



ORIGINAL ARTICLE

Best practice rehabilitation pathway for the management of single and double-level lumbar fusion surgery: a modified Delphi Study

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ABSTRACT

BACKGROUND: There is limited evidence to guide the rehabilitation of patients following single or double-level lumbar fusion surgery (LFS). This is reflected in extensive variability in current rehabilitation regimes and subsequent low clinical success rates, which urges a call for a consensus rehabilitation pathway.

AIM: To establish consensus on the optimal pre-, peri- and postoperative rehabilitation of LFS.

DESIGN: A modified Delphi Study.

SETTING: Belgium and the Netherlands.

POPULATION: A multidisciplinary panel of 31 experts in the field of LFS and rehabilitation participated. Nine patients validated the consensus pathway.

METHODS: A three-round online Delphi questionnaire was followed by an in-person consensus meeting. In each round, experts could suggest new statements, and received group summary statistics and feedback for reconsidered statements. Consensus threshold was set at $\geq 75\%$ agreement. The resulting rehabilitation pathway was validated by patients through an online questionnaire and subsequent in-person focus group.

RESULTS: A total of 31 experts participated in the first online round, with 27 (87%) completing all online rounds, and 17 (55%) attending the in-person consensus meeting. Consensus was reached on 122 statements relating to pre-, peri- and postoperative rehabilitation of LFS, and validated by patients. Key components of the rehabilitation pathway included prehabilitation, education, physiotherapy in every phase, early postoperative mobilization, and little movement restrictions. Patients emphasized the need for support during the return-to-work process.

CONCLUSIONS: This process resulted in 122 expert-consensus statements on best practice rehabilitation for managing LFS, validated by patients.

CLINICAL REHABILITATION IMPACT: The proposed rehabilitation pathway can serve as guidance to support clinicians, reduce practice variability, and subsequently improve clinical outcomes after LFS.

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KEY WORDS: Spinal fusion; Lumbar vertebrae; Patient care management.

The number of lumbar fusion surgeries (LFS) performed shows an upward trend worldwide and is associated with high medical and societal costs.¹⁻³ As per the most recent guidelines and scientific evidence, LFS can be beneficial in treating persistent radicular pain and disability caused by neural compression, or when low back pain is caused by gross instability of the vertebrae, consistent with radiological findings.^{4,5} There is a lack of clinical evidence supporting the use of spinal surgery for other indications and the broader evidence suggests it is not effective or even contra-indicated.^{4,5} Hence, LFS should be reserved for well-considered cases.

Historically, research mainly focused on technical and surgical advancements of LFS, leading to higher structural success rates in terms of bony fusion, decompression, and sagittal alignment.⁶ The clinical success rate, however, remains unsatisfactory. Up to 40% of patients report persistent pain and no functional improvement after LFS.⁷⁻¹⁰ In addition, disappointing return-to-work rates contribute to the already high socio-economic burden.⁹ In the case of well-indicated LFS, this discrepancy between good structural and poor clinical outcomes might be due to inadequate rehabilitation.

Best practice rehabilitation in the pre-, peri- and post-operative period is proposed as a window of opportunity to improve clinical outcomes after LFS.¹¹⁻¹³ A recent meta-analysis showed that patients undergoing LFS benefit from exercise embedded in a multimodal framework.¹³ Despite this growing evidence, there are currently no specific rehabilitation guidelines for LFS. The considerable variation in everyday practice reflects this. For example, surveys among surgeons in the Netherlands and Sweden revealed no consistent timing or content of rehabilitation following LFS.^{14,15} Similarly, rehabilitation in the United Kingdom and Australia shows no uniformity in exercise prescription, setting, timing, or advice regarding return to activities.¹⁶⁻¹⁸

A guideline on best practice rehabilitation offers the potential to reduce random clinical variation, optimize the allocation of resources, and ultimately improve clinical outcomes.

A Delphi process is a well-established method for developing a consensus-based guideline when empirical evidence is not sufficiently available to answer a particular question.¹⁹ Thereby, this study aimed to build expert consensus on recommendations for an optimal rehabilitation pathway for patients requiring single or double-level LFS for degenerative conditions or adult (isthmic) spondylo-lysthesis.

Materials and methods

Study design

This 4-round modified Delphi Study was conducted in accordance with existing guidelines,¹⁹⁻²² and consisted of a 3-round online Delphi questionnaire, followed by an in-person consensus meeting. The process took place between November 2018 and November 2019. The classic Delphi process was modified by 1) providing preliminary statements instead of open-ended questions;²² and by 2) adding an in-person consensus meeting.²¹

The preliminary statements were derived by merging two databases by two independent researchers (LB, TT), and were evaluated by a third independent researcher (TWS). On the one hand, *qualitative data* were obtained from semi-structured interviews of 36 caregivers and patients.²³ On the other hand, a *systematic literature review* suggested a multimodal framework for rehabilitating LFS.¹³ Merging these two databases, provided the basis for the first round of the current study.

After the modified Delphi study, patient input on the collected expert consensus statements was solicited through an online questionnaire and an in-person focus group in December 2019.

Ethical approval was obtained from the KU/UZ Leuven Ethics Committee research (S60109), and participants' consent to participate was inferred from their voluntary participation. The reporting of this study follows the COnsolidated Criteria for REporting Qualitative Research (COREQ) guideline and the Conducting and REporting DELphi Studies (CREDES) Guideline.^{19,24} The protocol was prospectively registered at ClinicalTrials.gov (NCT03427294).

Modified Delphi study process

Expert panel participants

A multidisciplinary panel was composed of 31 recognized experts from Belgium and the Netherlands. It has been established that a panel of 23 experts yields reliable results,²⁵ and we anticipated a 25% dropout. This panel was purposely selected based on their extensive clinical and/or research experience in the field of low back pain, LFS, and/or (surgical) rehabilitation of patients with low back pain. Efforts were made to ensure diversity in terms of discipline, gender, and primary work setting. Composition and characteristics of the 31-member panel are provided in Table I. Most of the panelists were affiliated with a university hospital and reported at least ten years of experience.

TABLE I.—Expert panel participant characteristics.

Expert characteristics	No. of experts (N.=31) (%)
Clinical discipline	
Neurosurgery	5 (16)
Orthopedic surgery	5 (16)
Physical medicine and rehabilitation	3 (10)
Physical therapy	8 (26)
Psychology	5 (16)
Physician assistant	1 (3)
General medicine	1 (3)
Clinical epidemiology	1 (3)
Nursing	2 (6)
Country of living	
Belgium	25 (81)
The Netherlands	6 (19)
Main work setting	
University hospital	16 (52)
Regional hospital	5 (16)
Private practice	5 (16)
University	3 (10)
Rehabilitation center	2 (6)
Years of experience with rehabilitation for lumbar fusion surgery	
>20 years	14 (45)
Between 10-20 years	12 (39)
Between 5-10 years	4 (13)
<5	1 (3)
Average number of lumbar fusion surgeries performed per year (No. of surgeons = 10)	
20-50	6
>80	3
No answer	1
Number of articles published in Medline database	
1-10	7
11-49	9
50-99	3
>100	3
None	9
Age	
30-39	7 (23)
40-49	9 (29)
50-59	13 (42)
≥60	2 (6)
Gender	
Female	12 (39)
Male	19 (61)
Self-rated expertise (7 or more on a scale from 1-9) with	
Lumbar fusion	20 (69)
Low back pain	25 (86)
Rehabilitation	16 (55)

Three-round Delphi questionnaire

Three iterative rounds of online questionnaires were distributed using SurveyMonkey®. Experts were asked to rate each statement on a 9-point Likert Scale for importance (1 ‘absolutely not important’ to 9 ‘extremely important’). A priori, the cut-off for consensus was set at 75% percentage of agreement, according to most literature.²⁰ This implies

that 75% of experts should score a statement as important (rating ≥ 7) or not important (rating ≤ 3) to be respectively integrated or not in the consensus rehabilitation pathway. In each round, experts received the chance to elaborate on their answers, propose additional statements, and/or leave answers open (*e.g.*, in case the statement felt outside their core domain of expertise).

In Round 1, panelists rated preliminary statements regarding the content of the rehabilitation pathway. Some of these statements were explorative, for which panelists were asked to rank statements in importance (*e.g.*, professional background of a case manager) or to rate multiple statements on the same rehabilitation intervention (*e.g.*, different indications for preoperative psychological therapy). This facilitated refinement of these statements in subsequent rounds. In case less than half of the participants rated a statement, this statement was excluded after Round 1.

Rounds 2 and 3 consisted of refinement of statements without consensus and additional statements based upon participant feedback. After each round, each expert received an anonymous summary of the overall group opinion per statement (median score, % of experts scoring ≤ 3 , 4-6, and ≥ 7).

In-person consensus meeting

Round 4 was an in-person consensus meeting, facilitated by an independent, experienced moderator (MV). After an open discussion with the possibility of clarifying statements, experts voted anonymously in an online poll (PollEverywhere) “pro” or “contra” the proposed statements to be included. Consensus was achieved if 75% of panelists voted “pro.”

Validation of expert consensus by patients

After Round 4, nine patients, who underwent LFS, were selected based on balanced patient characteristics and clinical outcomes (poor as well as good). These patients were asked to rate a sample of 45 statements that previously reached expert consensus, which they may have encountered during their rehabilitation, on a 9-point Likert scale for importance. The threshold for consensus was 75% agreement (regarding rating ≥ 7 , or rating ≤ 3). This online questionnaire was anonymously conducted in SurveyMonkey®, and intended to act as a starting point for formulating their thoughts and opinions in the following focus group, where patients could nuance and elaborate on their opinions on the entire rehabilitation continuum. This focus group was moderator-facilitated (MV), and patients were blinded for the previously obtained expert-based consensus.

Data processing and statistics

Descriptive statistics were performed with R software.²⁶ Data from the in-person expert meeting and the patient focus group were audio and manually recorded. According to accepted guidelines,²⁷ the thematic analysis was performed and independently checked by two researchers (LB, TT).

Data availability

The data associated with the paper are not publicly available but are available from the corresponding author on reasonable request.

Results

Modified Delphi Study process

A total of 31 panelists (100%) participated in round 1 and achieved consensus on 59 statements. The remaining statements were refined or retained in round 2 along with 23 new statements proposed by the panelists.

In round 2, 27 panelists (87%) responded. Consensus was reached on an additional 46 statements. No new statements were proposed. Eight statements were refined, for

example the statement “The case manager should be a physical therapist, a clinical support manager or a specialist in Physical and Rehabilitation Medicine” was refined to “The clinical support manager has the proper competence profile with sufficient biomedical and psychosocial skills.”

The same 27 panelists (87%) completed round 3, in which an additional ten statements reached consensus.

A total of 17 experts (55%) participated in the fourth and final in-person round. During this meeting, additional consensus was obtained on seven statements. After the four rounds, no consensus was reached on 17 statements (Supplementary Digital Material 1: Supplementary Table I).

Figure 1 shows the number of expert panelists and how statements were refined at each round.

Ultimately, consensus was reached on 122 statements in this modified Delphi study process (Supplementary Digital Material 2: Supplementary Table II).

Validation of expert consensus by patients

All nine selected patients participated in the *online questionnaire* and agreed on 30 statements, leaving 15 statements without consensus (Supplementary Digital Material 3: Supplementary Table III). Seven of these patients participated in the semi-structured in-person *focus group* and shared their views on each phase of their rehabilitation

Figure 1.—Overview of the 4-round modified Delphi study process.

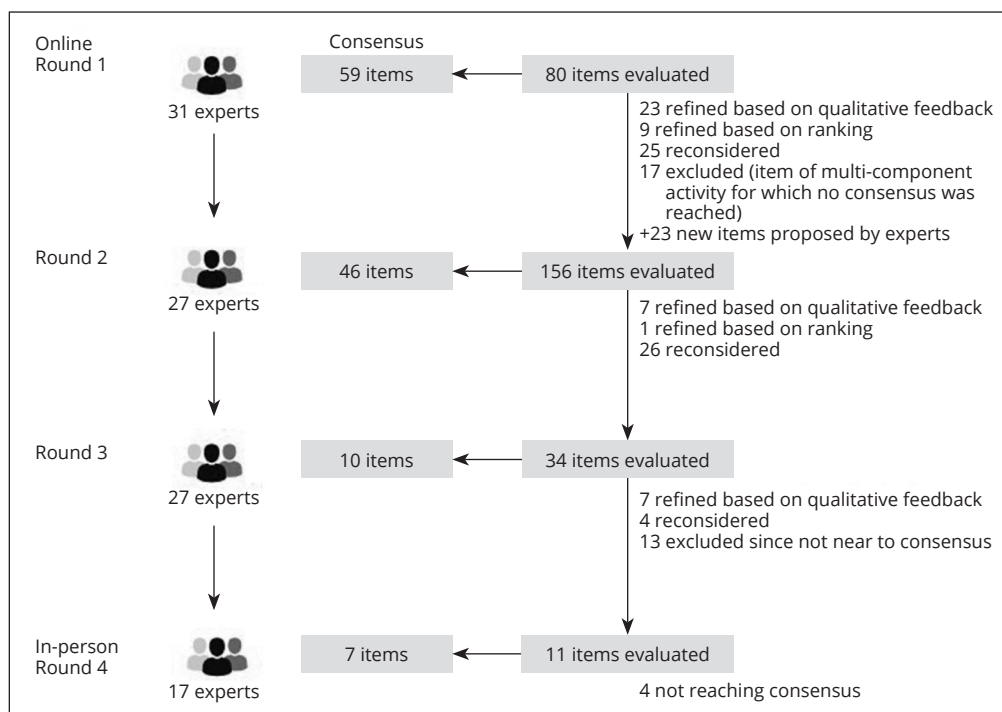


TABLE II.—Themes and opinions emerging from the patient focus group.

Timing	Themes and opinions of patients
Preoperative phase	<p>Decision for lumbar fusion must be shared between patient and surgeon (\pmgeneralist\pmspecialist in physical and rehabilitation medicine)</p> <p>Confidence in their surgeon is high and is based on clear communication and experience of their surgeon (“it’s their job”)</p> <p>There was a lack of relevant information on the preparation and the course of the hospitalization from their hospital (brochure and/or website) early in the care process and large inter-patient variability in need for detailed information (information hunting versus blunting)</p>
Hospitalization phase	<p>Questions immediately after the operation, which may be answered by any caregiver (<i>e.g.</i>, nurse, physical therapist, surgeon)</p> <ol style="list-style-type: none"> 1) “Was the surgery successful?” 2) “Can I ask for analgesics if necessary?” 3) “Can I move my legs and toes?” 4) “Which movements and activities may I do right now?” <p>Concerns: fear for falling, fear that the fusion construct is fragile</p> <p>Stimulation by caregivers to get out of bed and moving was fearful at that given time but retrospectively appreciated and important for their rehabilitation progress</p>
Postoperative phase after hospitalization	<p>Need for contact person for questions and concerns, especially in the first 6 weeks (period of uncertainty on resumption of activities and sensations of pain)</p> <p>Work resumption and sick leave remains an important and difficult issue for many patients</p>

journey following LFS. The themes and opinions emerging from this focus group are outlined in Table II.

Patients expressed the need for a single contact person during their rehabilitation process, lacking during their trajectory. This need was the highest in the first weeks postoperatively. All patients addressed the lack of relevant information available. However, there was large inter-patient variability in the amount of information desired before surgery: while some patients hunted for general information (*e.g.*, by searching online for videos of the operative procedure), others preferred to receive information only relevant to their case (information blunting). In contrast to this variable need for preoperative information, all agreed on the need for answers immediately after the fusion procedure (detailed in Table II).

Patients under retirement age were unanimous that re-

turn-to-work should be supported during their rehabilitation, by considering the biopsychosocial context as well as the work-specific context of patients. This was in contrast with the troublesome return-to-work process patients did encounter, mentioned by patients as “a better back does not equal a perfect person,” referring to the fact that less back pain was not correlated with a significant improvement in function or mental wellbeing (biopsychosocial context), and “all or nothing,” referring to the inability to progressively resume work or to distinguish between the low, moderate and high physical loading aspects of their job content (work-related context).

Discussion

Through a modified Delphi process, a multidisciplinary expert panel was able to achieve consensus on 122 statements regarding best practice rehabilitation of single and double-level LFS. Patients subsequently validated these statements. Based on the results of this process, a consensus rehabilitation pathway was designed. To the best of our knowledge, this pathway is the first unifying guideline across disciplines and across the full continuum of care (*i.e.*, pre-, peri- and postoperatively) for patients undergoing LFS (summarized in Figure 2).

This pathway addresses two critical challenges in the field of rehabilitation of LFS by 1) filling in existing knowledge gaps; and by 2) strengthening the ability to bridge the gap between research and clinical practice (*i.e.*, know-do gap).

Filling in the knowledge gaps

Even though the efficacy of multimodal rehabilitation in improving clinical outcomes after LFS has been demonstrated previously in the meta-analysis of Bogaert *et al.*, the specific timing, content, and do’s and don’ts remained unanswered.¹³ Consequently, caregivers still rely on their own experience and may feel unprepared, as has been seen accordingly in physiotherapists treating patients with non-specific low back pain.²⁸ Furthermore, this lack of guidance fuels practice variation in LFS management, as is previously demonstrated in Sweden, the Netherlands, the United Kingdom, and Australia.^{14-16, 18} The proposed rehabilitation pathway adds new insights to the existing evidence on LFS rehabilitation.

Firstly, the importance of starting mobilization early after LFS has been previously emphasized by the Enhanced Recovery After Surgery Recommendation.²⁹ This recommendation, however, is primarily focused on in-hospital

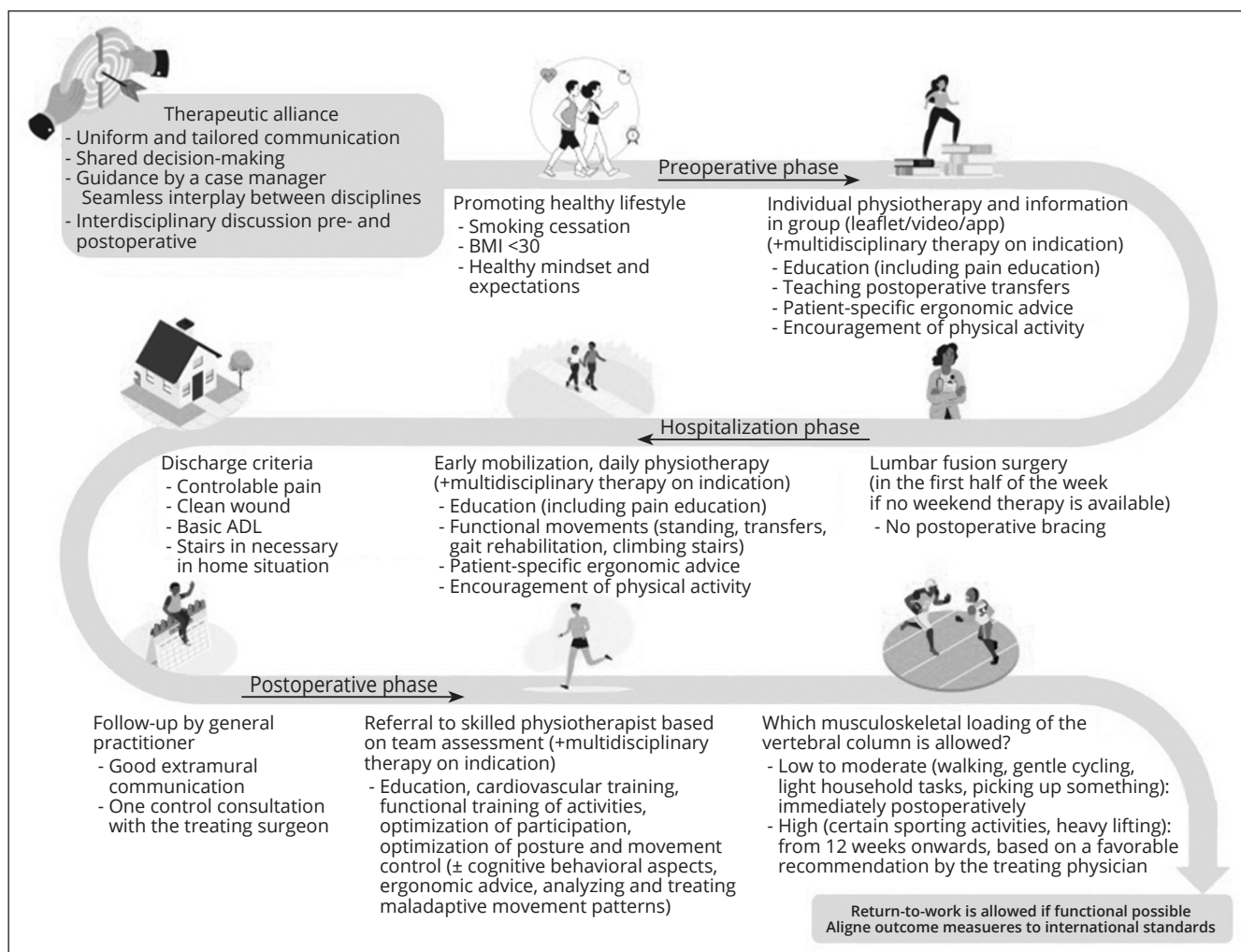


Figure 2.—Visual summary of best practices in the rehabilitation of lumbar fusion surgery.

(perioperative) care and on avoiding complications from a biomedical viewpoint.²⁹ In contrast, the results of our study acknowledge the importance of addressing a full spectrum of biopsychosocial components (*i.e.*, not only biomedical components) throughout the entire care continuum (*i.e.*, not only early postoperatively).

Secondly, the findings address the rehabilitation pathway to initiate already preoperatively. This is consistent with the transition from a reactive to a proactive approach that is also seen in the context of other surgical interventions, where patients are empowered early on as active participants in their own care.³⁰ In this proactive approach, a case manager has a vital role as a contact and trust person. The consensus statement on needing a case manager confirms that professional support is one of the central

components in rehabilitating LFS.³¹ Further, the proposed prehabilitation content of LFS comprises education, preoperative physiotherapy, and interventions focusing on tackling risk factors for suboptimal postoperative recovery. The latter is consistent with previously recognized risk factors, such as smoking,^{29, 32, 33} inactivity,³⁴ obesity,^{32, 35} depressive symptoms^{36, 37} and catastrophizing,³⁸ but adds to the evidence base by forming consensus on both indications and content of risk-mitigation interventions.

Thirdly, consensus on the need for preoperative education and information confirms previous findings that high-quality preoperative information can positively affect patient expectations, increase patient satisfaction, and induces greater treatment adherence.^{29, 38-40} This need for an improved preoperative informative approach results

from the fact that current patient information leaflets vary greatly,¹⁷ mirroring the large variation observed in clinical practice.^{14-16, 18} Answering this need might lead to more uniformity in rehabilitation practice, driving uniform education and information for patients.

Enhancing the ability to bridge the know-do gap

Evidence-based interventions frequently suffer from a know-do gap with real-world settings.^{41, 42} For example, surgeons predicate their prescribing patterns for bracing following LFS only for one-third upon evidence (from the literature) and two-thirds upon eminence (from personal experience or peer teaching).⁴³ A Delphi process allows for a critical analysis of current rehabilitation approach from the perspectives of key stakeholders. As a result, the ability to translate the Delphi findings to practice and policy is maximized. It is worth noting that we applied a rigorous methodology in accordance with the CREDES Guideline.¹⁹ This includes, for example, appointing independent researchers for study coordination, assigning a professional moderator for the in-person rounds, predefining the consensus threshold, and validating the expert consensus by a patient group. By capturing patients' perspectives separately from experts' opinions, points of (dis)agreement could be revealed, and may suggest possible barriers to rehabilitation adherence or highlight extra needs for patients.

Implementing the proposed rehabilitation pathway in clinical practice might help to minimize the current random variation in rehabilitation approaches; thereby fueling better quality of care and optimized allocation of resources, from which patients, physicians, hospitals, and society can benefit.

A next step is to clinically validate the effectiveness and implementability of this rehabilitation pathway with a hybrid design.^{44, 45} Another priority for future research is to gain insight into the maze of challenges related to return-to-work. This became apparent in the patients' opinion and is in line with the disappointing return-to-work rate after LFS.⁹ Experts agreed that clearing patients for return-to-work should be based on functional rather than time-based criteria. Possibly, (return-to-) work barriers (*e.g.*, functional problems, financial compensations) may be better captured by early and tailored rehabilitation. Additional research is needed to develop a complete picture of this return-to-work maze.

Limitations of the study

The present study has some limitations. Firstly, individual participant perspectives might influence the results, which

is inherent to a qualitative design. This limitation is mitigated by including an extensive expert panel from Belgium and the Netherlands, representing viewpoints from a wide range of related disciplines and work settings. Future research should consider transfer to other regions, including non-European countries.

Secondly, we acknowledge a lower participation rate in the fourth, in-person, round. However, a minimal risk for selection bias is hypothesized as most statements reached consensus during the first three rounds (115/122 statements, 94%) in which the response rate was 87%.

Conclusions

This rehabilitation pathway offers expert consensus-level guidance regarding pre-, peri- and postoperative rehabilitation for LFS, and aligns well with and adds essential concepts to the limited evidence available. The results provide a robust framework to support caregivers and policymakers in value improvement as it might help to reduce variation in rehabilitation and subsequently to improve patient outcomes such as long-term pain and disability after LFS.

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