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Discussion of treatment trials in intensive care☆,☆☆

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Abstract

Purpose: This study aimed to characterize whether and how the option of a treatment trial is discussed with surrogates in intensive care units.

Materials and Methods: We audio-recorded 72 family conferences for 72 patients at high risk for death or severe functional impairment in 5 intensive care units in San Francisco, California. We analyzed transcripts to develop a coding framework for whether and how trials were discussed.

Results: Trials were offered in 15% of conferences. We identified 2 types: (1) *time-limited trials*, defined as continuing all intensive, life-sustaining treatments, with a plan to reassess after a defined time period based on prespecified clinical milestones, and (2) *symptom-limited trials*, defined as using basic medical care aimed at survival (rather than purely comfort–focused treatment) once ventilatory support is withdrawn, with a plan to reassess based on patient symptoms. Clinicians frequently did not inform surrogates about key elements of the trial such as criteria by which the effectiveness of the trial would be evaluated and possible next steps based on trial results.

Conclusions: In this cohort of critically ill patients, trials were infrequently and incompletely discussed. Additional work is needed to improve communication about treatment trials and evaluate their impact on patient and family outcomes.

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1. Introduction

Decisions about treatment for critically ill patients in the intensive care unit (ICU) are complex and value laden. Family members most often act as surrogate decision makers because the patient is too ill to participate. Surrogates make choices about whether to continue life-sustaining treatment or transition to comfort care based on a consideration of their loved ones' values [1]. However, many patients have 2 desires in tension: to be alive with an acceptable quality of life and to not undergo prolonged invasive treatment if the chances of achieving that goal are small [2]. In the face of prognostic uncertainty, it can be difficult for clinicians and families to develop a treatment plan that reflects patients' values and preferences [3,4]. Many surrogates feel emotionally overwhelmed by decision making and need time to process their loved ones' values and prepare for the possibility of death or significant disability [3,5].

Efforts to improve surrogate decision making in the ICU, including proactive family conferences to discuss treatment options and goals of care, are widely endorsed by national and international critical care societies [6–8]. More recently, observations of the difficulty of making high stakes, value-laden decisions have led to the suggestion that physicians offer a third option in addition to continued intensive care or care focused solely on patient comfort: a treatment trial with clearly defined criteria for success or failure based on a consideration of the patient's goals and a plan for reassessment [9,10]. Treatment trials have been proposed as an approach to care for critically ill patients that may help to ensure that decisions reflect patients' values, decrease the burdens of surrogate decision making, achieve consensus about the best course of care, and decrease the use of unwanted interventions before death [4,9–13].

However, to date, the extent to which treatment trials are discussed or how they are presented in actual practice is not known. We therefore sought to characterize the frequency and types of trials offered by physicians in ICU family meetings about treatment decisions for critically ill patients.

2. Materials and methods

2.1. Study design, patients, and setting

We conducted this analysis as part of a larger, mixed methods cohort study of audio-recorded family conferences conducted in 5 ICUs at 2 hospitals in San Francisco, California, between January 2006 and August 2008. One hospital is an academic tertiary care center; the other is an academic county hospital serving a diverse indigent population. The overall purpose of the parent study was to understand how physicians and surrogates communicate about life support decisions. Two prior reports have focused on different aspects of physician-surrogate communication: how responsibility for decisions is balanced between physicians and surrogates [14] and the association between physician beliefs and whether families are informed about the option of comfort care [15]. No prior report has examined how physicians present treatment trials.

We identified ICU physician-family conferences that concerned a patient 18 years or older and were conducted in English through daily contact (Monday-Friday) with ICU charge nurses. To identify conferences about life-sustaining treatment decisions, we asked the attending physician if they anticipated that there would be discussion of withholding or withdrawing treatment or bad news. We excluded conferences in which the physician stated that these issues would not be discussed. For the purposes of this analysis, we further excluded conferences that ultimately included only a medical update without any discussion about treatment plans.

We obtained informed consent before audio-recording from all conference participants. Institutional review boards at each hospital approved all study procedures.

2.2. Coding and analysis

A medical transcriptionist transcribed the conference audio-recordings verbatim. Three investigators (Y.S., D.B.W., and G.T.) developed a codebook to capture physicians' discussion of treatment trials. Based on an initial review of all transcripts, we defined a trial as a course of treatment framed as an *effort* or an *attempt* with a prespecified plan for reevaluating the appropriateness of this course of treatment based on certain criteria. We excluded discussions of foregoing certain treatments (eg, not starting hemodialysis) without a plan for reevaluation. We also excluded examples in which the physician suggested the need for continued assessment and discussions (such as "I hope we can meet with everyone again" or "I would continue to treat him and see how things go") if there was no mention of *specific* criteria based on symptoms or clinical endpoints over a defined period that would trigger reevaluation.

Within each encounter that included discussion of a trial, we used the analytic technique of qualitative description with constant comparative techniques to inductively develop a framework categorizing (1) the type of trial and (2) discussed advantages and disadvantages of the trial. Qualitative description is a method used to provide an accurate and descriptive summary of qualitative data with interpretive validity [16]. We additionally assessed whether and how 3 key, previously described components of a trial were presented [9]: an explanation of clinical milestones to evaluate the outcomes of the trial, a suggested time frame for reevaluation, and a description of potential actions at the end of the trial.

To account for the possibility that a trial may have been discussed in prior conferences, we also developed a code to apply to statements referencing a previous discussion of a trial. We applied this code more broadly to statements by either the clinicians or family members referencing prior discussion about a treatment decision with a plan for reevaluation.