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CRC – IRB Proposal
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Effect of a decision support video on CPR preferences in patients with advanced illness

A. Study Purpose and Rationale

Proper discussion of code status is an essential component of advanced decision making for patients. This discussion involves determining whether a patient prefers for cardiopulmonary resuscitation (CPR) to be used in the case of cardiopulmonary arrest. In such discussions, doctors most commonly rely only on verbal descriptions of code status options. Videos have been shown to help improve patients' understanding of their medical conditions and aid in decision-making. And recent evidence has suggested that video decision support tools can be of benefit in helping patients better understand what CPR entails. This knowledge can affect preferences regarding code status.

The earliest use of videos to help patients in advanced decision-making was in patients with dementia. Volandes et al. demonstrated that geriatric patients who are shown a video of a patient with advanced dementia in addition to hearing a verbal description of the disease are more likely to choose comfort as their goal of care compared to those who hear only the verbal description. The same authors have applied the video model to patients with malignant glioma and an overall poor prognosis. In this study they examined the effect of viewing a video of a CPR effort in addition to receiving a verbal description of the intervention on patient code status preferences. The authors found that in their study population, 41% elected for CPR after a verbal description compared to 9% who elected CPR after viewing a video. More recently, these investigators have examined the effects of this video intervention on code status decisions in patients with a range of advanced cancers (prognosis <1yr) and found that patients who received a verbal description alone, 47.5% elected for CPR compared to 20% in those who got the video in addition to a verbal description. In both studies of cancer patients, the authors find that the video groups also demonstrate a higher mean knowledge score as measured by a pre and post-intervention questionnaire compared to the verbal group. They also show that patients who see such videos have a high level of comfort with such videos, 82.6% in one study reporting feeling "very comfortable" with the video.

These studies have demonstrated a significant benefit for the use of videos to inform code status discussions in patients with advanced cancer. At present, further research is needed to examine the generalizability of these findings across patients facing end-of-life decisions. The purpose of this study will be to examine the effect of a video depicting CPR on patient's decisions regarding CPR in patients admitted to NYPH-CUMC who have advanced illness and a short prognosis. This research will represent the most diagnostically diverse study population to date to receive this video intervention and will help assess the potential wider utility of the CPR video intervention in the hospital setting.

B. Study Design and Statistical Analysis

This study is a randomized-controlled trial comparing the code status decisions of those who view a CPR video in addition to having a verbal description of CPR to those who have a verbal description alone.

The study participants will be drawn from adult patients admitted to NYPH-CUMC whose medical condition is deemed by the attending of record to have a prognosis of 6 months to 2 years. (We limit to this prognostic window in order to ensure we are examining patients facing end-of-life decisions while not examining those at the end-stages of disease who would more likely be choosing against CPR prior to any intervention.) Patients will be stratified by age with stratification groups being those ages 50-70 and those ages 70+. (This line is drawn based on the fact that the average age of retirement in the US is in the mid-60s and at present data shows that non-retired workers expect to work until age 67). Stratified age groups will then be randomized to receive either a verbal discussion regarding CPR or a verbal description plus a CPR video. In both the verbal and video groups, a research assistant will accompany the patient's primary team at the time when that team deems a code discussion is warranted and deliver a standardized, verbal description of CPR (with the primary team on hand to address any case-specific questions). For patients in both arms, the research assistant will also provide written materials explaining the same information presented in the verbal narrative. The video will show a simulated code with clinicians demonstrating CPR. No outcome of the simulated CPR effort will be shown. The video's design and content will be screened by critical care intensivists, palliative care physicians and experts in medical ethics to help ensure that the video is truly a standardized representation of CPR efforts and is not coercive towards any one choice regarding CPR preference. After these interventions, all patients will be asked whether they would want to have CPR attempted. They will also be asked to rate their level of certainty regarding their decision. Patients in the video arm will be asked whether about their comfort level with the video on a 4 point scale (also to assess for any coercion caused by the video).

In this study, the primary outcome will be a patient's preference for or against CPR. Secondary outcomes will be patient certainty about their decision as well as, in the video group, patients overall level of comfort with the video. Chi-square tests will be used to compare the distributions of categorical outcomes. 91 patients will be needed in each arm of the study in order to have a power of 0.8 to detect a 20% difference in the proportions of patients who elect CPR. This study population size is based on the desire to look for a 20% difference between groups. While previous studies of cancer patients have found a difference of 30% in the proportions of patients who prefer CPR between intervention groups, this effect size we feel would remain significant with regards to potential changes to hospital policies. While we would consider examining a smaller effect size which we feel would still be significant to influence standards of care, (such as 10%), we feel our small prognostic window as an inclusion criterion will limit enrollment and thus the effect size we can detect. And so we compromise at an effect size of 20%.

We will perform subgroup analysis to determine if age affects the difference in proportion of patients who elect CPR. We will also examine whether level of comfort with the video is associated with choice for or against CPR using a paired t-test.

Study Procedure

No procedures will be used in this study.

From January-June, 2012 the number of palliative care consults has been tracked at NYPH-CUMC. At present, the census of this consult service is the best available proxy for the number of patients with advanced illness who may fit our study criteria. There have been 303 consults in this 6-month interval and thus an estimated 600 could be expected in any one-year. We feel our enrollment would be limited by our small prognosis window but aided by the fact that the palliative consult numbers represent just a subset of those with advanced illness in the hospital. Previous studies have shown an enrollment rate of 65% among those screened. Assuming conservatively that our rate were half this, we would still be reasonably able to recruit enough patients to complete the study within 12 months.

C. Study Drugs

None

D. Medical Device

None

E. Study Questionnaires

All patients will be asked to rate their comfort level with their decision regarding whether they would like to have CPR attempted. This questionnaire will be written as follows:

> *Please circle which of the following best describes your level of certainty with your decision regarding whether or not to attempt CPR*
>
> 1. *I feel very uncertain about my decision*
> 2. *I feel somewhat uncertain about my decision*
> 3. *I feel somewhat certain about my decision*
> 4. *I feel completely certain about my decision*

Among patients in the video arm, after offering their preference for or against CPR, they will be asked to fill out a questionnaire about their comfort level with the video. This questionnaire will be written as follows:

> *Please circle which of the following best describes your level of comfort with the video you just viewed:*
>
> 5. *I was very uncomfortable with the video*
> 6. *I was somewhat uncomfortable with the video*
> 7. *I was somewhat comfortable with the video*
> 8. *I was completely comfortable with the video*

F. Study Subjects

Inclusion criteria will be:

- Adult inpatients with prognosis of 6mo – 2yrs as estimated by the attending of record
- Age $\geq$50yrs
- Ability to provide informed consent

Exclusion criteria will be:

- MMSE < 24
- Language barriers preventing communication in English

G. Recruitment of Subjects

Attendings at across the various departments at NYPH-CUMC will be made aware of the study and asked to approach patient at time a code discussion is warranted and ask if patient would be willing to be approached by researchers examining decision-making tools in advanced illness. The research team would promptly approach the patient, explain the study and consent patients. For enrolled patients, a research assistant would accompany the primary team to the code discussion and administer the resources (verbal or verbal+video) appropriate to the arm to which the patient was randomized.

Confidentiality of Data

Each patient enrolled will have a unique identifier linked to his or her medical record number. This information will be stored in a secure location accessible only to the investigators.

H. Potential Conflict of Interest

There are no potential conflicts of interest in this study.

I. Location of the Study

The study will take place at New York Presbyterian Hospital – Columbia University Medical Center on the adult inpatient services.

J. Potential Risks

The only potential risk to patients is discomfort with the CPR video for those assigned to the video arm. This risk will be mitigated by rigorous screening of the video by an inter-departmental team of clinicians as described above in "study design".

K. Potential Benefits

The potential benefit to patients is that they are able to make a decision regarding CPR with a greater level of certainty as the video in addition to the verbal description could provide a more complete portrayal of CPR.

L. Alternative Therapies

Currently verbal discussion is the standard of care for discussions regarding CPR preferences. Video tools represent a potential new resource in patient decision-making. No alternative therapies are known outside of these.

M. Compensation to Subjects

There will be no compensation to subjects.

N. **Costs to Subjects**

There will be no costs to subjects.

O. **Minors as Research Subjects**

There will be no minors enrolled in this study.

P. **Radiation or Radioactive Substances**

There will be no radiation or radioactive substances used in this study.

References

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