Diabetes Manager CDSS: A Diabetes Management Tool for PCPs and Patients

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Diabetes affects 25.8 million people in the United States, accounting for 8.3 percent of the total population and 26.7 percent of Americans over the age of sixty-five (Fradkin, 2012). Additionally, 79 million Americans have been diagnosed with prediabetes, or "blood glucose levels that are higher than normal but not yet high enough to be diagnosed as diabetes" (American Diabetes Association, 2011) and an estimated "one in three American children born in 2000 is likely to develop diabetes over their lifetime" (Fradkin, 2012).

Patients who have diabetes are susceptible to a myriad of complications directly related to the disease, making diabetes difficult to manage for both the patient and the provider. Many of the complications are related to small blood vessel damage throughout the body which "affects the retina, kidney, and nerves, making diabetes the leading cause of kidney failure, blindness in working-age adults, and lower-limb amputations not resulting from trauma" (Fradkin, 2012). Additionally Fradkin (2012) points out that, "cardiovascular disease is found to be two to four times more prevalent in diabetes patients than in people without diabetes and accounts for nearly two-thirds of deaths in diabetes patients."

While eye, kidney, nerve, and heart problems may be some of the more common and well-known complications resulting from diabetes, there are several other complications that occur at higher rates in people with diabetes as compared to a person who does not have diabetes. These include: "dementia; pneumonia; periodontal disease; hearing loss; osteoporosis and fracture; liver disease; and pancreatic, colorectal, breast, endometrial, prostate, liver, and renal cancers. The rates of depression [in patients with diabetes] are doubled…often further compromising self-care" (Fradkin, 2012).

Not only does diabetes cause a number of health-related complications, it is also responsible for a large financial burden on the health care system. A study looking at the economic impact of diabetes found that the financial cost of diabetes in 2007 in the United States was $174 billion (Dall, Zhang, Chen, Quick, Yang, & Gofli, 2010). This amount included cost for medical care, disability, and premature death as a result of diabetes. However, "factoring in the additional costs of undiagnosed diabetes, prediabetes, and gestational diabetes brings the total cost of diabetes in the United States in 2007 to $218 billion" (Fradkin, 2012).

In recent years, the results of many diabetes studies and the publishing of clinical guidelines have brought about change in the way diabetes is managed. The "Diabetes Control and Complications Trial" published results in 1993 and highlighted the difference between intensive control of glucose and less intensive control. Looking at the hemoglobin A1c level, which is "a measure of average blood glucose over several months", it was found that the intensive control of glucose (or keeping the HbA1c level near 7 percent) "lowered microvascular complications by 50-76 percent" (Fradkin, 2012). The Department of Veteran Affairs and Department of Defense developed a Guideline Summary, most recently revised in 2010, providing national guidelines and objectives in the management of diabetes mellitus (U.S. Department of Health and Human Services: Agency for Healthcare Research and Quality, 2010). Additionally, in 2005, the "National Diabetes Quality Improvement Alliance Performance Measurement Set for Adult Diabetes" was published by the National Diabetes Quality Improvement Alliance in collaboration with many national organizations. This provided clinical recommendations and performance measures for ten categories in the management of diabetes, including: hemoglobin A1c management, lipid management, urine protein screening, eye examination, foot examination, influenza immunization, blood pressure management, aspirin

use, smoking cessation, and pregnancy counseling (National Diabetes Quality Improvement Alliance, 2005). Updated regularly, these guidelines have become national benchmarks in the management of diabetes.

Discussion

While diabetes is difficult to manage, associated with numerous complications, and extremely costly, patients and providers can collaborate and utilize tools aimed at optimizing care, reducing complications, and improving economic outcomes. According to Fradkin's January 2012 overview of diabetes, "control of glucose, hypertension, and lipids is improving. This improvement contributes to improved longevity." Providing a clinical decision support system to be used by primary care physicians and their patients with diabetes will facilitate the difficult decisions the primary care physicians are required to make in treating patients with diabetes and will empower the patients by allowing them to self-manage much of their care in order to reduce their complications and maintain a healthy lifestyle.

Stakeholders, Goals, Objectives

In this paper we propose a clinical decision support system (CDSS) for the management of diabetes in outpatient clinics by primary care providers and patients. The key stakeholders for the CDSS interventions are the systems' end-users, which include the primary care providers, patients, nurses, and other staff members who work directly with the patients and who will utilize this CDSS regularly.

The primary goal of this CDSS intervention is to provide a support tool to be to facilitate the management of diabetes by primary care providers and to empower patients and encourage self-management of their diabetes. Secondary goals resulting from the success of these

interventions include a decrease in complications related to diabetes as well as decreased overall costs related to diabetes management. Specific clinical goals and objectives are based on the recommended guidelines from the Department of Veteran Affairs and Department of Defense and the National Diabetes Quality Improvement Alliance. The clinical goals include using the CDSS tool to meet the target value and target frequency for each of the variables described in the Intervention Specifications section.

Information System Inventory

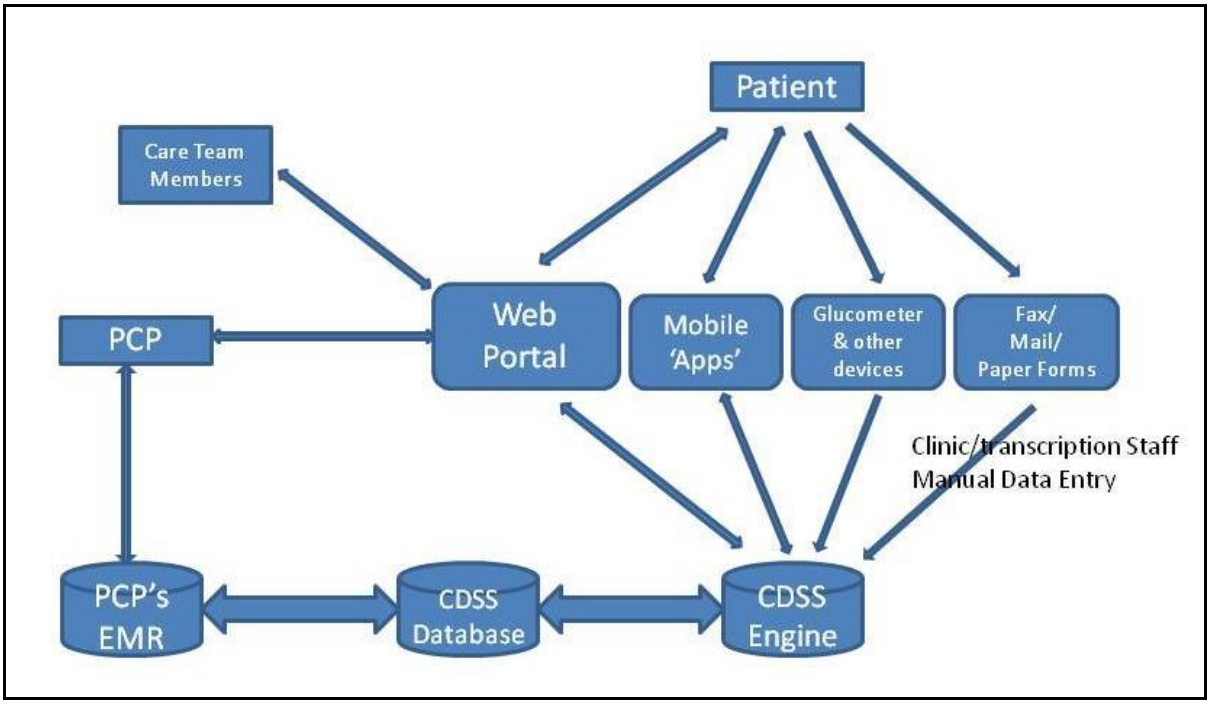

Figure 1. CDSS and its interactions with various systems and stakeholders

As shown in Figure 1, there are several information systems that contribute to the complete solution. The following is a description of the components:

Physician's EMR.

The CDSS will be an adjunct to the physician's EMR system. The EMR system will be the primary point of information input, such as capturing patient registration information, orders, appointments, etc. The CDSS Database will be populated with a set of data extracted in from the physician's EMR using database access tools such as Open Database Connectivity (ODBC).

CDSS Database.

This system will contain the extracted patient information as well as patient and clinician inputted data that will be used by the CDSS Engine.

CDSS Engine and Knowledge Base.

This part of the CDSS is the 'brain' of the system. In addition to the decision logic and processing engine, the knowledge bases such as patient education, diabetes resources, nutrition guidelines, etc. will be housed in this system.

Bundled patient tools.

Patients will have access to a Web Portal to view, track and update their diabetes-related information. For physicians whose EMR includes a patient portal, the Web Portal could be integrated into the patient portal so that patients do not need to log in to multiple systems.

A mobile 'app' version of the Web Portal will be available for patients who prefer this method of access.

Third party applications & devices.

Third party applications and devices such as the Diabetes Pilot desktop software and mobile application, pedometers and glucometers that allow data to be downloaded into the

computer facilitate and encourage patient self-management. The CDSS will provide support for easy uploading of information from these data sources into its database.

Intervention Selection and Workflow Opportunities

Advances in healthcare IT have enabled more real-time interventions in the outpatient setting to the benefit of both patients and clinicians. These advances have become important in the management of many chronic diseases. One example is in the management of a patient with diabetes where the interventions are both time and frequency-dependent. Having a clinical decision support system that involves both the patient and clinician in the management of diabetes and allows each to access the same information at any given time or place has the potential to positively impact the patient's outcomes and management of the disease. This could decrease the frequency and/or severity of complications from diabetes and decrease the costs associated with diabetes management.

A diabetes study performed in Canada under the COMPETE project and published in 2009 was used as a guideline in determining many of the listed opportunities for interventions in the management of diabetes. This project successfully used different communication media such as the web-portal, e-mail, and automated calling to facilitate disease management.

Because self-management is a crucial aspect in controlling diabetes and decreasing complications related to diabetes, providing patients with timely interventions and other resources based on information that they report to their primary care providers will be highly beneficial. This information includes glucose levels, blood pressure measurements when taken outside of a scheduled appointment, weight, level of activity, diet, and other pertinent information. This CDSS will allow patients to easily report these items in a manner that can

prompt an immediate response if necessary based on the information provided (i.e. instructions for treating hypoglycemia if the reported glucose level is too low) and/or alert the primary care provider if urgent attention is necessary.

Table 1 provides details about the workflows or processes and the associated users affected by the CDSS.

Table 1

Affected Processes/Workflows

Process/Workflow	Who is affected?	Action/Activity
Patient Visit	PCP/Case Manager	• Updates EMR with patient's vitals such as BMI, blood pressure, etc. • Reviews info (vitals, lab, most recent activities) and the CDSS' suggested interventions
Periodic review and patient follow-up	PCP/Case Manager	• Review overall patient base for trends in procedures, medication, quality of care (outcomes) and cost • Follow up with newly diagnosed/existing diabetic patients at risk for complications • CDSS detects the results and notifies the clinician of prediabetic patients. • Follow up with prediabetic patients
Receiving of lab results	PCP/Case Manager	• CDSS notifies clinicians if follow-up action needs to be taken.
Patient-initiated Update	PCP/Case Manager	• CDSS notifies clinicians if follow-up action needs to be

		taken.
Blood glucose monitoring	Patient	• Uploads information via web portal or smart-phone app
Patient Communication	Patient	• Receive appointment reminders via preferred option
Lifestyle assistance	Patient	• Nutrition Tracker - Enter daily diet intake via preferred option • Workout tracker – Enter daily activity via preferred option
Monitoring patient status	Other Care Team Member: • Optometrists • Podiatrists • Nephrologists • Endocrinologists • Dietitians/nutritionists • Pharmacists	• Use web portal to review patient's information and perform and document any suggested interventions, if applicable.

Change Management Plan

The implementation of this CDSS intervention will introduce changes in the business workflow and require changes in behavior for the clinical staff and the patient. It can also introduce unintended consequences. Changes in business workflow include the reduction of manual processes such as follow-up phone calls, input of test results, and input of indicators such as blood pressure or glucose. Changes in behavior for the clinical staff include learning to react to the alerts received from the CDSS. An unintended consequence could include a software defect that does not send an alert when the CDSS should. All of the above changes, if introduced without an effective change management plan, can result in the development of resistance to adopting the intervention. To manage the changes this intervention will introduce, the following change plan will be implemented:

Executive support.

The success of the adoption of this CDSS intervention is heavily dependent on the extent to which the leadership is involved. Attention to communication, implementation management, focus on overall goals and a strong commitment from leadership are keys to the success of this implementation. Therefore, early on, the leaders will be engaged with the implementation through the use of an executive steering committee. This group will be responsible for setting the tone for the organization. They will also initiate the planning, assist with the data collection, communicate the strategic direction of the organization and be responsible for providing final approvals regarding the CDSS implementation.

Communication.

Consistent, frequent and multiple channels will be used to share information regarding the status of the CDSS implementation. Channels of communication include in-person delivery, bulletin board memos, videos, intranet and e-mails. These channels will be used to communicate the vision, mission and objectives of the project.

The changes will be shared with all stakeholders to help them to understand how they will be affected. Recognizing that true communication is a "conversation", time will be set aside for group meetings which will allow questions to be asked and for stakeholders to provide input (Jones, 2004). Leaders and key "champions" will be available in-person to address any concerns by staff members. This is especially effective for addressing the concerns of resistors and detractors. Interactive workshops and forums will be held for all stakeholders so that they will have the opportunity to explore the changes together while learning more about the implementation.

Employee involvement.

Stakeholders will be identified throughout the organization and invited to participate in the design and implementation of the system. This will allow the change to cascade throughout the organization. These stakeholders will also be responsible for communicating to their peers to encourage them to learn about the CDSS project. They will provide regular status updates and allow their peers to provide input on various aspects of the system. They will also leverage peer learning and competition through the use of train-the-trainer process post-implementation.

Change steering committee.

Some of the changes introduced by this application will change the workflow of the users and affect their productivity. As they become more familiar with the use of the system, they will identify modifications and enhancements that they will like to have implemented. There may also be defects that are introduced with this change. The method for managing changes to the system will be through the use of a change steering committee (CSC). The CSC will consist of key stakeholders of the system representing the various functional areas of the organization. When users identify possible changes that are needed to the intervention, they will submit a request for change to the CSC. The CSC will then review the request to determine the appropriateness and impact on workflow. Requests that are deemed appropriate will be approved for development and implementation.

System Design, Model

The CDSS that is being suggested will have interactive and non-interactive components. The interactive components respond to input instantaneously and provide decision

recommendations. Non-interactive components of the CDSS provide additional functionality such as periodic reviews of the status of all diabetic patients, lists of prediabetic patients, or reminders to patients for upcoming scheduled appointments.

Interactive parts of the system follow the basic CDSS model found in the literature. (Gong, G. et al., 2008) This model is applicable to both the CDSS used by PCPs and supplemental, personal CDSS used by patients which connects to it and creates a full solution for diabetes care management. The components of the basic model and their functions in the model are listed below:

- Clinical input can be provided by a PCP or a patient. It includes symptoms, lab results, glucose readings by the patient, blood pressure, weight, nutrition details, etc.
- Inference or reasoning engine is a set of rules that uses the provided clinical input, available knowledge base, and defined set of rules to produce decision recommendations.
- Knowledge base is a collection of medical knowledge critical for providing recommendations.
- Recommendations are inputs into the system user regarding diagnoses or treatment options.

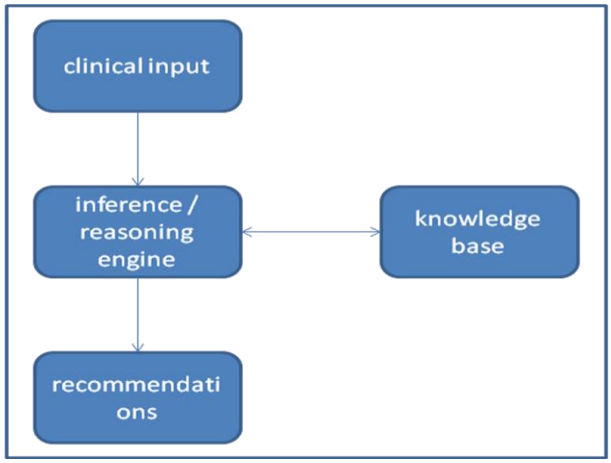

Figure 2. Basic CDS system model.

Design Document and Architecture

It is assumed that the core components of the CDSS including the processing engine, database, and knowledge base have already been developed such that the design document would facilitate the implementation of the system within a practice rather than with building the actual components.

The proposed design document to install and implement the CDSS will consist of the following sections:

Description of the goals, objectives, and scope of the system.

This section will provide a high level overview of what the system is designed to do.

Description of affected stakeholders.

This section will identify the stakeholders and the potential impact of implementing the CDSS.

Change management plans.

This section will provide suggestions on how to manage changes prior to, during and after the CDSS implementation.

Details of the interventions and feedback mechanisms.

This section will contain detailed workflow diagrams and descriptions that will not only help the implementation team understand the interventions involved, but also provide a framework to plan for user training. An example workflow diagram is shown in Figure 3 below.

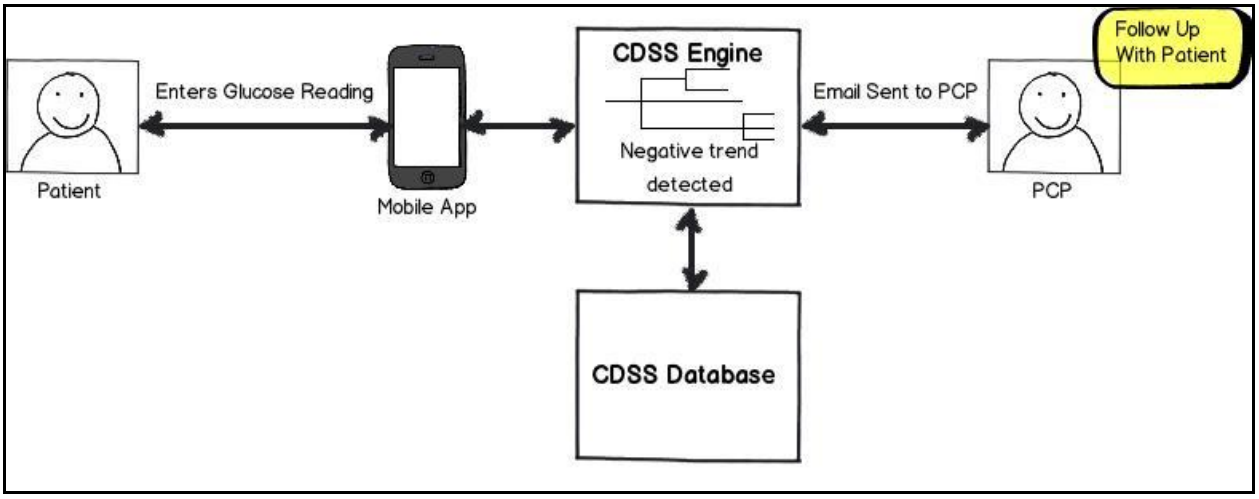

Figure 3. Sample workflow diagram.

Technical specifications.

This section will contain technical details such as:

Architecture.

Information regarding the CDSS' integration with external systems will be given here. For example:

EMR ←→ CDSS Database.

- As previously mentioned, ODBC-type access between physician's EMR and CDSS could be used to provide near real-time flow of information.
- Real-time triggers and transfer of information to and from the EMR could also be supported. For example, other protocols such as Simple Object Access Protocol (SOAP) or HL7 could be included to communicate with EMRs that support these protocols.

Hardware.

- Minimum server and client PC specifications will be based on the estimated number of concurrent users, population size, etc.
- For example, Microsoft Windows Server Operating System running on a desktop PC would probably suffice for a typical small practice whereas a larger practice would be advised to use dedicated server hardware.

Database.

- High level information about the relationship between entities such as patient, visits, diagnosis, plans, interventions, etc.
- Detailed database information such as the field definitions will not be part of this document.

Details on how to test the system.

This section will provide test plan templates for both unit and integration testing. Details such as suggested testing timelines and required resources will be detailed here.

Details on how to evaluate the system's performance.

The CDSS will contain reports that can be used to help the practice track how well the system has helped with improving diabetes measures in patients. This section provides details on how to set up baseline measures before the CDSS goes live and suggests how the practice should use the reports to periodically monitor performance.

Details on system and knowledge assets maintenance.

This section will inform the system administrators regarding the maintenance work required to keep the system running efficiently. Information such as recommended back-up plans and running periodic system diagnostics will be included.

In addition, the CDSS' decision logic (knowledge asset) and processing engine will be routinely updated and released to the practice. Information regarding the system/version upgrade process and suggested risk mitigation steps will be included in this section.

Intervention (Content) Specification

Interventions targeted at diabetes management aim to meet the well-established goals shown in Table 2.

Table 2

Variable, target value and target frequency associated with diabetes management goals

Variable	Target Value	Target Frequency
Visit PCP		3 months
Hemoglobin A1c Level	< 7%	3-6 months
Blood Pressure	< 130/80	3 months
Glucose	< 7.1	Daily/weekly
Lipids	LDL < 2.6 mmol/L	3 months

Kidney Protein	No microalbumuria (< 30 mg/24h)	6-12 months
Smoking	Cessation	3 months
Weight Control	BMI < 27	3 months
Feet Check	No ulcers or neuropathy	6 months
Eye Check	No retinopathy	6-12 months
Immunization	Annual flu shot	12 months, during fall
Medication	As appropriate	

The CDSS will use these goals as a basis to provide PCPs and patients with interventions that will help them meet the targeted criteria. The information content in the CDSS will be comprised of patient information related to the variables, target values, and target frequencies listed above as well as information such as patient home medications and patient diet and activity logs. The interventions will enable the patients and clinicians to collaborate and manage the diabetes proactively, effectively, and efficiently. To do this, certain interventions will be dependent on the clinician and will occur prior to the patient visit and/or during the patient visit. Additionally, the patient will be responsible for input/uploading of relevant information on a daily/weekly basis (such as glucose checks and diet/activity information if those variables require close monitoring due to BMI, kidney function, lipid profile, etc).

Intervention as part of a scheduled office visit.

In addition to suggesting in-office interventions to the clinician, the CDSS will attempt to make the visits more productive and efficient. With the patient's scheduled appointments available in its database, the CDSS will notify patients to take certain pre-visit steps, such as obtaining lab work.

Before a scheduled visit.

- One week prior to the appointment with the PCP, the patient will be reminded via their preferred method of communication (email, phone call, etc) to obtain blood tests so that results are available at the time of the appointment.
- Lab results will be sent to the PCP's office, ideally by electronic transmission. Otherwise, PCP's office staff enters results manually from fax/email.

During the scheduled visit.

- At the beginning of the appointment, the patient's current weight, height, and vital signs will be recorded and input into the EMR. This information will flow, in near real-time, from the EMR to the CDSS.
- The CDSS will analyze the information and give appropriate suggestions and recommendations based on the patient's variables. Figure 4 are example screens that provide information about the patient's current values, target values, recommended actions, and variable trends. User alerts will be limited and will occur only when urgent attention is required for a particular variable.

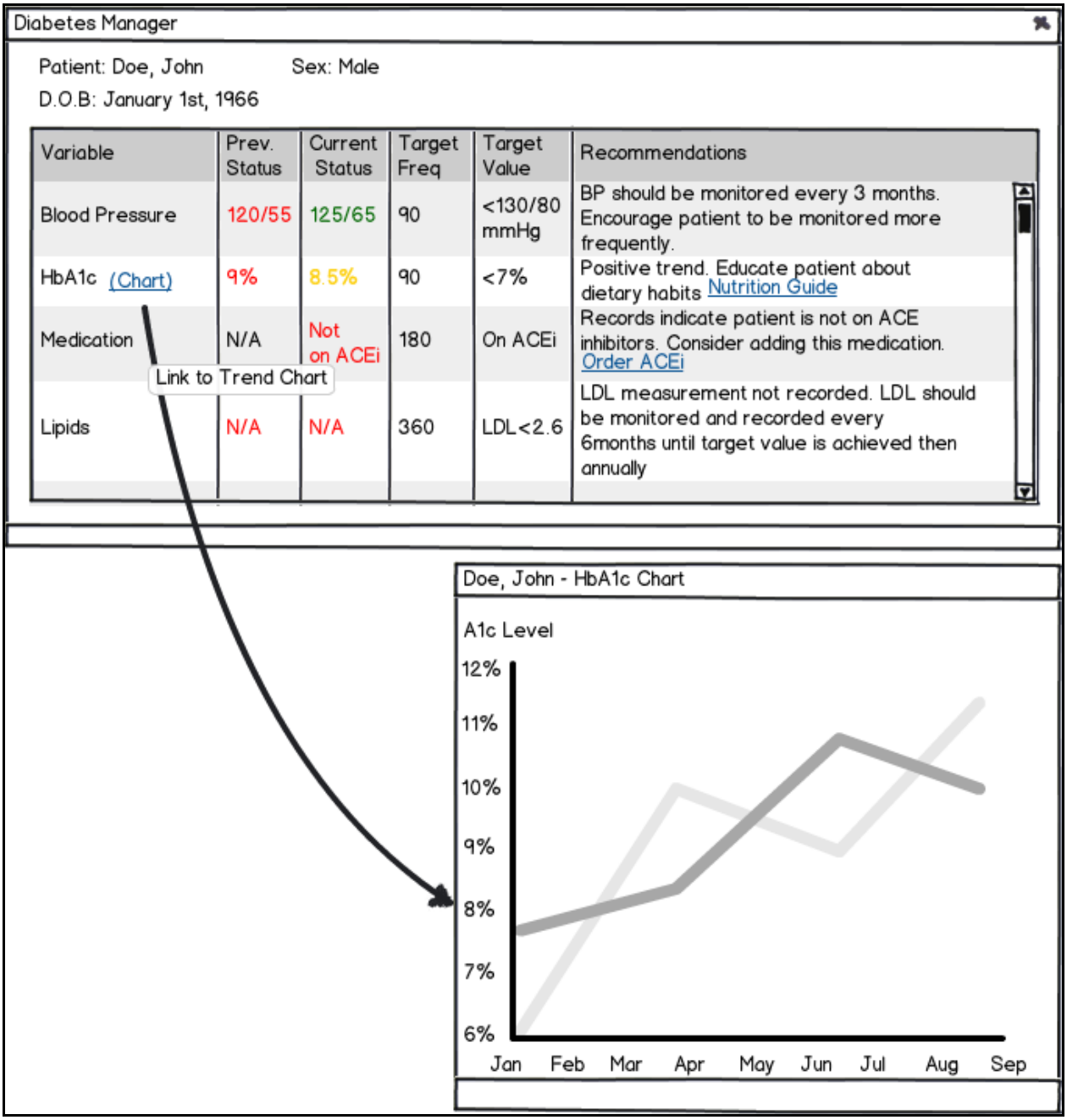

Figure 4. Diabetes goals, target values, recommended actions and Trend Chart.

- PCP reviews suggestions and, if appropriate:
    - Prescribes/changes medications

- Orders education appropriate for the patient (exercise regime, nutrition, etc.), which becomes available in the web portal. Nurses will also provide diabetes education at the time of the visit and as needed.
- Refers patient to foot or eye specialists for annual preventive exams.
- Gives flu immunization shots.

Intervention during periodic reviews.

PCP Performs Weekly or Monthly Review of Diabetic Patients.

- CDSS identifies patients who are at risk or have a negatively trending health status and displays them according to severity. Patient-provided information such as blood pressure and glucose levels will be evaluated by the CDSS.
- PCP reviews the list, shown in Figure 5, to determine which patients require follow-up (other than regularly scheduled appointments).
- PCP reviews CDSS-initiated interventions and updates to patient self-management reported by the patient.

Diabetes Manager

Dr. Natowski's Patient List

ID	Patient	Last Visit	BP	A1c	Glucose	Lipid	BMI	On ACEi	Feet	Eye	Flu Shot	Smoking	Exercise
20	Jones	2/1/2012	140/85	8.5%	5.6	2.05	77Kg (26.62)	Yes	Good	Good	N/A	Yes	<1.5hr /wk
8	Spoon	1/2/2011	130/65	8.1%	6.2	N/A	95Kg (27.71)	Yes	Has ulcers	Good	N/A	No	None
33	Zacks	4/2/2011	135/70	10.0%	8.0	N/A	99Kg (30.66)	No	Has ulcers	Nerve Damage	Up To Date	No	None

Figure 5. Overview of a PCP's list of diabetic patients and their variables.

CDSS identified interventions.

Patient initiated updates.

- The CDSS determines that a patient requires urgent attention based on glucose levels, blood pressure readings, etc. uploaded by the patient. PCP is contacted via preferred communication method.
- PCP reviews the information and notifies clinical representative to contact patient to provide recommendation, adjust medication, and/or schedule a follow-up appointment.

Missing expected patient updates.

- The CDSS stores frequency of expected patient updates and checks whether they have arrived. In case the expected input from the patient is missing, the CDSS creates an alert to staff and sends a reminder to the patient via the preferred communication method.

Weekly or monthly reviews for pre-diabetic patients.

- The CDSS identifies prediabetic patients. As previously described, these are patients who have elevated blood glucose levels (but not high enough to be diagnosed as diabetes). The CDSS could be configured to download - from the EMR - patients fitting these criteria and create a registry of prediabetic for the PCP's review.
- PCP reviews the information and notifies clinical representative to proactively contact patient to provide diet and exercise recommendations, diabetes prevention education, additional diagnostic testing, etc.

User Interface, Patient Self Management

Input required from the user.

The patients will be instructed by their providers to follow recommended self-management steps including regular feedback to the provider using their preferred communication method. The self-management steps and data collected include:

- Obtain glucose reading and record it; the frequency is dependent upon recommendation from the provider.
- Weigh daily or weekly per the recommendation from provider and record weight.
- Get blood pressure and record the results; the frequency is dependent upon recommendation from the provider.
- Take medication as prescribed.
- Record the nutrition and activity daily by the preferred method.
- Send the recorded information to the provider at the agreed-upon frequency.

Prior to visit.

- Provide samples to lab for testing prior to the appointment with PCP. This is in response to patient communication from the CDSS.

Communication to and from the patient.

Communication from the CDSS to patient is scheduled and the schedule is kept within the CDSS. Input from patient is expected at the agreed upon frequency and by one of the accepted methods. Not receiving patient input at the expected schedule triggers a communication from the CDSS to remind patient to send expected input.

Communication between patients and providers has to be flexible to support the various technologies for patient access to the provider. Information can be entered or exchanged with the provider by the Web Portal, smart phone apps, or desktop computer application. For those patients with limited access to electronic communication methods, the option to fax or mail the information on a standard form can be used. A form can then be entered by provider's staff, or automatically read by an optical reader (Hunt et al., 2001).

Web Portal.

The Web Portal provides a summary of patient data and is not only available to the patient, but is also the preferred method for data exchange between multiple providers caring for the patient. The Web Portal is an integral part of the CDSS system. Figure 7 shows the Web Portal page containing prior and upcoming appointments.

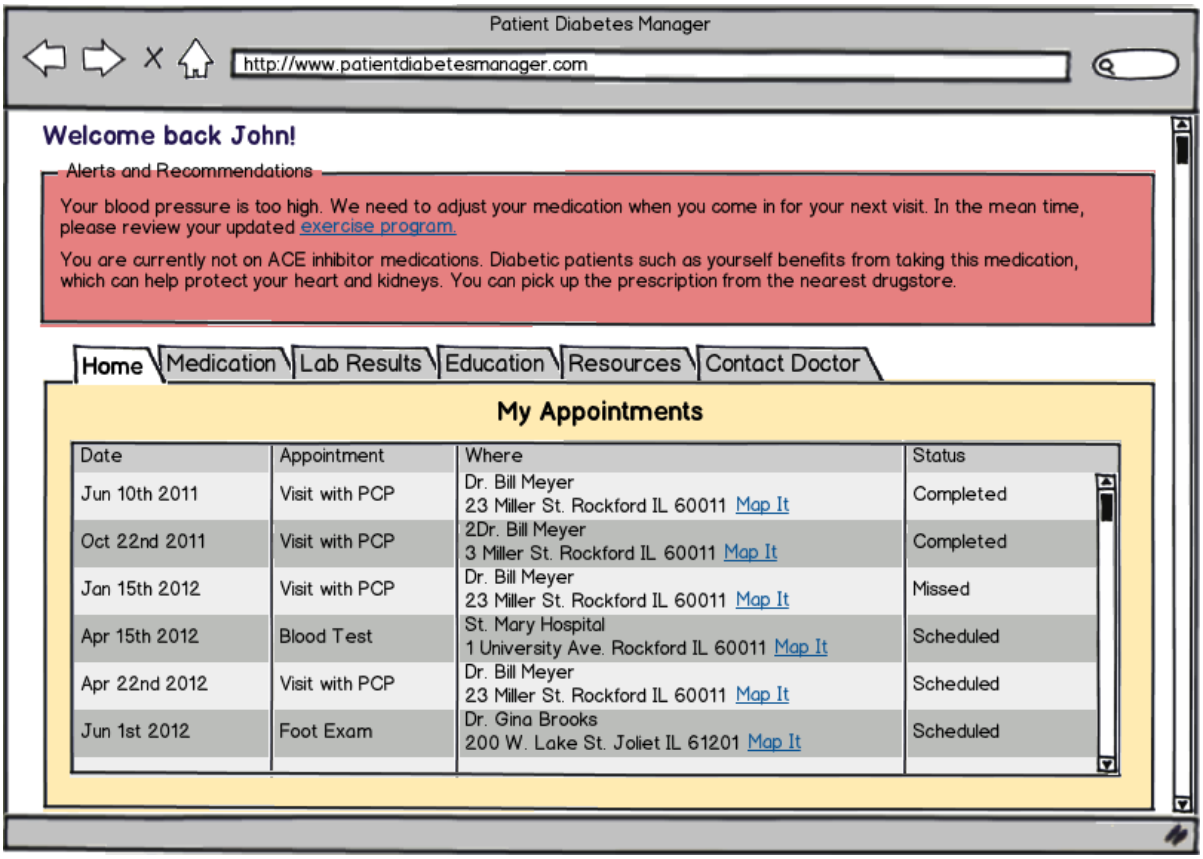

Figure 7. Web Portal home page.

3rd party self-management software.

Commercially available desktop computer applications and smart phone applications provide the patient with a structured environment for collecting and tracking self-management information, access to nutrition tracker and regular updates, daily physical activity tracking and advices, and links to patient communities. Information stored in these apps can be sent to the provider as reports or data files. One example of an application that has both a PC desktop or Mac version and a smart phone version is Diabetes Pilot. Figure 8 is an example screen from the Diabetes Pilot desktop software. Figure 9 are example screens from the Diabetes Pilot smart phone application.

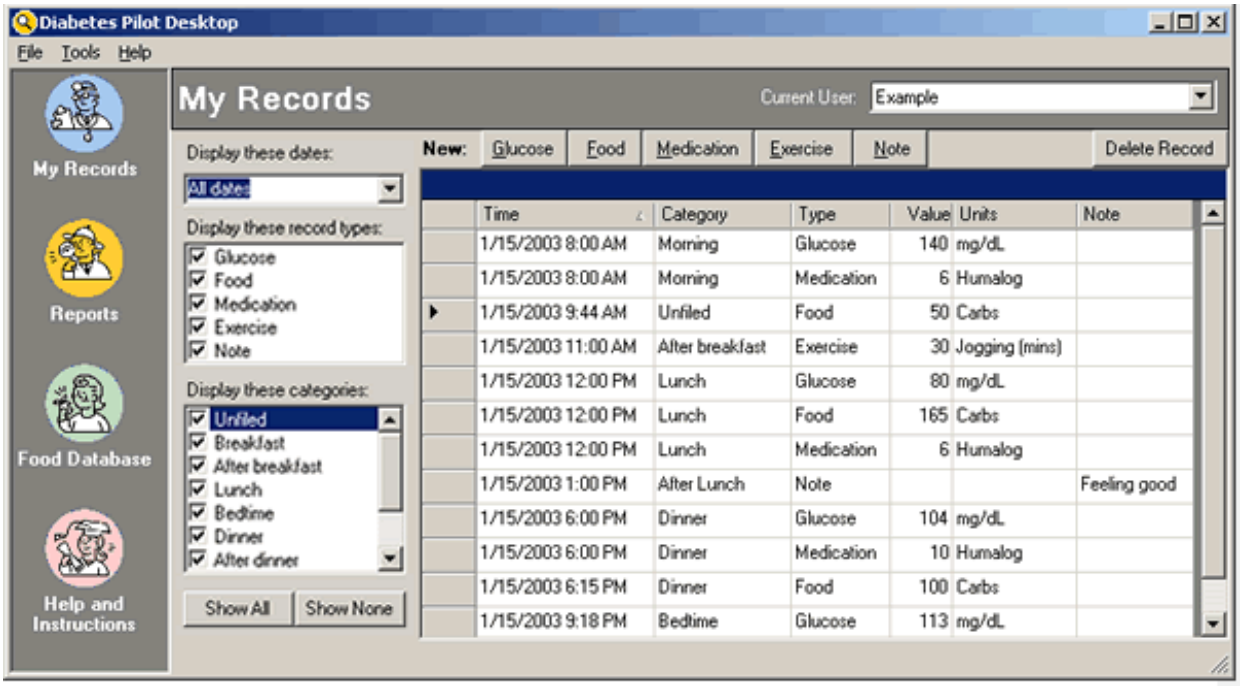

Image copyright: Diabetes Pilot

Figure 8. Diabetes Pilot desktop software.

Image copyright: Diabetes Pilot

Figure 9. Diabetes Pilot smart phone application showing different types of information.

Knowledge Engineering: Clinical Guidelines and Maintaining a Current Knowledge Base

The information and logic for this CDSS will be based on comprehensive diabetes management guidelines such as the *Management of Diabetes Mellitus (DM) Clinical Practice*

Guideline published by the Veteran Affairs and the Department of Defense, and those published by the American Diabetes Association as well as other authorities in diabetes research and management. While the focus of the CDSS is on diabetes mellitus (type 1 and 2), the CDSS is also applicable for the management of patients with prediabetes and complications related to diabetes.

To maintain a current knowledge base, periodic reviews of the clinical guidelines will be performed. Future versions of the CDSS will be released as necessary to incorporate new or updated guidelines and performance measures. Releases will be available on a predefined schedule. A major release reflecting changes in guidelines and recommendations will be yearly, and minor releases will be available quarterly.

The CDSS will also include a commenting tool that clinicians and patients can use to report issues or provide input with regards to the information provided by and the functionalities of the system. These inputs will be monitored and triaged by the CDSS developer for follow up or, if appropriate, incorporate into future releases.

Development of CDSS logic.

The CDSS' decision engine would be built using a tree-type structure. Once the initial decision tree is built using the clinical guidelines, a detailed gap analysis will be conducted using the decision-tree learning algorithm as described by Massoud et al. (2009). This step will identify decision nodes in which there are missing or incomplete clinical and non-clinical treatment recommendations. Once the gaps have been identified, a research team will be tasked with obtaining the missing recommendations using field data. The team will work with medical practices and hospitals to search the charts for patients whose clinical variables (e.g. BMI,

HbA1c, etc.) are a match with the variables associated with the target recommendation gaps. The treatment decisions that were documented for these patients will be compiled and analyzed by the clinical experts. For each recommendation gap, the goal is to find a sufficient number of consistent treatment decisions that have led to improved health status before incorporating the treatment decision into the CDSS.

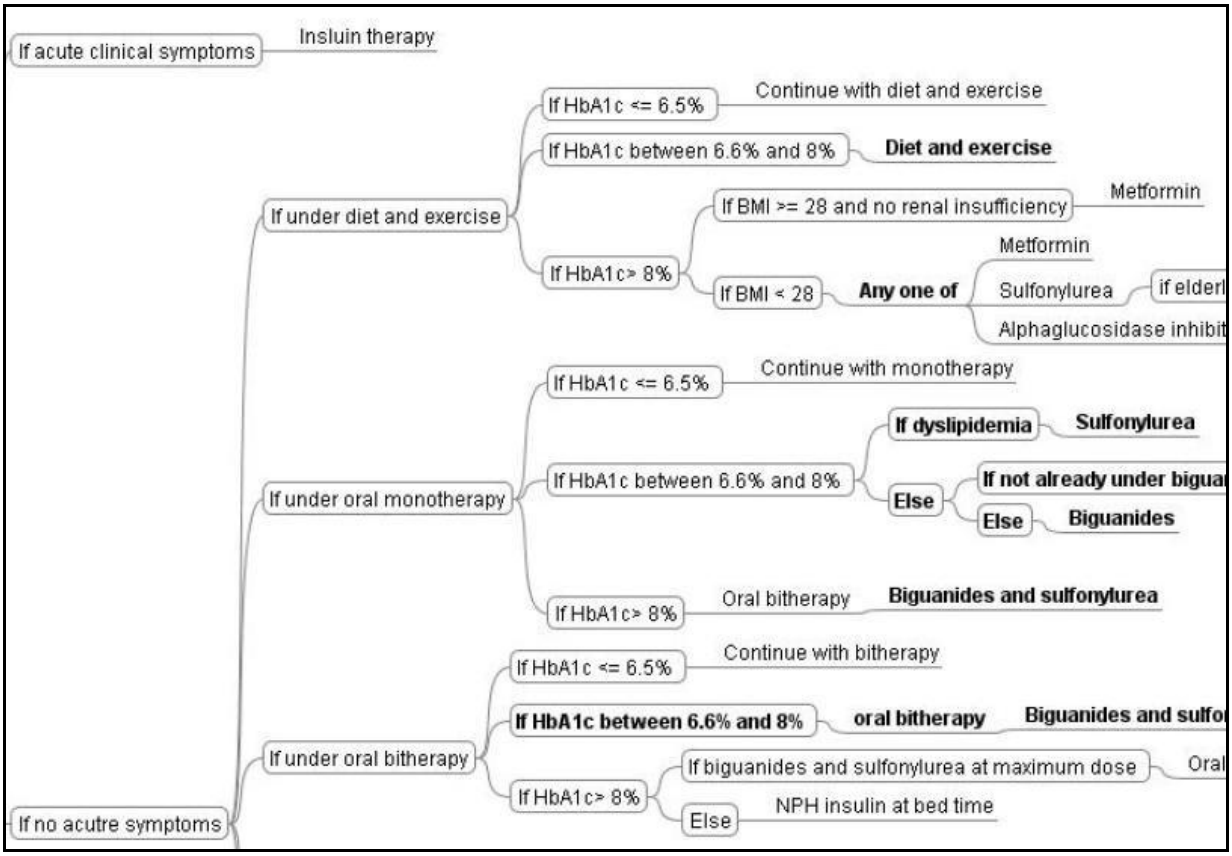

Image copyright: Massoud et al. (2009)

Figure 6. Part of decision tree logic. Bold text represents gaps in recommendations that were filled with treatment information from field data.

Evaluation

During the development of the system and its subsequent releases, various methods need to be applied to test the system. Because this is a clinical decision support system, an input of clinical experts will be required to test usability of the system as a whole and ensure appropriate use of clinical knowledge base and implementation of clinical guidelines and protocols. A prototype will be developed using input from stakeholders, clinical experts, literature, and current users. The prototype will be made available to a selected number of experts to test and evaluate prior to making the system or its release ready for deployment.

After the system has been developed and implemented the results of its use as part of daily work in a PCP practice need to be evaluated in order to not only understand the use of the implemented system, but also to provide valuable information for improvements and evolution of the systems in its future releases. The information will be collected by observing during the system implementation warranty period and via periodic surveys of the users within PCP practices and their patients. The literature suggests that collecting input via unstructured email or phone feedback is not as effective as periodic surveys.

In order to verify the quality of the CDSS, implementation of the expected functionality within a specific workflow and fit for use in a PCP practice it will be important to evaluate whether the system is built and implemented correctly and as intended. Usability of the system will be verified by collecting input on the length of time required for users to be fully trained and use the system without major training issues. This system verification method includes identification of classes of users, functionality each group is using, training they are getting, and a support model. One measure for the usability of the system and effectiveness of training is the

number and type of support calls over a period of time. In addition, improvements in workflow processes and effectiveness of daily work need to be evaluated. Possible measures for this evaluation include number of tasks performed within a period of time, number of tasks expected but not performed, number of tasks introduced by the system, and number of tasks eliminated. The CDSS provides alerts and input for patient communication and collection of patient inputs. Verification will include checking the number of alerts created, number of inputs received, etc. Measures for the assessment of effectiveness of regulatory, internal practice and patient reporting will be included in system verification.

Validation that the implemented system has the right functionality will include the assessment of outcomes in terms of quality of care and cost. One such set of measures is quantitative and includes number of appointments, number of prediabetic patients identified by the system, reduction in number of missed appointments, number of messages generated to remind patients of missing or late input, number of patients using electronic communication methods to log their input, frequency of providing patient input, and cost per diabetic patient for the period of time. Qualitative measures will include overall satisfaction of PCP practice staff and diabetic patients, improved patient understanding of the impact of nutrition choices and exercise on daily glucose levels and blood pressure, improved weight control, and assessment of the motivation for self care.

The assessment of clinical efficacy of the system will include a number of accepted recommendations by PCPs and patients regarding diagnoses and therapy, improvements in information display and availability for PCPs and patients, improvements in creating regulatory

reporting through the use of standardized guidelines and terminology, impact on public health such as numbers of flu shots taken. (Wright, A. 2009)

In addition to clinical content, the overall solution includes patient access to the nutrition, exercise and lifestyle web sites dedicated to patients with diabetes as well as patient blogs. Assessment of the efficacy of this expanded knowledge sharing and interaction on improvements in self-care will be reviewed via periodic structured surveys.

Final comments

The proposed CDSS can be developed based on the current medical knowledge and technology. The proposed system is flexible in terms of accepting input via various channels and technologies and notifying and making information available to the patients. It is designed to leverage third party patient solutions available on the market. A good implementation pilot would be a medical home with a broad patient base and strong presence in the community. This would ensure a reasonable number of users of the system and feedback for the system evaluation.

While the proposed CDSS is modular and will allow users to access the screens from their EMR, it will likely require a fair amount of integration work to implement a complete and robust system. Data exchange between the systems will not be trivial, especially if bi-directional communication is employed. For example, physician users' experience would be enhanced as they could be redirected back into their EMR's order entry screen upon clicking on a suggested medication within the CDSS. In the future, it will be advantageous for a diabetes management CDSS to be an integral part of an EMR system as a bolt-on tightly integrated application. This is the most likely evolution path for such a system. Tight integration will simplify data exchange,

consolidation, and display. The web portal will be an integral part of the single integrated patient web portal out of an EMR system that will contain all relevant patient health information.

Consolidation and standardization of medical vocabularies and codes, expected sometime in the future, will be a strong enabler of the seamless integration of the CDS system and various EMR systems. Data exchange protocols and related legal regulations will make possible easy data exchange between providers, labs, pharmacies, and other healthcare professionals caring for the patient, and automated updates to their EMRs and other systems.

Patient participation will also be a major factor in the success of this CDSS. Without patients' cooperation in providing their input and following recommendations, the burden will fall almost entirely on the providers' part. Because of this, providers must properly educate their patients on the importance of self-management and give them tools that are intuitive to use and are easily accessible. Insurers and the government should also step in to provide incentives for chronic disease patients to take part in management their own health. As previously mentioned, chronic diseases such as diabetes are a major contributor to the high cost of health care in the US. Thus, any effort to moderate the growth in health care cost must include patient self-management.

A complete diabetes CDS system like the one that is being proposed can be a key enabler in improving diabetes chronic care management and patient self management. Because diabetes affects over 8% of the population in the US, this can result in measurable improvements in overall quality of care and healthcare cost.

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