ICCR Study Proposal

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The PROXE trial

imPRoving surrOgate understanding: an eXErcise

Study Purpose and Rationale:

In today's medical practice, clinicians have come to rely upon the surrogate decision-maker in the event that patients are incapacitated and are therefore unable to assent to or decline medical care. This is a relatively new concept. As recently as the early 1980s, common practice was for physicians to decide amongst themselves which patients should undergo cardiopulmonary resuscitation in the event of cardiac arrest; such decisions were not necessarily documented. However, in the setting of controversy and even legal action resulting from lack of formalized end-of-life planning, all 50 states currently have legislation that authorizes the use of advanced directives and/or surrogates. The role of the surrogate or "health care proxy" was formalized nationwide through the Patient Self-Determination Act of 1990.[1] This act required that all institutions receiving Medicare or Medicaid funding give patients information about their right to decide on advance directives and their right to designate a surrogate to make their treatment decisions if they are unable. Importantly this law does not require patients to draft advance directives, nor does it require patients to appoint a surrogate. If the patient does not designate a surrogate, state statutes appoint one. [2]

The surrogate's role is to make decisions based on the standard of "substituted judgement" - which means making the treatment decision the patient him/herself would have made. This *can* be distinct from making the treatment decision the health care proxy thinks best. In New York State, the role of the surrogate has recently been broadened via the Family Healthcare Decisions Act, which now allows family members to make decisions about withholding or withdrawal of life-sustaining treatment.[3]

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[1] La Puma J, Orentlicher D, Moss RJ. Advance directives on admission. Clinical implications and analysis of the Patient Self-Determination Act of 1990. *JAMA* 1991 Jul 17; 266 (3): 402-5.

[2] Kelley K. The Patient Self-Determination Act. A matter of life and death. *Physician Assist.* 1995 Mar; 49, 53-6.

[3] http://www.state.ny.us/governor/press/031610FHCDA.html, accessed 04/08/10

However, the accuracy of the surrogate as a decision-maker has been called into question.[45] A 2006 meta-analysis in the Archives of Internal Medicine identified 16 studies examining how accurately surrogates predict patients' treatment preferences.[6] The studies involved 151 hypothetical scenarios and found that overall, surrogates predicted patients' treatment preferences with 68% accuracy. Interestingly, they found no difference in the accuracy of patient-appointed versus statue-appointed surrogates. Quite surprisingly, a randomized study that examined the benefit of various interventions in improving surrogate decision-making also found no benefit.[7] This study randomized patients to one of four intervention conditions in which surrogates made predictions after reviewing a scenario-based directive or a value-based directive already completed by the patient and either reviewing or not reviewing this directive with the patient directly. In the study, none of these interventions resulted in any significant improvement in corcordance of surrogate and patient decision-making.

So where does that leave us? It is important to note that the studies compromising the meta-analysis sampled different populations - ranging from terminally ill patients to outpatients. Interestingly, surrogates were most accurate in scenarios that involved the patient's current state of health, and least accurate in scenarios involving dementia and stroke. Furthermore, the randomized trial I noted above was conducted in an outpatient population. Taken together, this could suggest that there is a role for further discussion with patient and HCP within the hospitalized setting (when the "current health" state makes the hypothetical situations perhaps closer to reality).

Thus, this leaves open the need for further research. The issue is quite timely, given recent legislative changes. Moreover, our hospital population provides an ideal study sample given its diversity of backgrounds and disease states. It is important to note that prior studies of surrogacy accuracy have not all used a hospitalized population. I would argue that a hospitalized population provides a better study sample, as it brings a hypothetical situation closer to reality.

Thus, I propose to evaluate the efficacy of an intervention that aims to make surrogates' predictions more accurate. The primary purpose is to evaluate whether - in hospitalized patients specifically - a simple discussion mediated by a study coordinator will increase the likelihood that a health care proxy understands the goals of their family member or loved one. Secondary endpoints will also analyze whether there are specific variables that are correlated to patient/health care proxy discordance.

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[4] Perkins HS. Controlling death: the false promise of advance directives. Ann Intern Med 2007; 147: 51-7.
[5] Principe-Rodriguez K, Rodriguez-Cintron W, Torres-Palacios A, Casal-Hidalgo J. Substituted judgement: should life-support decisions be made by a surrogate? *P R Health Sci J.* 1999; 18: 405-409.
[6] Shalowitz DI, Garrett-Mayer E, Wendler D. The Accuracy of Surrogate Decision Makers: A systematic review. *Arch Intern Med* 2006 Mar; 166: 493-497.
[7] Ditto PH, Danks JH, Smucker WD, Bookwala J et al. Advance Directives as Acts of Communication: A Randomized Controlled Trial. *Arch Intern Med* 2001 Feb; 161: 421-429.

My hope, ultimately, is that the results of this study can be used as a stepping off point for discussions among patients and their families. We can never know how a health care proxy will choose to act when actually faced with the end of life. However, my goal is to identify specific interventions that can help us to increase the chance that the surrogate truly serves as the patient's voice.

Study Design and Statistical Analysis

This is a randomized study that will enroll patients admitted to the hospital during the study period. We will screen for enrollment patients who are admitted to the housestaff-run medicine inpatient services (General Medicine 1, General Medicine 2, Cardiology or Oncology services). Patients eligible for enrollment will be those > 70 years old or patients who have a diagnosis of heart failure or cancer, and have a health care proxy (defined as the person they would want to make their medical decisions if they were no longer able) assigned at the time of admission. We will engage the medicine housestaff in reporting to the study coordinators whether they have admitted patients who fit these criteria and could be screened for enrollment. We will enroll both patients who *do* and patients who *do not* have prior advance directives, given that advance directives need to be reaffirmed at the time of each new hospital stay. Patients who do not have an available surrogate decision maker or cannot give informed consent would be excluded from the study group.

We will also collect demographic data such as the race, sex, age, primary language and admitting diagnosis for each patient enrolled in the study.

We will randomize each participant into one of two groups: the intervention group or control group. During the first 24 - 72 hours of their hospital stay, patients in the intervention group will be contacted by a study coordinator who will arrange a meeting with the patient and the patient's surrogate decision-maker to discuss the patient's advance directive wishes. During this meeting, the study coordinator will discuss with the patient in the presence of the surrogate their advance directive wishes, specifically as regards CPR, intubation and withdrawal of care in the event of a health insult from which they would likely not recover (ie stroke, requiring prolonged mechanical ventilation). To best standardize these conversations, there will be a general script from which the study member can deviate. The patient will not have to fill out any documentation during this meeting. The health care proxy would be encouraged to ask questions of the patient's wishes. If the health care proxy is not available to meet in person at the time of the hospital admission (out of state, etc) they will be contacted by telephone.

At least one day subsequent to this discussion, prior to discharge, the patient and health care proxy will each be asked to answer two questions. These questions will be based on the Life Support Preferences

Questionnaire[8]. I have however modified this questionnaire to limit the number of questions and to simplify the scenarios somewhat.

1. If you/patient had an acute but life-threatening illness and could possibly return to your present level of health after recovery, would you want to receive cardiopulmonary resuscitation?
   a. a. yes
   b. no
2. If you/patient suffered a debilitating event (ie stroke) that required you to have a breathing tube placed and there was little chance that you would fully awaken to your present state of alertness, or be able to breath on your own, would you want your doctors to:
   a. remove the breathing tube, potentially allowing you to die
   b. to continue to treat you aggressively with all possible procedures
   c. to continue to treat you aggressively with all possible procedures except for CPR

The control group will complete these two questions without having had any prior conversations except for those independently initiated by their admitting or primary physicians.

Concordance is defined as identical responses in a patient/HCP pair. Discordance will be defined as one item of difference between the pairs. Based on data from the meta-analysis cited previously, I estimate a similar 68% accuracy in our patient population. Any improvement in concordance is beneficial, in theory, however for the purposes of this study I have determined the smallest difference of clinical interest to be an improvement in concordance of 10% (from 70% concordance to 80% concordance). By the chi-square test, I have determined that we will need a sample size of 412 patient/HCP pairs (206 in each group) to detect this difference.

A pre-specified subgroup analysis will also analyze whether primary language (English versus non) and diagnosis (cancer versus other) are related to concordance among patient/HCP pairs.

Study Procedures:

No procedures will be involved in the study.

Study Questionnaires:

The questionnaire used is based on the Life Support Preferences Questionnaire, which has been independently developed. (Addendum 1). The purpose of this questionnaire is to simplify the LSPQ while still providing a fair assessment of health care surrogate understanding of patient wishes.

Study Subjects:

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Inclusion criteria:

* Admission to Housestaff-run medicine service (GM1, GM2, Oncology, Cardiology)
* Age > 70 or admitting diagnosis of cancer, congestive heart failure
* Available surrogate decision-maker (either in person or via conference call)

Exclusion criteria:

* No surrogate decision maker
* Medical staff can request that patients/families not be contacted in certain instances (ie if concerned about the effect of this discussion given family disagreement or new diagnosis)
* Escalation of care requiring transfer to step-down unit/ICU prior to administering survey

Recruitment:

A research assistant will identify eligible patients upon admission. Housestaff will also be aware of the ongoing project and can alert us if they admit a participant who might be eligible.

Confidentiality of study data:

All patient contact information will be kept confidential. The responses to our survey will also be kept confidential and will be depersonalized and identified by a number that links each patient/HCP pair. These will not be retained in the patient's chart as an advance directives document.

Potential conflict of interest:

There are no potential conflicts of interest.

Potential risks:

There are no potential risks to participants' physical health. There is, clearly, a potential emotional risk given the emotional weight of the survey. Our research assistants will be aware of these potential risks. Once the surveys have been completed, we will encourage the patients to discuss any concerns with their admitting physicians and - if the study changes any of their opinions regarding end-of-life care - will encourage them to communicate with their admitting physicians.

Potential benefit:

This study has the potential to improve the accuracy of health care proxy decision-making. If we demonstrate (contrary to prior studies) that a targeted intervention within the hospital can improve the accuracy of HCP understanding, then this could become an important adjunct to advance directive conversations for hospitalized patients.

Alternatives:

An alternative to the current format is for HCP/patient pairs to be surveyed by telephone or at a follow-up visit following discharge. We selected this method as it is most likely to result in the highest participation rate.

Compensation:

There will be no costs incurred by the patients enrolled and no compensation.

Addendum 1: Life Support Preferences Questionnaire[9]

The next set of questions concern your attitudes toward various medical treatments that you might be offered in some future situation. I will ask about antibiotics, gall bladder surgery, cardiopulmonary resuscitation (called CPR), and artificial nutrition and hydration (called artificial or tube feeding). Would you like to me to describe or explain any or all of these treatments? I will read a series of medical scenarios each describing a different medical condition and ask you how much you would want to receive each treatment under each medical scenario.

1. If you had some acute illness but would return to your present level of health after recovery, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?

The next questions are about hypothetical situations.

2. If you had Alzheimer's disease with moderate impairment, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?
3. If you had emphysema and were limited in your physical activity, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?
4. If you had had a stroke and had some chance of recovery, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?
5. If you had had a stroke and had no chance of recovery, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?
6. If you were in a coma but had some chance of recovery, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?

[9] Winter L, Parker B. Current health and preferences for life-prolonging treatments: An application of prospect theory to end-of-life decision making. *Social Science & Medicine* 2007 Oct; 65: 1695-1707.

7. If you were in a coma with no chance of recovery, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?

8. If you had liver cancer but no pain, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?

9. If you had liver cancer and were in pain, how much would you want to receive (antibiotics/gall bladder surgery/ CPR/ tube feeding)?