In Brief

Although cardiovascular disease (CVD) is the major cause of mortality in people with type 2 diabetes, CVD risk factors are undertreated in this population. The communication of individualized CVD risk to patients before clinical encounters may facilitate the discussion of CVD risk between patients and health care providers and lead to more timely therapeutic intensification. This article presents a CVD risk communication intervention designed for an urban primary care population, utilizing an electronic health record system. Preliminary analyses indicate that the intervention increases the likelihood of patients discussing CVD risk with their physicians and makes it easier for them to participate in these discussions.

Project RedCar: Cardiovascular Disease Risk Communication for People With Type 2 Diabetes

Combining the Power of Electronic Health Records and Computer-Based Multimedia Technology

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Providing diabetes patients with information about their disease status and involving them in decisions regarding their own care—an approach referred to as shared decision making—can improve clinical outcomes and both patient and provider satisfaction with care.[1,2] However, the rapid pace of workflow, large caseloads, limited time during clinical encounters, and a wide variance in patients' cognitive abilities and literacy levels are all barriers to effective patient-provider interactions in the outpatient setting. These barriers can be addressed by combining interactive computer technology with data obtained from electronic health records (EHRs) to provide patients with personalized health information before their clinical encounters.[3–5]

The presentation of personalized CVD risk information to people with type 2 diabetes provides an ideal context for facilitating health communication for a number of reasons.

First, CVD among people with type 2 diabetes is a major public health problem with staggering social and economic costs. Almost 24 million people in the United States have been diagnosed with diabetes (8% of the population and 23% of all people ≥ 60 years of age), and the incidence of type 2 diabetes continues to rise annually.[6] Eighty percent of people with type 2 diabetes will develop CVD, and up to 80% will die from it.[7,8] From an economic perspective, the costs associated with macrovascular disease are 10 times those for microvascular disease.[8]

Second, highly effective therapies are available to address the four major modifiable CVD risk factors: hyperlipidemia, hypertension, hyperglycemia, and smoking. Despite the demonstrated efficacy of multiple CVD risk factor control, therapies to reduce CVD risk factors are underutilized; a mere 7% of people with diabetes are meeting treatment goals for the primary modifiable CVD risk factors.[9,10]

Third, CVD risk can be estimated using readily available medical information. The increasing use of EHRs allows this information to be easily ascertained for an entire clinic population. Equations have been published for the estimation of CVD risk in both diabetic and nondiabetic populations; these can be applied to clinical data to provide risk estimates for clinic populations.[11,12]

Fourth, patients with type 2 diabetes lack sufficient knowledge about their CVD risk status. The majority of people with diabetes are unaware that they are at increased risk for CVD.[7] Additionally, patients in general typically have an inappropriately optimisitic bias with respect to CVD risk, especially those from lower socioeconomic status (SES) and minority populations who are at higher risk for both diabetes and CVD.[13–15] Patients are more likely to agree with and adhere to therapeutic recommendations if they understand the nature and magnitude of their risk and if they know that effective therapeutic options are available to reduce that risk.[16] Several studies have shown that CVD risk communication is associated with increased risk reduction efforts on the part of both patients and providers.[17–19]

Fifth, failure to achieve treatment targets for CVD risk factors may be the result of clinical inertia on the part of physicians (i.e., recognition of a problem but failure to act on it).[20–22] Moreover, health professionals are not accurate in their assessment of absolute CVD risk in the absence of an algorithm for CVD risk assessment.[23] Physicians may feel more compelled to intensify therapy when presented with patients' risk information and if patients independently express appropriate concern regarding their risk status and an interest in their treatment plan.[1,2,18]

We have developed a tablet computer-based health promotion tool designed to facilitate communication between patients and primary care providers about CVD risk. The tool uses multimedia technology to educate patients with type 2 diabetes about their personal CVD risk, explain therapeutic options, and most importantly, motivate them to discuss therapy options with their provider. The program software incorporates personalized health information from the EHR to create personalized risk messages. Effective interaction with the tool does not require computer skills.

The graphics capabilities of interactive multimedia permit the creation of vivid and engaging risk-related messages through digital video, animation, sound, and text, and these message characteristics have been shown to modify risk perception in at-risk individuals.[14]

The ability of the tablet computer multimedia presentation to integrate case histories and testimonials into the risk presentation is an especially helpful feature. Case histories have been shown to be more persuasive than similar information presented as statistics or didactic facts, and the quality of exemplars has been shown to have a strong effect on one's view of the importance of a problem.[13,14] Testimonials can be tailored to the sex and ethnic background of each patient.

Patients interact with the computer-based program just before visits with their primary care providers so they are informed and activated to discuss risk reduction during their clinical encounters.

We elected to study the efficacy of this intervention in an urban, low-SES population. Our multimedia presentations have been specifically tailored to the needs of those with low literacy and SES, a population with an increased prevalence of diabetes and an increased likelihood for underestimating their health risk.[15] Interventions that increase communication, improve access to health information, and transfer knowledge to actions are likely to reduce the negative impact of low literacy on patients' access to and use of health services.[24]

Methods

We first developed a library of multimedia modules centered on various topics and published approaches to risk communication.[13,14,25–29] Risk metaphors, risk graphics, and narrative content were piloted with small numbers of patients during the development of the modular content.

The intervention is designed to begin with the viewing of an initial Core Module at the first encounter, followed by a series of topic-specific modules at subsequent clinic visits.

The Core Module, which is ~ 10 minutes in duration, is the centerpiece of the multimedia library and is shown at Visit 1 in the present study. The software calculates and displays individual 10-year CVD risk using risk equations from the U.K. Prospective Diabetes Study (UKPDS)[12] alongside age- and sex-matched risks for a nondiabetic individual without risk factors based on Framingham risk equations.[11] Graphic displays are also instantaneously created to show the status of individual risk factors (A1C, LDL cholesterol, and systolic blood pressure) alongside treatment targets recommended by the American Diabetes Association. This module also provides an overview of the manifestations of CVD, including a video testimonial from an actual patient who has suffered a myocardial infarction. The core presentation also provides specific information about how uncontrolled CVD risk factors lead to blood vessel damage and subsequent CVD, an overview of therapeutic options aimed at decreasing risk, a brief tutorial on how to address needs and questions with the physician, and an opportunity to indicate one question the patient would like to discuss with the physician during the visit.

Six additional modules, each ~ 5 minutes in duration, have been developed to offer more specific topical content.

A Glucose Control Module illustrates that the damage to blood vessels caused by high glucose levels leads to the micro- and macrovascular complications of diabetes, including CVD. The module concludes with a testimonial from a patient who has had partial foot amputations and who offers suggestions to others regarding risk-reducing behaviors.

A Lipid Control Module illustrates the vascular effects of chronic hyperlipidemia. The meaning of "good" and "bad" cholesterol is presented, and treatment goals are identified. The importance of medication adherence and the value of patient-physician collaboration, especially regarding concerns about medication side effects, are emphasized through narrative, graphic images, animations, and a patient testimonial. The Glucose Control and Lipid Control modules are bundled and shown to intervention subjects at Visit 2.

A Diet and Exercise Module (shown at Visit 3) stresses the need for and benefits of regular physical activity and moderation in diet. A testimonial from an actual person with diabetes (not an actor) who has been successful in incorporating dietary modifications and physical activity into daily activities appears at the end of the module.

A Blood Pressure Control Module (shown at Visit 4) illustrates "pressure" within blood vessels as a destructive force using simple metaphors. The meaning of the "top" and "bottom" numbers of the blood pressure measurement is illustrated, and treatment goals are presented. The content stresses the likelihood that more than one medication will be required to control blood pressure, the need to continue to take medications regularly even when blood pressure is controlled, and the importance of discussing possible medication side effects with the care provider so that alternate medications can be used if necessary.

A What Is Diabetes? Module (shown at Visit 5) outlines the pathophysiology of diabetes using simple metaphors and graphics. It illustrates the importance of blood glucose monitoring as a guide to therapy and the need to discuss the personal factors that affect glucose control (diet, physical activity, and medications) with the provider during office visits.

A seventh Smoking Cessation Module is under development.

At each visit, after the visit-specific module is viewed, a summary CVD Risk Update Module is shown. This module replicates the graphics shown at Visit 1, adding any new data so that patients and providers can track changes over time.

At the conclusion of the presentation, the program generates for patients a 1-page printed color graphic summary of the patients' 10-year CVD risk and the status of their modifiable CVD risk factors. At each subsequent visit, an updated report is generated to show the data contained in the CVD Risk Factor Update Module described above. A similar summary is printed and delivered to physicians before each encounter and contains a brief description of how estimated risk will change based on improvement in one or more risk factors.

We are conducting a randomized, prospective, controlled, parallel comparison of the intervention versus usual care with respect to the frequency of therapeutic intensification directed toward CVD risk factors, the frequency of talk between patients and providers about CVD risk and CVD risk factors, and changes in risk factors (A1C, LDL cholesterol, systolic blood pressure, and smoking). We chose two clinic sites and randomly assigned physicians at each site to the intervention or control groups. Randomization was stratified according to the number of unique patients who met entry criteria and were seen by the provider during the past 12 months. Physicians involved in the study are faculty members within the Indiana University School of Medicine in Indianapolis. We elected to make the physician the unit of randomization to avoid contamination (i.e., the potential for physicians with both intervention and control patients to alter their approach to control patients after exposure to the intervention).

Patients who were eligible for the study were identified via the computerized Regenstrief Medical Records System (RMRS), an EHR system that stores clinical data on all patients within our primary care system. Patients who were ≥ 18 years of age, had type 2 diabetes, had been seen at least once in the previous 12 months, and had at least one uncontrolled CVD risk factor (A1C > 8%, systolic blood pressure > 150 mmHg, or LDL cholesterol > 130 mg/dl) were identified by a RMRS query, as were upcoming primary care visit dates and times. Seven hundred and nine patients meeting these criteria were identified; 353 were approached and invited to participate in the study, 146 consented to participate, and 109 have completed at least one study visit.

Before patients' next scheduled clinic visit, research assistants (RAs) obtained from the EHR the information necessary for the UKPDS Risk Engine to generate a 10-year CVD risk presentation. The tablet computer was programmed with the UKPDS risk equations such that risk was calculated and graphics were generated instantaneously when data were entered into the tablet computer. Framingham equations were employed to illustrate the level of risk for an age- and sex-matched individual without diabetes or other CVD risk factors.

At the next visit after recruitment (Visit 1), subjects completed a baseline questionnaire that addressed demographics, patient knowledge and perception regarding the presence of CVD risk and risk factors, and other patient-specific factors. Patients in the intervention group viewed the Core Module (described above) just before their encounters with their providers.

Immediately after the clinical encounters, RAs conducted exit interviews with both intervention and control patients to obtain information about their clinical encounter. After Visit 1, patients saw their providers for their regularly scheduled visits (generally every 3–4 months), and laboratory tests were performed according to usual care (i.e., the study protocol did not dictate the number or frequency of clinic visits or laboratory evaluations). Patients viewed different multimedia content at each visit as outlined above. As of the time of the analysis presented here, patients had been followed for 12–24 months.

The analyses presented here are related to exit interview data, all of which is based on subjects' recollec-

Table 1. Demographics of Study Subjects

Variable	Intervention	Control	*P* value*
Age [mean years (SD)]	57.1 (11.6)	57.8 (11.1)	0.752
Duration of diabetes [mean years (SD)]	10.7 (6.9)	9.9 (7.4)	0.446
Male [*n* (%)]	9/51(17.65)	11/47 (23.40)	0.480
Education [*n* (%)]			0.490
• Less than high school	17/51 (33.33)	21/47 (44.68)	
• Graduate high school	21/51 (41.18)	15/47 (31.91)	
• Some college education	13/51 (25.49)	11/47 (23.40)	
Income [*n* (%)]			0.536
• < $20,000	29/39 (74.36)	32/40 (80.00)	
• $20,000–40,000	6/39 (15.38)	3/40 (7.50)	
• > $40,000	4/39 (10.26)	5/40 (12.50)	
Diagnosed with hyperlipidemia [*n* (%)]	28/46 (60.87)	33/45 (73.33)	0.206
Diagnosed with hypertension [*n* (%)]	39/50 (78.00)	38/47 (80.85)	0.729
Current smoking [*n* (%)]	13/51 (25.49)	14/47 (29.79)	0.634

*χ^2 *test for categorical variables,* t *test for age, and Wilcoxon rank sum test for duration of diabetes.*

tion of what occurred during the visit. During the exit interview, subjects were asked if heart attack risk; ways to lower blood glucose, blood pressure, or cholesterol; or ways to stop smoking were discussed during the visit. Subjects in the intervention group were asked if seeing information on the tablet computer made them think about making changes to reduce heart attack risk, made it easier to discuss health problems with their doctor, or helped them understand why maintaining good control of blood glucose, blood pressure, and cholesterol and avoiding smoking were important.

Statistical methods

Characteristics of the study patients at baseline were compared between the intervention and control groups using Pearson's χ^2 for categorical data and either Student's *t*- test or Wilcoxon rank sum tests for continuous data. Between-group comparisons were performed with respect to the number of patients who indicated discussion of individual CVD risk factors at each of the first three visits using logistic regression models.

Because patients had repeated measurements and were nested within physicians, repeated-measures analyses included patient and physician as nesting factors, and the Generalized Estimating Equations method was used to estimate the regression coefficients in the model. However, because of the small number of smokers in the study population, the between-group comparison with respect to the frequency of discussion of smoking cessation was analyzed using Fisher's exact test at each visit.

Because this was an exploratory study, *P* values between 0.05 and 0.15 were considered a trend toward significance, and *P* values < 0.05 were considered to be statistically significant. Responses of intervention subjects with respect to the efficacy of the multimedia content are presented in percentages.

Results

The demographics of the study subjects are shown in Table 1. Patients were similar with respect to demographic characteristics, smoking status, and the presence of hyperlipidemia and hypertension (diagnoses ascertained from the EHR) between the intervention and control groups.

Table 2. Number of Study Visits

Visit	Number of subject-visits	Cumulative number of visits	Cumulative percentage of all visits
V1	98	98	39
V2	72	170	67
V3	44	214	84
V4	23	237	93
V5	13	250	98
V6	4	254	100

Table 3. Percentage (*n*/total) of Patients Reporting the Discussion of Specific Topics at Individual Visits

	Visit 1	Visit 2	Visit 3
Risk for heart attack	52 versus 34% (24/46 versus 16/46) *P* = 0.116	72 versus 42% (26/36 versus 15/36) *P* = 0.008	56 versus 31% (10/18 versus 8/26) *P* = 0.076
Ways to lower cholesterol	NS	39 versus 22% (14/36 versus 8/36) *P* = 0.132	47 versus 23% (8/17 versus 6/26) *P* = 0.139
Ways to stop smoking (smokers only)	54 versus 15% (7/13 versus 2/13) *P* = 0.097	86 versus 0% (6/7 versus 0/5) *P* = 0.015	100 versus 20% (2/2 versus 1/4) *P* = 0.143

At the time of the present analysis, 98 subjects had completed 254 visits, as shown in Table 2. In order for adequate numbers of subjects to be represented for each visit, data from only the first three visits (V1, V2, and V3) were included, representing 214 visits or 84% of the total number of visits. Three providers in Clinic A and two providers in Clinic B saw subjects during 99 intervention visits; two providers in Clinic A and three providers in Clinic B saw subjects during 109 control visits. Non-study providers saw subjects during the remaining six visits, and procedures appropriate to subjects' original randomization groups were performed.

There were statistically significant differences or an indication of a difference in favor of the intervention group for discussion of three of the five topics covered by the exit questionnaire. Those results are summarized in Table 3. Between-group comparisons for discussion of ways to lower blood glucose and blood pressure were not statistically significant, nor was there a trend toward significance, and those results have been omitted from Table 3.

Of patients surveyed from the intervention group, the vast majority of respondents indicated that viewing the tablet computer presentation made it easier to talk to their doctor during the subsequent encounter and helped them understand why maintaining CVD risk factor control was important. Results of the intervention group survey are shown in Table 4.

Discussion

Increasing evidence suggests that patients who take a more active role in their care achieve better health outcomes, and the risk communication tool described here appears to facilitate this process. Our results indicate that its use increases the frequency and ease of discussion of CVD risk between patients with type 2 diabetes and their physicians.

Interestingly, smoking cessation was more often discussed in the intervention group (in the subgroup who smoked) even though specific content regarding this topic was not included in the multimedia content. This suggests that the patient-provider discussion focused on this crucial CVD risk factor once elevated risk was identified. Future analyses will examine the effect of the intervention on risk factor levels, disease state knowledge,

Table 4. Patient Survey Regarding Tablet Computer Efficacy (% [*n*])

	Yes (Visit 1)	Yes (Visit 2)	Yes (Visit 3)
Did seeing the information on the computer:			
Cause you to think about making changes to reduce your risk of heart attack?	98 (41)	94 (34)	100 (17)
Make it easier to talk with your doctor about your health problems?	90 (41)	97 (31)	75 (16)
Did the computer presentation help you understand why it is important to:			
Lower your blood sugar?	100 (41)	100 (34)	100 (17)
Lower your blood pressure?	100 (39)	100 (34)	94 (16)
Improve your cholesterol levels?	100 (38)	94 (32)	100 (17)
Stop smoking?	100 (12)	70 (10)	75 (4)

treatment satisfaction, and therapeutic intensification, which is defined as the initiation of or increase in the dose of a medication or referral to a specialist or health program for management of a risk factor.

The tool described here can be adapted easily to communicate information related to other chronic conditions such as asthma, congestive heart failure, and obesity. Additionally, the technology enables content to be translated into virtually any language, thereby increasing its effectiveness in addressing language and literacy issues in multiethnic populations. In fact, we have linguistically and culturally adapted the presentations to be appropriate for Spanish-speaking Latino people with type 2 diabetes (identified using our EHR), and this is being used successfully in a local community clinic serving the Hispanic population.

Future research will focus on the implementation of our intervention in real-world settings, without benefit of database specialists and research assistants. The primary tasks related to implementation will be the selection of patients to be exposed to the intervention, the entry of clinical data into the intervention software, and the integration of the intervention into clinic workflow. The first two tasks will depend in large part on the ability to query an EHR to identify patients with out-of-range risk factor levels, their physicians, and the dates of the clinic visits at which they will interact with the multimedia program. A tablet computer–based intervention developed by our group to facilitate communication between Spanish-speaking patients and non–Spanish-speaking providers has been directly linked to our EHR, allowing seamless integration of clinical information into the software and program output used by busy clinicians.[30,31] We hope to link the intervention described here to the EHR in a similar manner.

Integration of the tool into clinic workflow will depend on individual clinic factors such as the nature of the physical space, the availability of computers or kiosks, and the availability of personnel to shepherd patients through the system and distribute printed reports. We hope to study this in the near future in collaboration with our primary care colleagues using a systems-redesign approach. Patients could also be exposed to the intervention using a Web-based approach, perhaps as part of a communication system similar to the "patient Internet portal" described by Weingart et al.[32]

The widespread use of EHRs, combined with the availability of powerful multimedia computer technology, creates a tremendous opportunity to improve patients' access to personalized health information. This should, in turn, increase the efficiency of patient-provider interactions and facilitate efforts to manage health risk. Future research should focus on the implementation of effective interventions in real-world settings.

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