hospital
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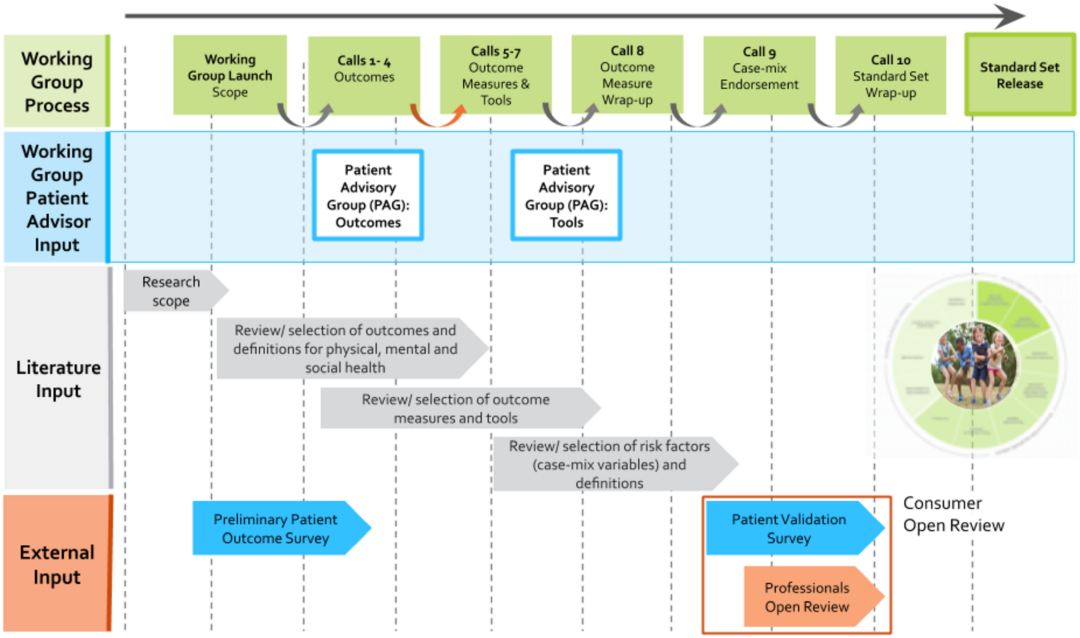
Kathy J. Jenkins, MD, MPH	Professor of Pediatrics; Pediatric Cardiologist; Executive Director of Center for Applied Pediatric Quality Analytics; Chair of the Working Group	United States	High	Harvard Medical School; Boston Children's Hospital
Timothy L. Switaj, MD, MBA, MHA	Primary Care Leadership; Quality Improvement	United States	High	U.S. Army

*as defined by the World Bank Group, April 2020 (https://data.worldbank.org/income-level/)

WG members were recruited in a two-step process. First, sponsorship opportunities were presented to children's hospitals. Then, the confirmed sponsors were asked to nominate WG members. Additionally, ICHOM recruited volunteers to expand the WG and enable broad representation of experience and geography. Recruitment included participants from low-income countries, however, these participants faced challenges, including unaffordable technology and lack of internet connectivity which ultimately precluded them from participating.

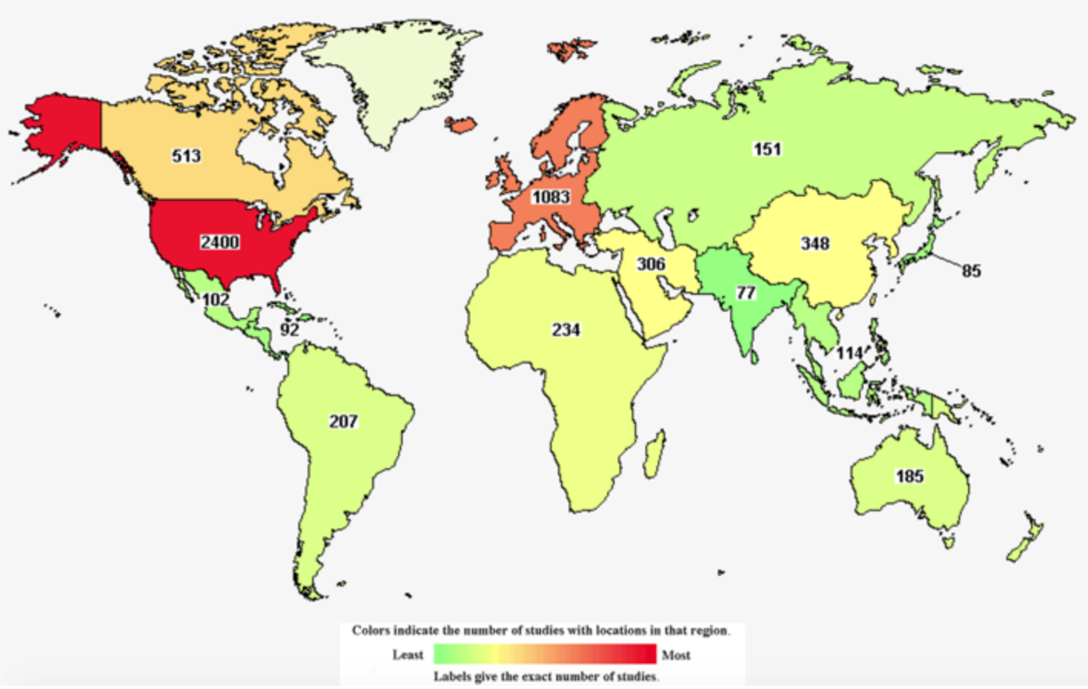


eFigure 1. Overall Pediatric Health Standard Set development process overview.

Between each call a survey was sent out to the Working Group, grey arrows indicate single round survey, orange arrow indicate a modified Delphi process. The PAG was hold with two patient advisors who lead patient advocacy foundations.

WG members were asked to rank outcomes using a 9-point Likert Scale via an electronic survey (Qualtrics Online Survey Platform was used for *all* electronic surveys in this consensus process), with the opportunity to give additional free text feedback.

The voting results of the first round and respondents' comments were anonymized and published for the WG members before voting in a second round. Inclusion of the specific health outcomes and measures in the Standard Set required that at least 80% of the WG members voted the outcome to be very important, i.e. the outcome needed to be ranked between 7-9 points (on a 9-point Likert Scale) in each voting round. During the subsequent WG videoconferences, results of each round were presented to the WG members and the items that did not reach consensus were discussed before being presented for a final (i.e. third) vote determined by a simple yes/no vote with a 70% cut-off for inclusion.



eFigure 2: Geographic overview of the scanned clinical trials, N=4345

Extracted outcomes from clinical trials on www.clinicaltrials.gov
Search terms: pediatric OR paediatric,
Included status: recruiting, not yet recruiting, active, not recruiting, enrolling by invitation studies
Results: N=4345 clinical trials

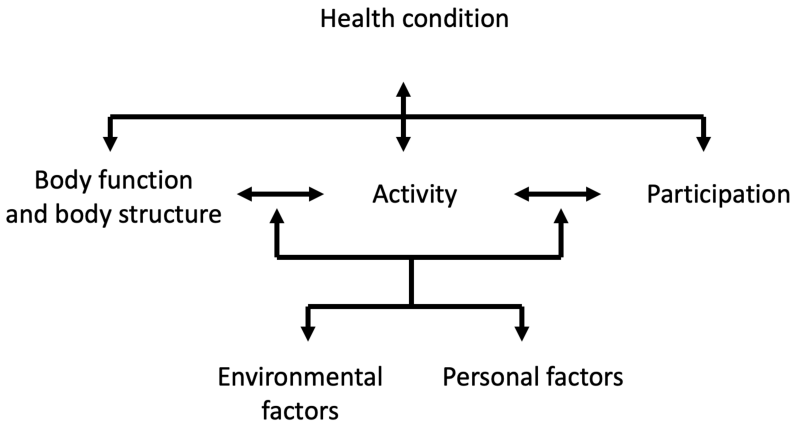
eTable 2. Search Strategy

Search Block	**Search terms**	**Combined with**	**Blocks combined with**	**Databases**
Population	child*, adolesc*, pediatric, paediatric, youth	**OR**	**AND**	• Cumulative Index to Nursing and Allied Health Literature (CINAHL), • the Education Resource Information Center (ERIC), • PsycINFO from the American Psychological Association (APA), the United States National Library of Medicine PubMed including Medical Literature Analysis and Retrieval System Online (Medline)
Outcomes	patient preference, instrument*, scale, measure*, patient reported outcome measures, quality of life, clinical outcome, functioning	**OR**		
	In order to receive a manageable amount of results, search terms were restricted to title and abstract from the last ten years, and limited to searches in PubMed and PsycINFO, with only reviews being extracted due to the otherwise tremendous amount of results (n=20740 and n=12751 respectively). Since reviews are expected to evaluate and summarize many existing outcome measures (including those published earlier than in the last ten years), we deem the strategy is appropriate to identify most of health outcomes that are important to measure.			
Age-ranges included	Age Groups: Infant, Newborn: birth-1 month, Infant: 1-23 months, Child, Preschool: 2-5 years, Child: 6-12 years, Adolescent: 13-18 years, All Infant, All Child			

eTable 3. Example of health outcomes identified by categorizing the extracted measures in accordance to the phenomenon/topic/ health outcome that they were considered to measure.

Instruments sorted from literature scan	Health outcomes
Culture Fair Intelligence Test-Revised (CFT 20-R) (Weiss)	Intelligence
Full-Scale Intelligence Quotient (FIQ)	
Kaufman Brief Intelligence Test, Second Edition (K-BIT 2)	
Stanford Binet Intelligence Scales (SB_5)	
Test of Nonverbal Intelligence (TONI) (Brown et al)	
the Kaufman Brief Intelligence Test, 2nd edition (KBIT-2)	
Wechsler Abbreviated Scale of Intelligence (WASI)	
Wechsler Adult Intelligence Scale-3rd Edition (WAIS-III)	
Wechsler Intelligence Scale for Children , Fourth Edition	
Wechsler Intelligence Test for Adults (WIE) (Aster et al)	
Neonatal Pain, Agitation, and Sedation (N-PASS) Scale	Pain
Pain Assessment Scale for Preterm Infants (PASPI)	
Pain Observation Scale for Young Children (POCIS)	
the Movement Assessment Battery for Children-2 (MABC2)	Movement
Active Movement Scale	
Movement ABC	
Movement Assessment Battery for Children	
Movement Disorder-Childhood Rating Scale	
Peabody Developmental Motor Scales-2 (PDMS-2)	Development (including
Battelle Developmental Inventory, Second Edition (BDI-2)	other domains as well, like
Bayley Scales of Infant Development (Bayley III)	cental health, self-concept,
Child development - mental rotation 3d test	Communication, anxiety)
Child development - New Reynell Developmental Scales	
DeMoulin Self-Concept Developmental Scale for Children	
Developmental Neuropsychological Assessment-Second Edition	
Developmental status - Brigance Early Childhood Screen II, Ages and	
Explore Early Development (SEED)	
Griffiths Mental Development Scales	
Kids' Empathic Development Scale (KEDS)	
National Institute of Child Health and Human Development (NICHD)	
NSMDA (Neurological, Sensory, Motor, Developmental Assessment)	
the Test of Gross Motor Development (TGMD)	
Developmental Disability-Child Global Assessment Scale	
Communication and Symbolic Behaviour Scales--Developmental Profile	
Language - MacArthur Communicative Development Inventory	
Revised Children's Manifest Anxiety Scale-Second Edition (RCMAS-2)	Anxiety
Anxiety - Spence Children's Anxiety Scale-Parent Report	
Anxiety and Related Emotional Disorders (screen child)	
Anxiety Disorders Interview Schedule for "DSM-IV"	
Beck Anxiety Inventory (BAI)	
Child Anxiety Impact Scale	
Multidimensional Anxiety Scale for Children (MASC)	

In order to assure that the identified outcomes reflect a holistic perspective encompassing the physical, mental and social functioning, these outcomes were mapped to the World Health Organization's International Classification of Functioning, Disability and Health (ICF), as a conceptual platform to capture health and health-related domains.



eFigure 3. The model and framework of the International Classification of Functioning, Disability and Health (ICF, World Health Organization (WHO), 2001).

In line with the definition of health by WHO as physical, mental and social well-being and not merely the absence of disease (1946), integrates the ICF the biomedical and psycho-social perspective of health, and models health and well-being as the result of the interactions of Body Functions and Anatomical Structures with individuals' Activities and Participation that are influenced by Environmental and Personal Factors.

eTable 4. Overview of the identified health and health-related outcomes regarding ICF Body Functions stratified by respective resource.

ICF framework	Health outcomes	Instruments from literature scan	Pediatric PROMIS	Pediatric *health* registries and surveys	Pediatric ongoing clinical trials
ICF Body Functions					
b1 Global and specific mental functions	Mental + cognition	15	√	√	114
	Intelligence	17			24
b1 Temperament & personality functions	Efficacy, self-esteem, mastery	15			52
	Coping	4			22
b1 Emotional functions	Depression	17	√	√	103
	Anxiety	22	√	√	152
	Worry, emotion mood	8			64
b1 Sleep functions	Sleep	8			109
b1 Energy and drive functions	Fatigue	3	√	√	40
b2 Sensory functions and pain	Visual/seeing	1		√	24
	Pain	4	√	√	283
	Hearing	3		√	22
b3 Voice and speech	see also "Communication"			√	8
b4 Functions of cardiovascular, haematological, immunological and respiratory systems	Blood pressure			√	107
	Heart rate				71
	Breath+respiratory	1			155
b5 Functions of the digestive, metabolic and endocrine system	Blood glucose			√	21
b7 Neuromuscular function (see also mobility)	Motor (e.g. gross)	11	√	√	50
	Fitness	2			19
	Physical ability	1	√		0
b8 Functions of skin and related structures	Eczema			√	16

eTable 5. Overview of the frequency of identified health and health-related outcomes regarding Activities & Participation stratified by respective resource.

ICF framework	Outcomes	Instruments from literature review	Pediatric PROMIS	Pediatric *health* registries and surveys	Pediatric ongoing clinical trials
ICF Activities and Participation					
d1 Learning and Applying knowledge	Learning (see also intelligence, mental and cognition functions)	2			21
	Writing	4			1
	Reading	6			14
d2 General tasks and demands	Stress	12	√		150
d3 Communication	Language, speech, word, conversation	18			51
d4 Mobility	Movement (see also b7)	6			34
d5 Self-care/looking after one´s health	Eating/nutrition	2		√	87
	Salt intake			√	0
	Sexual health	1			14
	Substance use (e.g. alcohol, tobacco)	2		√	
	Physical activity	1	√	√	119
	Dental hygiene			√	21
d7 Interpersonal interactions and relationships	Interaction	4	√	√	18
d8 Major life areas/engagement in play	Engagement in play	2			15
	School	3		√	71

eTable 6. Overview of the frequency of identified factors influencing health and health-related outcomes regarding Environmental factors stratified by respective resource

ICF framework	Factors influencing outcomes	Instruments from literature scan	Pediatric PROMIS	Pediatric *health* registries and surveys	Pediatric ongoing clinical trials
ICF Environmental factors				√	33
e3 Support	Support	10			66
e4 Attitudes	Attitudes	5			29
e5 Services, systems and policies	Safe neighborhoods			√	

eTable 7. Overview of the frequency of identified health and health-related outcomes stratified by respective resource

	Outcomes	Instruments from literature scan	Pediatric PROMIS	Pediatric *health* registries and surveys	Pediatric ongoing clinical trials
Others					
Overall functioning	Disability	12			71
	Family	21	√	√	9
	Behavior	34			213
	Participation	8			31
Quality of life	Quality of life, Health-related quality of life; Oral health-related quality of life; life satisfaction; well-being, health (global)	68	√ (life satisfaction)	√	443
Abuse, violence	Abuse, violence	2		√	9
Development	Developmental	19			114 (growth)
Mindfulness	Mindfulness	11			10
Parents' substance use (alcohol, tobacco, drugs)	Parents' substance use (alcohol, tobacco, drugs)			√	
	Parents' health			√	
Anthropometric					
	Weight			√	238
	Height			√	114
	Size at birth			√	
	BMI				137
Health condition					
	Asthma	6	√	√	114
	ADHD	3			22
	Autism	13			59
	Burn	4			39
	Depression (see depression above)	17			34 (anxiety, bipolar, psychosis)
	Diabetes	6			130
	Cancer	2			111
	Leukemia	0			173
	Brain injuries/ cerebral palsy	4			87
	Mortality			√	
	Morbidity			√	

eTable 8. ICHOM's tool selection criteria.

Topic	Description
Scope Alignment	• Exclude condition-specific tools (i.e. Breast Cancer, Low Back Pain, Dementia, etc.) • Exclude PREMs and *process* measure tools (i.e. room cleanliness, wait times, etc.)
Coverage of Outcomes	• Tool must address outcomes voted for inclusion by the Working Group • Preference given to tools which cover the most outcomes
Scientific Acceptability & Clinical Utility	• Tools must have demonstrated good reliability (>0.7), validity, and responsiveness (sensitivity to change) • Tools should have demonstrated clinical utility by inclusion of meaningful scores for overall health, mental health, physical health, social health • Tools should have appropriate recall period
Patient Burden	• Tools should not be too long and burdensome for patients to complete • Tools with more than 100 questions will not be considered
Language Translations	• Tool must be available in English • Translations should be available in several other languages
Implementation	• Tools must be able to be implement within diverse, international, clinical settings. • Copyright & Licensing – ensure fees for use of tools are not too expensive as to become a barrier to uptake/adoption of the final OPH Standard Set

eTable 9. Example of systematic evaluation of identified measures and tools in accordance with ICHOM criteria.

Tool	Reliability (≥ 0.7)	Valididty	Covers OPH Age Range (Y/N)	Proxy (Y/N)	Self (Y/N)	Recall Period	PRO (Y/N)	Clinical Measure (Y/N)	# Questions in Tool	Completion Time	Copyright & Licensing Fees			# Languages
											Are there fees? (Y/N)	If yes, fee amount?	Criteria for fee	
AQoL-8D	Y (test in patients)	Y	Y(14+)	N	Y	7 days	Y	N	35	5 min	N			5
ITQoL	N (0.5-0.7)		Y (2months-5years)	Y	N	past 4 weeks, in general	Y	N	97	30-45mins	N			24
ITQoL-SF47	N (0.5-0.7)	Y	Y (2months-5years)	Y	N	past 4 weeks, in general	Y	N	47	30 mins	N			40
KIDSCREEN-52	Y	Y	Y (8-18)	Y	Y	last week	Y	N	52	15-20 min	N		free after registration	>30
PROMIS Scale v1.2 - Global Health	Y	Y	Y (18+)	N	Y	7 days	Y	N	10	2 min	N			14
PROMIS Pediatic scale- Global Health 7+2	Y		Y (8-17)	N	Y	7 days, in general	Y	N	9	2 min	N			14
PROMIS Parent Proxy Scale v1.0 - Global Health 7+2	Y	y	Y (5-17)	Y	N	7 days, in general	Y	N	9	2 min	N			14
KIDSCREEN-27	Y	Y	Y (8-18)	Y	Y	last week	Y	N	27	10 min	N		free after registration	35
KINDL ®	Y	Y	Y (4-16)	N	Y	last week	Y	N	24+6, 12 for age 4-7	5-10min	N		free after registration	15
PROMIS Pediatric Profile-25	Y	Y	Y(8-17, 5-17 proxy)	Y	Y	past 7 days	Y	N	25		N			4+1
Pre-School Language Scale-4	Y	Y	Y (0-7: 11)	N	N		N	Y		20-45 min	Y	823 US Dollars	Certification needed	4
NutriSTEP	Y (most questions)	Y	Y (18months-5y)	Y	N	3 days	Y	N	17	< 10 min	N			1
FLACC Behavioral Scale	y	y	Y (2months-7y)	N	N		N	Y	5	2-5 min (observation)	N		certification needed	9
NIH Toolbox - Sensation - Visual Acuity Test (3+)	Y	Y	Y (3+)	N	N		N	y	na	3 min	N		extra equipment is needed	na
PROMIS Peadiatric SF - Sleep Disturbance	Y	Y	Y(8-17, 5-17 proxy)	Y	Y	past 7 days	Y	N	15 (SV 4 or 8 items)	5-10 min	N			2

eTable 10. Example of the content-mapping of the measures to the agreed upon OPH outcomes.

TOOLS	15D®	16D®	17D ®	AQoL-8D	ITQoL	ITQoL-SF47	KIDSCREEN-52	PROMIS Scale v1.2 - Global Health	PROMIS Pediatic scale-Global Health 7+2
AGE RANGES	(16+ yrs)	(12-15yrs)	(8-11yrs)	(14 +yrs)	(2 mos-5 yrs)	(2 mos-5 yrs)	(8-18yrs)	(18+ yrs)	(8-17 yrs)
Administration Mode	Self/ Proxy	Self/ Proxy	Self/ Proxy	Self	Proxy	Proxy	Self/ Proxy	Self	Self
Outcomes:	*Tool covers outcome (Y/N)*	*Tool covers outcome (Y/N)*	*Tool covers outcome (Y/N)*	*Tool covers outcome*	*Tool covers outcome (Y/N)*	*Tool covers outcome (Y/N)*	*Tool covers outcome (Y/N)*	*Tool covers outcome (Y/N)*	*Tool covers outcome (Y/N)*
Mental Functioning									
Cognition: Intelligence	Y	Y	Y	N	Y	Y	N	N	N
Coping	N	N	N	Y	N	N	Y	N	N
Mood	Y	Y	Y	Y	N	N	Y	Y	Y
Self-efficacy	N	N	N	Y	N	N	Y	N	N
Self-esteem	N	N	N	Y	N	N	N	N	N
Mental Health	Y	Y	Y	Y	Y	Y	Y	Y	Y
Social/ General Functioning									
Communication	Y	Y	Y	N	Y	Y	N	N	N
School Attendance	N	N	N	N	N	N	Y	N	N
Functioning	Y	Y	Y	Y	N	N	Y	Y	Y
Development	N	N	N	N	Y	Y	N	N	N
HRQoL	Y	Y	Y	Y	Y	Y	Y	Y	Y
Physical Functioning									
Survival	ICHOM	ICHOM	ICHOM	ICHOM	ICHOM	ICHOM	ICHOM	ICHOM	ICHOM
Hearing	Y	Y	Y	N/A	N	N	N	N	N
Vision	Y	Y	Y	N/A	N	N	N	N	N
Eating	Y	Y	Y	N	Y	Y	N	N	N
Nutrition	N	N	N	N	N	N	N	N	N
Growth	N	N	N	N	Y	Y	N	N	N
Physical ability: mobility	Y	Y	Y	Y	Y	Y	Y	Y	Y
Fitness	Y	Y	Y	N	N	N	N	Y	Y
Pain-free	Y	Y	Y	Y	Y	Y	Y	Y	Y
Sleep	Y	Y	Y	N	N	N	N	Y	Y
Sexual Health	Y	N	N	N	N	N	N	N	N
# Outcomes Covered By Tool:	**14**	**13**	**13**	**9**	**9**	**9**	**9**	**8**	**8**
	M	**M**	**M**	**M**	**M**	**M**	**M**	**M**	**M**

eTable 11. Example of tool package 1 for age-range birth to 5 years

Recommendation 1 (Birth - 5 yrs)

- Total Outcomes Covered: **12**
- Total # of Questions: **20-39**
- Total time to completion: **30-41 mins**

Tool	All Psychometric Properties (Y/N)	Outcomes Covered (#)	Time to completion (mins)	# of Questions	# of Languages	Fee (Y/N)
CDC Milestone Checklist	N/A	Cognition: Intelligence, Mood, Mental Health, Functioning, Development, Communication, Physical Ability: Mobility **(7)**	10 - 15	10-29	2	N
NIH Toolbox - Sensation - Visual Acuity Test (3+) [Equipment Needed]	Clinical Measure	Vision **(1)**	3	-	1	N
WHO Growth Charts Early Yrs [Trained Admin]	Clinical Measure	Growth, Nutrition **(2)**	15 - 20	6	1	N
School Attendance	-	School Attendance **(1)**	1	1	-	N
ICHOM Standard Measure	-	Survival **(1)**	1 - 2	3	-	N

eTable 12. Example of tool package 2 for age-range birth to 5 years

Recommendation 2 (Birth - 5 yrs)

- Total Outcomes Covered: **14**
- Total # of Questions: **57**
- Total time to completion: ***45 - 56 mins***

Tool	All Psychometric Properties (Y/N)	Outcomes Covered (#)	Time to completion (mins)	# of Questions	# of Languages	Fee (Y/N)
ITQoL	Y	Cognition: Intelligence, Mental Health, Communication, Development, HRQoL, Eating, Growth, Physical Ability: Mobility, Pain-free. **(9)**	25-30	47	40	N
NIH Toolbox - Sensation - Visual Acuity Test (3+) [Equipment Needed]	Clinical Measure	Vision **(1)**	3	-	1	N
WHO Growth Charts Early Yrs [Trained Admin]	Clinical Measure	Growth, Nutrition **(2)**	15 - 20	6	1	N
School Attendance	-	School Attendance **(1)**	1	1	-	N
ICHOM Standard Measure	-	Survival **(1)**	1 - 2	3	-	N

eTable 13. Overview of the identified case-mix variables following the search for outcome measures.

Case-Mix	Type	Response option 1	Response option 2
Age	Demographic	years since birth	
Gender	Demographic	male, female, others	
Diagnose	Clinical	ICD-code	
Race	Demographic		
Treatment/surgical procedure	Treatment		
Parent income	Demographic	amount of salary	
Etnicity	Demographic		
Parent occupation/employment	Demographic	full time, part time, unemployed, home, retired, student, other	
Relationship	Demographic	Mother; father; other	parents, sibling, other relative, non-relative, missing, adolescent/young adult with a disability
Marital status	Demographic	married/de facto, single/never married, single/widowed, single/divorced	
Parent education	Demographic	primary, high school, trade, university, other	high school, graduated high school, some postsecondary, graduated postsecondary
Disability	Clinical		
Diagnose/disability severity	Clinical		
Migration	Demographic		
Socioeconomic status	Demographic	""The Family Affluence Scale (FAS), a socioeconomic indicator to be filled in by children, includes family car ownership, having own unshared room, the number of computers at home, and times the child spent on holidays in the past 12 months. The cross-cultural validity of the FAS has been shown in multinational surveys across 27 and 35 countries [27].""	
Public health insurance	Demographic	yes/no	
Premature birth	Clinical		
Postoperative analgesia / pharmacological influence	Treatment		
Neighbourhood	Demographic	Large city or metropolitan area (greater than 200000), urbanized area (between 50 000 and 200 000), town or small city (between 2500 and 50000), rural area or town (less than 500),	
Parents age at child birth	Demographic		
Social class	Demographic	low, middle, high	
Parent-reported chronic conditions of child	Demographic		
Parent-reported medical consumption	Demographic	with a low and a high parent-reported medical consumption	
Years since diagnosis	Clinical		
Spasticity	Clinical		
Treatment modality	Treatment		

eTable 14. Sampling strategy for patient validation survey.

Country	Institutional review board (IRB) exemption review
United States	Advarra Institutional Review Board (Pro00038212)
Colombia*	Ethics Committee for Clinical Research in Colombia (Comité de Ética en Investigación Clínica, CEIC-4187-2019)
Singapore*	The survey was carried out as a quality improvement initiative not needing IRB approval
United Kingdom	Patient Validation was exempt as it did not qualify as research needing ethical approval

A convenience sample of parents and caregivers of children and adolescents in Colombia, Singapore, the United States, and the United Kingdom were asked to validate the outcomes that reached consensus based on the Delphi-process. These four countries were chosen based on their ability to obtain an institutional review board (IRB) exemption review in a timely fashion. In the United States, the ethics and institutional review board (IRB) exemption for the survey was carried out by Advarra Institutional Review Board (Pro00038212) and in Colombia by the Ethics Committee for Clinical Research in Colombia (Comité de Ética en Investigación Clínica, CEIC-4187-2019). In Singapore, the survey was carried out as a quality improvement initiative not needing IRB approval. In the United Kingdom, the Patient Validation was also exempt as it did not qualify as research needing ethical approval. Between November 2019 and January 2020, an electronic survey was sent asking participants to rank the importance of these outcomes using a 9-point Likert Scale with an opportunity to give additional free text comments.

*Participants included parents and caregivers of children receiving pediatric care and surveys were administered while their child waited to receive care.

eTable 15. Overview of Patient Validation Survey respondent characteristics, N=270

	n	%
Country		
Colombia	86	32
Singapore	161	59
United Kingdom	5	2
United States of America	18	7
Number of children		
1	111	41
2	97	36
3	46	17
4	5	2
≥ 5	3	1
Sex of children		
Male	92	34
Female	84	31
Male and Female	89	33
Age-range of children		
0-5 years	143	53
6-7 years	51	19
8-12 years	105	39
13-17 years	51	19
18-24 years	35	13
Number of healthcare appointments in the last year		
0	11	4
1-4	149	55
5-9	78	29
≥ 10	32	12
Satisfied with child's healthcare (range 1-5)		
Unsatisfied (1)	3	1
Somewhat satisfied (2-3)	59	22
Completely satisfied (4-5)	208	77

eTable 16. Overview of characteristics of the healthcare providers that participated in the professionals open review, N=51

	n	%
Country		
Argentina	1	2
Australia	2	4
Brazil	2	4
Canada	1	2
Colombia	2	4
Malaysia	1	2
Netherlands	6	12
Portugal	1	2
Singapore	7	14
Spain	18	35
Sweden	1	2
United Arab Emirates	1	2
United Kingdom	2	4
United States of America	6	12
Profession		
Physician	37	72
Nurse	3	6
Healthcare Administration	7	14
Researcher	1	2
Policy Advisor	2	4
Other	1	2