DMA: A Diabetes Disease Management System

by

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ABSTRACT

There is a clear and present need to improve the quality of diabetes care. Information technology can be used as a means to that end. In this article, we discuss the design and implementation of a web-based diabetes application. We show the role of modeling clinical workflow in the design philosophy of our application, and summarize our application’s features and usage. Next, we describe observations made during and after design and implementation, and how they relate to the informatics literature. Finally, we elaborate on the paradigm of feedback control systems, its parallels with the design philosophy of our application, and its use as an organizational framework for the roles of information technology in diabetes care.

INTRODUCTION

There is a clear and present need to improve the quality of diabetes care. Despite its prevalence, morbidity and mortality, compliance with established care standards is low\textsuperscript{1}. The burden of disease that diabetes mellitus exerts on the American population is not trivial; it affects over 12\% of the adult U.S. population\textsuperscript{2}, and costs the U.S. health care system over $100 billion dollars annually\textsuperscript{3}. Type 2 diabetes (i.e. adult-onset diabetes) accounts for the vast majority of cases, and its prevalence has increased alarmingly over the past decade\textsuperscript{4}. Fortunately, there is a plethora of evidence from high-quality, randomized controlled trials that demonstrate how the complications of diabetes can be substantially reduced by aggressive risk factor reduction. National organizations such as the American Diabetes Association (ADA), the National Cholesterol Education Program (NCEP III), and the Joint National Committee on the Prevention, Detection, and
Treatment of High Blood Pressure (JNC VI) have developed clinical practice guidelines on the basis of these trials\(^5\)\(^-\)\(^7\). Unfortunately, despite the compelling evidence that is the basis of national clinical practice guidelines and care standards, compliance with them is low\(^8\). Such is also the case in diabetes care\(^9\)\(^-\)\(^11\). Thus, clearly there is a need to develop and implement methods that can improve the quality of diabetes care. Information technology is one tool that can be, and has been, used to achieve that end. In the next section, we discuss the theoretical and practical justifications for the role of information technology in improving diabetes care; we also briefly review prior efforts to apply information technology to diabetes care.

**BACKGROUND**

The idea of applying information technology is not new. Information technology has been used to support several different aspects of diabetes care\(^12\)\(^-\)\(^21\).

The listing below summarizes the different ways IT has been used (note: this list is not intended to be exhaustive):

**Figure 1: Ways in which information technology has been used in diabetes care.**

- Patient-care provider communication facilitation - oriented applications
- Data registries and collection for quality improvement
- Education
  - Patient education
  - Health care providers
- Decision Support
  - Diet planning
  - Insulin dose adjustment
  - Diabetes therapy (other than insulin) decision support
- Point-of-Care Clinical Information Systems
Recently there has been renewed interest in the last entry of this list – namely, point of care clinical information systems. This may be so for a number of reasons. First, over the past several years, there has been an increased emphasis on evidence based care and quality improvement. Quality improvement is even more of a priority given the recent articles on medical error in the health care industry. Efforts to implement evidence-based care and improve quality require clinical data, data that is best captured by the actual health providers at the point of care; obtaining this data by other means (i.e. billing data, diagnosis codes) is fraught with difficulty. Since diabetes care is a data-intensive process, requiring the acquisition, integration, and synthesis of data over time, the issue of data collection becomes even more vital. Encouraging health care providers to enter clinical data has been a long standing problem in medical informatics. In order to overcome this barrier, there must be benefits from the entered data that are clearly evident to the provider who enters it. Point of care information systems can provide such incentives by providing improved presentations of data.

Another justification for the use of point-of-care systems lies in the limits of human cognitive processing. As was mentioned previously, noncompliance with established care guidelines is prevalent in the care of patients with diabetes. Such noncompliance can be attributed to a number of causes. Among these causes are the following: lack of awareness (of the guidelines), lack of familiarity with the specifics of the guidelines, lack of consensus about what constitutes best practice, lack of outcome expectancy (i.e. that performance of the guideline will actually result in the expected benefit), and external barriers (i.e. time constraints, lack of infrastructure to practically implement the guideline, etc). Time and information processing constraints of care
providers can affect all of the above. Time pressure is often cited by physicians as being responsible for their mistakes\textsuperscript{29}. The information processing capacity of a clinician is finite and not infinitely perfectable\textsuperscript{30}; the peak informational (processing) loads of busy practice settings may overload this finite resource, resulting in an increase in random errors\textsuperscript{30}. Such shortfalls in information processing resources can be compensated for by devoting more time to processing of the relevant data; McDonald suggests that computer-based decision logic can reduce such errors, in part by taking some of this load, thereby freeing up time for the clinician to devote to other processing tasks\textsuperscript{30}. Just-in-time (JIT) information access can reduce the cognitive processing load by relieving the care provider of the task of maintaining an up-to-date inventory of clinically relevant information; they can also save time by aiding the retrieval of specific items from this inventory (i.e. patient specific information) when they are required in the clinical patient encounter\textsuperscript{29,31}. The utility of information being available “just in time” is highlighted by the observation that decision support is most effective in achieving care goals when it is given during the clinical encounter (8,32-35). Automated reminder systems can be viewed as providing “JIT” information access; results from clinical trials demonstrate the effectiveness these systems have in improving compliance with care standards, and reducing error\textsuperscript{1,8,18,20,35-38}. Thus, information overload, compounded by the (very often) limited time available for follow-up clinical visits (typically 15 minutes in many outpatient care facilities), may be an etiologic factor in the noncompliance of diabetes care with established care standards.

Information technology is particularly well-suited to assist in diabetes care, in that the data needed for diabetes management is both objective and quantitative (e.g. LDL
cholesterol, HbA1c, systolic and diastolic blood pressure, date of last foot and eye exam, spot urine albumin to creatinine ratio, etc). In order to investigate these possibilities we designed and built a web-based diabetes disease management application called the DMA (Diabetes Management Application). The effectiveness of this application was evaluated in a 2 year controlled trial, in which this application was an integral part of the intervention. Specific details about the study design and methods of analysis will be described in a forthcoming article by Meigs et al\textsuperscript{39}. What follows next is a description of the goals and methodology behind the design and implementation of the DMA.

**GOALS AND METHODS**

In designing the DMA, we wanted to achieve the following objectives:

1. Create a “just-in-time” web-based application that minimizes information overload by providing a summary “encounter-based” view of clinical information essential at the point of care.

2. Utilize the ability of electronic information technology to collate, integrate, and present data in ways that conventional “wood-pulp”-based technology (i.e. paper) cannot.

3. Incorporate evidence-based care guidelines into clinical data presentation and workflow.

4. Encourage documentation by providing opportunity to review and update clinical information

5. Provide educational resources for both patients and providers.
6. Facilitate the clinical workflow by expediting referral to frequently used consultations (nurse practitioner, eye clinic, podiatry).

In building the DMA, we first devised an overall visual layout for the application. In order to minimize "information overload," a rigorous effort was made to not clutter the "visual real estate" of the web page with nonessential information. We also wanted the visual flow of information to parallel the cognitive workflow of a clinical encounter.

**Web Page Layout**

We envisioned the clinical workflow of the primary care encounter as the following sequence of steps:

1. Review clinical data (including history, physical examination, and laboratory studies).
2. Interpret clinical data and make clinical recommendations
3. Perform necessary actions.

We devised a web page layout that paralleled (spatially) the workflow described above (see diagram below):
The diagram depicted above represents the overall layout of the “encounter view” the physician would see while treating a patient with diabetes. The arrows represent the clinician-user’s flow of attention through the different information areas.

Each of the above areas were broken down into the following specific sections:

1. Trended values: graphical plots of LDL and HbA1C.

2. Last known laboratory values: A listing of laboratory values -- Total, HDL, and LDL cholesterol; serum triglycerides; AST (liver function test); serum BUN and creatinine (renal function tests), urine albumin and microalbumin (tests for proteinuria), and serum glucose.

3. Recommendations: Automated decision support for management of hyperlipidemia, hyperglycemia, hypertension; reminders for yearly eye and foot exams.

4. Patient comorbidity registry: an area to review and update a patient’s comorbid conditions profile (retinopathy, nephropathy, neuropathy, peripheral vascular disease, stroke, coronary artery disease).

5. Action items: An area to schedule referrals for a dilated eye exam, nurse/n.p. visits, podiatry visit, and in addition document the performance of a foot exam.

6. Miscellaneous: other relevant information items, such as patient educational materials.
The content in each of these sections was chosen on the basis of the information requirements needed to comply with the American Diabetes Association (ADA) Annual Practice Recommendations current to that time (i.e. the year 1998)\textsuperscript{40}.

**Data Sources**

The DMA relied on various data sources. The two primary data sources were the COSTAR ambulatory record system and the laboratory information system (PCIS). We had real-time access to the latter, and batch-mode access to the former. The PCIS data source provided all laboratory results. COSTAR is a primary care oriented electronic medical record based on MUMPS (or M), and is used by the IMA (Internal Medical Associates) practices at MGH and other outpatient clinics. The COSTAR ambulatory record in use in the IMA stored information about prior clinical conditions (past medical history), medications, allergies, and physical examination findings. Due to the lack of real-time access to COSTAR at the time of development, we created a relational database (MS SQL Server) storing information about comorbid conditions (retinopathy, nephropathy, neuropathy, peripheral vascular disease, stroke, and coronary artery disease). We then pre-populated this database with information from COSTAR, and henceforth performed periodic batch updates.

**Decision Support**

We designed the DMA to provide decision support for 3 patient-specific guidelines and 2 static reminders. The static recommendations reminded the user (i.e. health care
provider) to have the patient undergo yearly dilated eye exams and foot exams. The three patient-specific guidelines dealt with hypertension, hyperlipidemia, and glycemic control. We derived a logical representation for each of these guidelines. As a starting point we began with the written text recommendations pertinent to each of the above mentioned treatment areas (hypertension, hyperlipidemia, and glycemic control)\textsuperscript{40-42}. We then derived flowchart representations of the logic described in these textual representations. We chose flowcharts as the base logic representation, in part because it was readily understandable and accepted by clinical domain experts. Next, we reviewed the flowchart with clinical domain experts, and made revisions based on their input as well as considerations of computability (coherent logic, available electronic information, etc). This cycle of review and revision was iteratively repeated until a final version was reached that was acceptable on the grounds of clinical accuracy as well as computational feasibility. This process of iterative refinement is not unlike that described by Lobach\textsuperscript{43}. Each patient-specific guideline presented recommendations in a “two level” approach: at the top level (i.e. the DMA encounter screen) a one or two sentence “headline” recommendation was displayed. If the user wanted more information or detail, she/he could click a hyperlink (i.e. “click deeper”) to get more in-depth information. What follows next are implementation details for each of the guidelines (hypertension, hyperlipidemia, and glycemic control).

**Hypertension guideline implementation**

We derived the logic for a hypertension management guideline from published recommendations and standards of care. These included the The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood
Pressure (JNC V)\textsuperscript{42}, the ADA position statement on diabetic nephropathy, and the American Diabetes Association’s consensus statement on the treatment of hypertension in diabetes\textsuperscript{40}. We encountered several challenges in implementing the logic for the hypertension management guideline. First, there was vagueness inherent in the text of the primary sources: JNC VI categorizes patients to some degree, but the categories are not mutually exclusive. In addition, within these categories there is much leeway with regards to what drug class (i.e. beta-blocker, ACE inhibitor, diuretic), and then what medication within a given drug class to use. Second, the information that was available electronically was limited: at the time of implementation, we had access to laboratory data and certain prior medical problems only; we did not have access to blood pressure values or medications data. In the process of repeated review and refinement, we took these constraints into account. In the end, we derived a logical representation of a hypertension treatment guideline that was consistent with published standards and inclusive of local practice preferences (as expressed by the clinical domain experts). It was also able to provide recommendations of varying specificity based on the amount and kinds of information available. The logic of this final form was implemented as inline code embedded into the main application.

**Glycemic control guideline implementation**

The logic specification of the glycemic control guideline was based in part on the standards of care issued by the American Diabetes Association\textsuperscript{40}, and text materials written by diabetologists at MGH. These sources were synthesized into a series of flowcharts, which were then subjected to the iterative cycles of review and refinement
described above. At the end of this process, the final logical specification was well formed and logically consistent, and had sufficient detail to be reasonably deterministic. The main obstacle to fully automating this specification was a lack of sufficient information; the logic depended upon information such as finger stick glucose levels and medication data. We tailored the implementation of the glycemic control guideline logic to the limited information available by utilizing a hybrid automated/non-automated approach. Because we had access to laboratory information -- namely the glycosylated hemoglobin (HbA1C), we were able to display (as the “top level” recommendation) on the main (encounter) screen whether or not the latest HbA1C level met goal levels. If there was no HbA1C value, we prompted the user to check HbA1C at least quarterly. If the user wanted more detailed treatment information, the user would click on a hyperlink which would take the user to a series of static HTML pages linked by HTML FORMs. The answer submitted on the HTML FORM of one page would determine what page the user would be taken to next. The user would continue to answer questions until she/he reached a final definite treatment recommendation.

**Hyperlipidemia guideline implementation**

Of all the three guidelines, the hyperlipidemia guideline was the easiest to convert into and implement in algorithmic form. The logic in the NCEP ATP II (National Cholesterol Education Program Adult Treatment Panel II) guidelines\(^{44}\) was very clearly and exactly specified. We used it as a starting point, and then modified it according to the American Diabetes Association’s position statement on and technical review of the management of dyslipidemia\(^{40}\). In addition, we also incorporated institutional formulary preferences.
Ambiguities such as time interval for follow up in titration of lipid lowering medications were resolved by consensus achieved through the iterative cycles of review and refinement. Of the three guidelines, the hyperlipidemia guideline was the most sophisticated implementation, mainly because of the three it had the most data available to drive it. The hyperlipidemia guideline required laboratory data and data on comorbid conditions (coronary artery disease) – information that was available electronically. As in the other guideline implementations, the hyperlipidemia guideline presented information at two levels: at the top level (i.e. on the main DMA page) the hyperlipidemia guideline would specify whether or not the LDL was at goal level, and if not suggest a medication. If the user wanted more information, she/he could “click deeper” and receive a more detailed recommendation. If no LDL value was available, it would prompt the user to have the LDL checked at least annually. As with the hypertension guideline, the logic was written so that it could cope with missing information, and nevertheless provide recommendations of varying specificity (depending on the amount of information available). For further details on the implementation of this guideline, please refer to [Dubey; Chueh, AMIA Symp 1998 ref].

Scheduling Referrals

In order to facilitate the scheduling of common referrals in diabetes care (to services such as ophthalmology, podiatry, and nurse/nurse practitioner visits), we incorporated into the DMA the ability to print referral forms with the patient’s name, address, and referral destination automatically filled in. To print the referrals, the user would select the appropriate checkboxes and then hit the submit button. The application would then print
out the appropriate pre-filled referral forms on a local printer directly connected to the computer workstation in the care provider’s office. The clinician would then give the referral form to the patient, who would then take to the scheduling secretary.
Architecture

The application was built using the server-side Javascript scripting environment of Microsoft Active Server Pages/Internet Information Server, Microsoft’s XML parser, and a public domain XML/XSL processor. Data retrieval from PCIS was accomplished using middle layer services. Retrieval from the SQL Server was accomplished using ODBC Active-X objects (part of the Microsoft Active Server Pages development platform). Visual graphs of trended data were rendered using a Java graphing applet. The DMA provided decision support for 3 patient-specific guidelines. The hypertension guideline was implemented using Javascript code that was integrated into the DMA application. The hyperglycemia guideline was implemented as a series of linked static HTML FORMs. The hyperlipidemia guideline was implemented as a separate, standalone “guideline engine.” Communication between the main DMA application and the guideline engine was accomplished using HTTP requests. The format of the data passed to and from the guideline engine was XML (extensible Markup Language). For more details about the implementation of the guideline engine, please refer to [Dubey, Chueh, 1998 ref]. A diagram of the architecture of the application appears below:
USAGE DATA

Users of the DMA had to log in with a username and password in order to use the DMA. Whenever a user accessed the DMA web page for a given patient, the user’s username would be mapped to a DMA-specific user id. This user id, along with the date and a unique patient identifier of the patient being viewed (via the DMA web page) was then stored in a usage table. This would only be done once per web session; thus, if the user accessed the DMA web page, went to another web page, and then returned, only one insertion would be made into the usage table. In a similar fashion, whenever a user clicked on a hyperlink for more detailed guideline advice, the DMA inserted into the usage table an entry containing the user id, unique patient identifier, day/time, and the type of detailed guideline advice being accessed.

SYNOPSIS OF STUDY DESIGN

It is beyond the scope of this article to fully discuss the study design, outcome measures, and analytic methods of the clinical trial in which the DMA was evaluated; thus, only a brief summary of the study design will be provided here. The Internal Medicine Associates (IMA) is an adult primary care clinic at Massachusetts General Hospital. It consists of 39 staff physicians, 5 nurse practitioners, and residents/interns supervised by staff physicians. The IMA is divided into 3 teams (for the purposes of managed care risk-sharing and oncall coverage). An intervention group and a control group were selected by coin toss. The intervention and control groups consisted of 12 and 14 staff physicians, respectively. Residents/interns (and their patients) were considered to be members of the same group as their preceptor. The intervention group was given access to the DMA; in addition, 3 educational sessions were held with the staff physicians and nurses in the
intervention group during the intervention period (5/98 thru 4/99). During these sessions, use of the DMA was demonstrated and encouraged. Although residents and interns were given access to the DMA, they were not subjected to the systematic exposure that nurses and staff physicians were exposed to.

**POST STUDY QUESTIONNAIRE DATA**

After the intervention period, a questionnaire inquiring about providers’ attitudes towards clinical guidelines was distributed to all care providers in all teams of the IMA practice. The purpose of this questionnaire was to assess the attitude of care providers toward clinical practice guidelines. Among the questions, ones relevant to our discussion here are listed below:

*Question 1.* How familiar are you with the content of published guidelines for management of the following conditions? (answered on a scale of 1 to 4; 1 = very familiar, 4 = not familiar)

- a. Hypertension
- b. Hypercholesterolemia
- c. Diabetes Mellitus

*Question 2.* For all of your patients with these conditions, please estimate how often you apply all or part of a specific guideline: (answered on a scale of 1 to 4; 1 = always, 4 = never)

- a. Hypertension
- b. Hypercholesterolemia
- c. Diabetes Mellitus

For each of the conditions (i.e. hypertension, hypercholesterolemia, and diabetes mellitus) in the two questions listed above, respondents were asked to answer using a modified Likert scale. The questionnaire was distributed to 119 individuals; 84 responded (response rate 70.6%).

**ANALYSIS METHODS**

The primary focus of this work is the design, implementation, and use of the DMA. Consequently, details regarding the analysis of the trial data will not be discussed here, and may be found elsewhere (Meigs, forthcoming). Usage is defined as the number of patients for whom the DMA was used in a given month divided by the number of
scheduled patients for that month. Confidence intervals were calculated for the proportion breakdown of access to in-depth guideline advice (i.e. “clicks deeper”) using the formula:

\[
95\% \text{ CI (proportion)} = p + - 1.96 \times \text{SQRT}(p \times (1-p)/n)
\]

where \( p \) = the sample proportion, \( n \) = number in the sample, and \( \text{SQRT}(x) \) is the square root of \( x \) (pagano, biostats, p.298).

The answers to the relevant Likert-type items in the questionnaire (listed above) were analyzed as ordinal and as interval data. Descriptive statistics such as mean and standard deviation (treating items as interval data), and frequency distribution/mean rank (treating items as ordinal data) were computed. In comparing the opinions subjects had on the various different guidelines (hypertension, hypercholesterolemia, and diabetes mellitus), since the same subject gave her/his opinion for each of the items in the questionnaire, we analyzed the data as repeated measures. In order to refute the hypothesis that the differences in opinion for the three guidelines may have resulted by chance alone, we performed both parametric (repeated measures ANOVA) and nonparametric (Friedman test) tests. These tests were performed using SPSS and WINKS (Windows Kwikstat) statistical software.
RESULTS

PRELIMINARY ANALYSIS OF TRIAL DATA

The number of hemoglobin A1c tests obtained per year increased significantly in the intervention group (+0.3 tests/year) compared to the control group (-0.04 tests/year, p=0.008), as did the number of LDL cholesterol tests (intervention: +0.2 tests/year, control: +0.01 tests/year, p=0.02). Levels of hemoglobin A1c fell by 0.2 in the intervention group and increased by 0.1 in the control group (p=0.09); proportions of patients with LDL-C <130 mg/dL increased by 20.3% in the intervention group and 10.5% in the control group (p=0.5) Most blood pressure outcomes were similar comparing groups. Proportions of patients with at least one eye exam per year increased slightly more in the intervention group (+5.5%) than in the control group (+1.7%, p=0.5), while proportions of patients with at least one foot exam per year increased significantly in the intervention group (+9.8%) but declined the control group (-0.7%, p =0.003). In this section we will show annotated screen shots of the DMA application. We will also list some of the application’s usage data. Results of the controlled clinical trial are described elsewhere (Meigs et al, forthcoming).

Figure 1 shows the main DMA page. There are four sections. In the upper left portion of the screen there are graphs of trended laboratory values and a list of recent laboratory values. In the upper right portion of the screen there recommendations (decision support) for hyperlipidemia, glycemic control, hypertension, eye and foot care. In the lower right corner there is a registry of comorbid conditions, a place to request referrals to ophthalmology, podiatry, and nursing visits, and a place to document performance of a
foot exam. In the lower left hand corner of the screen are various supporting information resources, including a link to a “patient information sheet’ designed to be printed and given to the patient.
Figure 2 shows the above mentioned divisions schematically:

1. **Trended data and recent laboratory values**
2. **Care guidelines (decision support)**
   - SBP goal: 130-150 mm Hg
   - DBP < 85 mm Hg
   - Treatment options: physician, medication
   - Annual eye exam by an eye care professional is advised.
   - Foot exam at each routine visit is advised.
3. **Patient comorbidities**
   - Retinopathy
   - Nephropathy
4. **Supporting information resources (including patient printout)**

The general idea is that the clinical user would look at each of the sections in sequence.

First, the clinician-user would look at laboratory trends and recent laboratory values.

Next, the user would look at the care guidelines. Third, the clinician would review the list of comorbidities and update/correct the list as needed. If necessary, the clinician would click the checkboxes for one or more referrals. When the user presses submit, the database containing the comorbidity data for the patient would be updated; in addition, any of the requested referrals would be printed on the appropriate form, pre-filled with the necessary information (vital data, requested service).
Figure 3 shows a blow-up of the graphs of trended values.

![Graphs of HBA1C and LDL](image)

Figure 4 shows a blow-up of the listing of last known values:

<table>
<thead>
<tr>
<th>Date</th>
<th>Test</th>
<th>Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/3/99</td>
<td>Hemoglobin A1C</td>
<td>9.60H</td>
<td>3.80-6.40 %</td>
</tr>
<tr>
<td>12/2/99</td>
<td>Total Cholesterol</td>
<td>330</td>
<td>DESIRABLE: &lt;200 mg/dl</td>
</tr>
<tr>
<td>12/2/99</td>
<td>High Density Lipoprotein</td>
<td>34</td>
<td>&gt;34 mg/dl</td>
</tr>
<tr>
<td>7/28/98</td>
<td>Low Density Lipoprotein</td>
<td>141H</td>
<td>&lt;100 mg/dl</td>
</tr>
<tr>
<td>12/2/99</td>
<td>Triglycerides</td>
<td>799</td>
<td>40-150 mg/dl</td>
</tr>
<tr>
<td>12/2/99</td>
<td>SGOT</td>
<td>17</td>
<td>9-25 U/L</td>
</tr>
<tr>
<td>10/7/99</td>
<td>Urine Albumin</td>
<td>NEG</td>
<td>NEG</td>
</tr>
<tr>
<td>4/9/98</td>
<td>Blood Urea Nitrogen</td>
<td>8</td>
<td>8-25 mg/dl</td>
</tr>
<tr>
<td>4/8/98</td>
<td>Serum Creatinine</td>
<td>0.6</td>
<td>0.6-1.5 mg/dl</td>
</tr>
<tr>
<td>11/12/98</td>
<td>Serum Glucose</td>
<td>249</td>
<td>70-110 mg/dL</td>
</tr>
</tbody>
</table>

Figure 5 shows a blow-up of the section containing guideline recommendations:

- LDL exceeds goal of 100. Consider starting atorvastatin.
- Hemoglobin A1C elevated. Initiate or modify drug therapy.
- Blood pressure goals are SBP < 130 and DBP < 85mm Hg.
- Annual eye exam by an eye care professional is advised.
- Foot exam at each routine visit is advised.
If the user wanted more detailed guideline advice, she/he could click on “treatment info” to get a more detailed recommendation. Figure 6 shows the screen containing more detailed hyperlipidemia recommendations:

**RECOMMENDATIONS for DEMO PATIENT1**

Intensification of glycemic control may help reduce hypertriglyceridemia.

If hypertriglyceridemia persists, assess LDL by direct measurement.

The patient may be a candidate for drug therapy.

Atorvastatin would be the most cost effective agent for LDL reduction.

If maximum doses of current regimen have been reached, options include changing to a more potent statin (if possible), combination therapy (such as statin plus gemfibrozil), or referral to lipid clinic. Given elevation of triglyceride level (799 mg/dL), resins should generally be avoided.

Figure 7, 8, and 9 show the successive screens a user might see if he/she clicked on “treatment info” for glycemic control:

**Figure 7 (relevant portion of screen)**

WHAT TYPE OF REGIMEN IS THE PATIENT CURRENTLY ON?

- ☐ no therapy
- ☑ diet and exercise only
- ☐ sulfonylurea only
- ☐ metformin only
- ☐ sulfonylurea and metformin
- ☐ insulin therapy

**Figure 8 (relevant portion of screen)**

WHAT TYPE OF REGIMEN IS THE PATIENT CURRENTLY ON?

- ☐ No insulin or OD injection of intermediate insulin
- ☑ BID injections of intermediate insulin
- ☐ BID intermediate insulin plus regular insulin
Figure 9

Patients on bid NPH Insulin and inadequate metabolic control

Monitor pre-lunch and bedtime glucose levels

If consistently above goal, addition of Regular insulin is recommended.

If only pre-lunch values are abnormal, add Regular insulin to pre-breakfast NPH. If only bedtime values are abnormal (and bedtime occurs > 2 hours after dinner) and a third injection of Regular insulin pre-dinner, if both pre-lunch and bedtime values are abnormal, add Regular insulin both pre-breakfast and pre-dinner.

Start Regular at dose of 0.075 U/kg

Adjust dose(s) weekly

Pre-lunch values:
< 80 decrease dose by 0.025 U/kg
81-120 no change
121-180 increase dose by 0.025 U/kg
> 180 increase dose by 0.05 U/kg

Bedtime values:
< 80 decrease dose by 0.05 U/kg
81-120 decrease dose by 0.025 U/kg
121-180 no change
> 180 increase dose by 0.075 U/kg

Figure 10 shows the section where the user can review and update a patient’s list of comorbidities, select referral forms to print, and document the performance of a foot exam in a clinic visit:

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy</td>
<td>Schedule diabetic eye exam</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>Schedule nurse/np visit</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>Refer to Podiatry</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>Foot Exam Performed Today</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td></td>
</tr>
</tbody>
</table>

Submit | Clear all
Figure 11 shows the section where miscellaneous supporting information materials are listed. What is interesting to note is the “patient information sheet” link. Originally, when the DMA was designed and implemented there was no provision for a page geared specifically towards patients. After the application was introduced in clinical use, some clinicians said they ended up printing out the main DMA screen to give to patients; they asked if it would be possible to have a simplified form of the DMA page, geared to printing out and handing to patients. Figure 12 shows part of the patient information sheet.

Figure 11:

MGH Formulary
Patient Education Materials
Patient’s Information Sheet

Figure 12:

How to improve your sugar control

Eating healthy foods is one of the basic tools of diabetes care. Good blood sugar control protects you from the health problems that diabetes can cause.

The right nutrition plan includes:
- eating the right foods
- eating the right amount of food for your needs
- balancing food intake with exercise and diabetes medicine

The following can help you lower your LDL (bad cholesterol) and raise your HDL (good cholesterol):
- Follow a low cholesterol, low saturated fat, high fiber diet
- Achieve and maintain ideal body weight
- Exercise
- If lipid lowering medication is prescribed, take it as directed.

Average Monthly Blood Sugar = 125 mg/dl.

Your blood sugar has been running high lately... Find out more about what you can do to keep your blood sugar under control.

Your LDL cholesterol has been running high lately... Find out more about what you can do to keep your cholesterol levels under control.

GENERAL RECOMMENDATIONS

1. You should have an eye exam by an eye care professional once every year.
2. Ask your doctor or nurse to check your feet at each visit.
3. Ask your doctor or nurse for foot care information.
4. Taking your medicines exactly as your doctor or nurse has prescribed will help prevent complications of diabetes.
## Usage Data

### Table 1 Usage data between from 5/98 thru 5/99

<table>
<thead>
<tr>
<th></th>
<th>Absolute amount</th>
<th>Relative to number of scheduled patients</th>
<th>Relative to # DMA page hits</th>
<th>Relative to # of clicks deeper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of scheduled patients</td>
<td>2817</td>
<td>1.00</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Total number of DMA page hits (on scheduled patients)</td>
<td>854</td>
<td>30.3%</td>
<td>1.00</td>
<td>--</td>
</tr>
<tr>
<td>Total number of referral printouts</td>
<td>24</td>
<td>0.852%</td>
<td>2.81%</td>
<td>--</td>
</tr>
<tr>
<td>Total number of patient comorbidity info updates</td>
<td>285</td>
<td>10.1%</td>
<td>33.4%</td>
<td>--</td>
</tr>
<tr>
<td>Total number of clicks deeper</td>
<td>59</td>
<td>2.09%</td>
<td>6.91%</td>
<td>1.00</td>
</tr>
<tr>
<td>Number of clicks deeper for hyperlipidemia</td>
<td>18</td>
<td>0.640%</td>
<td>2.11%</td>
<td>30.5% (20.2-43.2)</td>
</tr>
<tr>
<td>Number of clicks deeper for hypertension</td>
<td>5</td>
<td>0.177%</td>
<td>0.585%</td>
<td>8.5% (3.7-18.4)</td>
</tr>
<tr>
<td>Number of clicks deeper for glycemic control</td>
<td>36</td>
<td>1.28%</td>
<td>4.22%</td>
<td>61.0% (3.7-18.4)</td>
</tr>
</tbody>
</table>

Summary usage data is listed in table 1. On average, during the period from 5/98 thru 5/99, the DMA was used in 30.3% of scheduled patient visits. When providers used the application (i.e. accessed, or “hit” the web page), they updated the patient’s comorbidity data profile 33.4% of the time. However, they “clicked deeper” (i.e. clicked the “treatment info” link to more detailed guideline recommendations) only 6.9% of the time. When people “clicked deeper” to get more detailed guideline advice, they accessed the glycemic guideline 61% of the time, the hyperlipidemia guideline 30.5% of the time, and the hyperlipidemia guideline only 8.5% of the time. The relative use of each of the guidelines is depicted in Chart #1.
The least commonly used feature of the DMA was the printing of referrals: of all the times the DMA was used, this feature was used only 2.8% of the time.

Chart 2 demonstrates use of the DMA over time. In this chart the x axis represents time, and the y axis represents the % time the DMA was used on scheduled patients (for that month).

The period of the study was from May 98 thru April 99; during that time use of the application was encouraged by study personnel. This chart graphs usage from May 98 thru December 99. Use of the DMA dropped significantly after the end of the study period: From 5/98 thru to 4/99, the DMA was used on average around 33% (32.7%) of all scheduled patient visits; from 5/99 thru to 12/99, the DMA was on average around 7% (7.11%) of all scheduled patient visits.
Table 2: Frequency distribution of items for question #1 of post study questionnaire.

<table>
<thead>
<tr>
<th>item</th>
<th>hypertension</th>
<th>hypercholesterolemia</th>
<th>Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>33 (39.3%)</td>
<td>43 (51.2%)</td>
<td>21 (25%)</td>
</tr>
<tr>
<td>2</td>
<td>40 (47.6%)</td>
<td>37 (44.0%)</td>
<td>45 (53.6%)</td>
</tr>
<tr>
<td>3</td>
<td>10 (11.9%)</td>
<td>3 (3.6%)</td>
<td>17 (20.2%)</td>
</tr>
<tr>
<td>4</td>
<td>1 (1.2%)</td>
<td>1 (1.2%)</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>Mean</td>
<td>1.75</td>
<td>1.55</td>
<td>1.98</td>
</tr>
<tr>
<td>S.D.</td>
<td>0.7092</td>
<td>0.629</td>
<td>0.711</td>
</tr>
<tr>
<td>Mean rank</td>
<td>1.98</td>
<td>1.71</td>
<td>2.31</td>
</tr>
</tbody>
</table>

Table 3: Frequency distribution of items for question #2 of post study questionnaire.

<table>
<thead>
<tr>
<th>item</th>
<th>hypertension</th>
<th>hypercholesterolemia</th>
<th>Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15 (17.9%)</td>
<td>20 (23.8%)</td>
<td>12 (14.3%)</td>
</tr>
<tr>
<td>2</td>
<td>57 (67.9%)</td>
<td>56 (66.7%)</td>
<td>59 (70.2%)</td>
</tr>
<tr>
<td>3</td>
<td>11 (13.1%)</td>
<td>7 (8.3%)</td>
<td>11 (13.1%)</td>
</tr>
<tr>
<td>4</td>
<td>1 (1.2%)</td>
<td>1 (1.2%)</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Mean</td>
<td>1.98</td>
<td>1.87</td>
<td>2.04</td>
</tr>
<tr>
<td>S.D.</td>
<td>0.601</td>
<td>0.597</td>
<td>0.610</td>
</tr>
<tr>
<td>Mean rank</td>
<td>2.01</td>
<td>1.89</td>
<td>2.11</td>
</tr>
</tbody>
</table>

Table 4: Parametric (repeated measures ANOVA) and nonparametric tests for homogeneity of answers to questions 1 and 2

<table>
<thead>
<tr>
<th></th>
<th>Repeated measures ANOVA</th>
<th>Friedman Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question #1</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Question #2</td>
<td>p &lt; 0.037</td>
<td>p &lt; 0.027</td>
</tr>
</tbody>
</table>

Tables 2 and 3 present the frequency distributions and summary statistics for questions 1 and 2 from the post study questionnaire. Table 4 presents the results of parametric and nonparametric tests used to refute the null hypothesis that the differences observed in the mean and mean rank among the three guidelines areas are due to chance (i.e. that there is no difference among the mean and mean ranks of the three guideline areas).
DISCUSSION

Observations from the usage data

One can glean several qualitative observations from the above usage data. One interesting trend was that when clinicians were actually using the application, close to 30% of the time they were not averse to entering/updating data (i.e. the patient’s comorbidity profile). Quality improvement requires good data, some of which is best acquired at the point of care. The article by Bloomgarden suggests that health care providers need to be motivated to collect data at the point of care, and that computer applications that improve data presentation and workflow efficiency may be a means to that end\textsuperscript{23}. Our usage data regarding data entry is consistent with this hypothesis. Another interesting observation was that very few people used the referral form printing function of the DMA. This may have been because the functionality of automatically printing pre-filled referral forms conferred minimal "added value" over the manually filled form; regardless of how the form was produced it still had to be (manually) given to the scheduling person.

The usage data shows some interesting findings. First, care providers "clicked deeper" on the guideline-related hyperlinks infrequently – roughly only 7% of the time (when the initial DMA page was loaded). Given such infrequent access, it may be prudent to display the most important information at the topmost level of the web-based application. The differences observed in proportional use of detailed guideline advice seems to be significant, in that the 95% confidence intervals do not overlap. The pattern observed in the breakdown of "clicks deeper" was unexpected: of all the dynamic guidelines, the glycemic guideline required the most user input in order to provide detailed guideline
advice – and yet it was the detailed guideline resource most commonly used. The most sophisticated of the guidelines – the hypercholesterolemia guideline – required the least user input and provided the most specific advice; however, it was the second most commonly used detailed guideline resource. The fact that the hypertension guideline was the least used resource is not entirely unexpected; unlike the other 2 guidelines, where the application had enough information to flag on the main level whether or not the patient was meeting care parameters – the absence of electronically available blood pressure data made such flagging on the main level DMA screen impossible. There are other reasons that potentially could account for the above mentioned trends. One possibility may be that, relative to the management of hypertension and elevated lipids, glycemic management is more complicated. Another possibility may be that problems and issues related to glycemic management may come up in primary care practice more often than those related to elevated lipids and/or blood pressure. Third, of all three treatment areas, perhaps care providers are least familiar with the care guidelines and management of hyperglycemia.

The last mentioned possibility seems to be consistent with the data from question #1 of the post-intervention questionnaire. Question #1 examined respondents’ familiarity with guideline content in three areas (hypertension, hypercholesterolemia, and diabetes mellitus). Using a modified Likert scale, a value of 1 indicates the most familiarity and 4 the least familiarity. Arranging the mean scores from lowest to highest, one gets the following:

hypercholesterolemia < hypertension < diabetes
Thus, it would seem that respondents were most familiar with the cholesterol guideline content and least familiar with the guideline content related to diabetes. The differences in the mean scores and mean ranks among the hypertension, diabetes, and hypercholesterolemia guidelines appear to be statistically significance – both the parametric and non-parametric tests yielded similar and consistent results.

Question #2 inquired about how often respondents felt they applied certain care guidelines in caring for patients for whom such guidelines were applicable. A score of 1 meant always and a score of 4 meant never. Arranging the mean scores from lowest to highest, one gets:

\[ \text{hypercholesterolemia} < \text{hypertension} < \text{diabetes} \]

Thus, it appears that respondents felt they used the cholesterol guideline the most often, and diabetes guidelines the least often, with the hypertension guideline use being somewhere in between. The differences among the mean scores for question #2 were statistically significant. These results appear to be consistent with those from question 1: it makes sense that respondents were most familiar with the guideline they applied the most (and likewise, that they were least familiar with the guideline they used the least).

In making these interpretations, one must keep in mind that the group surveyed in the questionnaire is a superset of those in the intervention group. In addition, although the differences in proportional use of the 3 guidelines seem to be statistically significant, one must keep in mind that the number of “clicks deeper” was a small number – only 6.9% of total web page hits to the DMA application. Nevertheless, the results of our analyses
suggest that utilization by users of hyperlinked guideline content may be related to how familiar the users are with the guideline content.

Thus, given the infrequent use of hyperlinked guideline content (~7%), it may be prudent to present important information to the user as quickly as possible -- “one click away” may be “one click too far.” Second, use of hyperlinked guideline content may be less related to dependence on user input and sophistication of implementation and more to the information needs of the end users.

**Relation of the DMA to other published works**

Others have commented on features and functionalities deemed to be essential for successful clinical application of information technology (both generally and in the specific case of diabetes care). In a workshop report titled “A Role for Computers in Diabetes Care,” C.D. Williams and others summarize the results of meetings where participants attempted to derive a functional specification for a diabetes-care specific information system via consensus. This group thought the following list of functionalities was desirable in a diabetes clinic management application:

1. **Data storage**
   -- storage of relevant patient data
2. **Register of patients with diabetes**
   -- list of patients, along with demographic data
3. **Summaries**
   -- clear and concise summary of clinical information relevant to a clinical care encounter
4. **Letters**
   -- generation of patient-specific correspondence, to be sent to patients and other clinicians.
5. **Reports**
   -- ability to perform queries on aggregated patient data
6. **Prompts and patient recall**
-- automated prompts reminding care providers to perform preventive care and/or contact patients at risk to be lost to follow-up.

7. **Audit**
-- ability to compile and process information necessary for quality assessment and improvement.

8. **Research**
-- ability to collect information to aid in clinical research (i.e. for selection of patients for clinical trials, data mining, observational studies, etc).

9. **Data entry**
-- fast and accurate data entry

10. **Appointments System**
-- a system to track and schedule appointments

11. **Back-up and system support**
-- ability to restore data and maintain functions essential to the operation of a clinical practice in the event of hardware/software failure; ability to remedy such failures in a timely fashion.

This inventory of desirable and essential capabilities was compiled in 1988, 10 years before the implementation of the DMA. Although it was not designed with these criteria explicitly in mind, the DMA is able to perform (to some degree) 5 out of the 11 functions (data storage, register of patients, clinical summaries, prompts, and data entry). In an article published after the implementation of the DMA, Shiffman et al describe an Information Management Services Model for the successful integration of automated guidelines into real-life clinical workflows\(^{34}\). This model identifies 8 services that promote such integration. They are:

1. **Recommendation**: the provision of patient-specific, “just in time” guideline advice.
2. **Documentation**: the collection of relevant clinical information.
3. **Explanation**: the provision of background and supporting information/evidence/literature for the given “just in time” advice.
4. **Presentation**: the creation of displays of information that facilitates comprehension and processing of relevant clinical data.
5. **Registration:** the recording and storage of demographic and administrative data.
6. **Communication:** services that facilitate electronic exchange of information among care providers and other related entities (i.e. clinical laboratories, administration, etc).
7. **Calculation:** the derivation of useful information from primary clinical data via computation and other kinds of information processing.
8. **Aggregation:** the derivation of population-based information (such as quality assessments, outcomes, cost of care, etc) from individual patient data.

Although the DMA was built before this publication, it supports (to some degree) several of these services. The DMA provides guideline recommendations that are as specific to the patient as possible (given constraints of available electronic information). It facilitates documentation, albeit crudely, by allowing the user to record and update patient information. It supports explanation by listing the data values on which a recommendation is based, as well as hyperlinks to justification of the recommendation's rationale. The DMA gives an encounter-based “presentation” of information to facilitate care by providing graphs of trended values over time (LDL, HbA1C), a list of last known laboratory values relevant to diabetes medication management, guideline advice, and a summary of comorbidities. It also provides a view of information geared towards the patient (the patient information sheet). The DMA supports registration in the sense that it maintains a list of “enrolled” patients that clinicians and other care providers can add to. The automated printout of referrals can be considered to be a kind of communication service: however, it was rarely used, and supported pulp-based (i.e. paper) rather than electronic exchange of information.
The Design of the DMA, the role of IT in diabetes care, and the paradigm of feedback control systems.

The process of diabetes care itself fits very well within a paradigm that is omnipresent throughout both engineering and nature – namely, the paradigm of feedback control systems. In his article titled “The Promise of Computerized Feedback Systems for Diabetes Care,” McDonald describes how the concept of feedback control system can be usefully applied in developing computer decision support applications for diabetes care. A feedback control system performs 3 tasks: First, it gathers information. Second, it processes that information, in order to make decisions about what actions to take. Third, the actions decided upon are taken. After the actions are performed, the feedback control system checks to see if the action has resulted in the desired outcome; in order to do this, this cycle of 3 tasks is repeated, again and again, and so on. This process is diagrammed below:

1. Gather Information
2. Make Decision
3. Take Action

The workflow of diabetes disease management (both at the individual patient and population-wide level) can be expressed in terms of this three-step process, by grouping the tasks in accordance with each of these steps. An example of such a grouping is depicted below:
With this grouping of tasks, for each step (and its associated tasks) one can systematically identify areas where information technology may be usefully applied. A grouping of identified roles for information technology is depicted below:
In designing the DMA, we wanted to develop an application that would integrate with the workflow of clinicians as seamlessly as possible (given realistic and pragmatic constraints). In doing so we concurrently addressed each of the 3 steps of the process detailed above. In incorporating various functionalities for each of the steps listed above, we explored one of several potential applications of IT in diabetes care. The roles of other prior IT applications in diabetes care can also grouped according to the steps in the feedback control paradigm. The paradigm of feedback control systems can help guide the systematic development and exploration of other diabetes related IT applications. The

<table>
<thead>
<tr>
<th>Individual patient level</th>
<th>Data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Electronic Medical Record functionality.</td>
</tr>
<tr>
<td></td>
<td>• Provider data entry</td>
</tr>
<tr>
<td></td>
<td>• Online access to ancillary data (laboratory tests)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population-wide level</th>
<th>Data aggregation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Electronic capture of patient clinical and demographic data (for panels and populations of patients)</td>
</tr>
<tr>
<td></td>
<td>• Electronic capture of interventions of care providers (medications prescribed, referrals made, etc).</td>
</tr>
<tr>
<td></td>
<td>• Online access to laboratory values and other relevant outcomes data.</td>
</tr>
<tr>
<td></td>
<td>• Online access to health service utilization (outpatient visits, inpatient visits).</td>
</tr>
<tr>
<td></td>
<td>• Online access to billing and other costs data</td>
</tr>
<tr>
<td></td>
<td>• Using data mentioned above to create research databases and clinical patient registries.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical decision making</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Automated clinical algorithms</td>
</tr>
<tr>
<td>• Automated reminders</td>
</tr>
<tr>
<td>• Graphic display of trended values</td>
</tr>
<tr>
<td>• A summary, “just-in-time” view of the patient’s clinical data, integrating data from multiple sources, over time</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Facilitate scheduling of referrals (via printing pre-filled referral forms)</td>
</tr>
<tr>
<td>• Facilitate patient education (by providing access to general resources as well as patient-specific educational materials).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Real-time analysis and determination of aggregate measures of quality, compliance with established care parameters, costs and cost/benefit.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality improvement intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Electronic communication (e-mail, list servers, etc).</td>
</tr>
<tr>
<td>• Electronic interchange of clinical data sets of entire patient populations.</td>
</tr>
</tbody>
</table>
feedback control paradigm embodied in the DMA is at the level of individual patients; one can also use this paradigm on a population based level. Such a level is alluded to in the list of desirable and essential functions described by Williams\textsuperscript{45} and Shiffman\textsuperscript{34}. Currently we are exploring the potential applications of information technology in diabetes care on a population level basis.
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