American Society for Enhanced Recovery (ASER) and Perioperative Quality Initiative (POQI) Joint Consensus Statement on Patient Reported Outcomes (PROs) within an Enhanced Recovery Pathway

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4

Abstract

Patient reported outcomes (PROs) are measures of health status that come directly from the patient. PROs are an underutilized tool in the perioperative setting. Enhanced recovery pathways (ERP) have primarily focused on traditional measures of health care quality such as complications and hospital length of stay. These measures do not capture post discharge outcomes that are meaningful to patients such as function or freedom from disability. PROs can be used to facilitate shared decisions between patients and providers prior to surgery and establish benchmark recovery goals after surgery. PROs can also be utilized within quality improvement initiatives and clinical research studies. An international group of experienced clinicians from North America and Europe met at Stony Brook NY, on December 2-3, 2016, to discuss the evidence supporting the use of PROs in the context of surgical recovery. In the "Perioperative Quality Initiative (POQI) Patient Reported Outcomes" workgroup, the expert panel conducted a literature review and discussion to determine best practices for the incorporation of PROs within an ERP. We reviewed several patient reported outcomes measures (PROMs) commonly used in ERPs. PROMs in the perioperative setting should be collected within the framework of physical, mental and social domains. This data should be collected preoperatively at baseline, during the immediate postoperative time period, and after hospital discharge. In the immediate postoperative setting we recommend using the Quality of Recovery-15 score. Following discharge at 30 and 90 days, we recommend the use of measures such as the World Health Organization Disability Assessment Scale 2.0, or a tailored use of the Patient Reported Outcomes Measurement Information System (PROMIS). Future work that consistently applies

PROMs within an ERP will define the role these measures will have evaluating quality and guiding clinical care.

Consensus Statements

- Patient reported outcomes (PROs) provide an opportunity to improve clinical care and assess quality.
- 2. We recommend that institutions consistently document PROs.
- 3. We recommend that PROs should be collected at baseline, throughout the inpatient stay, and after hospital discharge.
- 4. At the current time we recommend that PROs should be collected using the QoR-15 during the immediate postoperative period (at a minimum on postoperative day #1 and at discharge) and either the WHODAS 2.0, or PROMIS at 30 days and 90 days after surgery.
- 5. Future research is needed to evaluate the consistent application of patient reported outcomes measures within an Enhanced Recovery Pathway (ERP) to determine their ability to assist in clinical decision-making, enhance recovery via a biopsychosocial approach, and provide benchmark quality metrics on a population level.

Introduction:

The Role of Patient Reported Outcomes in Enhanced Recovery Pathways

Patient reported outcomes (PROs) are measures that come directly from the patient without interpretation by a clinician or anyone else. The use of PROs allows clinicians to focus on outcomes that are important to patients. Enhanced recovery pathways (EPRs) have improved outcomes such as hospital length of stay and certain postoperative complications. One of the core tenants of perioperative PROs is the application of multidimensional measures that can provide a more comprehensive view of recovery after surgery. Multidimensional PROs provide the possibility to further enhance and evaluate recovery via preoperative stratification, immediate postoperative optimization, and post discharge surveillance/evaluation. Designing care systems by leveraging such actionable PROs provides an effective tool for quality improvement and comparative effectiveness research.

Within clinical practice, PROs can characterize biopsychosocial recovery trajectories and benchmarks. Patients who significantly deviate from an expected recovery trajectory after surgery can be identified. For example, if a patient reports on postoperative day five that they still have severe pain, this could trigger a call to the patient to set up an earlier postoperative clinic visit. Alternatively, if nutritional intake, physical function, or social interaction is not as expected 1 to 3 months after major surgery, then interventions (and the resources required) could be targeted in order to improve overall patient recovery. Overall, these interventions would provide opportunity

to return patients to an expected recovery trajectory and possibly decrease variables such as hospital readmission, additional clinic visits, or avoidable interventions with added resources such as home health.

Knowledge of normal recovery patterns, which can be generated from large scale data collection can allow perioperative care teams to better educate patients about expectations and goals after surgery.³ PROs can provide insight into an individual patient's postoperative course as well as insight into recovery trajectories for entire patient populations. For example, Ho et al. compared preoperative and postoperative PROs in patients undergoing ankle surgery and found that patients with low preoperative physical function and high pain interference experienced superior outcomes after surgery whereas patients with less profound perturbation in preoperative physical function and pain experienced a smaller benefit.⁴ Accordingly, use of PROs within the perioperative setting has the potential to enhance shared decision making between surgeons and patients regarding treatment options that can be specific to the type of surgery that they are planning.

Lastly, PROs can be used as a tool in quality improvement initiatives and clinical research studies. While ERPs have largely focused on objective measures such as length of stay and immediate complications, PROs allow for a multidimensional, patient centered complement to such variables when comparing treatment regimens. Larger system comparisons are also possible (e.g. inter-clinician, inter-hospital, etc).

The goal of our work is to provide recommendations regarding the use of Patient Reported Outcome Measures (PROMs) within the context of an ERP.

Methods/Design

Applying a modified Delphi method⁵ designed to use the collective expertise of a diverse group of experts to answer clinical questions, we achieved consensus on several topics related to patient reported outcomes within the context of an ERP.

Expert Group

An international group of experienced clinicians from North America and Europe met at Stony Brook, NY, on December 2-3, 2016, to discuss the evidence supporting PROMs. In the "Perioperative Quality Initiative (POQI) Patient Reported Outcomes" workgroup, the expert panel conducted a literature review and discussion to determine best practices for the incorporation of PROs within an ERP.

Process

A list of relevant questions was collectively developed and circulated electronically prior to the meeting. In preparation for the meeting, a comprehensive literature search was also performed to identify relevant articles. The search was conducted using the keywords "patient reported outcomes", "PRO", "patient reported outcome measures", "patient centered outcomes", "health related quality of life," "enhanced recovery after surgery," "ERAS" and "enhanced recovery program" using PubMed and Google. Based on literature searches performed by members, questions were formulated.

In the first plenary session, the POQI PRO subgroup presented these questions to the entire POQI workgroup, to receive feedback and assistance in refining the questions.

The subgroup then worked together to formulate answers to these questions, supported by evidence when available and by expert opinion when no clear evidence was available. These were presented in the second plenary session. After receiving feedback, the subgroup refined a series of consensus statements, which was then reviewed with and modified by the entire POQI group in the final plenary session. The manuscript is based on these multiple round of feedback from all the experts present at the second POQI meeting.

Results/Discussion:

What are patient reported outcomes?

PROs are outcome measures that come directly from the patient without interpretation from the health care team. PROs can be categorized into outcomes, outcome measures, or performance measures.⁶ Table 1 illustrates these definitions of PROs using postoperative pain as an example. A patient's report of pain is an example of a PRO. A patient's pain can be further defined by using a patient reported outcome measure (PROM) such as the Brief Pain Inventory ⁷, a questionnaire that assess the severity of clinical pain and its impact on functioning.

The National Quality Forum published guidelines for developing performance measures from PROs aimed at improving the delivery of health care services, patient health outcomes and population health. ⁶ A patient reported outcome – performance measure (PRO-PM) is based on aggregated data for a population using a PROM. Continuing with the example in Table 1, the percentage of surgical patients with Brief Pain Inventory Scores above baseline on postoperative day 30 would be an example of a PRO-PM.

PROMs are typically categorized as composite score measures or trait/domain specific measures. Composite score measures, such as the Quality of Recovery score (QoR) ⁸, the World Health Organization Disability Assessment Schedule (WHODAS) ⁹, or the EuroQol five dimension questionnaire (EQ5D) ¹⁰ can provide summative scores to aid in the assessment of patient reported health.

Such general PROMs suffer from numerous limits such as ceiling and floor effects, limited use in individual decision-making, and marked differences in domains measured. On the other hand, domain or trait specific measurement tools (e.g. Beck Depression Scale 12, or PROMIS Pain Behavior 13) create the opportunity for personalized optimization of domains that impact recovery. Currently a vast number of PROMs (both composite score and domain specific) have been utilized in surgical populations. Those previously used in the context of enhanced recovery after abdominal surgery and the domains of health covered by each PROM are summarized in Table 2.

Summary of PROMs of Potential Relevance to Enhanced Recovery Pathways

There is no universally accepted and validated PROM for assessment of recovery after surgery. Many traditional measures were created for medical patients and may not be well suited for use in the perioperative period. Some recently used PROMs have utilized more modern psychometric principles such as item response theory (IRT) to develop instruments to maximize precision and minimize response burden. An important consideration for choosing a PROM is the time frame that patients are asked to consider (i.e. recall period). For example, the Quality of Recovery score (QoR-15 and QoR-40) has been validated in the immediate postoperative setting and is gueried over 24 hour intervals. 14,15 PROMIS asks patients to report on their well-being over the past 7 days.¹⁶ The EQ-5D, a frequently employed PROM in the United Kingdom, queries patients about their quality of life "today." The WHODAS-2.0 and SF-36 query patients over the last 30 days. 9,17 Therefore it is key to choose an appropriate PROM for the time interval of interest. Regardless of which measure is used, it is important to include a preoperative measurement to assess a patient's return to baseline during their recovery after surgery.

Quality of Recovery Score (QoR) - QoR-9, QoR-15, QoR-40

The quality of recovery scores, QoR-9, QoR-15, QoR-40 were reported by Myles and colleagues in several studies. ^{8,14,15} The goal of the QoR score is to provide a valid, reliable, and responsive measure of quality of recovery after anesthesia and surgery. The most comprehensive measure, the QoR-40, covers five health dimensions related to mental and physical well-being: 1. patient support, 2. emotions, 3. comfort, 4.

physical independence and 5. pain, each scored on a zero to ten point scale. The QoR-40 showed superior validity and reliability in comparison to the QoR-9, however it requires approximately ten minutes to administer. Alternatively, the QoR-15 can be completed in 3 minutes and evidence supports its validity, reliability, responsiveness and feasibility in surgical patients in clinical practice. All QoR scores ask patients to evaluate their health with a 24-hour period, which makes them an attractive instrument for the immediate perioperative period. After colorectal surgery, QoR-40 scores were found to drop significantly on postoperative day 1, with significant improvement by postoperative day 3 and return to baseline on postoperative day 6.18 Compared to a variety of other patient centered tools, the QoR scores have shorter recall periods (24-hours) allowing for their use in the dynamic immediate postoperative phase when most ERP interventions continue.

WHODAS 2.0

The World Health Organization – Disability Assessment Scale 2.0 (WHODAS 2.0) is directly linked to the structural concepts with the World Health Organization's (WHO) International Classification of Functioning, Disability and Health, more commonly known as ICF. ⁹ Disability is defined by the WHO as a difficulty in functioning at the body, person, or societal level. Disability occurs in one or more life domains, as experienced by an individual with health conditions in interaction with contextual factors. WHODAS 2.0 follows a biopsychosocial model of health and covers 6 domain functions: 1. Cognition: understanding and communication, 2. Mobility: moving and getting around, 3. Self-care: hygiene, dressing, eating and staying alone, 4. Getting along: interacting with

other people, 5. Life activities: domestic responsibilities, leisure, work and school, and 6. Participation: joining in community activities. WHODAS 2.0 is a generic assessment instrument for health and disability and can be used across all diseases, including mental, neurological and addictive disorders. It is short, simple and easy to administer (5-20 minutes). It has application in both clinical and general population settings. It is a tool that can be used to produce standardized disability levels and profiles applicable across cultures in all adult populations.¹⁹

Recently, the WHODAS 2.0 has shown adequate validity, reliability and responsiveness in a diverse surgical population.²⁰ Five-hundred patients were assessed using the WHODAS 2.0 instrument following surgery. The WHODAS 2.0 correlated with QoR scores at 30 days, and measures of pain interference and physical function at 3, 6, and 12 months after surgery. Patients with increased hospital length of stay or complications within the first 30 days correlated with a new disability in a life domain.²¹ This initial validation within the perioperative setting further supports its possible use within an ERP.

PROMIS

In 2004, the National Institutes of Health began the development of a system of PROs in order to overcome barriers to large scale clinical and research use of patient centered outcomes. The Patient Reported Outcome Measurement Information System (PROMIS-www.healthmeasures.net) leverages modern psychometric principles in order to provide a precise and widely applicable system of PROs.²² PROMIS measures are administered

as item banks that are grouped under the three domains: 1. physical, 2. mental, 3. and social health. Each item bank underwent rigorous development utilizing item response theory (IRT) that maximizes precision in each item bank, increases flexibility and allows for tailored administration. Additionally, PROMIS can utilize Computer Adaptive Testing (CAT) through which questions are selected based on a patient's previous answer. CAT adds the benefit of minimizing the number of questions to be answered without sacrificing reliability in the scores produced. A critical benefit of PROMIS is its use of a standardized metric, the T score. This is normalized to the general population and allows providers to longitudinally "speak the same language" across a variety of care settings. In institutions without the capability for CAT, PROMIS measures also are available in short form item banks (e.g. depression, pain interference) or short form profile instruments (e.g. PROMIS-29).

PROMIS measures are being integrated rapidly by surgical services (e.g. orthopedics, oncological surgery) and represent a cutting edge opportunity for pain physicians to influence rational evidence-based pain care.²³⁻²⁷ A scoping review characterized 21 publications where PROMIS measures were used in the perioperative setting. The authors applauded the utility of PROMIS measures to provide standardized, accurate and efficiently captured patient constructs.²⁸ A PROMIS profile instrument (PROMIS 29-a non-computer adaptive profile) was used in an interdisciplinary opioid reduction program in patients preparing to undergo spine surgery where significant benefits in pain interference occurred throughout the perioperative period.²⁹

Additionally, when compared to measures such as WHODAS and EQ5D, PROMIS has displayed similar performance in numerous populations.^{30,31} Numerous PROMIS item banks (e.g. Pain Interference, Depression, Sleep Disturbance, etc.) have also shown to be equivalent if not superior compared to reference legacy instruments (e.g. Brief Pain Inventory, Center for Epidemiological Studies Depression Scale, Pittsburgh Sleep Quality Index). PROMIS measures, indexed over a 7-day period, provide the opportunity to assess the impact of ERP interventions and also the ability to act upon biopsychosocial variables that affect recovery in the immediate and sub-acute post discharge phases. Such frequent assessment would allow for construction of expected recovery trajectories where early intervention may further enhance function. PROMIS allows for users to tailor domain measures based on what health status measures they wish to assess. (Table 3) This allows for a tailored approached in a condition specific manner unlike generic measures (e.g. SF-36, EQ5D). While a good prospect for any PRO program, future work is needed to further establish the utility of PROMIS measures in surgical population with or without an ERP.

EQ-5D

The EuroQol 5 dimension questionnaire (EQ-5D) is one of the mostly commonly used generic questionnaires to measure health related quality of life. ¹⁰ The questionnaire covers five domains: 1. mobility, 2. self-care, 3. usual activities, 4. pain/discomfort, and 5. anxiety/depression. A patient grades their level of disability on a three-grade scale: severe, moderate or none. The EQ-5D-5L asks the same questions but with a 5-point scale instead of a 3-point scale. Conceptually, the EQ-5D was created with a holistic

view of health, which is comprised of medical, physical independence, emotional and social functioning components. The questionnaire includes both positive (well-being) and negative (illness) questions. The EQ-5D combines both a questionnaire and a visual analog scale – EQ-VAS. The EQ-5D asks patients to rate their health status "today."

The EQ-5D is used in the National Health System (NHS) in England for assessment of patient outcomes after specific surgical procedures.³² The NHS has been collecting EQ-5D information since 2009, and this represents an effort to measure patient-reported health in several ways. Between April and June 2016, an increase in general health was recorded for 49% of patients after groin hernia surgery and 47% of patients after varicose vein surgery as measured using the EQ-5D index.³³ The National Joint Registry offers one model for the use of PROMs in comparative effectiveness research. EQ-5D score was higher at 6 months for unicompartmental knee arthroplasty (UKA) compared to total knee arthroplasty (TKA). UKA patients (n=3519) were more likely to achieve excellent results and be highly satisfied compared to TKA patients (n=10557). These authors concluded that the high revision rate of UKA may not be because of poorer clinical outcome. ³⁴

Overall, the EQ-5D is a widely used instrument internationally to assess numerous quality indices. However, some studies suggest that EQ-5D has limited content validity, construct validity and responsiveness in the context of surgical recovery.³⁵ This instrument is not very discriminative and has a significant ceiling effect when used after

surgery, particularly with abdominal and thoracic surgery.^{36,37} Future work in the perioperative and ERP arena must also focus on its use to provide actionable outcomes to enhance recovery instead of its sole use at remote time point distant from surgical intervention.

Short Form – 36 Health Survey

The Short Form – 36 Health Survey (SF-36) was created in 1992 by the Medical Outcomes Study as part of the RAND Corporation. The SF-36 was designed for use in clinical practice, research, health policy evaluations and general population surveys. SF-36 was built on the premise that good medical care should result in a more "effective life" and preserve function and well being. SF-36 can be self-administered, collected via telephone or in-person interview. One potential critique of the SF-36 is that it was designed for use in medical populations; however, there are studies contributing evidence for the measurement properties of the SF-36 in surgical populations. The studies are studies contributing evidence for the measurement properties of the SF-36 in surgical populations.

The SF-36 contains 8 health concepts: 1. Limitation of physical activities – health problems, 2. Limitation of social activities - physiological/emotional, 3. Limitation – usual role activities – physical health problems, 4. Bodily pain, 5. General mental health, 6. Limitation – usual role activities/emotional problems, 7. Vitality (energy/fatigue) and 8. General health perceptions. The SF-36 has been employed in thousands of studies, undergone hundreds of separate validations, and translated into more than 50 languages/cultures. The SF-36 contains items that are queried over various timeframes such as "compared to one year ago," "on a typical day," and "during the last 4 weeks."

Several studies have made use of the SF-36 in surgical patients where it was commonly administered at remote time points, such as 30 days postoperatively and beyond. 17,39-41 In one example, the SF-36 did not find differences in patients who had open versus laparoscopic abdominal surgery. While this may relate to the validity of the SF-36 in ERPs, it suggests that measurement during the immediate post discharge phase throughout standard surgical follow up appointments (e.g. 30 days) is possibly needed to detect possible opportunities for further enhancement of recovery.

EORTC QLQ- C30

The European Organization for Research and Treatment of Cancer, QoL C30 (EORTC QLQ-C30) consists of 9 multi item scales. ⁴³ The EORTC-QLQ-C30 is currently used in all major oncology trials in Europe as a measure of quality of life. The survey incorporate 5 functional scales (physical, role, cognitive, emotional, social), 3 symptom scales (fatigue, pain and nausea/vomiting), global heath and a quality of life scale. The average time to perform the EORTC QLQ-C30 is 11 minutes. A number of symptoms that are commonly reported by cancer patients, e.g. dyspnea, loss of appetite, insomnia, constipation, and diarrhea, are included in the survey. The survey also inquires about the financial impact of the disease. The EORTC-QLQ-C30 was found to contain a high number of meaningful measures of recovery. ³⁵

Other instruments

There are many other instruments that can be used to measure patient reported outcomes after surgery. These include the Postoperative Recovery Index (PORI)⁴⁴ and

the Gastrointestinal Quality of Life Index (GIQLI)⁴⁵ as examples. The PORI is a quality of recovery scoring system that is self-reported and multi-dimensional. This measure has applicability across various surgeries and surgical settings, from immediately post-surgery throughout discharge and covering the first 30 days of recovery. The GIQLI was an instrument designed to measure quality of life specifically for patients with gastrointestinal disease. Table 2 lists the WHO International classification of functioning, disability and health (ICF) domains and highlights which PRO instruments survey these specific domains. Currently, no single PROM has shown to capture all requisite domains, and there is a need for further research to identify and validate PRO tools for surgical patients within ERPs.

A Framework for Perioperative PROs in ERPs

Figure 1 illustrates the recovery profile of a patient following surgery. Immediately after surgery, a patient's health status sharply decreases from their baseline. During the days, weeks and months following surgery, the patient proceeds to recover to their baseline health status. New interventions, such as implementation of an ERP, should result in a faster and more rapid return to baseline following surgery compared to standard practices.

Health care quality of life is composed of various physical, mental and social domains, which are measured by PROMs. Figure 2 illustrates various factors that contribute to overall quality of life. In the immediate postoperative period, the primary focus of recovery is return of normal biological functions and physical symptoms. Patients must meet specific criteria to qualify for discharge: adequate pain control, eating, drinking, urination, bowel function, ambulation, and activities of daily living. These are measures that health care providers emphasize as important markers of the recovery process and thus impact on the postoperative length of stay. However, a growing body of literature solidifies the critical role of biopsychosocial modulators in relation to the above biologic and physical recovery variables. For example, certain pain behaviors, such as catastrophizing, modulate opioid use, pain, and physical function following a variety of surgeries. However, a doption of comprehensive PROs within an ERP model embraces a biopsychosocial model of recovery that may provide additional clinical interventions that can further optimize recovery.

Furthermore, the process of recovery after surgery continues after discharge from the hospital. Patients view recovery from surgery in terms of freedom from pain, freedom from disability and return to higher functioning activities.⁴⁸ The post-discharge period is characterized by a larger mental and social focus as patients return to baseline and desire freedom from disability.

Examples of PROs within an ERP

Evaluation of an enhanced recovery pathway

A variety of PROMs have been used to measure the impact of ERPs outside of traditional objective measures such as length of stay or return of bowel function. In a study of patients undergoing hip and knee arthroplasty randomized to typical care versus an ERP, the EQ-5D questionnaire was administered at baseline and 3 months postoperatively. While the intervention group had a decreased length of stay, this group was also characterized by a greater gain in EQ-5D scores at 3 months. Wang et al. used PROMs to evaluate patient outcomes and short-term quality of life in patients undergoing colonic surgery. Fifty-seven patients were randomized to an ERP and 60 were randomized to conventional care. Using the EORTC QLQ-C30 and EORTC QLQ CR 29 (European organization for research and treatment of cancer – quality of life for colorectal cancer questionnaire), they demonstrated that short term quality of life was better in patient in the ERP group on postoperative days 3, 6, 10, 14 and 21.

However, improvement in PROMs within ERPs has not been universally observed. King et al also used the EORTC QLQ-C30, and EORTC – QLQ – CR 38 to measure patient reported outcomes and quality of life after colorectal cancer surgery. ⁵¹ Sixty-six patients

assigned to an ERP were compared to 86 historical controls. Quality of life health economic outcomes were not significantly different at two weeks and three months after surgery. One interpretation of this result is that the ERP within this population did not have an impact on patient quality of life. A second plausible interpretation is that the instruments used to measure quality of life may not have been sensitive and responsive in the post-surgical period.

Assessment of recovery profiles

PROMs have been measured within an ERP to assess recovery profiles after surgery. This represents a departure from using PROMs at static time points following an intervention in the distant past to assess performance. Instead, assessment of patterns and trajectories of a variety of biopsychosocial outcomes provide the opportunity to intervene upon such variables to improve rehabilitation.

Shida et al. collected QoR-40 scores on patients undergoing colorectal surgery within the context of an ERP.¹⁸ (Figure 4) QoR-40 scores significantly decreased on POD#1 and POD#3. By POD#6, QoR-40 scores had recovered dramatically and were not significantly different from baseline. The QoR-40 scores at 1 month were also similar to baseline.

Larsen et al. collected patient reported outcomes before and after total hip replacement within an ERP at 3 and 12 months. ⁵² EQ-5D scores continued to rise after surgery and even exceeded population norms at 12 months. However, SF-36 scores after hip

replacement were below population norms at 3 months but were equivalent at 12 months postoperatively. Not only does this highlight the dynamic nature of health related quality of life measures postoperatively but also that there is a poor understanding of which PROMs best match with surgical subtypes.

A second study by Larsen et al. analyzed patient health related quality of life (HRQOL) scores after total knee surgery. Patients were categorized into two groups: a higher baseline HRQOL or a lower baseline HRQOL. Patients with higher HRQOL scores matched normal levels at 4 months. Patients with low HRQOL were below population norms at 4 and 12 months and had additional need for postoperative rehabilitation. This observation highlights the ability of PROs to identify a subgroup of patients who may benefit from targeted intervention. Further research is needed to determine the potential benefits of preoperative optimization and postoperative monitoring of such biopsychosocial variables.

Consensus Recommendations

Recommendation #1: We recommend that all ERPs administer and act upon a set of PROMs that is applicable to their respective clinical population and health care system.

PROs provide a critical complement to standard measures, e.g. length of stay, within ERPs. Understanding the key concepts of physical, mental and social domains, which comprise overall health and quality of life, and the timeframe of inpatient and post-discharge time periods after surgery will allow for the assessment of ERP quality and interventions that may further enhance recovery.

Recommendation #2: We recommend that PROs should be collected at baseline, throughout the in-hospital phase, and post discharge (Figure 3).

- → <u>Baseline</u>: PROMs collected preoperatively should include PROMs intended for inpatient and post-discharge administration. We recommend that immediate postoperative tools such as the QoR-15 and longitudinal PROMs such as WHODAS 2.0, or PROMIS be administered at baseline.
- → In-Hospital: We recommend that the QoR-15 be used in the immediate postoperative period on a 24-hour basis during the inpatient phase of recovery until 3 days postoperatively but ideally until discharge.
- → <u>Post-Discharge</u>: During the immediate post discharge phase, we suggest, where feasible at increased intervals, PROs tools be continued until the first post surgical visit which commonly occurs 14-30 days postoperatively. Following this, we recommend administering a chosen instrument(s) (e.g. WHODAS 2.0 or PROMIS) at the first surgical follow up visit and at feasible intervals until patients have returned to baseline

or transitioned to the primary care system. For institutions wishing to utilize PROMIS, we suggest a tailored approach utilizing CAT. However, for institutions without such a capability, we recommend the use of a PROMIS Profile such as PROMIS-29 or PROMIS-43. These instruments, as opposed to others, comply with the minimum standards for PRO measurement in patient-centered outcomes research.⁵⁴

Recommendation #3: We recommend that institutions longitudinally track PROMs in surgical subtypes for the use in quality assurance and benchmarking across multiple surgical populations.

Research recommendations

The use of PROs in the perioperative period has been limited. Research regarding PROs after surgery should focus on defining the normal trajectory for recovery after surgery for various procedures. PROs should be used to identify gaps in the recovery process after surgery. Further work is needed to develop new PROMs that are sensitive and validated to the surgical patient. PROMs must capture both general health care related quality of life domains as well as disease specific domains. Additionally PROMs must be developed in parallel with performance-based measures to enhance the evaluation of both the subjective and objective recovery trajectories. Lastly, as outlined by Pezold et al, there is a need to incorporate PROs within normal clinical practice with integration into the electronic medical record.⁵⁵

Summary

PROs are any measure of health status that comes directly from the patient. The use of PROs in the perioperative period and within an ERP is limited. PROs will allow us to better capture the patient experience after surgery. Collection of PROs will allow us to better understand normal recovery trajectory pattern after surgery. PROs provide us a tool to assess our patients after hospital discharge and identify patients who will benefit from interventions aimed to enhance recovery. Changes in clinical practice can be assessed using PROs. At the present time, we recommend that ERPs collect preoperative PROs and postoperative PROs using the QoR-15 for the immediate postoperative period and either the WHODAS 2.0 or PROMIS at 30 and 90 days after surgery. Further research should target development and validation of PROMs for the perioperative period.

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Table 1. PROs vs PROM vs PRO-PM

Concept	Example:
PRO (patient reported outcomes)	Symptom: Pain
PROM (instrument, tool, single item measure)	Brief Pain Inventory
PRO-PM (PRO based performance measure)	Percentage of patients who have a Brief Pain Inventory Score greater than baseline on postoperative day #30.

Table 2. Important recovery related International Classification of Functioning, Disability and Health (ICF) categories that are represented in the PRO instruments used to measure recovery. Adapted from Lee et al. How well are we measuring postoperative "recovery" after abdominal surgery. Quality of Life Research. 2015: 24(11) 2853-90.

Recovery Content	EORTC	EQ	GIQLI	QOR	SF36
	QLQ	5D			
B: Body functions					
B1102 Quality of consciousness					
B1300 Energy Level	Х		Х		Х
B1302 Appetite	Х		Х		
B134 Sleep Functions	Х		Х		
B1400 Sustaining attention	X				
B280 Sensation of pain	X	Х	X	Х	Х
B4550 General physical endurance			X		
B525 Defecation functions	X		X	X	
B5350 Sensations of Nausea	Х		Х		
B730 Muscle Power	Х		Х		
d. Activities and Participation					
D230 Carrying out daily routine	Х	Х	Х		Х
D410 Changing basic body position	Х				Х
D430 Lifting and carrying objects	Х				Х
D450 Walking	Х	Х			Х
D460 Moving around in different locations	Х				
D550 Eating	Х		X		
D640 Doing housework	Х				Х
D660 Assisting others					
D750 Informal social relationships	Х		Х		Х
D760 Family relationships	Х		X		Х
	J	1	1	1	1

D850 Work and employment	X		X
D920 Recreational Activities		X	X

EORTC QLC – European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – C30. GIQLI- Gastrointestinal Quality of Life Index, QOR – Quality of Recovery Score, SF 36 – Short Form 36.

Table 3. Suggested minimal PRO set using PROMIS within an ERP

Baseline	Inpatient/Early Recovery	Post Discharge/
Preoperative	Period - Day 7	Late Recovery Period –
		Day 30 & 90
Anxiety	Anxiety	Anxiety
Depression	Physical Function	Depression
Physical Function	Pain Behavior	Physical Function
Pain Interference	Pain Interference	Pain Interference
Pain Behavior	Sleep Disturbance	Pain Behavior
Sleep Disturbance		Sleep Disturbance
Ability to participate in		Ability to participate in social
social roles/activities		roles/activities

Figure Legends:

Figure 1. Recovery after surgery. Inpatient and post discharge domains of patient reported outcomes. Examples of Patient reported outcome measures that can be used during their respective time periods.

Figure 2. A Simplified Wilson-Cleary Classification of Patient Outcomes. Adapted from Neville A et al. Systematic review of outcomes used to evaluate enhanced recovery after surgery. *The British Journal of Surgery*. 2014;101(3):159-70.

Figure 3. Proposed timeline for patient reported outcome measures for incorporation within and ERP using the QoR-15, WHODAS 2.0, or PROMIS measures.

Figure 4. The use of the QoR-40 score in colorectal surgery within an ERP. QoR-40 scores decrease significantly from baseline on Day 1 and Day 3. By Day 6, QoR-40 scores are not significantly different from baseline. The median (25th, 75th percentiles) of perioperative global QoR-40 scores is presented as box and whisker plots. From Shida et al. The postoperative patient-reported quality of recovery in colorectal cancer patients under enhanced recovery after surgery using the QoR-40. *BMC Cancer*. 2015. 15: 799.

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