An Analysis of Methodologies That Can Be Used to Validate if a Perioperative Surgical Home Improves the Patient-centeredness, Evidence-based Practice, Quality, Safety, and Value of Patient Care

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ABSTRACT

Approximately 80 million inpatient and outpatient surgeries are performed annually in the United States. Widely variable and fragmented perioperative care exposes these surgical patients to lapses in expected standard of care, increases the chance for operational mistakes and accidents, results in unnecessary and potentially detrimental care, needlessly drives up costs, and adversely affects the patient healthcare experience. The American Society of Anesthesiologists and other stakeholders have proposed a more comprehensive model of perioperative care, the Perioperative Surgical Home (PSH), to improve current care of surgical patients and to meet the future demands of increased volume, quality standards, and patient-centered care. To justify implementation of this new healthcare delivery model to surgical colleagues, administrators, and patients and maintain the integrity of evidenced-based practice, the nascent PSH model must be rigorously evaluated. This special article proposes comparative effectiveness research aims or objectives and an optimal study design for the novel PSH model.

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N estimated 30 million major inpatient surgeries 1,2 and 50 million ambulatory outpatient surgeries 3,4 are performed annually in the United States. Widely variable and fragmented perioperative care plans, undertaken by different practitioners, currently expose these surgical patients to lapses in expected standard of care, increase the chance for operational mistakes and accidents, result in unnecessary and potentially detrimental care, needlessly drive up costs, and adversely affect the patient healthcare experience. 5–9

To address this fragmentation and depersonalization of surgical care, new approaches are needed that are more efficient and less costly yet emphasize the patient as the center of care. 8–10 The medical community and public are increasingly embracing shared decision-making, a process by which healthcare choices are made jointly by the practitioner and patient. 11–13 Akin to the Medical Home in outpatient primary care, 10,14–16 the Surgical Home has been proposed by the American Society of Anesthesiologists (ASA)# and others as an innovative, patient-centered, surgical continuity of care model that fully incorporates shared decision-making. 8,17

Like all areas of health care, the specialty of anesthesiology is also facing strong economic pressures which require a broader competitive strategy. 8,18,19 Hospital-physician collaborations continue to evolve to include greater economic integration, including major financial gain and risk sharing. 20,21 Furthermore, value-based purchasing of health care, 22–24 pay for performance, 25,26 and a changing payment paradigm that includes bundled payments or accountable care arrangements 27 are all powerful motivators to improve the effectiveness and efficiency of patient care via a surgical home type model. 8

There will very likely be multiple future variations of the surgical home concept that may work effectively, depending on institutional infrastructure and yet to be identified external forces. However, at its essence, the Perioperative Surgical Home (PSH) model integrates the three well recognized, but heretofore frequently fragmented, preoperative, intraoperative, and postoperative phases of patient care (fig. 1). 8 The PSH seeks to more intentionally engage the patient, family, clinicians, and other stakeholders, thereby enhancing the ability of patients to actively participate in shared decision-making concerning their surgical care. Fundamentally, the anesthesiologist-intensivist serves as the surgical patient’s “perioperativist”—the
primary physician who provides seamless continuity of current best practices of care—while actively involving the patient, family, and other healthcare providers. In the PSH model, an anesthesiologist-intensivist works with a nurse practitioner to provide, coordinate, and integrate pre-, intra-, and postoperative care. This anesthesiology-based team is readily available throughout the perioperative continuum to address the patient’s questions or concerns about their care. This team also oversees the patient’s transitional plans on hospital discharge—initiated, however, preoperatively. Specifically, tenets of the Institute for Healthcare Improvement’s “How-to Guide: Improving Transitions from the Hospital to Home Health Care to Reduce Avoidable Rehospitalizations” are translated into the perioperative setting (fig. 2). A key element of this perioperative Transitional Care Model is a nurse clinician (or medical social worker) serving as the patient’s “perioperative transitions coach.”

The implementation of such a PSH model will likely also be an evolutionary process that varies across local practice environments. Because a given PSH evolves from the existing local model of care, different institutions may well adopt different elements at different rates, with variable emphasis on specific surgical populations (e.g., total joint replacement) or specific portions of the perioperative continuum of care (e.g., preoperative medical optimization and patient education and counseling). Although this article examines more complex surgical procedures requiring postoperative admission, the proposed outcomes and methodology are applicable to outpatient surgeries, endoscopic procedures, and routine obstetrical care—high-volume areas in which anesthesiologists can also provide needed greater integration and coordination of care.

The Institute of Medicine (IOM) has defined comparative effectiveness research (CER) as the “generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.” In 2009, the IOM established a national CER agenda. “Health Care Delivery Systems” was the highest ranked IOM CER priority. The proposed PSH model falls squarely in this highest ranked IOM CER category.

In obligatorily assessing whether a new PSH model is superior to current conventional surgical care, four specific,
special CER aims or objectives include whether the PSH results in (1) enhanced patient-centered care of the surgical patient; (2) greater clinician adherence to evidence-based patient management guidelines; (3) improved quality and safety of perioperative care; and (4) reduced overall cost and thus enhanced value. The other fundamental question is what is the optimal study design for the PSH model? Most importantly, such an ability to define, obtain, and analyze outcomes in a rigorous way will be essential to test the variety of surgical home models that will likely be trialed in the next few years as surgical paradigms evolve—especially in response to economic influences.

Patient-centered Care of the Surgical Patient

In assessing whether the PSH model results in greater patient-centered care of the surgical patient, initial primary patient-reported outcomes would include conventional perioperative (1) pain intensity; (2) health-related quality of life; (3) quality of recovery; and (4) patient satisfaction.

The assessment of pain intensity is essential for clinical trials and effective pain management. Acute pain can be measured, both at rest (important for comfort) and during movement (important for function and risk of postoperative complications), using a valid and reliable unidimensional self-reported pain intensity scale. Health-related quality of life has become a well-accepted primary outcome measure in clinical studies, including in surgical patients. Quality of recovery, when assessed in a patient-centered manner, provides an additional important information in postsurgical patients. If measured with a robustly developed and subsequently validated instrument, patient satisfaction is a standard indicator of the quality of delivered health care and can contribute to a comprehensive evaluation of the classic triad of structure, process, and outcome, including with existing and new perioperative services. Patient satisfaction is most validly measured sequentially and in close proximity to the delivered health care (i.e., the patient’s surgical experience). This would ideally involve measurements before or at the time of hospital admission, during the postoperative phase on the day of hospital discharge, and at 28 days.
postdischarge. Interviewing the same patients three times during their surgical care continuum will provide them with the opportunity to express their expectations of perioperative outcomes, discuss benefits and risks of available treatment options, identify patients’ unmet needs, and explore the relevance of the measured outcomes.47

Undergoing a major surgical procedure is often one of the most stressful events in an individual’s life. An independent, well-informed, and proactive person can become a dependent, passive, and bewildered patient in the very foreign and often ironically hostile healthcare environment. Thus a very appropriate question posed by many surgical patients is “What can I do to improve the outcomes that are most important to me?” This questions speaks directly to the fundamental tenet of patient–stakeholder engagement—specifically, how to define it and how to measure it.

According to the Agency for Healthcare Research and Quality, stakeholders are “persons or groups who have a vested interest in the clinical decision and the evidence that supports that decision.”48 In the PSH model, stakeholders may include surgical patients, their families, and other lay caregivers, as well as anesthesiologists, surgeons, nurses, hospital administrators, and other professional healthcare providers. All these stakeholder groups, regardless of varied professional and personal interest in specific outcomes of patient’s perioperative surgical care, will likely have a vested interest in patient-centered health care and its associated outcomes. With the creation of the Patient-Centered Outcomes Research Institute by the Patient Protection and Affordable Care Act of 2010, CER has effectively been renamed “patient-centered outcomes research”—underscoring the goals and importance of person-centered medicine.49

It seems important that stakeholder engagement in the evaluation of the PSH model implementation follows the key principles of community-based participatory research.50 These principles emphasize stakeholder participation, equal power, and joint planning.51 Participation underscores the involvement of community members (e.g., surgical patients, their family members, and other lay patient caregivers) in a specific project with shared ownership, from setting project objectives to disseminating project outcomes. Performing research in collaboration with those affected by the issue (e.g., the perioperative patient experience) for the purpose of taking action or making change increases the likelihood that research findings will be accepted and used.52

Surgical patients and other invested stakeholders would ideally be involved in all phases of a PSH model—from the early stages of conceptualization and inception, to design and refinement of assessment instruments, data collection and analysis, and evaluation of project outcomes and related health benefits. Such active participation and collaboration will promote capacity building among all partners and will create an empowering environment for all stakeholders to equally contribute to the decision-making and control over all stages of the healthcare delivery process and the assessment of risks and benefits of the PSH model.53 A set of strategies have been recommended to ensure stakeholders’ consistent engagement with the project and active dissemination and implementation of the results (table 1).58,54,55

Assessment of stakeholders’ views can best be achieved using a mixed-method (integrated qualitative and quantitative) approach, as set forth in the “Best Practices for Mixed Methods Research in Health Sciences” commissioned by National Institutes of Health Office of Behavioral and Social Sciences Research.56 Collecting and meaningfully integrating data from qualitative narratives and quantitative measures allow exploring the views of all engaged stakeholders from multiple perspectives and in various phases in the project implementation and evaluation. For example, patients’ and caregivers’ experiences with provided health care can be explored by individual interviews at several stages in the perioperative care process to understand patients’ needs and expectations for preoperative, intraoperative, and postoperative patient care, to assess the relevance of the above_a_priori chosen conventional patient-centered outcomes, and to enhance patients’ engagement in shared decision making about their health care. Similarly, interviews of focus groups with professional healthcare providers can help solicit their input into the effectiveness of the PSH model and to enhance the establishment of outcomes that are patient-centered and that are tailored to patients’ personal characteristics, conditions, preferences, and needs.

Mixed-method approach would be particularly useful in developing new assessment tools to measure patient satisfaction with perioperative care that are tailored to their personal (individual) characteristics, conditions, preferences, and needs.10 Applying mixed methods to assessing patient satisfaction with perioperative health care entails an initial qualitative exploration of stakeholders’ views through patient interviews and/or focus groups and using the emerging themes to inform the subsequent development, testing, and validation of the quantitative questionnaire by administering

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Table 1. Strategies to Ensure Stakeholders’ Consistent Engagement with the Project and Active Dissemination and Implementation of the Results48,54,55

<table>
<thead>
<tr>
<th>Strategy</th>
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<tbody>
<tr>
<td>Building trust relationship</td>
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<tr>
<td>Using a highly collaborative process</td>
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<tr>
<td>Viewing stakeholders as partners in the research process</td>
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<td>Promoting voluntary participation</td>
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<tr>
<td>Fostering open, honest dialogue about their expectations and concerns</td>
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<tr>
<td>Building on strengths and resources within the community</td>
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<tr>
<td>Fostering capacity building among all partners</td>
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<tr>
<td>Remaining highly responsive to stakeholders’ concerns</td>
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<tr>
<td>Utilizing qualitative methods to reveal stakeholders’ unique viewpoints</td>
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<tr>
<td>Modifying existing quantitative instruments to address stakeholders’ concerns</td>
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it to a large sample. The procedural steps have been defined for developing a satisfaction instrument grounded in the views of surgical patients using a mixed-method approach (fig. 3).\(^\text{10}\) Finally, integrated qualitative and quantitative results from different stages in the PSH model implementation can be used for a summative evaluation of the model and an assessment of its effectiveness by patients, various healthcare providers, and other stakeholders.\(^\text{37}\)

**Clinician Adherence to Evidence-based Patient Management Guidelines**

In assessing whether the PSH model results in greater clinician adherence to evidence-based patient management guidelines and thus provision of current best practices, examples include those set forth by: (1) the American College of Chest Physicians for the perioperative management of anti-thrombotic therapy and the prevention of thrombosis in patients who require an elective surgery or procedure;\(^\text{58}\) (2) the Heart Rhythm Society/ASA on the perioperative management of patients with implantable defibrillators, pacemakers, and arrhythmia monitors;\(^\text{59}\) (3) the ASA for the perioperative management of acute pain;\(^\text{60}\) (4) the ASA for the perioperative management of patients with obstructive sleep apnea and vomiting;\(^\text{61}\) (5) the Society of Ambulatory Anesthesia for the for the management of postoperative nausea and vomiting;\(^\text{62}\) (6) the American College of Cardiology/American Heart Association for perioperative cardiovascular evaluation and care for noncardiac surgery, including perioperative β-blockade;\(^\text{63,64}\) (7) the European Society of Cardiology for the preoperative cardiac risk assessment and perioperative cardiac management in noncardiac surgery;\(^\text{65}\) and (8) the Society for Advancement of Blood Management,\(^\text{**\text{**}}\) the Network for Advancement of Transfusion Alternatives,\(^\text{66,67}\) and the American Association of Blood Banks\(^\text{68}\) for perioperative anemia and blood management.

A patient-centered approach to surgical patient blood management has been advocated by the ASA.\(^\text{69}\) Associated concerted efforts may thus be better termed, “patient-centered blood management,”\(^\text{69}\) to reflect the increasing emphasis on patient-centeredness in other areas of medicine and the consumer-perspective of health care.\(^\text{10,70,71}\) Additional patient-centered outcomes in the PSH model would thus, for example, be those associated with state-of-the-art patient-centered blood management and include (1) the immediate preoperative complete cell blood count; (2) the postoperative complete cell blood count at the time of hospital discharge; (3) the total number of units of packed erythrocyte units administered intraoperatively, postoperatively during the first 30 days after hospital discharge; and (3) clinician adherence to recently published guidelines on blood transfusion criteria (i.e., triggers).

**Quality and Safety of Perioperative Care**

In assessing whether the PSH model results in improved overall quality and safety of perioperative care, additional primary outcomes would include (1) perioperative mortality; (2) perioperative complications; (3) failure-to-rescue (FTR) rate; (4) a subset of current national performance metrics; (5) admission rate to an intensive care unit; (6) readmission rate to an intensive care unit from a regular inpatient unit; (7) length of stay in an intensive care unit and in the hospital; (8) readmission rate to the hospital after discharge home; and (9) not-present-on-admission diagnostic codes (International Classification of Diseases) that are indicative of potential complications. Several of these quality and safety outcomes also have current and future reimbursement and thus fiscal ramifications.

Reported surgical death rates vary widely across hospitals in the United States, from 3.5% in very-low-mortality hospitals to 6.9% in very-high-mortality hospitals.\(^\text{72}\) Payers (e.g., Centers for Medicare and Medicaid Services), regulators (e.g., The Joint Commission), and providers are currently focusing on ways of reducing postoperative complications, which may be one approach to reducing this observed variability in surgical mortality. However, based on Medicare administrative beneficiary data from 2005 to 2006, complication rates in patients undergoing major inpatient surgical procedures were similar at the worst and best hospitals (36.4% vs. 32.7%), but the worst hospitals had mortality rates 2.5-fold higher than the best hospitals.\(^\text{73}\) The above reported administrative data\(^\text{24,75}\) may have

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FTR was first defined in 1992 by Silber and colleagues.74 FTR was characterized as a mortality rate among surgical inpatients with serious treatable complications (“failure-to-rescue”).72,73,75 Contributors to FTR have been broadly categorized as the lack of a timely and more appropriate response to patient physiologic derangement, thus reducing the FTR rate, major complications from the American College of Surgeons National Surgical Quality Improvement Program;80 (4) the National Patient Safety Goals from The Joint Commission;81 and (5) the Patient Safety Indicators from the Agency for Healthcare Research.82 The majority of the Centers for Medicare and Medicaid Services Appropriate Care Measures are not applicable to our proposed perioperative patient care model. The effect of Surgical Care Improvement Project adherence in lowering surgical site infection rates at the patient or hospital level has recently been challenged.83–85 The National Patient Safety Goals from The Joint Commission lack adequate surgical specificity.

Therefore, for the purposes of comparing the quality, safety, effectiveness, and efficiency of perioperative care delivered in the PSH model versus current typical surgical care, a combination of conventional perioperative complications, Agency for Healthcare Research and Quality Patient Safety Indicators, Centers for Medicare and Medicaid Services Hospital-Acquired Conditions, and elements from Surgical Care Improvement Project and National Surgical Quality Improvement Program (table 2) appear to be the most appropriate quality and safety variables in assessing the effect of the PSH model.

Many of the above-mentioned perioperative outcomes and performance metrics are currently being collected by individual hospitals in their efforts to meet various national benchmarking, pay-for-performance, and value-based

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Table 2. Quality and Safety Variables to Be Applied in Assessing the Effect of the Perioperative Surgical Home Model

<table>
<thead>
<tr>
<th>Quality or Safety Variable</th>
<th>Definitions</th>
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<tr>
<td>All-cause mortality at 28 d, 60 d, and 1 yr postoperatively</td>
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<tr>
<td>Death in low-mortality DRGs</td>
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<tr>
<td>Death among surgical inpatients with serious treatable complications (“failure-to-rescue”)</td>
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<tr>
<td>Unplanned postoperative intubation</td>
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<tr>
<td>Iatrogenic pneumothorax</td>
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<tr>
<td>Prolonged mechanical ventilation (&gt;48 h)</td>
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<tr>
<td>Postoperative pneumonia</td>
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<tr>
<td>Postoperative SSI (including deep-wound or organ-space infection)</td>
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<tr>
<td>Selected infections due to medical care: CLABSI; CAUTI; HAP; VAP (as a subset of HAP)</td>
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<tr>
<td>Postoperative hip fracture</td>
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<td>Postoperative hemorrhage or hematoma</td>
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<td>Postoperative physiologic and metabolic derangements (electrolyte and fluid imbalance after surgery)</td>
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<td>Postoperative respiratory failure</td>
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<td>Postoperative deep vein thrombosis or pulmonary embolism</td>
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<td>Postoperative stroke</td>
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<td>Postoperative acute renal failure</td>
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<td>Postoperative myocardial infarction</td>
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<td>Postoperative sepsis and septic shock</td>
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<tr>
<td>Postoperative abdominal wound dehiscence (including fascial dehiscence)</td>
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<tr>
<td>Decubitus pressure ulcer</td>
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<tr>
<td>Blood transfusion (intraoperative or postoperative)</td>
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<tr>
<td>Blood transfusion reaction</td>
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<tr>
<td>Percent of surgery patients who receive an appropriate blood clot preventive therapy within 24 h before the surgical incision time to 24 h after the surgical end time</td>
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<tr>
<td>Percent of surgery patients who had the urinary catheter removed on postoperative day 1 or postoperative day 2 (day of surgery being day 0)</td>
<td></td>
</tr>
<tr>
<td>Percent of surgery patients who receive an appropriate blood clot preventive therapy within 24 h before the surgical incision time to 24 h after the surgical end time</td>
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CAUTI = catheter-associated urinary tract infection; CLABSI = central line–associated bloodstream infection; DRGs = diagnostic-related groupings; HAP = hospital-acquired pneumonia; SSI = surgical site infection; VAP = ventilator-associated pneumonia.
Table 3. The Revised Clavien-Dindo Classification of Surgical Complications to Be Applied in Assessing the Effect of the Perioperative Surgical Home Model

<table>
<thead>
<tr>
<th>Grade</th>
<th>Classification Criteria</th>
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<tr>
<td>Grade I</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside</td>
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<tr>
<td>Grade II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included</td>
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<tr>
<td>Grade III</td>
<td>Requiring surgical, endoscopic, or radiological intervention</td>
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<tr>
<td>Grade IIIa</td>
<td>Intervention not under general anesthesia</td>
</tr>
<tr>
<td>Grade IIIb</td>
<td>Intervention during general anesthesia</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Life-threatening complication (including CNS complications)* requiring IC/ICU management</td>
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<tr>
<td>Grade Iva</td>
<td>Single organ dysfunction (including dialysis)</td>
</tr>
<tr>
<td>Grade IVb</td>
<td>Multiorgan dysfunction</td>
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<tr>
<td>Grade V</td>
<td>Death of a patient</td>
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</table>

Suffix "d" (for "disability") is added to the respective grade of complication if the patient suffers from a complication at the time of discharge. This disability label indicates the need for a follow-up to fully evaluate the complication. CNS = central nervous system; IC = intermediate care; ICU = intensive care unit.

*p = Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks.

Reduced Cost and Enhanced Value

In assessing whether the PSH model results in reduced overall cost and thus enhanced value, potential outcomes include (1) total direct medical costs of the surgical procedure, anesthesia services, and related hospitalization(s); (2) the rate of surgical case delays and surgical case cancellations on the day of surgery; (3) the duration of specific surgical procedures; (4) the duration of postanesthesia care unit stay; and (5) other pertinent operational and fiscal measures (e.g., unplanned postoperative procedure admission, allogeneic blood transfusion rates for cardiac surgery).

Aggregate healthcare expenditures are projected to increase in the United States from $5,572 per capita (15.9% of gross domestic product) in 2005 to $8,832 per capita (2005 dollars) in 2025 (25.2% of U.S. gross domestic product). Specifically, aggregate surgical expenditures in the United States are expected to grow from $572 billion in 2005 (4.6% of U.S. gross domestic product) to $912 billion (2005 dollars) in the year 2025 (7.3% of U.S. gross domestic product). Thus not surprisingly, prospective healthcare initiatives will focus not only on quality and safety but also on delivering cost-effective care or enhanced value. Value in health care, including with anesthesia and surgical services, is broadly defined as the patient health outcomes achieved per dollar spent.

Efforts to provide enhanced patient care in the PSH model, while controlling unnecessary or wasteful healthcare expenditures, will presumably deliver “high-value, cost-conscious health care.” Whether an intervention like cardiac arrest) that might not result in a permanent adverse outcome but nonetheless should be captured. The Clavien-Dindo Classification System has been successfully applied in gastrointestinal surgery, gynecology, orthopedics, and urology.
the PSH provides such high value is predicated on assessing whether its associated improved health benefits justify its (added) costs.100,101 There are three key concepts in understanding how to assess the value of new versus existing health care interventions.100,101 First, assessing the benefits, harms, and costs of an intervention is essential to understand whether it provides a good value. Second, assessing the cost of an intervention should include not only the cost of the intervention itself but also any downstream costs that occur because the intervention was performed. Third, the incremental cost-effectiveness ratio estimates the additional cost required to obtain additional health benefits and provides a key measure of the value of a healthcare intervention.99–101

Full healthcare economic evaluation techniques conventionally include cost-minimization analysis, cost–benefit analysis, cost–effectiveness analysis, and cost–utility analysis.101–106 A cost–utility analysis is a cost–effectiveness analysis that measures outcomes using quality-adjusted life years or another similar measure. Such full economic evaluations require that two or more therapeutic interventions be compared in relation to both their costs and effects.103,107 The six fundamental steps in undertaking a full economic evaluation include: (1) identify the perspective of the study; (2) identify the alternatives that will be compared; (3) identify the relevant costs and effects; (4) determine how to collect the cost and effect data; (5) determine how to perform calculation for cost and effects data; and (6) determine the manner in which to depict the results, draw comparisons, and make conclusions.101,103,107,108

With proper planning, a full healthcare economic evaluation can be validly performed and reported alongside a clinical trial.100,109–113 However, given the logistical challenges of such a conjoint study,114 researchers often combine previously published cost and clinical outcomes data to create a decision-analysis model.100,115 The validity of such studies depends on how well the model reflects the key clinical issues and on the reliability of the parameters used to estimate costs, outcomes, and health status utilities.101 Sensitivity analyses are therefore critical for understanding how reported conclusions might change depending on the variability or uncertainty in key parameters.101

Methodologic Considerations for the Evaluation of the PSH Model

In assessing whether the new PSH model is superior to current conventional surgical care, a fundamental question is what is the optimal study design? Related issues include the use of composite outcomes as well as the need for a clinical proof-of-concept (PoC) study data before advocating wider implementation of this model.

Optimal Study Design

Randomized Controlled Trial. The randomized controlled trial (RCT) has been viewed as the de facto “definitive standard” of clinical trial design for evaluating the efficacy and safety (risk vs. benefit) of a treatment or intervention.116–118 The primary feature underlying the RCTs prominence is the ability to randomize study participants thereby dramatically reducing the opportunity for confounding, by both known and unknown factors, and thereby increasing internal validity relative to observational study designs.116,119 However, it is important to note that well-designed and executed observational studies have been shown to yield equally valid results with the added benefit of addressing the effectiveness of a population-based or systems-based intervention like the PSH model, in a more “real-life” and thus externally valid setting.120,121

Nonetheless, the RCT design is a reasonable choice for assessing many important questions related to the PSH model. There are a number of other RCT designs, which may, on a situational basis, be more appropriate to apply in conducting human research (e.g., the comparative effectiveness of the PSH model).122 Thus although the main Consolidated Standards of Reporting Trials Statement is focused on the typical two-group parallel RCT design,122 there are several different types of randomized trials, some of which have different fundamental designs, as well as types of interventions and data, for which specific Consolidated Standards of Reporting Trials Extensions exist.123–125

With respect to evaluating the PSH model, a cluster randomized trial (CRT) is the most suitable RCT design. Individual clinicians, group practices, clinics, hospitals, health plans, or even geographic regions (counties or states) can be defined as the clusters. In a CRT, all individuals within a given cluster are assigned to the same study arm.126 The methodology of CRTs has been widely discussed.127–129 The applicability of the CRT to the PSH model is largely attributable to the fact that it would be impractical for a given institution to modify its process of care on a patient-by-patient basis.

In addition, when evaluating a new therapy, or care model like the PSH, unlike a standard RCT, a CRT typically focuses on effectiveness by evaluating outcomes under conditions of actual use. A CRT is often done when individual randomization is not feasible. A CRT can also offer considerable cost and time efficiencies when implemented by a health system or health insurance plan that has extensively existing information about its members’ characteristics, treatments, and outcomes, along with a robust existing research infrastructure.126 A CRT design could thus be applied in a comparative study of the PSH model if a sufficiently large number of separate clusters (i.e., individual healthcare delivery sites) could be identified and enrolled.

However, compared with individually randomized trials, CRTs are more complex to design, require more participants to obtain equivalent statistical power, and require more complex analysis (e.g., adjustment for the intra-cluster correlation coefficient of the cluster randomization).130–132 A CRT is also typically not blinded. Thus not
surprisingly, the use of this trial design has been fraught with challenges, undermining the validity of some published findings.\textsuperscript{131,133}

\textbf{Cohort Study.} As noted above, observational study designs can yield valid results often in a more timely and cost-efficient manner and have greater ability to measure effects under “real world” clinical settings.\textsuperscript{134,135} Specifically, an observational prospective cohort study can assess in representative populations the comparative effectiveness of interventions (e.g., the PSH) to reduce risk from coexisting diseases, prevent adverse events, and improve patient-centered outcomes—once again in settings typically encountered in clinical practice.\textsuperscript{135,136}

An observational prospective cohort study design could also readily assess shared clinician-patient decision-making, a salient feature of the PSH model.\textsuperscript{135} Cohort study methodology has been widely discussed.\textsuperscript{116,137–144} Specifically, guidelines have been promulgated STrengthening the Reporting of OBservational studies in Epidemiology Initiative for analytic observational studies.\textsuperscript{145,146}

A cohort study design has several advantages in comparative effectiveness studies, including one comparing status quo surgical patient care with a new PSH model. By applying the active perioperative interventions at the clinic and hospital level, a cohort study would more readily investigate these therapeutic interventions under conditions of actual use. Furthermore, a prospective cohort study design is preferable in a setting where individual randomization is not feasible. For the purposes of studying the PSH, prospective outcomes data would be collected on a group of surgical patients, who receive their care after the implementation of the PSH model, and compared with those receiving conventional perioperative care. Given the relatively short timeframe (e.g., 30–90 days) of a perioperative study, differential attrition would not be expected to be a major concern (though it should be noted that such differential attrition is also a concern in an RCT). However, it will be necessary to explore and address confounding by first adjusting conducting stratified analyses according to (1) the indications for the surgical procedure (2) the presence of known risk factors for postoperative complications, specifically, the level of risk associated with the surgical procedure, and the presence of coronary artery disease, congestive heart failure, hypertension, cerebrovascular disease, diabetes mellitus, chronic renal insufficiency, chronic liver disease, and chronic obstructive pulmonary disease and, in the absence of differential effects, adjust for any characteristics that appear to act as confounders.

\textbf{Composite Outcomes}

A recent trend in clinical trials and some observational studies is the increasing use of composite outcomes,\textsuperscript{147} which may be applied to assessing the comparative effectiveness of a new PSH model. A composite outcome is comprised several separate yet related component outcomes (e.g., death, myocardial infarction, atrial fibrillation, congestive heart failure).\textsuperscript{147,148} These components should be a parsimonious set of individual outcomes, which when taken together, well represent the disease of interest (e.g., perioperative morbidity and mortality) and are very plausibly related to the intervention (e.g., the PSH model).\textsuperscript{149} A study subject is considered to have experienced the binary (dichotomous) composite outcome if one or more of the component outcomes occur.\textsuperscript{147,150}

Advantages to using composite outcomes include a reduction in required sample size to achieve adequate power and simplifying data presentation.\textsuperscript{147,151} The former is particularly relevant if an individual major outcome is rare yet the statistical power of a realistically sized trial is inadequate to demonstrate a statistically significant treatment difference.\textsuperscript{149} If many or all of the purported benefits of the PSH are considered clinically important and thus could influence the wider adoption of this nascent patient care model, it would be difficult to identify any single one as the primary clinical outcome.\textsuperscript{147} In contrast, a composite outcome would allow investigators of the PSH to report a broader but equally valid array of benefits (or harms).

However, the use of composite outcomes in trials can be problematic.\textsuperscript{150} Components are often unreasonably combined, inconsistently defined, and inadequately reported, resulting in an exaggerated observation of how well interventions work.\textsuperscript{152} Three major caveats with a composite outcome are that its individual components are similarly important to patients; occur with similar frequency; and are affected to a similar degree by the intervention.\textsuperscript{148} This assumed homogeneity of effect across its component outcomes can be substantiated by the concomitant reporting of data for each of the component elements as secondary outcomes.\textsuperscript{147}

\textbf{PoC Study}

A parallel can be drawn between the development of a new PSH model and the development of a new drug. PoC typically refers to early studies in clinical drug development, conventionally designated as phase I and phase IIa.\textsuperscript{153} Unlike a confirmatory RCT that is required for regulatory drug approval, a PoC trial is exploratory in nature, and designers of such trials have the liberty to choose the type I error rate and the power.\textsuperscript{154} However, the selection of clinical endpoints and their effect size, as well as choice of type I and type II error rates, are often at the center of heated debates in the design of PoC trials.\textsuperscript{155} A PoC trial also supports a so-called “Go-No Go” decision for further drug development.\textsuperscript{155} Clinical PoC (CPoC) has been defined as: “The construction of working prototypes of the necessary functionality and infrastructure in sufficient quality to investigate evidence for improving health in daily use for a suitable period of time; a limited but relevant set of people [patients] serving as [study] subjects.”\textsuperscript{88}

An initial, limited scale CPoC study could be appropriately undertaken at one’s institutional level to determine the operational and fiscal viability of further development and deployment (Go-No Go decision) of a novel yet nascent
PSH model for the management of surgical patients. The particular clinical endpoints that may make up a CPoC trial for the PSH are a point of active discussion and may include the collection of clinical outcomes proposed in this article, in addition to those recommended by patients, focus groups, institutional committees, payers, and other stakeholders. Permutation P value trend analysis has been used in CPoC trials to evaluate trends collectively across multiple endpoints. This decreases the likelihood of type II error in trend interpretation as a trend in one endpoint is more likely due to chance than trends in multiple endpoints. Finally, the CPoC process emphasizes the identification of previously unseen challenges and pitfalls unique to each particular environment to save time and resources and improve efficiency when a more robust trial is implemented.

Conclusions

The PSH model seeks to deliver a highly patient-centered, anesthesia-led yet interdisciplinary, and team-based system of coordinated care, which guides the patient throughout the entire surgical continuum, from the decision for the need for a surgery to discharge from a medical facility and beyond. By implementing evidence-informed best practices, standardization of processes where applicable, shared decision-making, and management accountability by a single coordinating service, patients are likely to get the most appropriate care possible. Eliminating overuse, underuse, and misuse of perioperative care may also lead to better outcomes at a lower cost—the definition of added value. However, such value assessments should be ongoing and result not only in the initial implementation of the surgical home concept but also its continued successful evolution. Traditional financial, patient, and surgical metrics will likely have to be redefined to accurately assess new definitions of value.

Nevertheless, the onus is clearly on the advocates and early adopters of this nascent alternate care model to demonstrate its ability to achieve its various espoused goals and objectives. Toward that end, it is prudent to capture the experience of these early adopters in the context of an observational cohort study for the purposes of not only establishing preliminary evidence for the effectiveness of the PSH model but also for providing pilot data necessary for the design of a CRT. This approach will allow a sufficient number of geographically distinct PSHs that would be required for such a trial to become well-established—likely in 3–5 yr.

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