Title of Project: Readmission for Heart Failure:
Incidence and Predictors

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Founding Sources: Cardiovascular Institute

1. *Purpose/Specific Aims*

The purpose of the study is to examine patient characteristics associated with the readmission for heart failure and to investigate trends in the incidence of recurrent heart failure.

1.1 Objectives

a) To determine the readmission rate for heart failure at 1 month, 3 months, 6 months and 1 year, and, the entire readmission curve.

b) To determine patient characteristics - demographic, comorbidity, myocardial infraction (MI)/ NOT MI, procedures associated with readmission for heart failure.

c) To determine the time trends in the readmission for heart failure

d) 2000 - 2013, looking back 6 years (to 1994), make sure that no admissions that include HF

e) Account for death before readmission.

f) Determine the rate of combined endpoint of death or readmission for heart failure

1.2 Hypotheses

a) Older age, hypertension, diabetes, prior myocardial infarction and other comorbidities will correlate with the readmission for heart failure.
b) Readmission for HF will shorten survival.
c) The incidence of readmission for heart failure has increased in recent years.

2. *Background and Significance*

2.1 The incidence of heart failure readmission

Heart failure is the leading cause of admission for elder population (>65 years) in the United States. (Desai & Stevenson, 2012) Initial admission with a primary diagnosis of heart failure accounted for a significant portion of the total Medicare expenditure and medical resources in USA. (Rosamond et al., 2008) It is

estimated that more than 1 million admission for HF occur annually, which accounted for 6.5 million hospital days. (Gheorghiade, Vaduganathan, Fonarow, & Bonow, 2013)

2.2 The significance about readmission rates

Despite the improvement in reducing the mortality of patients hospitalized due to HF, the readmissions following HF remain high and seem to be rising. The rates of readmission was approximately 30% within 2 to 3 months of discharge. In addition, more than 50% HF patients were readmitted within 6 months of the first discharge. (Chun et al., 2012; Gheorghiade et al., 2013; Joynt & Jha, 2011; Krumholz et al., 2009; Philbin & DiSalvo, 1999)
HF readmission has become a popular quality metric in HF clinical trials and a score for the hospital performance for some programs. (Gheorghiade et al., 2013)
One thing to clarify is that the readmission rates for patients admitted with HF discussed in many of the related studies have two types, the first is all-cause readmission rates while the other is HF-caused readmission rates.
In order to reduce the medical cost and evaluate the medical performance among hospitals, the readmission rates, especially the 30 days all–cause rates are required by the federal government to be reported since 2009. (Desai & Stevenson, 2012)
The need to reduce the readmission rates is urgent. Both government initiated or hospital-driven investigations are focusing on the prediction of the characteristics of patients who are more likely to get readmitted and the potential factors which may have a significant effect on the readmission rates.

2.3 *Models developed and indicators identified for all-cause HF readmission*

Using multivariate logistic regression model or Cox proportional hazards regression model with adjustment for baseline differences and covariates, investigators identified some potential predictors for the all-cause HF readmission rates, including patient demographic/social economic characteristics, comorbid illnesses developmental history, medical care process, post-discharge nurse directed care and hospital features. (Bradley et al., 2013; Philbin, Dec, Jenkins, & DiSalvo, 2001; Philbin & DiSalvo, 1999; Ziaeian & Fonarow, 2016)
However, it's been extensively reviewed that the current models designed to predict the readmission risk used very heterogeneous methodology and found few patient characteristics that have consistent predictive power (Ross et al., 2008)

2.4 Models developed and indicators identified for HF-cause HF readmission

Only slightly less than half of the readmission after HF is primarily due to HF. (O'Connor et al., 2010) In addition, the predictors of all-cause and HF-cause readmission rates have been debated heavily since two decades ago since a large portion of the variation in the risk of readmission is not well explained by the models available. (Philbin & DiSalvo, 1999; Rosamond et al., 2008) In contrast to the relatively extensively studied cause of all-cause HF readmission curves (Saito, Negishi, & Marwick, 2016), solid HF-cause readmission risk prediction model is very limited to the medical worker currently, especially the models

focusing on HF-related comorbidities and patients demographic characteristics. (Rosamond et al., 2008)

2.5 Readmission is not equal to mortality

Whether the 30-day readmission rates are good measurement for the quality and performance metrics for the medical practice is debatable. They don't necessarily correlate with mortality. (Ziaeian & Fonarow, 2016) Moreover, some patients may die before they're readmitted. We need to account for the cause of death. Noticing this, we may carefully model the rate of combined endpoint of death or readmission for heart failure

2.6 In summary

We plan to develop a convenient and reliable model to predict the risk of HF-cause readmission using demographic, comorbidity and procedure data from MIDAS.

3. Research Design and Methods

This is a retrospective data analysis using the MIDAS (Myocardial Data Acquisition System) database of all inpatient hospital admissions and readmission for heart failures from 1995 to 2014. All data for the study will be obtained from the MIDAS database. The system contains data regarding cardiovascular disease admissions and readmissions for subsequent events and invasive cardiology procedures to help characterize changing trends in cardiovascular disease in New Jersey. The Cardiovascular Institute at Robert Wood Johnson has taken precautions to prevent misuse of data by using electronic and physical security systems that protect the privacy of subjects.

Data collection and analysis will be performed on all adult patients in the database from 1995 to 2014. Data collected will include demographic data, admission for HF data, HF in the hospital data, comorbid conditions, and mortality. No additional patient contact will be necessary, as all data will be collected from the MIDAS database.

Researchers are not involved in the collection of identifiers, however, researchers do have access to identifiers. In this study, the identifiers are called patient–ID, which are randomly generated MIDAS DR specific unique identifier assigned to each de-identified patient.

3.1 Duration of Study

The study will include data collected in the MIDAS database from 1995 to 2014. The duration of the study is 20 years and zero month.

3.2 Study Sites

The study will be conducted at the Cardiovascular Institute.

3.3 Sample Size Justification

All men and women, aged 18 and older, who are part of the MIDAS database will be used. Children will not be included, as myocardial infarction is uncommon.

3.4 Subject Selection

3.4.1 Inclusion Criteria

- All adult subjects 18 years of age or older in the MIDAS database from 1995 to 2014
- Gender of subjects: Subjects of both genders will be included in the study.
- Age of subjects: Subjects will be 18 years of age or older.
- Racial and Ethnic Origin: Subjects of all racial and ethnic origins will be included in this study.
- Patients whose first heart failure occurred on or after 1995

3.4.2 Exclusion Criteria

- Patients younger than 18 years of age
- Patient with cancer diagnosis
- Patient with prior heart failure admission or diagnosis
- Myocardial infarction prior to 1995

4. Study Variables

4.1 Independent Variables or Interventions

As listed in Appendix A

MIDAS-DR Variables:

CAUSE – Cause of death
DEATHRNUM – NJ Death Certificate Number
DRG – Diagnosis-related Group
DSHYR – Discharge Year
DX1-DX9 - Diagnoses
HISPAN – Hispanic ethnicity
HOSP – Hospital Number
LOCATION – Location upon leaving hospital
NEWDTD – Date of death

PATIENT_ID – Patient ID – Randomly generated MIDAS DR specific unique identifier assigned to each de-identified patient
PRIME – Primary Insurance
PROC1-PROC8 – Procedure Codes
RACE – Race of Patient
RECDID – Record ID – Randomly generated MIDAS DR specific unique identifier assigned to each admission record in the data repository
SECOND – Secondary Insurance
SEX - Gender
SOURCE – Location before entering hospital
STATUS – Status upon discharge

4.2 Dependent Variables or Outcome Measures

Readmission for heart failure
There will be no interventions. This is a study using data from the MIDAS DR. Outcomes will be measured by looking at patients with heart failure admissions and readmissions

4.3 Chart Review Selection

This is a database study, so no additional data will be collected. All subjects' information that could link researchers to specific subject will be removed by the honest broker before the data is provided to the researchers. All data is stored in the MIDAS database. Records are.in a listing format.

4.4 Risks of Harm and of breach of confidentiality

This is a minimal risk study using de-identified data from the MIDAS database. The breach of confidentiality is minimal due to the same reason.

4.5 Potential for Benefit

There will be no direct benefit to the subjects. There will be the potential for benefit for the community, especially those patients who have been admitted for heart failure to understand the risks of getting readmitted. Understanding these reasons and trends for heart failure readmission will provide valuable information to clinicians and health care institutions to initiate treatment advances early and changes in therapy.

5. Subject Recruitment and Enrollment Considerations

5.1 Subject Recruitment

Records will only be obtained based on the presence of ICD-9 or ICD-10 codes for coronary heart and cardiovascular disease. All subjects are de-identified.

5.2 Consent Procedures

We have requested a waiver of the informed consent process. We will be using de-identified data from the MIDAS database.

5.3 Subject Costs and Compensation

There will be no cost or compensation to these subjects.

6. Data Handling and Statistical Analysis

The data entry, editing and de-identification was finished by the honest broker. The information will be recorded electronically The MIDAS DR data reside in computer files on the Rutgers RWJA HP computer in Piscataway. The offices of the MIDAS personnel are in New Brunswick. The researchers don't have the link between personal identifiers and data. The institute will keep the data for a minimum of six years.

The data set will be created by the honest broker, Judith Graber, Phd, MS. While limited Protected Health Information (PHI) is included in this dataset (namely dates and zip codes), there are minimal risks of disclosure of PHI associated with inclusion in MIDAS DR. The Cardiovascular Institute has taken precautions to prevent misuse of data by using electronic and physical security systems that protect the privacy of subjects. De-identified data will be used by the analysts other than age and gender.

Investigators will use self-developed R-package named Personal Disease Network to draw comorbidity development picture for every patient and cluster the patients according to their characteristics. In addition, after the data pre-selection step, categorical data analysis using the Chi square test will be performed. Moreover, survival analyses will be performed using Kaplan-Meier plots and Cox regression analyses. Logistic regression procedures will be used for HF readmission at one month, 3 months, 6 months, and one year after HF admission to model events and examine changes over time. Statistical analyses will be done using "R" or SAS® based programs.

7. Data and Safety Monitoring

N/A – this is a minimal risk study with no interventions

8. The Risk/Benefit Ratio

The risk is very low to de-identified subjects. The potential for benefit is considerable to the cardiovascular community. The ratio is greatly in favor of benefit.

9. Bibliography

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Appendix A: Data Collection Form

MIDAS-DR Variables:

CAUSE – Cause of death
DEATHRNUM – NJ Death Certificate Number
DRG – Diagnosis-related Group
DSHYR – Discharge Year
DX1 – Primary Diagnosis
DX2 – Secondary Diagnosis
DX3 – Secondary Diagnosis
DX4 – Secondary Diagnosis
DX5 – Secondary Diagnosis
DX6 – Secondary Diagnosis
DX7 – Secondary Diagnosis
DX8 – Secondary Diagnosis
DX9 – Secondary Diagnosis
HISPAN – Hispanic ethnicity
HOSP – Hospital Number
LOCATION – Location upon leaving hospital
NEWDTD – Date of death
PATIENT_ID – Patient ID – Randomly generated MIDAS DR specific unique identifier assigned to each de-identified patient
PRIME – Primary Insurance
PROC1 - Procedure 1 Code
PROC2 – Procedure 2 Code
PROC3 – Procedure 3 Code
PROC4 – Procedure 4 Code
PROC5 – Procedure 5 Code
PROC6 – Procedure 6 Code
PROC7 – Procedure 7 Code
PROC8 – Procedure 8 Code
RACE – Race of Patient
RECDID – Record ID – Randomly generated MIDAS DR specific unique identifier assigned to each admission record in the data repository
SECOND – Secondary Insurance
SEX - Gender
SOURCE – Location before entering hospital
STATUS – Status upon discharge