Published in final edited form as:
J Crit Care. 2013 October ; 28(5): 862–869. doi:10.1016/j.jcrc.2013.04.015.

Discussion of Treatment Trials in Intensive Care

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Abstract

Purpose—To characterize whether and how the option of a treatment trial is discussed with surrogates in ICUs.

Materials and Methods—We audio-recorded 72 family conferences for patients at high risk of death or severe functional impairment in 5 ICUs 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 two 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 pre-specified 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using basic medical care aimed at survival (rather than purely comfort-focused treatment) once ventilatory support is withdrawn, with a plan to reassess based on patient symptoms.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.

Keywords

intensive care; decision making; communication; withholding treatment; terminal care; palliative care

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Conflicts of Interest: The authors have no conflicts of interest to declare.

Data was collected at the University of California, San Francisco. Data was analyzed at the University of Pittsburgh.

Introduction

Decisions about treatment for critically-ill patients in the 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 two 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 it is not known the extent to which treatment trials are discussed or how they are presented in actual practice. 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.

Materials and Methods

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 two 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 prior to audio-recording from all conference participants. Institutional Review Boards at each hospital approved all study procedures.

Coding and analysis

A medical transcriptionist transcribed the conference audio-recordings verbatim. Three investigators (YS, DBW and GT) 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 pre-specified plan for reevaluating the appropriateness of this course of treatment based on certain criteria. We excluded discussions of foregoing certain treatments (for example, 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 of time 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 three key, previously-described components of a trial were presented [9]: an explanation of clinical milestones to evaluate the outcomes of the trial, a suggested timeframe for re-evaluation, 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.

The primary coder (GT) applied the final coding framework to all transcripts after extensive training with two other members of the study team (YS and DBW). Inter-rater reliability was assessed on a random sample of 63 quotes describing treatment options taken from 58% (42 of 72) conferences. The kappa statistics for our main results, presentation of a time-limited trial or symptom-limited trial, were 1.0 and 0.85 respectively. A kappa > 0.8 is considered excellent inter-rater reliability. [17]

We used Atlas.ti software, version 5.7.1 (Berlin, Germany) for management of qualitative data.

Assessment of demographics and conference characteristics

Surrogates and physicians completed demographic questionnaires. We abstracted patient demographic and clinical characteristics from the medical record on the day of the conference.

Results

We audio-recorded 70% (74 of the 105) eligible conferences identified. The physician refused to allow researchers to approach the family for 5 of 105 eligible conferences, and the family declined to participate after learning about the study for 26 of 105 eligible conferences. Two audio-recorded conferences were excluded from this analysis because they did not include any discussion of treatment plans, leaving a total of 72 conferences.

Audio-recorded conferences occurred an average of 10 (median 6, range 0 to 78) days after ICU admission. The average ICU length of stay was 23 days (median 12, range 1-366). The most common admission diagnoses were neurologic failure (38%) and cardiac failure or shock (29%). The inpatient mortality rate was 72%. Fifty-four different physicians led the 72 conferences (41 physicians conducted a single conference, 10 conducted 2 conferences, 2 conducted 3 conferences, and 1 conducted 5 conferences). Sixty-seven percent of the physicians leading the conferences were attending physicians; 33% were residents or fellows. The average conference length was 35 minutes (range 10 to 105 minutes). Table 1 shows characteristics of physicians leading the conferences. Additional characteristics of participating surrogates and patients are shown in the appendix.

Frequency and types of treatment trials

Trials were presented to surrogates as an option in 11 of 72 conferences (15%; 95% CI, 7%-24%). We identified two types of trials that physicians offered to surrogates: time-limited trials, defined as continuing all intensive, life-sustaining treatments with a plan to reassess the appropriateness of this treatment and the goals of care after a defined period of time based on pre-specified clinical milestones; and 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 the appropriateness of this treatment and the goals of care based on patient symptoms. An example of a time-limited trial is a plan to continue aggressive ICU care for a patient with sepsis for an additional four days, at which point the physician and family will meet again to reassess the appropriateness of this treatment and the goals of care based on the patient's blood pressure and need for ventilator support. An example of a symptom-limited trial is a plan to continue basic medical care such as antibiotics and frequent suctioning for a patient with a severe stroke once ventilator support is withdrawn, with the hope that the patient could survive but the plan to transition to a purely comfort-oriented approach if the patient develops progressive dyspnea. We present additional examples and representative quotes for each type of trial in Table 2.

Physicians offered a time-limited trial in 9 of 72 conferences (13%; 95% CI, 5%-20%) and a symptom-limited trial in 3 of 72 conferences (4%; 95% CI, 0%-9%). One conference included discussion of both a time-limited and a symptom-limited trial. In 2 conferences, discussion about a time-limited trial was initiated by family members; in the remainder, discussion of a trial was initiated by the physician. In all 9 conferences in which the option of a time-limited trial was presented, it was agreed to by the family. In the 3 conferences that included discussion of a symptom-limited trial, this option was pursued in 1 conference, declined in favor of pursuing a time-limited trial of intensive care in a second conference, and deferred to allow the family more time to consider the options in a third conference. Three additional conferences included references to prior discussions about treatment trials.

Components of Time-Limited Trials

Physicians discussed clinical milestones related to signs of improvement in specific organ function in 8 of 9 conferences in which time-limited trials were discussed, though little information was given about what would count as improvement or how these milestones would be interpreted to evaluate whether a trial was successful. For example, one doctor described looking for "objective evidence that her kidneys are getting better, the liver's getting better, within the next 12/24 hours." Another physician noted that "there's definitely the potential for his kidneys to reverse and to get better and for his heart to get better." Other organ-specific milestones mentioned by physicians included improved blood pressure, improved neurologic function, and needing less support from the ventilator. In 1 of 9 conferences the physician mentioned only the possibility of "discovering something

treatable" without referencing signs of organ-specific improvement (see Table 3) The suggested timeframe for reevaluation ranged from a few days to a week; one physician suggested a two-week trial.

Discussion of potential actions at the end of a time-limited trial was generally incomplete. In no conference did clinicians discuss both the possible treatment pathway if the trial was successful and if it was unsuccessful. Seven of 9 conferences included discussion of the treatment pathway only if the trial was unsuccessful, focused on transitioning to comfort-oriented care. For example, one physician said, you know, let's say we're on maximal support and there really is no getting outta this, you know, you could always go to the … we could make the transition to the palliative care floor …And have things go faster." One of 9 conferences included discussion of next step if the trial *did* go well, mentioning the possibility that the patient might improve to the point where he could transition to a lower level of care. One of 9 conferences did not include any discussion of next steps, with the physician saying only, "if there's no recovery on Monday, then we can change plans."

Advantages and Disadvantages of Time-Limited Trials

Advantages of time-limited trials discussed by physicians included that the patient may recover (3 of 9 conferences); that the trial may benefit the family (for example, by allowing time to be with the patient, 3 of 9 conferences); and that the trial may be in accordance with the patient's wishes (1 of 9 conferences). Discussed disadvantages were that the patient may be uncomfortable during the trial (3 of 9 conferences) and that the patient may not recover (1 of 9 conferences). Representative quotes are included in Table 4.

Components of Symptom-Limited Trials

While criteria for reevaluating a symptom-limited trial could be based on *any* important symptom, discussion of symptom-limited trials in these conferences all focused on clinical milestones related to respiratory status. A time frame when symptoms might be expected was mentioned in 1 of 3 conferences. This physician said, "and so it could be that he comes off the breathing machine quite well and has quite a bit of time, meaning days to weeks, we just don't know. Or, it could be that he comes … right when he comes off the machine, he goes into what you're describing, where he has trouble breathing. And then we have to immediately take action to make sure he's comfortable, which we can do and will do." Multiple potential actions at the end of the trial were discussed in 1 of 3 conferences (giving morphine in the ICU if the patient did not do well or transitioning to a lower level of care if the patient did do well). In 2 of 3 conferences, discussion of next steps included only transitioning to comfort care if the patient did not do well. For example, one physician said "if she aspirates, then we would probably focus, go more down that path that I introduced before, which was on comfort, if she sorta declares herself in not doing so well."

Advantages and Disadvantages of Symptom-Limited Trials

The advantages of symptom-limited trials discussed were that the patient may live longer (2 of 3 conferences); be more comfortable (1 of 3 conferences); that the trial may be in accordance with the patient's wishes (2 of 3 conferences); and that the trial may benefit the family (2 of 3 conferences). The disadvantage discussed in all conferences was that the patient may do poorly and not recover (see Table 4).

Discussion

To our knowledge, this is the first study to examine whether and how physicians discuss treatment trials with the families of critically ill patients. We identified two types of treatment trials: time-limited trials and symptom-limited trials. Physicians offered both trial

types infrequently, and when they did, often did not address key elements of treatment trials, such as specific criteria by which the effectiveness of the trial would be evaluated, possible next steps based on the results of the trial, and the advantages and disadvantages of a treatment trial.

Two prior studies in ICUs have examined the effects of a physician-family communication strategy which included discussion of time-limited trials. In a before-and-after study conducted in a single medical ICU, this strategy was associated with a shorter duration of critical care use before death and was not associated with increased mortality. [10] However, in a follow-up effectiveness trial conducted in 5 medical, surgical and neurologic ICUs, a similar strategy was *not* associated with a reduction in critical care use. [11] It is important to note that in this study clinicians did not receive intensive training in how to explain trials to surrogates, and therefore it is uncertain whether and how trials were offered. These findings suggest that proactive communication about treatment trials holds promise as an intervention to decrease use of unwanted intensive care before death, but that additional work is needed to ensure that clinicians have adequate communication skills. Our findings add to this work and identify potential targets for intervention. Increasing familiarity with the concept of a trial and providing specific communication training for physicians may be important steps to improve use of treatment trials as a “third option” – in addition to continued intensive care or purely comfort-oriented care - in discussions about goals of care.

Why might presenting treatment trials as an option in addition to intensive care and comfort-oriented care be beneficial? Offering the option of a treatment trial may help by 1) re-framing decisions as dependent on *outcomes*, thereby alleviating some of the burden experienced by families asked to choose a treatment course in the face of clinical uncertainty [4]; 2) creating signposts that may help families to process the ICU experience and formulate realistic expectations; 3) forecasting a poor prognosis, thereby giving families time to emotionally prepare and/or come together before the death of a loved one [18]; 4) allowing families to feel that everything was done before a possible decision is made to withdraw life-sustaining treatment; 5) offering a “third option” that may help to resolve disagreements among family members or between family and clinicians about appropriate treatment goals [19, 20]; and 6) ensuring a plan for subsequent discussion.

It is also possible that offering a treatment trial may be problematic, particularly when discussion of key elements is incomplete. For example, failure to fully describe clinical milestones may lead to conflict at the end of a trial about whether it was successful. Incomplete discussion of possible next steps may lead to lack of preparedness, worsened emotional burden and/or a lack of trust among families if expected outcomes do not happen.

What may explain the relatively low use of trials in the current study? Physicians may choose *not* to discuss treatment trials because they do not feel comfortable describing key elements of a trial with families or because they perceive a trial as holding up necessary decisions. Alternatively, physicians may simply lack familiarity with trials, as these options have received relatively recent attention as alternatives to unlimited intensive care or comfort care near the end of life. In our study, we found no evidence that family members were upset by the notion of a trial, and a minority of families suggested a trial themselves as a possible option. However, additional work is needed to directly measure how treatment trials are viewed by surrogate decision makers and how they impact patient care and family wellbeing.

Efforts to systematically evaluate treatment trials in the ICU should include randomized evaluation of communication interventions in which the option of a trial is presented using clear and consistent language. Our group is currently in the midst of this work. In addition,

more research is needed to describe the optimal ICU population to whom treatment trials should be offered and the optimal timing and frequency of these discussions.

Our study had several limitations. We audio-recorded conferences at two hospitals in San Francisco; discussions of treatment trials may be influenced by local culture and therefore differ among physicians at other sites. In addition, we audio-recorded a single conference per patient, and it is possible that treatment trials were discussed in other meetings with the same family group. However, we coded for reference to a prior discussion of a treatment trial and found only three additional conferences in which a prior trial was mentioned. Some physicians led more than one conference, which may have influenced our results if a physician's communication style was replicated in conferences with different families. Finally, the majority of participating physicians were trained in medicine or medical subspecialties; it is possible that discussions of treatment trials may differ among clinicians with other backgrounds.

Conclusions

In summary, we present a framework describing two types of treatment trials that may be offered to families of patients with a poor prognosis in the ICU. In this study, such trials were infrequently and incompletely discussed as an alternative to full intensive care or comfort care. Additional work is needed to teach intensivists about the key components of treatment trials and how to talk about them, assess how the option of a trial is perceived by surrogates, and evaluate how treatment trials affect patient and family outcomes.

Acknowledgments

Sources of Funding Dr. Schenker is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number KL2TR000146. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Dr. White is supported by a Greenwall Foundation Faculty Scholars Award and a Paul Beeson Award in Aging Research from the National Institutes of Health (AG032875) and the National Heart, Lung, and Blood Institute (R01HL094553).

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Table 1

Demographic Characteristics of 54 Physicians Leading Family Conferences

	N (%) or Mean (SD)
Gender	
Male	32 (59)
Female	22 (41)
Race/Ethnicity	
Non-Hispanic white	38 (68)
Non-Hispanic black	0 (0)
Hispanic	2 (4)
Asian/Pacific Islander	15 (27)
Native American	0 (0)
Other/undocumented	1 (2)
Age, yr, mean ± SD	37 ±9
Staff position	
Attending physician	36 (67)
Resident or fellow	18 (33)
Medical specialty	
Internal medicine	29 (54)
Neurology	8 (15)
Surgery	3 (6)
Medicine Subspecialty	
Cardiology	4 (7)
Oncology	4 (7)
Hepatology	4 (7)
Pulmonology	1 (2)
Palliative Care	1 (2)
Years in practice	7 (9)

Table 2

Types of treatment trials presented by physicians in ICU family conferences

Time-limited Trial	
Description	The option of continuing all intensive, life-sustaining treatments, with a plan to reassess the appropriateness of this treatment and the goals of care after a defined period of time based on pre-specified clinical milestones.
Example	An elderly patient with chronic lung disease has acute respiratory failure. The physician offers a plan to continue aggressive ICU care for four days to assess whether there will be an improvement in lung function, with a suggestion to reconsider goals if there is no clinical improvement.
Representative quotes	*That's … that would be my recommendation … is that we do what's called a time-limited trial, where we say you know, "We're gonna do everything we can, for the next 48 hours" and, if she's not getting better, that means she's getting worse… And at that point, we should probably withdraw the ventilator and let her die.* *Another option to kinda go from here, is to just say, you know, "We think he's doing ok. We really want him to get better, but we are also not sure which direction it's going and we want to wait and talk again in two weeks …" or pick a certain amount of time and we just call that like a time-limited trial and we see how he does over the next few weeks and we sit down again and say, "Boy it looks like things are going better …" Or, we say, "things are the same or getting worse and maybe we need to talk about different goals."*
Symptom-limited Trial	
Description	The option of using basic medical care aimed at survival (rather than purely comfort-oriented treatment) once ventilatory support is withdrawn, with a plan to reassess the appropriateness of this treatment and the goals of care based on patient symptoms.
Example	A patient with metastatic lung cancer is on mechanical ventilation for respiratory failure. The physician presents a plan to extubate with the hope that the patient will be able to breathe on his own. If the patient is able to tolerate this with minimal symptoms, medical treatments aimed at survival will be continued (e.g., antibiotics, oxygen, nutrition/hydration). If the patient is not able to tolerate this because of symptoms, then there would be an option of transitioning to purely comfort-oriented treatment.
Representative quotes	*And that's sort of another thing we want to address. Our hope is that when we remove the tube, he's able to breathe ok. But, if he has trouble breathing and goes into distress with that, we would want to do things to make him more comfortable.* *even if we turn the ventilator off, took her breathing tube out, I think she would actually do fine for a while. The question is, what happens if, two weeks from now, she's the same, in terms of her mental status and she aspirates something and develops another infection. At that point, would she want to get another breathing tube in, more antibiotics, more interventions? Or would she rather take this window of opportunity to maybe sort of make sure that these next two weeks or so are centered more around her being comfortable and family around and all this.*

Table 3

Components of treatment trials presented by physicians in ICU family conferences

Component	Description	Example	Representative Quotes
Clinical Milestones	Objective signs of improvement or deterioration used to evaluate the outcome the trial.	An improvement or deterioration in kidney function.	*to see if we can make him better with, even better being just the … his lungs, with medications and making him pee and see if we can sort of do things so that tomorrow he'd be a little better than today.*
Timeframe	Duration of the trial with planned time for re-evaluation.	Meeting again in one week to assess clinical status.	*Why don't we reassess all this on Monday, as far as his neurologic status and how much he's waking up, and we'll know a little bit more, as time goes on, just how much he moves and those sort o' things. And as you say, he is a little different this morning, than he was two days ago. So we'll see. We'll know a little bit more on Monday.*
Potential Actions	Potential next steps at the end of the trial depending upon patient's clinical progress.	Possibility of continuing life-sustaining measures for a defined period of time versus changing the goals to comfort and removing the ventilator.	*if there's not a real significant improvement, she's not gonna make it. And at which point, we would likely determine it's hopeless and that we should recommend obeying her wishes and withdrawing support.*

*Components of a treatment trial adapted from Quill and Holloway, JAMA 2011

Table 4

Advantages and disadvantages of treatment trials presented by physicians in ICU family conferences

Time-Limited Trial	
Advantages	**Example**
Patient may recover	*But we want to give him a chance to recover from these few things that are happening right now.*
In accordance with patient's wishes	*And we want to respect his life and his wishes and not do things that would be beyond what he would want, you know.*
Provide benefit to family	*I mean this period is to make sure that all friends… who might wish to see her … and if there are other relatives … have the opportunity, you know, I think for them to travel here, there's still time…* *… and then wait over the weekend, you have some time to get some sleep.*
Disadvantages	**Example**
Patient may not recover	*We feel that, in the next two days, if there's not a real significant improvement, she's not gonna make it.*
Uncomfortable	*We don't want to cause undue suffering.*
Symptom-Limited Trial	
Advantages	**Example**
Patient may live longer	*I think that once we remove the breathing tube, he could continue to breathe fine, on his own, which would be what we would hope.*
In accordance with patient's wishes	*And what some families do decide is that they're willing to take that risk, because their mother or wife wouldn't want to have a hole in her trachea and have this prolonged course.*
Non-invasive or more comfortable.	*So at that point, we wouldn't need to be monitoring him.* *So, if anything were to happen, he would just go and go comfortably.*
Provide benefit to family	*But our goal would be to give him the medication, hopefully get him off of the ventilator pretty soon, even later today, so he could wake up and you guys could spend some time with him.*
Disadvantages	**Example**
Patient may not recover	*If you want, we can take it out [the breathing tube], but I'm just stating, it's more of a risk.* *We know that by doing that [removing the breathing tube], we run the risk that she may aspirate again. She may develop an aspiration and possibly a pneumonia with that.*