University Hospital Southampton
NHS Foundation Trust

Core outcome set of daily monitoring of gastrointestinal function (COSMOGI)

Online Delphi Survey

Participant information sheet for Professionals
Version 1.2
27th April 2023

You are being invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.
Thank you for reading this.

Background and rationale

Gastrointestinal (GI) dysfunction is a common occurrence in critically ill patients. Research in that field has gained interest over the last decade and the gastrointestinal organ is recognized as an important system in critically ill patients and GI failure has a major impact on patient outcome. Studies that assess gastrointestinal function in critically ill patients currently report different monitoring data using varying definitions and timepoints. Comparison across different studies is made difficult by this heterogeneity.

A solution to this problem is to establish a 'core outcome set' (COS). A COS is a collection of outcomes that ***should be measured as a minimum*** standard in every trial that focuses on a particular area. Establishing a COS is best undertaken using a Delphi Study. A Delphi study is used to get expert consensus on a topic using sequential rounds of questionnaires, whereby anonymised feedback of the responses from the previous round is provided, prompting reflection and gradually consensus evolves.

What is the purpose of the study?

The purpose of this study is to reach consensus on:

(1) the core outcome measures that should be reported daily in trials assessing gastrointestinal function or nutrition in critically ill patients.

(2) the definitions of these outcomes.

Invitation to participate in the study

To reach a valid consensus we have invited key stakeholders including clinical researchers, healthcare professionals and ICU patients/caregivers who have expressed an interest to participate, and who have relevant clinical or research experience in critical care settings.

What does my participation involve?

Participation involves completing four to six questionnaires in two stages. You will receive a link to the questionnaire in your email. Each questionnaire will take around 10 to 15 minutes to complete. Completing the online survey implies that you provide your consent to participate. You can contact the lead researcher (Dr Kaspar Bachmann) via email or phone if you have any queries or difficulties completing any aspect of the online survey. The details are at the end of this information sheet.

Do I have to participate?

No, you may withdraw at any time without explanation. This study has a better chance of success if you answer both questionnaires, therefore we ask you not to participate if you feel you cannot complete all the questionnaires. You can also take part in the survey but decline to take part in a follow up meeting that is planned as part of this study. Only a small portion of participants will be required to attend a follow up meeting. If you are invited to this meeting, you are under no obligation to attend.

What does the study involve?

Stage 1

First questionnaire – What outcomes should we measure daily?

The questionnaire will contain a list of possible daily outcomes (e.g. measurements) of gastrointestinal function in ICU patients. Each of these outcomes will be categorized

into at least one specific domain of gastrointestinal function. These domains are presented at the end of this document. We will ask you to score how important each item is on a scale of 1-9, and to complete and return the questionnaire within a week of receiving it via email. There will be an opportunity to add any additional measurements you feel should be included in the core set and that do not appear on the list provided.

Second questionnaire

This questionnaire will show the same list of outcomes, and a summary of how the other participants scored them in the first questionnaire so you can see which items were considered more or less important by the other participants. Again, you will be asked to score each item depending on how important you think it is. If new items were suggested there may be a third questionnaire to score these.

Stage 2

How should we define these outcomes?

Stage 1 will identify the core outcomes that should be measured and reported on a daily basis. In stage 2, we will try to find consensus on the specific definitions of these outcomes. We expect that we will not find consensus on all specific definitions, but this is also an important result that we will report transparently.

Similar to stage 1, there will be two questionnaires providing possible definitions for each core outcome, identified through a systematic literature review. We will be asked to rate each definition on how important you think it is. Each outcome and its definition will be ratified at the end of the study in a consensus meeting, where you will be invited to participate.

Who has reviewed this study?

This study was reviewed and is endorsed by the ESICM research committee. It has been presented and ratified by the Feeding, Rehabilitation, Endocrinology & Metabolism (FREM) section of the ESICM. No ethical approval is needed for this study.

Will my taking part be kept confidential?

Before starting Round 1, we will ask you to provide information about yourself; your name, geographic location, and profession. Your name will not be associated with your responses in the questionnaire feedback and will not be attributed to your responses in any report or publication. However, we would like to acknowledge your participation in the study in the final publication. At the end of the questionnaire, we will ask if you would like to be acknowledged. This will appear in an acknowledgement list.

We will give your questionnaire a unique study number. All questionnaires will be stored securely under the Data Protection Act 2018 and as stipulated by the Trust regulations.

What are the possible risks or disadvantages of taking part?

The only possible disadvantage to taking part in this study is that we will have your name and email contact address. However, this information will be kept separate in a separate folder from all research data generated during the online survey and will be stored securely on the QMUL server.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study. However, this research project will provide valuable information for critical care researchers and potentially improve the quality of future research studies assessing gastrointestinal function and nutrition in intensive care settings in the future. The results of this project will also better inform clinicians what measurements may be important in assessing gastrointestinal function and how these items are defined. This in turn will benefit future patients in intensive care.

What if something goes wrong?

If you have any concerns about any aspects of the study, you can contact the Primary Investigator, Dr Kaspar Bachmann (Telephone +41 31 664 15 69). Should you remain unhappy and wish to make a formal complaint, you can contact the Research Management Team at University Hospital Southampton NHS Trust (Telephone: 023 8120 4989; Email: researchmanagement@uhs.nhs.uk).

What will happen to the results of the research?

We will disseminate our findings in scientific and medical journals and also present our findings at national and international multi-disciplinary conferences. We will also liaise with representatives from national and international funding agencies and policy-makers to ensure the core set of outcomes decided on in this study will be adopted by future researchers conducting clinical trials in this area. We will provide lay summaries to relevant patient and carer support groups and organisations.

Who is organising and funding the study?

A short version of this study is publicly available at https://www.comet-initiative.org/Studies/Details/2609. This study is being run by an international research team originating from all over the world. There is no specific additional funding for this study.

Contact for further information

If you have any questions or concerns regarding this study please contact us:

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This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection visit the University Hospital Southampton clinical research website: https://clinicalresearch.uhs.nhs.uk/take-part/about-clinical-research.

Thank you for your interest in this study and for taking the time to read through this information sheet.

List of gastrointestinal function domains

Digestion

Outcomes related to digestion of nutrients. Example outcomes in this domain are pain or abdominal distension.

Absorption

Outcomes related to absorption of nutrients. Example outcomes in this domain are diarrhea or paracetamol absorption test.

Upper gastrointestinal motility

Outcomes of upper gastrointestinal tract motility including swallowing and esophageal function. Example outcomes in this domain are gastric residual volume and vomiting.

Lower gastrointestinal motility

Outcomes of lower gastrointestinal tract motility. Example outcomes in this domain are absence of stool passage or response to enteral nutrition.

Mesenteric arterial circulation

Outcomes related to arterial circulation, e.g. the supply of blood to the gut. Example outcomes in this domain are GI bleeding or pain.

Mesenteric venous circulation

Outcomes related to the venous circulation of the gastrointestinal tract, e.g. the venous drainage of blood from the gut. Example outcomes in this domain are esophageal varices bleedings (Hematemesis).

Mesenteric lymphatic circulation

Outcomes related to gastrointestinal lymphatic circulation. Example outcomes are presentation of chyloaszites.

Mesenteric microcirculation and barrier function

Outcomes related to the gastrointestinal mucosa, barrier function and microbiome. Example outcomes are specific biomarkers or signs of inflammation.

Gastrointestinal immunological function

Outcomes related to endocrine function. Example outcomes include specific biomarkers.

Gastrointestinal endocrine function

Outcomes related to endocrine function. Example outcomes include specific biomarkers.

Complex clinical assessment (Clinical scoring systems)

Already existing scoring systems including their specific items / outcomes will be added to the survey.