Accounting for Patient Preferences Regarding Life-Sustaining Treatment in Evaluations of Medical Effectiveness and Quality

Allan J. Walkey^{1,2}, Amber E. Barnato^{3,4}, Renda Soylemez Wiener^{1,5}, and Brahmajee K. Nallamothu⁶

¹Division of Pulmonary and Critical Care Medicine, the Pulmonary Center, and ²Evans Center for Implementation and Improvement Sciences, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts; ³Section of Decision Sciences, Division of General Internal Medicine, Department of Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; ⁴Department of Health Care Policy and Management, University of Pittsburgh Graduate School of Public Health, Pittsburgh, Pennsylvania; ⁵Center for Healthcare Organization & Implementation Research, Edith Nourse Rogers Memorial VA Hospital, Bedford, Massachusetts; and ⁶Division of Cardiovascular Medicine and Center for Health Outcomes and Policy, University of Michigan Medical School, Ann Arbor, Michigan

ORCID ID: 0000-0003-4685-6894 (A.J.W.).

Abstract

The importance of understanding patient preferences for life-sustaining treatment is well described for individual clinical decisions; however, its role in evaluations of healthcare outcomes and quality has received little attention. Decisions to limit life-sustaining therapies are strongly associated with high risks for death in ways that are unaccounted for by routine measures of illness severity. However, this essential information is generally unavailable to researchers, with the potential for spurious inferences. This may lead to “confounding by unmeasured patient preferences” (a type of confounding by indication) and has implications for assessments of treatment effectiveness and

healthcare quality, especially in acute and critical care settings in which risk for death and adverse events are high. Through a collection of case studies, we explore the effect of unmeasured patient resuscitation preferences on issues critical for researchers and research consumers to understand. We then propose strategies to more consistently elicit, record, and harmonize documentation of patient preferences that can be used to attenuate confounding by unmeasured patient preferences and provide novel opportunities to improve the patient centeredness of medical care for serious illness.

Keywords: end-of-life care; epidemiologic biases; quality of healthcare

Engaging patients in decision-making is a goal of high-quality, patient-centered medical care, and is especially important in acute care. To enhance patient autonomy to guide healthcare decisions, clinicians are encouraged to elicit and document patients' preferences for life-sustaining treatments early in the course of hospitalization. The most commonly documented limitations of life-sustaining treatments include “do not resuscitate” (DNR) or “do not intubate”

orders. Although the importance of eliciting and documenting patient preferences to guide individual clinical care decisions is well described, the effect variation in patient preferences may exert on evaluations of medical care outcomes and quality has received little attention.

Decisions to limit life-sustaining treatment are strongly associated with a high risk for death (1–4). Mechanistically, patient preferences for treatment limitations can

be conceptualized as both predictors of mortality risk and effectors of mortality risk. Older patients and patients with preexisting serious illness who are more likely to die with an acute illness are more likely to have treatment limitations (2–4). In addition, patients with treatment limitations are less likely to receive a treatment that might stave off death during an acute illness (1). Thus, it is unsurprising that the presence of a DNR order was the strongest

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Correspondence and requests for reprints should be addressed to Allan J. Walkey, M.D., M.Sc., Boston University School of Medicine, 72 East Concord Street, R-304, Boston, MA 02118. E-mail: alwalkey@bu.edu

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contributor to mortality prediction (more important than comorbidities, age, and physiology-based severity of illness scores; i.e., Simplified Acute Physiology Score II) in a study designed to predict 6-month mortality rates among intensive care unit survivors (4). Yet, we routinely disregard information on patient preferences for life-sustaining treatments in assessments of treatment effectiveness, healthcare quality, and reimbursement. In this article, we present case studies from observational studies and randomized trials in critical care to highlight the important issue of bias and “confounding by unmeasured patient preferences” (a type of confounding by indication). In addition, we explore strategies to incorporate patient preferences into evaluations of care delivery and quality.

Influence of Patient Preferences on Research Findings

Although there are many potential threats to the validity of observational research, unmeasured confounding by patient preferences is a particularly serious threat. For example, in the case of activated protein C (APC) for sepsis, multiple observational studies suggested APC reduced mortality (5). Reanalysis of the data accounting for patient DNR status showed that patients with preexisting limits on resuscitation were less than half as likely to receive APC and approximately twice as likely to die during sepsis, demonstrating the potential for strong confounding by unmeasured patient preferences when assessing treatment effectiveness (3). After accounting for patient DNR status at admission, APC had a null effect on mortality (3), a conclusion that aligned with subsequent randomized trials that led to withdrawal of APC from the market.

Studies of organizational approaches may also be affected by variation in processes for eliciting and recording patient preferences. In the case of nighttime intensivist staffing models, observational studies reported inconsistent relationships between nighttime intensivists and risk-adjusted mortality (6–9), and a single-center randomized controlled trial found similar outcomes regardless of nighttime intensive care unit staffing (10). Analyses using databases with information regarding patient preferences for life support found that nighttime intensivist staffing, compared

with no nighttime physician, may paradoxically increase mortality risks by increasing the likelihood of (11) and reducing the time until (12) initiation of treatment limitations based on patient preferences. Thus, measurement of patient preferences for life-sustaining treatment can improve our understanding of etiological pathways in studies of interventions (such as nighttime intensivist staffing) that differentially elicit and act on patient preferences for treatment limitation. Measurement of preferences for life-sustaining treatments in research is therefore important to better account for confounding, as well as to understand potential mediators of study outcomes.

Patient preferences also have an important role to play in randomized clinical trials. Because increased risk for death from prior comorbidities and choices to limit life-sustaining treatment are unlikely to be modifiable by treatments under study, inclusion of patients with limitations on life-sustaining treatments in randomized trials is likely to bias results to the null. For this reason, most randomized trials exclude patients with existing treatment limitations. However, rates of trial exclusion for life-sustaining treatment preferences vary, and trials of early goal-directed therapy for septic shock suggest substantial differences by geographic regions, with rates of exclusion for preexisting treatments limits ranging from 33% in the U.S.-based PROCESS (Protocolized Care for Early Septic Shock) trial to 43% in the U.K.-based ProMiSe (Protocolised Management in Sepsis) trial (13, 14). Large differences in the rate of eliciting preferences for treatment limitations before trial enrollment across centers or geographic regions may result in different likelihoods that a particular trial may be biased toward the null by latent preferences that are elicited only after trial enrollment.

Lack of blinding may also increase the likelihood of bias by latent preferences to limit life-sustaining treatments in randomized trials. Despite exclusion criteria for prior limitations on treatment, nearly 30% of ARDSNet (Acute Respiratory Distress Syndrome Network) trial participants transitioned to DNR status after randomization, with 97% mortality rates among participants with postenrollment DNR orders (15). Expectation bias from lack of blinding could theoretically result in differential practices for eliciting patient preferences for life-sustaining treatment

in trials of critical illness. Anticipating this concern, the Targeted Temperature Management trial for post-cardiac arrest coma used blinded prognostic assessments and standard protocols for initiating conversations about withdrawing life-sustaining treatment to avoid confounding by “self-fulfilling prophecies” in differential recommendations to withdraw life support in the control arm (16).

Influence of Patient Preferences in Evaluations of Hospital Quality

Growing advocacy for preference-sensitive healthcare recognizes that quality care extends well beyond providing efficacious treatments (17–19). Rather, high-quality medicine applies scientific knowledge in the context of patient values (20, 21). For example, patients with advanced chronic illness may choose to forgo invasive mechanical ventilation that may improve short-term mortality (22), but that conflicts with their values and goals for comfort, communication, or autonomy at the end of life. However, the recent proliferation of measures that seek to reward efficacious care may simultaneously create incentives for care that ignores patient values. A straightforward example of potential conflicts between preference-sensitive healthcare and hospital quality measures is provided by the 30-day surgical mortality quality measure (23). Although some patients with poor prognosis have not yet recovered by 29 days postoperatively may wish to withdraw life support, hospitals have a perverse incentive to continue full support until day 31 to avoid adversely affecting quality metrics.

Similarly, hospitals that treat many patients with preexisting DNR orders may have high mortality rates, which are the basis for publicly reported quality rankings that determine reimbursement (2, 24). In a study of patients with pneumonia, hospitals with higher DNR rates tended to have better patient satisfaction ratings and performance on quality process measures compared with hospitals with low DNR rates (2). However, the hospitals with higher DNR rates were more likely to be characterized as low-quality outliers in mortality measures. Leaving resuscitation preferences unaccounted for in the evaluation of healthcare delivery carries the risk of penalizing hospitals that appear to

provide high-quality, patient-centered care (2). This penalty may not simply accrue to hospitals located in communities in which patients happen to have less intensive treatment preferences; it may accrue to hospitals with proactive, skilled physicians who are better at eliciting, documenting, and adhering to patient's values.

Strategies to Incorporate Patient Preferences into Effectiveness Research and Quality Measurement

With few exceptions, patient preferences for life-sustaining treatment are often unavailable or unreliably recorded in most routine claims data or electronic health records. Variation in consistency and quality of processes to elicit and to map patient values onto categories of treatment limitation represents a key challenge to the use of patient resuscitation preferences in the evaluation of healthcare quality. Behavioral and decision science suggest that many personal preferences are constructed, rather than uncovered, in the context of making specific decisions (25). Thus, eliciting patient preferences is not as simple as a "biopsy" of patient-wishes, but rather involves iterative, bidirectional exchange of information that often shapes uncertain, incomplete, or inconsistent patient values into actionable categories of preferences for life-sustaining treatments. Although the goal of consistently and comprehensively eliciting, documenting, retrieving, and adhering to patient preferences for life-sustaining treatment, and then accounting for these preferences in quality assessment, is lofty and highly complex, we nevertheless propose some potentially actionable recommendations for each of these steps (Figure 1).

Eliciting Preferences

Multiple barriers need to be overcome to improve on low rates of advance care planning. For example, clinicians describe lack of time, training, and tools for prioritizing patients in whom advance care planning may be most urgent (26–29). Decision aids and tools designed to increase advance care planning produce modest improvements (e.g., 10–15% increase) in rates of advance care plan completion, highlighting challenges in routinely eliciting

Figure 1. Strategies to facilitate incorporation of patient treatment preferences into evaluation of healthcare outcomes. *Blue:* Processes to better incorporate patient preferences into healthcare evaluation. *Green:* Examples of strategies to improve relevant process.

patient preferences for life-sustaining treatments (30–33). Although recent reimbursement of advance care planning conversations by the Centers of Medicare & Medicaid Services (CMS) potentially addresses time constraints often cited by physicians, early surveys suggest that only 14% of physicians have billed CMS for advance care planning (29). Thus, further tools are likely necessary to improve rates and quality of advance care plans. For example, automated risk scores (34) calculated from the electronic health record may be used to overcome the barriers to more pressing advance care planning discussions of identifying patients at risk for requiring life-sustaining treatments and triage patients. Once patients at high risk for death or for requiring organ support are identified, high-quality discussions of advance care plans with clinicians could be expedited, potentially through programs, such as the Respecting Choices model, that use evidence-based strategies to facilitate advance care planning conversations and standardize documentation (35, 36).

Documenting Preferences

Once preferences are elicited, they must be documented in a standardized and

accessible manner. Poor documentation (37) and accessibility of advance care planning discussions has led several U.S. states and the Veterans Health Administration (38) to implement programs to improve the documentation of patient preferences. For example, Oregon and California have enacted centralized state registries of Physician Orders for Life Sustaining Treatments (39). In addition, Ohio standardized documentation of patient preferences at hospital admission by further specifying the scope of preferred for life-supportive therapies as “comfort care only” and “eligible to receive aggressive interventions short of CPR or mechanical ventilation,” resulting in better adherence to patient goals (40). Similar efforts to standardize and specify documentation of resuscitation preferences in the Kaiser Permanente healthcare system paired implementation of the Respecting Choices program with mandatory entry of 1 of 4 advance directive options in hospital admission orders (full code, partial code, DNR, and comfort care only; personal communication, Vincent X. Liu, MD, and Gabriel Escobar, MD). Increased specificity and standardization of documenting patient preferences at Kaiser Permanente has led to improved data quality for the conduct of research on advance care planning (41) and has been used to improve the validity of

internal hospital benchmarking models (42). Strategies to increase the specificity of preferences to withhold life-sustaining treatments by delineating comfort care only from limits on resuscitation represent a feasible starting point for more widespread standardization of preference documentation.

Retrieving Preferences

Although regional efforts to enact systems that improve documentation of patient resuscitation preferences may serve as encouraging case examples, coordinated and widespread efforts are required to allow for preference-sensitive healthcare evaluation. Critical next steps include improved systems to retrieve patient preferences, including a centralized, standardized, editable, and readily accessible repository accessible for clinical care and linkable to research databases. Although private companies currently run repositories of patient preferences for clinical use (e.g., <http://www.uslivingwillregistry.com/>), these are not widely used, and few options exist to access documentation of patient preferences for research and benchmarking purposes. Using states such as Oregon and California as examples, CMS represents a logical site for further centralization of a repository of patient preferences for life-sustaining treatments. Working with systems such as Patient Orders for Life Sustaining Treatments, CMS could standardize documentation of patient preferences and provide a resource for patients, clinicians, and researchers alike. With appropriate safeguards for the privacy of identifiable healthcare data already in place for the wealth of healthcare information already available from CMS, a centralized repository of patient preferences could then be linked to CMS and other databases used to evaluate treatment effectiveness and healthcare quality. Nationally standardized processes for the documentation of patient preferences would thus potentially allow for improved individual patient autonomy, increased validity of effectiveness research, and development of preference-sensitive measures (22) of the quality of healthcare delivery.

Adhering to Preferences

The potential for labile preferences presents additional challenges to preference documentation. Lability in decision-making

may suggest that documented advance directives inaccurately convey future patient preferences (43–45). However, preferences to avoid CPR or other life-sustaining treatments are relatively stable: approximately 90% of patients maintain preferences to avoid CPR (46, 47). Rather, changes to preferences are more likely to occur among patients who previously chose no treatment limitations (47). Further, stability of preferences increases with prior advance directive discussions with a physician (48). Thus, documented preferences for life-sustaining treatments are not inviolable, requiring systems that document preferences to allow modifications and edits to patient preferences. Although accurate and up-to-date preferences are obviously ideal, for the purposes of research, it is likely that prior orders to withhold life-sustaining treatment contain unmeasured information regarding patient prognosis that may effectively reduce unmeasured confounding.

Accounting for Preferences

Multiple opportunities exist to better account for patient preferences for life-

sustaining treatments in clinical research. Randomized trials, especially nonblinded efficacy studies in critical illness, could standardize the reporting of patient preferences for life-sustaining treatments and the processes for eliciting patient preferences during pre- and postrandomization periods. Trials should also seek to minimize the effect of hospital-level variation in eliciting patient preferences for life-sustaining treatments in design choices (i.e., preferential use of individual patient randomization stratified by center, or use of cluster crossover rather than parallel cluster design) and analytic stages (accounting for correlated practice in models). Observational studies may seek to exclude patients with baseline treatment-limiting advance directives (mirroring most trial exclusion criteria) or include baseline preferences for treatment limitation in risk-adjustment strategies. Similar to randomized trials, changes in patient preferences for life-sustaining treatments during the course of observational studies should be described, but not included in risk adjustment, to evaluate potential mediators of outcome. Similarly, wide variation in rates of preferences for treatment limitations across hospitals

Figure 2. Example strategy for documenting and incorporating patient preferences into hospital quality measures for sepsis. More granular preference category documentation may improve preference adherence and risk adjustment. Patients may move between quality measures based on preference reassessment and be included in different quality measures based on initial preference and final preference. For example, patients admitted with no limitations would be included in traditional process and outcome measures; patients who change preferences to comfort care after admission preference assessments could also be included in palliative-based quality measures. *Dark gray boxes:* Examples of standardized preference documentation. *White boxes:* Examples of process and outcome measures. CPR = cardiopulmonary resuscitation.

warrants methods to account for correlated practices (i.e., hospital random effects), as well as methods that attenuate between-hospital differences in mortality rates associated with preferences for treatment limitation (i.e., random slopes models) in risk adjustment (2). In situations during which patient preferences for life-sustaining treatments are unavailable or unreliable, investigators can include analyses that estimate the effects of a strong unmeasured confounder (49) (e.g., limits on life-sustaining treatments are associated with odds ratios of 3 for mortality and 0.5 for receipt of treatments of interest) (3) or exclude groups with a high prevalence of treatment limitations (e.g., elderly patients with metastatic cancer) in sensitivity analyses (50). Further investigations of methods to optimally account for patient preferences for life-sustaining treatments in trials and observational studies may improve the validity of future clinical research.

How might preference-sensitive measures of healthcare delivery and quality work? In the simplest form, patients who have elected to limit life-sustaining treatment may be excluded from traditional outcome or process measures of healthcare quality such as mortality or readmissions. For example, the CMS measures of quality

of severe sepsis and septic shock processes of care take into account the potential for variation in patient preferences by excluding patients with “directives for comfort care.” However, incentives to inappropriately remove patients at increased risk for poor outcomes from the analytic pool by “pushing” limits on life-sustaining treatments or comfort care would need to be counteracted by incentives to appropriately elicit and follow patient preferences. The “right” quality measures should create incentives for effective and patient-centered care without high risks for gaming and unintended consequences. Strategies to reduce gaming of quality measures that exclude patients with treatment limitations could shift these patients into a different “pool” that measures the quality of end-of-life care. For example, patients excluded from sepsis measures based on pursuit of comfort-directed care could be evaluated for achievement of documented end-of-life goals (e.g., effective palliative care), as well as family and surrogate decision-maker satisfaction and mental health outcomes. Patients who choose not to receive CPR or mechanical ventilation, but who otherwise would agree to treatment with antibiotics and vasopressors, may be included in process-based measures, as well as in

preference-adjusted outcome measures. In such a system, measures would better match patient preferences, would be less at risk for gaming, and would create incentives for high-quality end-of-life treatment (Figure 2).

In short, discussions of patient preferences are a necessary, but insufficient, steps toward improving healthcare delivery. Programs that better elicit, record, and harmonize documentation of patient preferences across healthcare systems can improve the processes of care and outcomes for seriously ill patients, as well as allow researchers and policy-makers to attenuate confounding by unmeasured patient preferences in research and quality assessments. Continued expansion of programs that measure quality and outcomes into increasingly broad areas of consequence to the healthcare system should be met with equal efforts to improve the quality of our measurement tools by incorporating patient preferences. ■

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