MedStar – EMR Search Process

Step 1: Get IRB approval.

In order to receive approval for EMR searches, you need to submit a HIPAA Waiver Application to your IRB. I've attached the MedStar IRB HIPAA Waiver Application which we filled out for D2d for reference. Each IRB likely has their own forms for this, but our answers/justifications for the use of the medical record search utility should be of utility to sites.

Step 2: Set up your search criteria.

Figure out how to run "reports" or "searches" of your medical records database. Our hospital system uses the Centricity system, so if any site wants detailed advice on running searches on that platform, I would be happy to meet with them.

Regardless of your software, you will need to devise logic for a search that will give you a high yield of qualified potential participants. The logic we use for our searches follows:

Find Patients where:
HGBA1C (last entry) is greater than 5.9
HGBA1C (last entry) is less than 6.5
Date of Last Observation Entry is before [yesterday's date]
Date of Last Observation Entry is on or after [date 90 days before yesterday's date]
Birthdate is before [maximum age bound]
Birthdate is on or after [minimum age bound]
BMI (last entry) is less than 41
BMI (last entry) is greater than 22
Problem Code, Active (Diagnosis lookup) is not DM (ICD-250.00)
Medication Code, Active (Classification lookup) is not ANTIDIABETICS
Medication Code, Active (Classification lookup) is not VITAMIN D
Medication Code, Any (Classification lookup) is not PREDNISONE
Problem Code, Active (Diagnosis lookup) is not CHRONIC KIDNEY DISEASE STAGE V (ICD-585.5)
Problem Code, Active (Diagnosis lookup) is not CHRONIC KIDNEY DISEASE STAGE IV(SEVERE) (ICD-585.4)
Problem Code, Active (Diagnosis lookup) is not HYPERCALCEMIA (ICD-275.42)

This search logic has yielded the best-qualified leads at our site; individual sites should experiment with their search criteria in order to determine the logic which leads to the best yield of qualified patients in their EMR system.

Step 3: Prescreen your search results and determine which patients you would like to contact.

After you have run your search and exported your search results (patient list) to a workable format such as an Excel file, you will need to sort through the results by hand and determine which patients you would like to contact. This involves reviewing each chart and making notes on the subject's eligibility. Typically I record any health conditions which might violate or approach the inclusion/exclusion criteria, the patient's last A1c or FPG and date, and the name of their PCP. When you are done you should have a list of patients you think are qualified for the study and would like to contact.

Step 4: Obtain permission from primary care providers to contact qualified patients.

Once you have identified qualified participants, your IRB will probably require that you get permission from the patient's PCP to contact the patient. We have approached this in three different ways at our clinic over the years: contacting each PCP about each patient, contacting a PCP with a list of patients, and negotiating with primary care practices within our system to have blanket permission to contact all their patients about a given study. In all three cases it is important to draft a "Dear Colleague" letter to inform the primary care provider about the trial; I have attached our "Dear Colleague" letter for reference.

Step 5: Reach out to potential participants by phone and mail.

The important components for calling and mailing patients are a good "Dear Patient" letter and a good script for recruiting potential participants via phone calls. We typically see best results when we send a letter out to a group of prospective participants and then follow the letter up with a call to each participant during the next 2-7 days. I have attached a recruitment telephone script and our "Dear Patient" letter for reference.