Title: **COSMIC: a core outcome set for intravenous maintenance fluid therapy trials in children**

Short title: **COSMIC**

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BDW: conceptualization, methodology, investigation, project administration, supervision, writing–original draft, writing–review & editing. VFV: conceptualization, methodology, investigation, project administration, supervision, writing–review & editing. CF, DO, DEL, HK, IS, KP, KMCJ, LJ, LHJ, MHF, MSM, MRM, MC (Claire Morice), MC (Clémence Moullet), NAM, NJ, ÖS, RBL, PJV, RC, SLJ, TH, TK, VSC: investigation, data curation, project administration, writing–review & editing. BAM, HW, RK, LLLH, HAWF, MG, RS, GSJ, FOC, GB, LSW, WJ, AMSD: investigation, data curation, formal analysis, validation, project administration, writing–review & editing. FSJ, MS, MML: investigation, writing–review & editing. TLN: conceptualization, methodology, supervision, writing–original draft, writing–review & editing.

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Declarations

Ethical approval: Our protocol was analyzed by the Research Ethics Committee (CLERS) of the University Hospital of Caen and was approved in April 2024 (ID 5380). This study protocol was deemed to comply with the legal standard applicable in France and with the European regulation on the protection of individuals.

Conflict of interest: No financial or non-financial benefits have been received or will be received from any party related directly or indirectly to the subject of this article. The authors have no conflict of interest to declare.

Data availability: All data that support the findings of this study will be available from the corresponding author upon reasonable request.

COSMIC: a core outcome set for intravenous maintenance fluid therapy trials in children

Abstract

Background: Intravenous maintenance fluid therapy is one of the most common therapies for hospitalized children, yet the field lacks standardized outcomes to evaluate its effectiveness. Although intravenous maintenance fluid therapy has been used for nearly two centuries, existing studies show wide heterogeneity in reported endpoints, limiting the ability to perform meta-analyses and generate robust evidence. No core outcome set specific to pediatric intravenous maintenance fluid therapy currently exists, and previous initiatives have focused narrowly on fluid accumulation rather than the five components of intravenous maintenance fluid therapy prescription. This study aimed to create a comprehensive core outcome set—COSMIC—to standardize outcome reporting across research involving indications, tonicity,

balanced solutions, composition, and volume of intravenous maintenance fluid therapy in children.

Methods: The study followed the core outcome measures in effectiveness trials and core outcome set–standards for development guidelines and was prospectively registered. Four phases were undertaken: a systematic literature review (1960–2023), extraction and classification of all reported intravenous maintenance fluid therapy-related outcomes, a two-round modified Delphi process involving international experts and non-experts, and two online consensus meetings to finalize the cos. Eligible participants included authors of intravenous maintenance fluid therapy publications and healthcare professionals. Outcomes were rated on a 9-point Likert scale, and predefined consensus thresholds determined inclusion or exclusion. Items without consensus were discussed and voted on during the final meetings.

Results: The literature review identified 259 outcomes, of which 104 unique items entered Delphi round 1. Ninety participants completed round 1 and 82 round 2. Participants represented all continents. Four outcomes were deemed essential for all five PICO-based intravenous maintenance fluid therapy questions: 28-day mortality, survival free of organ dysfunction, hospital length of stay, and natremia. Additional outcomes were defined specifically for each of the five intravenous maintenance fluid therapy components, resulting in a structured and globally applicable core outcome set.

Conclusions: COSMIC is the first comprehensive core outcome set to address all core questions related to pediatric intravenous maintenance fluid therapy. It covers the full spectrum of prescription components and includes outcomes feasible across diverse healthcare settings. COSMIC adheres to the standards and provides a practical, internationally relevant framework. Its adoption will harmonize reporting, strengthen future trials, and support meta-analyses, ultimately improving evidence-based intravenous maintenance fluid therapy in children.

Key words: Critical care; Fluid therapy; Health Care; Intravenous; Outcome assessment; Pediatrics

Introduction

Intravenous maintenance fluid therapy (IVMFT) is one of the most commonly prescribed therapies and is considered the standard of care for hospitalised children [1]. IVMFT was first used nearly 200 years ago and has been investigated and discussed in medical literature ever since [2–4]. In 1957, Holliday and Segar proposed the first calculation for fluid volumes and composition in children and their recommendations remained the gold standard until recently [5-7]. A recent systematic review showed large heterogeneity in outcomes used in studies of IVMFT [6]. With many IVMFT studies showing differing results, being able to pool these in a meta-analysis is important. However, the lack of standardisation in outcomes has prevented this for many IVMFT questions [8].

For this reason, a core outcome set can help minimise the heterogeneity of outcomes and their measurement used in future studies on IVMFT [9–11]. A core outcome set is defined as the minimal agreed standardised collection of outcomes that should be measured and reported in all clinical trials [11,12]. A core outcome set proposes the outcomes that must be consistently reported but does not prevent researchers from using or developing other outcomes. Furthermore, a core outcome set use is not limited to clinical trials and is relevant in other types of research and in routine clinical practice [10–12].

No core outcome set has currently been developed for IVMFT trials in children. In 2023, the Pediatric Acute Disease Quality Initiative recommended harmonized terminology for fluid balance and for describing a pathologic state of fluid overload for clinical practice and research [13]. In this, Selewski et al. proposed a set of endpoints, but focused solely on fluid

accumulation or overload, rather than on a full core outcome set for all IVMFT components [13]. Therefore, there was an urgent need to develop a core outcome set which includes all five components of IVMFT: (1) indication for IVMFT; (2) fluid tonicity, defined primarily by sodium concentration; (3) balanced fluid, defined by the partial replacement of chloride with an organic anion; (4) composition, defined as the glucose and other electrolyte content (potassium, calcium, magnesium and phosphorus); and (5) volume, defined as the prescribed amount of fluid [4, 6].

The objective of this study was to develop a core outcome set, untitled COSMIC (core outcome set for IVMFT trials in children), to evaluate the effectiveness of interventions concerning the five components of IVMFT in children. This core outcome set was developed to apply to research studies, especially clinical trials but can also guide patient follow-up in routine practice.

Methods

Protocol entry and ethics

This study was developed in accordance with the recommendations published in the "Core Outcome Measures in Effectiveness Trials" (COMET) handbook [9]. The study protocol followed the core outcome set-standards for development recommendations [14] and was prospectively registered in the COMET database (https://www.comet-initiative.org/Studies/Details/3051, registration number: 3051). The protocol was approved by the Research Ethics Committee of the University Hospital of Caen in April 2024 (ID 5380). The results of this core outcome set development process are reported using the core outcome set–standards for reporting guidelines [15].

COSMIC steering group

The COSMIC study steering group was formed in 2024. Three project leaders (DB, LT and FVV) enlisted a group of members within the Metabolism Endocrinology and Nutrition section of the European Society of Pediatric and Neonatal Intensive Care (ESPNIC). This group comprised medical doctors, nurses and dieticians, and was created following a call for interested candidates. Selection by the project leaders was based on expertise in the methods and experience in the field of pediatric acute and intensive care and research. This work group collaborated with an academic librarian specialized in systematic reviews, a systematic review methodologist, an epidemiologist and a biostatistician specialized in meta-analyses and a pharmacist specialized in pediatric and pediatric intensive care.

Study design

The development of this core outcome set consisted of four phases [11, 12, 14] (Fig. 1): (1) phase 1: systematic review of the literature to identify the relevant studies; (2) phase 2: identification of the reported outcomes; (3) phase 3: development of a preliminary core outcome set using two rounds modified Delphi method; and (4) phase 4: online consensus meetings to discuss and agree on the final IVMFT core outcome set (COSMIC).

Systematic review of literature

For the systematic review, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for systematic review and applied the same procedures as previously described in the 2022 ESPNIC clinical practice guidelines on IVMFT in acute and critically ill children [6, 16]. Inclusion criteria for papers were as follows: (1) all papers published from December 2020 to December 2023; (2) written in English; (3) inclusion of critically ill or acutely ill (in the hospital setting) children aged from 37 weeks' gestational age to 18 years of age; (4) included study designs were randomized controlled trials, cohort studies,

before-and-after studies, case-control studies, and literature reviews. Editorials were sought and their reference lists checked, but they were not included in the data extraction. Animal studies, case studies, conference abstracts and letters were excluded. The search equations were the same as the ones used in the 2022 ESPNIC clinical practice guidelines on IVMFT in acute and critically ill children with the consideration of five Population, Intervention, Control, and Outcome(s) (PICO) structured questions [6]: (1) PICO1—indication: does IVMFT versus other hydration therapies (none, oral or enteral route) impact on clinical outcomes? (2) PICO2—tonicity: do isotonic solutions versus hypotonic solutions (as IVMFT) impact on clinical outcomes? (3) PICO3—balanced fluids: do balanced solutions versus non-balanced solutions (as IVMFT) impact on clinical outcomes? (4) PICO4—composition: does the composition of IVMFT in terms of glucose, electrolytes (phosphorus, magnesium, calcium, potassium), vitamins and trace elements impact on clinical outcomes? And (5) PICO5—amounts: does the use of a restrictive IVMFT volume versus the standard Holliday and Segar calculated volume impact on clinical outcomes? The PICO5 equation was modified with addition of the following key words: "fluid overload", "conservative fluid management", and "protocolized fluid management".

Papers from the search were imported into Rayyan software (Rayyan Systems Inc. Cambridge, Mass, USA; https://new.rayyan.ai/), which access was shared with all the members of the working group for screening by two reviewers independently. If there was a discrepancy a third reviewer was involved and any discrepancies resolved. These were first selected by title and abstract as per inclusion criteria. Second, a similar screening process was applied to full text manuscripts, as previously described [6]. The selected articles were combined with the 56 articles previously extracted from the systematic review of literature, from 1960 to 2020, performed during the elaboration process of the 2022 ESPNIC clinical practice guidelines on IVMFT in acute and critically ill children for the identification of the reported outcomes [6].

Outcomes extraction

Once papers were agreed for inclusion for each PICO, papers were independently analyzed by two group members. Each member extracted: (1) articles' information: study's design, corresponding author's name and mailing address, country in which the study was conducted; (2) all outcomes, as reported in the study: name, units, time points, type of variable. Outcomes were divided into two categories: "independent of the clinical condition under study" or "dependent on the clinical condition under study". Outcomes that were "dependent on the medical condition under study" concerned, for example, the duration of diarrhea in studies of patients with gastroenteritis or the assessment of graft function in studies of kidney transplantation. By definition, an outcome considered "dependent on the medical condition under study" was deemed unsuitable for inclusion in the core outcome set. This classification of the outcomes was carried out during the data extraction process and approved by the steering committee. Consequently, only independent outcomes were considered for the Delphi procedure. Furthermore, outcomes deemed impossible to measure in all international contexts (e.g., costly or highly specialized laboratory tests in low- and middle-income countries) were excluded.

Core outcome set development

After the outcomes were extracted, outcomes that were judged "dependent on the clinical condition under study" were removed. Outcomes that were considered very similar were combined according to the team's evaluation. Finally, the remaining outcomes were listed and classified into seven categories (overall, clinical, biological, organ failure and support, nutrition, adverse events and intervention) according to the COMET taxonomy [17] (Table 1). The consensus process was then undertaken to agree a core outcome set.

Participants

We invited participants to the Delphi study in September 2024. Two types of participants were recruited: experts in the field of IVMFT and non-experts: (1) experts were defined as 1) corresponding authors of a publication included in the review and 2) authors of the 2022 ESPNIC clinical practice guidelines on IVMFT in acute and critically ill children [6]; (2) non-experts were IVMFT prescribers, pharmacists, nurses and dieticians who were not involved in any publication on IVMFT. Non-experts were recruited through several pediatric intensive care unit (PICU) societies: ESPNIC, the Pediatric Acute Lung Injury and Sepsis Investigators, the Australian and New Zealand Intensive Care Society Paediatric Study Group, the Pediatric Acute and Critical Care Medicine Asian Network and the Latin American Pediatric Intensive Care Society. Participants from Africa were recruited through email, and snowball recruitment from colleagues. Recruitment lasted eight weeks.

Consensus process

An online survey was developed using the LimeSurvey® software (Version 3, Limesurvey GmbH. Hamburg, Germany; http:// www. Limesurvey.org) and was hosted on the University of Caen Normandy platform. Participants could save their answers and complete the survey in several stages. However, all outcomes were to be evaluated. Consequently, at the end of each round, incomplete surveys were excluded.

Round 1 took place from November 4th to December 29th, 2024 (eight weeks). Participants were asked to rate 104 outcomes; each outcome was rated in relation to its relevance for each PICO question (each outcome was rated five times). Outcomes were organized by categories (Table 1). Participants were asked to rate outcomes based on their importance for inclusion in the core outcome set, using a 9-point Likert scale, with 1 (not important) to 9 (critical) for inclusion. Outcomes that reached “consensus in” or “consensus out” during the first round were not included in round 2. Participants were allowed to suggest other outcomes they felt to be important that were not included in the survey. The suggested

outcomes were reviewed by the COSMIC Steering Group and were included in round 2 if considered relevant. Reminder emails were sent every two weeks during the round.

Round 2 took place from February 24th to April 20th, 2025 (eight weeks). Participants were asked to rate the remaining outcomes and any newly added outcomes using the same 9-point Likert scale. Outcomes were organized by PICO questions. Results of the round 1 were presented for each outcome.

Consensus definition

"Consensus in" means a consensus that the outcome should be included in the core outcome set. "Consensus in" was defined by an outcome rated from 7 to 9 by ≥ 70% of participants and from 1 to 3 by < 15% of participants. "Consensus out" meant a consensus that the outcome should not be included in the core outcome set. "Consensus out" was defined by an outcome rated from 1 to 3 by ≥ 70% participants and from 7 to 9 by < 15% of the participants [18]. Anything else was considered as a no consensus and was resolved through discussion and re-voting at online meetings.

Consensus meetings

Consensus on the final outcomes to be included in the core outcome set was achieved through two online meetings held on June 3rd and July 08th, 2025, on Zoom (Zoom Communication, San Jose, California, USA). Participants were members of the COSMIC steering committee and volunteers from the participants of both rounds. Based on the results of both rounds, participants at the consensus meetings were asked to vote (include or not) on any items not meeting consensus in or out. Anonymous voting was facilitated by participants using the voting function on Zoom. During the consensus meeting, a more pragmatic approach was considered, and the outcome was included in the core outcome set when voted in by more than 50% of the participants. Prior to the vote, the participants were reminded of the objectives of the core

outcome set, its application and its applicability to all international contexts. Outcomes that were considered very similar or closely related were specifically discussed and combined when considered necessary. At the end of the second online meeting, a core outcome set was agreed for each PICO.

Results

Participants

One hundred and seventy-five healthcare professionals were invited to participate in the Delphi study, of which 90 (51%) participated in round 1, and 82 (47%) in round 2. The participants were most commonly pediatric intensive care consultants [72 (80%)] working in a dedicated PICU [67 (74%)] (Table 2). Participants were representative of all five continents, with the largest proportion [37 (41%)] from Europe and were evenly distributed between experts [42 (47%)] and non-experts [48 (53%)] (Table 2). Thirty (33%) participants took part in the online consensus meetings to generate the final core outcome set.

Outcomes

A total of 4025 abstracts were reviewed (Supplementary Fig. 1) from the literature review from 2020 to 2023, to which were added 56 articles used for the ESPNIC 2022 guidelines [6]. Subsequently, 80 articles published between 1985 and 2023 were included for outcome extraction (Supplementary Fig. 1). After outcome extraction from the literature, 259 outcomes were identified (Fig. 2). According to the steering committee evaluation, 96 outcomes that were considered "dependent on the clinical condition under study" or considered as impossible to measure in all international settings or standardized, were excluded. Of the remaining 163 outcomes, 59 were considered as similar items and combined. A final list of 104 outcomes was

included for each PICO in the Delphi round 1 (Table 1, Supplementary Table 1). After round 1, 47 outcomes achieved "consensus in" in at least one PICO and one reached "consensus out" in one PICO. Twenty-eight additional outcomes were proposed by participants, among which eight were included in the round 2 of the Delphi. At round 2, 16 outcomes reached "consensus in" in at least one PICO and 22 reached "consensus out" in at least one PICO (Supplementary Table 1).

COSMIC

The final list of outcomes in the core outcome set is presented in the Table 3. Four outcomes were considered essential for all the PICOs: (1) 28-day survival or death at 28 days; (2) survival and free of organ dysfunction; (3) length of hospital stay; and (4) natremia. In addition to these four outcomes, 17 outcomes were considered for trials on IVMFT indication, 10 for trials on fluid tonicity, 9 for trials on balanced fluid, 6 for trials on fluid composition and 19 for trials on fluid volume.

Discussion

This is the first study to develop a specific and focussed core outcome set for five different clinical questions around IVMFT in hospitalised children. The results of this can guide future researchers internationally and ensure a more consistent reporting of trial outcomes to generate stronger evidence for IVMFT in children. IVMFT is the most commonly prescribed therapy in daily practice and yet, often remains overlooked [19]. Over two centuries, healthcare professionals have developed, prescribed and studied IVMFT, but have never agreed on optimal outcomes to guide therapy, to assess its impact and to compare the superiority of one IVMFT solution or volume strategy over another [2, 3, 5–7].

In accordance with current guidelines, we have generated COSMIC, a core outcome set for each component of IVMFT prescription. We found four outcomes that were common to all five PICOs related to the five components of IVMFT prescription [6]. We also agreed on specific outcomes relating to different PICO questions. In 2024, Selewski et al. generated a core outcome set related to IVMFT [13]. However, this only focused on fluid assessment, fluid balance, and fluid overload in sick children, it did not address some of the more nuanced clinical questions that clinicians and researchers need to know. Covering all five components of IVMFT prescription, the scope of application of COSMIC is more comprehensive than Selewski et al. Nevertheless, it is interesting to note certain similarities between these two core outcome sets in terms of the outcomes included. Two of the four main outcomes of COSMIC (namely mortality and length of hospital stay) are the same as Selewski's core outcome set, as well as the need for organ support (invasive mechanical ventilation, renal replacement therapy or vasoactive support) or admission to intensive care. Conversely, Selewski et al. included several endpoints that we deemed inappropriate for this core outcome set, either because they cannot be feasibly measured internationally including in low- and middle-income countries settings (health-related quality of life) or because they have little relevance to IVMFT (sepsis). We believe the differences and similarities between these core outcome sets reinforce the relevance and reliability of COSMIC, which is more comprehensive and easier to apply, particularly in resource-limited settings.

This study followed our previously registered study protocol with two exceptions. Firstly, during the systematic review phase, systematic reviews themselves were not excluded after article selection to ensure the completeness of data extraction. Secondly, participants were exclusively healthcare professionals. We did not include patients and caregivers of children who were hospitalized and required IVMFT during their hospital stay, as initially planned. The reasons for this were a lack of funding to pay parents/caregivers for their involvement, language

barriers, the risk of biasing this in favor of English-speaking families only and the time taken to do this would significantly prolong this core outcome set development. Nevertheless, this is a significant limitation of our core outcome set which we acknowledge. In addition, our study has several other limitations. We decided to include only English-language articles in our literature review. In addition, we only re-searched literature after the publication of our 2022 guidelines in which systematic reviews were overlooked [6]. However, considering the number of articles included and the number of outcomes extracted, we are confident that we have identified all important outcomes. Secondly, there is a risk of selection bias in the participants included. We managed to recruit participants from around the world, but despite our best efforts, those from countries with limited resources were underrepresented, particularly those from Africa. Although underrepresented, we were keen to involve healthcare professionals practicing in low- and middle-income countries at every stage of developing this core outcome set, to improve its validity and implementation on an international scale [10]. Conversely, experts in the field of IVMFT may have been overrepresented. The ratio of approximately 1:1 between experts and non-experts is probably not representative of the ratio among healthcare professionals. However, we believe that this overrepresentation of experts may be important in the implementation of the core outcome set. Likewise, PICU professionals were overrepresented. We also acknowledge that conducting the Delphi procedures and meetings in English may have limited the understanding of instructions by non-native English speakers, and our participation rates for these meetings were lower than anticipated and represented participants predominantly from high-income countries (Europe and North America).

Future work is now required to provide more detail around how these outcomes will be measured in terms of timing, frequency and units of measurement. Secondly, exploration of the importance of these outcomes by parents/patients and caregivers is essential going forward, to ensure outcomes are also patient-centered and meaningful to patients and families. However,

this core outcome set does meet the COMET requirements and has been developed robustly and presented in accordance with all standards [9, 10, 12, 14, 15]. Of course, core outcome sets represent the minimum set of outcomes that must be measured and reported in all therapeutic trials [11,12]. Nonetheless, this does not prevent other outcomes deemed relevant from being collected and reported in addition to those included in the core outcome set. Meanwhile, some outcomes may be considered difficult to measure (e.g., cost, cumulative fluid balance, fluid overload), in a pediatric ward setting or in low- and middle-income countries. Yet, all outcomes in the core outcome set were agreed as essential, and researchers should try, where possible, to collect them. This is essential to move the evidence in the field forward. With so many predominantly single center trials undertaken, with varying results, systematic reviews (with meta-analyses) are essential to generate a more accurate understanding of the evidence for IVMFT interventions. The COSMIC core outcome set is reliable and should be disseminated and used in clinical studies aimed at investigating one or more components of IVMFT. Furthermore, in addition to being useful to the scientific community, the COSMIC will be of great help to clinicians faced with fluid management and fluid stewardship keen to implement monitoring tools and procedures guiding IVMFT prescription and de-escalation [20, 21].

In conclusion, in accordance with standards, this study identified COSMIC, a core outcome set intended for use in randomised trials and other studies evaluating any of the five components of IVMFT. The use of COSMIC will standardise the reporting of results and, consequently, improve the synthesis of results and comparison of studies.

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Figure legends

Fig. 1 Timeline of the study. *ESPNIC* European Society of Pediatric and Neonatal Intensive Care, *COS* core outcome set

Fig. 2 Outcomes' flowchart. *COS* core outcome set, *PICU* pediatric intensive care unit

1 Classified outcomes included in the round one of the Delphi procedure

area	Outcome domain	Outcomes
	Mortality or survival	28-d survival Death or mortality Survival free of organ dysfunction or sequelae PICU-free survival Ventilation free days Days organ-free support
ılogical or ıl	Blood and lymphatic system	Hemoglobin
	Cardiac outcomes	Heart rate Blood pressure Hypertension[a]
	Endocrine outcomes	ADH levels
	Gastrointestinal	Feeding intolerance (vomiting)[a]
	General outcomes	Weight Organ dysfunction scores (PELOD/MODS) SOFA score Mortality score (PIM 3 or PRISM) Dehydration[a] Generalized oedema[a] Fluid overload[a]
	Infection and infestation	CRP Infection[a] Nosocomial infection[a]
	Metabolism and nutrition	Natremia Hypernatremia[a] Hyponatremia[a] Osmolarity Chloremia Hyperchloremia[a] Hypochloremia[a] Kalemia Hyperkalemia[a] Hypokalemia[a] Calcemia Hypercalcemia[a] Hypocalcemia[a] Magnesemia Hypermagnesemia[a] Hypomagnesemia[a] Phosphatemia Hyperphosphatemia[a] Hypophosphatemia[a] Glycemia Hyperglycemia[a] Hypoglycemia[a] pH Acidosis[a] Alkalosis[a] Bicarbonate Base excess Lactate Anion gap Ketone level Calorie intake Protein intake Respiratory quotient
	Nervous system	Glasgow Coma score Seizures
	Renal and urinary	Serum creatinine Serum urea Azotemia Urine output Urine creatinine Urine excretion of chlore

Classification based on Dodd et al. [17]. *PICU* pediatric intensive care unit, *ADH* anti-diuretic hormone, *PELOD* pediatric logistic organ dysfunction, *MODS* multiple organ dysfunction score, *PIM* pediatric index of mortality, *PRISM* pediatric risk of mortality, *CRP* C-reactive protein, *NG* nasogastric, *OG* orogastric, *IV* intravenous. [a]Adverse events

Variables	Non-experts	Experts
n (%)	48 (53)	42 (47)
Continent, *n* (%)		
Africa	2 (4)	3 (7)
America	15 (31)	11 (26)
North	9 (19)	4 (10)
South	6 (12)	7 (17)
Asia	15 (31)	3 (7)
Europe	16 (33)	21 (50)
Oceania	0 (0)	4 (10)
Type of unit, *n* (%)		
Dedicated PICU	37 (77)	30 (71)
Mixed NICU and PICU	7 (15)	7 (17)
Mixed ICU and PICU	1 (2)	0 (0)
Dedicated NICU	1 (2)	0 (0)
Dedicated pediatric intermediate care unit	1 (2)	1 (2)
Mixed neonatal and pediatric intermediate care unit	0 (0)	0 (0)
Mixed adult and pediatric intermediate care unit	0 (0)	2 (5)
Dedicated PECU	1 (2)	1 (2)
Other	0 (0)	1 (2)
Profession, *n* (%)		
Pediatric intensivist physician	42 (88)	30 (71)
Pediatrician	2 (4)	7 (17)
Anesthetist	1 (2)	2 (5)
Dietician	0 (0)	2 (5)
Nurse	2 (4)	1 (2)
Pharmacist	1 (2)	0 (0)

Table 2 Characteristics of the participants

PICU pediatric intensive care unit, *NICU* neonatal intensive care unit, *PECU* pediatric emergency care unit

Table 3 Selected outcomes following the Delphi procedure and after the online-meetings

Variables	Indication	Tonicity	Balanced fluid	Composition	Volume
Overall outcomes					
28-d survival/death at 28 d	✓	✓	✓	✓	✓
Survival free of organ dysfunction or sequelae	✓	✓	✓	✓	✓
Length of hospital stay	✓	✓	✓	✓	✓
Natremia	✓	✓	✓	✓	✓
Admission in the pediatric intensive care unit	✓	✓	✓		✓
Cost	✓				
Clinical outcomes					
Hemodynamic clinical data					✓
Urine output	✓	✓	✓		✓
Biological outcomes (plasma)					
Osmolarity		✓			
Chloremia		✓	✓		
Kalemia				✓	
Calcemia				✓	
Phosphoremia				✓	
Magnesemia				✓	
Glycemia				✓	✓
pH			✓		
Bicarbonate			✓		
Organ failure or organ support outcomes					
Acute Kidney Injury (development of)	✓	✓	✓		✓
Renal replacement therapy (requirement for)			✓		✓
Invasive ventilation (requirement for)					✓
Length of Invasive ventilation					✓
Vasoactive agents (requirement for)					✓
Nutrition outcomes					
Calorie intake	✓				
Time to initiate feeds (enteral or oral)	✓				
Time to oral feeding	✓				
Feeding intolerance (vomiting)	✓				
Adverse events outcomes					
Dehydration (clinical signs)	✓	✓			✓
Pulmonary oedema (documented)					✓
Generalised oedema					✓
Weight gain	✓				✓
Seizures or hyponatraemic encephalopathy		✓			
Local intravenous site complications	✓				
Intervention outcomes					
Cumulative fluid volume received	✓	✓	✓		✓
Cumulative fluid balance or fluid overload	✓	✓	✓		✓
Need for diuretics	✓	✓			✓
Need for extra-electrolyte additions				✓	
Duration of intravenous maintenance fluid therapy	✓				✓
Fluid boluses required	✓				✓

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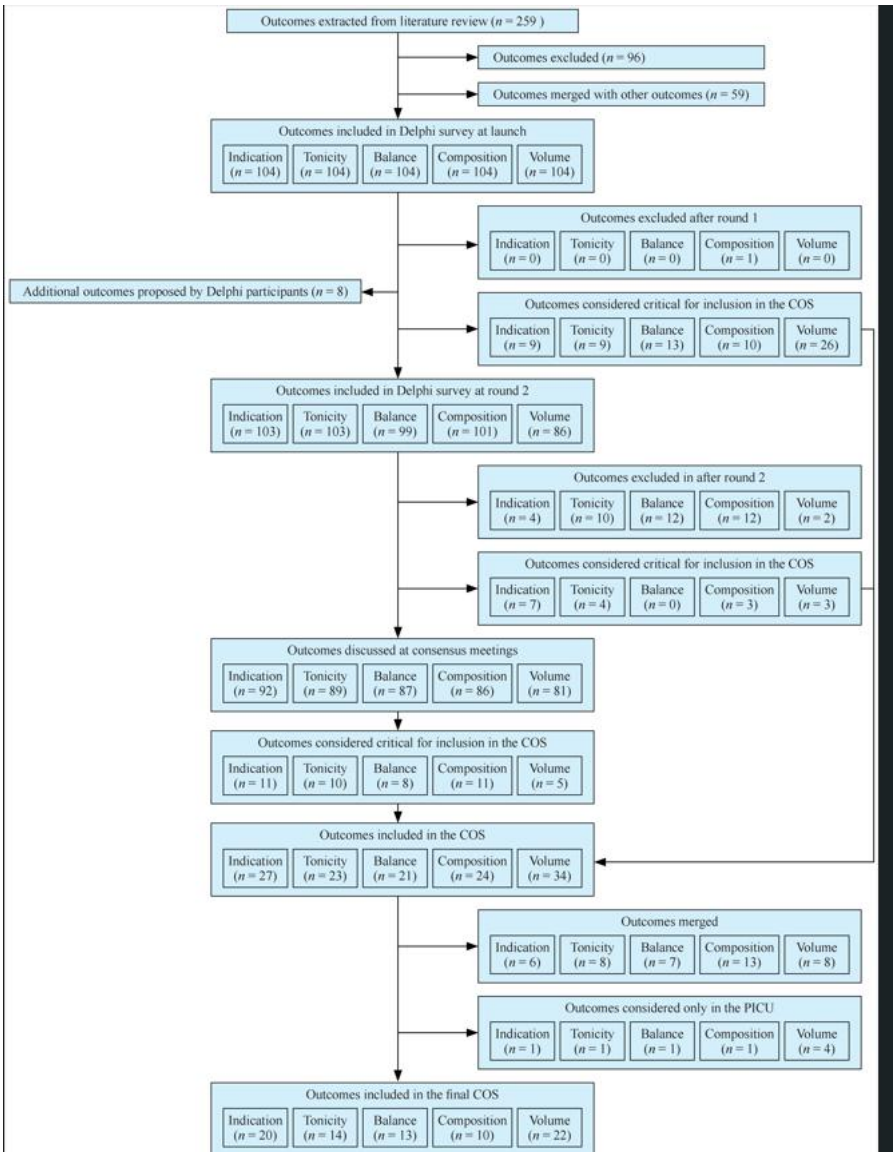
1 Figure 2



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