A Core Outcome Set for Pediatric Critical Care

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ABSTRACT

Objective
More children are surviving critical illness but are at risk of residual or new health conditions. An evidence-informed and stakeholder-recommended core outcome set is lacking for pediatric critical care outcomes. Our objective was to create a multinational, multi-stakeholder-recommended Pediatric Critical Care Core Outcome Set for inclusion in clinical and research programs.

Design
A 2-round modified Delphi electronic survey was conducted with 333 invited research, clinical, and family/advocate stakeholders. Stakeholders completing the first round were invited to participate in the second. Outcomes scoring > 69% “critical” and < 15% “not important” advanced to round 2 with write-in outcomes considered. The Steering Committee held a virtual consensus conference to determine the final components.

Setting
Multinational survey.

Patients
Stakeholder participants from 6 continents representing clinicians, researchers, and family/advocates.

Main Results
Overall response rates were 75% and 82% for each round. Participants voted on 7 Global Domains and 45 Specific Outcomes in Round 1, and 6 Global Domains and 30 Specific Outcomes in Round 2. Using Overall (3 stakeholder groups combined) results, consensus was defined as outcomes scoring > 90% “critical” and < 15% “not important” and were included in the final PICU COS: 4 Global domains (Cognitive, Emotional, Physical and Overall Health) and 4 Specific outcomes (Child Health-Related Quality of Life, Pain, Survival, and Communication). Families (n=21) suggested additional critically important outcomes that did not meet consensus, which were included in the PICU COS-Extended.

Conclusions
The PICU Core Outcome Set and PICU COS-Extended are multi-stakeholder-recommended resources for clinical and research programs that seek to improve outcomes for children with critical illness and their families.

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Introduction

Approximately 480,000 children and young adults < 20 years old are admitted to pediatric intensive care units (PICUs) annually at a cost of $8 billion in the United States alone. Mortality has decreased to 2-4% in high-resource settings. However, child and family survivorship and recovery are frequently affected by ongoing and/or new impairments in physical, emotional, cognitive, and/or social health functioning, termed Post-Intensive Care Syndrome pediatrics.

The vast majority of pediatric critical care research studies employ short-term (in-hospital) physiologic or mortality outcomes, with few studies assessing outcomes post-hospital discharge. Researchers report that key monetary and resource barriers to carrying out high quality trials include assessment of outcomes post-hospital discharge. Furthermore, heterogeneity in outcome measures and time points selected in studies prohibits systematic review and meta-analysis.

The status quo for PICU outcomes is shifting towards inclusion of outcomes prioritized by providers, patients, and families rather than solely by investigators. Core Outcome Sets (COS), defined as “a patient outcome, health-related condition, or aspects of health that relevant stakeholders agree are essential to assess in all clinical research studies evaluating outcomes”, have been developed and implemented successfully for other critically ill populations, but not for pediatric critical care. Additionally, use of a COS allows for increased ability to compare outcomes across studies and populations and decreases the potential for reporting bias.

Our objective was to develop a multi-stakeholder-informed PICU-COS. The product of this effort is a minimum set of outcome domains that should be incorporated
into clinical and research programs to evaluate outcomes of critically ill children and families.
Materials and Methods

Study Design

We incorporated recommendations for methodology and quality standards for design and reporting for COS\textsuperscript{18-20}. This manuscript reports on the Delphi consensus process yielding the final PICU COS. Additional description of the study protocol\textsuperscript{21} and preliminary aims were published\textsuperscript{6,22,23}. This project was approved by the University of Utah Institutional Review Board.

*Modified, international Delphi consensus – process overview*

**Delphi content.** Investigators created a list of unique Global Domains and Specific Outcomes from a scoping review, qualitative study, and other relevant sources\textsuperscript{13,14,16,24}. Domains and Outcomes were paired with lay definitions that were reviewed by the Collaborative Pediatric Critical Care Research Network (CPCCRN)’s Family Network Collaborative, composed of 1-2 family volunteers from each of the 7 centers. The Steering Committee approved the Domains, Outcomes, and lay definitions. The CPCCRN's Data Coordinating Center prepared the Delphi software.

**Stakeholders and Steering Committee members.** The Steering Committee was recruited by the primary investigators. Candidates were invited with consideration for expertise in PICU Outcomes and diversity in background, region, and gender. All were fluent in English.

The Steering Committee invited 333 participants from three stakeholder groups – Research, Clinical, and Family - via an introductory email. After consenting, stakeholders were asked to respond based on their own perspective, except for those...
who represented an organization. Members of the Steering Committee were included as stakeholders as they represented leaders in pediatric critical care outcomes and families of children with critical illness.

**Modified Delphi Consensus Methods.** We planned for a minimum of two Delphi rounds to reach consensus. Panel members scored components using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Scale, which consists of a 9-point scale: “not important for inclusion” (scores 1-3), “important but not critical for inclusion” (scores 4-6), “critical for inclusion” (scores 7-9), and “unable to score” (score 10)\(^2\). Global Domains and their related Specific Outcomes were randomized into four different orders and randomly assigned to panel members each round. Stakeholders were given approximately 3 weeks to complete each round. Non-respondents received a weekly personalized email, telephone call, or text reminder. Stakeholder response rates were calculated as the number of respondents who completed each round as a proportion of those for whom an email invitation was sent. Those who participated in Round 1 were invited for Round 2.

In Round 1, we recorded demographic information and assigned each consented participant a unique identifier. Respondents could propose novel outcomes. *A priori* criteria for an outcome domain from Round 1 to be included in Round 2 required >70% of responses rating ≥7 AND <15% of response rating <3. The Steering Committee used consensus to confirm the outcomes panel for Round 2. The Steering Committee reviewed new outcome suggestions from Round 1 to ensure they represented a new contribution for inclusion in Round 2.
During Round 2 voting, respondents were provided aggregate responses from the first round for all stakeholders and by stakeholder group, their own response from Round 1, and new outcomes from Round 1. The Steering Committee used consensus to confirm the final COS components taking into account number of domains and importance based on scores by stakeholder group, ultimately as those in Round 2 with >90% of responses rating ≥7 AND <15% of response rating <3.

**Analysis and reporting.** Each outcome’s score was analyzed based on the total number of respondents who answered the question. We report measures of central tendency, score distribution, and score changes by round of PICU COS Global Domains and Specific Outcomes as well as those considered for inclusion.
Results

Steering committee and stakeholders

The Steering Committee consisted of 23 members, including at least two representatives from each of the six continents and a heterogeneous group of clinical and research experts as well as a member from the family stakeholder group (Supplementary Table 1). The Steering Committee recommended a geographically diverse group of participants for each of the stakeholder group members (n=333 total): Research (n=59), Clinical (n=226), and Family (n=48) (Supplementary Table 2). The largest group, clinicians, included nurses, allied health practitioners, palliative care providers, physicians from multiple disciplines (e.g., pediatric critical care, physical medicine and rehabilitation, complex care pediatrics, pediatric surgery, and pulmonology), and others involved in the care of PICU patients during and after hospitalization (e.g., healthcare system and payor administrators). Researchers included authors who had published studies on post-pediatric intensive care outcomes, research coordinators, and funding agency representatives. Family stakeholders included parents, guardians, adults who survived pediatric critical illness, and members of PICU-related advocacy groups. Table 1 describes stakeholder characteristics for those who responded to both rounds. Notably, there were more female respondents for each stakeholder group. Most family respondents were located in North America (81.0%). All stakeholders reported at least some post-secondary education.

Delphi Round 1
The response rate for Round 1 was 251/333 (75.0%) overall and 180/226 (80.0%) for clinicians, 38/59 (63.3%) for researchers, and 33/48 (68.8%) for family stakeholders. The Round 1 survey included 7 Global Domains and 45 Specific Outcomes (Figure 1). No outcomes met criteria for "not important for inclusion" among any stakeholder group (Supplemental Table 3). There was good general agreement in Global Domain scores among the groups (Supplemental Table 4). Family stakeholder group scores were generally higher than other groups for Specific Outcomes, especially for domains related to family function. Six Global Domains (all except Health Care Utilization) and 22 Specific Outcomes met the a priori cutoff of 70% of responses rating ≥7 AND <15% of response rating <3 for inclusion in Round 2. Within Global Domains, 4 of 6 Specific Outcomes from cognitive function, 7 of 10 overall health, 4 of 5 physical function, 2 of 5 emotional health, 3 of 9 family function, 2 of 6 health care utilization, and no social function met this threshold.

The Steering Committee elected to include in Round 2 an additional 4 Specific Outcomes that had an overall score from Round 1 approaching the inclusion threshold (69-69.9%) and were strongly regarded as "critical" by the Family stakeholder group (Sleep, Parent/ Legal Guardian Quality of Life, Child Participation, Hospital/Intensive Care Unit Readmission).

Participants submitted 61 write-ins from Round 1, resulting in 5 new outcomes voted on during Round 2. These included the division of Parent/Legal Guardian Overall Health into 4 Specific Outcomes (Emotional, Physical, Social, and Overall Function) as
well as the addition of a new outcome (New Medical Conditions or Diseases). The remaining write-in responses were either outcome instruments or not new, unique outcomes and were not included. Definitions for some outcomes were modified to clarify criteria (Supplemental Table 5).

Delphi Round 2

The Round 2 survey had a response rate of 206/251 (82.1%): 150/180 (83.3%) for clinicians, 35/38 (92.1%) for researchers, and 21/33 (63.6%) for family/advocacy stakeholder groups. The Round 2 survey included 6 Global Domains and 30 Specific Outcomes. No outcomes met criteria for “not important for inclusion” among any stakeholder group (Supplemental Table 6). Some participants made relatively minor changes to their scores between rounds (Figures 2a and 2b). The Steering Committee approved four Global Domains (Overall, Cognitive, Physical, and Emotional Function) in addition to 4 Specific Outcomes (Child Quality of Life, Survival, Pain, and Communication) that are ultimately included in the final COS (Table 2). Four of 7 Family Function Specific Outcomes met a priori criteria for inclusion, but none met the adjusted criteria (Supplemental Table 7, Supplemental Figures 1a and 1b).

Further, hospital and ICU readmission were among the lowest-scoring outcomes in Round 2. The lowest scoring Specific Outcomes were some of the newly
added family outcomes which had widely disparate scoring among Family, Clinician and Research stakeholders.

Scoring disparities among stakeholder groups were discussed by the Steering Committee via webinar. Ultimately, to recognize Family Stakeholder priorities, the Steering Committee recommended creation of a PICU COS – Extended tool (Table 2, Supplemental Figures 1a and 1b). The PICU COS – Extended includes 14 Specific Outcomes that met the “critical for inclusion” threshold by > 90% Family Stakeholders from the Global Domains Overall Health, and Family, Emotional, and Physical Function.
Discussion

We developed a multinational, multi-stakeholder and evidence informed COS for clinical and research use in pediatric critical illness. Two rounds of a modified Delphi survey led to consensus. A supplemental COS – Extended was also created by the Steering Committee to recognize outcomes important to family members that did not meet consensus.

No guidelines exist for the follow-up of pediatric critical care patients as they do for neonates and infants with congenital heart disease, or adults surviving critical illness. Furthermore, pediatric critical care research programs infrequently include post-discharge outcomes. Finally, the status quo for outcome assessment for clinical care and for research has not yet evolved to include input from stakeholders such as patients and families.

Development of a multi-stakeholder-informed COS to guide clinicians and researchers in choosing post-hospital discharge outcomes in addition to other outcomes vital to clinical and research aims will increase program value and facilitate evidence robustness.
We followed international guidelines for the development of COS including a mixed-methods approach to the generation of outcomes and a multinational and multi-stakeholder Steering Committee and Delphi respondent panel.

The final PICU COS features the Global Outcome Domains of Cognitive, Emotional, and Physical Function and Overall Health. In addition, Specific Outcomes under Cognitive Function (Child Communication), and Overall Health (Child Survival, Health-Related Quality of Life, and Pain) were also included. All three stakeholder groups scored these outcomes as critically important, with some differences in most highly valued outcomes by group, including Global Emotional Function and Communication by Families, and Survival by Researchers and Families. Lasting emotional health effects in children and families affected by pediatric critical illness can be substantial, requiring monitoring and treatment. Survival and pain are frequently assessed within the hospital epoch but not post-hospital discharge despite reports of late pediatric deaths and ongoing pain symptoms reports in adults. Health-related quality of life, a subjective outcome incorporating a proxy/patient’s perception of the interplay of multiple outcome domains, was the highest rated Specific Outcome and is one of the more commonly reported post-discharge outcomes in pediatric critical illness. Cognitive function post-discharge has been overwhelmingly assessed using measures of intelligence, memory, attention, and/or executive function; reports on child communication function are lacking.

Patient and family stakeholders, despite placing generally greater importance on outcomes compared to the other two stakeholder groups, clearly show value.
preferences for certain outcomes compared to clinicians and researchers. Family 
functioning is impacted by pediatric critical illness and can also influence the trajectory 
of recovery and long-term functional outcomes. Further, the scope and depth of 
post-hospital discharge problems with sleep and physical function, and post-traumatic 
stress in both children and parents may go unrecognized by many stakeholders outside 
of the Family group. Hence, we recognized the need for the Extended outcome set to 
promote the outcomes valued by families. Additional goals for inclusion of these 
additional outcomes are to stimulate and support awareness, education, and research 
across the inpatient-outpatient spectrum of stakeholders. Post-PICU follow-up clinics 
are beginning to service this need but more systematic investment is needed.

Implementation of a COS would be facilitated by recommendations for specific 
instruments for each outcome in a Core Outcome Measurement Set. Thus, the next 
task for our Steering Committee is to recommend feasible (e.g., low cost, widely 
available, minimal administration time), reliable, age-appropriate and validated 
measurement instruments along with recommendations for timing of assessments post-
hospital discharge to evaluate outcomes. Some outcomes in the COS may not have 
validated instruments available that meet these criteria and there may be overlap in 
some of the content of outcomes in the COS. These recommendations will require 
frequent reassessment as new information and outcome measures become available.

Finally, the last aim of the PICU COS program is to strategize for broad 
dissemination and implementation of the PICU COS. In addition to creation of a 
Steering Committee and Delphi stakeholders with diverse membership, we registered 
this program on the Core Outcome Measures in Effectiveness Trials’ Initiative (COMET)
website (http://www.comet-initiative.org/Studies/Details/1131). Further, we will publish the PICU COS and PICU COS – Extended on the CPCCRN website (https://www.cpccrn.org/network-projects/) and Pediatric Acute Lung Injury and Sepsis Investigators [PALISI], POST-PICU Investigator sub-group website (https://www.palisi.org/subgroups, in development). We plan to submit abstracts and manuscripts for each program aim and secondary analyses to disseminate academically. We will provide approved fact sheets and infographics to all stakeholders for efficient dissemination to patient advocates and academic groups. We will develop an efficient process to monitor future use of the PICU COS in research proposals, grants, quality improvement initiatives, and publications. We will also lead a social media campaign to disseminate the COS after publication.

**Limitations**

Although we worked to recruit an equitable number of family stakeholders, this group had the smallest representation in the Delphi. Stakeholders had to be fluent to participate in the Delphi. Thus, we may have missed input from families and other stakeholders with importantly different backgrounds and experiences. Similarly, the number and breadth of geographical distribution of representatives of research funding agencies, payors, and hospital administrators was relatively small; overall, stakeholders from North America were over-represented. The PICU COS was created to serve all children with critical illness. However, we recognize that children admitted to PICUs have a diverse range of ages; ethnicities; hospital admission condition, severity, and comorbidities; social determinants of health; family structures; geographical locations;
quality of healthcare resources and access to care; each of which may require an additional personalized approach and evaluation of utility to outcomes selection.

We encourage re-evaluation of the PICU COS content every 5-10 years to improve upon methodology and evolution of best practices for post-discharge outcomes in this rapidly developing field. Finally, we recommend considering the inclusion of patients and families in other aspects of the clinical/research process in addition to outcomes choices.
Conclusions

The PICU COS and PICU COS-Extended are multi-stakeholder-approved resources for clinical and research programs that seek to more systematically study and improve outcomes for children with critical illness and their families.
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Availability of data and material. The dataset supporting the conclusions of this article will be made available in the Eunice Kennedy Shriver National Institute of Child Health
and Human Development Data and Specimen Hub (DASH) repository,
References


Figure Legends

**Figure 1.** PICU Core Outcome Set: Modified Delphi Survey Flow Diagram

**Figures 2a and 2b.** Differences in scores from Round 1 to round 2 by PICU Core Outcome Set stakeholder group.

**Supplemental Figures 1a and 1b.** Delphi Survey Round 2 results by stakeholder group. Results presented as median (interquartile range) with mean identified by open diamonds and outliers identified by open circles.