Development of a Patient-Reported Outcome Measure of Recovery After Abdominal Surgery: A Conceptual Framework

Roshni Alam, BSc

Department of Experimental Surgery
McGill University, Montréal
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DEDICATION

I dedicate this thesis to my parents. You have relentlessly worked from the ground up to give me and my sister a chance at the opportunities you did not have. Thank you, now and always, for your love, support, and ceaseless belief in our potential.

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CONTRIBUTION OF AUTHORS

Ms. Roshni Alam (Manuscript I & II):

Author of this thesis, principal author of manuscript I and II, involved in all stages of the research presented (protocol design, project coordination, data collection, analysis and interpretation)

Dr. Julio F. Fiore Jr. (Manuscripts I & II):

Primary thesis supervisor, principal investigator of the research presented, development of research question and protocol design, project coordination, data collection in Canada and Brazil, data interpretation, manuscript and thesis revision and approval

Dr. Liane S. Feldman (Manuscripts I & II):

Thesis co-supervisor, principal investigator of the research presented, development of research question and protocol design, data interpretation, manuscript and thesis revision and approval

Dr. Nancy E. Mayo (Manuscript I & II):

Senior qualitative research advisor, development of research question and study design, interpretation of data, manuscript revision

Dr. Lawrence Lee (Manuscript I & II):

Development of research question and study design, manuscript revision

Dr. Sabrina M. Figueiredo (Manuscript I):

Development of research question and study design, data collection, manuscript revision

Dr. Saba Balvardi (Manuscript I):

Development of research question and study design, data collection, manuscript revision

Ms. Bénédicte Nauche (Manuscript I):

Study design, development of search strategy for literature review, manuscript revision

Ms. Tara Landry (Manuscript 1):

Study design, development of search strategy for literature review, manuscript revision

Dr. Joel Montanez (Manuscript II):

Senior qualitative research consultant, development of research question and study design, data collection in Canada, second independent analyst, manuscript revision

Dr. Susan Law (Manuscript II):

Qualitative research advisor, development of research question and study design, manuscript revision

Dr. Nicolò Pecorelli (Manuscript II):

Development of research question and study design, data collection in Italy and manuscript revision

Dr. Watanabe Yusuke (Manuscript II):

Development of research question and study design, data collection in Japan, manuscript revision

Dr. Hirano Satoshi (Manuscript II):

Development of research question and study design, data collection in Japan, manuscript revision

Dr. Chiavegato D. Luciana (Manuscript II):

Development of research question and study design, data collection in Brazil, manuscript revision

Dr. Massimo Falconi (Manuscript II):

Development of research question and study design, data collection in Italy, manuscript revision

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LIST OF ABBREVIATIONS

PRO: Patient-reported outcome

PROM: Patient-reported outcome measure

MRDP: Mesures des résultats déclarés par les patients

HRQL: Health-related quality of life

ERAS: Enhanced recovery after abdominal surgery

SMART: Surgical multimodal accelerated recovery trajectory

ICF: International Classification of Functioning, Disability and Health

CIF: Classification internationale du fonctionnement, du handicap et de la santé

WHO: World Health Organization

FDA: Food and Drug Administration

SAGES: Society of American Gastrointestinal and Endoscopic Surgeons

ISOQOL: International Society for Quality of Life Research

ISPOR: International Society for Pharmacoeconomics and Outcomes Research

WISP: Well-Being Index for Surgical Patients

QOR-9: Quality of Recovery-9

PSR Scale: Post-Discharge Surgical Recovery Scale

QOR-40: Quality of Recovery-40

SRI: Surgical Recovery Index

ASIS: Abdominal Surgery Impact Scale

CARE: Convalescence and Recovery Evaluation

RI-10: Recovery Index-10

SF-36: Short-Form 36/RAND-36

PRP: Postoperative Recovery Profile

PQL: Postoperative Quality of Life

FRI: Functional Recovery Index

PGSQL: Post General Surgery Quality of Life

SRS: Surgical Recovery Scale

PoRI: Post-Operative Recovery Index

SF-6D: Short-Form 6 Dimension

QOR-15: Quality of Recovery-15

EQ-5D / EUROQOL-5D: Euro Quality of Life 5 Dimension

PREFACE

This thesis is organized in a manuscript-based format and is comprised of two unique manuscripts. The first manuscript was presented as a podium presentation at the SAGES 2018 Annual Congress and was published in Surgical Endoscopy in May 2018. The second manuscript was presented as a podium presentation at the SAGES 2019 Annual Congress and was accepted for publication in Surgical Endoscopy in May 2019.

ABSTRACT

Background

The use of patient-reported outcome measures (PROMs) are central for delivering high-quality patient-centered care to postoperative patients. However, the evidence underpinning the measurement properties of PROMs currently in use to measure recovery after abdominal surgery is weak. To bridge this knowledge gap, we initiated a research program to develop a conceptually relevant and psychometrically sound recovery-specific PROM. In compliance with best-practice recommendations for PROM development, this thesis project aimed to develop a conceptual framework representing the health domains relevant to the process of recovery after abdominal surgery.

Methods

This study was conducted in two parts:

Part 1 (Manuscript 1): A hypothesized conceptual framework of recovery was developed based on literature review and expert opinion. Firstly, a systematic review was undertaken to identify PROMs currently used in the context of recovery after abdominal surgery. All items contained in the PROMs were categorized into health domains covered by the International Classification of Functioning, Disability and Health (ICF). To acquire expert input, 35 perioperative care experts from major surgical societies in North America and Europe were invited to participate in a 2-round Delphi study in which they rated their agreement with each domain. Domains deemed as relevant (>75% agreement) were organized into a diagram comprising a hypothesized conceptual framework of recovery after abdominal surgery.

Part 2 (Manuscript 2): A final conceptual framework of recovery was developed based on patient input. Patients from 4 different countries (Canada, Italy, Brazil and Japan) participated in qualitative interviews focusing on their lived experiences of recovery after abdominal surgery. Interviews were guided by the previously developed hypothesized framework. Interviews were analyzed according to a modified grounded theory approach and transcripts were coded according to the ICF. Codes for which thematic saturation was reached were classified into domains of health that are relevant to the process of recovery after abdominal surgery. These domains were organized into a structured diagram.

Results

Part 1 (Manuscript 1): The systematic review identified 19 PROMs covering 66 ICF domains. 23 experts (66%) participated in the Delphi process. After Round 2, experts agreed that 22 ICF health domains are potentially relevant to the process of recovery after abdominal surgery.

Part 2 (Manuscript 2): 30 patients with diverse demographics and surgical characteristics were interviewed (50% male, age 57±18 years; 66% major or major extended surgery). 39 unique domains of recovery emerged from the interviews, 17 falling under the ICF category of "Body Functions" and 22 under "Activities and Participation". These domains constitute the final conceptual framework of recovery after abdominal surgery.

Conclusion

The research reported in this thesis provides comprehensive insight into the health domains that are relevant to the process of recovery after abdominal surgery. This conceptual framework will support content validity and provide the pivotal basis for the

development of a novel PROM to inform patient-centered research and quality improvement initiatives in abdominal surgery.

RÉSUMÉ

Introduction

En chirurgie, l'utilisation des « mesures des résultats déclarés par les patients » (MRDPs) joue un rôle central dans la prestation de soins de santé de haute qualité fournis au patient. Cependant, les MRDPs actuellement utilisées pour évaluer le rétablissement suite à la chirurgie abdominale manquent de preuves appuyant leurs propriétés métriques. Pour combler ce manque de connaissance, nous avons lancé un programme de recherche qui vise à développer une MRDP conceptuellement pertinente, psychométriquement valable et spécifiquement conçue pour l'évaluation du rétablissement. Basée sur les recommandations de meilleure pratique pour le développement des MRDPs, l'objective de cette thèse était d'élaborer un cadre conceptuel identifiant les domaines de la santé pertinents au processus de récupération après la chirurgie abdominale.

Méthodes

Cette étude a été réalisée en deux parties :

Partie 1 (manuscrit 1) : Un cadre conceptuel hypothétique de la récupération a été établi à la suite d'une analyse documentaire et des opinions d'experts. Premièrement, un examen systématique des MRDPs qui sont actuellement utilisées dans le cadre du rétablissement suite à la chirurgie abdominale a été fait. Les questions incluses dans les MRDPs ont été catégorisées d'après les domaines de la Classification internationale du fonctionnement, du handicap et de la santé (CIF). Ensuite, 35 experts en soins periopératoires, qui sont membres des sociétés chirurgicales en Amérique du Nord et en Europe, ont été invités à participer à deux séries d'un sondage Delphi. Les experts ont indiqué leur degré d'accord avec la pertinence de chaque domaine CIF. Les domaines

jugés pertinents par >75% des experts ont été inclus dans un schéma représentant un cadre conceptuel hypothétique du rétablissement suite à la chirurgie abdominale.

Partie 2 (manuscrit 2) : Un cadre conceptuel final, basé sur l'avis des patients, a été développé. Des patients provenant de 4 pays (Canada, Italie, Brésil, Japon) ont participé aux entretiens qualitatifs qui portaient sur leurs expériences personnelles durant la période de récupération postopératoire. Les entrevues ont été guidées par le cadre conceptuel hypothétique développé dans la partie 1. Elles ont été analysées selon la théorie à base empirique modifiée et les enregistrements ont été codés en fonction de thèmes selon le CIF. Les codes qui ont atteint un point de saturation thématique ont été inclus dans le cadre conceptuel du rétablissement suite à la chirurgie abdominale.

Résultats

Partie 1 (manuscrit 1) : L'examen systématique a identifié 19 MRDPs couvrant 66 domaines CIF. 23 experts (66%) ont participé à l'étude Delphi. Les experts ont convenu que 22 domaines CIF sont potentiellement pertinents au processus de récupération après la chirurgie abdominale.

Partie 2 (manuscrit 2) : 30 patients de caractéristiques démographiques, cliniques et chirurgicales diverses ont passé un entretien individuellement (50% femelle, 57±18 ans, 66% chirurgie majeure ou majeure prolongée). Les entrevues ont produit 39 domaines CIF dont 17 relèvent de la catégorie des « fonctions du corps » et 22 relèvent de la catégorie des « activités et la participation ». Ces domaines constituent le cadre conceptuel identifiant les éléments pertinents au processus de récupération après la chirurgie abdominale.

Conclusion

La recherche décrite dans cette thèse offre un rapport assez exhaustif des domaines de santé pertinents au processus de récupération après une chirurgie abdominale selon la perspective des patients. Ce cadre conceptuel soutiendra la validité de contenu et fournira la base centrale pour le développement d'une MDRP qui contribuera à la recherche centrée sur le patient et les initiatives d'amélioration de la qualité dans le domaine de la chirurgie abdominale.

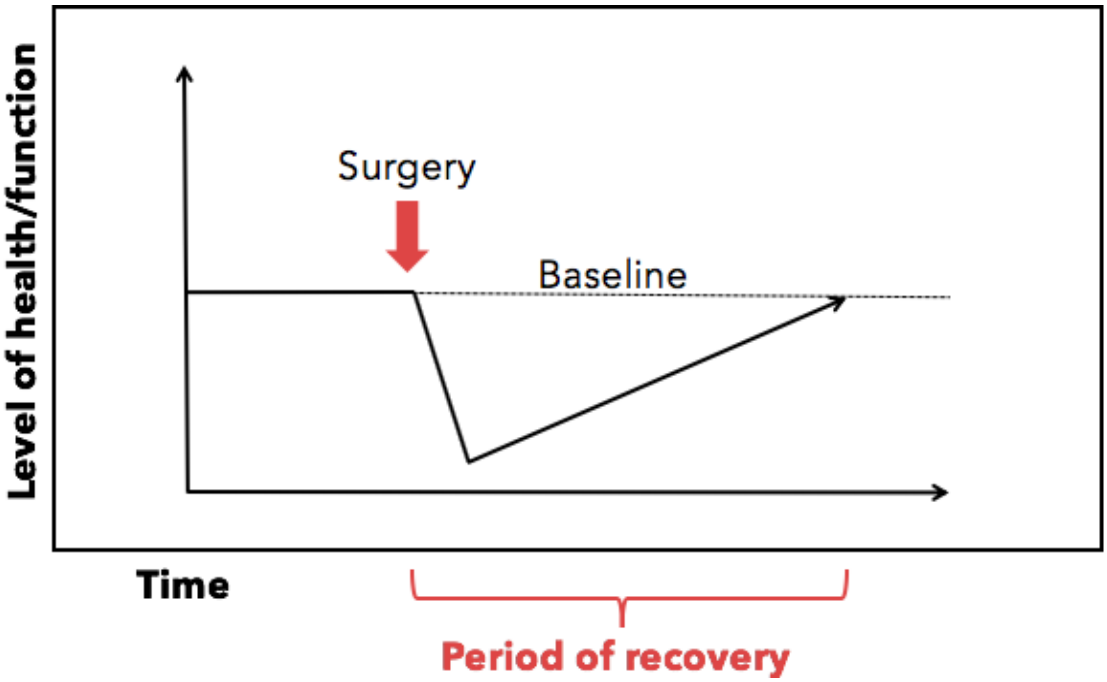
CHAPTER 1

INTRODUCTION

1.1 Recovery after abdominal surgery

Abdominal surgery accounts for the highest volume of in-hospital operations performed in North America [1, 2]. The trend is for this volume to rise even more as, with greater life expectancy, ageing-related morbidities that require surgical intervention will continue to increase [3, 4]. For patients, abdominal surgery represents a major stressor leading to a rapid health decline postoperatively, followed by a gradual return to preoperative health or above [5] **(Figure 1-1)**. This health decline is mainly caused by the "stress response" to surgery, a cascade of metabolic and hormonal effects triggered by tissue injury that may be further exacerbated when postoperative complications occur [6].

Figure 1-1. Surgical patient postoperative recovery trajectory



The lives of recovering patients are impacted in a multitude of ways after they undergo an abdominal surgery procedure. During the period of recovery, the process of progressively returning back to "normality" (i.e. reaching preoperative levels of physical, social, and psychological functioning [7]), patients may withdraw from certain self-care, household, recreational, and economic activities, and often require assistance from others [8, 9]. A full recovery may require weeks to months, and the occurrence of postoperative complications may further lengthen convalescence [5].

From a healthcare system and societal cost perspective, the recovery process following abdominal surgery also imposes a substantial economic burden due to the fact that it is very resource intensive [9]. As hospital stays are getting shorter [10] the costs of postoperative hospitalization are increasingly impacted by recovery after hospital discharge [9, 11], where patients require post-operative follow-up care with surgeons or other specialists, utilize outpatient services (e.g. visits to community health centers), and may need assisted-care facilities (e.g. rehabilitation and convalescence care) [9]. All of this boils down to funding sourced from Canada's public health care system budget. From a societal perspective, the impact of recovery after abdominal surgery may be observed in the context of out-of-pocket payment of medical (e.g. medication) and nonmedical (e.g. hired homecare) expenses, and productivity loss related to the patient's time off of remunerative work [9]. It is also important to consider individuals such as family members and friends that might spend time away from their job to support and assist the patient (i.e. caregiver burden) [9]. Given the multifaceted impact of abdominal surgery, it is critical that surgical research continues to explore ways to improve the patient experience and optimize the use of limited health care resources.

1.2 Measuring 'recovery'

The field of abdominal surgery is rapidly evolving and many advances in operative techniques and perioperative care have been proposed to improve postoperative recovery for patients and potentially reduce care burden [12, 13]. However, "postoperative recovery" is a latent construct (i.e. not directly observable or quantifiable [14]) that is very difficult to define [7]. The process of recovery is highly dynamic and, especially when observed from the patient's perspective, it comprises multiple dimensions of health. This level of complexity cannot be fully captured by a single metric unless the concept of "recovery" itself is well understood. For this reason, evidence regarding the benefits of these innovations have primarily relied on traditional proxy measures such as hospital length of stay and complication rates [15].

Several studies have demonstrated that enhanced recovery pathways (ERPs; perioperative health care programs aiming to accelerate postoperative recovery [16]) and minimally invasive techniques such as laparoscopic surgery [17], decrease hospital length of stay and postoperative complication rates [13, 18]. Although such outcomes are certainly important, they have shortcomings as measures of recovery [19]. Hospital length of stay may be influenced by external factors that are not directly related to surgical recovery itself (e.g. individual hospital discharge criteria, cultural and socioeconomic factors) [20]. Complications are also often measured inconsistently, precluding appropriate comparison across studies measuring this outcome [21]. Such measures also fail to reflect the complexity of the recovery process which involves multiple domains, including functional status, symptom experience and psychological well-being [7]. Previous research supports that patients define recovery as being able to perform

activities as they did prior to surgery, as opposed to being able to leave the hospital earlier or not having complications [22]. Traditional proxy measures such as length of stay and complication rates only address short-term outcomes and disregard patients' longer-term experiences of recovery following hospital discharge [19]. Lastly, such measures are not patient-centered and fail to capture the patient's perspective of their recovery process [23].

Given the research gaps presented, it is essential that we expand from these traditional measures to include longer-term, recovery-specific, and importantly, patient-centered measures of recovery that take the patient's views into account.

1.3 The patient perspective

Historically, assessments of symptom improvement and pertinent functions were primarily completed by physicians who observed and interacted with their patients [24]. Today, the paradigm of optimal medical care has shifted towards a patient-centered approach that incorporates the patient's perspective into various aspects of healthcare assessment. This is particularly important in the field of surgery, where the patient's perception of surgical success can be quite different from the measurable clinical outcomes that are commonly used by clinicians [15].

The discrepancy between the patient and physician's perspective has been explored in previous literature. Wilson and Cleary [25] noted that clinicians are poorly equipped to measure and understand numerous health topics that are relevant from the patient's perspective, including: physical functioning, social functioning, mental health and general health perceptions. Lee et al. [19] conducted one-on-one interviews with patients

and healthcare professionals in order to identify the elements they believed are important when recovering after abdominal surgery. There was discordance between the health concepts important to patients and those important to healthcare providers. Generally speaking, people that occupy different roles in the recovery process (e.g. patients, healthcare providers, family members) may have different opinions about what is relevant during recovery, and these opinions naturally reflect their roles. Therefore, the measurement of recovery from the patients' perspective must address outcomes that actually matter to patients based on the principles of patient-centered care [26, 27].

1.4 Patient-centered care, outcomes and measures

"Patient-centered care" is the practice of care that is compassionate, empathetic, and focused on the patient's own worldview, goals, preferences, values, and needs [14]. This approach is based on the active involvement of patients and their families in health decision-making and self-management, supported by research evidence addressing outcomes that matter to patients [26, 27]. Previous studies suggest that involving patient in their care has the potential to improve outcomes, enhance patient experience and decrease healthcare costs [28-30]. Hence, the patient-centered approach is considered an integral part of delivering value-based, high-quality patient care [31].

It is increasingly recognized across numerous fields of healthcare that many subjective outcomes such as symptom experience, physical function, phycological and social well-being are best captured by patient-reported outcomes [32-34]. Patient-reported outcomes (PROs) are reports of health coming directly from the patient without interpretation by others [35]. They are very versatile in a sense that these outcomes can be measured in absolute terms, such as a patient rating the severity of a symptom [36].

Or they can be used to track changes, such as new onset of a symptoms such as nausea or pain [36]. When assessing health outcomes, there is a strong and growing interest in assessing PROs alongside traditional clinical outcomes because they complement one another and paint a more holistic picture of the patient experience with their care [15, 37].

PROs are assessed using tools called PRO measures (PROMs); these generally come in the form of questionnaires that are completed by patients to provide information on aspects of and changes in their health status [38]. PROMs can either be generic or condition-specific in nature [39]. Generic PROMs (e.g. commonly used health-related quality of life (HRQL) questionnaires such as the Short-form 36 [40]) examine domains that fit a variety of health conditions and provide the opportunity to compare outcomes across different conditions [41]. In contrast, condition-specific PROMs, as the name suggests, contain items that pertain to specific conditions, making them more sensitive (i.e. responsive to change) than generic PROMs when used in specific contexts of care [39].

Overall, PROMs are useful health assessment tools that are associated with several important advantages. Firstly, they are able to capture complex and multidimensional concepts by containing questions that broadly cover health across various domains [23]. They abide by the central values of patient-centered care by integrating the patient's perspective into their healthcare [26, 27]. PROMs can also be completed at several timepoints permitting the assessment of progress or change over time which is potentially informative for numerous stakeholders [23].

1.5 PROMs used in the context of recovery after abdominal surgery

In accordance with the principles of patient-centered care, recent literature advocates that the definition and measurement of recovery after abdominal surgery should include the patients' voice through the use of PROMs [5, 15, 42, 43]. PROMs can contribute to patient engagement and involvement in decision-making related to the surgical care they receive [33]. Their use in surgical trials and daily surgical practice introduces the opportunity to measure valuable outcomes that extend into the post-hospital discharge recovery period [44]. And importantly, PROMs can provide an added dimension to the evaluation and comparison of new surgical innovations by enabling surgeons to better measure outcomes that are historically considered subjective (e.g. postoperative symptom intensity and functional improvement) [33].

Interestingly, studies evaluating the benefits of modern surgical care innovations (e.g. "enhanced recovery pathways" [45] minimally invasive surgery [46]) in terms of impact on PROMs demonstrated that these innovations do not result in clinically relevant differences [41, 47]. These findings beg the question of whether or not such innovations actually translate into improvement in outcomes from the perspective of patients, or perhaps the PROMs themselves fail to accurately measure 'recovery' [19]. It is indeed crucial to explore this question in order to draw valid conclusions.

In 2018, Fiore et al. [48] conducted an extensive literature review that appraised the level of evidence supporting the measurement properties of PROMs used in the context of postoperative recovery after abdominal surgery. Of the 22 PROMs identified in the review, 4 focused specifically focused on abdominal surgery while the remaining 18 were either focused on nonspecific surgeries or were generic PROMs [48]. The study's findings

concluded that none of the PROMs identified fulfill the International Society for Quality of Life Research (ISOQOL) minimum standards for the selection of PROMs for use in patient-centered outcomes and comparative effectiveness research [48, 49]. Given that these PROMs lack robust measurement properties, they cannot be recommended for use in surgical research or clinical practice [48]. This important shortfall may be attributed to the fact that the PROMs currently used in the context of recovery after abdominal surgery were not developed according to optimal scientific standards [24, 50, 51]. The prominent deficit associated with existing PROMs is poor evidence supporting their 'content validity' (i.e. the extent to which the PROM reflects all aspects of the construct it is trying to measure [50]). This introduces the risk of these PROMs failing to cover important domains of health that are relevant to patients. In other words, it is uncertain whether or not the PROMs identified indeed measure 'recovery after abdominal surgery'.

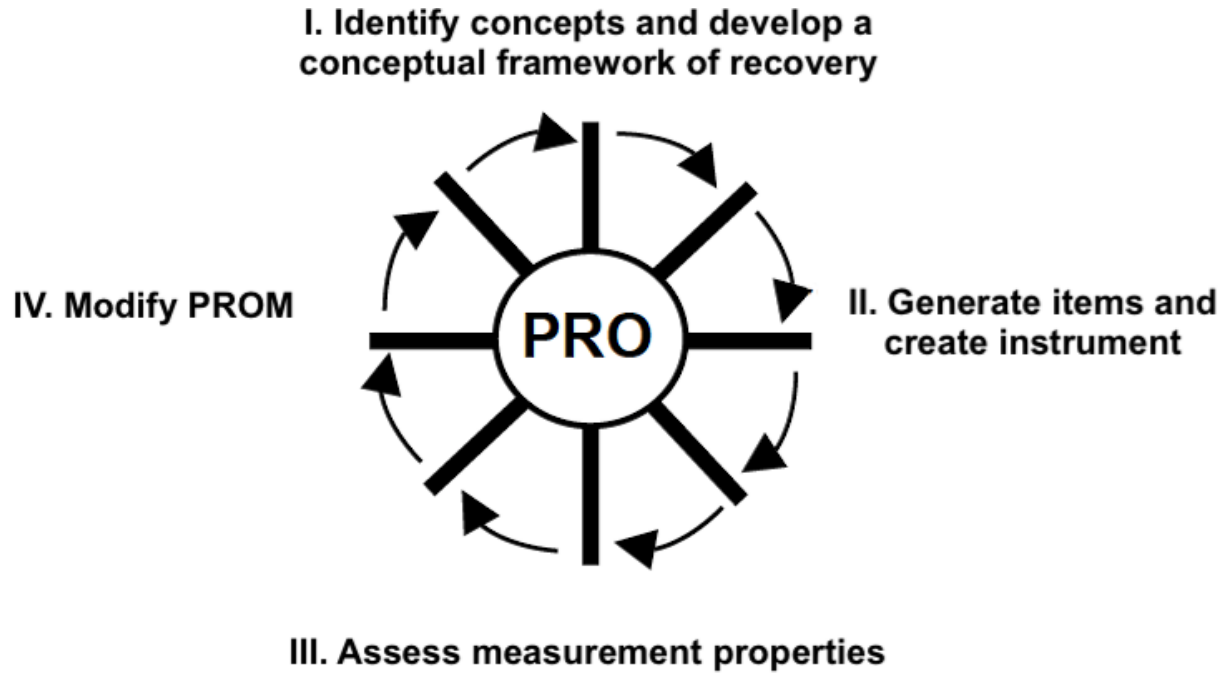
1.6 Current methodological standards for PROM development

Until recent advancement in the field of PRO measurement, it was generally believed that developing patient questionnaires was a straightforward task that can be accomplished with the use of common sense and minimal scientific consideration [52]. Consequently, the development of PROMs has suffered from a lack of theory and poor basic development work [48]. It is now acknowledged that there is a great deal of science and methodological rigor involved in producing high quality PROMs [52].

In 2006, the Food and Drug Administration (FDA) of the United States Department of Health and Human Services published specific guidelines for the development of PROMs to support labeling claims **(Figure 1-2)**. The guidelines heavily emphasize the need for a protocol-driven development process in which the establishment of content validity is

central to creating a PROM that will reliably and accurately measure the specific concept of interest. It is strongly advised to first develop a conceptual framework i.e. an explicit and illustrative diagram that defines the concept to be measured by the PROM [24]. In 2011, The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) followed suit and published a detailed two-part report that describes optimal research practices that address methods for ensuring and documenting the content validity of newly developed PROMs [50, 51]. These ISPOR documents further support the use of a conceptual framework to serve as the critical foundation for PROM development. It is important to note that none of the existing PROMs used in the context of recovery of abdominal surgery that were identified in the review conducted by Fiore et al. [48] followed current best practice recommendations for PROM development [48].

Figure 1-2. FDA PROM development recommendations [24]



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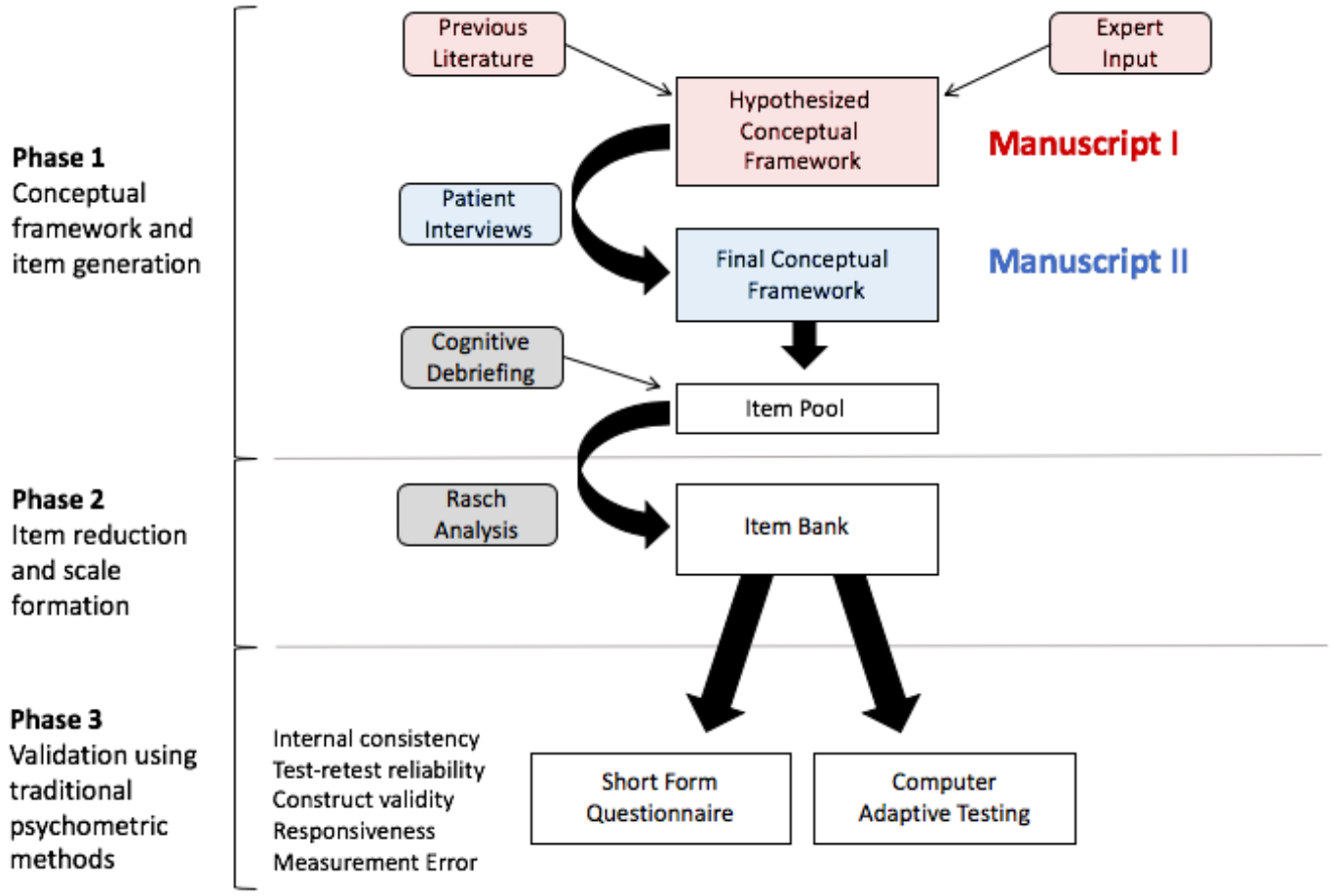
1.7 Thesis objectives

In light of the research gaps discussed, the Minimally Invasive Surgery research group at McGill University initiated a research program to develop a novel conceptually relevant and psychometrically sound PROM to assess recovery after abdominal surgery **(Figure 1-3).** This research complies with FDA [24] and ISPOR [50, 51] guidelines for PROM development.

Figure 1-3. Outline of the process of PROM development [23]



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The core aim of the research projects contained within this thesis was to complete the initial steps of PROM development by establishing a final conceptual framework of recovery after abdominal surgery. Given the multistep nature of this work, it has been divided into two manuscripts. The first manuscript reports the development of a hypothesized conceptual framework of recovery after abdominal surgery based on previous literature and expert input. The second manuscript focuses on finalizing the conceptual framework of recovery based on patients' perspectives elicited from interviews

that explored a wide variety of patients and their unique postoperative recovery experiences.

CHAPTER 2

MANUSCRIPT 1 - Published in Surgical Endoscopy (May 2018)

Development of a Patient-Reported Outcome Measure of Recovery After Abdominal Surgery: A Hypothesized Conceptual Framework

Roshni Alam, BSc [1,2]; Sabrina M Figueiredo, PhD[3,4]; Saba Balvardi, MS[1,2]; Bénédicte Nauche, MLIS[5]; Tara Landry, MLIS[5]; Lawrence Lee, PhD[1,2]; Nancy E Mayo PhD[3,4]; Liane S Feldman, MD[1,2,6]; Julio F Fiore Jr, PhD[1,2 ,6]

[1]Steinberg-Bernstein Centre for Minimally Invasive Surgery and Innovation, McGill University Health Centre, Montreal, QC, Canada

[2] Department of Surgery, McGill University Health Centre, Montreal, QC, Canada

[3] School of Physical and Occupational Therapy, McGill University, Montreal, QC, Canada

[4] Division of Clinical Epidemiology, McGill University, Montreal, QC, Canada.

[5] Medical Libraries, McGill University Health Centre, Montreal, QC, Canada.

[6] Centre for Outcomes Research and Evaluation (CORE), Research Institute of the McGill University Health Centre, Montreal, QC, Canada

Corresponding author

Julio Flavio Fiore Jr, PT, MSc, PhD (ORCID: 0000-0002-0019-8673), Assistant Professor, Department of Surgery, McGill University, Montreal General Hospital. 1650 Cedar Ave, E19-125. Montreal, Quebec, Canada H3G 1A4

Tel: (514) 709-2066

Fax: (514) 934-1934 (ext. 48475)

Email: julio.fiorejunior@mcgill.ca

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Running Title

Hypothesized Conceptual Framework of Recovery

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2.1 ABSTRACT

Background

We initiated a research program to develop a novel patient-reported outcome measure (PROM) to assess postoperative recovery from the perspective of abdominal surgery patients. In light of FDA recommendations, the first stage of our program aimed to, based on previous literature and expert input, develop a hypothesized conceptual framework portraying the health domains that are potentially relevant to the process of recovery after abdominal surgery.

Methods

This study was conducted in three phases: (1) systematic review to identify PROMs with measurement properties appraised in the context of recovery after abdominal surgery, (2) content analysis to categorize the health domains covered by the PROMs according to the ICF, and (3) two-round Delphi study to gain expert input regarding which of these health domains are relevant to the process of recovery. Participants were experts in perioperative care identified through two major surgical societies (35 invited).

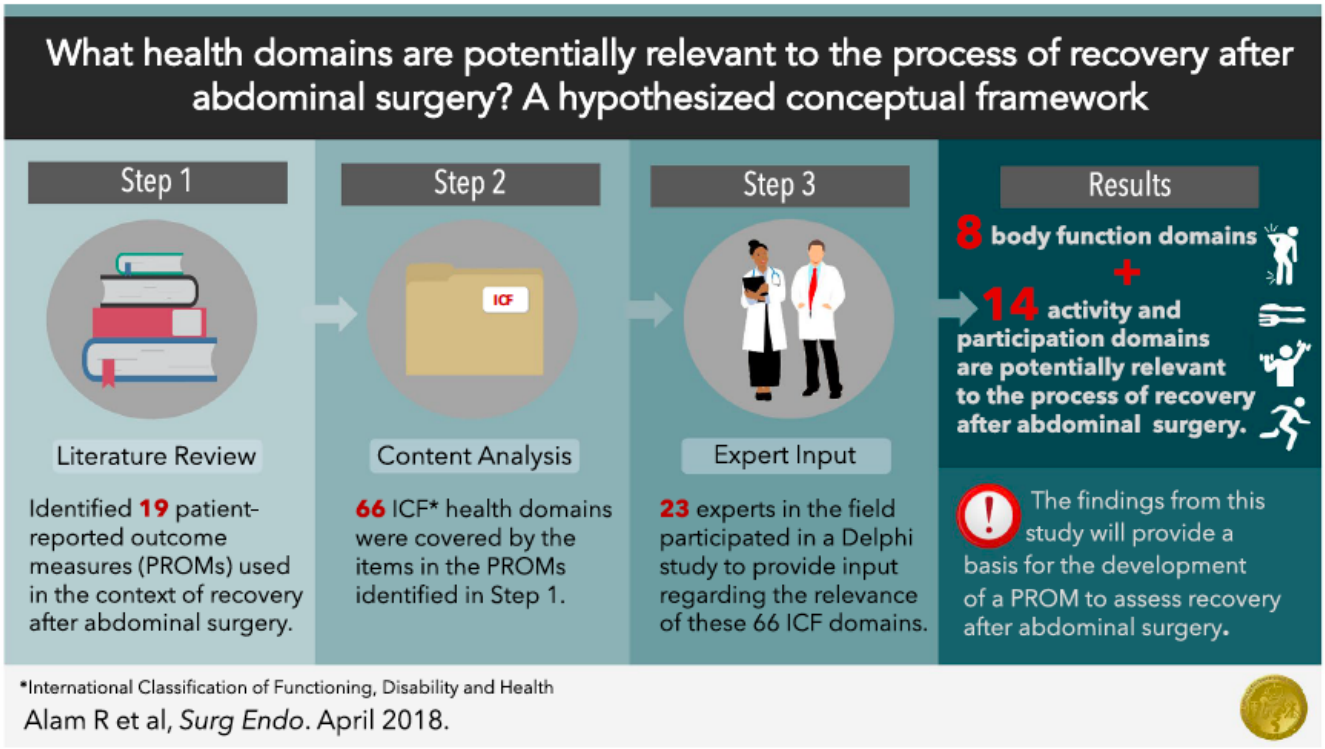
Results

The systematic review identified 19 PROMs covering 66 ICF domains. Twenty-three experts (66%) participated in the Delphi process. After Round 2, experts agreed that 22 health domains (8 Body Functions, 14 Activities and Participation) are potentially relevant to the process of recovery after abdominal surgery. These domains were organized into a diagram, representing our hypothesized conceptual framework.

Conclusions

This hypothesized conceptual framework is an important first step in our research program and will be further refined based on in-depth qualitative interviews with patients. The sound methodological approach used to derive this framework may be valuable for studies aimed to develop PROMs according to FDA standards.

Figure 2-1. Graphical abstract



Keywords

Patient Outcome Assessment, Questionnaires, Self-Report, Abdominal Surgery, Postoperative Period, Recovery of Function

2.2 INTRODUCTION

As with any major operation, patients undergoing abdominal surgery invariably experience a rapid health decline postoperatively, which is followed by a gradual return towards preoperative health [5] . Clinical manifestations of this decline include symptoms (e.g. postoperative pain and fatigue) and changes in functional status and psychological well-being. Length of postoperative recovery, defined as the time to return to preoperative health or 'normal', varies depending on patient characteristics, extent of surgery and occurrence of postoperative complications [8, 53, 54]. Older patients, for example, may take three to six months to recover from a major abdominal operation and some never return to baseline functioning [8]. Prolonged or incomplete postoperative recovery not only increases healthcare costs but is also associated with substantial burden to patients and caregivers (e.g. time away from work, leisure, family and social activities) [9].

In line with the principles of patient-centered value-based care [55], there is growing interest in using patient-reported outcomes (PROs; reports of health coming directly from the patient without interpretation by others) to measure surgical recovery. Recent literature advocates that PRO measures (PROMs) should be a key component of research to support patient-centered decision making and inform quality improvement initiatives [5, 44, 56]. If collected routinely in surgical practice, PROMs can also be a useful tool to guide clinician-patient communication about recovery expectations like the time to return to normal activities [57] and to promote self-management (e.g. empower patients to track their own recovery trajectory and identify complications) [58]. However, a recent systematic review of PROMs that have been used in this context found that they were not developed according to optimal scientific standards and have little evidence supporting

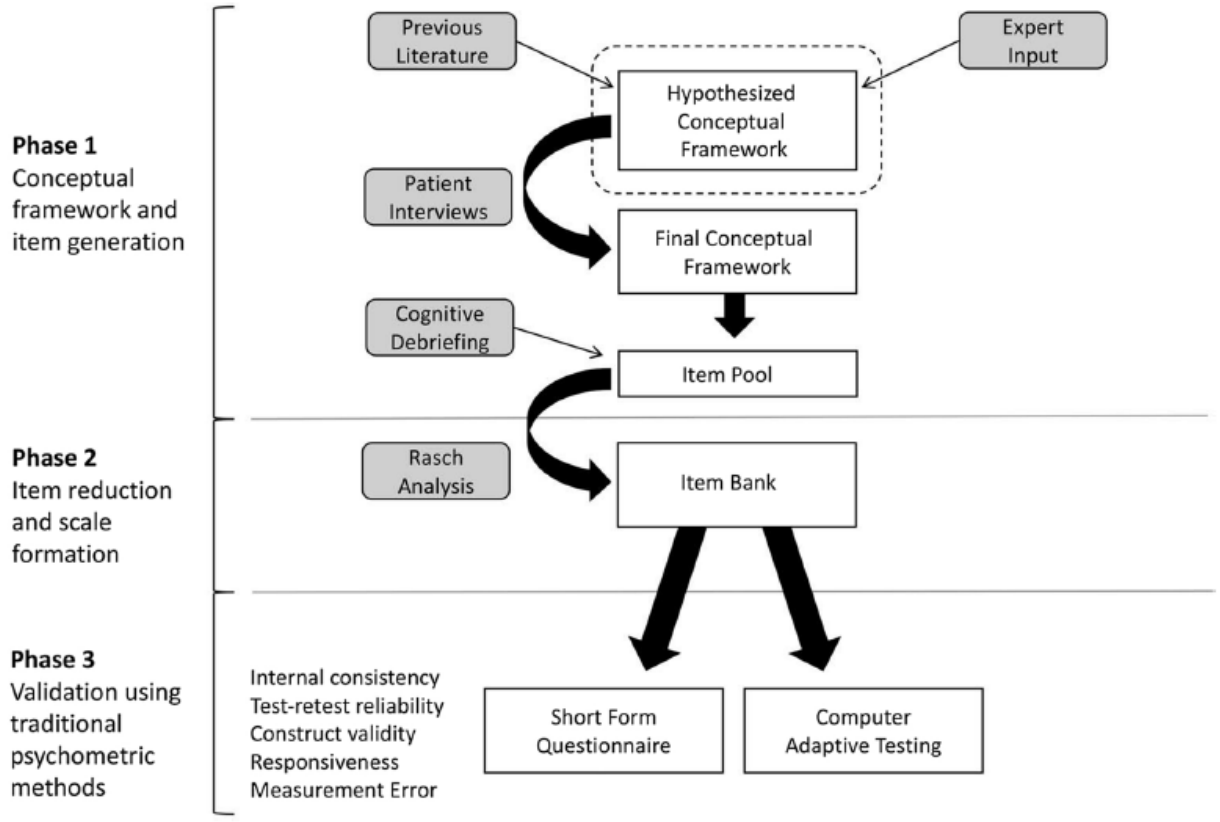
their measurement properties [48]. To bridge this knowledge gap, we initiated a research program to develop a conceptually relevant and psychometrically sound PROM to measure recovery after abdominal surgery.

The field of PROMs has evolved in recent years after the US Department of Health and Human Services Food and Drug Administration (FDA) [24] published specific standards for regulatory approvals based on PRO data. The document emphasizes that PROMs should have strong evidence of 'content validity' (i.e. the extent to which the PROM reflects all aspects of the construct it is trying to measure) supported by a process involving (1) the development of a hypothesized conceptual framework based on literature review and expert opinion and (2) qualitative interviews with patients based on the domains identified, with subsequent adjustment of the conceptual framework as needed. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) also supports the need to develop a hypothesized conceptual framework to outline the initial PROM structure and, most importantly, inform the subsequent stages of PRO development involving patient interviews [50, 51].

In this study, we developed a hypothesized conceptual framework portraying the health domains that, according to previous literature and expert opinion, are potentially relevant to the process of recovery after abdominal surgery. In line with FDA and ISOPOR guidelines, this is an essential step within the first phase of development of a novel PROM to measure postoperative recovery from the perspective of patients undergoing abdominal surgery.

2.3 METHODS

Figure 2-2. Outline of the process of PROM development. This paper describes the development of our hypothesized conceptual framework (enclosed by the dashed line)



The process of PROM development guiding our entire research program is outlined in **Figure 2-2**. Development of the hypothesized conceptual framework was conducted in three steps: (1) systematic literature review to identify PROMs used in the context of recovery after abdominal surgery, (2) content analysis to categorize the health domains covered by the PROMs identified, and (3) Delphi study to gain expert input regarding which of these health domains are relevant to the process of recovery after abdominal surgery. Steps 1 and 2 were informed by preliminary data from a systematic review and content analysis conducted by our group and published elsewhere [48].

2.3.1 Step 1. Systematic literature review

Patient-reported outcome measures previously appraised in the literature were identified using preliminary data from a systematic review assessing the measurement properties of existing PROMs used in the context of recovery after abdominal surgery [48].To inform the development of this hypothesized conceptual framework, we analyzed PROMs identified from a literature search carried out from the 9th to 14th of October 2014 (in the previously published work, the search was updated in August 2016 [48]). Data extraction focused on the specific items (questions) included in each PROM. PROMs were excluded from the analysis if specific items could not be retrieved from the literature or internet search engines, or by contacting the authors. Further details about the search strategies, selection criteria and data extraction methods have been reported elsewhere [48].

2.3.2 Step 2. Content analysis of the PROMs

To categorize the domains of health covered by each PROM identified in the literature, individual items included in each measure were linked to the World Health Organization's International Classification of Functioning, Disability and Health (ICF) [59], which provides a common language for describing health and health-related states. In the present study, PRO items were linked to the ICF up to the two-level classification [60]. For example, a symptom such as abdominal pain, which is part of the Body Functions (B) chapter, is classified under 'Sensory Functions and Pain' (B2; first level classification) and 'Sensation of Pain' (B280; second level classification). Further details about our process of ICF mapping have been previously reported [48]. At the end of this process, we compiled a list of ICF health domains covered by the PROMs identified.

2.3.3 Step 3. Delphi study

To finalize our hypothesized conceptual framework of recovery after abdominal surgery, we conducted a web-based Delphi study to gather expert input regarding the relevance of each health domain identified in the literature. The Delphi technique is a method of systematically surveying a group of experts to reach consensus opinion on a specific topic. It involves the anonymous completion of a series of questionnaires interspersed with summary and feedback derived from previous responses [61, 62]. We followed current recommendations for conducting and reporting Delphi studies in health research [63]. The Delphi study was approved by the McGill University Ethics Review Board (study # A03-E13-16B).

Panel nomination and recruitment

A multidisciplinary panel of clinicians with expertise in perioperative care and strategies to enhance recovery after abdominal surgery were invited to participate in this study. Potential participants were identified though major surgical organizations in North America (members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) SMART Enhanced Recovery task force; n=15) and Europe (board members, executive committee and committee officers of the Enhanced Recovery After Surgery (ERAS) Society; n=10). An invitation letter was sent via e-mail providing a brief outline of the project, its objectives, expected number of rounds and anticipated time commitment. As the study was conducted in English, ability to communicate in English was a prerequisite for participation. A positive response to the invitation letter served as informed consent.

Delphi process

The Delphi study was conducted in 2 rounds and surveys were responded to electronically via secure web-based survey software (QuestionPro, Survey Analytics LLC; Seattle, WA). Prior to each round, surveys were pilot tested among surgeons at our institution; changes in structure and word clarity were made in response to their feedback. At each round, a web link to the survey was distributed via email and experts were given two weeks to respond. A reminder to complete the survey was sent at one week. An interval of one week between rounds was used to summarize the data and develop the next survey.

Round 1

Members of the expert panel were presented a list of all health domains covered by the PROMs identified in the systematic review, including the specific definition of each domain according to the ICF. They were asked to, based on their clinical experience and knowledge from previous literature, use a 4-point Likert scale (strongly disagree; disagree; agree; strongly agree) to rate their agreement as to whether each specific health domain is relevant to the process of recovery after abdominal surgery. A space was also provided for experts to present arguments and literature citations in support of their opinion or to suggest new domains to be added. As we were only interested in factors associated with functional recovery (i.e. ICF domains corresponding to body function, activity and participation), domains related to environmental factors (e.g. satisfaction with care, support from health professionals) were not included in the survey.

Round 2

The summary of responses obtained in Round 1 (distribution of Likert scale scores and percentage agreement with each health domain), expert comments, and literature

citations were incorporated into a second survey. During this round, experts were given the opportunity to view the group results and change their own ratings in light of their colleagues' responses and arguments.

Data analyses

Distribution of Likert scale scores in Rounds 1 and 2 were extracted from the summary reports generated by the survey software (QuestionPro, Survey Analytics LLC; Seattle, WA). Domains of health rated as agree or strongly agree by ≥ 75% of the experts after Round 2 were deemed relevant to the process of recovery. These health domains were then organized into a structured diagram, representing our hypothesized conceptual framework of recovery after abdominal surgery.

2.4 RESULTS

2.4.1 Systematic review

A total of 11054 unique articles were identified by the search and 145 underwent full-text review. Of these, 117 were excluded. Twenty-eight studies fulfilled our selection criteria and were analyzed [40, 64-90]. These studies appraised a total of 19 different PROMs which are listed in **Table 2-1**. The number of items included in each PROM ranged from 5 to 40. A full description of the article screening process, details about the included studies (i.e. targeted population, sample characteristics, measurement properties assessed) and characteristics of the PROMs identified have been reported elsewhere [48].

Table 2-1. List of patient-reported outcome measures appraised to inform the development of a hypothesized conceptual framework of recovery after abdominal surgery

Patient-reported outcome measures		
Full name	Abbreviation	# of ICF domains covered
Well-Being Index for Surgical Patients [79]	WISP	7
Quality of Recovery-9 [19, 69, 80]	QOR-9	8
Post-Discharge Surgical Recovery Scale[67, 85]	PSR Scale	8
Quality of Recovery-40 [73, 74, 76, 81, 87]	QOR-40	13
Surgical Recovery Index [86]	SRI	9
Recovery of Finnish Short-Stay Surgery [84]	-	9
Abdominal Surgery Impact Scale [70, 88, 89]	ASIS	8
Convalescence and Recovery Evaluation [72]	CARE	6
Recovery Index-10 [76]	RI-10	5
Short-Form 36/RAND-36 [19, 40, 76]	SF-36	9
Postoperative Recovery Profile [65, 70]	PRP	14
Postoperative Quality of Life [71, 75]	PQL	8
Functional Recovery Index [90]	FRI	6
Post General Surgery Quality of Life [66]	PGSQL	15
Surgical Recovery Scale [82]	SRS	6
Post-Operative Recovery Index [68]	PoRI	11
Short-Form 6 Dimension [77, 78]	SF-6D	8
Quality of Recovery-15 [83]	QOR-15	10
Euro Quality of Life 5 Dimension [78]	EQ-5D	10

2.4.2 Content analysis

A total of 66 two-level ICF domains were covered by the 19 PROMs (27 Body Functions, 35 Activities and Participation, 4 Environmental Factors). These domains were subsequently included in the Delphi study and are identified in the first column of **Table 2-1.** The ICF domains covered by each specific PROM have been previously reported [48]. The domains most commonly covered were 'sensation of pain' (n=18), 'energy and drive function' (n=15), 'emotional functions' (n=12), 'carrying out daily routine' (n=12) and 'remunerative employment' (n=11). Several PROMs comprised items that are not

classifiable by the ICF due to lack of precision (e.g. 'how would you rate your general health?') (n=11). After the completion of ICF mapping, domains related to environmental factors were excluded from further analysis.

2.4.3 Delphi study

Of the 35 experts contacted, 23 (66%) responded to the invitation letter and participated in at least one round of the Delphi process. The rate of survey completion was 88% in Round 1 (n=21) and 75% in Round 2 (n=18). The expert panel comprised 20 surgeons (87%), one anesthesiologist (4%), one nurse (4%) and one physiotherapist (4%). Panel members were from four different countries (United States 61%, Canada 26%, Denmark 9% and Spain 4%). The Round 1 survey was sent on March 10th, 2016. The Round 2 survey was sent on April 4th, 2016. Data collection for the study was completed within 6 weeks.

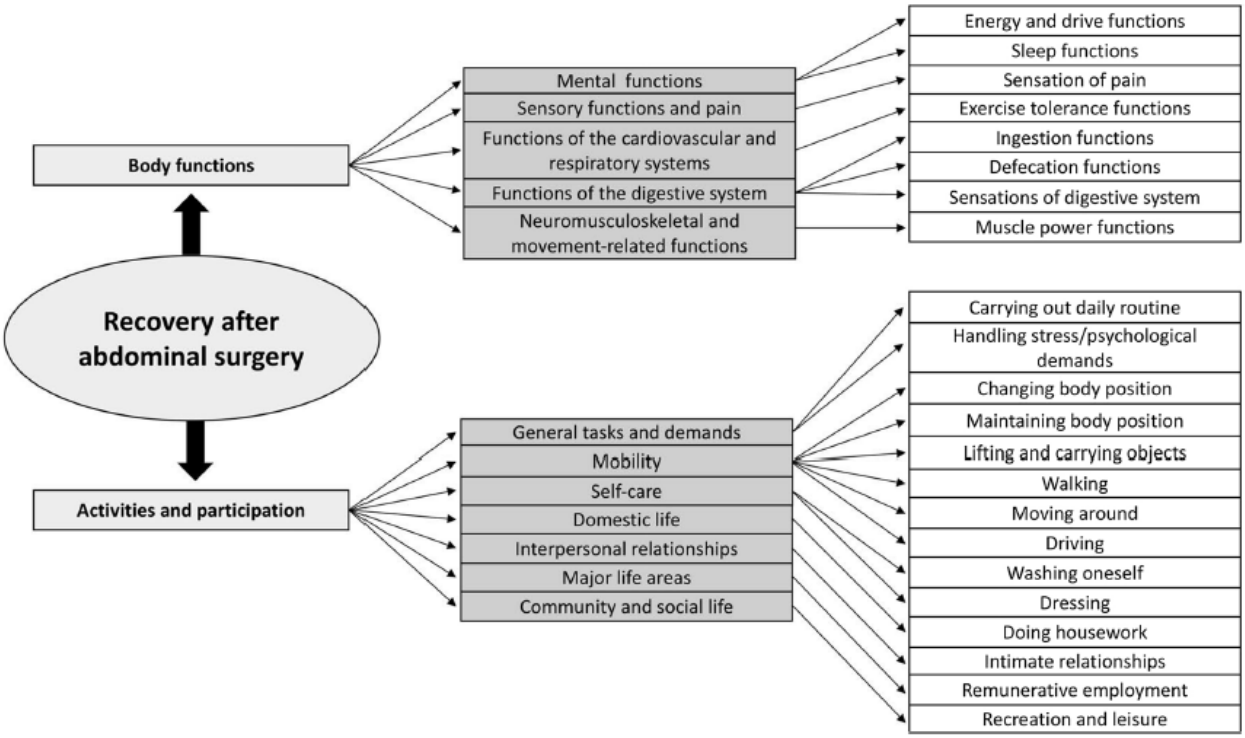
Table 2-2 shows the summary of responses obtained in Rounds 1 and 2. None of the participants suggested the inclusion of new domains between rounds. Likert scale scores distribution varied between rounds for all domains. Achievement of consensus criteria (≥75% agree or strongly agree) varied between rounds for three domains. The domains 'attention functions' and 'respiration functions' were only endorsed in Round 1 but not in Round 2; therefore, they were removed from the framework. The domain 'intimate relationships' was only endorsed and included in the framework after Round 2. None of the participants provided arguments to justify their change in opinion. At the completion of the last round, the panel agreed that 22 health domains (8 Body Functions, 14 Activities and Participation) are relevant to the process of recovery after abdominal surgery. **Figure 2-3** shows the hypothesized conceptual framework of recovery after abdominal surgery proposed in light of these results.

Table 2-2. Distribution of Likert scale scores and achievement of consensus criteria in Rounds 1 and 2 of the Delphi study

ICF Domains	Round 1					Round 2				
	Strongly disagree	Disagree	Agree	Strongly agree	**Consensus achieved (≥75% agree/strongly agree)**	Strongly disagree	Disagree	Agree	Strongly agree	**Consensus achieved (≥75% agree/strongly agree)**
Body functions (B)										
Mental Functions (B1)										
Consciousness function (B110)	0%	33%	38%	29%		0%	61%	33%	6%	
Orientation function (B114)	14%	24%	52%	10%		6%	61%	33%	0%	
Temperament and personality functions (B126)	24%	24%	33%	19%		11%	61%	28%	0%	
Energy and drive functions (B130)	0%	5%	55%	40%	**X**	0%	6%	28%	67%	**X**
Sleep function (B134)	0%	5%	57%	38%	**X**	0%	6%	22%	72%	**X**
Attention functions (B140)	0%	14%	67%	19%	**X**	0%	28%	39%	33%	
Memory functions (B144)	5%	29%	57%	10%		6%	56%	33%	6%	
Emotional functions (B152)	10%	19%	48%	24%		0%	33%	67%	0%	
Sensory functions and pain (B2)										
Sensation of pain (B280)	0%	0%	14%	86%	**X**	0%	0%	6%	94%	**X**
Voice and speech functions (B3)										
Fluency and rhythm of speech functions (B330)	19%	57%	14%	10%		33%	61%	6%	0%	
Functions of the cardiovascular, hematological, immunological and respiratory systems (B4)										
Respiration functions (B440)	0%	14%	38%	48%	**X**	6%	33%	44%	17%	
Exercise tolerance functions (B455)	0%	0%	33%	67%	**X**	0%	0%	17%	83%	**X**
Functions of the digestive, metabolic and endocrine systems (B5)										
Ingestion functions (B510)	0%	0%	43%	57%	**X**	0%	6%	11%	83%	**X**
Defecation functions (B525)	0%	10%	29%	62%	**X**	0%	6%	18%	76%	**X**
Sensations associated with the digestive system (B535)	0%	10%	29%	62%	**X**	0%	0%	22%	78%	**X**
Genitourinary and reproductive functions (B6)										
Urinary excretory functions (B620)	0%	33%	38%	29%		0%	28%	72%	0%	
Neuromusculoskeletal and movement-related functions (B7)										
Muscle power functions (B730)	5%	0%	71%	24%	**X**	0%	11%	44%	44%	**X**
Involuntary movement functions (B765)	25%	40%	30%	5%		24%	71%	6%	0%	
Functions of the skin and related structures (B8)										

Repair functions of the skin (B820)	10%	43%	33%	14%		6%	61%	33%	0%	
Activity and participation (D)										
Learning and applying knowledge (D1)										
Watching (D110)	19%	48%	29%	5%		17%	83%	0%	0%	
Reading (D166)	14%	43%	38%	5%		11%	83%	6%	0%	
Writing (D170)	19%	43%	29%	10%		11%	83%	6%	0%	
General tasks and demands (D2)										
Carrying out daily routine (D230)	0%	10%	52%	38%	**X**	0%	0%	59%	41%	**X**
Handling stress and other psychological demands (D240)	0%	5%	71%	24%	**X**	0%	0%	67%	33%	**X**
Communication (D3)										
Communicating with - receiving - spoken messages (D310)	24%	38%	24%	14%		11%	78%	11%	0%	
Conversation (D350)	24%	43%	29%	5%		11%	83%	6%	0%	
Mobility (D4)										
Changing basic body position (D410)	0%	5%	30%	65%	**X**	0%	0%	22%	78%	**X**
Maintaining body position (D415)	0%	14%	48%	38%	**X**	0%	11%	44%	44%	**X**
Lifting and carrying objects (D430)	0%	5%	29%	67%	**X**	0%	0%	33%	67%	**X**
Hand and arm use (D445)	14%	33%	29%	24%		0%	83%	17%	0%	
Walking (D450)	0%	5%	62%	33%	**X**	0%	6%	39%	56%	**X**
Moving around (D455)	0%	5%	43%	52%	**X**	0%	0%	33%	67%	**X**
Driving (D475)	0%	14%	62%	24%	**X**	0%	17%	50%	33%	**X**
Self-care (D5)										
Washing oneself (D510)	5%	0%	62%	33%	**X**	0%	6%	33%	61%	**X**
Toileting (D530)	10%	19%	48%	24%		0%	33%	61%	6%	
Dressing (D540)	0%	19%	38%	43%	**X**	0%	11%	72%	17%	**X**
Eating (D550)	14%	29%	38%	19%		0%	72%	22%	6%	
Looking after one's health (D570)	0%	43%	33%	24%		0%	61%	39%	0%	
Domestic life (D6)										
Doing housework (D640)	0%	5%	48%	48%	**X**	0%	6%	44%	50%	**X**
Interpersonal interactions and relationships (D7)										
Intimate relationships (D770)	0%	33%	33%	33%		6%	6%	72%	17%	**X**
Major life areas (D8)										
Remunerative employment (D850)	0%	5%	48%	48%	**X**	0%	6%	39%	56%	**X**
Community, social and civic life (D9)										
Recreation and leisure (D920)	0%	14%	48%	38%	**X**	0%	6%	50%	44%	**X**

Figure 2-3. Hypothesized conceptual framework of recovery after abdominal surgery



2.5 DISCUSSION

This study outlines a hypothesized conceptual framework of recovery after abdominal surgery based on information from previous literature and expert opinion. This framework emphasizes the potential impact of abdominal surgery on body impairments, activity limitations and participation restrictions, and based on this information, hypothesizes which health domains should be addressed in a PROM targeting the process of postoperative recovery after abdominal surgery. Our study provides an essential first step in a research program aimed to develop a novel recovery-specific PROM and will guide subsequent steps of PRO development, providing guidance for domains to address in patient interviews.

Although the development of an initial hypothesized conceptual framework is recommended by current guidelines for PRO development, these guidelines do not suggest specific methods to derive these frameworks [24, 50, 51]. This study provides a sound methodological approach to develop hypothesized conceptual frameworks using a systematic literature review to identify available evidence followed by a Delphi study to obtain input from experts. The Delphi method has been widely used in healthcare research as it provides several advantages over other methods to gather expert opinion (e.g. face-to-face meetings), such as allowing anonymous discussion without the influence of personal status, enabling alteration of personal views without embarrassment and combining opinions from experts who are geographically dispersed [61-63]. Another strength of our study was that this hypothesized framework was built around the ICF, an international model that provides a unified, holistic and standardized language to classify and describe health and functioning [59]. Using the ICF language enables a broad understanding of our framework by clinicians and researchers from various disciplines and allows comparison with other frameworks, within and across health conditions.

Many PROMs have been developed and tested in the context of recovery after abdominal surgery. However, a recent systematic review by our group highlighted that there is limited evidence supporting their measurement properties [48]. Poor evidence of content validity was common, as few PROMs were supported by a conceptual framework of recovery. Therefore, it is unclear whether their domains and items are appropriate and comprehensive in relation to the intended measurement concept, use and targeted population. The lack of a conceptual framework may, in part, explain the impressive variety of health domains covered by the different PROMs in the study [48]. Some PROMs covered domains that are potentially irrelevant to the process of recovery (e.g.

temperament functions such as extraversion and agreeableness), while others failed to address domains that are likely to be important (e.g. gastrointestinal function). Previous research suggests that the latter issue is often observed when generic PROMs are used to measure postoperative recovery (e.g. Short-form 36 (SF-36) and EUROQOL-5D (EQ-5D)) [19]. This finding supports that PRO measurement in abdominal surgery should be underpinned by a condition-specific framework.

Three previous studies specifically outlined conceptual frameworks of recovery after abdominal surgery [19, 72, 88], but the development process was poorly reported and did not follow current standards by FDA and ISPOR. Furthermore, results were somewhat conflicting. For example, postoperative fatigue is a widely recognized symptom experienced after abdominal surgery [91] that was included in some [19], but not all conceptual frameworks of recovery [72, 88]. The framework hypothesized in the current study resonates with domains that have been included in previous frameworks and will be further refined based on patient input. It is important to emphasize that the PROM to be developed will focus on recovery outcomes related to impairments (i.e. problems with body functions), activity limitations and participation restrictions; therefore, issues classified by the ICF under the umbrella 'environmental factors', were not included in the Delphi study surveys and will not be addressed in future steps of PRO development.

Some limitations of the study need to be acknowledged. First, in light of the Delphi process timeline, only PROMs identified up to October 2014 were assessed in the present study. In an update search conducted in August 2016 another three relevant PROMs were identified (Cleveland Global Quality of Life, PROMIS 10 and WHO Disability Assessment Schedule 2.0) [48]; however, content analysis of these PROMs supports that they would not have contributed new relevant health domains to our framework [48]. Three authors

of this paper (JF, LL and LF) are members of one of the surgical societies involved in this study (SAGES), hence, they also responded to the Delphi questionnaires. However, risk of 'researcher bias' (i.e. study results being intentionally or unintentionally skewed towards the authors' opinion) was minimized by using an independent survey platform to collect data and produce summary reports. Another important limitation of our Delphi study was that our panel comprised mostly surgeons (87%). Consequently, the perspectives of clinicians from other disciplines may have been underrepresented. For example, our Delphi process missed the viewpoint of primary care clinicians (i.e. family physicians) and gastroenterologists who may have important insights about the long-term recovery of patients undergoing abdominal surgery. Lack of information regarding further participant characteristics (e.g. subspecialty of interest, years of experience in research and/or clinical practice) is another limitation. Also, the panel was only comprised of experts from Europe and North America. As perceptions of postoperative recovery may be sensitive to differences in culture and health-systems, this may limit the generalizability of the framework proposed in this study. This limitation will be addressed in the next steps of PROM development (Figure 1) as this framework is refined through international qualitative interviews with patients from a wider variety of settings, which will also underpin the generation of items for the new PROM. This framework may also be further revised as we conduct cognitive interviews to ensure that domains and items are comprehensive and well understood by patients [51]. Modern psychometrical methods (Rasch measurement theory) will be used to optimize item selection and inform scoring algorithms, determining the viability of producing an overall 'recovery score' or the need to score different domains of recovery separately [92].

The lack of PROMs with sound content validity is a major knowledge gap that limits patient-centered research and quality improvement initiatives in abdominal surgery. In this study, we propose a hypothesized conceptual framework of recovery after abdominal surgery based on information from previous literature and expert input. This framework is an important first step in our research program and will be further refined in future stages of PRO development. The sound methodological approach used to derive this hypothesized framework may be valuable for studies aimed to develop PROMs according to FDA and ISPOR standards.

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University Medical Center, Nashville, USA), Dr José Ramírez (Hospital Clinico Universitario, Zaragoza, Spain), Dr Michele Riordon (The Methodist Hospital, Houston, USA), Dr Anthony Senagore (University of Texas Medical Branch at Galveston, Galveston, USA) Dr Vadim Sherman (Houston Methodist Hospital, Houston, USA), Dr Tonia Young-Fadok (Mayo Clinic College of Medicine, Phoenix, USA)

2.7 DISCLOSURES

Roshni Alam, Saba Balvardi, Bénédicte Nauche and Tara Landry have no conflicts of interest or financial ties to disclose. Dr Sabrina M Figueiredo and Dr Nancy E Mayo have no conflicts of interest or financial ties to disclose. Dr Julio F Fiore Jr and Dr Liane S Feldman report a grant from SAGES during the conduct of the study. Dr Lawrence Lee reports a grant from Johnson & Johnson outside the submitted work.

BRIDGE

Chapter 2 described the development of a hypothesized conceptual framework of recovery that is based on previous literature and expert input. According to FDA and ISPOR recommendations [24, 50, 51], hypothesized models provide the preliminary structural groundwork necessary to inform qualitative patient interviews involved in the next step of PROM development. However, after the completion of this hypothesized framework, conducting qualitative interviews with the targeted surgical population is key to building strong evidence supporting the content validity of a future PROM. After all, a robust PROM will exclusively ask questions concerning health domains that are relevant and meaningful to patients; the key stakeholders that are living the recovery process. Therefore, the next chapter answers a very important question in order to finalize the conceptual framework, "What domains of health are relevant to patients during their recovery after abdominal surgery?"

CHAPTER 3

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Development of a Conceptual Framework of Recovery After Abdominal Surgery

Roshni Alam[1,2]; Joel Montanez[3]; Susan Law[4,5]; Lawrence Lee[1,2]; Nicolò Pecorelli[6]; Yusuke Watanabe; Luciana D Chiavegato[8]; Massimo Falconi[6]; Satoshi Hirano[7]; Nancy E Mayo[9,10,11]; Liane S Feldman[1,2,11]; Julio F Fiore Jr[1,2,11]

[1] Steinberg-Bernstein Centre for Minimally Invasive Surgery and Innovation, McGill University Health Centre, Montreal, QC, Canada

[2] Department of Surgery, McGill University Health Centre, Montreal, QC, Canada

[3] St. Mary's Research Centre, St. Mary's Hospital, Montreal, QC, Canada

[4] Institute for Better Health, Trillium Health Partners, Mississauga, ON, Canada

[5] Institute for Health Policy, Management and Evaluation, University of Toronto, ON, Canada

[6] Division of Pancreatic Surgery, Pancreas Translational & Clinical Research Center, San Raffaele Scientific Institute, Milan, Italy

[7] Department of Gastrointestinal Surgery, Hokkaido University Graduate School of Medicine, Sapporo, Japan

[8] Department of Medicine, Pulmonary Division, Federal University of Sao Paulo, Sao Paulo, Brazil

[9] School of Physical and Occupational Therapy, McGill University, Montreal, QC, Canada

[10] Division of Clinical Epidemiology, McGill University, Montreal, QC, Canada.

[11] Centre for Outcomes Research and Evaluation (CORE), Research Institute of the McGill University Health Centre, Montreal, QC, Canada

Corresponding author

Julio Flavio Fiore Jr, PT, MSc, PhD (ORCID: 0000-0002-0019-8673), Assistant Professor, Department of Surgery, McGill University, Montreal General Hospital. 1650 Cedar Ave, L8-121. Montreal, Quebec, Canada H3G 1A4

Tel: (514) 709-2066

Fax: (514) 934-1934 (ext. 48475)

Email: julio.fiorejunior@mcgill.ca

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Running Title

Final Conceptual Framework of Recovery

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3.1 ABSTRACT

Background

There is a lack of patient-reported outcome measures (PROMs) with robust measurement properties to assess postoperative recovery and support patient-centered care after abdominal surgery. The aim of this study was to establish a conceptual framework of recovery after abdominal surgery to support the development of a conceptually relevant and psychometrically sound PROM.

Methods

Patients from 4 different countries (Canada, Italy, Brazil and Japan) participated in qualitative interviews focusing on their lived experiences of recovery after abdominal surgery. Interviews were guided by a previously developed hypothesized conceptual framework established based on a literature review and expert consensus. Interviews were analyzed according to a modified grounded theory approach and transcripts were coded according to the International Classification of Functioning, Disability and Health (ICF). Codes for which thematic saturation was reached were classified into domains of health that are relevant to the process of recovery after abdominal surgery. These domains were organized into a structured diagram.

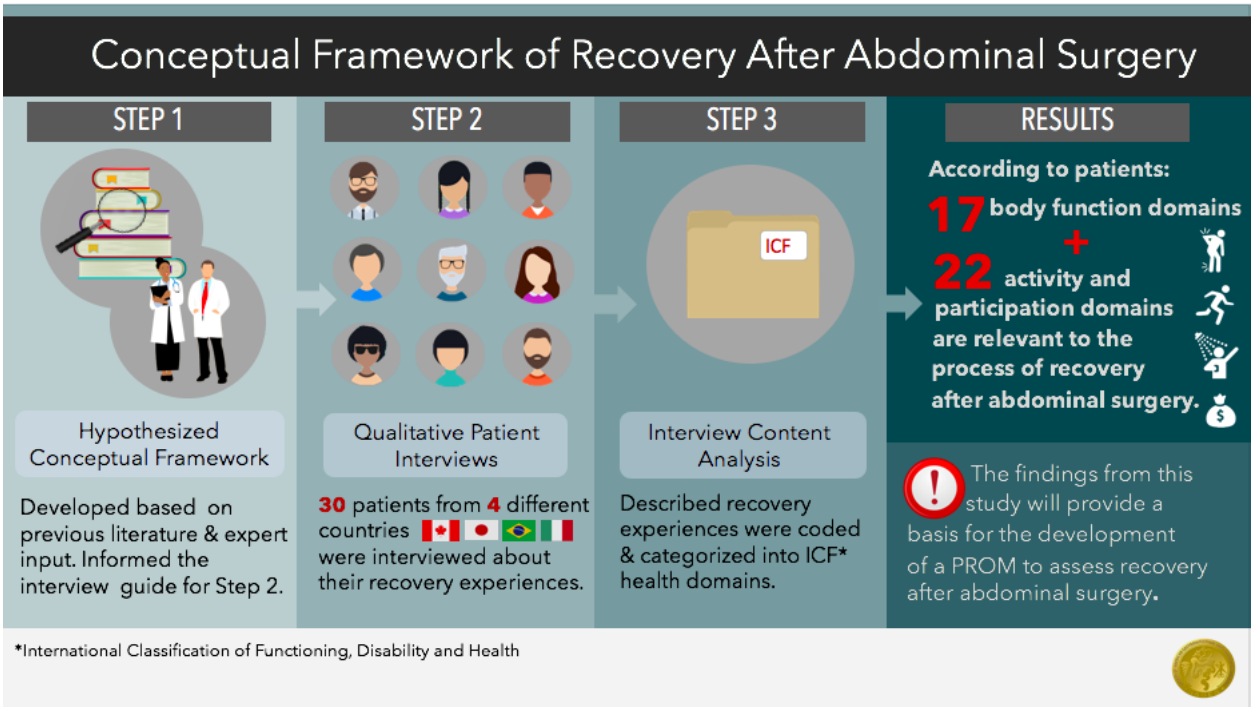
Results

30 patients with diverse demographics and surgical characteristics were interviewed (50% female, age 57±18 years, 66% major or major extended surgery). 39 unique domains of recovery emerged from the interviews, 17 falling under the ICF category of "Body Functions" and 22 under "Activities and Participation". These domains constitute the conceptual framework of recovery after abdominal surgery.

Conclusions

This study provides comprehensive insight into patients' perspectives of the recovery process after abdominal surgery. This conceptual framework will support content validity and provide the pivotal basis for the development of a novel PROM to inform quality improvement initiatives and patient-centered research in abdominal surgery.

Figure 3.1 Graphical Abstract



Keywords

Patient Reported Outcome, Questionnaires, Self-Report, Abdominal Surgery, Postoperative Period, Recovery of Function

3.2 INTRODUCTION

The field of abdominal surgery is rapidly evolving. Over the last 20 years numerous innovations have emerged such as minimally invasive surgery [46], robotics [45] and enhanced recovery pathways [93]. While improving postoperative recovery for patients is an overarching goal of these innovations, “recovery" is a complex latent construct (i.e. not directly observable or quantifiable [14]) that is comprised of multiple dimensions of health (e.g. symptoms, functional status and psychological well-being). As it currently stands, recovery after abdominal surgery is measured inaccurately and inconsistently due to the lack of a clear definition of what it represents [5, 19]. This definition takes on an additional degree of complexity when considering the many stakeholders involved in the recovery process (e.g. patients, family members, healthcare providers, administrators), each of whom may have a different take on its meaning.

In accordance with the principles of patient-centered care, recent literature advocates that the meaning and measurement of recovery should incorporate the patients' voice through the use of patient-reported outcomes (PROs; reports of health coming directly from the patient without interpretation by others[24]) [19, 44, 56]. In comparison to proxy measures of recovery traditionally used in abdominal surgery literature (e.g. length of stay, complication rates) [15], the use of PROs to measure recovery leads to several advantages: (1) it allows patients to remain the principal stakeholders during their recovery process, (2) it allows a broad assessment of health across various domains hence capturing the multidimensionality of recovery, and (3) given that PRO measures (PROMs) generally come in the form of questionnaires, they can be completed at several timepoints permitting the assessment of a patient’s recovery trajectory [19]. A recent comprehensive systematic review, however, revealed that PROMs currently used in the

context of recovery after abdominal surgery lack adequate measurement properties as they were not rigorously developed according to optimal scientific standards [48]. Lack of a robust conceptual framework to support 'content validity' (i.e. the extent to which the PROM reflects all aspects of the construct it is trying to measure [50]) was a major issue identified in the existing PROMs.

The guidelines on PROM development put forward by The US Department of Health and Human Services Food and Drug Administration (FDA) strongly recommend that content validity should be supported by a conceptual framework (i.e. an explicit and illustrative diagram that defines the concept to be measured by the PROM) [24]. It is questionable what a PROM actually measures in the absence of such a framework. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) also supports the need for a conceptual framework to serve as the groundwork for subsequent stages of PROM development [50]. From a clinical perspective, patient-centered conceptual frameworks may also contribute to improvements in delivery of care by raising awareness about issues that are experienced by patients but are not easily recognized by clinicians (e.g. mental wellbeing). Therefore, in the context of recovery after abdominal surgery, a conceptual framework alone is central for researchers and healthcare providers in measuring recovery while targeting and better addressing the concerns and needs of patients.

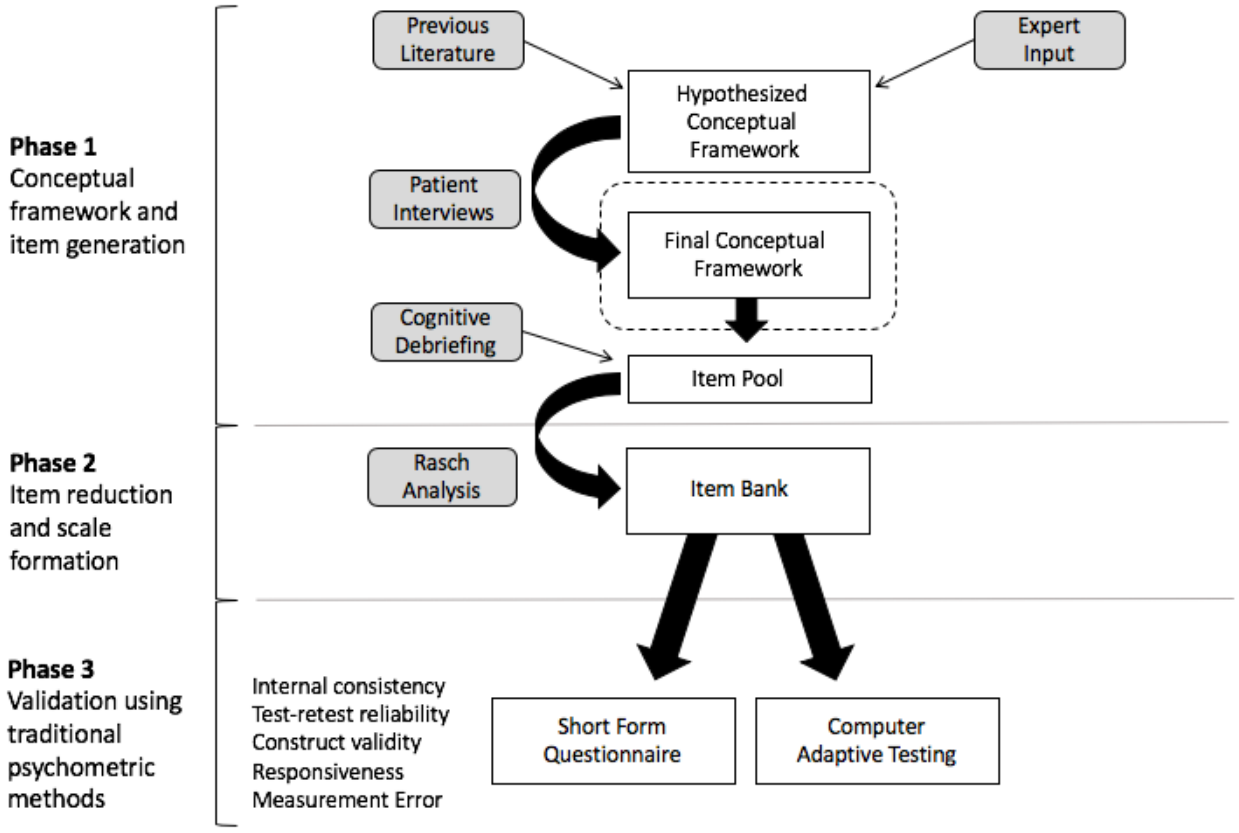
In light of the aforementioned research gaps, the objective of this study is to develop a conceptual framework portraying the health domains that are relevant to patients recovering from abdominal surgery. This framework will support the development of a conceptually relevant and psychometrically sound PROM to measure recovery.

3.3 METHODS

The multistep process of PROM development guiding our entire research program is outlined in **Figure 3-2**. The development of a conceptual framework of recovery after abdominal surgery was conducted in three main steps: (1) development of a 'hypothesized conceptual framework', (2) international qualitative interviews with abdominal surgery patients, and (3) content analysis of interviews to categorize relevant health domains. Our research methods are in concordance with FDA and ISPOR recommendations [24, 50, 51]. The protocol was approved by the McGill University Ethics Review Board (study # A03-E13-16B) and the research ethics committees of all participating international health centres. We adhered to SRQR (Standards for Reporting Qualitative Research) guidelines [94] to ensure complete and transparent reporting of this study **(Appendix 1).**

During the study period, an advisory panel comprised of the primary author (RA), two experienced qualitative researchers (JM, SL), a measurement expert (NM), a surgeon (LF), a surgical outcomes researcher (JF), and two abdominal surgery patients periodically convened together to discuss progress, address challenges, and set mitigation strategies.

Figure 3-2. Outline of the process of PROM development. This paper describes the development of our final conceptual framework (enclosed by the dashed line)



Adaption of figure reprinted by permission from Springer Nature. License #: 4543180324229; Alam R et al (2018) Development of a patient-reported outcome measure of recovery after abdominal surgery: a hypothesized conceptual framework. Surg Endosc 32(12):4874-4885

3.3.1 Step 1. Hypothesized Conceptual Framework (preliminary work)

To lay the groundwork for this study, as per FDA and ISPOR recommendations [24, 50, 51], we previously developed a hypothesized conceptual framework of recovery based on a systematic literature review and input from perioperative care experts [23]. We searched 8 bibliographic databases and identified 19 PROMs previously used in the context of recovery after abdominal surgery. The content of these PROMs was then analyzed by linking each item included in the PROMs to the WHO International Classification of Functioning, Disability and Health (ICF) [60], which provides a common

language for describing health-related states. A total of 66 ICF health domains were covered by the PROMs identified. To obtain expert input, 35 board members of major surgical societies in North America (Society of American Gastrointestinal and Endoscopic Surgeons) and Europe (Enhanced Recovery After Surgery Society) were invited to participate in a 2-round Delphi process [95] and rate their agreement to the domains identified by the systematic review. 23 experts (66%) participated in the Delphi process and after round 2, they agreed on the relevance of 22 recovery domains (8 Body Functions, 14 Activities and Participation). These domains were organized into a diagram representing our 'hypothesized conceptual framework' of recovery after abdominal surgery. Further details about this preliminary work are reported elsewhere [23]

3.3.2 Step 2. Qualitative Interviews

To account for potential cross-cultural differences in recovery experiences, this study enrolled patients from 4 different countries with varying demographic, socioeconomic and healthcare setting characteristics. The collaborating international health centers included: McGill University Health Centre (Montreal, Canada), Vita-Salute San Raffaele Scientific Institute (Milan, Italy), Hospital Sao Paulo (Sao Paulo, Brazil), and Hokkaido University Hospital (Sapporo, Japan). This international approach is in line with the ISPOR's recommendation that potential differences across countries and cultures should be considered as early as possible in the PROM development process to facilitate future translation and cultural adaptation [50, 51].

Table 3.1. Patient inclusion and exclusion criteria

Inclusion criteria	▪ Age ≥18 years old ▪ Abdominal surgery within three days to three months before enrolment ▪ Fluent in the local language ▪ Willing and able to provide written informed consent
Exclusion criteria	▪ Documented mental impairment ▪ Palliative care ▪ Preoperative co-morbidities that may impact recovery (e.g. advanced musculoskeletal, neurological, pulmonary or cardiac disorders) ▪ Organ transplantation ▪ Cesarean section

Sampling and patient recruitment

Eligibility criteria for patients are described in **Table 3-1**. The minimum targeted sample size was 30 patients, and interviews were planned to continue until thematic saturation was reached (i.e. point after which no new concepts emerged) [96]. In order to capture the heterogeneity of abdominal surgery procedures and improve sample representativeness, a purposive maximal variation sampling method was used [97]. To achieve maximal sample variation, our research group agreed upon specific patient recruitment quotas corresponding to varying demographic, clinical and surgical characteristics as shown in **Table 3-2.** As for the recruitment process, quotas were fulfilled by screening the operating room booking lists of the respective study sites. Patients were contacted to participate in the study by telephone or in person at the hospital. Written informed consent was obtained prior to all interviews.

Table 3.2. Targeted sampling quotas

Characteristic	Target quotas
Age (years)	
≤ 45 years	≥ 20%
≥ 65 years	≥ 30%
Sex	
Male	≥ 40%
Female	≥ 40%
Surgery extension*	
Moderate	≥ 30%
Major	≥ 30%
Extended major	≥ 30%
Surgical approach	
Laparoscopic	≥ 40%
Open	≥ 30%
Previous abdominal surgery	
Yes	≥ 20%
No	≥ 20%
Physical status	
Low (ASA score ≥ 3)	≥ 20%
High (ASA score = 1)	≥ 20%
Education level	
Low (< high school)	≥ 20%
High (≥ university degree)	≥ 20%
Official employment status	
Working or studying	≥ 30%
Retired	≥ 30%
Occupation type**	
Physical (ISCO skill level = 1 or 2)	≥ 30%
Nonphysical (ISCO skill level = 3 or 4)	≥ 30%
Body mass index	
Low (< 20)	≥ 20%
Obese (≥ 30)	≥ 20%
30-day complications	
Yes	≥ 30%
No	≥ 60%
Time from surgery	
< 1 week	≥ 20%
1 to 4 weeks	≥ 30%
5 to 12 weeks	≥ 30%
Hospital status at time of interview	
Inpatient	≥ 20%
Outpatient	≥ 70%

ASA: American Society of Anesthesiologists;
*Classified according to Copeland GP et al (1991) POSSUM: A scoring system for surgical audit. Br J Surg 78(3):355-60. Moderate surgeries include: appendectomies, cholecystectomies, hernia repairs; major

surgeries: colonic resections, gastrectomies, nephrectomies, hysterectomies; major extended surgeries: rectal, pancreatic & liver resections.
**Classified according to International Labour Office (2012) International Standard Classification of Occupations 2008 (ISCO 08): Structure, Group Definitions and Correspondence Tables. Geneva

Interview Guide

Our hypothesized conceptual framework (step 1 [23]) served to inform the interview guide used by interviewers to complete one-on-one semi-structured qualitative interviews with patients. The goal of the guide was to prompt in-depth narratives of patients' lived experiences while recovering from abdominal surgery. The interview guide was collectively produced by our research team according to a standardized approach [98]. It comprised of interview instructions to provide patients, questions to pose to stimulate the development of their recovery narratives, and how to incorporate follow-up prompts. We used broad open-ended questions so that patients could lead the flow and direction of the interview and discuss any topics that they deemed relevant to their recovery. A pilot interview was conducted with a patient, after which point our research team reconvened to refine the guide according to the interviewer's impression and the patient's feedback. The resulting interview guide **(Appendix 2**) was iteratively adapted throughout the study in an effort to further iteratively explore additional domains mentioned during patient interviews.

Interview Procedures

All interviews were conducted by experienced researchers specifically trained for the purpose of this study. In order to ensure congruence during data collection, all interviewers received structured training sessions from a senior qualitative research consultant (JM) from Canada. For international sites, training sessions were completed via the provision of online material and videoconferencing. Training was finalized with the evaluation of mock patient interviews followed by constructive feedback from the

senior qualitative researcher. Interviews in languages other than English were conducted by bilingual interviewers fluent in the local language and English. International interviewers were also responsible for the translation of the interview guides into the local language. Interviews were completed at the hospital or at the patient's home, depending on patient preference, and took 1-2 hours to complete.

3.3.3 Step 3. Interview Content Analysis

All interviews were audio recorded and transcribed by an ISO certified transcription agency (vananservices.com). Non-English interviews were transcribed directly into English by bilingual translators and verified by the bilingual researchers who conducted the original interviews. All transcriptions were quality checked iteratively to provide feedback to translators and additional training to the interviewers if deemed necessary. Patient identification as well as names and institutions mentioned during the interviews were anonymized.

Data Analysis

The goal of interview analysis was to organize and catalog patients' described experiences while recovering from abdominal surgery. This was done by identifying recovery-related domains and linking them to the World Health Organization's International Classification of Functioning, Disability and Health (ICF) [60]. The interview data was analyzed according to the modified grounded theory approach proposed by Broad et al [99], where an initial coding dictionary based on a hypothesized framework is modified iteratively according to information obtained from the interviews. The coding process was assisted by a qualitative analysis software (Transana version 3.01), which is a useful tool to facilitate the organization of interview audio files, videos, and transcribed data.

Data analysis followed a 'peer system model' which is an approach that serves to augment coding accuracy over time [98, 100]. In line with this model, the first four interviews were independently completed by a primary analyst (RA) and a senior qualitative research consultant (JM) to harmonize the coding strategy. Remaining interviews were coded by the primary analyst and verified by the senior qualitative research consultant. During this process, notes concerning coding and any related analytical decisions made were documented by the primary analyst in Transana and, for every 5 to 10 transcripts coded, the senior qualitative research consultant (JM) independently reviewed all of the patient quotes and assigned domains. Any unresolved questions or issues that could not be resolved via discussion between the primary analyst and senior qualitative research consultant were brought forth to the advisory panel to reach final consensus.

All the domains of recovery identified were linked to the ICF up to third-level classification. For example, a symptom such as nausea, which is part of the body functions (B) chapter, is classified under ‘functions of the digestive system' (B5; first-level classification), and ‘sensations associated with the digestive system' (B535; second-level classification). Third-level classification was additionally completed to acquire a more specific definition of the symptom experienced, for example 'sensation of nausea' (B5350).

It is important to note that our framework is intended to capture patients’ experience with physiological and functional recovery relating to body impairments, activity limitations and participation restrictions. Therefore, process-related factors such as experiences with healthcare providers and patient satisfaction were excluded from the analysis [101]. Domains related to recovery issues that are organ- or procedure-specific (e.g. adaptation

to living with a new stoma after rectal or bladder surgery, issues related to prolonged urinary catheterization after prostatectomy) were also excluded.

Thematic saturation

Both ISPOR and FDA guidelines emphasize that assessment and documentation of thematic saturation (i.e. the point after which no new relevant information is elicited) is critical to support the content validity of a PROM [24, 50, 51]. The point of saturation is taken to indicate that sufficient data has been collected to allow a broad understanding of the subject of interest (i.e. 'we heard it all') [96]. In this study, the assessment of saturation was iteratively done with a saturation table that documented the emerging ICF health domains following the analysis of each individual interview. Codes for which saturation was reached were classified into domains of health that are relevant to patients during the process of recovery after abdominal surgery. These domains were organized into a structured diagram, portraying the final conceptual framework of recovery after abdominal surgery.

3.4 RESULTS

3.4.1 Qualitative interviews

A total of 30 patients were interviewed: 10 English Canadian, 5 French Canadian, 5 Brazilian, 5 Italian, and 5 Japanese. Patient characteristics are presented in **Table 3-3**. All of the targeted patient characteristics quotas listed in **Table 3-2** were met, hence the recruitment of a diverse and heterogenous abdominal surgery patient population was accomplished.

Table 3-3. Characteristics of interviewed patients

Characteristic	n = 30
Mean age, years (SD)	57 (18)
≤ 45 years	8 (27 %)
≥ 65 years	15 (50 %)
Female	15 (50 %)
Surgery extension*	
Moderate	10 (33 %)
Major	10 (33 %)
Extended major	10 (33 %)
Surgical approach	
Laparoscopic	16 (53 %)
Open	14 (47 %)
Previous abdominal surgery	17 (57%)
Physical status	
Low (ASA score ≥ 3)	8 (27 %)
High (ASA score = 1)	6 (20 %)
Education level	
Low (< high school)	6 (20 %)
High (≥ university degree)	12 (40 %)
Official employment status	
Working or studying	16 (53 %)
Retired	10 (33 %)
Occupation type**	
Physical (ISCO skill level = 1 or 2)	10 (33%)
Nonphysical (ISCO skill level = 3 or 4)	9 (30 %)
Body mass index	
Low (< 20)	7 (23 %)
Obese (≥ 30)	6 (20 %)
30-day complications	12 (40 %)
Time from surgery	
< 1 week	6 (20 %)
1 to 4 weeks	12 (40 %)
5 to 12 weeks	10 (33 %)
Hospital status at time of interview	
Inpatient	9 (30 %)
Outpatient	21 (70 %)

ASA: American Society of Anesthesiologists;
*Classified according to Copeland GP et al (1991) POSSUM: A scoring system for surgical audit. Br J Surg 78(3):355-60. Moderate surgeries include: appendectomies, cholecystectomies, hernia repairs; major

surgeries: colonic resections, gastrectomies, nephrectomies, hysterectomies; major extended surgeries: rectal, pancreatic & liver resections.
**Classified according to International Labour Office (2012) International Standard Classification of Occupations 2008 (ISCO 08): Structure, Group Definitions and Correspondence Tables. Geneva

3.4.2 Content analysis

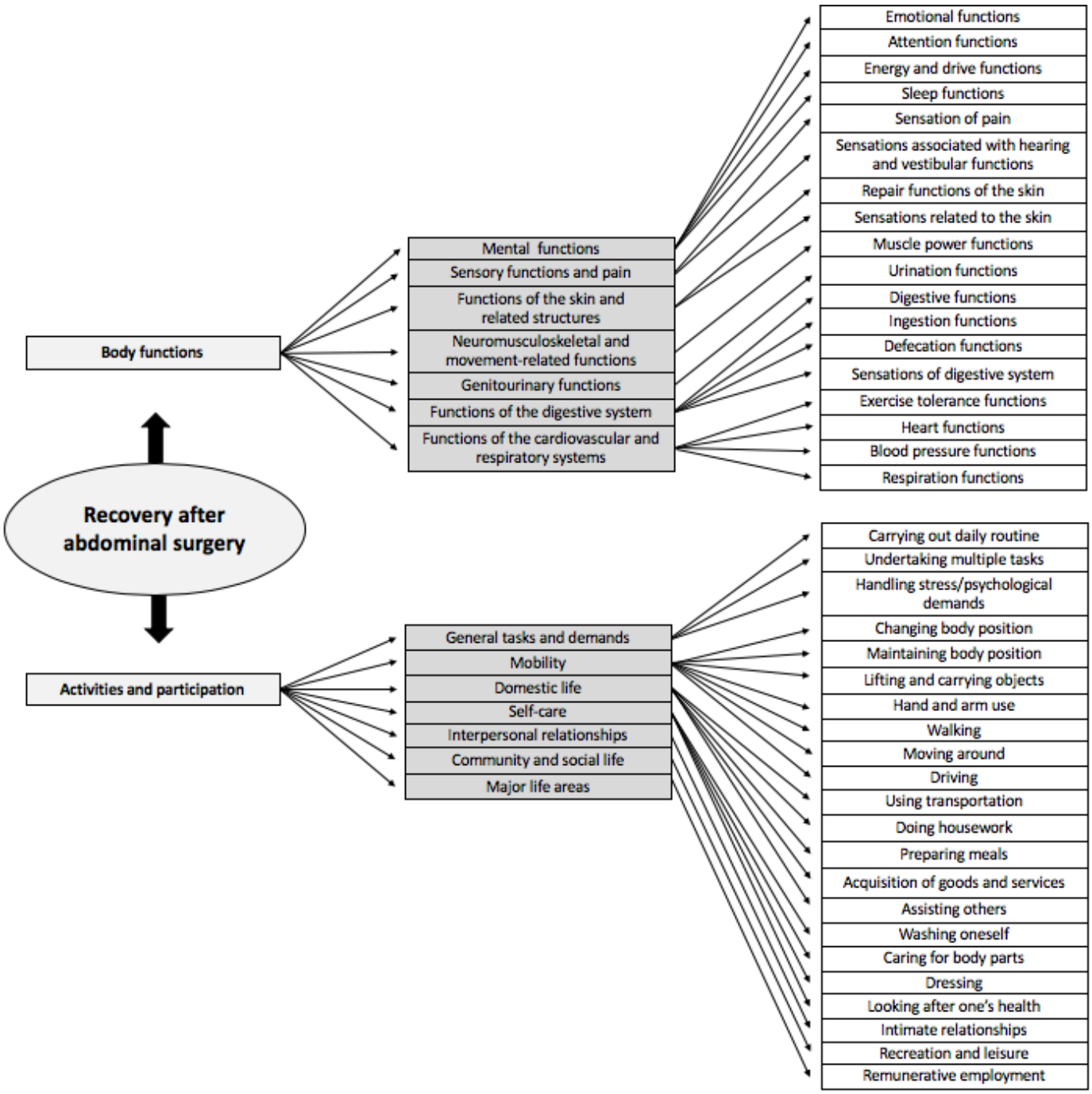
Following the coding of patient interviews, a total of 39 ICF domains were identified out of which 17 were linked to the ICF category 'body functions' and 22 to 'activities and participation'. **Table 3-4** demonstrates the relative frequency of domains cited by the patients interviewed. The body function issues most commonly mentioned by patients were related to 'sensation of pain' (n=30), 'emotional functions' (n=27), 'energy and drive' (n=27), 'defecation functions' (n=27), and 'exercise tolerance functions' (n=25). The activities and participation issues most commonly mentioned concerned 'walking' (n=28), 'changing basic body position' (n=27), 'carrying out daily routine' (n=26), 'moving around' (n=26), and 'dressing' (n=25). All 22 ICF health domains that comprised the hypothesized conceptual framework of recovery after abdominal surgery [23] were supported by patient interviews and 17 new domains were identified. Thematic saturation was reached by the twelfth interview, after which no new domains emerged. The saturation table used to document emerging ICF health domains, third-level classification of ICF domains, and empirical data containing coded patient quotes from all interviews are available from the authors upon request. In light of our results, the final conceptual framework of recovery after abdominal surgery is portrayed in **Figure 3-3**.

Table 3-4. Relative frequency of ICF domains cited by interviewed patients

ICF Code	Domain	Patients (n= 30)
B	Body functions	-
B280	Sensation of pain	30 (100%)
B152	Emotional functions*	27 (90 %)
B130	Energy and drive	27 (90 %)
B525	Defecation functions	27 (90 %)
B455	Exercise tolerance functions	24 (80 %)
B820	Repair functions of the skin*	24 (80 %)
B730	Muscle power functions	23 (77 %)
B134	Sleep functions	20 (67 %)
B535	Sensations associated with the digestive system	20 (67 %)
B510	Ingestion functions	18 (60 %)
B240	Sensations associated with hearing and vestibular functions*	9 (30 %)
B440	Respiration functions*	7 (23 %)
B515	Digestive functions*	6 (20 %)
B140	Attention functions*	6 (20 %)
B840	Sensations related to the skin*	5 (17 %)
B620	Urination functions*	5 (17 %)
B420	Blood pressure functions*	2 (7 %)
D	Activities and participation	-
D450	Walking	28 (93 %)
D410	Changing basic body position	27 (90 %)
D230	Carrying out daily routine	26 (87 %)
D455	Moving around	26 (87 %)
D540	Dressing	25 (83 %)
D430	Lifting and carrying objects	24 (80 %)
D920	Recreation and leisure	24 (80 %)
D640	Doing housework	23 (77 %)
D415	Maintaining a body position	22 (73 %)
D850	Remunerative employment	18 (60 %)
D510	Washing oneself	18 (60 %)
D475	Driving	15 (50 %)
D630	Preparing meals*	13 (43 %)
D220	Undertaking multiple tasks *	11 (37 %)
D240	Handling stress and other psychological demands	10 (33 %)
D470	Using transportation*	10 (33 %)
D570	Looking after one's health*	10 (33 %)
D770	Intimate relationships	7 (23 %)
D620	Acquisition of goods and services*	6 (20 %)
D445	Hand and arm use*	5 (17 %)
D660	Assisting others*	5 (17 %)
D520	Caring for body parts*	4 (13 %)

*Indicates domains that were not a part of the hypothesized conceptual framework of recovery after abdominal surgery[23]

Figure 3-3. Final conceptual framework of recovery after abdominal surgery



3.5 DISCUSSION

In this study, we used rigorous and sound qualitative methodology to develop a conceptual framework of recovery after abdominal surgery based on patients' perspectives. This framework supports that abdominal surgery directly impacts several domains of a patient's health postoperatively (i.e. body functions, activities and participation) and they should all be taken into account when measuring recovery. Based on the health domains identified, this framework will serve as the groundwork for the development of a recovery-specific PROM for patients undergoing abdominal surgery.

A major strength of our study is that our methodology was strictly in line with FDA and ISPOR guidelines for establishing content validity of newly designed PROMs [24, 50, 51]. All of the framework domains were elicited directly from patients. To account for cross-cultural differences in recovery experiences, we enrolled patients from four countries in different continents. All interviews were conducted by culturally sensitive bilingual interviewers who fluently spoke the local language. The option to conduct one-to-one interviews (as opposed to e.g. focus groups [102]) proved to be ideal for the purpose of this study due to our international context and the disclosure of potentially sensitive or private topics. We also believe that this approach increased patients' level of comfort and ensured openness to share their rich personal narratives. Pre-arranged times and locations for interviews were chosen solely based on patient convenience to reduce participation burden. The use of a maximal variation sampling method [97] was also advantageous to gain insight into recovery from diverse angles representative of the heterogenous target population. Purposefully selecting specific patient characteristics quotas assured that the sample represents a broad range of patient experiences (e.g. inpatient/outpatient, presence/lack of complications, various extents of surgery, etc.). As

a result, the PROM that will be developed based on this framework will be widely applicable to a diverse abdominal surgery patient population. Sampling bias during recruitment was prevented by screening operating room lists and selecting consecutive eligible patients according to our established targeted characteristic quotas. An additional strength is that coding of data was according to the ICF, a universal model that uses standardized language to describe and categorize health and functioning [59]. The ICF is used internationally and across numerous disciplines, thus this conceptual framework may be widely understood by those involved in the realm of surgery and beyond.

A recent systematic review completed by our research group revealed that there is very limited evidence supporting the content validity of existing PROMs currently used in the context of recovery after abdominal surgery [48]. Researchers traditionally use generic PROMs to measure recovery (e.g. SF-36, EQ-5D), but these measures may not comprehensively capture all the health domains that are relevant to patients recovering from abdominal surgery [48]. Condition-specific PROMs tend to be more sensitive (i.e. responsive to change) when used in specific contexts of care [39], however it is imperative that these measures be supported by condition-specific frameworks [24, 50, 51]. Our review identified that three previous studies proposed conceptual frameworks of recovery after abdominal surgery [19, 88, 103], but none of them used current methodological standards set by ISPOR [50, 51] and the FDA [24], nor reported the development process in enough detail to ensure reproducibility. Only two of these studies explicitly listed the domains populating their conceptual framework [19, 88], but they were not as exhaustive as the framework developed in the current study. Some domains of recovery highly endorsed in the current study (e.g. energy and drive (b130), emotional functions (b152)) were not unanimously captured by previous frameworks, indicating that they have

important gaps. The current framework encompasses all of the domains addressed in the previous frameworks alongside numerous other relevant domains, such as: maintaining a body position (d415), using transportation (d470), and intimate relationships (d770), to name a few. This suggests that our rigorous qualitative methodology, with interviews conducted with a diverse abdominal surgery population until the point of data saturation, captured a more comprehensive overview of patients' recovery experiences. The fact that thematic saturation was reached relatively quickly (12th interview out of 30) highlights the comprehensiveness of the established conceptual framework, i.e. the domains initially included in the framework fully captured the themes elicited from the remaining 16 patient interviews.

The ultimate goal of any therapeutic doctor-patient relationship is undoubtedly to improve the patient's health and experience with care. To do so, a communicative collaboration is imperative so as not to disregard the perspective and needs of the patient [104]. Interestingly, this study demonstrates important discrepancies between what healthcare providers believe is relevant to patients recovering from abdominal surgery versus what is indeed important according to patients. The domains of recovery addressed by the hypothesized conceptual framework set by healthcare providers [23] missed seventeen health domains that were ultimately included in the patient-centered conceptual framework. For example, 90% of the patients (n=27) expressed that their 'emotional function (b152)' was negatively impacted by the surgery, but this domain was omitted by healthcare providers. The most common manifestations of this issue included decreased control of emotional regulation (e.g. decreased patience, easily angered/irritated) as well the experience of a wide range of negative emotions (e.g. fear, anxiety, powerlessness). Other examples of issues overlooked by providers were wound

repair (i.e. healing of the surgical incision site) [b820, 80% (n=24)] and sensations associated with the incision [b840, 80% (n=24), e.g. numbness, itchiness, and burning]. These results support that, in line with the principles of patient-centered care, understanding postoperative experiences from the *patient's perspective* is pivotal not only to measure recovery, but also to guide targeted interventions to improve the recovery process that patients themselves experience.

It is important to acknowledge the limitations of this study. Qualitative research relies on truthful and transparent reporting from participants to draw meaningful conclusions. However, such research often risks 'social desirability response bias' which is the tendency of participants to present a favourable image of oneself or gain approval from the interviewer [105]. To minimize this potential bias, interviewers were carefully trained to remain neutral throughout the interview in order to avoid any verbal or non-verbal cues indicating approval or disapproval of experiences reported by patients. Interviewers also clearly explained that the intent of the interview was not to *evaluate* how well they recovered, but rather to hear and learn from their personal experiences; "There is no right or wrong answer". One might also consider the sample size of the study (n=30) to be a limitation. However, research reveals that 20 to 40 interviews were needed to reach data saturation in existing multisite and cross-cultural qualitative research [106]. According to ISPOR, no one rule can be used to determine the sample size required to develop a conceptual framework [51]. What is of utmost importance is that thematic saturation is reached. Moreover, the FDA guidance document states that the number of patients during framework development is not as critical as the interview quality and patient diversity included in the sample [24]; both these elements were strategically planned in our study. The countries where patients were interviewed were chosen by convenience (i.e. based on

our research collaboration network). Although we were able to capture the perspectives of culturally diverse patients treated in distinct healthcare systems in North America, South America, Europe and Asia, we cannot exclude that views of recovery may be different for patients treated in settings outside the scope of our study. We also recognize that the sample size in each individual country was relatively small, precluding the comparison of results across countries. Although the PROM that will result from this research program will be primarily developed in English, our international approach will facilitate future cultural adaption and translation to different languages.

In summary, the current qualitative study is a required step to better understand the patient's perspective regarding the process of recovery after abdominal surgery. Based on our findings, we propose a comprehensive conceptual framework of recovery that lays critical groundwork for the development of a novel PROM to support patient-centered care in abdominal surgery.

3.6 ACKNOWLEDGEMENTS

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3.7 DISCLOSURES

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CHAPTER 4

CONCLUSION & FUTURE DIRECTION

The elusive construct of postoperative recovery has long been a challenge to define and measure. The use of PROMs allows us to objectively measure such highly abstract constructs, all the while representing patients' perspectives and experiences. In the context of recovery after abdominal surgery, there is currently no existing PROM that fulfills the criteria for psychometric soundness and conceptual relevance. To address this gap, our research team designed a research program aiming to develop a recovery-specific PROM. The work contained in this thesis completed the first step in the PROM development process by establishing a conceptual framework of recovery.

The first study used findings from a literature review and expert input to establish a hypothesized conceptual framework of recovery. A multidisciplinary panel of clinicians with expertise in perioperative care and strategies to accelerate recovery after surgery agreed upon health domains that are potentially relevant to patients. They recognized that surgery may impact numerous aspects of a patient's life by limiting their usual activities and participation, and by negatively affecting certain body functions. The hypothesized conceptual framework that resulted from this study served to orient the direction of our research program by providing a better sense of domains that could potentially be of importance to patients recovering from abdominal surgery.

One can only truly comprehend the patient's perspective by speaking to the patients themselves. Therefore, the second study involved refinement of the hypothesized framework of recovery using direct input from patients recovering from abdominal surgery. By following a rigorous methodological approach, this study established a final

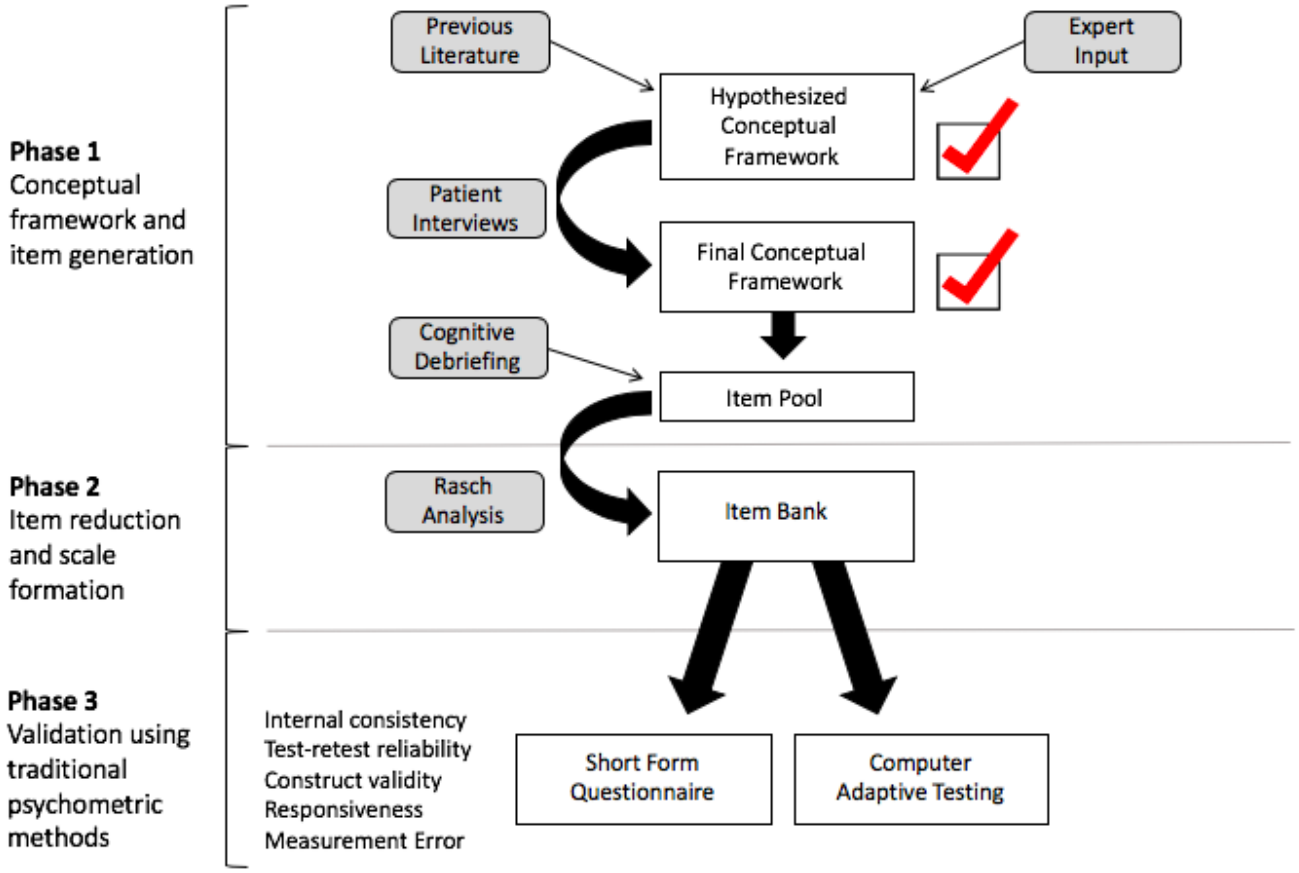
conceptual framework of recovery that comprehensively captured the domains of health that are relevant to the process of recovery from the patients' perspectives. While all of the domains hypothesized to be relevant were validated by participating patients, several domains had not been previously identified by healthcare providers and existing PROMs.

We believe the deep root of this discrepancy may be a lack of adequate communication and mutual understanding between patients and their physicians. As discussed earlier in the thesis, while assessing postoperative outcomes, physicians tend to focus on audit measures that fail to capture the patient's complex and multidimensional experience of surgical recovery [15]. Furthermore, studies support that physicians frequently underestimate the complaints of patients when it comes to the impact of surgery on various aspects of their lives [107]. This phenomenon is well known in numerous fields of medicine [107, 108]. Interestingly, some of the recovery issues most frequently cited during our patient interviews involved Emotional Functions (b152), yet this domain was not included in the hypothesized conceptual framework due to lack of agreement amongst expert physicians. Existing research highlights that physicians tend to overlook cues and concerns related to how an intervention can impact a patient's negative emotions and rather focus the discussion on other medical issues [109]. This further justifies why it is so important to incorporate patient views into their healthcare in order to gain a proper understanding of their views and needs. Looking ahead, we hope that our conceptual framework will serve to enlighten healthcare providers that may not necessarily recognize the wide array of issues that abdominal surgery may inflict on patients' lives during the recovery period. This comprehensive framework and eventual resulting PROM aim to ameliorate patient-physician communication about recovery needs and expectations.

Ultimately, this could lead to initiatives and research aiming to improve the healthcare and services delivered to postoperative patients.

This conceptual framework lays the integral foundation required to continue the subsequent stages of PROM development **(Figure 4-1)**. The next step involves the generation of items (i.e. questions) for the future PROM which will be based on the domains populating the conceptual framework of recovery. Understanding of the questions will be assessed via cognitive interviews with abdominal surgery patients. In Phase 2, modern psychometric methods (Rasch Analysis [110]) will be used to help refine the items and generate scoring rules for the questionnaire. This will result in a paper and electronic format (computer adaptive testing (CAT) [111]) of the intended recovery-specific PROM. In the final phase of the program, the measurement properties of both the paper and electronic format of the questionnaire will be assessed using traditional psychometric methods (classical test theory [112]). This will provide important information regarding measurement properties that can be compared with existing PROMs and against current standards for PROM properties (i.e. construct validity, internal consistency, test-retest reliability, responsiveness, measurement error and interpretability) [48, 113]**.**

Figure 4-1. Outline of the process of PROM development



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Looking ahead, the work completed in this thesis project is an essential first step that contributes to the development of a future PROM that will (1) provide a novel sensitive patient-centered measure for comparative effectiveness research of innovations in abdominal surgery and (2) inform clinician-patient communication about recovery expectations. Also importantly, this measure may be used in the future to assist in making decisions about fitness to return to normal activities [114-116], and for some patients, fitness to undergo further treatments (e.g. adjuvant oncologic therapies) [117, 118]. Using modern data collecting platforms such as mobile operating systems and web portals to administer the PROM may also serve to empower patients by allowing them to keep track

of their own recovery trajectory in real-time and potentially identify complications at earlier time points when they may be more easily treated. We also envision that, in the near future, recovery-specific PROM data may be collected in routine clinical practice and incorporated into electronic health records. This would provide the unique and valuable opportunity for recovery auditing and database-driven research. There is still much research to be done before PROM data will be fully embraced by the many stakeholders in the field of surgery; however, this project provides a pivotal first step towards incorporating the patients' perspective into abdominal surgery care.

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Appendix 1. Standards for Reporting Qualitative Research (SRQR) Checklist

No.	Topic	Item	Reported
	Title and abstract		
S1	Title	Concise description of the nature and topic of the study	✓
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication	✓
	Introduction		
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	✓
S4	Purpose of research question	Purpose of the study and specific objectives or questions	✓
	Methods		
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate	✓
S6	Research characteristics and reflexivity	Researchers' characteristics that may influence the research (e.g. qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	✓
S7	Context	Setting/site and salient contextual factors; rationale	✓
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary; rationale	✓
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent; other confidentiality and data security issues	✓
S10	Data collection methods	Types of data collected; details of data collection procedures; rationale	✓
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection	✓
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study	✓
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization of excerpts	✓
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; rationale	✓
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking); rationale	✓
	Results		
S16	Synthesis and interpretation	Main findings; might include development of a theory or model, or integration with prior research or theory	✓
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	✓
	Discussions		
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability	✓
S19	Limitations	Limitations Trustworthiness and limitations of findings	✓
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions	✓
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	✓

O'Brien BC.et al (2014) Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 89(9):1245-51

Appendix 2. Qualitative Interview Guide

Development of a Conceptual Framework of Recovery

Annotated qualitative interview guide for interviewer

-Reiterate the purpose of the project, purpose of their interview and how it will be used.

-Consent forms must be signed before commencing interview.

-Be sure to answer any questions they may have.

-Prompts are italic – use as needed – or to follow narrative

General Intro Points - You may elaborate.

We are especially interested in hearing how you describe your postoperative experience and what recovery means to you. Remember there is no right or wrong answer, we just want to learn from your recovery journey. It would really help if you described any thoughts and feelings you experienced as well. I'll ask you a few questions as we progress and if you get stuck, I can help you with some specific questions. We can stop at any point if you want and please feel free to tell me if you do not wish to answer a specific question. **Please try not to mention specific names of doctors or hospitals, the names of your partner/spouse, or children, friends and names of places.** It is better to say: my doctor, the hospital, the city that I live in or my child, etc. If you do mention names, please don't worry because we can edit it out later.

Questions?

HIT RECORD BUTTON - start interview

General Questions

- Is there anything you would like to say about your health, everyday life and activities *before* you had your abdominal surgery?
- Let's begin speaking about your recovery *after* surgery. Can you share the story of your recovery process starting from right after the surgery? Can you describe in detail to me what has happened to you from the surgery until now?

  Can you tell me what you noticed about your health, everyday life and activities after the surgery?

  Can you describe to me what you have been experiencing?

  What sorts of sensations have you felt?

  Can you tell me about the intensity of these sensations?

- Now I'd like to ask you about your experience specifically during the first days after surgery as well as your experience afterwards. What were the main issues you encountered during *the first days* after the surgery?

  How did you feel during the first days after the surgery?

  How did you feel during your time in the hospital?

  Can you tell me about your activities in the first days after the surgery? Examples?

  Were there any issues that were only problematic in the first days after the surgery, but then resolved?

  Were there any issues that were only problematic in the first days after the surgery, but then did not resolve?

- (Not applicable to in-patients) And what were the main issues you encountered *after the first days till now*?

  How did you feel after the first few days?

  How did you feel after the first few days out of the hospital?

  Can you tell me about your activities after the first few days? Examples?

  Can you tell me about your activities after the first few days out of hospital? Examples?

- What has changed in your everyday life since the time of your surgery? How are those changes? What is the extent of these changes?

  Would you say that things are the same or different regarding your health, everyday life and activities after your surgery?

  If you think of the last time you did your everyday activities after your surgery, what comes to mind?

- (Not applicable to in-patients) Following your discharge from the hospital, did/do you have help and support at home?

  Who was it/were they?

  What did they help you with?

  Was/is the help available whenever you need(ed) it?

  Do you feel that the help and support you received/ are receiving was/is sufficient? If not, why?

Everyday life (daily routine, housework, employment, recreation, other)

- How has your daily routine been after surgery?

Any challenges with your daily routine?

Has your daily routine changed compared to before the surgery?

Why has it changed? Specific examples?

Have you been able to complete the daily tasks that you have to do?

Do you need help carrying out your daily routine? For which activities?

- To what extent is your daily routine back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- (Not applicable to in-patients) Can tell me about your ability to do work around the house after the surgery?

  What sort of housework did you usually do before surgery?

  How has it been now compared to before the surgery?

  Can you give specific examples of the housework activities that you had/have difficulty with?

  What was/is it about them that made/make them difficult?

- (Not applicable to in-patients) To what extent is your ability to do housework back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- Did you have a paid job before the surgery?

  If you had a paid job before your surgery, what is/was it?

- (Not applicable to in-patients) Have you returned to this job since your surgery?

  If no:

  Why haven't you returned yet?

  What specific aspects of your job do you believe would be difficult to complete?

  Why?

  When would you consider yourself ready to go back to your job?

  What is your doctor's view regarding your going back to work?

  If yes:

  How did you find you return to work?

  Did you face any challenges with your return to work?

  Have you had difficulty with any activities related to your job after the surgery?

  If yes, can you give examples of activities that you had/have difficulty with?

  Why were they difficult?

- Can tell me about your engagement in recreational and/or leisure activities since your surgery?

  Did you participate in any regular physical activities or have any hobbies before the surgery?

  Have you been able to do these (recreational or leisure) activities after the surgery? If no, what is it about them that make them difficult?

  Did you face any challenges with your recreational or leisure activities after your surgery?

  What is your doctor's view regarding your going back to these (recreational or leisure) activities?

- To what extent is your ability to do these (recreational or leisure) activities back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- Can tell me how your social life has been since the surgery?

  Has anything changed compared to before the surgery?

  Have you socialized with your friends and family as much as you did before the surgery?

  Can you give examples of situations where your social life was affected by the fact that you had a recent surgery?

  Did you face any challenges with your social life after surgery?

- To what extent is your social life back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- (Not applicable to in-patients) What were your main means of transportation (means of going from one place to another) before the surgery (driving, taking the bus, biking, etc..)?

  Were there any challenges with using this mean of transportation after the surgery?

  Was/is using this mean(s) of transportation impacted by the surgery in any way? Explain.

If yes, what was/is it about using this/these mean(s) of transportation that was/is difficult for you?

When did you start using this/these mean(s) of transport again since your surgery?

Did/does this affect your daily routine?

- (Not applicable to in-patients) To what extent is using this/these mean(s) of transportation back to normal now?

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

<u>Energy and drive function</u>

- How has your energy level been since the surgery?

Did you face any challenges with your energy level?

Is your level of energy different compared to before the surgery? Can you describe how you feel?

Has your level of energy affected your life since the surgery? How?

Are/were there specific activities that you have to perform differently because of your level of energy?

- Can you tell me the story of your level of energy from the time of your surgery until now?
- To what extent is your level of energy back to normal now?

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

- Tell me about your general level of motivation since the surgery.

Did you face any challenges with your motivation level?

After your surgery, did/do you feel as motivated as you were before the surgery?

If not, why not?

- To what extent is your level of motivation back to normal?

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

<u>Dressing & hygiene</u>

- Can you please tell me about your routine for getting dressed since the surgery?

Did you face any challenges getting dressed?

Did the surgery affect your ability to get dressed? If yes, what was/is it about getting dressed that was/is difficult for you?

How much time and effort are/were required for you to get dressed? More or less than before?

- To what extent is your ability to get dressed back to normal?

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

- What about your routine for washing yourself?

  Did you face any challenges washing yourself?

  Did the surgery affect your ability to wash yourself? If yes, what was/is it about washing yourself that is/was difficult for you?

  How much time and effort are/were required for you to wash yourself? More or less than before?

- To what extent is your ability to wash yourself back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

Pain

- Can you tell me about your body sensations since the time of surgery?

  Did/do you have any type of body discomfort? Where?

- Has pain or discomfort been an issue?

  Where was/is your pain located?

- Can you tell me the story of your pain sensation from the time of your surgery until now?

  What words would you use to describe your pain after surgery?

  How strong or weak has it been?

  How did your pain change with time?

- Does/did pain have an impact on your everyday life and activities?

If yes, how did/does pain affect(s) you everyday life?

Can you give specific examples of situations where pain affected your everyday life and activities?

- To what extent did/do you have to modify your activities because of pain?

Are (were) there specific activities that you have to perform differently because of pain?

- Do/did you have any specific strategy to manage your pain?
- Has the pain resolved completely now?

If yes, <u>how long did it take</u>?

- *Has dizziness been an issue after the surgery?*

If yes:

When exactly did you feel dizzy?

How intense was the dizziness? Did it make you nauseous?

Has the dizziness resolved completely now? *If yes, <u>how long did it take</u>?*

<u>Surgical incision</u>

- Did you have any challenges with your surgical incision(s) since the time of surgery?

If yes, can you describe?

Does/did your incision(s) has/have an impact on your everyday life and activities?

If yes, how did/does your incision(s) affect(s) your everyday life?

Can you give specific examples of situations where incision(s) affected your everyday life and activities?

- Are any issues with your incision(s) resolved completely now?

If yes, how long did it take?

Changing and maintaining body position

- Can you tell me about your ability to change body positions after surgery (e.g. from lying down to sitting, from sitting to standing, bending, getting in/out kneeling position etc..)?

Was this affected by the surgery? How?
What was/is the main reason for your difficulty changing body positions?
Did/does this impact your everyday life? How?

- To what extent is your ability to change body positions back to normal now?

If back to normal, how long did it take?
If not back to normal, what seems to be getting in the way?

- What about your ability to maintain a body position for longer periods of time? (e.g. lay down, sit or stand, kneeling, squatting etc..?)

Was this affected by the surgery? How?
For what positions?
What was/is the main reason for your difficulty maintaining body positions?
Did this impact your everyday life? How?

- To what extent is your ability to change and maintain body positions back to normal now?

  If back to normal, <u>how long did it take</u>?

  If not back to normal, what seems to be getting in the way?

<u>Sleep function</u>

- Has your sleep been impacted by the surgery?

  Compared to before,

  Did/do experience problems with your sleep after the surgery?

  Did/do you have trouble falling asleep?

  Were you able to/are you able to remain in deep sleep?

  Are (were) you able to get a good amount of sleep?

  Do you feel rested after sleeping?

  Do/did you feel sleepy during the day?

  Do (did) you feel the need to have naps during the day?

- Did/does sleep problems affect your everyday life?

  Can you tell me how sleep problems affect(ed) you everyday life?

  Can you give examples of situations where sleep problems affect(ed) you everyday

- To what extent is your sleep back to normal?

  If back to normal, <u>how long did it take</u>?

  If not back to normal, what seems to be getting in the way?

  If not back to normal, what are you doing to help manage your sleep problems?

Exercise tolerance (lifting objects, moving around and walking)

- Has the surgery had an impact on your ability to do physical activities? How?

  Are you normally an active person?

  Did you have to limit your physical activities after the surgery? Why? Examples?

  What was/is it about these physical activities that made/make them difficult?

- To what extent is your ability to do physical activities back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- How have you felt about your body strength after the surgery?

  Do you feel like your body strength was impacted by surgery? If yes, how?

  Were/is there any situation or activity during which you felt/feel that you lack(ed) strength?

- To what extent is your body strength back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

  If not back to normal, what are your objectives for strength – what do you want to be able to do?

- Was lifting and carrying objects impacted by the surgery?

  If yes, what was/is it about these lifting and carrying that made/make them difficult?

- To what extent is your ability to lift and carry objects back to normal?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- Tell me about your ability to walk after the surgery

  Has your ability to walk changed after the surgery?

  If yes, what was/is it about walking that made/make it difficult?

  Are (were) you able to walk short distances (around the house or hospital, <1Km)?

  Are (were) you able to walk long distances (outside the house or hospital, >1Km)?

  Can you give me examples of situations where you have/had difficulty walking?

- To what extent is your ability to walk back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- (Not applicable to in-patients) What about your ability to conduct more demanding activities, such as walking upstairs, jogging, running?

  Have your ability to perform these activities been impacted by the surgery?

  For which specific activities? What was/is it about these activities that made/make them difficult?

  Can you give me examples of situations where you had difficulty with these activities?

- (Not applicable to in-patients) To what extent is your ability to do these (more demanding) activities back to normal now?

  Any challenges while doing more demanding activities?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

Ingestion, defecation and sensations associated with the digestive system

- Can you tell me about your eating and drinking habits since the surgery?

  Was your appetite affected by the surgery?

  Did you have any difficulty tolerating food?

  Did you have any episodes of nausea after the surgery? When?

  Did you have any episodes of vomiting after the surgery? When?

- To what extent are your eating and drinking habits back to normal?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- Can you tell me about the function of your bowels after the surgery?

  Did you have difficulty eliminating faeces? When?

  Did you feel bloated at any stage? When?

- To what extent are your bowel habits back to normal now?

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

- Did you have any other issues with other functions of your body?

  If yes, is it back to normal now & <u>how long did it take</u>?

  If not, what seems to be getting in the way?

<u>Handling stress, emotions and other psychological demands</u>

- How are you dealing with life demands, pressure, tension, stress after the surgery?

  Did anything change compared to before the surgery?

  If yes, can you describe the changes that you noticed?

  Any challenges dealing with stress?

- To what extent is this back to normal now?

  If back to normal, <u>how long did it take</u>?

  If not back to normal, what seems to be getting in the way?

- Have you been in control of yourself and your emotions since the time of the surgery?

  Has there been a time when you felt that you lost control of yourself or a situation since your surgery?

  What about your emotions and behaviours?

- Can you tell me how your emotions have been after the surgery?

Did anything change compared to before the surgery?

If yes, can you describe the changes that you noticed?

If yes, what do you think is/are the cause(s) of these changes in your emotion?

- To what extent *are your emotions back to normal now?*

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

- Can you tell me how your mood/humour has been after the surgery?

Did anything change compared to before the surgery?

If yes, can you describe the changes that you noticed

- To what extent *is your mood/humour back to normal now?*

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

- Did you notice any other changes to your mental state after the surgery?

Did you notice changes in your level of attention?

Did you notice changes in your ability to concentrate?

Did you notice changes in your ability to resolve intellectual problems?

If yes, can you describe?

- To what extent *is your mental state back to normal now?*

If back to normal, <u>how long did it take</u>?

If not back to normal, what seems to be getting in the way?

Relationships (personal and confidential questions)

- Can you tell me about how your relationship with significant others (partner, friends, family) has been after the surgery?

  Did you notice changes compared to before the surgery?

  If yes, can you describe?

- (Not applicable to in-patients) Can you tell me about your intimate relationship with your partner/spouse after the surgery?

  Did/does the surgery affect your sex life? How?

  Did/does this have an impact in your life?

- *To what extent is it back to normal now?*

  If back to normal, how long did it take?

  If not back to normal, what seems to be getting in the way?

Self-care and vulnerability

- Can you tell me about your ability to care for your own health and comfort during your recovery?

  Any challenges caring for yourself?

  Was your ability to care for yourself affected by the surgery?

  Do/did you feel dependent on others?

  Can you give me examples of situations where this affected your life?

- Were there any stages of your recovery where you felt vulnerable or at risk?

At what stage? Can you explain?

Meaning of recovery

- What does 'recovery' mean to you? Or what has it meant in your life?

Did your perception of recovery change after the surgery compared to before the surgery?

- Overall, do you feel that you are already completely recovered (i.e. back to normal)?

If yes, how long did it take for you to be back to normal?

If yes, what made consider that you were completely recovered?

If no, when will you consider that you are completely recovered?

Please, complete these sentences:

The most challenging issue in my experience recovering from abdominal surgery was (have been).....

The aspect of my life that was most affected during my recovery was...

The most important sign of recovery for me was...

Last Topics

Are there any other issues that have not been covered, but that you feel you would like to add to?

Questionnaire measuring recovery

- If you had a questionnaire measuring how well or poorly you are recovering from abdominal surgery, what specific topics do you think that this questionnaire should cover?
- Can you give examples of questions that should be included in this questionnaire?
- In order to appropriately track your recovery (i.e. detect possible changes in your health after the surgery), how often do you think this questionnaire should be administered/responded (e.g. every day, every 2 days, 3 days, 4 days, every week, every month)?
- Do you believe there is a difference between the early and late phases of your recovery process?

  If so, please explain.

  When do you think your early recovery phase finishes and the late recovery phase starts?

  What-topics relate specifically to the short-term recovery phase? And the long-term recovery phase?