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Protocol for the development of enhanced recovery after surgery (ERAS) recommendations for individuals undergoing surgery for degenerative cervical myelopathy

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STUDY DESIGN: Protocol for the development of enhanced recovery after surgery (ERAS) recommendations for DCM surgery.
OBJECTIVES: To develop ERAS recommendations in collaboration with the ERAS Society to optimize care for individuals having surgery for degenerative cervical myelopathy (DCM)—the most common type of nontraumatic spinal cord injury.
METHODS: The study protocol was developed in line with the AGREE II checklist for clinical practice guidelines and the ERAS Society standards for guideline development. A multidisciplinary international guideline development group (GDG) including a representative from the ERAS society, clinical experts in the surgical care of people with DCM, and people with lived experience of having surgery for DCM has been established. The recommendations will follow the GRADE methodology and will therefore include the following steps. 1) Framing the health care questions. 2) Selecting and rating the importance of outcomes for each ERAS candidate interventiont. 3) Summarizing the evidence for each ERAS candidate intervention. 4) Judging the quality of evidence for each ERAS candidate intervention. 5) Judging the strength of the recommendations for each ERAS candidate intervention. 6) Developing recommendations statements for the included ERAS interventions and achieving consensus on the ERAS intervention statements to be included in the final guideline. Following the recommendation statements' development, key stakeholders will be invited to externally review the guidelines.
CONCLUSION: ERAS recommendations for DCM aim to reduce the incidence and severity of adverse events, optimize patient outcomes, improve the efficiency and quality of care, and patients' experience and satisfaction with care.

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INTRODUCTION

Degenerative cervical myelopathy (DCM) is the most common cause of nontraumatic spinal cord injury in adults worldwide [1]. In 2017, an international clinical practice guideline for DCM was published which recommended that all patients with moderate to severe DCM, progressive DCM, and those at high risk of progression should be offered surgery to decompress their compressed cervical spinal cord [2]. Recently published data from the hospital episodes statistics database in the UK has reported the incidence of surgical intervention for DCM as 7.44 per 100,000 (SD ± 0.32) [3], although this is likely a significant under-estimation of DCM prevalence due to low rates of detection [4].

Many different surgical strategies are used to treat DCM, with significant global variability in surgical practice. Broadly, thus far, these surgical techniques have been shown to have equivalence in terms of neurological recovery, with a recognition that the surgical strategy must be individualised [5]. Despite the known equivalence in outcome by surgical approach, an international cohort study has reported wide variation in the short term outcomes such as length of stay and discharge destination in DCM surgery, in the incidence and severity of adverse events and the long term functional outcome achieved [6–10]. A review of data from the national inpatient sample has identified that 20% of people who have surgery for DCM in the United States have an extended LOS (> 3 days) and the average mortality rate for DCM surgery is 0.6% [6], which is a relatively high mortality rate for elective degenerative spine surgery [11]. Two recently published spinal registry studies that have investigated the adverse event

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rate within three months or 12 months of surgery have reported a 28-29% complication rate for DCM surgery in real world clinical settings in high income countries, [12, 13], which is a substantially higher complication burden than anticipated. Complications included neurological injury, dural tears, cerebrovascular events, urinary tract infections, pneumonia, thromboembolic events, deep and superficial wound infections, dysphagia, dysphonia, and hardware complications.

People with DCM can experience a gradual, stepwise, or rapid neurological deterioration and approximately 10-20% of people require emergency surgical intervention [3, 12]. Emergency surgery is associated with higher risk of mortality, complications, and adverse outcomes [14].

In DCM, there is evolving evidence that the application of surgery should be considered a complex intervention; one important element of a series of parallel and multidisciplinary interventions which when delivered in tandem ensure that each individual patient derives as much benefit as possible. Developing strategies to optimize surgical outcome has been identified as one of the top research priorities in the field of DCM through a multistakeholder international consensus process including strong representation from people with DCM led by AO Spine RECODE-DCM. Whilst efforts, led by myelopathy.org, a DCM charity, have also highlighted the unmet care needs of people with DCM, which include the management of pain, improved patient education and a greater emphasis on shared decision making [15, 16].

Enhanced recovery after surgery (ERAS-) pathways are a multimodal and multidisciplinary evidenced based approaches to perioperative care which aim to reduce the incidence and severity of adverse events, optimize patient outcomes and improve the efficiency and quality of care [17]. The ERAS concept is based on the principle that actions undertaken to modulate the surgical stress response can improve recovery after surgery. It was initially applied to patients undergoing colorectal surgery, where it has led to fundamental changes in peri-operative management [18, 19]. ERAS consensus statements and guidelines have now been developed and implemented in multiple different surgical specialties with excellent outcomes [20, 21]. There has been a steep increase in the volume of ERAS related publications and guidelines in recent years, which have been of mixed methodological quality. However, for DCM there is no consensus for ERAS recommendations to date. The ERAS Societies' ERAS guidelines can be differentiated from other ERAS guidelines in several ways, including their comprehensive, multidisciplinary design, broad literature search, rigorous evidence synthesis and strong grounding in ERAS expertise. The ERAS Society has developed standards for the development of ERAS Society guidelines; to safeguard the quality and methodological rigor of any new ERAS society guidelines [22]. These standards provide a structured methodology for multidisciplinary guideline development teams to agree by expert consensus on the evidence based multimodal and multidisciplinary interventions that should be routinely applied to people having a specific surgical procedure to enhance their recovery after surgery.

The objective of this guideline development project is to develop an ERAS guideline in collaboration with the ERAS Society to provide recommendations on the optimal multidisciplinary care for individuals having surgery for DCM. This guideline will generate best practice recommendations for the pre-operative, perioperative and early post-operative (0-4 weeks) care. The target population for this guideline are interdisciplinary teams involved in the surgical care of people with DCM.

METHODS

Composition of guideline development group

This research represents a collaborative effort between the ERAS society and members of RECODE DCM. This collaboration is a collection of people with DCM and clinicians from all phases of DCM clinical care, who are working together to accelerate knowledge discovery and implementation of evidence-based care in the field of DCM. The guideline development group includes an international multidisciplinary group of expert clinicians involved in the surgical care of people with DCM and a lived experience advisory panel (LEAP) of people who have had surgery for DCM. The professional background and affiliations of the GDG are detailed in Table 1. The Guideline Development Group [GDG] have been selected based on their clinical expertise, expertise in knowledge synthesis, and expertise in ERAS methodology. Members of the GDG will be required to complete a disclosure form detailing financial, personal, and intellectual conflicts of interest. In advance of any voting activities, individuals with relevant conflicts of interest will be asked to recuse themselves from voting.

Throughout the guideline development process, consensus will be defined as 80% or more agreement on key discussion points [23]. All working group members must agree to abide by consensus decisions even if the final decision is contrary to their own personal viewpoint. All areas of discussion or disagreement will be documented.

Public and patient involvement

The Guidance for Reporting Involvement of Patients and the Public (GRIPP) 2 checklist will be used to report the PPI involvement in this guideline development project [24]. To be eligible to be a PPI contributor, individuals must have had surgery for DCM. This CPG will use both an open and targeted approach to recruiting PPI members. Members of the GDG will be asked to nominate individuals who have had surgery in their centers for DCM to ensure that the advisory panel has international representation. An advertisement for PPI contributors will also be placed through myelopathy.org, including its online support group for people with DCM, hosted on Facebook, to provide the opportunity for all those who are interested to contribute. All proposed or interested individuals will be provided with a standardized information leaflet which outlines the background and aims of the project in addition to the role and personal specifications considered desirable for PPI contributors. Interested individuals who meet the role criteria will also be asked to complete a brief application form to facilitate the selection of a diverse groups of PPI contributors in terms of demographics, geographical dispersion, experience of surgery, and outcome from surgery [25]. People with DCM who have expressed an interested in participating will also be invited to briefly describe any experience they have as an active volunteer or as a patient or public representative and to share anything that they think would add to the diversity and success of the advisory panel. At the initial meeting, the LEAP members will be provided with a lay overview of the guideline development process. There will be continuous engagement of the LEAP contributors throughout the guideline development process [26]. Their anticipated involvement include:

- Topic Selection: LEAP members will nominate candidate ERAS interventions they believe are important based on their lived experience of DCM surgery. They will also vote on a preliminary list of candidate interventions, with their aggregated ratings being presented to the Guideline Development Group (GDG) to inform prioritization.
- Outcome Prioritization: LEAP representatives will participate in working groups tasked with identifying and rating outcomes of importance for each candidate intervention, ensuring that patient-relevant outcomes are adequately considered in the evidence synthesis.
- Participation in Working Groups: One LEAP member will be invited to join each evidence synthesis working group. Although they will not be involved in technical tasks such as summarizing the evidence or appraising the quality of studies, they will contribute to discussions on the relevance of findings and will participate in grading the strength of the recommendations, bringing in a patient-centered perspective.
- Review of Draft Recommendations: LEAP members will review the draft guideline recommendations to ensure that the language is accessible and that the content reflects patient priorities and concerns.
- Development of a Patient Version of the Guideline: LEAP members will co-develop a patient-friendly version of the final guideline to support shared decision-making and improve accessibility for people undergoing surgery for DCM [25].

While LEAP members will not participate in the formal GRADE rating of evidence certainty, their perspectives will inform the contextual interpretation of the evidence and guide the GDG in shaping the strength and wording of the recommendations. Their input will be documented and

Table 1. Members of the Guideline Development Group (ERAS in DCM surgery).

Name	Affiliation	Country	
Dr David Anderson	University of Sydney	Australia	Physiotherapist and researcher and Chair of RECODE DCM rehabilitation incubator.
Dr Harvinder Singh Chhabra	Sri Balaji Action Medical Institute, New Delhi.	India	Director, Spine and Rehabilitation, Sri Balaji Action Medical Institute; Past President of the International Spinal Cord Society (ISCoS)
Dr Ben Davies	University of Cambridge	UK	Neurosurgical trainee, researcher and co-founder of myeloapathy.org
Professor Michael Fehlings	Toronto University Health Network	Canada	Consultant neurosurgeon and scientist and 1st author of the international DCM clinical guideline.
Mr Mike Hutton	Get it Right First Time Programme, NHS England	UK	Consultant Orthopaedic spine surgeon and UK national lead for spinal surgical services
Dr Jed Lazarus	University of Cape Town	South Africa	Neurosurgical Spinal fellow
Dr Anoushka Singh	Toronto University Health Network	Canada	Neurosurgical theatre Nurse and researcher
Dr Daniel Stubbs	University of Cambridge	UK	NIHR Advanced fellow and Honorary Consultant Anaesthetist
Caroline Treanor	Royal College of Surgeons in Ireland/ Beaumont Hospital	Ireland	Physiotherapist and researcher and ERAS in DCM surgery project lead
Professor Lakshmikumar Venkat Raghavan	Toronto University Health Network	Canada	Consultant Neuro-anaesthetist and researcher
Aditya Vedantam	Department of Neurosurgery, Medical College of Wisconsin, Milwaukee, WI	USA	Consultant Neurosurgeon and associate professor.
Professor Tom Wainwright	University of Bournemouth	UK	ERAS Society representative (1st Author of hip and knee arthroplasty ERAS guideline and 2nd author of lumbar fusion ERAS guideline). Physiotherapist and researcher
Juan Jose Zamorona	Universidad Del Desarrollo & Universidad Andres Bello, Santiago	Chile	Consultant Orthopaedic Surgeon
Dr Carl Zipser	Spinal Cord Injury Center, Balgrist University Hospital	Switzerland	Consultant neurologist and researcher

integrated transparently in both the consensus process and final guideline outputs. The format for LEAP involvement will reflect the methods of the guideline development process and include a multimodal online approach involving modified Delphi consensus processes, commenting on draft guidelines and virtual group meetings. The meetings of the LEAP will be moderated by the project lead who will liaise with all the LEAP members individually in advance of the first group meeting and follow up after meetings to receive feedback on their experience and identify if anything can be improved for subsequent meetings. Practical supports offered to LEAP contributors will include the opportunity to influence the duration of meetings and the frequency of breaks and how to navigate the virtual meeting platform. To ensure that the LEAP contributors understand the complex medical information, the GDG will develop plain language explanations of medical terminology in collaboration with the LEAP as required and members of the LEAP will be signposted to online resources for PPI contributors to improve their understanding of research methods and terminology. A member of the advisory panel will be invited to join to the guideline leadership team. The contribution of LEAP members will be acknowledged in any publications arising from the guideline development process.

Study design

This guideline will follow the GRADE methodology and will therefore include the following steps [27]:

1. **Framing the healthcare questions:**
   - Defining the patient population and candidate ERAS interventions for consideration.
   - Formatting the research questions for each candidate ERAS intervention.
2. **Selecting and rating the importance of outcomes for each ERAS candidate intervention**.
3. **Summarising the evidence for each ERAS candidate intervention:**
   - Finding and critically appraising systematic reviews
   - +/- Preparing protocols for Systematic reviews and undertaking systematic reviews.
   - Preparing evidence profiles and summary of findings tables
4. **Judging the quality of evidence for each ERAS candidate intervention**.
5. **Judging the strength of the recommendations for each ERAS candidate intervention**.
6. **Developing recommendation statements** for the included ERAS interventions and achieving consensus on the ERAS interventions recommendation statements to be included in the final guideline.

Framing the healthcare question:Defining the patient population and candidate ERAS interventions for consideration

The target population for this ERAS guideline are people having surgery for DCM. The GDG will adopt the definition of DCM which has recently been agreed through an international multi-stakeholder consensus process, which included 54 people with DCM, 149 surgeons and 45 healthcare professionals [28]. DCM is defined as a spinal cord injury which occurs secondary to narrowing of the spinal canal caused by cervical spondylotic myelopathy, ossification of the posterior longitudinal ligament, ossification of ligamentum flavum, Klippel-Feil syndrome, diffuse idiopathic skeletal hyperostosis, degenerative disc disease or cervical disc herniation. It can be exacerbated by a pre-existing stenosis. A variety of surgical techniques can be used to treat DCM. All types of surgical intervention designed to alleviate symptomatic cervical cord compression (including cervical disc replacement, anterior

cervical discectomy and fusion, laminectomy +/- fusion, laminoplasty, laminotomy and corpectomy) will be included. Studies including single or multiple level fusion, anterior or posterior approach, with or without instrumentation will be considered relevant to this guideline. This guideline will apply to people with all grades of DCM severity who are managed with surgical decompression of their central spinal canal.

The first step in the guideline development process will be for the GDG to generate a list of the interventions for consideration as candidate ERAS interventions in DCM. This study will use the methodology used by the ERAS guideline for neonatal intestinal surgery to achieve consensus within the GDG on the list of included candidate ERAS interventions [29]. As part of the preparatory phase, the GDG will undertake a systematic review of the evidence to identify all the primary research investigating the effectiveness of ERAS pathways in spine surgery to establish which ERAS interventions have been included in existing protocols. The results of this review will be presented to the GDG to inform the development of the preliminary list of candidate ERAS interventions for DCM surgery. In addition, ERAS interventions from other relevant ERAS guidelines—particularly those developed for hip and knee arthroplasty and lumbar fusion surgery—will be reviewed and shared with the GDG to provide further context [29, 30].

To ensure that the list reflects the specific needs of the DCM patient population, ERAS experts, clinical experts in DCM surgery, and the LEAP will also be invited to propose de novo ERAS interventions considered relevant and applicable to the perioperative care of DCM patients. Interventions that could potentially generate recommendations for ERAS will be selected for consideration. A modified Delphi method will be used by the GDG to reach consensus on the candidate ERAS interventions in DCM. The opinion of all members of the GDG and LEAP will be sought. Each member of the GDG and LEAP will be sent an email regarding the potential ERAS interventions for consideration. They will be asked to rate the 'Agreement of inclusion into the guideline' of each intervention based on a nine-point scale [where one [1] is completely disagree, and nine [9] is completely agree]. While LEAP scores will not be counted in the formal rating process, they will be presented to the GDG in a summarized format to inform discussions:

- **Median score 7–9**: "Very important to the LEAP"
- **Median score 4–6**: "Important to the LEAP"
- **Median score 1–3**: "Not important to the LEAP"

Following the GDG voting, ERAS interventions that have an overall median panel score of greater or equal to seven [out of nine] will be included as candidate ERAS interventions in DCM. Interventions with a score of 1-3 will be excluded. Interventions with a score of between 4 and 6 will be discussed further within the group and the decision for inclusion will be based on group consensus.

A virtual meeting will then be held where all interventions with a score between 4 and 6 and new interventions proposed by the GDG not included in the original list of potential ERAS interventions in DCM will be discussed. As there are 14 members of the guideline development group, a quorum of 7 will be required for the consensus meetings. A second email survey will then be sent to members of the GDG and LEAP where they will be asked to rate the necessity for inclusion of each of the remaining interventions on the same nine-point scale used previously. Following a review of the GDG ratings, a final list of candidate ERAS interventions in DCM for recommendation development will be generated. The ratings of the recommendations for both included and eliminated interventions will be reported including an interclass correlation to provide a measure of rater agreement.

Formatting the research questions/s for each ERAS element

The list of candidate ERAS interventions in DCM will be divided into core theme which are likely to include patient preoptimization, perioperative pain management, peri operative nutritional care, intra operative anesthetic care, intraoperative surgical care, strategies to reduce infection and thromboembolic events and rehabilitation. A member of the GDG will lead the evidence synthesis for each ERAS theme based on their expertise and preference. They will assemble a review team which will include clinicians and researchers not part of the GDG but with the necessary clinical and methodological expertise. All members of the international research team will complete online training in the study methods to standardize the process of evidence synthesis across the review teams. The evidence review team for each topic will be asked to generate potential target research questions specific to their topic based on a screen of the literature. The review team will then formulate a clear review question using the PICO (Population, Intervention, Comparator and Outcome) framework which will aid a systematic review of relevant evidence for their nominated topic.

Selecting and rating the outcomes of importance for each ERAS intervention

The review team will first consider whether health benefits and harms of an ERAS intervention are important to the decision regarding the optimal management strategy, or whether they are of limited importance. If the team thinks that a particular outcome is important, then it will consider whether the outcome is critical to the decision, or only important, but not critical. The review team will ensure the perspectives of people with DCM are incorporated by referring to the core outcome set in DCM which has been developed in partnership with people with DCM as a component of the AO spine supported RECODE (Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy) initiative [30, 31]. To facilitate ranking of outcomes according to their importance the team will rate outcomes numerically on a 1 to 9 scale (7 to 9 – critical; 4 to 6 – important; 1 to 3 – of limited importance) to distinguish between importance categories.

The review team will consider surrogate outcomes only when evidence about population-important outcomes is lacking. If surrogate outcomes are used, this will be acknowledged as it may lead to down grading of the quality of the evidence because of the indirectness. Outcomes selected by the review team will be included in an evidence profile whether information about them is available or not as it highlights a knowledge and research gap.

Summarising the evidence for each candidate ERAS intervention

Literature Search. A search strategy will be developed for each review question (linked to the specific candidate ERAS intervention) with a medical librarian to identify all relevant primary literature and published systematic reviews +/- meta-analysis [32]. A broad set of search terms will be identified for each concept and logically combined with the OR Boolean operator to achieve sensitivity within concepts. A validated [33] MEDLINE search strategy for DCM will be used, which will be adapted for other databases. The results for both concepts (DCM and the candidate ERAS intervention) will then be combined using the AND Boolean operator to ensure that each concept is represented in the final search results. The search strategy will be customised for each database and used a combination of text words and standardised subject terms (i.e., Mesh / Emtree) and will be documented. The following electronic databases will be searched: PUBMED (CENTRAL), EMBASE (Elsevier), Scopus (Elsevier), and the Cochrane Central Register of Controlled Trials (CENTRAL). A filter will used to restrict the search to adults and humans. The search strategy will be peer reviewed by a second clinical librarian prior to execution using the peer review of electronic search strategies (PRESS) checklist [34]. Details of the flow of studies from the number of references identified in the search to the number of studies included will be reported using a PRISMA (preferred reporting for systematic reviews and meta-analysis) flow diagram [35].

The review team will also undertake a citation search, a review of their personnel archives and well as contact with the wider GDG and RECODE community to obtain important published or unpublished information relevant to their candidate ERAS interventions in DCM. The grey literature will also be searched. The GDG will be provided with clear guidance as to when expert evidence can be introduced and there will be a clear distinction made between expert evidence and expert opinion.The principles of disclosing and managing conflicts of interest will be applied to expert evidence [36]. The GDG will use systematic and transparent methods to collect expert evidence.

Inclusion criteria. The following process will be used to select studies for inclusion in each of the candidate ERAS intervention reviews. The search results from different sources will be merged using systematic review management software (Covidence.org) and uploaded onto endnote X20. Duplicate records of the same reports will be removed. The title and abstracts will be screened by two reviewers to remove reports irrelevant to the candidate ERAS intervention in DCM. The full text of potentially relevant reports will be retrieved.

Study selection. The full text reports will be examined for relevance to the specific candidate ERAS intervention and compliance with the reviews

eligibility criteria by two authors working independently. Only full text reviews in the English language will be included in the review. Disagreements about whether a study should be included will be resolved by discussion and if that fails, another member of the GDG will be called upon to adjudicate. The screening process for each candidate ERAS intervention will be recorded within a PRISMA diagram.

If the candidate ERAS intervention has not been studied specifically in people undergoing surgery for DCM, the research team will look to identify research from related surgical cohorts such as surgery for cervical radicular pain or radiculopathy secondary to degenerative cervical spine pathology or surgery for non-degenerative causes of cervical myelopathy. The review team will undertake a systematic review of the literature to identity any primary research investigating the effectiveness of ERAS pathways in spine surgery. The results of this review will be used to identify research evidence that has informed the use of ERAS interventions in other spine surgery pathology groups. In the absence of any spine specific research evidence, ERAS guidelines from other surgical specialities and a wider search for evidence specific to the candidate ERAS intervention in other surgical populations will be undertaken. The search strategy and the dates of all searches will be recorded in a standardised format and included as supplementary material in the published guidelines. The search strategy will be reviewed by two independent experts appointed by the ERAS society, external to the GDG.

Data extraction

A data extraction tool will be created which will include all the relevant data elements from the DCM minimum data set for clinical studies [37] and additional items specific to the research question relevant to each candidate ERAS intervention. The method of ascertaining harms and the case definition of harm outcomes for included studies will be reported [38]. Data will be extracted by one reviewer.

Study quality appraisal

The methodological quality assessment tools will be standardized for the evidence appraisal of all the guideline topics. The AMSTAR 2 will be used to critically appraisal any systematic reviews that include randomized or nonrandomized studies of healthcare interventions [39]. Version 2 of the Cochrane risk of bias tool (ROB2) for randomized trials will be used for randomized clinical trials [40]. For non-randomized studies of interventions, the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) V2 tool [41] will be used. The relevant Joanna Briggs institute critical appraisal tools will be used for analytical cross-sectional studies, cohort studies, case control studies and case series [42]. A GRADE assessment form with a final rating of the quality of evidence will be provide for every included study.

Following a review of the evidence the review team will reassess the relative importance of the outcomes in the included studies.

Judging the quality of evidence for each ERAS intervention

Following an appraisal of the evidence, the review team for each candidate intervention will generate evidence profiles which will include the judgment of each factor that determines the quality of evidence for each important outcome in addition to summary of finding tables. The final number of studies to be included in the table of evidence will be decided by the GDG depending on the quality of evidence supporting each candidate ERAS intervention.

The overall quality of evidence will be determined using methods outlined by the GRADE working Group [27]. The risk of bias, consistency, directness, precision, and publication bias will be assessed across included studies for each critical or important outcome. The initial quality (strength) of the overall body of evidence will be considered "High" for randomized controlled trials and "Low" for observational studies in most instances. The body of evidence may be downgraded one or two levels based on the following criteria: [1] risk of bias (study limitations), [2] inconsistency of results, [3] indirectness of evidence, [4 imprecision of the effect estimates (eg, wide confidence intervals), or [5] failure to provide an a priori statement of subgroup analyses. If there are no downgrades, the body of evidence may be upgraded one or two levels based on the following criteria: [1] large magnitude of effect, [2] dose-response gradient, or [3] effect of plausible residual confounding. The final overall quality (strength) of evidence will express the confidence that the effect estimate lies close to the true effect: high (high confidence that the estimate reflects the true effect), moderate (moderate confidence), low (low confidence), or very low (very little confidence; the true effect is likely to be substantially different from the estimated effect).

Grading the strength of the recommendation

The recommendations can be graded as either 'strong' or 'weak'. A strong recommendation is one for which the review team is confident that the desirable effects of a candidate ERAS intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention). Strong recommendation implies that most or all individuals will be best served by the recommended course of action.

A weak recommendation is one for which the desirable effects probably outweigh the undesirable effects (weak recommendation for an intervention) or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists. A weak recommendation implies that not all individuals will be best served by the recommended course of action. There is a need to consider more carefully than usual the individual patient's circumstances, preferences, and values. The review team may also make a recommendation to only use a specific candidate ERAS intervention in DCM in research, or they may make no recommendation. The GDG may make no recommendation if confidence in the effect estimates is so low that a recommendation is considered speculative, the trade-offs are so closely balanced and the values, preferences and resource implications are not known or are too variable or two management options have very different undesirable consequences.

Following their assessment of the quality and strength of the evidence the review team for each topic will draft one or more recommendations which satisfy the ERAS criteria for an intervention. The ERAS intervention must be an action/intervention that can be performed in the preoperative, intraoperative, or early postoperative period (0-4 weeks post-surgery), it must have an evidence-supported link to a measurable improvement in clinical outcome or system efficiency, and despite good evidence of benefit, be inconsistently performed. It should also be simply defined and applied and easily measured as having been completed [22].

The recommendations will specify the population and a detailed description of the recommended intervention. Where relevant, the recommendation may include a reference to the setting (e.g. primary or tertiary care, high- or low-income countries, etc.) and the comparator. In the setting of low or very low evidence, there will be significant burden on the GDG to defend a strong recommendation. In this eventuality, the magnitude of effect, cost-effectiveness and expected treatment burden for the patient will be considered.

Review by two independent experts

Once the literature searching, quality appraisal, GRADE assessment of evidence and presentation of recommendations has been completed by the GDG, all the steps will be reviewed by two independent experts appointed by the ERAS society. These two experts must approve the process before it can be considered complete and will be jointly responsible for the recommendations and participate as guideline co-authors.

Presentation of recommendations

This study will use the methods employed by the Neonatal intestinal surgery ERAS guideline to present the recommendation statements to the GDG. The objective of this process is to achieve consensus on which recommendation statements should be included in the final guideline and the strength and wording of the included recommendation statements [29]. The GDG will be expanded for this component of the study to include representatives of the LEAP and other key stakeholders to ensure broad representation and to help support the process of effective dissemination and implementation.

Members of this expanded group will be sent the candidate ERAS interventions recommendation statements by email with the evidence summaries and summary of finding tables for each individual recommendation. They will be asked to rate the clarity and ambiguity of each recommendation statement as well as the necessity of including it in the ERAS for DCM surgery guideline taking into consideration the evidence summaries and the summary of findings tables and their own knowledge and experience. These ratings will be performed on a nine-point scale. Members of the expanded GDG will be asked to provide comments or suggestions regarding the wording of the recommendation statements, the necessity and strength of the recommendation or general comments.

The second round of the consensus process will be a virtual workshop which will be moderated. At this meeting, each review team will present

their recommendations to the expanded GDG in a standardized format. This will include a modified PRISMA flow chart, a table of the evidence including a judgment on the confidence of the effect estimates and the results of the ratings from round one including the distribution and median scores and the feedback from round one.

Each recommendation statement will be discussed in terms of potential measurable outcomes resulting from implementation of the recommendation. Recommendations will be revisited through group discussion or identified for further development. The recommendation statement will then be voted on for necessity for inclusion in their current format using a nine-point scale. Those recommendations which achieve consensus for inclusion (a median score of greater or equal to 7) will be included in the final guideline. The ratings for the recommendation statements at each stage will be reported including an interclass correlation to provide an objective measure of rater agreement.

The GDG will identify candidate interventions for which it has been particularly difficult to generate a recommendation statement. This situation may arise in the setting of evidence that is difficult to interpret or translate into recommendations, or recommendations that may be controversial or radically alter previous knowledge. A Delphi consensus process will be undertaken with an expanded panel of no more than 10 relevant experts. The most complicated or controversial issues will be summarised and distributed in the form of structured questions to the panel of experts will answer questions anonymously, weight and justify their responses. The process may undergo several rounds, to encourage the panel to attain consensus.

External review

An international multi-disciplinary group of key stakeholders will be invited by the GDG to externally review the guideline. Their comments will be reviewed by the GDG leadership and incorporated into a final draft of this guideline. The external reviewers will be asked to disclosure any financial or intellectual conflicts of interest. The revised guideline and the external reviewers' comments will be shared with the wider GDG. Any proposed substantive changes to guideline will be subject to consensus agreement from the GDG.

Finalizing the process and submitting the guidelines

The final draft of the guideline will be approved by all co-authors before submission to a peer reviewed journal. An agreement will be made with the journal in advance of submission that the guideline is made available for free or open-access download via the ERAS society website.

Updating procedure

Every 2-3 years, the lead author or designated alternative will present a formal report of the guideline to the ERAS society with a brief re-evaluation of the guideline. If there is any new evidence which would impact on any of the recommendation statements, a new guideline update will be performed where the relevant recommendation statements will have an updated search performed to include papers published since the last guideline. The process for summarizing the evidence, grading the quality and strength of the evidence, generating a recommendation statement by consensus, and externally reviewing the recommendation statement will be consistent with this guideline. The GDG will also consider whether there is evidence supporting the addition of any new ERAS elements to the guideline.

DATA AVAILABILITY

Data sharing is not applicable to this article as no datasets will be generated or analysed during the proposed guideline development project.

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AUTHOR CONTRIBUTIONS

CT, BD, DA, DS, TW and MF was responsible for designing the guideline protocol and writing the guideline protocol. CT & JW was responsible for designing the electronic surveys. CT, KS and BD were responsible for designing the search strategy. HC, MH, LVH, JL, AS, DS, AV JS and CZ provided feedback on the design of the protocol and the written protocol.

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COMPETING INTERESTS

Caroline Treanor, David Anderson, Mike Hutton, Jed Lazarus, Carl Zipser and Daniel Stubbs, declare no relevant competing interests. Professor Fehlings as Editor-in-Chief of Spinal Cord has had no role in the peer-review or adjudication of this manuscript. Aditya Vedantam is undertaking funded research in DCM on diagnosis and prognosis and is the director of the Medical College of Wisconsin, Myelopathy Centre. Juan Jose Zamorano Perez is a member of the RECODE DCM perioperative research incubator and an active member of the AOSPINE Technical Commission Cervical Spine research group. Benjamin Davies is a trustee of Myelopathy.org, and director of its RECODE-DCM strategy. He sits within the AO Spine Spinal Cord Injury Knowledge Forum.

ETHICAL APPROVAL

This is a protocol for a clinical practice guideline and therefore did not require ethical approval. The study protocol was developed in line with the AGREE II checklist for clinical practice guidelines and the ERAS Society standard for guideline development.

ADDITIONAL INFORMATION

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