

Recruiting healthy subjects for research studies using Epic's electronic health record

Oregon Clinical and Translational Research Institute (OCTRI)

Oregon Health & Science University (OHSU)

Mary H. Samuels, M.D. Professor of Medicine
Director, Clinical and Translational Research Center

Robert Schuff, M.S.
Director, Clinical Research Informatics

Introduction:

Many clinical research studies, whether observational or interventional, include healthy subjects as the primary research cohort, or as a control group for comparison to patients. Healthy research subjects are often recruited via traditional methods such as posting flyers or sending out mass letters, as well as via more modern methods such as social media. These efforts can be time consuming and often result in low recruitment rates at high cost.

Adoption of electronic health records (EHRs) by hospitals and clinical entities has become increasingly common. Most patients enrolled in EHRs have chronic illnesses and receive chronic medications, which would exclude them from enrollment as healthy subjects into research studies. However, some patients with EHR records are actually healthy, and are receiving routine medical care for prevention or treatment of minor, self-limited conditions. It is not clear how many patients enrolled in EHRs would be eligible to participate in research studies as healthy subjects. If this number were substantial, then recruitment of healthy subjects via EHRs could be feasible and cost-effective.

Methods:

Using ICD-10 codes, we developed a SQL-based algorithm in Clarity, the database holding data from Epic, OHSU's EHR, for a computable phenotype of healthy subjects. For a given patient in Clarity, we searched their problem lists and visit diagnosis codes. If the patient's codes were all for minor or acute issues (e.g., acute nasopharyngitis), then we accepted the patient as healthy. If the patient had a single code that was NOT on our list of "healthy" codes (or if their diagnoses did not include only our healthy codes), we excluded them. Some of the healthy ICD-10 codes we used included sub-codes of minor conditions within broader codes. Examples of acceptable diagnostic codes were overweight and obesity (E65, E66) and disorders of ocular muscles, binocular movement, accommodation and refraction (H49-H52). We also included patients who were listed with the following acceptable medications: over-the-counter drugs, antibiotics, hormonal or other contraception, allergy, non-steroidal anti-inflammatory drugs, and acetaminophen. A total of 659 codes were used to find possible healthy patients.

We pulled 858 records of possible healthy patients using this algorithm from Clarity using SQL. Validation of our algorithm was performed by manual chart review of 5% of the charts (48 charts), and it was found that only one patient should have been excluded, as the diagnosis of epilepsy was in the free text of the provider's note and not in the problem or medication lists. Thus, our algorithm appears to be effective in finding healthy subjects from an EHR. We cannot ascertain from this process whether we missed healthy subjects in Epic, but we are reassured that we did not include subjects who should have been excluded, and our query resulted in substantial numbers of records.

The patient list generated from this algorithm can easily be used to directly contact potential subjects via a number of IRB-approved methods, including Epic MyChart emails, other emails, phone calls, or letters. We are happy to share our algorithm with any interested investigators who have access to Epic's customer portal (Userweb) at no charge. We have placed our Clarity-based SQL code and ICD-10 codes on Epic's Userweb (login required)

Diagnosis Codes List: <https://userweb.epic.com/Thread/61473>

Clarity SQL: <https://userweb.epic.com/Thread/61634>

Please contact the Oregon Clinical & Translational Research Institute (OCTRI) at octri@ohsu.edu if you are interested in further information.