A Direct-to-Patient Alert for Glycated Hemoglobin Screening Using Prediction Modeling and Mobile Health (mHealth)

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Dates: 4/1/2019 to 3/31/2022

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Abstract

Purpose: The goal is to improve the efficiency of identifying and screening patients at the highest risk for hyperglycemia.

Scope: Approximately 36% of all adult Americans have pre-diabetes. The investigators have built a calculator for predicting levels of glycated hemoglobin using structured features from a widely used EHR. The use of this calculator could improve the efficiency of targeted screening.

Methods: Aim 1: Develop an mHealth text message intervention to improve the early identification of patients with hyperglycemia. Appropriate messages will be created using feedback from focus groups. Aim 2: Evaluate the impact of a text message, mHealth, glycated hemoglobin screening program. The intervention will be conducted by applying a previously developed A1c risk calculator to identify 500 high risk patients to receive text messages offering the opportunity to receive free glycated hemoglobin testing   Aim 3: Perform telephonic surveys of patients participating in the texting intervention. The sample will consist of a mix of patients who did and did not complete screening.

Results: Approximately 10% of patients who received a text message requested a screening HbA1c test. Participants responded positively to receiving an alert for HbA1c screening. The patient-physician relationship emerged as a recurring theme in which patients either had a desire or held an assumption that their provider would be working behind the scenes throughout each step in the process, suggesting that participation in this type of intervention would benefit from a strong patient-provider relationship.

Key Words: Electronic Health Records, Risk Prediction, Diabetes Screening, Text Messaging, Clinical Decision Support.

Purpose

The goal of this mixed-methods project is to improve the efficiency of identifying and screening patients at the highest risk for hyperglycemia.

Specific Aims:

1. Develop an mHealth text message intervention to improve the early identification of patients with hyperglycemia.
   a. Create a simple state engine to automatically transmit text messages to patients based upon their predicted risk and responses to previous messages.
   b. Conduct focus groups (n=36) with adult patients. The focus groups will provide feedback on the texting algorithm and help to craft appropriate messages. The goal of the messages will be to empower patients through information, to re-engage patients with the health care system, to reduce barriers to testing, and to avoid miscommunication.
2. Evaluate the impact of a text message, mHealth glycated hemoglobin screening program in the Department of Family Medicine
   a. Apply the calculator previously developed to patients without a history of hyperglycemia in the Department of Family Medicine who have not had glycated hemoglobin testing in the past year. Select the 500 highest risk patients who meet the inclusion criteria who will receive text messages alerting them to their elevated risk and offering the opportunity to receive free glycated hemoglobin testing. Estimating the number of patients who will respond to the targeted text messaging is crucial data for a future randomized controlled trial.
3. Perform telephonic surveys on 100 patients (50 who completed screening and 50 who did not complete screening).
   a. The surveys will be used to determine potential factors that impacted patients' decision to accept or decline the free screening. This information will help to inform future direct-to-patient alerts using text messaging and provide suggestions to improve the implementation.

Scope

BACKGROUND

Recent analyses of the National Health and Nutrition Examination Survey showed that 36.5% of all adult Americans have pre-diabetes, 12.3% meet the criteria for diabetes, and 25.2% of these prevalent cases of diabetes are undiagnosed. Given the widespread existence of hyperglycemia and the solid clinical trial data indicating that glycemic control in patients with type 2 diabetes (T2D) decreases complications screening for T2D in high risk adults has been an unquestioned standard of practice for decades. In 2015, Selph et. al. published a systematic review of the United States Preventive Services Task Force (USPSTF) of T2D screening that some experts have used to question the benefits of any glucose screening in asymptomatic adults. The most consequential finding from the USPSTF review was that screening for T2D did not prevent premature mortality. The authors do not dispute the findings of the review but vociferously disagree with the conclusion by some experts that all glycemic screening of asymptomatic adults should be discontinued as screening can reduce morbidities and positively impact quality of life.

The American Diabetes Association (ADA) and the USPSTF itself continue to recommend screening. The USPSTF recommends screening for abnormal blood glucose in persons 40-70 years of age who are overweight or obese. The USPSTF acknowledges that patients with other high risk characteristics (e.g. family history of diabetes, personal history of gestational diabetes etc.) may need to be screened sooner but this is left up to the discretion of the physician. Meanwhile, the guidelines published by the American Diabetes Association (ADA) for diabetes screening recommend screening of patients with an elevated body mass index (>25kg/m2) with another risk factor (e.g. hypertension, physical inactivity, family history of diabetes etc.) beginning at 45 years of age at 3 year intervals for most patients. The USPSTF and ADA guidelines encourage physician judgment in the application of screening, but do not provide specific guidance. Simple classification methods like the USPSTF guidelines for identifying patients for diabetes screening are notoriously poor at discriminating high- and low-risk patients. Cost-effectiveness analyses indicate that universal screening for type 2 diabetes is cost-prohibitive while targeted screening using the existing classification systems are only moderately cost-effective. Diabetes risk is multifactorial and the best prediction will likely be made by considering numerous variables simultaneously. Simplified classification methods used in cancer have been notoriously poor at discriminating between high and low-risk patients. The investigators created a calculator for predicting current HbA1c levels in patients without any previous evidence of diabetes or hyperglycemia. (http://dx.doi.org/10.2196/10780) This calculator was created using data on adult patients who have undergone a serum HbA1c test prior to evidence of hyperglycemia or diabetes recorded in the Electronic Health Record (EHR).

CONTEXT

EHRs provide an opportunity to alert clinicians about recommended preventive services such as screening tests. Clinical Decision Support Systems (CDSS) have been promoted as a way to improve quality by alerting clinicians at the point of care to recommended preventive services and address care gaps. CDSS have been instituted in an attempt to improve vaccination rates, chronic disease management and a myriad of other conditions. Evaluations, however, of the impact of CDSS have demonstrated largely process-oriented improvements, but a paucity of patient-centered outcomes and disappointing results when it comes to improvement in this area. A review by Souza and Sebalt, et al (2011) examined the role of CDSS in primary preventive care and found support for effectiveness in screening for dyslipidemia, but inconsistent evidence for cancer and mental health-related screening, vaccinations, and a variety of preventive care services and interventions. Additionally, Roshanov and Misra et. al. (2011) concluded that CDSS in chronic disease management has not shown convincing evidence in improving outcomes.

There are a variety of reasons for the poor performance of CDSS initiatives. Lack of conformance to the "5 rights" of CDSS outlined by Osheroff (2012) may explain some of the deficiencies. Additionally, Ash (2007) and Van der Sus (2006) have described the phenomenon of "alert fatigue" in which busy providers are inundated with alerts in EHR systems that are largely ignored. This was a central reason for physician overrides, which occurs in 49-96% of cases in the realm of medication management.

This proposal addresses some of the potential CDSS pitfalls by proposing "direct-to-patient alerts" as a method for targeting high risk patients directly and ordering HbA1c in patients who are interested. This approach empowers patients to take ownership of their own health and provides a method to overcome the potential systematic barriers at the physician level/described above while simultaneously removing other rate limiting steps to screening (e.g. need for an office visit) before a definitive test is ordered. Texting has already been shown to be a viable method to improve outcomes such as medication adherence. Combined with an improvement in the classification of high risk patients through the aforementioned calculator, there is a potential for a significant increase in the efficiency of screening for abnormal glucose. In other words, more patients with abnormal glucose can be identified with fewer tests.

SETTINGS

The study was conducted in the primary outpatient clinic of the Department of Family and Community Medicine at the Wake Forest University School of Medicine in Winston-Salem, North Carolina. The Department contains a residency program and over 20 clinical providers. The patient population consists of approximately 20% minorities.

PARTICIPANTS

- 36 adult patients participated in focus groups.
- Text messages offering hemoglobin A1c testing were sent to 500 patients.
- Telephone surveys were completed on 43 patients who received text messages.

PREVALENCE

- During the creation of the risk calculator it was found that 26% of the patients had a hemoglobin A1c greater than or equal to 5.7%. This population excluded patients with previous testing for hemoglobin A1c.

INCIDENCE

- The incidence of elevated hemoglobin A1c (1/13) in the study could not be accurately estimated in the study due to low response rates.

Methods

The proposed research project will use the HbA1c calculator recently created by the PI that was described earlier in the proposal. The calculator will be used to identify patients at high risk for having abnormal glucose values. The high risk patients will receive direct-to-patient alerts via text message from the medical center encouraging free, serum HbA1c screening. The laboratory testing will be ordered and the results will be reviewed by the PI, who will notify the patients of results. A sample of patients who do and do not accept the offer for HbA1c testing will be surveyed telephonically to help understand the reasons for participation and non-participation. Prior to initiating the texting intervention, the research team will conduct focus groups on adult patients to determine the optimum content and timing of the texts. A simple state machine will be programmed during year 1 to automatically send and receive appropriate messages between the medical center and the patient.

The Focus Groups in this project will involve enrolling multiple groups of adult patients from Family Medicine at Piedmont Plaza. Each group will participate in a 1-2 hour long focus groups. The focus groups are being conducted in order to create the most appealing text messages possible that will encourage patient participation.

The overarching themes of the focus group are shown in the following table.

Table 3: Overarching Themes From the Focus Groups
Overall Perception of Texting
a. Prefer texting over other modes of communication
b. Texting is already used for appointment reminders
c. Texting is immediate and indicates urgency
Positive Content
a. Phrases such as "Take Control of Your Health"
b. A salutation such as "Good Morning" is personable
c. Official signature reduced concern about possible "spam"
d. The word "free" associated with test was important
Negative Content
a. "risk/abnormal" were anxiety-provoking/unfavorable
b. Concern that some may not know definition of HbA1c.
c. "Computerized risk score" was confusing
d. Lack of clarity about when to visit the laboratory
Process Suggestions and Comments
a. Ability to Opt-in/Opt-out of the text was important
b. Website with information about the study, diabetes, testing, why they were selected, and a telephone number
c. Participants preferred all results be sent to physician
Concerns
a. Possibility of other people viewing messages
b. Possibility of changed phone number
c. Incurred cost of receiving a text message

Patients will be systematically recruited using "opt-out" letters that will be mailed to potential participants and followed with telephone calls. Basic demographic information will be collected in an attempt to achieve a sample that is evenly split among African American and white, men and women, respectively across four groups. Homogeneity of patient characteristics will be desired among individual groups to encourage participation. However, the group will not employ "snowball sampling" in which participants recruit acquaintances. In addition, the investigators will make an attempt to group members based on level of tech "savvy". Focus groups will be conducted to solicit perceptions about proposed general procedures to inform and encourage HbA1c testing as well as the specific wording of the text messages. Dr. Joanne Sandberg in Family Medicine will personally conduct the focus groups using a guide to ensure that major domains of interest are addressed. She will facilitate discussion to ensure expression of diverse viewpoints and encourage participation among all participants. Focus groups will not enable the research team to generalize due to small sample sizes, but will serves as an efficient way to solicit feedback. Interactions among participants can encourage other participants to think about issues and concerns not previously considered. Participants will be asked to respond to questions and comment on other participants' responses.

Qualitative data analysis is an analyses process that begins with completion of each focus group. Audio recordings of sessions will be transcribed verbatim within one week by a professional service Verbalink™ experienced in interview transcription; this time frame allows the investigators to review transcripts to inform further data collection, initiate formal data analysis, and further develop coding dictionaries established with the pilot data. The mechanics of transcript coding and analysis will be specific for ATLAS.ti software.

Using the results from the qualitative analyses, the investigators will create a schematic detailing specific automated test messaging depending upon patient response. Approval of the final version will be obtained from the institutional review board and privacy officials prior to implementation. Messages will be sent using the text platform Twilio with protected health information redacted. Patients targeted for text messaging will be identified through a weekly SQL query of the electronic health record database to extract data on eligible patients. A list of high risk individuals will be obtained by applying the hemoglobin A1c risk calculator to these data.

Patients receiving text messages, after confirming their identity, can ignore the texts, opt-out of future messages, or request testing. Patient's requesting testing will receive a message indicating that the order has been placed along with information about laboratory locations and hours. HbA1c testing will be personally reviewed by the PI and addressed using current clinical protocols. Lab results are automatically visible on the portal to patients that are actively enrolled. Non-urgent results for patients who are not enrolled in the patient portal will be sent via the US postal service. Abnormal results (e.g. elevated HbA1c levels) will be sent via electronic messages to both the patient and the patient's primary care provider on record. If patients do not read the message within one week, the EHR will automatically alert the PI and either the PI or clinic staff will call patients directly to discuss results. Patients with elevated results will be encouraged to schedule an office visit with their primary care physician. All patients with extreme HbA1c results (<=4.5 or >11.5) will be called by the PI within 48 hours to triage their risk of hypoglycemic or hyperglycemic symptoms and potential need for more urgent medical attention.

The investigators will conduct brief, 10-15 minute telephone surveys on approximately 100 patients comprised of both patients who did and did not complete the HbA1c screening. Participants will be recruited through an "opt-out" letter followed by a phone call within 5-10 days. The surveys will ask several structured questions followed by an open ended question aimed at assessing overall impression of the intervention. Structured questions will ask about usual texting habits and reason for participation or non-participation in the study. The telephone surveys provide an "insurance policy" if patients do not respond in significant numbers to the texting intervention in which case it may provide an opportunity to address issues inhibiting patient participation and allow adjustments for an additional pilot project using a different protocol. Alternatively, the surveys may provide compelling evidence that text messages are not likely to be an effective means for encouraging HbA1c screening. Patients who complete the IRB-approved phone survey will first be required to provide a simple verbal consent for this component of the project. Other topics to be addressed during the telephone interviews include: 1. Recollection of text messages and associated activities, 2. Attitudes about use of text messaging from providers to provide health information, 3. Use of other text messaging services in context of health promotion, 4. Actions taken in response to intervention (did they view website that provided more information about study), 5. Experience associated with receiving HbA1c result. 6. overall evaluation of the experience.

Results

- The first publication resulting from this research entitled, "Patient Perspectives on a Targeted Text Messaging Campaign to Encourage Screening for Diabetes: A Qualitative Study" is available as a pre-print at https://preprints.jmir.org/preprint/41011.
- The authors are preparing a second manuscript that will include results from the text messaging intervention including surveys.

FOCUS GROUP RESULTS

Six focus groups were conducted at Wake Forest Baptist Health between October 2019 and February 2020. The participants were adult patients without diabetes who had completed an in-person visit at the Family and Community Medicine clinic within the previous year. We displayed a series of text messages and asked the participants to react to the message content and suggest improvements. Content was deductively coded with respect to the Health Belief Model and inductively coded to identify other emergent themes that had the potential to impact engagement with text messages and follow-through with an HbA1c test.

The participants (n=36) responded positively to receiving an alert for HbA1c screening. They preferred plain language, personalization, and content, which highlighted perceived benefits over perceived susceptibility and perceived severity. The patient-physician relationship emerged as a recurring theme in which patients either had a desire or held an assumption that their provider would be working behind the scenes throughout each step in the process, suggesting that participation in this type of intervention would benefit from a strong patient-provider relationship.

TEXT MESSAGING RESULTS

- A link to the website created for text messaging patients is available at http://a1ctext.phs.wakehealth.edu/.
- Example text messages crafted after the focus groups are shown below:
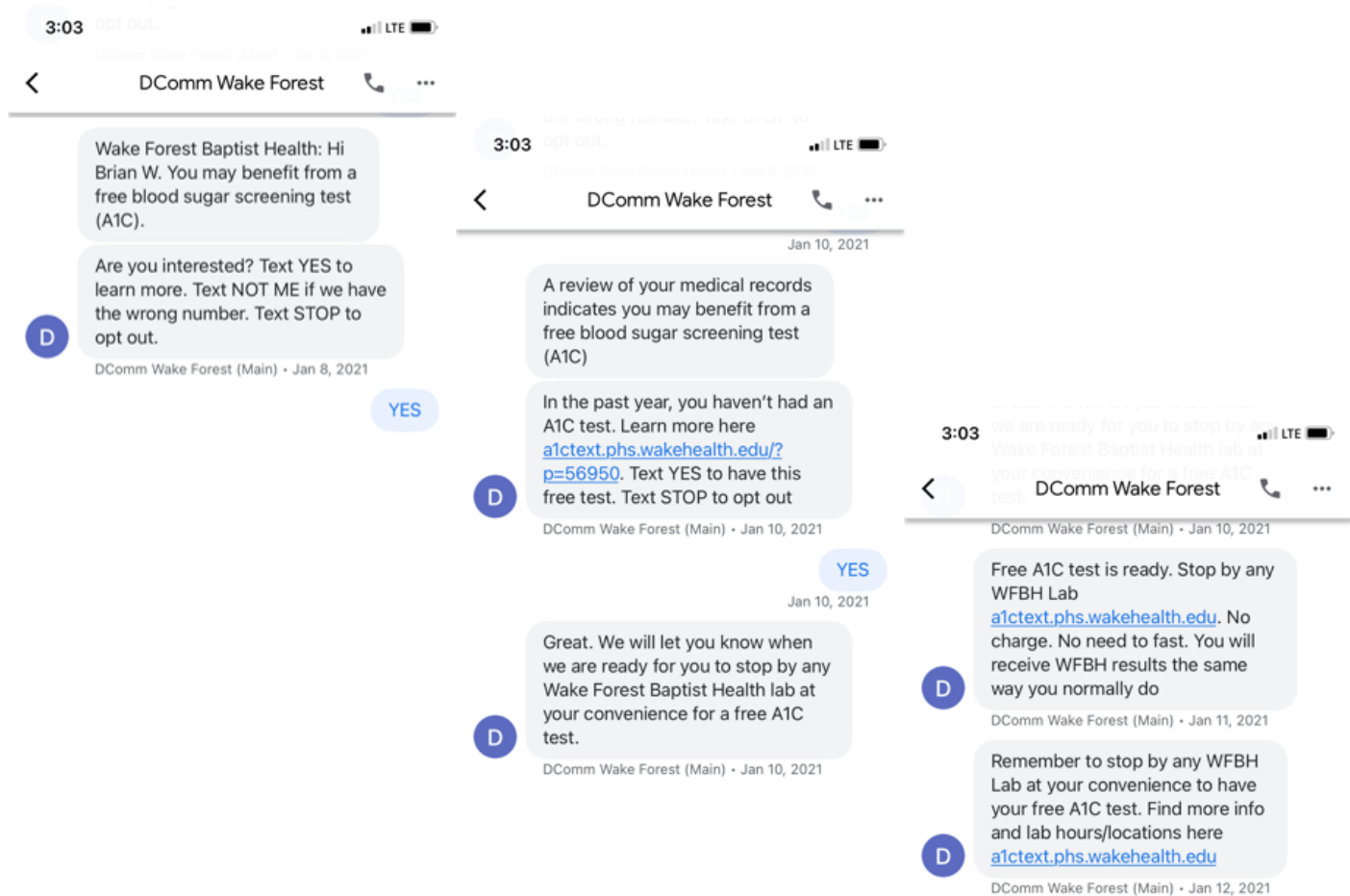
During the course of the study, one of our co-investigators (Dr. David Miller) successfully created and leads the digital communication core (DComm). The core processes applications for sending text messages to patients for clinical care, quality improvement, and research. Applications are reviewed by a panel that includes representatives from the institutional review board, privacy and security, and administration. This study was the first approved DComm project. The service is made possible through licensing costs shared by individual investigators and the creation of a secure and confidential IT framework.

- Over the course of several months, the team sent text messages to 500 individuals.
  - Patients opted out at rate of 22% (n=109)
  - The majority of patients did not respond
  - Overall, hemoglobin A1c tests were ordered on 40 patients.
  - 13 individuals completed the test
  - 1 person was found to have a hemoglobin A1c greater than or equal to 5.7%.

SURVEY RESULTS

Surveys were completed on the following patients.

- 9/13 who completed hemoglobin A1C testing.
- 10/27 for which tests were ordered but not drawn.
- And 24 patients who did not respond to text messages.

The surveys indicated that some patients thought the text messages were SPAM and some were clearly confused about the project. Survey analyses are ongoing and we anticipate a paper submission within the next 6 months.

LIMITATIONS

The study was conducted during the COVID 19 pandemic, which had several impacts on the research. Patients were reluctant to travel outside their homes, research with patients at our institution was temporarily suspended, patients were less likely to have in-office visits in the previous 3 years, and we suspect that things such as hemoglobin A1c screening were considered to be a low priority. Over the past few years, SPAM sent via text messaging has increased dramatically and likely made patients reluctant to participate. We struggled to reach the intended numbers of survey participants despite increasing the effort spent on recruitment. Ultimately, the team manually attempted to contact all 391 patients who did not opt out of the texting intervention.

CONCLUSIONS

The research team demonstrated that "cold" texting of patients for quality improvement is feasible from a technological and governance perspective. In general, patients are open to this form of communication but concern about SPAM is a significant deterrent. In addition, although patients are accepting of direct–to–patient alerts, they would like their physicians to be involved in some capacity. The percentage of patients interested in hemoglobin A1c was disappointing especially since only 13 individuals completed testing. However, it is unknown how much the COVID pandemic played a role in these results. Furthermore, the low-cost, automated process used in this study could still make a significant impact on other conditions if used on a large number of individuals.

It is possible that communication via text messaging may have different results depending on the patient population and condition involved. This study specifically targeted individuals believed to be at high risk for hypoglycemia but who may have not had much interaction with the health system. Although these are high-priority individuals from a public health perspective, they may be less engaged in their healthcare. Text messaging may also play a role in these kinds of interventions if coupled with patient portal messaging and alerts directed at the patients primary care provider.

Our findings suggest that patients accept text messages that alert them to a higher risk for elevated hemoglobin HbA1c but need clarification of the new processes in which they are asked to engage. Future research is necessary to determine whether these text messages lead to meaningful health behaviors in practice and whether this could apply to other opportunities.

PUBLICATIONS

Lenoir KM, Sandberg JC, Miller DP, Wells BJ. Patient Perspectives on a Targeted Text Messaging Campaign to Encourage Screening for Diabetes: A Qualitative Study. JMIR Preprints. 11/08/2022:41011