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Development of a core outcome set of quality indicators for enhanced recovery after surgery in minimally invasive cardiac heart valve surgery by interprofessional Delphi consensus

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Summary

A core outcome set for measuring the structural, process, and outcome quality of enhanced recovery after surgery in patients with minimally invasive heart valve procedures was developed. Indicators either identified in a systematic literature search or listed by an interprofessional panel were judged by relevance and condensed using Delphi rounds.

Quality Indicators for ERAS in Minimally Invasive Cardiac Surgery

Pre-operative
(n = 4)

Intra-operative
(n = 1)

Post-operative
(n = 6)

Rehabilitative
(n = 2)

Long-term outcomes indicators (n=3)



Complications (n = 6)

Across phase (n = 2)

Legend: ERAS = Enhanced recovery after surgery

Abstract

OBJECTIVES: A core outcome set (COS) giving indicators of the quality of the process for minimally invasive valve surgery embedded into enhanced recovery after surgery (ERAS) protocols should be developed.

METHODS: Using web-based questionnaires, a Delphi process with three rounds was conducted from January to December 2022. Prior to the rounds, a systematic database search was performed identifying potential quality parameters. Experts for the panel were selected reflecting the interprofessional nature of the ERAS protocol. In the first round, participants could make suggestions of indicators in the pre-, intra- or postoperative and rehabilitative phase. These suggestions form together with the indicators of the literature a first indicator

list. In the second round, participants could rate the relevance of the indicators resulting in a condensed indicator list. The third round was performed for further condensation based on importance ranking of the remaining indicators.

RESULTS: Three studies could be included in the systematic literature search providing a list of 22 indicators. Twenty-one experts participated in the Delphi survey. The experts named 315 indicators in the first round. After condensation in two further rounds, the final COS consisted of 24 indicators in the categories structure, process, outcome and complications.

CONCLUSIONS: A consensual minimum set of quality measurements during pre-, intra- and postoperative and rehabilitation phase for patients with minimally invasive heart surgery is now available for enhancing the quality of clinical practice and facilitating comparisons across different ERAS programs.

Keywords: core outcome set • enhanced recovery after surgery • heart valve surgery • minimally invasive cardiac surgery • interprofessional

ABBREVIATIONS

COS	Core outcome set
ERAS	Enhanced recovery after surgery
LOS	Length of stay

INTRODUCTION

Valvular heart diseases are common with an increasing prevalence and high morbidity and mortality rates worldwide [1]. Minimally invasive heart valve surgery has made a significant contribution to advancing the care of patients with valvular heart diseases. Less invasive and less traumatic surgery has been shown to be safe and reproducible and has therefore been increasingly adopted in routine care [2, 3]. Minimally invasive approaches reach comparable clinical outcomes than conventional surgery and can reduce the length of stay (LOS) [4, 5].

Cardiac surgery has also changed with the implementation of enhanced recovery after surgery (ERAS) protocols [6]. ERAS integrates surgery, anaesthesia, nursing, physiotherapy and other professions in pre-, peri- and postoperative columns of care [7]. Compared with standard care, ERAS protocols in conventional cardiac surgery are associated with lower complication rates, decreased pain and analgesia, increased postoperative physical activity, shorter LOS and reduced costs [8, 9]. Recently, ERAS protocols have been applied to minimally invasive heart valve surgery with promising results [10–13]. They may reduce pain, LOS and healthcare costs [12, 13], although more research is needed.

Core outcome sets (COS) have been developed to strengthen the evidence from clinical trials and to reduce the heterogeneity of the outcomes. A COS is an agreed-upon minimum set of outcomes for a specific health problem that should be included in clinical trials but could also guide healthcare management [14, 15]. COS have also been recommended for use in cardiothoracic surgery [16]. For adult cardiac surgery trials in general, a COS has been developed using structured consensus [17]. In addition, outcome sets are available for transcatheter aortic and mitral valve procedures. Nonetheless, they have been developed without the use of structured consensus methods [18, 19].

However, there is no COS for minimally invasive valve surgery embedded in an ERAS protocol. The aim of this study was to develop a COS for minimally invasive valve surgery that incorporates the ERAS steps using an adapted Delphi method. The developed COS is part of a large randomized controlled trial evaluating the effectiveness of ERAS in minimally invasive heart

valve surgery. We hypothesize that quality indicators for minimally invasive surgery may differ, at least in part, from quality indicators for full sternotomy surgery.

MATERIALS AND METHODS

A web-based, multi-stage Delphi process was conducted over the course of three rounds, from January to December 2022. The Delphi process is a systematic method of consulting a group of experts in order to reach a consensus [20].

The study was conducted as part of the project ‘Interdisciplinary and Cross-Sectoral Care in Cardiac Surgery Using Minimally Invasive Heart Valve Interventions as an Example—INCREASE’ [10]. The study protocol was approved by the Ethics Committee of the Medical Association Hamburg, Germany, on 7 June 2021 (reference number 202010276-BO-ff). Participants signed written informed consent.

Systematic literature review

In the first step, a systematic literature search was conducted by two researchers (SGRK and AB) independently using the following databases from the inception until September 2021: PubMed, CINAHL, PEDro, Cochrane, PsycINFO and Web of Science. This search identified published indicators for assessing the treatment and care outcomes of patients with minimally invasive heart valve surgery in the ERAS pathway. The search strategy comprised terms and synonyms for the patient cohort (patients with minimally invasive heart valve surgery) and the intervention (ERAS). They were connected within each group with the Boolean operator ‘OR’, and between the two groups with the operator ‘AND’. The search was limited to English and German literature, with no restrictions on publication date or other parameters. The electronic search strategy is described in detail in the Online [Supplementary File S1](#). Two reviewers (SGRK and AB) selected articles and evaluated their quality independently using the SANRA [21] and STROBE [22] tools. Any discrepancies were resolved through discussion and, if necessary, by consulting a third review author (EG). The included studies were synthesized in a narrative format, with an emphasis on describing the key characteristics of the utilized ERAS programs and the principal effects observed. The objective was to ascertain the quality indicators utilized in the included studies, whether as primary, secondary or safety outcomes. The aforementioned indicators were subsequently extracted and entered into the Delphi process during the second round.

Selection of expert panel

The second step involved a Delphi survey. According to the literature, the optimal number of experts for a Delphi panel is between 15 and 30, as an insufficient number of participants limits representation, while an excess of participants results in low response and agreement rates [20]. A targeted selection of experts from the fields of cardiac surgery, anesthesiology and intensive care, cardiology, general medicine, nursing and physiotherapy was made, thereby encompassing the perspective of the healthcare service provider.

The recruitment process was based on a convenience sample, whereby individuals were selected based on their availability or accessibility. The experts from each of the German-speaking countries—Austria, Germany and Switzerland—were recruited via email. The restriction to German-speaking countries was based on the observation that these nations exhibit common features in their cultures, including shared characteristics of their healthcare systems, which resulted in a unified understanding of the phenomenon under study. Furthermore, patient representatives from the German Heart Foundation were included to capture the perspective of the healthcare service user, while representatives from social health insurance funds were included to capture the perspective of the healthcare service financiers. The Delphi rounds were conducted using open-source LimeSurvey. Each Delphi round was accompanied by a reminder email and conducted anonymously.

Delphi process

Round 1: collection of indicators. The initial questionnaire consisted of free-text questions, in which experts could propose quality indicators for four phases (preoperative, intraoperative, postoperative and rehabilitation) within the ERAS process for minimally invasive heart valve surgery. For each indicator provided, experts were asked to delineate a specific end-point that would indicate when the criterion had been met. The experts were not explicitly requested to provide a definition of the fundamental concept underlying the indicators. However, they were afforded the opportunity to offer such definitions in their free-text responses. The responses from round 1 were subjected to analysis, operationalization and incorporation into a questionnaire for the second round, along with indicators described in the literature. The study authors concurred on the use of consistent terminology for each indicator and end-point. The precise wording was adopted wherever feasible. The identified indicators were organized according to the structure, process, and outcome indicators proposed by Donabedian (1980) [23].

Round 2: evaluation and consensus building. In the second Delphi round, participants were requested to evaluate the identified indicators from the initial round and from the literature with regard to their relevance in assessing the outcomes of patients undergoing minimally invasive heart valve surgery in the ERAS pathway. The round was conducted using a five-point Likert scale, with the following response options: 'very relevant', 'rather relevant', 'less relevant', 'not relevant' and 'I cannot judge'. Subsequently, a summary of responses (mean ranks and % agreement) prompted the third Delphi questionnaire.

Round 3: consensus building. In the final Delphi round, the experts reviewed the group results and could modify their own statements in consideration of the responses provided by the other participants. The participants were requested to rank the indicators in order of importance. Furthermore, they were asked whether the listed indicators were considered essential for measuring the quality of the ERAS concept in minimally invasive cardiac surgery, using a 'yes' or 'no' question.

Data analysis

The free-text responses from the initial round were analysed with qualitative content analysis in accordance with the procedures outlined by Mayring [24] using MAXQDA 2020 (VERBI Software). The data from the second and third rounds were exported to Excel files (Microsoft Office 2016) and subjected to descriptive statistical analysis. Mean ranks and % agreement were calculated for each indicator. A consensus was deemed to have been reached when the indicators were rated as either 'very relevant' or 'somewhat relevant' on the Likert scale by a minimum of 85% of the experts in round 2. In the third round, consensus for an indicator was achieved when at least 85% of the experts answered with 'yes'. The objective of the study was not to determine group differences; therefore, there is no separate consideration of individual responses based on participant weighting.

RESULTS

Results of the literature search

In the systematic literature search, 903 potentially relevant publications were identified. The title and abstracts of $n = 835$ papers were screened after the removal of duplicates. This resulted in 14 manuscripts being deemed eligible for screening at the full-text level. Following a full-text screening, an additional 11 papers were excluded, leaving three publications suitable for inclusion. Figure 1 displays the literature search in an adapted PRISMA flow diagram [25].

The three included studies [11–13] describe the implementation and evaluation of two ERAS protocols in patients undergoing minimally invasive heart valve surgery in France and Germany. The two ERAS programs shared several key characteristics, including the involvement of various healthcare professionals, such as surgeons, anesthesiologists, physiotherapists and nurses. Additionally, both programs provided preoperative counseling and education, optimized intraoperative anesthesiologic and surgical management, and initiated early tracheal extubation, along with early mobilization and intensive physiotherapy. In comparison to the control group, which received standard care, the ERAS group exhibited a significantly shorter LOS in both the intensive care unit (26.5 vs 46.6 hours, $P = 0.010$) [12] and the total hospital stay (6.1 vs 7.7 days, $P = 0.007$; 7 vs 10 days, $P < 0.001$) [12, 13]. Furthermore, the direct healthcare costs per patient were significantly lower for the ERAS approach than for the standard treatment (€11,200.00/patient vs €13,109.80/patient, $P = 0.006$) [12]. A summary of the characteristics of the included studies can be found in [Supplementary File S2](#). Twenty-two quality indicators for ERAS approaches in minimally invasive heart valve surgery were identified from the three studies (Table 1).

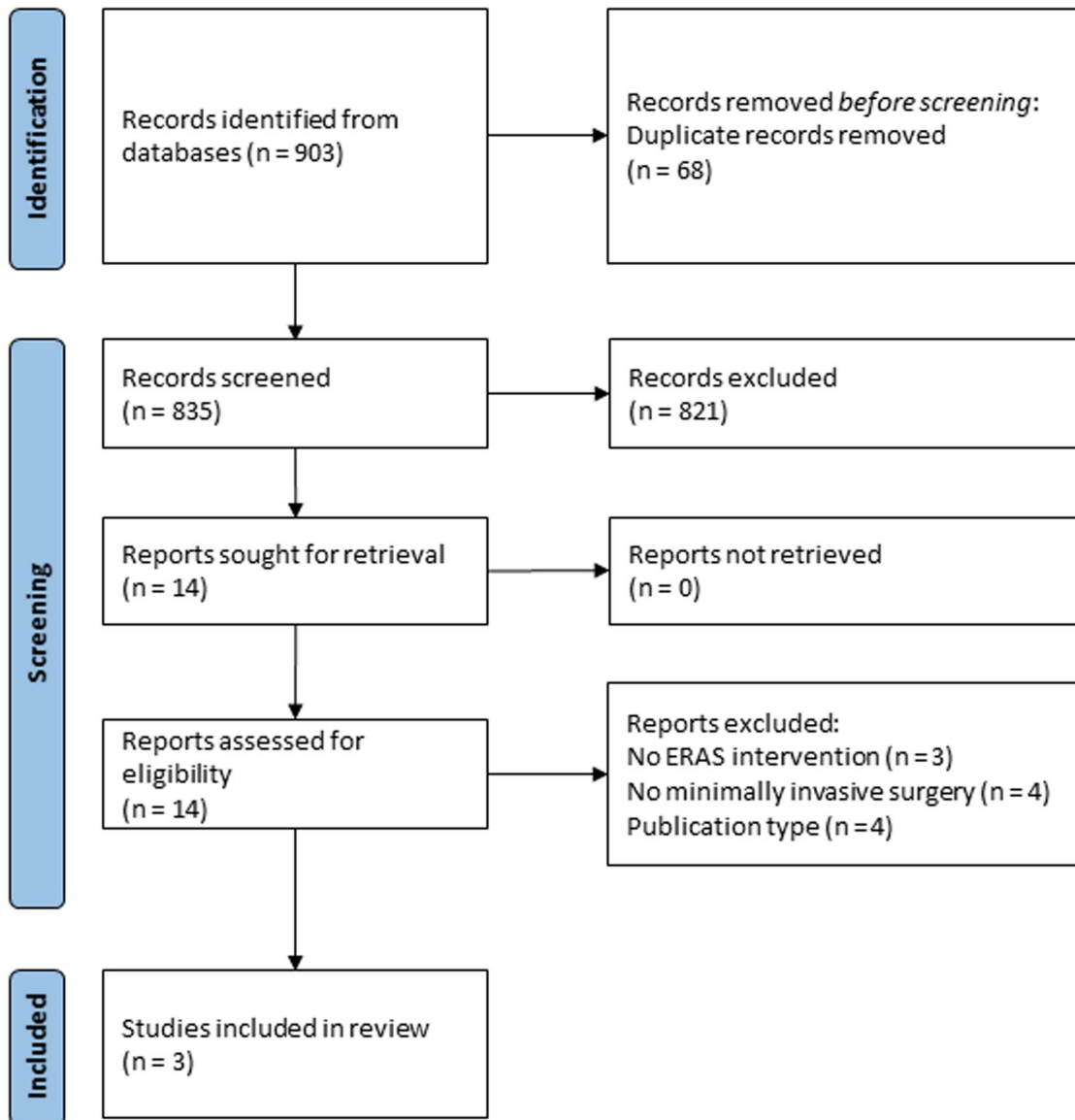


Figure 1: PRISMA flow diagram (adapted from Page et al. 2021).

Demographic characteristics of experts

Twenty-one of the 32 invited experts consented to participate in the Delphi survey. Of these, 79% were male and 21% female, while two individuals did not provide any information regarding their sex. Three individuals were aged between 36 and 45 years, 10 between 46 and 55 years and 8 between 56 and 65 years. Almost half of the participants (45%) had work experience between 21 and 30 years and were employed in inpatient care.

Results of Delphi rounds

During the first round, the participants identified 315 indicators. These indicators were grouped and merged with the 22 indicators from the literature. Following the second round, the list of indicators was reduced to 122 based on the participants' ratings. A further reduction was achieved in the final round, resulting in a COS comprising 24 indicators. The aforementioned indicators have been determined to have achieved the consensus

threshold, as indicated by a minimum of 85% of the panel deeming them relevant (Table 2).

Final core outcome set

The final COS is presented in Figure 2. Quality indicators for peri-operative structure and process were classified according to the three ERAS phases pre-, intra-, and postoperative. A fourth column was included to represent the subsequent rehabilitation phase. Furthermore, general indicators, complications, and long-term outcomes were identified. Although complications may be classified as outcome indicators according to the Donabedian model, they have been presented separately to facilitate the differentiation of the various dimensions of outcomes. The Delphi panel underscored the significance of interprofessional collaboration by incorporating it into the pre- and postoperative phases, the rehabilitative aspects of the ERAS process, and the general indicators for the entire process. Furthermore, mobility and activities of daily living (ADL) were identified as patient-reported

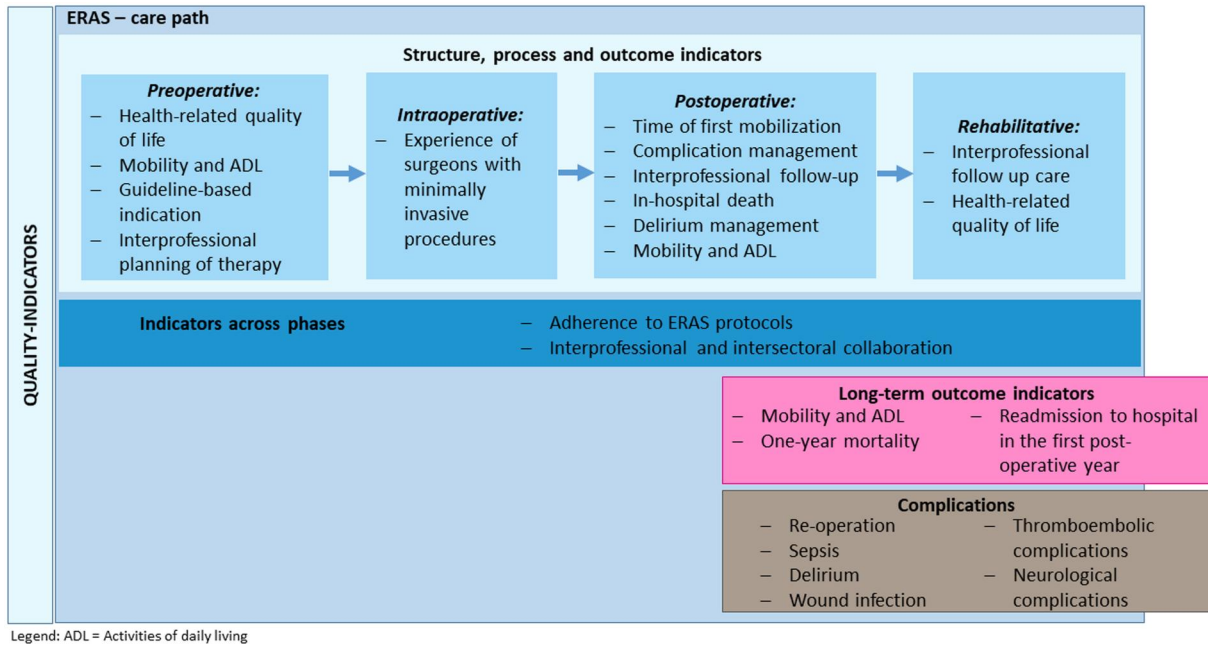


Figure 2: Final core outcome set for ERAS programs in minimally invasive cardiac surgery.

Table 1: Quality indicators for ERAS in minimally invasive cardiac surgery identified in the literature

General	<ul style="list-style-type: none"> • Postoperative hospital length of stay • Percentage of patients adhering to the protocol
Tracheal extubation	<ul style="list-style-type: none"> • Number of patients extubated on the operating room table • Time to tracheal extubation after the last skin suture • Reintubation for respiratory failure
Pain and postoperative recovery	<ul style="list-style-type: none"> • Postoperative pain scores • Pain intensity • Morphine consumption during the first two postoperative day • Time to first flatus
Complications	<ul style="list-style-type: none"> • Postoperative infection • In-hospital urinary tract infection • Surgical site infection • Bronchopulmonary infection • Postoperative complication • All-cause intensive care unit admission • All-cause 30-day readmission • In-hospital death
Costs	<ul style="list-style-type: none"> • Costs per patient for the surgery • Costs per patient for intensive care unit • Costs per patient for general ward • Costs per patient for duration of total inpatient stay • Costs per patient for internal activity allocation

outcome parameters, which were named in the pre- and postoperative phase and as a long-term indicator. While multiple indicators were identified for the other three phases, the Delphi panel was only able to reach consensus on a single indicator for the intraoperative phase.

DISCUSSION

An online Delphi method, involving a diverse range of professionals across three survey rounds, was employed to develop a COS for ERAS in minimally invasive cardiac surgery. The final quality indicator set comprised 24 indicators, classified into the categories structure, process, outcome and complications.

Twenty-one multiprofessional experts evaluated a range of indicators to ascertain their clinical significance in ERAS-supported minimally invasive heart valve surgery. To ensure representation of all stakeholders' perspectives, the panel included social health insurance fund representatives and patients, as a COS should be patient-centred [16]. The inclusion of multiple stakeholders and the implementation of two scientific analysis methods—a systematic review and a Delphi study—ensured the relevance of the developed COS.

The COS can assist in reducing the heterogeneity of outcome concepts across ERAS programs by providing an agreed-upon minimum set of parameters that should be measured [14, 15]. Consequently, the comparability of different programs can be enhanced, facilitating benchmarking. Such comparisons can assist clinicians, researchers, and healthcare managers in identifying potential areas for improvement and support patients in evaluating the performance of different programs. In order to facilitate the adoption of the COS in clinical practice, the COS provides a list of quality indicators without specifying the assessments or methods of measurement that should be used. This flexibility allows for adaptation to local conditions, thereby increasing the likelihood of the COS being implemented on a wider scale. However, no particular definitions of the concepts that underpin the indicators were identified or formulated during this Delphi study, which might prove beneficial for some indicators. Nevertheless, the majority of the indicators are regarded as intrinsic. Future research may wish to focus on defining the indicators, as well as determining which assessments are recommended. Moreover, future ERAS guidelines may integrate the COS into their recommendations,

Table 2: Indicators in round 3 achieving at least 85% of consensus

Category of indicator	Consensus
Structural indicator	
Interprofessional follow-up rehabilitation	94%
Experience of surgeons with minimally invasive procedures	89%
Interprofessional and intersectoral collaboration	89%
Interprofessional follow-up postoperative	89%
Interprofessional planning of therapy	89%
Process indicator	
Adherence to enhanced recovery after surgery protocols	100%
Complication management	89%
Delirium management	89%
Guideline-based indication	89%
Time of first mobilization	89%
Outcome indicator	
Mobility and ADL preoperative	100%
Mobility and ADL long-term	94%
Health-related QOL preoperative	89%
Health-related QOL rehabilitation	89%
In-hospital death	89%
Mobility and ADL postoperative	89%
One-year mortality	89%
Readmission to hospital in the first postoperative year	89%
Complication	
Neurological complications	94%
Reoperation	94%
Thromboembolic complications	94%
Delirium	89%
Sepsis	89%
Wound infection	89%

thereby endorsing the concept of uniform assessments across disparate programs.

The COS encompasses the preoperative, perioperative, postoperative, and rehabilitative phases of the healthcare process. Consequently, this study encompasses not only a multiprofessional perspective but also the entire care pathway, which has not been evaluated to this point. The previous homogeneity of professions in outcome reporting in cardiac surgery may impede the generation of research syntheses and meta-analyses, thereby hindering evidence-based care development [26]. Similarly, the lack of standardized outcome measures precludes direct comparisons between the various perioperative measures [27] and interventions employed in the process, underscoring the significance of our study.

Twenty-four indicators for ERAS-supported minimally invasive valve surgery were identified. Nevertheless, the survey participants achieved complete consensus on the indicators 'adherence to ERAS protocol' and 'mobility and ADL'. The latter is a patient-centred outcome, representing the patient's perspective in a manner that is not reflected in 'hard end-points', such as mortality or postoperative complications. Nevertheless, the indicators 'in-hospital death', '1-year mortality', 'readmission' and 'delirium' were also identified as significant measures of the quality of ERAS-supported healthcare, thereby reinforcing the impact of such outcomes. The impact of the 'delirium management' indicator is unsurprising given the high prevalence of delirium following cardiac surgery, which occurs in 26–52% of cases [28]. Therefore, standardized screening, early detection instruments and adapted delirium management protocols are

crucial in the perioperative care of patients who have undergone cardiac surgery [29].

Furthermore, the COS for ERAS-supported minimally invasive valve surgery encompasses the indicators of functional recovery and quality of life (QOL). The indicator 'health-related QOL' has already been established in the context of cardiac surgery, as evidenced by numerous published sources (e.g. [17–19]). In contrast, patient-centred healthcare processes and structural indicators such as the timing of initial mobilization, postoperative complication management, and interprofessional follow-up have not yet been addressed previously. It is noteworthy that the interprofessional care indicator has been comprehensively delineated solely within the context of heart-team decision-making (e.g. [18, 19]).

Although the COS was developed in the context of minimally invasive surgery, it may also be applicable to sternotomy. A substantial number of the COS indicators have been identified as already being utilized in sternotomy care processes [30]. The results of another Delphi consensus study indicate that our COS may also be applicable to other surgical procedures, as some overlap exists [31]. However, the Delphi consensus was specifically designed to postoperative pain management following surgical procedures. Further research could concentrate on the question of applicability to other surgical procedures.

There are some methodological limitations. First, the systematic review was limited to studies published in English or German and certain databases, which may have resulted in the exclusion of additional studies. The three identified studies were unable to corroborate the findings of the expert panel at this juncture. However, they were utilized to identify indicators ($n = 22$), which were subsequently incorporated into the Delphi study. Furthermore, the identified studies may be subject to certain methodological limitations, given that they are non-randomized pragmatic studies. However, the objective of the literature search was not to ascertain the effectiveness of the ERAS programs, but to identify potential relevant quality indicators. Second, a Delphi survey can only provide an insight into the opinions of the respondents. Moreover, the responses may be influenced by a number of factors, including the composition of the panel and the design of the survey [32]. Despite the heterogeneous composition of the panel, there is a possibility that individual professions and advocacy groups may not be adequately represented. The participants had limited experience with ERAS, yet they were considered experts in their respective fields of cardiovascular medicine. Additionally, the number of male participants exceeded that of females, which may introduce a selection bias. Moreover, the study participants represent their healthcare system. Indicators may be potentially different in other countries and specific healthcare systems. The interprofessional composition of the panel, which did not include an excess of any particular health profession, may be responsible for the reduction in indicators from the second to the third round. The indicators that are primarily pertinent to one or a few professions, such as motor skills, cross-clamp time or metabolic imbalance, frequently did not meet the predefined threshold. However, the objective of developing a COS for an interprofessional approach can only be achieved when all professions are represented nearly equally in the panel. Consequently, our study approach could serve as a model for achieving interprofessional equality. In addition, patient representatives were included in the panel giving patients an immediate voice instead of being represented by health professionals as advocate.

CONCLUSION

The developed COS should be considered as a minimum outcomes measurement for ERAS-supported minimally invasive valve surgery. It aims to improve the comparability of ERAS-based publications in cardiac surgery and reduce reporting bias and heterogeneity in outcome assessments. The study highlights the fact that process and structural indicators such as 'interprofessional treatment planning', 'interprofessional follow-up/visits' and 'surgeon experience with minimally invasive procedures' are further key elements in the ERAS-supported heart valve surgery. However, the implementation of such indicators can be challenging and requires standardized pathways, which are obligatory for all healthcare providers. Additionally, the COS should be regularly reviewed and updated to ensure relevant outcomes for all stakeholders and to implement new evidence as needed [15].

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

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Conflict of interest: none declared.

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DATA AVAILABILITY

The data underlying this article will be shared on reasonable request to the corresponding author.

Author contributions

Susanne G.R. Klotz: Conceptualization, Methodology, Formal Analysis, Investigation, Data curation, Writing—original draft, Writing—review & editing, Visualization, Project administration. **Anke Begerowb:** Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing—original draft, Writing—review & editing, Visualization. **Evaldas Girdukas:** Conceptualization, Validation, Resources, Writing—review & editing, Supervision, Funding acquisition.

Reviewer information

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