

Investigator's Packet

Clinical Research Proposal to the

Jersey City Medical Center Institutional Review Board

Research Investigator Submission Checklist

Principal Investigator: Mabel LaForgia MSN, RN. CNL Date of Submission _____

Title of Proposal: Multi-site Retrospective Chart Review of Heart Failure (HF) Patients Readmitted within 30 days of Discharge.

- ❑ **Detailed description of**
 - ❑ **Research project and its objectives**
 - ❑ **Methodology to be used, including type of study, number of subjects, subject inclusion and exclusion criteria, tests, and statistical analyses.**
 - ❑ **Appropriateness of research methodology to the field of study and the objectives of the research.**
 - ❑ **Appropriateness of subject selection criteria and techniques.**
 - ❑ **Risks to research subjects and how risks, if any, will be minimized**
 - ❑ **How consent will be obtained, and by whom.**
 - ❑ **How treatment and/or compensation will be provided to research subjects if harm occurs.**
 - ❑ **How costs of the research are to be funded. Specify possible costs to subjects or to Jersey City Medical Center**
- ❑ **Summary discussion of expected results.**
- ❑ **A copy of the proposed Consent form, completed except for signatures;**
- ❑ **Completed Chair/SVP Approval Statement**
- ❑ **A statement indicating that a report will be submitted to the IRB annually, or more often if required**
- ❑ **Investigator credentials;**
 - **Identification of all co-investigators, including their institutions and possible conflicts of interest**
 - **Name and address of the individual or institution to be notified if the proposal is approved by the IRB, requires modification, or is not approved.**
- ❑ **Copies of completed Assurance Training Certificate. Visit website to obtain certification through brief modular training: <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>**

Title of the Study:

Multi-site Retrospective Chart Review of Heart Failure (HF) Patients
Readmitted within 30 days of Discharge.

Date of Protocol: 2/14/2011

NORTHERN NEW JERSEY RESEARCH CONSORTIUM MEMBER
HOSPITALS:

ENGLEWOOD HOSPITAL AND MEDICAL CENTER,
HACKENSACK UNIVERSITY MEDICAL CENTER, HOLY NAME
MEDICAL CENTER, JERSEY CITY MEDICAL CENTER, ST.
JOSEPHS HEALTHCARE SYSTEM, THE VALLEY HOSPITAL,

FEBRUARY 14, 2011

Detailed description of Research Project and Objectives

Background

Heart Failure (HF) is defined as a chronic, progressive disease in which the heart muscle weakens and decreases in its ability to perfuse body tissues (Heart Failure Online, 2010). Each year over 1 million people are admitted to an inpatient setting for heart failure, and 27% of these patients are readmitted within 30 days of discharge (Jencks, Williams & Coleman, 2009). Further, recent estimates indicate that currently as many as 5.7 million people in the U.S. suffer from HF (American Heart Association, 2009), with 550,000 new patients diagnosed each year (Burke, 2010; CDC, 2006). It is the number one DRG in the country, accounting for over 6.6 million hospital days each year (Hunt, et al., 2001). Hospitals are focusing on increasing quality of health care to improve outcomes in heart failure patients, such as prevention of unnecessary readmissions.

The national average readmission rate is 24.7% (CMS, 2010) costing an estimated 17.4 billion dollars per year. Reducing readmission rates has the potential for significant cost savings. A recent Medicare payment reform states that hospitals with high readmission rates would have a 20% reduction in the original admissions payment if the patient is readmitted within 7 days, and a 10% reduction if the patient is readmitted within 15 days (Baucus, 2009). Fifty-four percent of HF readmissions may be unavoidable (Burke, 2010).

Nursing leaders at six Magnet hospitals in northern New Jersey have formed a Nursing Evidence-Based Research Consortium to improve quality of patient care by expanding evidence-based practice (EBP) and nursing research. All six hospitals participating in this Consortium address the components of current evidence-based practice guidelines, and CMS requirements, but the HF readmission rates are higher than the national average of 24.7% (EHMC 25.4, Valley 25.6, HUMC 26.6, St Joseph's 27.1, Holy Name 27.9, and JCMC 29.3).

Significance and Summary of expected results

The Consortium determined a need for improving outcomes in HF patient's readmission rates at all six member hospitals with a focus on improving outcomes in heart failure patients. In all six institutions, nursing plays an active role in the implementation of evidence based approaches to decrease readmission rates. At this time, all HF patients within the six institutions are given patient/family education and discharge planning based on the evidence to support decreased readmission rates, but the focus has not been on HF patients at high risk for 30-day readmission (Burke, 2010).

A descriptive retrospective study has been proposed to determine the differences, if any, between the six hospitals in the demographic, physiologic and psychosocial variables that accompany

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those heart failure patients that are re-admitted within 30 days after being discharged from the respective hospitals. The assumptions made in this proposed descriptive study are that, in order to best identify and implement nursing interventions aimed at reducing heart failure readmissions, the six area hospitals will need to see what those predominant, identifiable demographic, physiologic and psychosocial variables are. There may be acute differences in the frequencies of identified risk factors associated with heart failure re-admission between the six area hospitals. If so, it would support tailoring nursing interventions identified in the literature as evidence based to those predominant risk factors associated with re-admission within the hospitals' serving communities.

The six hospitals in this Consortium all have readmission rates higher than the national average thus posing a potential need for improvements in processes and outcomes for HF patients. In all six institutions, nursing plays an active role in the implementation of evidence based approaches to decrease readmission rates, but the numbers remain flat. In a review of HF practices at the six Northern NJ Magnet Consortium Hospitals, it was found that there was limited knowledge of which patients were at highest risk of readmission in each institution. At this time, all HF patients within the six institutions are given the full spectrum of evidence based care to support decreased readmission rates. Many nursing hours are devoted to patient education and follow up of HF patients, translating into a substantial cost to the institution.

Purpose

The purpose of this retrospective chart review is to determine which demographic, physiological and psychosocial characteristics are most frequently seen in those HF patients who were readmitted within 30 days of discharge in 2010 in the six Consortium member hospitals.

Research Questions:

The relevant research questions associated with this purpose are as follows:

- 1: What demographic factors are associated with the adult heart failure patient population that is readmitted within 30 days to six acute care hospitals in northern New Jersey?
- 2: What physiologic factors are associated with the adult heart failure patient population that is readmitted within 30 days to six acute care hospitals in northern New Jersey?
- 3: What psychosocial factors are associated with the adult heart failure patient population that is readmitted within 30 days to six acute care hospitals in northern New Jersey?

Methodology

Study design:

This is a descriptive retrospective study utilizing a tool developed by the Consortium based on a review of the literature that identified characteristics of HF patients who were readmitted within 30 days of discharge (See attachment II). A code book will be utilized as well to ensure consistency in the data collection process (See attachment I).

Setting:

This study will be conducted through the Northern NJ Research Consortium which includes six northern New Jersey Magnet hospitals, namely Englewood Hospital and Medical Center, Hackensack University Medical Center, Holy Name Medical Center, Jersey City Medical Center, St. Joseph's Healthcare System, and The Valley Hospital.

F. Data Collection

Exclusion criteria:

- Patients with pregnancy-induced cardiomyopathy
- Younger than 18 years of age
- Cardiac transplantation
- Trauma from MVAs
- Gunshot
- Crushing injury

Inclusion criteria:

- Patients 18 years of age or older discharged with a primary diagnosis of HF readmitted within 30 days of discharge with any readmitting diagnosis.

Data Collection Procedure:

The medical records department will provide the patient records based on the inclusion criteria from January 1st, 2010- December 31st, 2010. Medical records will supply the investigator with all of the records of all HF patients readmitted within 30 days of discharge spread out over a month by month basis for 12 months. The investigator will then select every fourth medical record number until the total sample size for each site is reached.

Sample Size:

Number of subjects sought will be 25% of each hospital's total readmission rates for 2010 based on 2009 Health and Human Services (HHS) reported data.

Data analysis:

Descriptive statistics, including *t* tests will be utilized to answer the research questions.

Protection of Human Subjects

No risk is anticipated. Risk related to privacy of chart review material is minimal. Data collected will be related to demographic, physiological and psychosocial variables. No names, social security numbers or other personal identifiers will be collected.

Research Costs

There are additional costs for this research study that will require funding. This study has been partially funded by the American Association of Critical Care Nurses. Jersey City Medical Center or the Subjects in this research study will not be subjected to any costs.

Consent

Due to the nature of this study consent will not be required

Completed Chair/SVP approval

Please see attached (appendix III)

Research Costs

There are additional costs for this research study that will require funding. This study has been partially funded by the American Association of Critical Care Nurses. Jersey City Medical Center or the Subjects in this research study will not be subjected to any costs.

IRB Reports

A report will be submitted to the IRB annually, or more often if required by applicable State, Federal, and local laws and/or applicable Jersey City Medical Center rules regulations, and requirements.

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Investigators

Principle Investigator: Mabel Pinto LaForgia MSN, RN, CNL
Jersey City Medical Center
Clinical Nurse Leader
Critical Care Division

I am also employed as an adjunct clinical instructor for the department of Nursing at the University of Medicine and Dentistry of NJ.

Other sites participating in this study include:

- ENGLEWOOD HOSPITAL AND MEDICAL CENTER
- HACKENSACK UNIVERSITY MEDICAL CENTER
- HOLY NAME MEDICAL CENTER
- ST. JOSEPHS HEALTHCARE SYSTEM
- THE VALLEY HOSPITAL

There are no conflicts of interest identified.

Approval Notification

Individuals and Institutions to be notified if the proposal is approved by the IRB, requires modification or is not approved:

Mabel LaForgia
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Literature Cited

- American Association of Colleges of Nursing. (2002). Hallmarks of the professional nursing practice environment. Accessed on October 4, 2010 from: www.aacn.nche.edu/publications/positions/hallmarks.htm
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- Discriminant Properties of Commonly Used Quality of Life Measures in Heart Failure Author(s): Susan J. Bennett, Neil B. Oldridge, George J. Eckert, Jennifer L. Embree, Sherry Browning, Nan Hou, Melissa Deer, Michael D. Murray Source: *Quality of Life Research*, Vol. 11, No. 4 (June, 2002)
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- Kasovsky, M., et al. (2000). Unplanned Readmissions of Patients with Congestive Heart Failure; Do They Reflect In-Hospital Quality of Care or Patient Characteristics? *The American Journal of Medicine*, 109(October 1, 2000), 386-390.
- Krumholz, H., et al. (2000). Predictors of readmission among elderly survivors of admission with heart failure. *Outcomes, Health Policy, and Managed Care*, 139(1 part 1), 72-77.
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Van Such, M., et al. (2006). Effect of discharge instruction on readmission of hospitalized patients with heart failure; Do all of the Joint Commission on Accreditation of Healthcare Organizations heart failure core measures reflect better care? *Quality Safe Health Care*, 15, 414-417.

Van Walraven, C. et. al. (April 6, 2010). Derivation and validation of an index to predict early death or unplanned readmission after discharge from hospital to the community. *Canadian Medical Association Journal*, 182(6), 531.

Appendix I

Code Book for Heart Failure Data Collection

Any information that is not available is coded as NA=0

Medical Record #

Hospital ID:

1. ENGLEWOOD HOSPITAL AND MEDICAL CENTER
2. HACKENSACK UNIVERSITY MEDICAL CENTER
3. HOLY NAME MEDICAL CENTER
4. JERSEY CITY MEDICAL CENTER
5. ST. JOSEPHS HEALTHCARE SYSTEM
6. THE VALLEY HOSPITAL

Date of readmit

Age:

1. 18-39yrs old
2. 40-49
3. 50-59
4. 60-69
5. 70-79
6. 80-85
7. 86-90
8. 91-95
9. 96+

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Gender (M/F): M=1, F=2

Primary Readmission Dx :

Enter information

Secondary Readmission Dx:

Enter information:

Religion _____

Enter information: _____

Ethnicity

Enter information: _____

Race

Enter information: _____

Primary Language

Enter information: _____

LOS of Readmit: number of days _____

Living Arrangements prior to admission N:1, Y:2, Unknown: 3 (H (home), A(apartment),

S(stairs), NH(nursing home), SA(subacute), AL(assisted living)(O-other-specify): where patient

is admitted from

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Discharge disposition N:1, Y:2 , Unknown:3 (home, apartment ,stairs, nursing home),

SA(subacute), AL(assisted living)(O-(other)-specify): where patient is being discharged, at end of this readmission

Level of Education: 1: Grammar School, 2: Highschool, 3: College, 4: Graduate school, 5: unknown

Social Support : 1: lives alone, 2: spouse/ partner, 3: with extended family

ADLs (1: with assist, 2: independent, 3: dependent)

Payment: 1:Self pay, 2:Private, 3:Medicare, 4:Medicaid, 5:charity care

LVEF%: raw number or specify other (Look to echocardiogram first if available, then MD progress notes, MUGA, cardiac MRI, Cardiac cath lab report)

BUN on Admit: raw number

Cr on Admit: raw number

Meds on Admit: raw number, including all PRNs, vitamin supplements, herbals, and number of medications on the medication reconciliation

Non-Adherence with therapeutic regimen: Y:1, N: 2: as noted in an MD, social worker, case manager note

NYHA class: if noted: I, II, III, IV

Marital Status (1: Married 2: Unmarried,3: Separated 4: Divorced, 5: Widowed)

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Smoker? (1:Y, 2:N) _____

Alcohol Abuse? (1:Y, 2:N): if defined in MD progress note/ H&P

note _____

Substance Abuse? (1:Y,2: N): if defined in MD progress note/ H&P note _____

Co-Morbidities Y:1, N:2 for each(Hypertension, Diabetes Mellitus, Cancer, Chronic Obstructive
Pulmonary Disease, CVA, Depression, Dementia, Afib/ Dysrhythmia,

Other) _____

Additional Important Comments _____

Appendix II

Data Collection Tool

Appendix III

Department Chair/SVP Approval Statement

Principal Investigator: Mabel LaForgia MSN, RN, CNL,

Department Nursing

Protocol Title: Multi-site Retrospective Chart Review of Heart Failure (HF) Patients Readmitted within 30 days of Discharge.

Amount of Funds Allocated/Requested: None

Summary of Research Project

This is a descriptive retrospective study conducted through the Northern NJ Research Consortium which includes six northern New Jersey Magnet hospitals, namely Englewood Hospital and Medical Center, Hackensack University Medical Center, Holy Name Medical Center, Jersey City Medical Center, St. Joseph’s Healthcare System, and The Valley Hospital. The purpose of this retrospective chart review is to determine which demographic, physiological and psychosocial characteristics are most frequently seen in those HF patients who were readmitted within 30 days of discharge in 2010 in the six Consortium member hospitals.

APPROVED BUDGET

None

Division Chief (if applicable) _____
Date

Department Chair or Senior Vice President _____
Date

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POLICIES AND PROCEDURES

MEDICAL RECORDS DEPARTMENT

TOPIC: Providing Medical Records for Research Purposes

POLICY: Upon approval of IRB research protocols requiring access to medical records, a copy of the IRB protocol must be submitted and placed on file.

PROCEDURE:

1. Person who will be doing the record review must meet with the Medical Record Director or her Designee.
2. Confidentiality agreement must be signed.
3. Portions of Medical Records may be copied only if the patients' identification is obliterated.
4. Medical Records can be reviewed by appointment only.
5. Funding to retrieve off-site medical records must be allocated.