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Design, Development and Deployment of a Diabetes Research Registry to Facilitate Recruitment in Clinical Research

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Abstract

Background and Aim—A major challenge in conducting clinical trials/studies is the timely recruitment of eligible subjects. Our aim is to develop a Diabetes Research Registry (DRR) to facilitate recruitment by matching potential subjects interested in research with approved clinical studies using study entry criteria abstracted from their electronic health records (EHR).

Method—A committee with expertise in diabetes, quality improvement, information technology, and informatics designed and developed the DRR. Using a hybrid approach, we identified and consented patients interested in research, abstracted their EHRs to assess common eligibility criteria, and contacted them about their interest in participating in specific studies. Investigators submit their requests with study entry criteria to the DRR which then provides a list of potential subjects who may be directly contacted for their study. The DRR meets all local, regional and federal regulatory requirements.

Results—After 5 years, the DRR has over 5,000 registrants. About 30% have type 1 diabetes and 70% have type 2 diabetes. There are almost equal proportions of men and women. During this

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period, 31 unique clinical studies from 19 unique investigators requested lists of potential subjects for their studies. Eleven grant applications from 10 unique investigators used aggregated counts of potentially eligible subjects in their applications.

Conclusion—The DRR matches potential subjects interested in research with approved clinical studies using study entry criteria abstracted from their EHR. By providing large lists of potentially eligible study subjects quickly, the DRR facilitated recruitment in 31 clinical studies.

Keywords

Research registry; patient recruitment; diabetes mellitus

INTRODUCTION

Major advances in the understanding and treatment of diabetes are often based on results of large, multicenter, randomized, controlled clinical trials (1–4). A major challenge in conducting such studies is the timely recruitment of subjects who meet study entry criteria (5, 6). Delayed recruitment has many consequences - delayed results, increased cost, early termination, and wrong conclusions (7). We describe a diabetes research registry that matches patients interested in research with approved clinical studies using study entry criteria abstracted from their electronic health records (EHR) to facilitate recruitment of subjects.

Recruitment begins with identifying potential subjects with the disease. Ways to identify such subjects include presentations at clinical rounds, contacting health-care providers, community outreach, paid advertisements, internet, social media, electronic health records, and disease registries (8). Once identified, the next step is to determine whether potential subjects are interested in participating in research. If they are, their eligibility for the specific study is then determined based on the study's entry criteria. All these steps are time-consuming and can delay recruitment.

Advanced digital technologies enable registries and electronic health records (EHR) to identify potential subjects for research. Registries are structured databases containing uniform information collected in a systematic way about the registrants. Unless they are organized to identify potential subjects for research, registries often function as contact lists. As such, they provide insufficient information to assess a subject's eligibility based on the study's entry criteria.

Electronic health records can also identify potential subjects with a disease for research. Structured data (diagnoses from problem lists, drugs from medications list, etc) can be used to identify potential subjects. Many detailed information in the EHR are found only in the free text. Researchers have to manually search the free text of EHR to determine whether a potential subject meets a study's entry criteria. The process is time-consuming.

In an institution without an “opt out” system (i.e. the Institutional Review Board does not permit investigators to contact potential subjects about a study or to even send them

information about the study without first obtaining approval from their health-care providers), waiting for health-care providers' approval can be time-consuming (9).

A research registry linking subjects interested in research with a clinical database that can provide information on study entry criteria (e.g. the registrants' EHR) can strategically accelerate recruitment (10). Based on their experience of comparing electronic health records and a quality improvement registry to recruit subjects for a clinical trial, Weng et al proposed a design "to generate protocol aware research registries to facilitate electronic screening for clinical trial recruitment" (11, 12).

Having a registry of subjects who have expressed an interest in research, consented to have their EHR data abstracted, and agreed to be contacted directly by researchers can facilitate recruitment for clinical research. Our aim is to design, develop, deploy and evaluate a Diabetes Research Registry (DRR) to facilitate recruitment of subjects for prospective clinical research in diabetes and to estimate the number of potential subjects for a specific diabetes study in grant applications.

METHODS

Design

We designed, developed, deployed, and evaluated the DRR in a tertiary care academic center (Center), University of Michigan Health System, which provided care to about 14,800 diabetes patients in its ambulatory care clinics in 2014. These patients can be potential subjects for clinical diabetes research in this Center. The Center uses an EHR and its quality improvement program has many registries, including one for diabetes. Patients in this quality improvement diabetes registry meet the pre-established eligibility criteria in Table 1.

To enhance clinical research and to facilitate subject recruitment, a DRR was proposed. An interdisciplinary Steering Committee of 5 experts (2 in diabetes, 1 in quality improvement, 1 in information technology, and 1 in informatics) designed the DRR. An approach was employed to identify patients who express interest in diabetes research, obtain their informed consent to access their EHRs to determine their eligibility for approved studies, and contact them directly about their interest in participating in specific studies to become DRR registrants. A hybrid approach to identify potential subjects for approved studies by matching DRR registrants with their major study entry criteria abstracted from their EHR was used (Figure 1). It was recognized that the DRR must meet all local, regional and federal regulations and be Health Insurance Portability Accountability Act compliant. The DRR was approved by the Center's Institutional Review Board.

Development

Adult (18–75 years) diabetes patients receiving care at the Center's ambulatory care clinics in the Departments of Internal Medicine [Divisions of Metabolism, Endocrinology & Diabetes, General Medicine, and Geriatric Medicine], Family Medicine, and Ophthalmology were approached in person by trained research assistants and invited to join the DRR when they attended regularly scheduled appointments (Figure 1). Their signed informed consent allowed [a] DRR staff to collect additional diabetes information from them in a simple, one-

page questionnaire (Figure 2); [b] abstract their EHRs to assess common eligibility criteria; and [c] research staff to contact them directly about their interest in participating in studies for which they are eligible.

As the DRR's purpose is to facilitate recruitment for clinical research, including clinical trials, we selected the common data elements in the diabetes domain that help us achieve our goal. Some of these data elements are collected in a questionnaire (Figure 2) which obtains information often used as study entry criteria and not readily available in the structured EHR. These include type of diabetes, the year of diagnosis (to enable calculation of duration of diabetes), the presence or absence of microvascular complications (in the eyes, kidneys and nerves), macrovascular complications (in the heart, brain and extremities), and comorbidities (dyslipidemias, hypertension and depression). The patients also indicate the way they prefer to be contacted (email, US postal service or phone) by the research staff.

This information is then entered into a database module in a secure clinical trials management system, Velos eResearch (13), and checked using an electronic medical record search engine (EMERSE) for free text in the EHR (14). Using EMERSE involves entering a set of medical record numbers of patients who have consented and a set of keywords separated by spaces (e.g., "diabetes A1c, retinopathy, monofilament") in a manner similar to using an internet search engine e.g. Google. The system then retrieves all relevant documents for each patient with the keywords highlighted. The authorized user then manually validates the questionnaire information provided by the patient. If discrepancies are identified, a diabetologist resolves them.

Velos eResearch's built-in protections enforce regulatory compliance and meet Health Insurance Portability Accountability Act's security and privacy requirements. The validated patient information is recorded on a case report form in Velos eResearch. The Velos eResearch database is then linked to the Center's quality improvement diabetes registry (Figure 1). When this project began the quality improvement diabetes registry received data from the center's Clinical Data Warehouse and was updated monthly. With the adoption of Epic as the center's EHR in August 2012, the data are now embedded within the EHR and updated daily. These data elements obtained include information about medications (glucose-lowering, lipid-altering and blood pressure control medications, and glucocorticoids); laboratory tests and results (HbA1c, hepatic, renal and thyroid function, lipid profile), pertinent exams (diabetic eye exam; diabetic foot exam), immunizations (influenza and pneumococcal vaccines), blood pressure, body mass index; and demographics. The DRR is the overlap of these two components - the list of consented registrants with validated diabetes information and the relevant requested information from their EHR (Figure 1) and is viewed through the Center's Clinical Research Data Warehouse, an Oracle database protected by a firewall, which permits restricted access.

When infrequently used study entry criteria (GAD 65 antibody, C-peptide level, etc) are requested, EHRs are searched in a semi-automated way using EMERSE.

Deployment

Investigators who wish to identify potential subjects in the DRR for their research must first request and receive IRB approval for their study. They then submit their request to the DRR with information on their study, the study's major inclusion and exclusion criteria, the type of data they are requesting, where the data will be stored, and the agency funding their study (required information in Investigator Request Query in Figure 1). The DRR "gatekeeper", a data analyst familiar with DRR, obtains the requested data and transfers it to the investigator using a secure file transfer system in the Center. The investigator must sign a data use agreement as prepared by the Center's Office of Compliance before receiving their dataset. The requests for DRR data can include [a] identified lists of potential subjects who may participate in Institutional Review Board approved studies; and [b] aggregate counts of DRR registrants who may be eligible for proposed studies to be used when submitting a grant application.

When DRR registrants agreed to participate in specific approved clinical treatment trials, their attending physicians are informed by the investigators as per protocol.

The DRR is updated periodically. Registrants who wish to withdraw from the DRR notify the DRR staff and are then removed. The National Death Index is queried periodically to generate a list of DRR registrants who have died. These registrants are similarly removed from the active registry (Figure 1).

We periodically conduct audits of the DRR to ensure the informed consent forms are properly signed and dated. We also periodically conduct audits to ensure diabetes questionnaire data provided by the registrants are correct compared with the information in the EHR.

Identifying Diabetes Registries used for Research

In February 2015, we conducted a search in PubMed using the search terms "Diabetes Registries" and "Diabetes Registers". The intent was to discover how many published diabetes registries/registers were used to recruit patients for clinical research. It was not intended to conduct a systematic review of diabetes registries or registers.

In April 2015, we also searched the internet using Google for "Diabetes Research Registries" to determine what registries are available and whether they are used for recruitment and have access to the patients' medical records.

From these searches we plan to discover whether there are published or unpublished diabetes research registries for recruitment of subjects for clinical research similar to our registry.

RESULTS

The Diabetes Research Registry

Five years after its launch, 5,168 diabetes patients consented to become registrants in the DRR. During this period, 240 were removed - 16 withdrew their consent, 143 died, and 81

were ineligible because of incomplete informed consent. The remaining 4928 patients form the active registry – potential subjects eligible for research if they are matched to a specific study.

There are almost equal proportions of men (49.6%) and women (50.4%). About 30% have type 1 diabetes and 70% have type 2 diabetes. The average age was 54.3 ± 15.9 years for the total group with 41.4 ± 15.4 years in the type 1 diabetes group and 59.9 ± 12.4 years in the type 2 diabetes group. The average duration of diabetes is 15.8 ± 11.2 (Mean $\pm$ SD) years for the total group with 22.3 ± 13.2 years in the type 1 diabetes group and 12.8 ± 8.8 years in the type 2 diabetes group. The racial composition included 72% Caucasians, 10% African Americans, and 2% Asian Americans.

Recruitment

The majority of the registrants (~96%) were recruited in Metabolism, Endocrinology & Diabetes clinics with ~4% from Family Medicine, General Medicine, Geriatric Medicine and Ophthalmology clinics.

Our single part-time recruiter is stationed in the Metabolism, Endocrinology & Diabetes clinics because 200–300 patients receive their diabetes care there each week. Of these 1–5% are diabetes patients new to the clinic. Our attempts to recruit from clinics in Family, General, and Geriatric Medicine and Ophthalmology, which each provide care to 15–30 diabetes patients per week, had relatively low yield as we were not able to place recruiters there routinely.

Approximately two-thirds of patients invited to become registrants enrolled in the DRR. To understand why patients declined to enroll, we specifically requested the reason from 500 consecutive patients. Slightly more than half of those who did not enroll (54%) declined to give a reason. Among the remaining patients, the top 3 reasons were “too busy” (23%), “not fluent in English” (7%), and “no longer have diabetes” (5%). Other reasons given (2–3% each) included “too many health issues”, “travel too much”, “borderline diabetic”, “get research information elsewhere”, and “not interested in research”.

Deployment

During this period, 31 unique approved research studies from 19 unique investigators requested lists of potential subjects who met the major entry criteria for their studies. Six of these studies requested more than one query for at least 3 reasons - they had not recruited the number of subjects needed for the study, their study entry criteria had been modified, and recruitment was over such a long time frame that they wished to identify patients newly added to the DRR. Eleven unique grant applications from 10 unique investigators used aggregate counts of potential subjects. The studies received funding from various agencies – 16 from public agencies, 6 from private agencies, 4 from nongovernmental organizations, and 5 from the Center. To use the DRR, the principal investigator must be a faculty member of the Center.

The number of potential subjects for studies varies. With the DRR, we were able to quickly provide a large list of adult type 1 diabetes registrant who could be invited to join the Type 1

Diabetes Exchange. Of approximately 1000 adult type 1 diabetes registrants who were approached to join the Type 1 Diabetes Exchange, almost half joined. In another study, we were able to identify over 2,000 type 2 diabetes registrants to enable the investigator to rapidly match those who have had the specific test for his “Big Data” research. Depending on the complexity of the query and schedule of the data analyst, the response time to a query ranges from 1–7 days.

Other Published Diabetes Registries

The PubMed search identified 730 citations from 168 diabetes registries in 44 nations. Of these citations, there were 521 retrospective studies which used the data and/or specimens in the registry. There were 95 prospective studies which used the registries to recruit patients or relatives of the patients. The remaining 114 citations were studies unrelated to recruitment (methodology to set up national diabetes registries, quality improvement diabetes registries, physician surveys, diabetes care models, and others).

Diabetes Research Registries used for Recruitment

In the internet search for diabetes research registries, we found 2 registries similar to the DRR (obtaining informed consent to become a registrant, having access to the registrant’s EHR, and inviting the registrant to participate in approved clinical research) – the Western Diabetes Institute Diabetes Registry (15) and the Children’s Hospital of Pittsburgh Diabetes Center Registry (16). There were several other diabetes research registries used for contacting patients for research including, but not limited to, the Take Control of Your Diabetes-Behavioral Diabetes Institute Registry (17), the University of Chicago Monogenic Diabetes Registry (18), the Benaroya Diabetes Institute Registry at Virginia Mason in Seattle (19), the Harold Hamm Diabetes Center Registry at University of Oklahoma (20), the Yale Diabetes Center Registry (21), and the University of North Carolina Diabetes Care Center Registry (22).

DISCUSSION

Many types of disease registries have been used to identify, screen, and recruit potential subjects for clinical research (8). Registries can quickly and efficiently identify large numbers of potential subjects for screening for research. Without access to the registrants’ EHR, the identification of potential subjects for research using patient disease registries has limitations. When linked with EHR information on study entry criteria, such registries become “research registries” that can be more efficient and effective in identifying potential subjects for specific clinical studies (10). Electronic health records are now commonly used to identify potential subjects for research. Usually, EHRs use the structured data (diagnosis from problem list, current medications from medications list, etc) to identify potential subjects with the disease. Unlike research registries, EHRs may not be as adept and specific in identifying study entry criteria unless the study staff searches the free text. Moreover, identifying potential subjects through EHR does not mean they have expressed interest in research. Based on their experience of comparing EHR and a quality improvement registry to recruit subjects for a clinical trial, Weng et al proposed the design ELiXR (Eligibility Criteria Extraction and Representation) “to generate protocol aware research registries to

facilitate electronic screening for clinical trial recruitment” (11, 12). The DRR is an example of this concept.

By giving informed consent to the DRR staff to access their EHR, the registrants enable the DRR staff to determine their eligibility for an approved research study using its major study entry criteria. The Velos DRR module and the Center’s quality improvement diabetes registry are queried on an ad hoc basis for each study. This allows quick and efficient identification of a list of potential subjects, sometimes a very large list, who can be further screened for eligibility by the study’s research staff. By giving informed consent for the investigator to contact them directly about their interest in participating in a study, potential subjects can decide whether they wish to participate. In an institution without an “opt out” system (9) this approach saves time and can facilitate recruitment.

In the PubMed search, 616 citations used diabetes registries for recruitment; only 13% were for prospective clinical research (in questionnaire surveys, in studies of relatives of the registrants, etc). We found two diabetes registries (15, 16) similar to the DRR in the Internet search. The others seem to be contact registries used to recruit subjects for prospective research.

In 2009, the National Institutes of Health announced the first US research study disease-neutral recruitment registry (ResearchMatch) as a strategy to meet the recruitment challenge for clinical trials [23, 24]. This disease-neutral registry is not linked to EHR. Similarly, the Scottish Health Research Register was established to facilitate recruitment in clinical research but with linkage to EHR. [25].

Disease registries are increasingly used to match patients for research (26). A Parkinson’s disease registry with access to the patients’ medical records is available (27). In Alzheimer’s disease, registries are established and maintained by research groups to recruit patients (28). In primary care, a group developed a research registry for community based research (29). An otolaryngology tumor registry used for recruiting patients for clinical research has also been reported (30).

Although they expressed interest in research, not all DRR registrants agree to participate in research when invited. This is to be expected as reported by Lasagna et al in 1979 (31). He described his group’s effort to recruit subjects for a clinical trial – starting with 8047 potential subjects and ending with enrolling 100. By providing a large list of potential subjects to contact and screen for a specific study, registries can facilitate recruitment. In the ASCEND trial, 423,286 subjects with diabetes were identified from centrally held and local registers and invited to participate [32]. From this large group, 26,480 (6.25%) entered the run in phase of the recruitment process. Of these, 15,480 (58.5%) were enrolled. Similarly, the DRR was able to provide large numbers of potentially eligible patients for a specific study as reported in the Results section.

The DRR has limitations. First, most of the registrants are recruited from Metabolism, Endocrinology & Diabetes clinics. These subjects tend to have long-standing diabetes with many complications and comorbidities. As a result, the DRR does not have many potential subjects who are managed only with lifestyle modification or a single glucose-lowering

medication. For research requiring such subjects, the DRR can only identify small numbers. The second limitation is the racial and ethnic origin of the registrants. Not surprisingly, the racial and ethnicity of the registrants reflect the diabetes population served by the Metabolism, Endocrinology & Diabetes clinics which recruited almost all the DRR registrants. The third limitation is its search capability. As structured, the DRR can easily and rapidly identify potential subjects based on the variables used in building it. It cannot search for details like >50% stenosis in coronary angiograms, ECG changes on exercise stress test, and other similar details. If investigators have new criteria that are not already in the DRR, we have permission to search the EHR for additional structured data or use EMERSE for searching unstructured data. This is a benefit since without patient permission the investigator cannot search for subjects meeting these new criteria.

When we initiated the DRR in 2010, the NIH Common Data Element Initiative (first published on June 18, 2012) was not yet available (33). Since we developed the DRR before the NIH Common Data Elements webpage was available, we used our own definitions following these guidelines – a registry's domain and purpose determines the data elements needed for the specific registry (34). As the DRR's purpose is to facilitate recruitment of subjects for clinical research, we selected data elements that help us achieve our goal. Now that the NIH Common Data Elements Resource Portal is available, investigators should refer to that site (33) for definitions of common data elements in diabetes.

Since the introduction of the Health Insurance Portability Accountability Act, researchers are required to obtain informed consent before accessing subjects' identifiable protected health information (29). Registries used for clinical research must meet local, regional, and national regulatory guidelines (35). Subject data must be stored in secured computerized databases with security codes. Use of the registry data must meet the requirements of the secured databases. The DRR meets these regulatory requirements.

Conclusion

The DRR matches potential subjects interested in research with approved clinical studies using study entry criteria abstracted from their EHR. This matching process is made possible by these subjects consenting to provide information on their diabetes, allowing investigators to access their EHR to determine their eligibility for approved studies, and contact them directly about participating. The DRR is designed, developed, and governed by an interdisciplinary team and is deployed by part-time staff consisting of a director, data analyst and recruiter on a small budget. The information provided by DRR in a query can be more adept and relevant for a specific research study as the study's entry criteria are considered. Approved by the Center's Institutional Review Board, DRR meets local, regional and federal regulatory requirements. In addition to facilitating recruitment for clinical studies, DRR is used to estimate the number of potential subjects for upcoming multicenter studies. Although developed for diabetes, our research registry can be replicated for other diseases at a health institution involved in clinical research. Finally, by facilitating potential subject recruitment, it can be an opportunity to overcome a major challenge in conducting clinical research.

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Figure 1.
Diabetes Research Registry Flowchart

University of Michigan Diabetes Research Registry Questionnaire

Name (please print): First _____ Last Name: _____

UM Hospital Registration No: _____

Your Diabetes History:

Diagnosis

Year of Diagnosis: _____ [If you are not sure, give your best estimate]

At diagnosis you were told you had (Please check one)

- ☐ Type 1 diabetes (you were started on insulin within 6 months of diabetes diagnosis)
- ☐ Type 2 diabetes (you were first started on diet and/or glucose lowering tablets for 6 months or longer)
- ☐ Gestational diabetes (you were pregnant when you first developed diabetes)

Diabetes Related Diseases

Do you have or have you had (this includes your doctor telling you) any of these diabetes related diseases? (Check all that apply):

☐ Diabetes eye disease or retinopathy	☐ Stroke
☐ Diabetes kidney disease or nephropathy	☐ Circulation problems in legs or Feet
☐ Diabetes nerve disease or neuropathy	☐ High blood pressure
☐ Heart attacks/disease	☐ High cholesterol or blood fats
	☐ Depression

Your Contact information

Address: _____ City: _____ State: ____ Zip code: _____

Phone (Home): (____ _) ____ _ - ____ _ (cell): (____ _) ____ _ - ____ _

Email: _____

How would you like us to contact you? (Check all that apply)

☐

By mail

☐

By phone

☐

By email

Figure 2.

Diabetes Research Registry Questionnaire

Table 1**Criteria for Patients in the Center's Quality Improvement Diabetes Registry**

-
- 1) At least one admission, one emergency room visit, or two outpatient visits with a diagnosis of diabetes within the past three years;
  - 2) Documentation of one of the following in the patient's EHR:
    - a. diagnosis of diabetes in a clinical note's problems list,
    - b. use of glucose-lowering medication(s),
    - c. use of diabetes supply (strips/lancets/glucose meter),
    - d. an HbA1c > 6.4%, or
    - e. two or more plasma glucose levels ≥ 200 mg/dL] OR a diagnosis entered by a physician in the problem summary list in the EHR.
-

Patients were excluded if they have only a diagnosis of gestational diabetes or steroid-induced diabetes in the problem summary list.