

MedStar Recruitment Strategy

At our site, the recruitment strategy for the D2d trial will be modeled after previous successful recruitment strategies implemented in our clinical trials. The recruitment strategies will combine the following: a) electronic database searches, b) newspaper and radio advertisement, c) direct engagement of referring physicians, d) enrollment of previous study participants, and e) community based outreach and screening. We have successfully used all approaches to meet recruitment goals for both commercially sponsored and NIH-funded clinical trials. To describe each method in greater detail:

a) Electronic Medical Record database search: All individuals receiving care within the MedStar Health system provide initial consent for care and, with IRB approval, can be contacted if a research protocol is available for which they might qualify. With IRB approval, a search of the EMR database (Centricity) will allow us to identify individuals by inclusion and exclusion criteria who would qualify for this particular trial. The medical records of potential participants are reviewed by the study coordinator and an investigator, to insure those subjects identified meet all inclusion criteria. Flags are placed in the electronic medical record for the primary care provider identifying their patient as being eligible for the particular clinical trial, together with a short description of the trial. Permission to contact the subject is requested as per protocol established by our Office of Research Integrity. Patients can then be contacted and information about the clinical trial shared. To assess the feasibility of this trial with our patient population, we queried our clinical electronic database on 12-8-11, the results of which are shown in Table 2b. From our electronic medical record database alone, we estimate that 8166 current active patients may be eligible to screen for D2d.

Total Active Patients	518,857
Age > 30	370,146
Age > 30 and BMI > 25	144,555
Age > 30 and BMI > 25 and <u>no</u> diabetes medications	116,938
Age > 30 and BMI > 25 and no diabetes medications and 5.8 < HbA1c > 6.5%	8,166

Table 2b.

b) Newspaper and radio advertisement: IRB-approved radio and newspaper advertisements and flyers are effective means to inform the community at large of our ongoing research efforts. This method has been particularly effective for us in screening studies (e.g. to identify individuals with previously unrecognized pre-diabetes or diabetes) and in studies related to obesity or disease prevention.

c) Direct engagement of referring physicians: MedStar Health consists of 9 hospitals and a large network of outpatient primary care and specialty clinics in the greater DC area. Through newsletters, grand rounds, electronic and in-person communications, we keep our clinical providers informed of current research opportunities for their patients. Through use of a common electronic medical record system, we have the capacity to enter research progress notes and laboratory findings into the shared electronic medical record, and thus can partner with the primary care physician, incorporating them into the trial and keeping them informed.

d) Enrollment of previous study participants: The quality of care provided to participants and the confidence engendered by our staff have led to frequent requests from participants in studies to participate in future trials. With their permission, we keep lists of previous participants. For D2d, we will review our database of research participants from previous clinical trials and invite eligible individuals to screen and participate.

e) Community based outreach and screening: This method has demonstrated success in studies related to disease prevention and screening, as we found in the NIH-funded Diabetes Prevention Program. Methods of community based outreach and screening include diabetes screening in the community, at local stores or employee health, and at community health fairs.

For the D2d study, we will employ each technique. We will provide general information to our medical community via medical conferences and grand rounds and hospital information bulletins. As perception of the study increases, we will contact physicians and potential subjects identified through our Centricity outpatient electronic medical record search based upon the final inclusion/exclusion criteria for participation in the trial. All recruitment processes are outlined and approved by the Office of Research Integrity and IRB prior to implementation. In addition, the proposed Principal Investigator, Dr. Aroda, currently has an NIH KL2 award which will utilize an EMR-based clinical decision support system to enhance screening and identification of individuals at risk for pre-diabetes/diabetes in the primary care setting. This study will complement the efforts of recruitment for the D2d study.

We are confident given the 8166 current active patients identified in our electronic medical record system who may qualify for D2d and our experience and expertise in clinical trial recruitment and conduct that we will be able to successfully meet if not exceed recruitment and retention goals in the D2d study without any difficulties.