

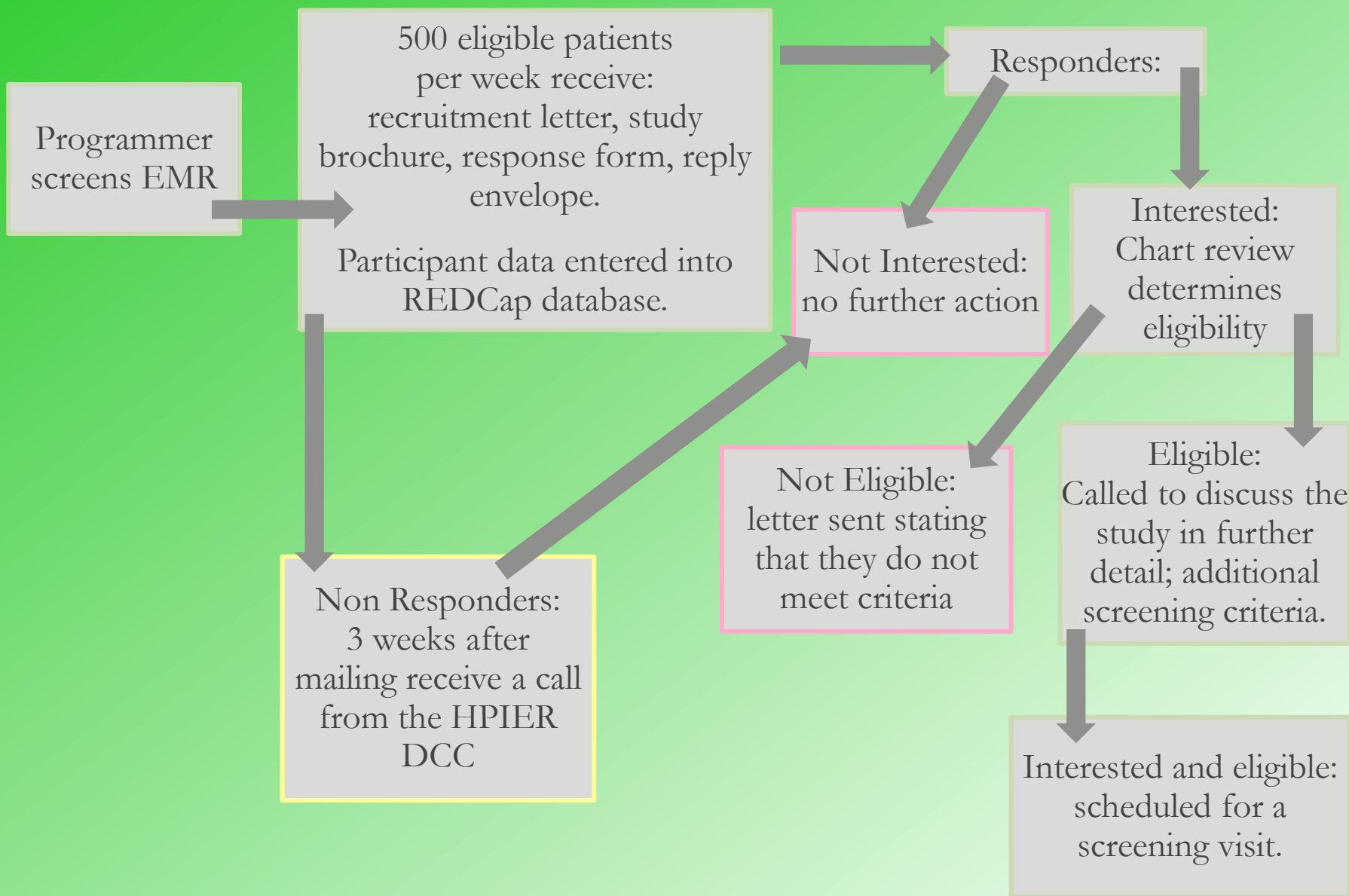


RECRUITMENT STRATEGY AT HEALTHPARTNERS

CHHAVI CHADHA, MD



Recruitment Process





Database Search Criteria

Inclusion Criteria:

- 1) Current age ≥ 30
- 2) Body Mass Index (most recent) ≥ 24 and ≤ 42 kg/m²
- 3) At least one of the following lab values from the past two years:
 - Fasting plasma glucose (FPG) 100-125 mg/dL, inclusive
 - 2-hour plasma glucose (2hPG) 140-199 mg/dL, inclusive
 - Hemoglobin A1c (HbA1c) 5.7-6.4%, inclusive



Database Search Criteria

Exclusion Criteria:

1) Diabetes based on the following:

- In diabetes registry
- Ever (in past 5 years) had 2 or more of the following dx codes: 250.xx, 357.2, 366.41, or 362.01-07
- History (past one year) of hypoglycemic pharmacotherapy (oral or injectable medication approved by FDA for type 2 diabetes) used for any condition.
- Meeting glycemic criteria for diabetes as defined by ADA guidelines (past 3 years): FPG ≥ 126 mg/dL; 2hPG ≥ 200 mg/dL; or HbA1c $\geq 6.5\%$



Database Search Criteria

Exclusion Criteria:

- 2) History (past 3 years) of hyperparathyroidism, nephrolithiasis, hypercalcemia, sarcoidosis (dx codes: 252.0, 592.x, 275.4, 135)
- 3) History (past 2 years) eGFR <50 (twice) or eGFR <40 (once)
- 4) History (past two years) serum calcium >10.2



EMR statistics

D2D Sample as of 9/24/2013, using EMR data—updated 2/4/2014 by decreasing A1c range

Step	Count	Count via A1c 5.9-6.4%	Notes	updated through 2/28/2014	
Number of patients, 30+, with a visit and BMI in the past 3 years*	3E+05	333626		350,561	
Number of patients meeting BMI criteria	2E+05	222190	most recent BMI in past 3 yrs *	231,481	
Exclusion criteria	39831	39831		40,979	
b1. diabetes registry	8681	8681		8,577	
b2. 2 codes: 250.xx, 357.2, 366.41, 362.01-07	21117	21117	in past 3 yrs *	22,069	
b3. hypoglycemic med	21846	21846	in past yr	22,578	
b4. glycemic criteria for DM	21323	21323	any in past 3 yrs *	22,178	
b5. 252.0, 592.x, 275.4, 135	3365	3365	in past 3 yrs	2,949	
b6. eGFR<50 (x2) or eGFR<40	8383	8383	any in past 2 yrs	8,525	
b7. serum calcium >=10.2	5328	5328	any in past 2 yrs	5,360	
Meeting study criteria	13523	11352		13,531	35,701
a2. FPG 100-125 mg/DL	8233	8233	a1-a3 in the past 2 yrs	9,394	29,242
a3. 2hPG 140-199 mg/DL	257	257	a1-a3 uses most recent lab result	294	294
a4. A1c 5.7-6.4%	6308			6,792	6,792
a4. A1c 5.9-6.4%		3777	968 already in REDCap, so 2,809 potentials		
** need to add pre-DM dx code back in					
Meet BMI and age criteria, but no pre-DM	60600	60600			

* chose to look at in past 3 yrs to cut down on

Changing FPG from 100-125 to 80-99 nearly triples the population Meeting Study Criteria



Recruitment Letter

November 15, 2014

Dear [patient]:

We would like to invite you to participate in a research study on the relationship between vitamin D and the prevention of type 2 Diabetes. The goal of the research is to learn whether taking vitamin D can prevent type 2 Diabetes in people at high-risk for diabetes. The study is supported by the National Institutes of Health and is conducted at HealthPartners Riverside Clinic. Enclosed is a brochure that describes the study.

Since you are receiving this letter, you may be eligible for the study. Whether you wish to enroll in the study or not is entirely up to you. The study may help answer an important question that may help many people who are at risk for diabetes.

During the study, you will have lab testing and the results will be communicated to your care team.

The study will be done at the following location:

HealthPartners Riverside Clinic
2220 Riverside Avenue
Minneapolis, MN 55454

Please respond by completing the response form and returning it to us in the enclosed postage-paid envelope. If you prefer, you may call the study site at 612-341-1950. For more information, you may also visit the study's website at www.d2dstudy.org. If we do not hear from you within a few weeks we will be calling you to see if you may be interested in participating in the study.

Sincerely,

Chhavi Chadha, MD, Principal Investigator, D2d Study
Shelly Cook, RN, Coordinator, D2d Study
Luanne Welch, RN, Coordinator, D2d Study



Response Form

Research Study – Response Form

Please provide the following information:

Name:

Address:

City:

State:

Zip:

Date of Birth: _____ or

HealthPartners ID #: _____

PLEASE CHECK ONE OF THE FOLLOWING:

☐ **INTERESTED.** I am interested in learning more about this research study and give permission to the study staff to review my medical record for study eligibility. Please call me to discuss this further. The best time to call is _____. The best phone number to reach me is _____.

☐ **NOT INTERESTED** in this research study. I do not want to participate and do not wish to receive another letter or phone call about them.

Please return this form in the enclosed postage paid business reply envelope to HealthPartners Riverside Clinic/Research Dept; 2220 Riverside Ave, Minneapolis, MN 55454. If you wish to call us instead, please call our support staff at 612-341-1950.



Prescreening

Chart Review:

- Ensure the patient does not have any exclusion criteria listed in the D2d MOP
 - Including but not limited to a history of kidney stones, bariatric surgery, history of malignancy, etc.

Phone screen:

- The patient is educated about the study, and the number of appointments, times of the appointments (weekday mornings), and location of the study clinic are emphasized.
- The patient is asked if they are currently taking any supplements, what kinds and how many mgs/IUs. The limits of calcium, vitamin D, and tanning prohibition are explained.



Recruitment Statistics*

Total number of 1st mailings sent: 9490

Total number of responses to 1st mailing: 2616 (28%)

Total number of interested from 1st mailing: 765 (8.1%)



Total number of 2nd mailings sent: 2704

Total number of responses to 2nd mailing: 402 (14.9%)

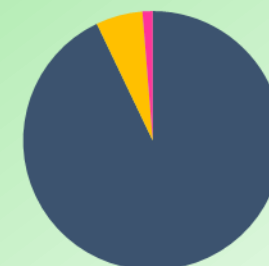
Total number of interested from 2nd mailing: 100 (3.7%)



Total number of 3rd mailings sent: 1182

Total number of responses to 3rd mailing: 69 (5.7%)

Total number interested from 3rd mailing: 15 (1.1%)



■ No Response

■ Responded

■ Interested

* As of November 12, 2014



Recruitment Challenges

- Only fasting glucose data for those patients now being recruited
 - Can lead to higher screen-fail rate
- Time commitment, especially for full-time workers
 - Baseline visit can take up to 4 hours (including travel time)
- Clinic location
 - Patients often wish to participate at their local HealthPartners clinic
- Vitamin D & calcium Washout
 - Some patients are over the supplement threshold limits and have to be scheduled 8-12 weeks out
 - Some patients forget to include all of their supplements, putting them over the limits, but don't realized until their appointment

Recruitment Team

