

## **Changes in Code Status Following a Standardized Educational Video in Medical ICU Patients**

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### **A. Study Purpose and Rationale**

#### **Background**

The ICU is perhaps one of the busiest locations within the hospital, containing severely ill, high acuity patients requiring near constant supervision. Given the severity of disease present, discussions regarding the extent of resuscitation efforts in the event of cardiopulmonary arrest, or “code status,” are sometimes addressed quickly and without due consideration. Patients and families may enter into the ICU with little information regarding its workings, yet they nevertheless have the right to dictate care based on their own beliefs or values. Part of this decision, however, should be contingent on possessing adequate information regarding therapeutic options during cardiopulmonary arrest, including their benefits and harms.

#### **Review of the Literature**

While code status is widely acknowledged to be an important component of a patient’s overall plan of care, discussions regarding code status are variable in both duration and quality. Larochelle found high rates of inter-physician variability regarding code discussions; this variability resulted from physician comfort when discussing end-of-life care, a physician’s personal beliefs regarding the end-of-life, and fear of failing. Physician-led discussions also depended on the physician’s previous interaction and comfort with the health care system.

Certainly, patients and surrogates enter into the code status conversation with prior beliefs regarding in-hospital CPR, but these beliefs may not coincide with actual data. Schonwetter found 92% of patients over 62 reported obtaining information on CPR from watching television. In 1996, Diem performed a comparison of in-hospital CPR and resuscitation event success rate on television versus the real world and found significantly higher rates of successful resuscitation (75%) and favorable outcomes in television shows (67% surviving to hospital discharge).

Examining what patients and/or surrogates actually remember following code discussions can further elucidate this knowledge gap. In 2009, Almoosa found that less than half of surrogates recalled the core components of CPR, but most were able to report good understanding of resuscitation techniques. Troubling, however, was the finding that less than half of surrogates were involved in code discussions, suggesting another barrier to ensuring a patient’s wishes are fulfilled. Finally, Gehlman in 2011 found patients and/or surrogates lacked adequate knowledge regarding in-hospital CPR and likelihood of success, and that the patient’s code status preference may not be accurately reflected in hospital orders. Understanding these studies, then, demonstrates that barriers remain in fully informing both patients and surrogates on the risk and benefits of in-hospital CPR.

**Hypothesis:** Patients and families lack complete information regarding cardiopulmonary resuscitation and underutilize DNR/DNI status.

### **B. Study Design and Statistical Analysis**

#### **Conceptual and Operational Definitions**

*Code Status:* Designated by the patient or, if the patient lacks decision-making capacity, the appropriate surrogate.

*Full Code:* A code status in which life-saving and heroic measures will be undertaken in the event of a cardiopulmonary arrest. These measures include, but are not limited to; intubation, CPR and chest compressions, IV medications, and electrical cardioversion if medically indicated. These measures can be halted if determined to be medically futile at the discretion of the healthcare provider in charge.

*DNR/DNI:* Stands for “Do Not Resuscitate” and “Do Not Intubate.” A code status in which life-saving and heroic measures described above are deferred by the patient and/or surrogate. In the event of a cardiopulmonary arrest, the patient is allowed to expire.

### Study Design/Sample Size

Two arms will be analyzed for the study:

1. A retrospective cohort control arm of patients previously admitted from the CUMC ED to MICU A. For a  $p < 0.05$  and 80% power, this will entail 220 patients.
2. A prospective cohort of patients newly admitted from the CUMC ED to MICU A. For a  $p < 0.05$  and 80% power, this will entail 220 patients.

Calculations determining the number of enrollees were performed using the chi-square test of proportions at CUMC Division of Biomathematics/Biostatistics (<http://biomath.info/power/chsq.htm>). The Group 1 proportion is set at 10%, representing the estimated proportion of MICU A patients who chose DNR/DNI as a code status. The Group 2 proportion is set at 20%, representing the proportion of patients who will choose DNR/DNI as a code status following the educational video intervention. This study is therefore powered to look for an absolute increase of 10% and relative increase of 50% in DNR/DNI as code status.

### Statistical Analysis

At the conclusion of the study, the proportion of patients in the prospective cohort who opt for DNR/DNI status will be compared with the proportion of patients in the retrospective cohort who opted for DNR/DNI status. The two proportions will be analyzed via the chi-squared test to determine if statistical significance is met.

The study will also stratify patients by APACHE-2 score, a statistically-validated measure for ICU mortality. The proportion of patients who chose DNR/DNI for each APACHE-2 stratification will be compared using the chi-squared test to the retrospective patient cohort with the same APACHE-2 score.

### **C. Study Procedure**

Patients admitted to the CUMC ED and transferred to MICU A will first be medically treated if found to be unstable. If the patient is not medical stable and a decision regarding code status is emergently required, the patient will be excluded from the study. Once the patient has stabilized, he/she will be interviewed as normal by MICU A housestaff. When determining code status, the patient will be notified of the current study, including its potential risks/benefits, and will be consented for participation in the study. If the patient consents, he/she will then be shown a short educational video (See “D. Medical Device”). After the video, the patient may discuss any outstanding issues with the

admitting housestaff. Once all questions are answered, the patient will determine their code status—this will be marked in their medical record. It is estimated that 10-15 minutes will be required for the study intervention.

In the event the patient lacks decision-making capacity (for example, due to sedation from intubation, dementia/delirium, or acute neurological trauma), an appropriate surrogate will consent to the study, watch the video, and determine the patient's code status. This surrogate will be determining using the standard "Order of Surrogacy." If no surrogate is available, the patient will be designated "Full Code" and not enrolled in the study until such time as a surrogate or the patient with decision-making capacity is available. If a patient initially lacked decision-making capacity but later regains it, he/she is entitled to watch the educational video and make his/her own code decision.

All medical housestaff will undergo a short, 10-minute orientation prior to starting on MICU A outlining this study and the appropriate procedure for determining code status in eligible patients.

The study procedure described above will make every effort to not impede the medical care of study enrollees, and should the patient require emergent life-saving intervention, code status and other treatment decisions will proceed in the current standard-of-care fashion.

#### **D. Medical Device**

This study will utilize a novel educational video to be produced at CUMC prior to the start of the study. The video will consist of a short introduction to the Medical ICU and go on to describe what happens during a cardiopulmonary arrest. Potential medical interventions, including those mentioned in the "Full Code" definition above, will be described and their risks and benefits delineated. Also, the video will present data describing the success rate of resuscitation following cardiopulmonary arrest, including potential outcomes following arrest.

#### **E. Study Questionnaires**

This study will not utilize any questionnaires.

#### **F. Study Subjects**

Potential subjects for this study include all admissions to the CUMC ED who are determined to be appropriate for ICU level care and are transferred to MICU A. This study will exclude patients transferred from the general medical wards and other ICUs to MICU A to minimize the number of previous code status discussions during this admission. Patients admitted with a pre-determined code status ("traveling DNR/DNI") or transferred from another facility will also be excluded from the study.

In the event the patient lacks decision-making capacity (for example, due to sedation from intubation, dementia/delirium, or acute neurological trauma), an appropriate surrogate will consent to the study, watch the video, and determine the patient's code status. This surrogate will be determining using the standard "Order of Surrogacy." If no surrogate is available, the patient will be designated "Full Code" and not enrolled in the study until such time as a surrogate or the patient with decision-making capacity is available.

This study will not be restricted to patients on the basis of gender, race, ethnicity, creed or religion. Baseline data, including gender, age, race, ethnicity, religion, diagnosis, and APACHE-2 score will be collected.

### **G. Recruitment of Subjects**

Each month, MICU A receives approximately 40 admissions, of which half are admitted directly from the CUMC ED. Therefore, the study will require 12 months to enroll an adequate number of patients for statistical analysis.

Medical housestaff will determine if the patient is appropriate for the enrollment in the study based on the criteria in “F. Study Subjects,” as well as the immediate clinical situation, including patient stability.

### **H. Confidentiality of Study Data**

Each patient’s code status will be entered into their private medical records. The code status of each patient and study participant will be accessible to all necessary healthcare providers, including but not limited to medical housestaff, attending physicians, nurses, care coordinators, physical/occupational therapists, respiratory therapists, and social workers. The patient and designated surrogates or family members will also have access to the code status.

The patient’s code status will not be made available to any entity or group outside CUMC, in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

### **I. Potential Conflict of Interest**

Physicians involved in the creation of the educational video may take part in discussions regarding “code status” with patients enrolled in the study.

### **J. Location of the Study**

The study will take place in Medical Intensive Care Unit A of the Milstein Hospital, Columbia University Medical Center, 177 Ft. Washington Street, New York, NY 10032.

### **K. Potential Risks**

The author does not foresee any potential risk to the patient from participating in the study. However, the patient’s clinical course is likely to be impacted based on their code status decision.

### **L. Potential Benefits**

The author does not foresee any potential benefit to the patient from participating in the study. However, the patient’s clinical course is likely to be impacted based on their code status decision. If a statistically-significant increase in the number of patients opting for DNR/DNI is seen, there is the potential for decreasing suffering at the end-of-life, as well as decreased healthcare expenditure.

### **M. Alternative Therapies**

Presently, discussions on code status are conducted by individual physicians without a standardized approach. This study will continue to involve individual physicians while examining the potential benefit of a standardized educational intervention.

### **N. Compensation to Subjects**

Subjects will not receive any compensation for their part in this study.

**O. Costs to Subjects**

The educational video will be shown at no cost to the patient and/or their families.

**P. Minors as Research Subjects**

As patients will be admitted to MICU A, no study subjects will be under the age of 18. Therefore, all subjects, if possessing decision-making capacity, will be fully-consentable legal adults.

**Q. Radiation or Radioactive Substances**

This study will not introduce additional exposure to radiation or radioactive substances.

**R. References**

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