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A Core Outcome Measurement Set for Pediatric Critical Care

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Abstract

Objectives: To identify a Pediatric Intensive Care Unit Core Outcome Measurement Set (PICU COMS), a set of measures that can be used to evaluate the PICU Core Outcome Set (PICU COS) domains in PICU patients and their families.

Design: A modified Delphi consensus process

Setting: Four webinars attended by PICU physicians and nurses, pediatric surgeons, rehabilitation physicians, and scientists with expertise in PICU clinical care or research (n=35). Attendees were from eight countries and convened from the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Pediatric Outcomes Studies after PICU (POST-PICU) Investigators and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) PICU COS Investigators.

Subjects: Measures to assess outcome domains of the PICU COS: cognitive, emotional, overall (including health-related quality of life), physical, and family health. Measures evaluating social health were also considered.

Interventions: None.

Measurements and Main Results: Measures were classified as general or additional based on generalizability across PICU populations, feasibility, and relevance to specific COS domains. Measures with high consensus, defined as 80% agreement for inclusion, were selected for the PICU COMS. Among 140 candidate measures, 24 were delineated as general (broadly applicable) and, of these, 10 achieved consensus for inclusion in the COMS (7 patient-oriented and 3 family-

oriented). Six of the seven patient measures were applicable to the broadest range of patients, diagnoses, and developmental abilities. All were validated in pediatric populations and have normative pediatric data. Twenty additional measures focusing on specific populations or in-depth evaluation of a COS subdomain also met consensus for inclusion as COMS additional measures.

Conclusions: The PICU COMS delineates measures to evaluate domains in the PICU COS and facilitates comparability across future research studies to characterize PICU survivorship and enable interventional studies to target long-term outcomes after critical illness.

Keywords

patient reported outcome measures; critical care outcomes; patient outcome assessment; family health; intensive care units; pediatric; survivorship

Introduction

Children who survive critical illness can experience long-term sequelae affecting their health [1–5]. Pediatric critical illness can also impact family functioning which can influence child outcomes. Post-intensive care syndrome-pediatrics (PICS-p) encompasses the cognitive, emotional, physical, and social health problems that newly develop or worsen after critical illness and persist after PICU discharge for children and their families [6, 7]. Identifying the extent and burden of PICS-p is a crucial first step to guiding the development of interventions to improve pediatric intensive care unit (PICU) survivorship. In 2017, the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) network’s Pediatric Outcomes Studies after PICU (POST-PICU) Investigators and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) developed a novel collaboration to improve the understanding of long-term outcomes after pediatric critical illness.

The PALISI POST-PICU and CPCCRN Investigators conducted a scoping review of pediatric critical care medicine (PCCM) outcomes literature from 1970–2017, characterizing domains of health and instruments used to measure outcomes in these domains among PICU survivors or their families [8]. This scoping review identified the: 1) increasing attention to this area of research and 2) heterogeneity of studies that included 366 unique measurement instruments (“measures”) to evaluate seven domains of health (cognitive, emotional, overall health, health-related quality of life [HRQL], physical, family, and social). The scoping review highlighted the challenge of comparability across studies and informed the development of a PICU core outcome set (COS) to serve as a minimal set of patient outcomes essential to assess in clinical research [9]. Use of a COS increases consistency and comparability among studies without precluding researchers from evaluating other outcomes [10–12]. The investigator team recommended evaluation of four COS domains: cognitive, emotional, overall health (including HRQL), and physical function as well as an additional fifth domain (family) and key subdomains delineated in the PICU COS-Extended [13].

To facilitate implementation of the PICU COS, we employed an international, multistakeholder-informed consensus process to identify a Core Outcome Measurement Set (COMS) comprised of recommended outcome measures which are accessible and feasible to

use and demonstrate suitable measurement properties to evaluate the domains of the PICU COS and COS-Extended.

Methods

We developed the methodology for the PICU COMS based on the Outcome Measures in Rheumatology initiative which involved three stages: 1) developing candidate instruments, 2) selecting a preliminary COMS, and 3) a consensus process to determine the final COMS [14]. The PICU COMS study was registered with the Core Outcome Measures in Effectiveness Trials Initiative [15]. The COMS was developed by a 35-member Expert Panel convened from the PALISI POST-PICU and CPCCRN Investigators (33 members), which included PICU physicians and nurses, pediatric surgeons, rehabilitation physicians, and scientists with expertise in PCCM research and clinical care of critically ill children [Supplemental Digital Content (SDC) Table 1] [13]. Two additional pediatric neuropsychologists with expertise in PCCM research, and common data element/COS development were recruited to the panel. Panel members were from eight countries (Argentina, Australia, Canada, Netherlands, Singapore, South Africa, United Kingdom, and the United States). Although a protocol was not submitted to an IRB, all panelists agreed to participate.

Due to the relatively early stage of PCCM outcomes research, heterogeneity of PICU populations, and diversity of resources available, the Expert Panel sought to develop the PICU COMS as a set of outcome measures that *can* (rather than typical definition of “must”) be used to study the domains of the COS [14]. *A priori*, our objective was to identify a COMS for seven domains of health: the six core outcome domains recommended in the PICU COS and COS-Extended (cognitive, emotional, overall health [including HRQL], physical, and family) [13], and the social health domain. Social health was included due to its interrelatedness with other domains and prior inclusion in the scoping review [8] and PICS-p conceptual framework [6, 8].

Preliminary COMS

Candidate measures were identified from the scoping review that characterized measures evaluating long-term outcomes of critically ill and injured children in studies published between 1970 and 2017 [8]. Akin to the methodology used to develop the COMS for adult acute respiratory failure [11], the five most frequently used measures for each domain were selected. Because newer measures may not have reached this publication threshold, we also included measures that were first used in publications in the final ten years of the scoping review’s inclusion dates (2007–2017).

PALISI POST-PICU and CPCCRN Investigators (SDC Table 2) with expertise in each of the seven domains reviewed the measures allocated to their domain. These investigators also recommended “write-in” measures, to allow for inclusion of measures not identified in the scoping review due to its inclusion dates and measures commonly used in other research fields. The investigators vetted the candidate measures based on attributes delineated in SDC Table 3 and recommended a preliminary COMS. For the preliminary COMS,

the investigators prepared detailed tables with instrument-specific information including applicability to the general PICU population, age range, validation across clinical settings, normative data availability, administration modalities, completion time, specialized training requirements, availability, cost, and suitability for longitudinal use including pre-illness baseline assessment.

Modified Delphi Consensus Process

The Expert Panel used a modified Delphi consensus process with two rounds of voting to achieve consensus for development of the PICU COMS [11]. Panelists met via four monthly webinars (January 2021 - April 2021) to vet the preliminary COMS. Before each webinar, all panelists received the preliminary COMS instrument tables for the domains to be discussed. In voting Round 1, panelists used data from these tables to categorize instruments as: “general” if widely applicable, “additional” if more suitable for specific studies or populations, or “excluded” if not applicable to PICU outcomes research. Measures encompassing multiple domains were reviewed in each individual domain. Results from Round 1 were reported to the Expert Panel to facilitate discussion of each instrument during the webinar. Additionally, the panelists had the opportunity to recommend “write-in” measures which were considered unless the measure had already been excluded during development of the preliminary COMS.

Following these discussions, we conducted a second round of voting using the Poll Everywhere platform (Poll Everywhere; San Francisco, CA) to determine the final COMS; the Expert Panel was able to view polling results in “real time” during the webinar. Panelists categorized instruments as general or additional measures. Based on voting, the instruments were further categorized as “High Consensus” if 80–100% agreement for inclusion in the COMS was attained, “Medium Consensus” if 70–79% agreement, and “Low Consensus” if 50–69% agreement. Measures with “High Consensus” were included in the COMS. If <50% of the Expert Panel voted to include a measure, it was excluded.

Results

Of the 366 unique instruments identified by the PCCM scoping review, 140 measures were considered based on frequency and timing of use (Figure 1). From these, the PALISI POST-PICU and CPCCRN Investigators recommended 58 measures plus 5 write-in measures as the preliminary COMS. During voting Round 1, the Expert Panel reviewed these 63 measures and recommended 20 write-in measures, which were considered for voting round 2 (SDC Table 4).

Among these 83 measures, the Expert Panel recommended 24 as general measures (SDC Table 5) and 42 as additional measures (SDC Table 6). Ten general measures and 20 additional measures achieved “high” consensus for inclusion in the COMS (Table 1). Eight measures achieved consensus in more than one domain as either general or additional measures: Pediatric Evaluation of Disability Inventory-Computer Adaptive Test (PEDI-CAT), Participation and Environment Measures Children and Youth and Young Children’s Participation and Environment Measure (PEM-CY and YC-PEM), Impact of

Events Scale-Revised (IES-R)/Child Revised Impact of Event Scale (CRIES), Ages and Stages Questionnaire (ASQ), Bayley Scales of Infant and Toddler Development, Mayo Portland Adaptability Inventory (MPAI), Posttraumatic Growth Inventory for Children-revised (PTGI-C-R), and Children's Sleep Habits Questionnaire (CSHQ) (SDC Tables 5 and 6).

COMS General Measures

The general measures included in the COMS were: 1) National Institutes of Health (NIH) Toolbox Cognition Measures [16], 2) Patient Reported Outcomes Measurement Information System (PROMIS) Pediatric Cognitive Function [17, 18], 3) Strengths and Difficulties Questionnaire (SDQ) [19], 4) Functional Status Scale (FSS) [20], 5) Pediatric Quality of Life Inventory (PedsQL) [21], 6) Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT) [22], 7) Impact on Family Scale [23], 8) PedsQL Family Impact Module [24], 9) Posttraumatic Diagnostic Scale (PDS) [25], and 10) NIH Toolbox Emotion Measures: Social Relationships [26] (Figure 2 and Table 1). Seven of the ten measures were patient-oriented, and three were family-oriented. Six of the seven patient-oriented measures applied to the broadest range of PICU patients, including a wide range of ages, diagnoses/conditions, and developmental abilities (Table 2). All seven patient-oriented measures were validated in pediatric populations, including three in a PICU population. Normative data are available for the seven patient-oriented measures and two of the three family-oriented measures. All measures have demonstrated feasibility regarding administration and ease of use. Specifically, all ten have been administered via multiple modalities (e.g., telephone, mail/paper, electronic), with eight requiring less than 20 minutes to administer and none requiring specialized training for administration. Longitudinal assessment, including the ability to estimate pre-illness status, was available for eight measures. Five measures were publicly available without a fee.

COMS Additional Measures

Twenty additional measures achieved consensus for inclusion in the COMS (Table 1). These measures included instruments that focus on younger-age cohorts (e.g., Brief Infant Toddler Social Emotional Assessment (BITSEA), Ages and Stages Questionnaire (ASQ)) or more specific populations such as children with a narrower developmental capacity (e.g., Bayley Scales of Infant and Toddler Development). The additional measures also include instruments that evaluate a more specific component of a COS domain (e.g., Child Post-Traumatic Stress Reaction Index (CPTS-RI), Multidimensional Anxiety Scale for Children (MASC), Children's Sleep Habits Questionnaire (CSHQ)).

Application

Overall, the COMS is a tool to facilitate evaluation of the COS domains. The ten general instruments are applicable to a heterogeneous PICU cohort and are likely feasible across a wide range of study designs and locations. Clinicians and researchers can select instruments from this group to evaluate the COS domains in the general PICU population. The twenty additional instruments provide clinicians and researchers with measures that may be more

applicable to focused populations or subdomains of interest, allowing more specific or in-depth analysis of particular populations or outcomes. SDC Tables 7–12 provide detailed characteristics for the general and additional measures.

Discussion

The heterogeneity of PICU survivorship research necessitates a consensus approach to prioritizing outcome domains and measures for clinical and research programs. The PICU COMS provides a robust resource for evaluating long-term outcomes, facilitating its application in PICU survivorship research and clinical care [13]. Moreover, the PICU COMS was designed as an accessible resource by providing measures which may be used in outcomes evaluation that are broadly applicable to the PICU population and feasible to use, while also allowing for flexibility based on study design, target population, and focused nature of the evaluation to limit the burden on clinicians, researchers, patients, and families. The PICU COMS builds upon the PICS-p conceptual framework and the PICU COS, providing recommendations for instruments to consistently measure the multidimensional impact of critical illness on children and their families after hospital discharge. The COMS highlights the importance of considering long-term family outcomes and the process of social re-integration, resonating with the unique aspects of the conceptual framework for PICS-p that are distinct from adult PICS [7]. Together, a multistakeholder-informed PICU COS and COMS will advance the understanding of long-term outcomes after pediatric critical illness, with the goal of identifying interventions to improve patient- and family-centered outcomes.

The characteristics of the recommended measures can inform selection of measures for future studies. The PICU COMS highlights the applicability, feasibility, and psychometric properties of included measures. In doing so, the COMS substantiates that many of the measures can be consistently employed across studies without imposing an undue burden on researchers, patients, or families. Similarly, the characteristics of the additional measures may facilitate incorporation of supplemental evaluations based on a project's specific goals. Thus, the PICU COMS serves as a vetted repository of information and is a valuable resource for clinicians and researchers without prior experience assessing long-term outcomes. The COMS also delineates the gaps in existing instruments (e.g., age range, applicability to varying developmental capacities, feasibility of administration) that uniquely apply to the PICU survivor and family, highlighting areas for future measure development.

The PICU COMS underscores two distinct aspects of PICS-p and pediatric longitudinal outcomes. First, children who survive critical illness must be considered within the context of their families [27]. For example, the emotional and financial health of the child's caregivers has downstream consequences for the child's health and emotional well-being, including access to resources and services. The PICU COS and COMS encourage clinicians and researchers to simultaneously evaluate the impact of critical illness on children and their families, recognizing their interdependence. Second, the process of social reintegration after critical illness has challenges that span the child's cognitive, emotional, overall, and physical health as well as the family's health. Although the social domain was not specifically delineated in the PICU COS, the Expert Panel included the social domain in the PICU

COMS due to its interconnectedness with other domains and to emphasize the importance of measuring social reintegration and context, including home, school, work, and community settings. Optimizing social reintegration may facilitate long-term recovery of critically ill children and their families.

A strength of this work is that the PICU COS and COMS were developed by an interdisciplinary and multistakeholder collaboration between two of the largest research groups in PCCM including international experts. This collaboration involved 104 investigators, emphasizing the increased recognition of long-term morbidity among PICU survivors [4]. The Expert Panel was assembled from a diverse group of clinicians and researchers to facilitate discussion of the applicability and feasibility of measures in different cultural, linguistic, and socioeconomic settings. The dissemination and use of the PICU COS has been supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and the designation of recommended outcome measures in the COMS provides clinicians and researchers with a practical approach for COS implementation. [28]

Our study has important limitations. The scoping review from which we derived the preliminary COMS included studies primarily from the U.S., and most of the scoping review investigative team was also from the U.S. However, for the Expert Panel, the Steering Committee deliberately recruited international members including representation from a low-middle income country, allowing for an enriched discussion regarding measure applicability and feasibility across diverse settings. The scoping review did not include studies after 2017 and selection of the most frequently used instruments may reflect publication bias. To address these biases, the Steering Committee encouraged the investigators to submit “write-in” measures, and 25 were discussed. We also considered measures newly published in the last ten years of the scoping review. The investigators evaluated measures based on publicly available information and their own expertise. Measures for which this information was not publicly available were less likely to be considered. Periodic updating of the COMS will be essential to address these potential biases. The COMS was intentionally designed to be non-restrictive, providing measures that can be used consistently across studies, and did not proscribe specific timing of assessments. Future iterations may consider providing guidance for measurement intervals. Although rigorous evaluation of each instrument was not within our scope, more in-depth analysis of candidate measures for the COMS was provided in the scoping review and domain-specific manuscripts [8, 29, 30]. Additionally, the Expert Panel intentionally included pediatric neuropsychologists with expertise in the psychometric properties and evaluation of instruments. Finally, while the COMS was derived from the COS, which included family stakeholders, the Expert Panel did not solicit family input regarding feasibility or acceptability of the measures. Assessing time burden of these measures in updates to the COMS will further inform our ability to select family-centered outcome measures for future studies.

Conclusions

Widespread implementation of the PICU COMS into clinical and research programs will facilitate implementation of the PICU COS to better characterize PICU survivorship. An

improved understanding of recovery from pediatric critical illness will enable development and assessment of targeted interventions including post-PICU clinical follow-up programs to improve long-term outcomes of children who survive critical illness.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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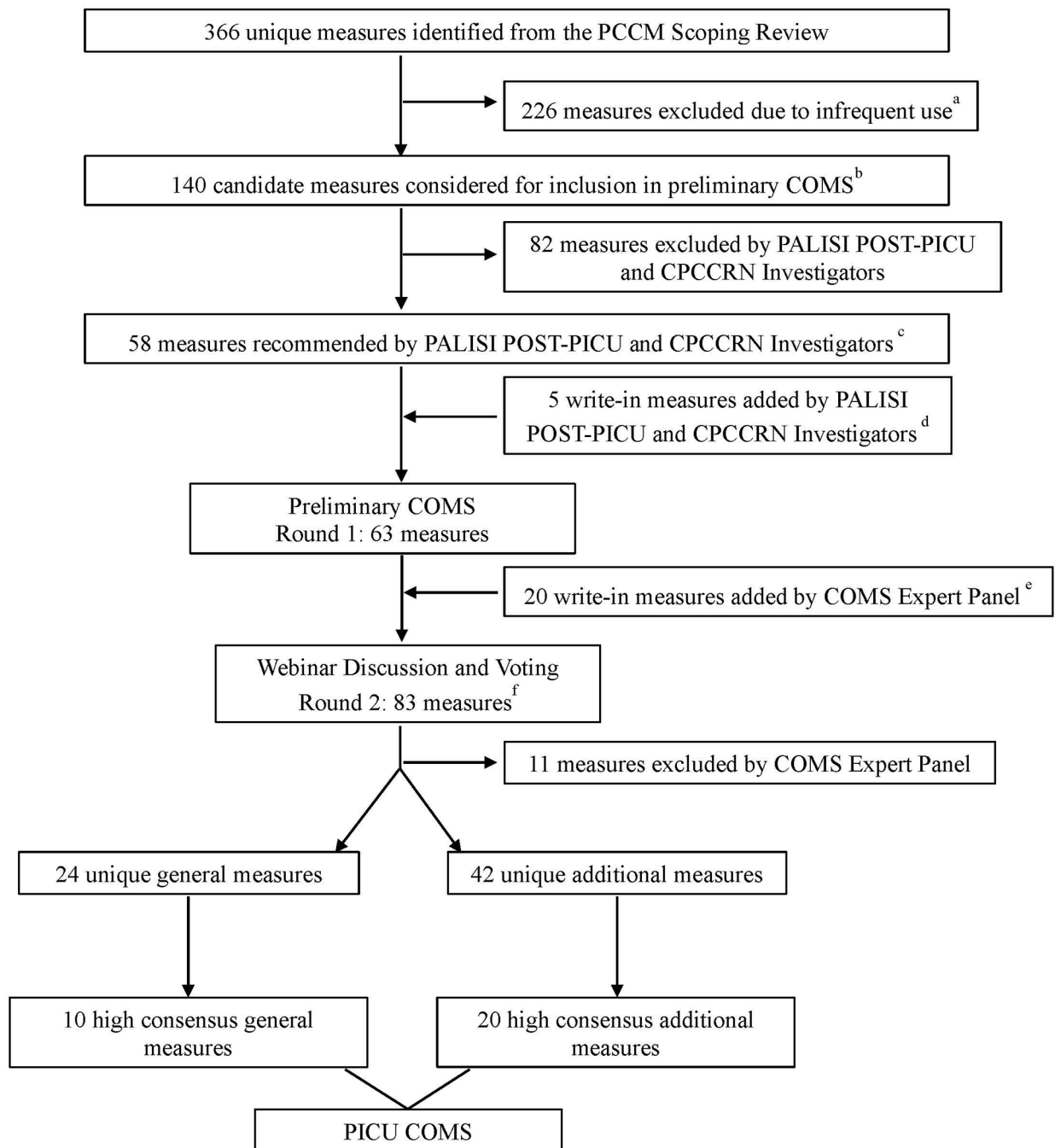


Figure 1: Core Outcome Measurement Set Instrument Selection

^aMeasures which had their first use in publications of the scoping review in the final 10 years of the inclusion dates (2007–2017) were not excluded as these instruments may not have had time to reach a sufficient publication threshold

^bThe 140 candidate measures included 31 cognitive, 23 emotional, 26 overall health/HRQL, 17 physical, 24 family, and 19 social measures.

^c The 58 recommended measures included 9 cognitive, 16 emotional, 10 overall health/HRQL, 7 physical, 11 family, and 5 social measures.

^d The 5 write-in measures included 2 emotional and 3 family measures.

^e The 20 write-in measures included 8 cognitive, 8 overall health/HRQL, 1 family, and 3 social measures

^f Measures that evaluated more than one domain had a round of voting for each applicable domain. Thus, there were more rounds of voting than unique measures.

PCCM: pediatric critical care medicine; COMS: core outcomes measurement set; PALISI POST-PICU: Pediatric acute lung injury and sepsis investigators Pediatric Outcomes Studies after Pediatric Intensive Care Unit; CPCCRN: Collaborate Pediatric Critical Care Research Network.

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Post Intensive Care Syndrome - Pediatrics (PICS-p)

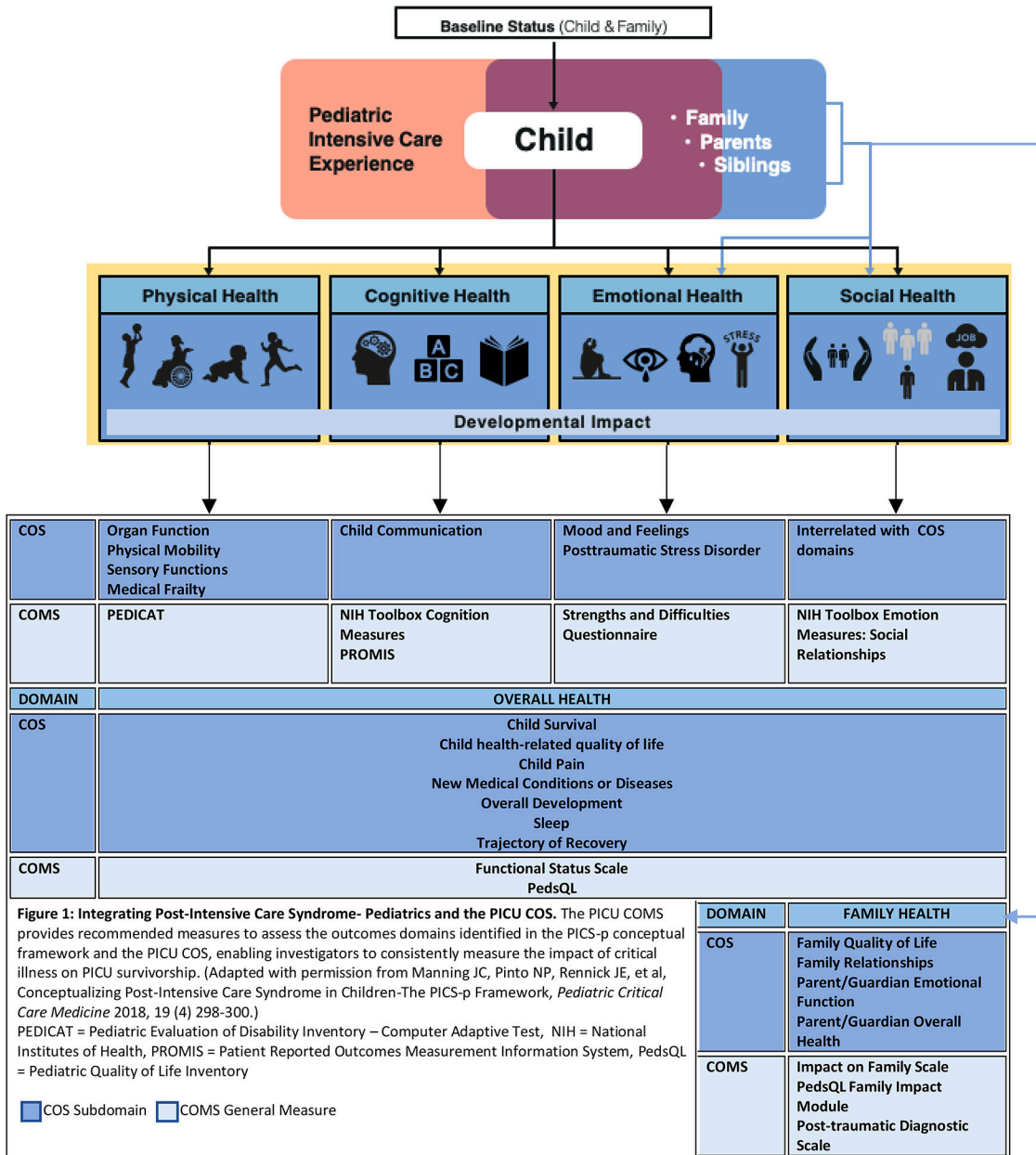


Figure 2: Integrating PICS-p, the PICU COS, and PICU COMS

The Pediatric Intensive Care Unit (PICU) Core Outcome Measures Set (COMS) provides recommended measures to assess the outcomes domains identified in the Post-Intensive Care Syndrome-pediatrics (PICS-p) conceptual framework and the PICU Core Outcome Set (COS), enabling investigators to consistently measure the impact of critical illness on PICU survivorship. (Adapted with permission from Manning JC, Pinto NP, Rennick JE, et al, Conceptualizing Post-Intensive Care Syndrome in Children-The PICS-p Framework, *Pediatric Critical Care Medicine* 2018, 19 (4) 298–300.)

PEDICAT = Pediatric Evaluation of Disability Inventory – Computer Adaptive Test,
PROMIS = Patient Reported Outcomes Measurement Information System, NIH = National
Institutes of Health, Pediatric Quality of Life Inventory
COS Subdomain COMS General Measure

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Table 1

Core Outcome Measurement Set (COMS)

COMS Category ^a	DOMAIN					
	Cognitive	Emotional	Overall Health and Health Related Quality of Life (HRQL)	Physical	Family	Social
GENERAL	National Institutes of Health (NIH) Toolbox Cognitive Measures Patient Reported Outcomes Measurement Information System (PROMIS); Pediatric Cognitive Function	Strengths and Difficulties Questionnaire (SDQ)	Functional Status Scale (FSS) Pediatric Quality of Life Inventory (PedsQL)	Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT)	Impact on Family Scale Pediatric Quality of Life Inventory Family Impact Module (PedsQL-FIM) Posttraumatic Diagnostic Scale (PDS)	National Institutes of Health (NIH) Toolbox Emotion Measures: Social Relationships
ADDITIONAL	Adaptive Behavior Assessment System (ABAS) Ages and Stages Questionnaire (ASQ) ^b Bayley Scales of Infant and Toddler Development Differential Abilities Scale (DAS)	Behavior Assessment System for Children Behavior and Emotional Screening System (BESS) Brief Infant Toddler Social Emotional Assessment (BITSEA) Child Post-Traumatic Stress Reaction Index (CPTS-RI) Multidimensional Anxiety Scale for Children (MASC) Mayo-Portland Adaptability Inventory (MPAI) Young Child Post Traumatic Stress Disorder (PTSD) Screen	Child and Adolescent Scale of Participation (CASP) Children’s Sleep Habits Questionnaire (CSHQ) ^b EQ-5D Youth (EQ-5D-Y) KINDL TNO AZL for Preschool Children’s Health-Related Quality of Life and Children’s Health-Related Quality of Life (TNO AZL)	Visual Motor Integration Test Children’s Sleep Habits Questionnaire(CSHQ) ^b	Impact of Event Scale-Revised (IES-R)/Child Scale (CRIES) The Short Post Traumatic Stress Disorder Rating Interview (SPRINT)	Ages and Stages Questionnaire (ASQ) ^b Vineland Adaptive Behavior Scales (VABS)- Social Domain

^aThe Expert Panel categorized measures as “general” measures for more widely applicable measures and “additional” measures if they were more applicable to specific populations, subdomains, or studies.

^bTwo additional measures achieved high consensus in more than one domain: the Ages and Stages Questionnaire (cognitive and social) and the Children’s Sleep Habits Questionnaire (overall health and physical).

Table 2:

Characteristics of the Core Outcome Measurement Set (COMS) General Measures

Domain	Instrument	Applicability	Validated	Normative Data available	Administration modalities		Longitudinal Assessment
					Time for completion	Training Required Availability/Cost	
Cognitive	NIH Toolbox Cognition Measures	***	**	***	**	**	**
			**	***	**	**	***
Emotional	Patient Reported Outcomes Measurement Information System (PROMIS): Pediatric Cognitive Function	***	**	***	**	***	***
			**	***	***	***	***
Overall Health and HRQL	Strength and Difficulties Questionnaire (SDQ)	***	**	***	***	***	***
			**	***	***	***	***
Physical	Functional Status Scale (FSS)	***	***	***	***	***	***
			***	***	***	***	***
Family	Pediatric Quality of Life Inventory (PedsQL)	***	***	***	***	***	***
			***	***	***	***	***
Social	Pediatric Evaluation of Disability Inventory - Computer Adaptive Test (PEDI-CAT)	***	**	***	**	***	***
			***	***	**	***	***
Family	Impact on Family Scale	NA	***	**	***	***	***
			***	**	**	***	***
Social	Pediatric Quality of Life Inventory Family Impact Module (PedsQL-FIM)	NA	**	***	***	***	***
			**	***	**	***	***
Social	Posttraumatic Diagnostic Scale (PDS)	NA	NA	*	***	***	**
			***	***	***	***	***
Social	NIH Toolbox Emotion Measures: Social Relationships	***	**	***	***	***	***
			***	***	***	***	***

Applicability in 3 characteristics: age, diagnosis/condition, developmental abilities: * = broadly applicable in 1 characteristic; ** = broadly applicable in 2 characteristics; *** = broadly applicable in 3 characteristics

Validated: * = not validated in pediatric patients; ** = validated in pediatric patients but not specifically PICU patients or PICU survivors; *** = validated in PICU patients

Normative Data: * = no normative data available; ** = normative data available for narrow range of pediatric patients; *** = normative data available for broad range of pediatric patients

Administration modalities: * = in person assessment only; ** = 2 potential methods of assessment (mail/paper document, telephone, electronic); *** = 3 potential methods of assessment

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Duration of participant involvement: * = 1 hour or longer; ** = 20 minutes to less than 1 hour; *** = less than 20 minutes

Training for administration: * = educational degree or significant training required for administration; ** = online module or minimal training required; *** = self-administered or no training required to administer

Availability/Cost: * = proprietary; ** = available for a fee; *** = free and publicly available

Longitudinal assessment: * = only able to measure at one time point (either during the hospitalization or after discharge); ** = can measure longitudinally but not able to capture baseline data (e.g., no proxy report available); *** = able to capture baseline and longitudinal data

HRQL: health-related quality of life; NA = not applicable; NIH: National Institutes of Health