Effect on family satisfaction of palliative care services in end of life care in the CUMC ICU

IRB Protocol

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A. Study Purpose and Rationale

In the 1980s, end of life care (also known as palliative care) was a rare focus of physicians and health care systems and only existed informally. Over the last few decades, modern health care has come to incorporate more and more end of life care into regular practice as health care providers have come to realize the importance of symptom relief and comfort at the end of life. Hospice and Palliative Medicine is now a recognized medical subspecialty in the United States and abroad. 80% of US hospitals with more than 300 beds now have palliative care programs. (1)

Palliative care today revolves around symptom management. It is designed to relieve suffering in patients with serious disease burden. Most often it is provided in end of life situations; however it can often be provided alongside continued therapeutic management to enhance patient comfort. Newer models involve palliative care specialists who operate in multidisciplinary teams to provide complete symptom management.

Multiple studies have demonstrated the wide reaching benefits of palliative care. Effective symptom management has been shown to result in improved patient and family satisfaction. Early palliative care can reduce unnecessary treatments and hospitalizations resulting in cost savings. Some studies have even shown a potential therapeutic benefit with prolonged survival compared to conventional therapy. (2,3,4,5)

Twenty percent of persons who die in the US will die either during an ICU stay or shortly afterwards. (6) This thus presents a natural location for palliative care interventions. Studies have shown that the inclusion of palliative care in ICU models of care have resulted in improved family and patient satisfaction as well as decreased utilization of intensive treatments and costs. (7)

Within the last two years, a comprehensive palliative care service was implemented at Columbia University Medical Center (CUMC). Prior to this, symptomatic management was managed by intensivists and their teams within the ICU. Now, in addition to the care of intensivists, board certified palliative care specialists are available with their own multidisciplinary teams to provide consultative services.

The goal of this study is to quantify the effect on family satisfaction brought on by the introduction of comprehensive palliative care services to the CUMC ICUs. To accomplish this, this study will look at those groups of patients with the most undesirable outcome of dying in the ICU. Since the inception of palliative care services at CUMC, many of such patients have gone on to receive palliative care consults and the benefits of symptom management and family counseling during their last days of life. Family satisfaction with physician and hospital services will then be assessed through standardized Press Ganey scores.

In brief, Press Ganey scores are measurements of patient and family satisfaction. They are surveys sent to patient's and families following a hospital stay that assess a broad range of satisfaction items related to their hospital stay. Although imperfect, they are used by a majority of high ranked hospitals in the US and serve as a consistent source of satisfaction data across patients and care settings.

The rationale for this study is to show whether the introduction of palliative care for critically ill patients in the CUMC ICU's has resulted in a measurable improvement in family satisfaction.

R. Study Design and Statistical Analysis

This will be a retrospective cohort study that will be designed to determine if there is a significant difference in family satisfaction between patients who received palliative care at the end of life in a CUMC ICU and those who did not. The two groups being studied will both be comprised of patients who died within the ICU. The rationale for this is that patients who die within the ICU would be prime candidates for palliative care interventions given the likely critical nature of their illness. Patients who died within 24 hours of ICU admission will be excluded from this study as these patients would have progressed too quickly to an endpoint of death for palliative care to have been initiated.

The two groups will differ on the intervention of a palliative care consult. One group will be comprised of patients who received palliative care consults after palliative care was established at CUMC. The other group of patients will be comprised of patients before palliative care was established at CUMC.

Two control groups will also be selected for this study in order to reduce confounding from changes in clinical practice at CUMC before and after initiation of palliative care. These two groups will be comprised of patients before and after initiation of the palliative care program who did not reach an endpoint of death in the ICU.

In order to properly power the study for an unpaired t-test, 162 patients will be needed from the two study cohort groups. This number of patients was derived from average press-ganey scores at CUMC, the desired effect change in press ganey scores, and standard deviation of press ganey scores from literature. Average CUMC press-ganey scores are between 80-90. Assuming an ICU average of 85, a desired effect change would be a difference of 5 in satisfaction score, or a score of 90. Standard deviation from large assessments of Press-Ganey scores were approximately 15. (8,9)

All groups will be selected randomly from the pools of available patients who satisfy their specific group criteria.

R. Study Procedure.

From retrospective chart review, patients will be identified who satisfy the criteria of aforementioned of having died in the ICU 24 hours after their admission. Those who received palliative care consults after the initiation of palliative care will be identified. And separated from the group of patients who did not receive palliative care during the time period when it was not yet offered at CUMC. 162 patients will then be randomly selected from the group of patients who did not receive palliative care and those who did. Patients before and after the initiation of palliative care at CUMC who did not die in the ICU will then be selected randomly as controls.

Press-Ganey scores will be obtained for these patient's families and compared. An unpaired t-test will be used to determine statistically significant difference between satisfaction scores between the palliative care group and non-palliative care group.

Other demographic data will also be collected from these patients in order to assess the possible impact of other variables on patient satisfaction in end of life care. These demographics will include ethnicity, sex, age, insured vs. uninsured status, religious affiliation (if any), broad category of terminal disease.

D. Study Drugs*

N/A

E. Medical Device.*

N/A

F. Study Questionnaires

N/A

G. Study SubjectS

Inclusion/exclusion criteria for palliative care group: all patients who were hospitalized in a CUMC ICU and died within the CUMC ICU more than 24 hours after admission who received palliative care consults.

Inclusion/exclusion criteria for non-palliative care group: all patients who were hospitalized in a CUMC ICU and died within the CUMC ICU more than 24 hours after admission before palliative care was established at CUMC and who did not receive palliative care consults.

H. Recrultment of Subjects

No recruitment necessary as study will be done by retrospective chart review.

R. **Confidentiallty of Study Data**

All patient information will be de-identified and a unique code assigned to each patient. Only investigators will have access to the data.

J. Potential Conflict of Interest

N/A

K. Location of the Study

Columbia University Medical Center

L. Potential Risks

N/A

M. Potential Beneflts

N/A

N. Alternative Therapies

No alternative therapies

R. Compensation to Subjects

No compensation to subjects

P. Costs to Subjects

No cost to subjects

Q. Minors as Research Subjects

No minors involved

R. Radiation or Radioactive Substances

No radiation involved

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