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Defining Serious Illness Among Adult Surgical Patients

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Abstract

Context.—Palliative care (PC) for seriously ill surgical patients, including aligning treatments with patients' goals and managing symptoms, is associated with improved patient-oriented outcomes and decreased health care utilization. However, efforts to integrate PC alongside restorative surgical care are limited by the lack of a consensus definition for serious illness in the perioperative context.

Objectives.—The objectives of this study were to develop a serious illness definition for surgical patients and identify a denominator for quality measurement efforts.

Methods.—We developed a preliminary definition including a set of criteria for 11 conditions and health states. Using the RAND-UCLA Appropriateness Method, a 12-member expert advisory panel rated the criteria for each condition and health state twice, once after an in-person moderated discussion, for validity (primary outcome) and feasibility of measurement.

Results.—All panelists completed both rounds of rating. All 11 conditions and health states defining serious illness for surgical patients were rated as valid. During the in-person discussion, panelists refined and narrowed criteria for two conditions (vulnerable elder, heart failure). The final definition included the following 11 conditions and health states: vulnerable elder, heart failure, advanced cancer, oxygen-dependent pulmonary disease, cirrhosis, end-stage renal disease, dementia, critical trauma, frailty, nursing home residency, and American Society of Anesthesiology Risk Score IV-V.

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Conclusion.—We identified a consensus definition for serious illness in surgery. Opportunities remain in measuring the prevalence, identifying health trajectories, and developing screening criteria to integrate PC with restorative surgical care.

Keywords

Surgical palliative care; serious illness; quality improvement; quality measurement; RAND-UCLA Appropriateness Method; Delphi methods

Introduction

Palliative care (PC) is interdisciplinary care aimed at improving quality of life and reducing suffering for seriously ill patients and families. When delivered alongside curative or restorative surgical care, PC decreases symptom burden, reduces health care utilization, and improves the quality of end-of-life care without impacting mortality.^{1–3} In light of these benefits, there have been increasing calls to integrate PC with surgical care, including a statement of principles from the American College of Surgeons (ACS), a national research agenda sponsored by the National Institute of Aging and National Palliative Care Research Center, the release of PC best practice guidelines within ACS quality improvement programs, and ACS endorsement of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care.^{4–8} Furthermore, there are ongoing efforts to develop quality indicators to guide primary PC delivery by surgical teams, which would measure access to and the quality of PC delivered across the surgical episode.⁹

However, efforts to integrate PC into routine surgical care are hindered by the lack of consensus around the seriously ill population that would benefit most from receiving PC concurrent with surgical care. Serious illness is a broader definition of high-risk patients, defined as “a health condition that carries a high risk of mortality and either negatively impacts a person’s daily function or quality of life or excessively strains their caregivers.”^{8,10} This definition accounts for the burden of symptoms and treatment for serious medical conditions and includes the functional and social impact of illness on the patients and their family. Although there are ongoing efforts to operationalize a serious illness definition among medical populations,^{11–14} these definitions may not be sensitive enough to capture serious illness within the dynamic context of the surgical episode. In particular, the physical resiliency necessary to recover after a health stressor such as surgery is a key characteristic that highlights a need to operationalize a definition for serious illness for surgical populations that is separate from medical populations.¹⁵ For example, healthy patients or those with earlier stages of chronic medical illness may acutely worsen during the perioperative period or after traumatic injury, placing them at high risk of mortality or chronic functional and cognitive impairment. Therefore, a surgical patient may be seriously ill preoperatively due to their underlying health condition or become seriously ill perioperatively due to the physiological impact of the surgical condition or procedure.

A crucial step toward integrating PC with surgical care is to develop a highly sensitive definition of serious illness, one that broadly identifies a population that could benefit from early primary PC during the surgical episode and could be detected in the electronic health

record. We engaged a multidisciplinary expert advisory panel to develop a consensus definition for serious illness among adults in the perioperative setting. Our objective was to define the denominator population to which surgical PC quality indicators should be applied.

Methods

We used the RAND/University of California, Los Angeles Appropriateness Method (RAM), a modified Delphi method, for this study. Although originally developed to reach consensus on the appropriateness of clinical interventions,¹⁶ this method has been modified in other studies and shown to be a reliable and valid method for developing definitions for quality indicator or standards in other settings.^{17–20} The RAM process relies on both evidence-based research and expert panel review to achieve consensus on an issue. We adapted this method to develop a threshold definition of serious illness, one that would be highly sensitive to identify a seriously ill surgical patient preoperatively.

Definitions Development Process

The American Society of Anesthesiologists (ASA) risk score has been used to identify “high-risk” patients. However, the score is a subjective measure that relies on clinical judgment without objective criteria. There is not yet an operationalized definition for which older surgical adults are considered seriously ill. Therefore, we drew from a) existing literature on defining serious medical illnesses,^{11–14} b) PC quality indicators in geriatrics, palliative medicine, and other specialties related to surgery,^{17,21–24} c) guidelines for goals and decisionmaking in geriatric surgery^{20,25,26} and PC guidelines in oncology and trauma,^{6,7,27,28} and d) and a review of the literature regarding the impact of high-risk conditions^{29–66} and health states, such as frailty^{67–76} or nursing home residency,^{77–80} on postoperative outcomes including mortality, morbidity, and functional disability. The preliminary definition included detailed criteria for 11 conditions and health states encompassing serious illness in the perioperative context, independent of the procedural risk (Appendix Table 1).

Expert Advisory Panel

An expert advisory panel comprising 12 experts in surgery, anesthesia, palliative care, geriatrics, health policy, quality improvement, nursing, and patient advocacy was recruited from a geographically broad range of academic and private institutions. Many had extensive experience conducting health services research or developing quality indicators.

Definition Rating Criteria

Consistent with the RAM process, panelists independently rated the preliminary definition for validity and feasibility in two rounds: 1) remotely and 2) during an in-person meeting on a scale of 1–9 for validity and feasibility, where 1 is definitely not valid or feasible and 9 is definitely valid or feasible. Validity was defined as “Adequate scientific evidence or professional consensus exists to support that this definition describes serious illness in the context of patients considering surgery and could be applied to surgical patients.” Feasibility was defined as “Whether hospitals and/or surgeons within a range of practice settings (private or public, academic or nonacademic, urban or rural) could identify a patient with the

definition given reasonable effort.” Panelists reviewed a monograph of the supporting literature for the preliminary definition before returning their first-round ratings electronically. For each of the criteria, we calculated a median score and a measure of agreement for both validity and feasibility. We considered agreement among panel members if three or fewer panelists rated outside the median tertile. A median score of 7 or greater without disagreement was considered to reflect a valid or feasible rating. A median score of 4–6 or evidence of disagreement in the dispersion of ratings was considered to reflect uncertain validity or feasibility. A median score of less than 4 was considered invalid or infeasible.

The second round of ratings took place on April 24, 2019 in Portland, Oregon, with 11 panelists participating in-person and one panelist participating remotely. Individualized summary sheets were distributed to each panelist with their individual rating, median score, and the dispersion of the group. A discussion, led by an independent facilitator with extensive experience in moderating RAM and Delphi panels, focused on areas where there was disagreement and/or uncertainty among panelists. The proposed criteria were then modified based on panel discussion, and panelists subsequently rerated the criteria electronically. Those rated as valid were included in the final serious illness definition. No criteria were excluded based on feasibility.

Results

All 12 panelists completed both rounds of ratings. After the first round of ratings, none of the proposed criteria for the 11 conditions and health states were rated as invalid, two were rated with uncertain validity (vulnerable elder, heart failure), and nine were rated as valid. None of the proposed criteria were considered infeasible, four were rated to have uncertain feasibility, and seven were rated as feasible. After extensive discussion of the supporting evidence, criteria for two of the conditions were modified by panelists during the in-person meeting before the second round of rating (Appendix Table 1). These modifications included the following: a) increasing the age cutoff for vulnerable elder from >74 years to >84 years old to better target the at-risk older surgical population; then b) clarifying the heart failure definition to indicate all-cause hospitalization and changing the time period of hospital use from the last three years to the last six months before surgery to better target symptomatic disease in the time period proximate to the surgical episode.

After rerating, all definitions were rated as valid, 10 (91%) definitions were rated as feasible, and one (9%, ASA Risk) was rated as uncertain feasibility (Appendix Table 2). The final definition of serious illness consisted of the following conditions and health states with specified criteria:

1. ASA Risk score: Class IV or V
2. Vulnerable elder (older adult > 84 years old, older adult > 64 with any functional or cognitive disability)
3. Advanced cancer (Stage III or IV solid cancers and hematologic malignancies) and at least one hospitalization in prior year

4. Oxygen-dependent pulmonary disease
5. Heart failure diagnosis with any all-cause hospitalization or at least two ED visits in past six months
6. Cirrhosis with any Child-Turcotte-Pugh (CTP) Class or Model for End-Stage Liver Disease (MELD) score
7. End-stage renal disease on dialysis or eligible for dialysis
8. Dementia with impaired daily function and at least one hospitalization in prior year
9. Frailty
10. Trauma patients with
 - a. Severe traumatic brain injury (TBI) with Abbreviated Injury Scale (AIS) score of 3 or greater, or Glasgow Coma Scale score of 3–8; or
 - b. Critical injury (Injury Severity Score >25 and/or >24 hours intensive care unit admission)
11. Nursing home residents.

Discussion

Conceptually, a serious illness definition for surgical patients is critical to identify the denominator population for PC quality measurement and improvement efforts, recognizing that one single condition or health state is inadequate to encompass the entire high-risk surgical population who should receive primary PC. In this study, we reached a consensus on a definition of serious illness in the perioperative context and extensively expand on ASA Risk and age, which have traditionally been the predominate markers of serious illness in surgery. We also included severe traumatic injury, a novel addition that is unique to surgical care. A key difference from existing definitions for serious medical illness is that the panel included chronic conditions in earlier stages of advanced disease in the definition of serious illness in surgery. For example, as part of work by Walling et al. to develop PC quality indicators for patients with cirrhosis, an expert panel defined the denominator population as patients with end-stage disease, with either a CTP Class C or MELD 20.¹⁷ However, our panel determined that patients in earlier stages of cirrhosis are also at risk for poor postoperative outcomes and can experience acute decompensation after surgery.^{46,48} Therefore, the panel included patients with a diagnosis of cirrhosis at any stage as seriously ill in the perioperative context. Finally, unlike other serious illness definitions, the panel also included high-risk health states such as frailty and nursing home residency. The definition identified in this study provides the basis for future quality improvement efforts to integrate PC processes for seriously ill surgical patients.

The ability to identify the population who are at the highest risk for mortality or functional disability in the perioperative setting is central to measuring the population-level impact of PC processes on surgical outcomes. Most of the 11 conditions and health states in this definition, such as heart failure and advanced cancer, are easily identifiable from

administrative data sets and the electronic health record. Frailty may be a notable exception because there are multiple scoring instruments that are difficult to standardize. However, panelists agreed that including frailty within the serious illness definition is highly valid and encourages health systems to standardize a method of frailty measurement. Already, there are efforts to include functional impairment in geriatric surgery risk assessment and operationalize a definition of frailty from data sets, such as the ACS National Surgical Quality Improvement Program (NSQIP) and Medicare claims, that will likely increase the feasibility of frailty measurement in the near future.^{81,82} Functional and cognitive impairment are also conditions that are often not concretely defined or consistently included in administrative data. However, the NSQIP Geriatric Surgery Pilot Project showed that collecting such data from the electronic health record is feasible using trained data abstractors.⁸³

Although the intention of this study is to develop a highly sensitive definition to determine whom high-quality surgical PC should be delivered to, a more specific, high-resource utilization group will need to be identified for large-scale quality improvement efforts. Presently, clinical quality improvement programs such as ACS NSQIP have existing data collection structures that can identify the definition's criteria for the 11 conditions and health states from standardized clinical elements in the electronic health record. However, a more specific, operational definition will be needed for large-scale quality measurement. Health systems could use the electronic health record and computer-assisted data abstraction to identify seriously ill surgical patients and examine their outcomes.⁸⁴ A critical next step will be to measure the prevalence of the serious illness definition for surgical patients, then investigate their health trajectories and outcomes using a variety of data sources.

Traditionally, PC delivery has been targeted near end of life and is underutilized by surgical teams in the earlier stages of the surgical episode, thereby depriving the seriously ill surgical patient of the benefits, such as care focused on quality of life. In this study, we identified a definition that can be applied to establish screening criteria for earlier primary PC delivery. Population-based interventions, such as systemic screening criteria for serious illness, can deliver PC early and also improve surgical outcomes.¹ For example, Ernst et al. implemented a systemic frailty risk calculator to trigger preoperative PC consultation before elective surgery for older patients who were the highest risk for mortality.² After implementation of the frailty trigger, the proportion of surgeon-initiated PC consults and the proportion of preoperative versus postoperative consults doubled. Although this study did not examine functional or caregiver outcomes, the relative risk of one-year mortality was reduced by 33%, coinciding with lower rates of patients undergoing surgery (94% pre, 81% post). Like this study, health systems can use screening criteria based on underlying illness to identify surgical patients who should receive early primary PC concurrent with their surgical care.

There are a few limitations to note. First, the overall prevalence and the degree of overlap between the criteria for each of the 11 conditions and health states are presently unknown. Thus, although this definition may be highly sensitive, future study is needed to determine the specificity, mainly whether outcomes and health trajectories are consistent with serious illness in the perioperative context. We did not include pediatric patients in these efforts.

Future study can also include conditions where there was limited evidence to link with poor outcomes in the surgical population, such as neurodegenerative diseases. However, the panel discussed that those patients with significant functional impairment would likely be captured under frailty. Finally, while we included one nurse and one patient advocate, we did not include any patients or caregivers on the panel. Future work to refine this definition could consider including these representatives.

Conclusion

PC delivery is critical to improve the value and quality of surgical care for seriously ill patients. The definition identified in this study, supported by the RAND-UCLA Appropriateness Method, serves as a denominator for quality improvement for seriously ill surgical patients. We highlight opportunities to determine the prevalence of this population, measure health trajectories and outcomes, and develop systemic trigger criteria for surgical PC delivery.

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Appendix

Appendix Table 1

Preliminary and Modified Serious Illness Definitions Presented to the Expert Advisory Panel

Preliminary Definition	Modifications After Expert Advisory Panel In-Person Discussion
ASA Risk: Class IV or V	NC
Vulnerable elder ^{19–22,24,25}	Vulnerable elder
<ul style="list-style-type: none"> • Older adult >74 years old • Older adult >64 with any functional or cognitive disability 	<ul style="list-style-type: none"> • Older adult > 84 years old • Older adult >64 with any functional or cognitive disability
Advanced cancer ^{7,11,13,26}	NC
<ul style="list-style-type: none"> • Stage III and IV solid cancers OR hematologic malignancies • AND at least one hospitalization in prior year 	
Oxygen-dependent pulmonary disease ^{11,13,59–62,84,85}	NC

Preliminary Definition	Modifications After Expert Advisory Panel In-Person Discussion
Heart failure diagnosis with any hospitalization or at least two ED visits in the past three years ^{11,13,43,44}	Heart failure diagnosis with any all-cause hospitalization or at least two ED visits in the past six months
Cirrhosis with any Child-Turcotte-Pugh Class or Model for End-Stage Liver Disease score ^{11,13,45-48,50,86}	NC
End-stage renal disease on dialysis or eligible for dialysis ⁵²⁻⁵⁴	NC
Dementia with impaired daily function and at least one hospitalization in prior year ¹¹	NC
Trauma patients ^{6,27}	NC
<ul style="list-style-type: none"> • Severe traumatic brain injury with Abbreviated Injury Scale of 3 or greater • Critical injury (Injury Severity Score >25 or >24 hours intensive care unit admission) 	
Frailty ⁶⁶⁻⁷⁵	NC
Nursing home resident ⁷⁶⁻⁷⁹	NC

ASA = American Society of Anesthesiology; NC = no change; ED = emergency department.

Appendix Table 2

Validity and Feasibility Ratings of Serious Illness Definitions After Two Rounds of Expert Advisory Panel Rating

Serial Number	Definition	Median Score for Validity ^a	Median Score for Feasibility ^b
1.	ASA Risk: Class IV or V	8.5	6.5
2.	Vulnerable elder <ul style="list-style-type: none"> • Older adult >84 years old • Older adult >64 with any functional or cognitive disability 	8	8
3.	Advanced cancer <ul style="list-style-type: none"> • Stage III and IV solid cancers OR hematologic malignancies • AND at least one hospitalization in prior year 	8	7.5
4.	Oxygen-dependent pulmonary disease	8	8
5.	Heart failure diagnosis with any all-cause hospitalization or at least two ED visits in past six months	8	7
6.	Cirrhosis with any Child-Turcotte-Pugh (CTP) Class or Model for End-Stage Liver Disease (MELD) score	8	7.5
7.	End-stage renal disease on dialysis or eligible for dialysis	9	9
8.	Dementia with impaired daily function and at least one hospitalization in prior year	8	7
9.	Frailty	7.5	7
10.	Trauma patients <ul style="list-style-type: none"> • Severe traumatic brain injury with Abbreviated Injury Scale score of 3 or greater • Critical injury (Injury Severity Score >25 or >24 hours intensive care unit admission) 	8	9
11.	Nursing home resident	8	8.5

ASA = American Society of Anesthesiology; ED = emergency department.

^aValidity was defined as adequate scientific evidence or professional consensus exists to support that a) this definition describes serious illness in the context of patients considering surgery and b) this definition could be applied to surgical patients. Validity was scored on a scale of 1–9, where 1 was definitely not valid and 9 was definitely valid.

^bFeasibility was defined as whether hospitals and/or surgeons within a range of practice settings (private or public, academic or nonacademic, urban or rural) could identify a patient with the definition given reasonable effort. Feasibility was scored on a scale of 1–9, where 1 was definitely not feasible and 9 was definitely feasible.

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