Provider Continuity and Glycemic Control in a Homeless Diabetic Population

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A. Study Purpose and Rationale

The purpose of this study is to assess whether provider continuity at a homeless shelter's medical clinic has an impact on the health outcomes of the clinic's diabetic men, as manifested in glycemic control. It is increasingly recognized that cardiovascular disease, and the associated cardiovascular risk factors including diabetes, are a significant health problem among homeless individuals. Cardiovascular disease is the second leading cause for homeless persons' hospitalizations; homeless men are 40-50% more likely to die of cardiovascular disease than men in the general population. Given the instability and complexity of these individuals' lives, it is extremely difficult to provide quality care for these patients' chronic illnesses, including diabetes. Lack of optimal care results in more frequent use of emergency services for diabetic complications. The homeless are, by definition, transient in their place of residence. However, there are long-term shelters and supportive housing facilities which provide residence as well as other services, including medical services, over an extended period of time. Homeless medical clinics are often staffed by a multitude of transient providers. It is debated in the literature as to whether continuity of care with a primary care provider has a beneficial impact on diabetics' outcomes. The literature does not address the impact of such a relationship between a provider and the homeless, a population that differs fundamentally from the insured, housed population examined in these studies. The proposed study seeks to address that issue.

The Fort Washington Clinic is housed in the Fort Washington Men's Shelter, which in turn is located in the New York City Armory building in the Washington Heights neighborhood in New York City. It is operated by Project Renewal, a nonprofit organization which operates a number of homeless shelters, medical clinics, and a mobile medical van in the city, as well as providing homeless individuals with job-training and a multitude of other social services. The Fort Washington Men's Shelter serves a population comprised of chronically and persistently mentally ill men. The shelter has 250 beds, and is nearly always at capacity. On average men reside in the shelter for approximately one to two years, with termination of shelter residence coming from placement in supportive housing or voluntary non-return by the clients. There is no requirement for clients to be sober or drug free in order to maintain their shelter bed. All men are evaluated by the medical clinic upon entrance to the shelter. Traditionally, the clinic has been staffed by a number of part-time and temporary providers, allowing for little continuity of care for the shelter's residents. Just recently, a full-time medical provider was hired to run the shelter's medical clinic. The impact of this change is unknown at present.

B. B. Study Design and Statistical Analysis

The study proposed here is a retrospective longitudinal chart review. The charts of two sets of subjects will be reviewed; first, from the 12 months prior to the provider's arrival; second, from a 12 month period following the provider's arrival (starting at 6 months after the date of arrival.)

The primary outcome will be the difference in the mean change in (as opposed to absolute value of) hemoglobin A1c at one year follow up between the pre-provider and the post-provider subjects. One year follow up results are to be ascertained at 9 months +/- 3 months. Secondary outcomes will be the change in the clinic's compliance with the ADA guidelines for diabetic patients. This includes both diagnostic and therapeutic guidelines: was urine microalbumin checked; were subjects referred for dilated retinal exams and podiatry exams; did subjects receive pneumococcal and influenza vaccines; were subjects on an aspirin, an angiotensin converting enzyme, and a statin (where appropriate.)

The study will be evaluated on the basis of a p-value that is significant at less than .05, and will be powered to 80%. Given that there is a set number of diabetics who will be included in the study (i.e. the number of subjects is not at the investigator's discretion, but rather is set by the number of diabetic patient's in the clinic's diabetic database), the power calculation will be done in reverse in order to determine what would be a significant change in hemoglobin A1c given the number of subjects. On average there are about 50 diabetics at the shelter at any given time. Data from the pre-provider phase estimates that about 60% of subjects will meet inclusion criteria by participating in the 1 year follow up (9 months +/- 3 months.) The standard deviation in change in hemoglobin A1c in the pre-provider phase was approximately 1.5. Thus, the study is powered to show a difference in the mean change of hemoglobin A1c if that change is 1.1 or greater.

An unpaired t-test will be used to analyze the significance of the results. Multiple regression analysis will then be used to assess other changes among the subjects that would affect the primary outcome, but that were unrelated to the provider's arrival. A chi-squared test will be used to analyze the secondary outcomes.

C. Study Procedure

This is a retrospective chart review and does not involve any procedures other than what the subjects had undergone as part of their routine medical care.

D. Study Drugs

This is a retrospective chart review and does not involve the administration of any medications other than what the subjects were taking as part of their own medical care.

E. Medical Device

No medical devices are to be used in this protocol.

F. Study Questionnaires

No study questionnaires are to be used in this protocol.

G. Study Subjects

The shelter's medical clinic maintains a computerized database of all the shelter's diabetic patients. The subjects will be all the shelter's diabetic patients who are either previously or newly diagnosed. Previous diagnosis will be based on self-report; new diagnoses will be made on the basis of the currently accepted guidelines for diagnosing diabetes. Subjects will be excluded if they did not have a return visit with a hemoglobin A1c check at 9 months (+/- 3 months) as the objective of the study is to assess diabetes control at 1 year follow up. The subjects will reflect the ethnic and racial diversity of the shelter. There will be no women in the study as the medical clinic serves the men's shelter.

H. Recruitment of Subjects

The subjects will be selected from the diabetes database that the medical clinic maintains. This is a chart review and as such will involve no direct recruitment of subjects by the investigator or physician.

I. Confidentiality of Study Data

Each patient is assigned a unique identifier to which only the principal investigator will have access. All analysis of the data will be done using this unique identifier which does not include the patient's identity. Data will be kept in a secure location.

J. Potential Conflict of Interest

There are no known conflicts of interest.

K. Location of the Study

This study will be done at the medical clinic located at the Fort Washington Men's Shelter, operated by Project Renewal (see 'Study Purpose and Rationale' for description.)

L. Potential Risks

As a retrospective chart review, without any intervention being administered, there are no risks for the subjects involved.

M. Potential Benefits

As a retrospective chart review, there are no direct benefits to the subjects involved. However, the increased understanding of how to effectively provide medical care to homeless diabetics may benefit the subjects in the future if they are still residing at the men's shelter.

N. Alternative Therapies

No experimental therapies are involved in this protocol.

O. Compensation to Subjects

No compensation will be provided to subjects.

P. Costs to Subjects

The subjects will not incur any costs as a result of participating in this study.

Q. Minors as Research Subjects

No minors will be included in this protocol.

R. Radiation or Radioactive Substances

No radiation or radioactive substances are involved in this protocol.