# Predictors of Failure to Adhere to a Diabetes Care Program Among Clinic Patients

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### A.  Study Purpose and Rationale

Type 2 Diabetes is one of the leading risk factors for heart disease worldwide.  It has reached epidemic proportions with an estimated 11 million affected individuals in the United States in 2000 (1). A large proportion of the published data on adherence to diabetes care has been focused on treatment methods including pharmacotherapy and behavioral therapy.  Research on barriers to care has looked at provider related barriers to follow established guidelines and socioeconomic barriers to care including access to medical care. One study surveyed a group of patients with diabetes on barriers to glucose monitoring and found that certain factors were associated with improved glucose monitoring. These factors were female gender, HbA1c >8%, higher diabetes knowledge scores, and insulin use (2).  Other studies have identified demographic and socioeconomic factors as barriers to diabetes education (3)

The Associates in Internal Medicine (AIM) clinic at Columbia University Medical Center is a major source of primary care in the Washington Heights community.  In this clinic population with a homogeneous socio-demographic composition, there are an estimated 5,000 patients with this disease and a disproportionate amount of these patients are poorly controlled.  There are two established diabetes education and treatment programs available to this patient population through referral by a primary care provider, but the retention rate in either of these programs has been estimated at less 10% of those referred. At this time there is no available data indicating why patients fail to participate in these programs. This study will aim to assess how coexisting medical conditions interfere with adherence to these two clinic-based diabetes care programs among adult patients with type 2 diabetes.

### B.  Study Design and Statistical Analysis

The Naomi Berrie Diabetes Center provides diabetes education and management under a structured setting.  The program includes nutrition classes, diabetes education classes and comprehensive diabetes care: close glucose monitoring, nurse and physician assessments, and on-site ophthalmology. Patients are expected to attend all scheduled classes and visits.  Those who do not adhere cannot participate in the program.  The nurse-directed diabetes care program provides comprehensive education and management within a more individualized program.  Patients meet in groups and individual sessions with the nurse educator.  All cases are discussed and management decisions are reached with a diabetes specialist.  Subspecialty referrals are done by the patient's primary care provider.

This is a retrospective cohort study of patients in the AIM clinic referred to diabetes education at either the Naomi Berrie Center or the Nurse educator.

All patients who have had at least three consecutive visits to either program in a period of 3 months will be considered to have completed the education program. Those patients who have been referred but have only attended less than three visits or failed to follow up on the referral will be considered non-completers.

In order to assess degree of co-morbidity, each subject will have a Charlson co- comorbidity index score (4) calculated at time of referral.

Power Analysis – Unpaired T-test power analysis will be used to calculate the number of subjects needed in each group.  For an estimated difference in the mean Charlson Co-morbidity index scales of 2 (completers 4 and non-completers 6), standard deviation of 3, alpha 0.05 and power of 80% the number of needed subjects in each group will be 37 in each group.  In order to ensure a minimum of 37 charts that

contain all necessary data to complete the study, each group will have a total of 50 subjects that meet all inclusion criteria.

Statistical Analysis – The mean comorbidity indices of the two patient groups will be compared using linear regression analysis. In addition, all variables (or diseases) accounted for in the Charlson model will be assessed individually to determine their independent association with adherence using multiple logistic regression analysis.

In addition, factors that may influence adherence that are not included in the Charlson index calculation will be evaluated using a multiple logistic regression model. These factors include depression, source of referral: attending vs. resident, gender and age.

Further analysis will be performed by sub-dividing the cohort into those who have completed the center program and those who completed the nurse educator program looking at the same variables stated above. Comparing these groups will help to identify any difference based on comorbidities or other independent variables.

## C. Study Questionnaires

There will be no questionnaires administered to volunteers. All reviewed charts will have a Charlson co-morbidity index calculated at the time of referral.

## D. Study Subjects

A retrospective chart review will be performed of all patients with an ICD9 code for diabetes, active AIM clinic patients, defined as having a documented clinic visit in the last 6 moths. All selected charts will be of patients who are at least 18 years old and have been referred to either the nurse educator or the diabetes center after January 1, 2004. A total of 100 patient charts will be reviewed: 50 who have completed and 50 who have not completed either program.

Patients who have either completed or failed to complete both programs will be excluded from the analysis.

## E. Recruitment of Subjects

Subjects will not have to be recruited for this observational study.

## F. Confidentiality of Study Data

All study data will be de-identified. Each subject will be assigned a study identification number. All collected data will be stored in a password-protected computer in the AIM clinic.

## G. Potential Conflict of Interest

There are no conflicts of interest for the investigators in this study.

## H. Location of the Study

Clinic charts will be reviewed at their respective sites.

## I. Potential Risks

There are no risks to subjects.  Confidentiality of data will be protected as explained in item F.

## J. Potential Benefits

There are many potential benefits to providers in the AIM clinic and future clinic patients.  The information obtained through this study will help to predict which patients would benefit more from referral to one of the existing diabetes education programs.   In addition, the results will help to elucidate the importance of disease comorbidity as a barrier to adhere to a diabetes program.  It may also help to identify other factors that affect compliance.  If these factors are modifiable, further studies could focus on this area.

## K.  Compensation to Subjects

There will be no monetary compensation for participation in this study.

## L.  Costs to Subjects

There will be no additional costs to the subjects.

## M.  References

1   Centers for Disease Control and Prevention, National Diabetes Fact Sheet: General Information and National Estimates on Diabetes in the United States, 2000, Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA (2002).
2   Diabetes Care 1997 (Apr; 20(4):556-61
3   Diabetes Educ 2005 May-Jun;31(3):410-7.
4   Charlson M, et al. A New Method of Classifying prognostic comorbidity in longitudinal studies: development and validation. J Chron Dis. 1987; 40:373-83.