Delphi study protocol

Version 2.0

13th April 2023

Core outcome set of daily monitoring of GI function

COSMOGI Investigators

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Introduction

Gastrointestinal (GI) dysfunction is a common occurrence in critically ill patients and has been associated with negative clinical outcomes [1, 2]. The range of definitions for GI symptoms in the critically ill varies widely and current approaches to monitoring GI dysfunction in critically ill patients are limited [3, 4]. No single symptom correlates with mortality, but an increasing number of symptoms strengthens the association with poor outcomes [2]. Clinical assessment of GI dysfunction is prone to subjectivity and a standardized approach is lacking [5]. Currently, different definitions of GI symptoms are used in research and standardizing the reporting of these symptoms has been identified as a research topic that needs addressing [6].

A recent scoring system, the Gastrointestinal Dysfunction Score (GIDS) for critically ill patients, defined a scoring grade ranging from 0 to 4 that allows assessment of GI dysfunction in critically ill patients [7]. The score implemented symptoms, examination features, interventions and complications, including absent bowel sounds or vomiting, measurements of gastric residual volume (GRV) and intraabdominal pressure (IAH), use of prokinetics, and presence of bleeding or mesenteric ischemia. This study aimed to assess the contribution of a broad spectrum of clinical manifestations of GI dysfunction to outcome, while a broad consensus on standardized features of the GI function/dysfunction that should be monitored on a daily basis is still lacking [7].

A recent systematic review structured the monitoring of GI dysfunction into 6 topics: abdominal signs and symptoms assessable at the bedside, estimates of gastric emptying, monitoring of intestinal motility, imaging techniques such as ultrasound or computerised tomography (CT), measures of perfusion and biomarkers [6]. To facilitate comparison between studies there is a need to reach a consensus about the minimum core outcome set (COS) of daily monitoring of GI function. We intend to conduct a modified Delphi consensus process in order to determine such a core set that should be reported in future clinical trials. This project is registered with the COMET (Core Outcome Measures in Effectiveness Trials) initiative (https://www.comet-initiative.org/Studies/Details/2609).

Research Question

What is the core outcome set for daily monitoring of GI function that should be reported in clinical trials assessing GI dysfunction or enteral nutrition in critically ill patients?

Objectives

Performing a modified Delphi consensus process which identifies a core set of daily monitoring of GI function that should be reported in clinical trials assessing GI dysfunction or conducting nutritional research in critically ill patients.

Context for use and scope of core outcome set

Condition: Critical illness

Population: Age over 18 years old and admitted to an intensive care unit (ICU)

Intervention: Prospective studies on GI dysfunction or enteral nutrition in critically ill patients.

Context for use: Implementation in all research trials and clinical studies assessing GI dysfunction or enteral nutrition in critically ill patients.

Methods

Stakeholders

Participants will consist of representatives from three categories: clinical researchers, ICU survivors and caregivers as well as healthcare professionals. We intend to gather a large panel of national and international professional society organisations, identified using the existing critical care networks.

Clinical researchers and healthcare professionals: recruitment through but not limited to ESICM (European Society of Intensive Care Medicine), ESPEN (European society of Clinical Nutrition and Metabolism), ASPEN (American Society of Parenteral and Enteral Nutrition), ANZICS (Australia and New Zealand Intensive Care Society), BDA (British Dietetic Association), Intensive Care Society (ICS) Research group.

ICU survivors and caregivers: recruitment through but not limited to patient and public involvement groups, patient support groups and personal contacts.

Recruitment

We will invite members of each stakeholder group to participate in the Delphi process through email. The email will contain information about the project and illustrate a timeline. Conduction will be performed entirely online, and each participant will be assigned a unique identifier. Consent will be implied at the beginning of the process through participation and participants may withdraw at any point during the process. Data will be used as stated in the invitation email and consent, unless active withdrawal occurs, will be inferred throughout the rest of the Delphi consensus process. Data will not be able to be removed if active withdrawal occurs after data analysis. Responses will not be used in any way that allows the identification of a participant.

Participants will be asked to vote based on their opinion rather than the organisation they are representing. Participants should not share information about the ongoing process or discuss it with other members outside of the consensus process. Participants will be listed as part of the Delphi panel at the end of the process.

Literature and sources of information

A recent systematic review, published in 2020, has identified 6 topics of monitoring and provides systematically identified literature [6]. The results of this review will be used to provide initial core domains and outcomes. We will conduct an additional systematic search based on the same protocol to include relevant literature that was published beyond November 2019. For this systematic review, we will use the previously published search terms. The outcome list, e.g. outcomes that may be monitored daily, will be refined based on additional literature relevant to the topic.

Identified monitoring will be reduced to a standard taxonomy for COS development [8].

Delphi Consensus Process

The process will provide a COS of daily monitoring of GI function. The list will be divided into essential, recommended and suggested outcomes. All survey rounds will be delivered electronically using DelphiManager software (COMET Initiative, University of Liverpool, UK). Consensus will be reached via a two-stage process with each stage containing two to three rounds, and a final consensus meeting similar to previous studies [9].

In Stage 1, participants will score each suggested outcome according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) scale. This scale ranges from 1 to 9 in terms of importance for inclusion. (1-3, not important for inclusion; 4-6, important but not critical; 7-9, critical to include). In Stage 2, participants score each definition according to the above GRADE scale. Criteria for 'essential' inclusion is a 'critical-to-include' rating of 7-9 in ≥70% of all responses and ≤15% of all responses rating the definition as 'not important' (i.e., score ≤3). Criteria for 'recommended' inclusion for both outcomes and definitions is a 'critical-to-include' rating of 7-9 in ≥60% of all responses and ≤15% of all responses rating the outcome or definition as 'not important' (i.e., score ≤3). Outcomes and definitions will receive a 'suggested' recommendation if a 'critical-to-include' rating of 7-9 in ≥50% of all responses and a 'not important' rating (i.e., score ≤3) in ≤15% of all responses is achieved. Criteria for exclusion will be ≥15% of all responses rating the outcome or definition as 'not important' (i.e., score ≤3). Following the Delphi process, there will be a consensus meeting to ratify the final COS contents or undertake any additional voting, e.g., in the event that the number of outcomes reaching consensus for inclusion in the COS is perceived to be too many. If additional voting is required, the criteria for consensus is ≥70% of participants at the consensus meeting voting in favour. If changes to the a priori consensus methodology were considered essential, for example, to ensure the feasibility of the COS, then these would be voted on at the consensus meeting and are only applied if a ≥70% in favour voting can be reached.

Stage 1

Domains will represent all GI functions and will be pre-specified through the steering committee. Additional domains may be suggested by members of the steering committee and the final list will be agreed based on consensus at the steering committee meeting.

Round 1: The steering committee will enter outcomes extracted from the data sources into the Delphi round. The outcome order is randomized. Each outcome will be mapped to a domain.

Participants will rate each outcome without considering the definition of the outcome. The opportunity to comment on existing or suggest new outcomes will be provided during this round.

The project team will review all additionally suggested outcomes to ensure they provide a novel contribution to the next Delphi round. An explanatory document will be provided for each outcome with a brief discussion of feasibility, impact on patient care, cost, accuracy and any relevant literature.

Round 2: Scores for each outcome will be distributed to the participants and the average score, summarized by stakeholders, will be presented. Participants will then re-evaluate each outcome, including any new outcomes that were added to the round.

An additional round 3 may be held if $\geq$ 70% of responses from at least one stakeholder group rated $\geq$ 7 for a newly suggested outcome during round 2. The steering committee will review the Stage 1 results and ratify the findings through an online conference. If any issues are raised, the committee will consider the views of all participants. If changes to the original methodology or consensus criteria are necessary, additional voting will be required. Consensus on proposed changes requires more than 70% of participants at the consensus meeting to vote in favour.

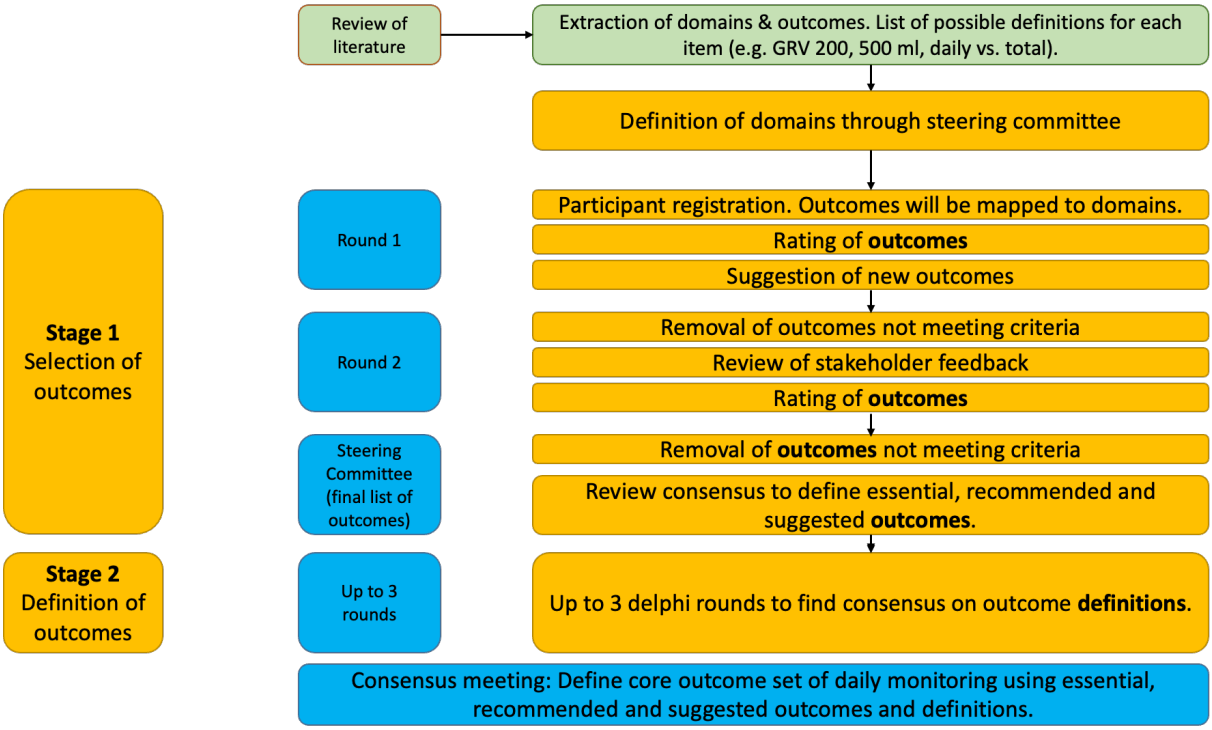
Stage 2

In Stage 2, outcome definitions will be defined. All outcomes reaching consensus for 'essential', 'recommended' and 'suggested' inclusion will be entered into Stage 2. Patient representatives will not participate in Stage 2 due to the clinical nature of a monitoring set. For each outcome, a list of possible definitions (extracted from the literature and above sources) will be provided and entered in randomized order into the Delphi rounds. A similar two-round consensus process with a steering committee meeting at the end will be used for the definitions as outlined above for outcomes.

Consensus Meeting

An online consensus meeting will be held to ratify the final COS contents or undertake any additional voting if required. The findings of the consensus process will be reviewed by the Steering Committee to determine the structure, format, and content of the Consensus meeting. All study participants will be invited to the consensus meeting, and we would ensure representation from each stakeholder group.

Workflow



Data analysis

Demographics and characteristics of participants will be presented. A summary of participants of each round will be presented, including the proportion of involved stakeholders. Each outcome and definition will be analysed based on the total number of participants voting in each round. Descriptive statistics will summarize and analyse the data. In each round, data are excluded if the survey was not completed in full.

Ethical approval

National guidelines will be adhered to, and ethical approval will be acquired prior to commencing the study, if necessary.

Dissemination of results

Results of this study will be submitted to a peer reviewed scientific journal. Presentation at national and international conferences as well as dissemination within professional organisations will help to distribute the results and ensure future implementation. All participants will receive the final version of the published manuscript.

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Conflicts of interests: ARB has received speaker or consultancy fees from Nestlé, Fresenius, Nutricia Danone and VIPUN Medical. The FREM section and its members have published on gastrointestinal dysfunction in critical illness.

Funding: No specific funding was received for this project.