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Development of an international core outcome set for treatment trials in paediatric inguinal hernia: protocol for a three-phase study including a systematic review and Delphi survey

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ABSTRACT

Introduction In children, open inguinal hernia repair has been the gold standard for treatment, but with recent technical advancements in laparoscopy, laparoscopic hernia repair is gaining popularity. Despite available results from comparative studies, there is still no consensus regarding the superiority of open versus laparoscopic treatment strategy. An important reason for lack of consensus is the large heterogeneity in the trials' reported outcomes and outcome definitions, which limits comparisons between studies and precludes conclusions regarding the superiority of treatment strategies. The development and implementation of a core outcome set (COS) is a solution for this heterogeneity in the selection, measurement and reporting of trial outcome measures across studies. Currently, there is no COS for the treatment of paediatric inguinal hernia.

Methods and analysis The aim of this project is to reach international consensus on a minimal set of outcomes that should be measured and reported in all future clinical trials investigating inguinal hernia repair in children. The development process comprises three phases. First, we identify outcome domains associated with paediatric inguinal hernia repair from a patient perspective and through a systematic review of the literature using EMBASE, MEDLINE and the Cochrane Library databases. Second, we conduct a three-step Delphi study to identify and prioritise 'core' outcomes for the eventual minimal set. In the third phase, an expert meeting is held to establish the final COS and develop implementation strategies with participants from all stakeholder groups: healthcare professionals, parents and patients' representatives. The final COS will be reported in accordance with the COS-Standards for Reporting statement.

Ethics and dissemination The medical research ethics committee of the Amsterdam UMC confirmed that the Dutch Medical Research Involving Human Subjects Act (WMO) does not apply to this study and that full approval by the committee is not required. Electronic informed consent will be obtained from all participants. Results will be presented in peer-reviewed academic journals and at relevant conferences.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is intended to facilitate uptake of the planned core outcome set for inguinal hernia repair, which will enhance outcome data comparison, pooling and subsequent meta-analysis; enable adequate and efficient comparison of treatment strategies; and enhance the interpretation and implementation of clinical trial results.
⇒ This international study will be applicable worldwide due to the inclusion of stakeholders from 25 countries in 5 continents.
⇒ The Delphi questionnaire will only available in English.

INTRODUCTION

The cumulative lifetime incidence of inguinal hernia ranges from 0.8% to 5% in the paediatric population.[1] The only curative treatment for inguinal hernia is surgery, which makes inguinal hernia repair one of the most frequently performed operations in children.[1] Traditionally, open inguinal hernia repair has been the gold standard for treatment, but with recent technical advancements in laparoscopy in young children, laparoscopic inguinal hernia repair is gaining popularity.[2] Laparoscopic repair also allows for contralateral exploration without making an extra incision and, in case of a contralateral patent processus vaginalis (CPPV), allows for repairing the CPPV simultaneously to prevent the development of a metachronous contralateral inguinal hernia.[3] While the open approach has been shown a safe and effective technique without a need for a laparoscopic learning curve for most (paediatric) surgeons, it also offers, opposite to the laparoscopic approach, the possibility for loco regional (caudal) anaesthesia in young

children.[4 5] Nonetheless, despite available comparative studies' results, a recent clinical management guideline concluded there is still no consensus regarding the superiority of the open versus the laparoscopic treatment strategy.[6]

An important reason for the lack of consensus on the optimal strategy is the large heterogeneity in the available studies as shown in a meta-analysis of clinical trials comparing the open and laparoscopic approach by Dreuning *et al*.[7] The investigators found that the methodological quality of the eight included randomised controlled trials (RCTs, total n=733 patients; age range 4 months–16 years) varied greatly and that there was clinical diversity in patient population and intervention characteristics. Moreover, Dreuning *et al* found that the reported trial outcomes and the outcome definitions used differed largely across the included studies.[7] This heterogeneity in trial outcomes selection and wide variability in outcome definitions impairs comparing studies and drawing conclusions regarding the superiority (or inferiority) of novel treatment strategies.

The development and implementation of a core outcome set (COS) is a solution that helps reduce heterogeneity in the selection, measurement and reporting of clinical trial outcomes.[8 9] A COS is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or healthcare.[10] Uptake of COS will enhance outcome data comparison, pooling and subsequent meta-analysis, enable adequate and efficient comparison of treatment strategies, and enhance the interpretation and implementation of clinical trial results.[10] Currently, there is no COS for the treatment of paediatric inguinal hernia.

The goal of this study is to systematically develop an internationally harmonised COS related to the treatment of paediatric inguinal hernia. Since most of the outcomes after inguinal hernia surgery are not only important to (paediatric) surgeons but also to patients and their parents, the Dutch Children and Hospital Foundation (Stichting Kind en Ziekenhuis) is involved as a research patient partner representing parents and patients throughout this study, that is, from the development of this protocol to participation in the consensus process to implementation of the results.

METHODS AND ANALYSIS

Study design

The aim of this study is to reach international consensus on the minimal set of core outcomes that should be measured and reported in all future clinical trials investigating any type of treatment for inguinal hernia repair in children aged 0–16 years.

The Inguinal Hernia COS (IH-COS) study was registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative on 16 March 2022. It has been designed in accordance with COS-STAndards for Development (COS-STAD) recommendations and the COMET Handbook.[10 11] Involvement of parents and patients' representatives will be described using the Guidance for Reporting on Involvement of Patients and Public short form checklist.[12]

Table 1 Description of the COS-IH development process

Phase	Activities COS development
1	Systematic review on outcome reporting in order to identify all outcomes used Protocol
2	A three-step Delphi procedure to identify a set of core outcomes (DelphiManager software)
3	Development of the final COS An expert panel meeting to ratify the final COS, including physicians, researchers and children/patient representatives Final COS development (max 10 outcomes and min 1 per core area (life impact, resource use, pathophysiological manifestations, death)

COS-IH, Core Outcome Set for Inguinal Hernia repair.

IH-COS development will consist of three phases (table 1): First, we will identify outcome domains regarding paediatric inguinal hernia repair. Eligible outcomes will first be identified from a patient perspective. Parents and patient's representatives from the Children and Hospital Foundation (patient advocate group in the Netherlands, patient partner) will be asked to provide a maximum of 10 outcomes which they think are most important after inguinal hernia repair. In addition, we will perform a systematic review of the literature on the treatment of paediatric inguinal hernia to identify outcome used in trials and cohort studies. Second, we will conduct a three-step Delphi study to identify and prioritise core outcomes for the outcomes selected in the literature review. During the third phase, we will hold an expert meeting with participants from all stakeholder groups to establish the final COS, its outcomes' descriptions and definitions. Involved stakeholder groups will be healthcare professionals ((paediatric) surgeons), parents and patients' representatives. The final COS will be reported in accordance with the COS-Standards for reporting (COS-STAR) statement. The COS-STAR Statement consists of a checklist of 18 items considered essential for transparent and complete reporting in all COS studies.[11]

Sample size

The COS-STAD recommendations report no rationale for determining the number of respondents for a Delphi study.[11] However, a minimum of seven respondents per stakeholder group has been suggested for a Delphi procedure to have a large enough group to allow for a consensus process.[13] Anticipating non-response to the invitation to participate and considering that not all responders may complete all three rounds of the Delphi process (attrition), we will invite a minimum of

40 respondents per stakeholder group per country. There will be no maximum number of participants.

Data collection and management

The handling of the collected personal data complies with the European General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation.[14] In addition, the study will be conducted following the Good Clinical Practice guidelines.[15] The Delphi study will be conducted online and managed using DelphiManager software developed by the COMET initiative.[16] To ensure participants' privacy, the personal information is stored separately from the answers given in the questionnaire and is only accessible for the principal investigator, the study coordinator and the project leader.

Phase 1: systematic review

To assess all reported outcomes related to inguinal hernia repair, we performed a systematic review of all available RCTs and meta-analysis that report treatment outcomes in children aged 0–16 years old with an inguinal hernia in October 2021 and updated the literature search in January 2023 (Prospero registration ID CRD42021281422).[17] The results of the systematic review were reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines using EMBASE, MEDLINE and the Cochrane Library databases. There were no restrictions related to the date of publication. The following subject headings (MeSH) and text words were used: inguinal hernia, children/child, p(a)ediatric, repair. The full search strategy is documented in online supplemental material 1. We did not distinguish between open or laparoscopic hernia repair or any other subtechnique since the aim of developing a COS for Inguinal Hernia repair (COS-IH) is that we can compare all different techniques for inguinal hernia repair so the superiority or inferiority of a novel treatment strategy can be established. Studies in which inguinal hernia repair was not the intervention were excluded. In addition, studies with a mixed population of children and adults, studies describing MESH repair and studies who were not written in English were excluded. Two authors conducted the screening and selection of studies based on title and abstract (level 1) and full text screening (level 2). Inconsistencies were solved by a third independent reviewer if necessary. The systematically extracted data from the included studies were collected in a designed spreadsheet. We found a total of 96 unique outcomes, which were mapped in 62 terms and, according to the method from the OMERACT FILTER 2.0, subdivided in five predetermined core areas: adverse events, life impact, resource use, pathophysiological manifestations and death.

Phase 2: international online Delphi study

Delphi participants: stakeholder selection

To develop a globally relevant and implementable COS for the treatment of paediatric inguinal hernia in various different jurisdictions and healthcare systems, we include two main groups of stakeholders from different countries: Healthcare professionals and parents and/or parents/patients' representatives. Stakeholders from different countries will be included so different views on inguinal hernia repair related to, for example, differences in resources and cultural differences can be considered. This will facilitate a final COS which reflects the opinions of the international community and provides an internationally applicable COS.

In the stakeholder group 'professionals', (paediatric) surgeons of different countries will be included. A subanalysis of the Delphi results in phase 2 will be performed by participant location and/or income status. After careful consideration and consultation of the international steering committee, there is decided not to include paediatricians, anaesthesiologist or general practitioners. This Delphi study is solely focused on developing a COS regarding the treatment of inguinal hernia repair in children. Although paediatricians, anaesthesiologist and general practitioners play a role in the diagnosis and care for children with an inguinal hernia, they are not involved in the final decision-making regarding treatment strategy. Furthermore, we will not include non-clinical researchers as a separate stakeholder group in this analysis. Since (paediatric) surgeons initiate almost all research regarding treatment of paediatric inguinal hernia, it is likely that researchers will be well represented in the (paediatric) surgeon stakeholder group.

In accordance with the COS-STAD recommendations, we also include parents and/or parents/patients' representatives in this study as stated before.[11] At least one participating hospital per country or per continent will be asked to recruit parents and/or parents/patients' representatives for this Delphi analysis. Since inguinal hernia occurs mostly in very young children with a peak incidence around 1 year of age for boys and 5 years of age for girls, we did not include patients themselves; their parents and parents and patients' representatives will act as the proxies for these young patients.[1]

Delphi participants: stakeholder recruitment

Research groups that are currently conducting clinical trials on the alternative procedures of paediatric inguinal hernia repair will be invited to participate in the development of the IH-COS. We used www.clinicaltrials.gov to identify these research groups by searching for 'inguinal hernia' with an age limitation of 16 years and exclusion of studies completed before 2016 or studies without an update after 2017 (online supplemental material 2). Out of 45 trials identified, 9 assessed the treatment of inguinal hernia repair in children. These studies were executed in the Netherlands, the USA, Egypt, Croatia, Switzerland and Jordan (table 2). Furthermore, we aim to include research groups that were involved in studies that were included in our systematic review. Overall, we will approach 40 stakeholders in each of 25 countries across five continents (Netherlands, Belgium, Germany, Austria, France, Italy,

Table 2 Number of outcomes found in the systematic review per core area

Core area	Example(s)	No of outcomes identified in the SR
Adverse events	Complications	28
Life impact	QoL, loss of ability to work	8
Resource use	Length of hospital stay, healthcare/social costs	5
Pathophysiological manifestations	Biochemical parameters, organ function, (ir)reversible manifestations (complications, etc)	20
Death	Death	1

QoL, quality of life; SR, systematic review.

Spain, Greece, the UK, Servia, Sweden, Denmark, Latvia, Turkey, Poland, the USA, Canada, Brazil, Japan, Malaysia, Indonesia, Pakistan, Australia, Israel and South-Africa). One contact person per country will be invited to participate by email or phone. If that person is not available, we will approach the next person in that country. After agreeing to this protocol, the contact persons are asked to locally (nationally) organise and invite stakeholder groups to participate in the Delphi study.

Stakeholders will also be identified at a national or centre level by the participating members of the international steering committee. Potential participants will be invited per email or per letter which will contain a link to an online registration system with all the study information and informed consent materials. Potential participants can reach the research team of this study by email or telephone to ask additional questions if necessary. After registration in our online system (DelphiManager software), the participants will be invited to the Delphi questionnaire. Participants will not receive any form of financial compensation. They can discontinue the study at any moment without giving a reason.

As mentioned above, this Delphi study will be conducted online and managed using DelphiManager software and will consist of three rounds. The outcomes identified in the systematic review will be formatted into questions that are going to be used in the Delphi questionnaire. These questions will be accompanied by a plain language description for the parents and/or patients' representatives. The Delphi questionnaires will be accessible simultaneously for all participants of all participating countries. All questionnaires will be developed in English, and they will be piloted by a group of lay persons (n=10) to check for ambiguity and readability. After each round of the Delphi process, the results of that round will be shared anonymously among all respondents.

This Delphi study will use a 9-point scale from 1 to 9 as recommended by the Grading of Recommendations Assessment, Development and Evaluation working group and COMET initiative.[10 18] Each candidate outcome will be scored by each individual Delphi participant. A score of 7–9 indicates that an outcome is considered critically important for assessing the effect of a treatment, 4–6 indicates that the outcome is considered important but not critical and 1–3 indicates that an outcome has low importance for assessing the treatment effect and should not be included in a 'core' set. There will also be 'unable to score' options in the questionnaire for participants who do not feel equipped to score certain outcomes.

Delphi round 1

Both stakeholder groups ((paediatric) surgeons and parents and/or parents/patients' representatives) will be asked to provide minimal demographic characteristics (age, gender and country). (Paediatric) surgeons will be asked to specify their workplace (academic, teaching hospital, non-teaching hospital), specialty (paediatric, general, abdominal and other) and whether they are involved in research regarding the treatment of paediatric inguinal hernia. Participants will be asked for their educational level, experience with inguinal hernia research, time passed from the initial diagnosis of inguinal hernia and if treatment was with or without any complications. All participants will be asked to score all identified outcomes according to their perceived importance for assessing the effectiveness of treatment. Outcomes will be presented by the four predetermined core areas (life impact, resource use, pathophysiological manifestations and death) and participants can propose additional outcomes that were not included in the Delphi round 1. The time frame to complete each Delphi round will be 3 weeks. We will send two reminder emails to the participants that did not yet complete the questionnaire in that time period.

Results of the Delphi procedure will be analysed separately for each stakeholder group, using descriptive statistics, since patients are expected to appoint different scores to outcomes compared with professionals, which has the potential to influence eventual outcome selection.[19]

'Consensus-in' will be defined as:

- >70% of the participants in both stakeholder groups rating the outcome as 7–9 and less than 15% rating the outcome as 1–3.
- >90% of participants within one stakeholder group rate the outcome as 7–9 'consensus-in'. This entails that those outcomes, which are only of interest to one stakeholder group, can also be included.

'Consensus-out' will be defined as:

- 70% of the participants in both stakeholder groups rating the outcomes as 1–3 and less than 15% of participants in both stakeholder groups rating it

7–9. Consensus-out can only be reached if there is consensus across both stakeholder groups.

If there are any outcomes that do not meet any of the above-mentioned criteria, they will be defined as 'no consensus'. No consensus outcomes will be taken to the next round of the Delphi study. If additional outcomes are suggested by Delphi participants, the study management group will determine if it is a new outcome and will classify it in one of core areas during their meeting after the Delphi round 1. In the same meeting, when necessary, the need for revision of the Delphi process will be assessed.

Delphi round 2

All participants who have completed the first Delphi round will be asked to participate in round 2. Outcomes that have been identified as 'consensus-in' or 'consensus-out' will be excluded from the Delphi round 2. Outcomes, for which there was only 'consensus-in' within a single stakeholder group, will still be presented to the other stakeholder group to evaluate whether consensus can be achieved in both stakeholder groups. An overview of included and excluded outcomes will be available and the outcomes for which there is no consensus will be presented with the participants' individual rating. The median scores for each stakeholder group will be combined with a histogram showing the scoring distribution. Any new suggested outcomes in the Delphi round 1 will be presented in the Delphi round 2. Respondents will be asked to rate the outcomes in round 2 of the Delphi process in the same manner as in round 1.

The results of round 2 of the Delphi process will be analysed per stakeholder group and for all participants, using descriptive statistics with the same definitions for consensus in/out as in the first Delphi round. There will be a sensitivity analysis to check for a divergent opinion from a single country or physicians with or without research experience. A study management group meeting will be organised to assess the need for alteration in the Delphi process deciding whether to proceed with the third Delphi round in the case of consensus in both stakeholder groups on more than 80% of the outcomes, and more than 10 outcomes with consensus in.

Delphi round 3

All participants who have completed the second Delphi round will be asked to participate in round 3. Outcomes that have been identified as 'consensus-in' or 'consensus-out' will be excluded from the third Delphi round. Outcomes, for which there was only 'consensus-in' within a single stakeholder group, will still be presented to the other stakeholder group to evaluate whether consensus can be achieved in both stakeholder groups. An overview of included and excluded outcomes will be available and the outcomes for which there is no consensus will be presented with the participants' individual rating. The median scores for each stakeholder group will be combined with a histogram showing the scoring distribution. Any new suggested outcomes in the Delphi round 2 will be presented in the Delphi round 3. Respondents will be asked to rate the outcomes in round 3 of the Delphi process in the same manner as in round 2.

The results of round 3 of the Delphi process will be analysed per stakeholder group and for all participants, using descriptive statistics with the same definitions for consensus in/out as in the first and second Delphi round. There will be a sensitivity analysis to check for a divergent opinion from a single country or physicians with or without research experience.

Phase 3: development of the final COS

Formal consensus meeting

Since a formal face-to-face consensus meeting can lead to a risk of selection bias of only participants that are able to attend the meeting and is not necessary for reaching consensus in a Delphi study, we will not organise such a meeting. Only the expert panel meeting will consist of a face-to-face meeting. Nonetheless, if consensus cannot be reached in the Delphi process on at least one outcome per core area, we will organise a virtual face-to-face consensus meeting to reach consensus.

Expert panel meeting

A face-to-face expert panel meeting will be organised after consensus is reached in the Delphi process. The expert panel will consist of selected individuals and will be organised to establish a pragmatic and well-defined COS and enhance support and implementation of the final COS. The meeting will be held at an international conference for paediatric surgery or will be held via a videoconference. Through purposive sampling, approximately 30 individuals in total from across the stakeholder group 'professionals' will be invited to participate in a face-to-face meeting. If possible, patient partners and parents are also invited to join the expert panel meeting through a video call.

The goal of this study is to develop a COS with a maximum of 10 outcomes and with a minimum of at least one outcome per core area. Highest level of consensus will be decisive if consensus is reached for more than 10 outcomes. This is dependent of whether there is consensus in stakeholder groups, the median score that was appointed to the outcome and the IQR of the median score as an estimate of the degree of consensus. If the maximum of 10 outcomes is reached after Delphi round 1 or 2 analysis, the Delphi analysis will be stopped at that round and will not continue to the next round. Sensitivity analyses of the Delphi results will be performed to test for country bias. The final COS will be categorised according to the four core areas.

Patient and public involvement

Patient partners provided feedback during the design of the Delphi survey and patient partners and parents helped identify 10 important outcomes for patients in addition to our outcomes identified through our rapid

literature review. Patient partners and parents are invited to a virtual consensus meeting if consensus cannot be reached. As mentioned above, if possible, patient partners and parents are also invited to join the expert panel meeting at an international conference for paediatric surgery through a video call.

Ethics and dissemination

The medical research ethics committee of the Academic Medical Centre Amsterdam confirmed that the Dutch Medical Research Involving Human Subjects Act (WMO) does not apply to this study and that full approval by the committee is not required. Each participating country/research group will be asked to ascertain ethical board approval or to confirm that an official ethics committee stated that this project is not in need of ethical approval. Electronic informed consent will be obtained from all participants. Dissemination of the results of this study will be accomplished by publication in an international peer-reviewed journal and by presentations of the results at relevant conferences. By involving the majority of the principal investigators who are currently involved in research on inguinal hernia repair in children, we aim to optimise uptake of the final COS in future clinical studies.

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Contributors JPMD, RRG, SCM, MO, NJB and ELWvH contributed to the design of this study protocol. HR contributed to the patient participation in study and organised a focus group regarding outcome measures related with inguinal hernia repair. SCM wrote the first draft of the manuscript and integrated critical revisions to the manuscript from all coauthors. SCM executed the systematic review of the literature, wrote the manuscript and integrated critical revisions from all coauthors. All authors (JPMD, RRG, SCM, MO, NJB and ELWvH) contributed to the design of the Delphi component of the study and contributed with provision of critical revisions to the manuscript. All authors approved the final version of the manuscript.

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