

Atlanta VA D2d Study Recruitment Plan

We plan to use two methods for D2d recruitment:

Method 1 – approach patients when they come for primary care clinic visits

Method 2 – traditional database query

We will be using both, but we think that Method 1 will be more successful. We have experience with approaching patients when they come for primary care visits, as part of a previous study in screening for diabetes and prediabetes. We see two dimensions of D2d recruitment: identifying prediabetes, and identifying patients willing to be in the 4 year study. We think that identifying prediabetes will be most difficult, so we will do that first – as efficiently as possible.

Method 1 - Approaching patients at primary care clinic visits

- A. We will approach patients who appear to have age >45 and BMI >25.
- B. If they don't have diabetes already, we provide a brief explanation about the diabetes epidemic.
- C. We tell them we are screening for prediabetes using a simple fingerstick test (A1c or post glucose challenge) – then if they have prediabetes, then they may be eligible for a study to see if vitamin D will help prevent diabetes. Patients take one pill every day, there's a visit every 6 months, blood tests to see if diabetes develops, and compensation for their time .
- D. We tell them we can screen for prediabetes now, and if it looks like they have prediabetes, we'll schedule them for a visit with additional tests – and if the tests confirm prediabetes, we'll put them into the vitamin D study (and we show a diagram outlining all this). If they're interested, we use a separate prescreening consent form, and then screen them.
- E. If they are not interested, we give them a different diagram which outlines how they can pursue screening with their primary care provider.

Method 2 - Traditional Database Query

- A. We use a database query of the VA's electronic medical record to identify subjects who appear to meet eligibility criteria based on A1c levels and their blood glucose laboratory values, etc.
- B. Once such patients are identified, we contact the patients' primary care providers to obtain permission to contact their patients.
- C. We send those patients a letter telling them a little about the study, and saying that their (named) VA primary care provider agreed to allow us to contact them about the study. We give the patients a telephone number to call if they are interested, or if they don't want to hear anything more about the study. We also tell them that if we don't hear from them, we may call them.
- D. After at least a week has gone by, if the patients leave a message saying that they are interested, or if we have not received a call from the patients, we call the patients to discuss the study further. We tell the patients more about the study, and if they indicate interest in participating, we send the patients a copy of the informed consent for their review.
- E. If the patients remain interested after reviewing the informed consent, we schedule them for a screening visit, which provides an opportunity to go over the study and the consent form with the patients in more detail, and to obtain informed consent.