Development of a Web-Based Registry to Support Diabetes Care in Free Medical Clinics

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by Norman McFadden, MD; Bryan Daniel, MS; Robert Hoyt, MD; and Dallas Snider, PhD

Abstract

The United States has more than 1,000 free medical clinics. Because these clinics do not bill Medicare or Medicaid, they are not eligible for federal reimbursement for electronic health record (EHR) adoption. As a result, most do not have EHRs or electronic disease registries. A web-based diabetes registry was created with all open-source components for use in an urban free clinic to manage patients with type 2 diabetes and comorbidities. The registry was modeled after the Chronic Disease Electronic Management System and recommendations of the American Diabetes Association. The software was enhanced to include multiple other features, such as progress notes, so that it can function as a simple EHR. The configuration permits other free clinics to join securely, and the software can be shared.

Keywords: chronic disease, diabetes, free clinics, open-source, diabetes registry

Introduction

According to the National Association of Free and Charitable Clinics, "free clinics" are defined as "safety-net health care organizations that utilize a volunteer/staff model to provide a range of medical, dental, pharmacy, vision and/or behavioral health services to economically disadvantaged individuals. Such clinics are 501(c)(3) tax-exempt organizations, or operate as a program component or affiliate of a 501(c)(3) organization. Entities that otherwise meet the above definition, but charge a nominal/sliding fee to patients, may still be considered Free or Charitable Clinics provided essential services are delivered regardless of the patient's ability to pay." On the basis of a 2011 survey, it was estimated that the United States has more than 1,000 free clinics. In spite of the Affordable Care Act, free clinic visits are on the rise, and the Congressional Budget Office (CBO) estimates that 30 million Americans will be uninsured in 2016. Therefore, free clinics will remain an important medical delivery model in the United States for years to come.

The majority of free clinics treat chronic diseases such as diabetes and obesity, both of which are commonly associated with poverty. 4.5 According to 2012 data from the American Diabetes Association (ADA), 9.3 percent of the US population has type 2 diabetes, with the percentage more than doubling in people older than 65 years, and the disease is associated with an annual price tag of \$245 billion. 6 Clearly, free clinics are on the front lines in efforts to manage the so-called "diabesity" epidemic.

Background

Traditionally, medical practices, including free clinics, have used paper forms and spreadsheets to track chronic disease in patients and populations. With the advent of electronic health records (EHRs), it is likely that some clinics are tracking chronic diseases with registries that are a feature of their EHR systems. However, free clinics are not eligible to receive federal government reimbursement for EHR use, and little is known about EHR usage by free clinics. It is likely that free clinics that use EHRs are associated with large healthcare systems that share their software.

A disease registry is a management tool that tracks and alerts clinicians (and sometimes patients) regarding lab tests, treatments, and recommendations, such as those of the American Diabetes Association. Electronic diabetes registries have been used since the late 1990s to monitor diabetes in a single practice, a city, a state, or a nation. Diabetes registries have been used by small clinics as well as large health plans, such as Kaiser-Permanente, which has more than 260,000 patients in its diabetes registry. Registries have been used for clinical care of patients as well as for epidemiological and

clinical research. Disease registries generally require manual inputting of patient data but could be populated by an HL7 feed or automatically populated as part of an EHR system. It is unknown how many commercial EHR systems have a comprehensive disease registry that includes diabetes. Most disease registries are based on a relational database system that can generate standardized and customized reports. Data suggest that using an electronic diabetes registry will improve the identification and tracking of diabetes, particularly in large healthcare organizations, but little has been reported from small clinics. 14-16

Several noncommercial diabetes registries that could be used by free clinics are available. The Diabetes Collaborative Registry is a global cross-disciplinary registry endorsed by several medical specialty organizations and sponsored by two pharmaceutical companies. ¹⁷ The registry was designed to adhere to the Physician Quality Reporting System (PQRS) program so that physicians could be reimbursed for thirteen quality measures, reported via a registry. ¹⁸ Free clinic physicians are not eligible for reimbursement through PQRS because they do not bill Medicare. ¹⁹

Another free disease registry is the Chronic Disease Electronic Management System (CDEMS), supported by West Virginia University. ²⁰ CDEMS is based on the relational database software Microsoft Access. Because it is client based, it lacks flexibility, extensibility, and shareability.

Because of the limitations currently associated with available diabetes registries, we created a web-based diabetes registry for a local free clinic. The primary objective of the project was to ease the workload of clinicians by providing a normalized database with an easily operated user interface. The registry is hosted online to permit remote access and inclusion of multiple independent free clinics.

Methods

Patient Population

Our Lady of Angels St. Joseph Medical Clinic in Pensacola, Florida, was established in 2002 by a small group of local physicians and parishioners. Its mission is to provide medical and dental services for uninsured, low-income patients in Escambia County, Florida. The walk-in clinic is staffed entirely by a volunteer group of doctors, dentists, nurses, social workers, and administrative personnel. The clinic's financial support comes from the community and from charitable donations. Medical patient visits in fiscal year 2015 totaled more than 8,000, with an additional 622 dental patient visits. Approximately 69 licensed healthcare providers and 31 general staff volunteers provide more than 20,000 volunteer hours per year. A large proportion of this patient population has metabolic syndrome or diabetes. A segment of the clinic's operating hours are dedicated specifically to a Metabolic Clinic, which uses a patient-centered, multimodal approach to patient care consisting of recurring lectures on diabetes self-management education and diabetes self-management support, as well as access to social workers, dietitians, and physician visits. 21 St. Joseph's Metabolic Clinic currently follows approximately 160 adult patients who have type 1 or type 2 diabetes and the comorbidities of obesity, hypertension, and hyperlipidemia. Table 1 displays the clinic demographics. Treatment and tracking are based on recommendations of the ADA. 22 One author (N.M.) developed the concepts and procedures to match the local clinic workflow with national diabetes recommendations, and another author (B.D.) created and developed the open-source web based registry architecture. The nurses and support staff were involved in the design phase. They contributed comments and suggestions for functionality throughout the process. The registry was implemented in steps and was refined as a local application before it was hosted and made available for sharing. The project included development of a clearly written user manual as well as an administrative manual. The user manual was distributed to the staff, and individual meetings were held to make sure that the staff members were familiar with the functionality of the registry and their responsibilities.

Table 1: Demographics of Clinic Patients

Characteristics	Number	Percentage
Age (years)		
<30	9	5
30-39	24	15

37	23		
67	42		
23	14		
Gender			
95	59		
65	41		
Race/Ethnicity			
83	52		
60	38		
15	9		
1	0.6		
1	0.6		
	67 23 95 65 83 60 15		

Technology

An Agile software development model was utilized for this project. The Agile model comprises incremental progression of functionality and frequent feedback from the client, allowing for adaptation to uncertain or changing requirements. The project commenced in September 2015 with a completion date of March 2016. During this period, approximately 600 hours were spent on development. Development tools utilized in this project were MySQL Workbench, Java Development Kit 8, Apache Tomcat 7, and NetBeans Integrated Development Environment. The MySQL Workbench provides a platform for data modeling, query development, and database administration functionality. The Java Development Kit 8 furnished the classes, libraries, and compilers necessary to create the web application. Apache Tomcat 7 is an open-source web server used to host the online registry. NetBeans Integrated Development Environment assists with Java application development, debugging, and testing.

The online registry utilizes MySQL as the relational database management system (RDBMS), while Java Servlets and Java Server Pages handle the application's end-user requests for data and content. The literature supports this technological approach. ^{28,29} The architecture of the registry relies on stored procedures in the RDBMS for data processing. Tasks involving data input or retrieval are associated with one or more stored procedures invoked by the application. For graphical display of statistical information and patient progress, the application utilizes the JFreeChart library. ³⁰

Several measures were taken to ensure the confidentiality and integrity of the patients' data in the registry. First, all transmitted data is encrypted using the TLS/SSL protocol. Second, access to the server is filtered to allow only those IP addresses added to the access log by the administrator. Third, user registration requires a unique key for each clinic, which is created and issued by the administrator. Fourth, access to the registry is protected by a user ID and password. Fifth, keys and passwords are encrypted in the database using the SHA-256 hashing algorithm. Sixth, patient identifiable data is encrypted in storage. Before a data element is written to the database, it is encrypted using AES-128 (Advanced Encryption Standard, key length 128 bits). Administrative access to the registry is limited to one physician (N.M.). Other clinicians can enter information into appropriate sections. All progress note entries are time stamped and identified. Except for demographic information, other data fields are not editable. Registry information is not released to an external entity.

The software components are all open-source and can be downloaded, along with a user guide, from a software repository. $\frac{31}{2}$

Results

The graphical user interface for adding new patients or editing a current patient is user friendly. <u>Figure 1</u> displays the main menu with the Add New Patient option displayed. The Update Patient button allows the user to edit a patient's personal information (name, birth date, race, etc.). The Data Entry page allows the user to enter lab results and other measurements (see <u>Figure 2</u>). The Patient Treatment page allows the user to update and save the patient's therapy and medications. The

Patient History page acts as a dashboard, showing the most recent data entered for individual patients, including all data entered on the data entry and treatment pages. Color-coded triggers indicate lab values that are out of range or missing (see <u>Figure 3</u>).

Figure 1: Diabetes Registry and "Add New Patient" Page

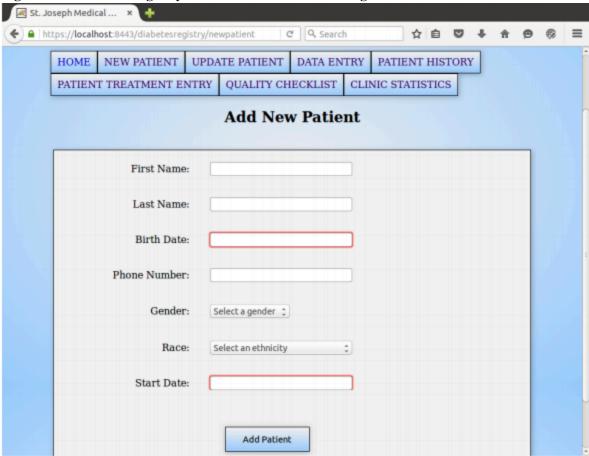


Figure 2: Data Entry Page

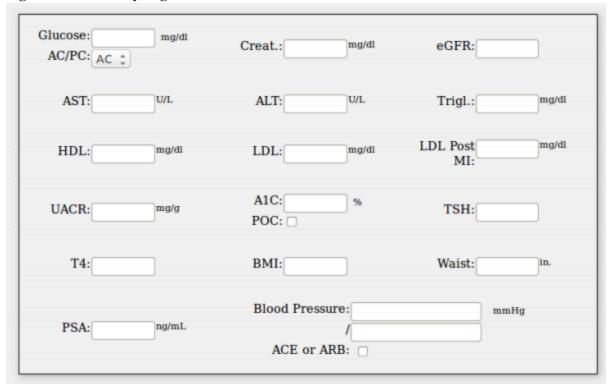
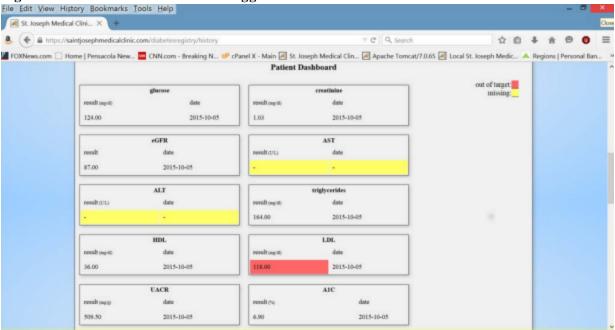


Figure 3: Color-Coded Lab Value Triggers



Longitudinal reports are available at the patient and clinic levels. Patient-level reporting can be visualized as tables and/or charts. Tables list the date and the value (e.g., blood pressure 120/80 on 2016-01-22), whereas the charts are line graphs with normal values noted (see <u>Figure 4</u>). <u>Table 2</u> displays the patient-level reports that are available in table and/or chart format, as well as which functions are recommended by the ADA.

Figure 4: Longitudinal Blood Pressure Chart

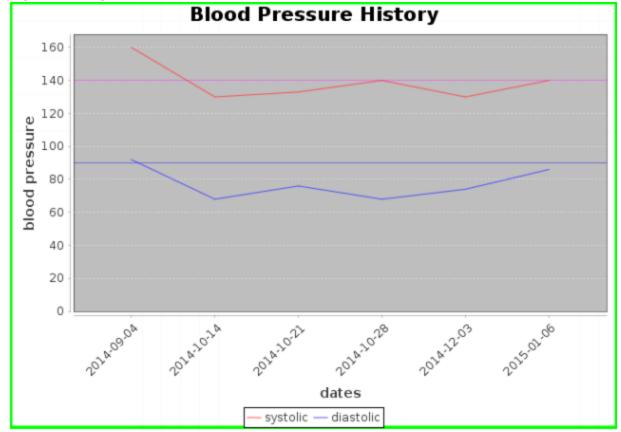


Table 2: Longitudinal Patient-Level Reports

Data Element	Available in Table Format	Available in Chart Format	American Diabetes Association Recommendation
A1c level	x	x	x
Alanine aminotransferase (ALT) level	x	x	x
Aspartate aminotransferase (AST)level	X	х	x
Blood pressure	X	X	x
Body mass index (BMI)	X	X	x
Creatinine	X	X	x
Estimated glomerular filtration rate (eGFR)	х	x	х
Eye screening	X		x
Flu vaccine	X		x
Foot screening	X		x
Glucose	х	х	X
Hepatitis B vaccine	х		X
High-density lipoprotein (HDL)	X	X	x
Low-density lipoprotein (LDL)	X		x
Metabolic class attendance	x		
Notes	X		
Patient-reported compliance	X		
PCV-13 (pneumococcal conjugate) vaccine	х		
Physical activity	X		x
PPSV-23 (pneumococcal polysaccharide) vaccine	х		х
Prostate-specific antigen (PSA)	X	х	x
Psychological screening (Patient Health Questionnaire [PHQ-9])	x	X	
Quality checklist	x		
Recent hospitalizations	x		
Smoking cessation	x		
T4 (thyroxine) level	X	х	x
Tdap vaccine	X		
Telephone follow-up	X		
Thyroid-stimulating hormone (TSH)	X	х	X
Treatment	X		
Triglycerides	X	х	X
Urine albumen to creatinine ratio	x	X	X
Waist measurement	x	X	
Zoster vaccine	x		х

Clinic-level reports are available in the "Clinic Statistics" section, which includes aggregate population statistics pertaining to demographics, glycemic control (see <u>Figure 5</u>), body mass index (BMI), and treatment.

The Progress Note function consists of four sections. The first section includes vital signs, allergies, average weekly glucose measurements, and any point-of-care A1c values. The second section includes eye, foot, and psychological screening information. The third section includes smoking history, medication compliance, and activity (minutes per week). The fourth section is for a SOAP (subjective, objective, assessment, and plan) note. The progress note can be converted to PDF format and printed. Progress notes contain all of the elements currently recorded in a paper chart and will function as a simple EHR. The Quality Checklist is used during each patient visit to document which activities in the checklist were performed.

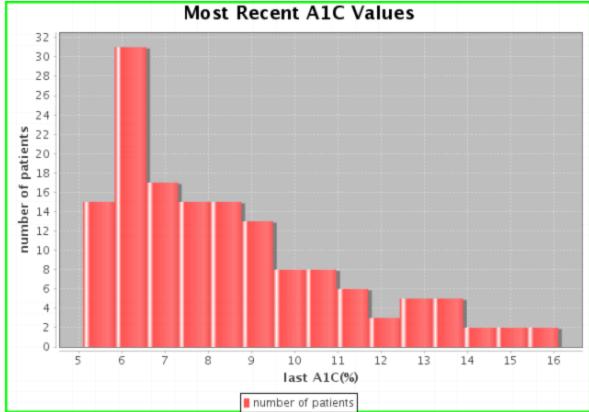


Figure 5: Glycemic Control Report in Clinic Statistics

A separate section allows the user to enter screening exams and immunizations with user-friendly drop-down menus.

Discussion

Free clinics are challenged to treat indigent patients with multiple chronic diseases, such as type 2 diabetes. In spite of their limited financial and technical support, evidence suggests that these clinics provide diabetes management on par with that of clinics that treat insured patients. 32,33 Free clinics need modern tools to track and treat complicated patients. Electronic disease registries offer many benefits over paper-based registries, such as data validation, automated messaging, extensive reporting, and integration with clinical notes. Optimally, comprehensive disease registries should be part of all EHR systems and should be shareable with other EHRs in other regions and states.

Diabetes registries perform multiple functions. They can be used at the point of care to remind the clinician and the patient about pending, missing, or abnormal parameters. Registries can generate aggregate reports of patients not meeting their goals for the disease management team. They can provide reports on the performance of clinicians and the disease management team. Disease registries are an essential aspect of the chronic disease model and case management. Furthermore, registries are often a source of data for epidemiological research and publication. Registries are also important for population health management, which is a critical element of accountable care organizations and patient-centered medical homes. 35,36

Gabbay et al. identified seven critical features associated with a successful diabetes registry. 37 Table 3 enumerates these success factors with comments on the registry created in this study. The registry has all of the success factors enumerated in the table, with the exception of a lack of feedback to clinicians.

Table 3: Diabetes Registry Success Factors

Registry Success Factor	Comments	
Identification of patients with diabetes	Identification should be based on ICD-10 codes, fasting blood sugars, or HbA1c levels.	
Capture of data elements electronically	Our registry is electronic, but it is not connected to an electronic health record, nor does it receive HL7 lab feeds at this time.	
Real-time availability	A web-based registry has the best access. The screen view can be shared with patients. Results can be printed for clinicians or patients.	
Searchability	Registry must be searchable for exam and lab details, per American Diabetes Association (ADA) guidelines.	
Web-based system linked to diabetes guidelines	Registry should be available to all clinic workers. ADA guidelines are embedded into the database tables.	
Feedback to providers	The means to compare physicians with peers or national benchmarks has not been established.	
Ability to generate patient letters	Patients can be automatically e-mailed directly from the registry. A list is generated when labs or visits are due. Available in English or Spanish.	
Note: Registry success factors were derived by an article by Gabbay et al. 37		

The registry in this study is a web-based diabetes registry that was designed and developed for an urban free clinic using open-source software, which offers a cost-effective alternative to paper-based disease tracking. The architecture that was chosen permits remote access and secure shareability with multiple other free clinics. The software components are available for download with instructions. 38

We opted to enhance functionality of the registry beyond the ADA guidelines by adding immunizations, mental health testing, reporting, and outpatient note sections. Reporting is available for individual and aggregate clinical and administrative parameters. It is highly unlikely that this free clinic will be able to afford a commercial EHR system; therefore, this enhanced registry will function as a simple EHR. This platform has been used for several months during the development phase and has functioned well. It is anticipated that a physician benchmarking option and automatic laboratory feeds using HL7 data standards will be created in the future.

It should be pointed out, however, that a diabetes registry is just a tool to expedite tracking and reporting; the care of patients with chronic diseases requires a well-coordinated and dedicated team of professionals to realize improvements in patient outcomes.

Conclusions

Type 2 diabetes is a very common chronic disease that is frequently not well controlled. A 2015 study reported that only 35 percent of older patients met strict glycemic, blood pressure, and cholesterol guidelines. Uncontrolled diabetes results in multiple long-term complications that are devastating to patients and the healthcare system. Chronic disease management requires a professional team and intelligent use of technology, including disease registries. To address this need, we created a secure web-based diabetes registry using open-source components that is being used by physicians and nurses at an urban free clinic. The registry is very easy to use, in terms of inputting data and requesting reports. Because the registry is based on national diabetes guidelines, we believe it can be easily adopted and implemented in other free clinics.

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Norman McFadden, MD, is a staff physician at Our Lady of the Angel St. Joseph Medical Clinic in Pensacola, FL.

Bryan Daniel, MS, is a graduate student at the University of West Florida in Pensacola, FL.

Robert Hoyt, MD, is an adjunct instructor and director of the Health Informatics program in the College of Health at the University of West Florida in Pensacola, FL.

Dallas Snider, PhD, is an assistant professor of computer science in the Hal Marcus College of Science and Engineering at the University of West Florida in Pensacola, FL.

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