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CRC IRB Proposal
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Does providing timely and accurate discharge summaries to heart failure patients and their outpatient physicians reduce 30-day readmissions and improve care quality?

A. Study Purpose and Rationale

Background

Hospital readmissions within 30 days of an inpatient hospital discharge are under intense national scrutiny. Current law, under the ACA, requires CMS to assign financial penalties to hospitals who underperform a predefined benchmark rate of readmission for at least three principal diagnoses, including heart failure. This effort is part of a larger national movement to improve the quality and cost of care provided in the US healthcare system. There is evidence that poor communication among healthcare professionals, particularly during the post-discharge period, may contribute to adverse outcomes directly related to continuity of care, patient safety, patient and clinician satisfaction, and resource use.[1-5] In one survey, outpatient physicians estimated that their follow-up management was affected adversely in about 24% of cases due to delayed or incomplete discharge communications.[1] Not only is there a high prevalence of errors related to discontinuity in care,[5] but there is also evidence of a significantly higher risk of readmission associated with failures of communication regarding diagnostic evaluations. Researchers found a trend toward greater risk of readmission among patients whose follow-up physician had not received a discharge summary. [1] Conversely, a population-based cohort study in Canada found that patients who were treated post-discharge by the same physician who provided inpatient care had a significant decrease in the relative risk of death or readmission at 30 days.[4]

Purpose

Current practice at NY-Presbyterian Hospital does not require the prompt completion or transmission of discharge summaries to patients or their outpatient follow-up physicians despite current 30-day readmission penalties for heart failure patients with traditional Medicare. Providing these in a timely, accurate, and reliable manner may be a simple yet significant intervention to improve care quality, reduce costs/penalties from preventable readmissions, and improve patient and physician satisfaction.

B. Study Design and Statistical Analysis

The proposed study design is a prospective cohort study. Patients who are admitted and treated at the CUMC and Weill-Cornell campuses of NY-Presbyterian Hospital on an inpatient cardiology “ward” service will be eligible to participate (see further inclusion/exclusion criteria below). They must have an index admission for a principal diagnosis of Heart Failure based on

ICD-9 codes at discharge (based on CMS criteria). Informed consent will be obtained according to IRB protocol, and patients will be randomized either to the intervention or control group. Patients treated in the intervention group will be given printed out copies of their complete discharge summaries at the time of discharge and a copy will be faxed to the patient's Primary Medical Doctor (PMD) as well. No significant intervention will be made to address the formatting or complexity of language used in discharge summaries, but they must include the following information to be eligible for the study and count as a complete:

Identification

- Patient's full name and age
- Date of admission and discharge
- Name of responsible hospital physician
- Name of physician preparing discharge summary
- Name of primary care physician

Medical Information

- Main diagnosis
- Other diagnoses
- Presenting symptoms
- History of Present Illness
- Medical History
- Social History
- Family History
- Admission Physical Exam Findings
- Admission Lab values
- Summarized hospital course, diagnostic test results, and treatment given
- Test results pending at discharge
- Discharge medication list and rationale for any changes from prior
- Discharge Instructions

Patients will be followed for up to 60 days with regards to hospitalization status (at NYP or any other hospital), follow up appointments, medications, and administered a standard satisfaction survey in addition to specific questions about diagnosis comprehension, medication adherence, and the utility of their discharge summary. Outpatient physicians will also be surveyed between 30 and 60 days post-discharge to solicit feedback regarding the utility of the discharge summary as it pertains to continuity of care, communication improvement, patient safety, and quality of follow up care.

A Chi-square test was used to determine that a total of 1,510 patients would need to be enrolled in this study. In a study of patients with acute medical illness treated at a Canadian hospital, van Walraven et al. found a trend toward a decreased risk of readmission for patients who were seen in follow-up by a physician who had received a discharge summary (relative risk 0.74, 95% confidence interval 0.50 to 1.11).[6] Although this was a nonsignificant finding, it is the closest study found to approximate the proposed effect of this study. Thus, assuming a similar decrease in relative risk, equal group size, an alpha of 0.05, and 80% power, this study will

require a minimum of approximately 755 patients in each of the two cohorts (total 1,510) to confidently accept or reject the null hypothesis.

There will likely be some cross-over given the fact that patients in the control group, and their PMDS, will not be barred from receiving discharge summaries. Current practices will be allowed to continue with the assumption that no significant changes will occur in follow-up communication during the course of this study. However, discharge summary receipt status will be taken into account during the analysis period with readmission risk determined in a manner of intention-to-treat to ensure standardization and consistency among patients enrolled in the intervention group.

A Chi-square test will be used to determine relative risk of readmission between the control and intervention cohorts. A t-test will be used to compare group means with respect to patient and physician surveys.

C. Study Procedure

Potential study subjects will be identified in real time via computerized inpatient lists at NY Presbyterian hospital, accessed through the electronic medical record system. At any point during hospitalization, patients' primary physician teams may be approached to first receive their willingness to participate in the study due to the requirement that a timely discharge summary be written by them. Next, patients will be randomized prior to enrollment. If they are deemed to be in the intervention group, they will be approached and asked to enroll after the research team and primary team explain the study protocol, risks and benefits. Finally, the patient's PMD will be contacted regarding the enrollment and to expect a discharge summary with interval survey follow up if they agree to participate. For the purposes of this study, it may not be appropriate to first ask for primary physician approval or patient willingness to participate prior to randomization because a significant number of both patients and physicians may demand the intervention (a discharge summary) regardless of study participation. In addition, inpatient providers may begin changing their behavior, which is a potential limitation since there is no explicit restriction on transferring discharge summaries for patients in the control group. For patients who fall into the control group and are therefore not subsequently approached to enroll, they and their physicians will be formerly enrolled and asked to participate in the study at a post-30 day follow up phone call and survey request since nothing will be different about their care otherwise, and no information will be used for analysis without informed consent obtained at this contact point. Patients and physicians will first be verbally consented and subsequently mailed or faxed the IRB informed consent documentation and survey to be filled out and returned via mail or fax to study headquarters.

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaires

The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey will be used to obtain subjective information from patients and physicians. From the CMS website:

"The HCAHPS is the first national, standardized, publicly reported survey of patients' perspectives of hospital care. HCAHPS (pronounced "H-caps"), also known as the CAHPS Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.

The HCAHPS survey asks discharged patients 27 questions about their recent hospital stay. The survey contains 18 core questions about critical aspects of patients' hospital experiences (communication with nurses and doctors, the responsiveness of hospital staff, the cleanliness and quietness of the hospital environment, pain management, communication about medicines, discharge information, overall rating of hospital, and would they recommend the hospital). The survey also includes four items to direct patients to relevant questions, three items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports.

The Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) includes HCAHPS among the measures to be used to calculate value-based incentive payments in the Hospital Value-Based Purchasing program, beginning with discharges in October 2012."

CAHPS® Hospital Survey:
http://www.hcahpsonline.org/files/HCAHPS%20V8.0%20Appendix%20A%20-%20HCAHPS%20Mail%20Survey%20Materials%20%28English%29%20March%202013.pdf

Of the eight sections included in the survey, two pertain specifically to discharge and follow up care. These sections are expected to change based on the proposed intervention:

- "When you Left the Hospital"
- "Understanding your care when you left the hospital"

A Physician satisfaction survey will also be developed and administered to determine each follow-up physician's level of satisfaction with regards to the quality of follow-up care and physician communication in those who received a discharge summary versus those who did not.

G. Study Subjects

Inclusion Criteria:

- Patients on the inpatient "ward" service with an index admission for principal diagnosis of Heart Failure based on ICD-9 codes at discharge (same as CMS criteria)
- Medicare beneficiaries aged 65 or older who were enrolled in Original Medicare (traditional fee-for-service Medicare) for the entire 12 months prior to their

hospital admission (and for readmissions, for 30 days after their original admission).

Exclusion Criteria:

- Patients on the Milstein "heart failure" service due to difference in levels of care, disease severity, many are "pre-selected" for high compliance/adherence as part of transplant workup, many already are with transplants, follow up is always with the same provider group, and the discharge summary is written by the clinical cardiology fellow on service.
- Patients with an in-hospital death;
- Patients transferred to another acute care facility because the measure evaluates hospitalizations for patients discharged to non-acute care settings
- Patients who were discharged against medical advice (AMA), because providers did not have the opportunity to deliver full care and prepare the patient for discharge.
- Admissions within 30 days of discharge from an index admission will not be considered index admissions. Thus, no hospitalization will be counted as both a readmission and an index admission within the same measure.
- Beneficiaries enrolled in Medicare managed care plans

H. Recruitment of Subjects

(see "C. Study Procedure" above)

I. Confidentiality of Study Data

All patient data obtained for the study will be de-identified and given a unique patient code corresponding to safeguarded identifying information. This information will be stored in encrypted and password protected computers only available to qualified study investigators and study coordinator.

J. Potential Conflict of Interest

none

K. Location of the Study

Inpatient cardiology wards of both campuses of NY Presbyterian Hospital: CUMC and Weill-Cornell

L. Potential Risks

There is minimal risk to either group of patients as those in the control group will receive current standard of care while those in the intervention group will merely receive a document to read and pass on to their outpatient physician. Patients will not be asked to ingest any medication, be exposed radiation, or take any other form of physical risk.

M. Potential Benefits

Potential benefits include improved care once patients leave the hospital and potentially decreased risk of coming back to the hospital in the near future.

N. Alternative Therapies
N/A

0. Compensation to Subjects
None

P. Costs to Subjects
None.

Q. Minors as Research Subjects
N/A

R. Radiation or Radioactive Substances
N/A

References

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