Development and Usability Testing of e-Quit worRx: an iPad App for Smoking Cessation Counseling and Shared Decision Making in Primary Care

Charles R. Doarn, MBA¹, Mary Beth Vonder Meulen, RN¹, Harini Pallerla, MS¹, Shauna P. Acquavita, PhD², Saundra Regan, PhD¹, Nancy Elder, MD, MSPH¹, Matthew R. Tubb, MD, PhD¹

¹Family and Community Medicine, College of Medicine and ²School of Social Work, College of Allied Health, University of Cincinnati, Cincinnati, Ohio

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Running Head – App-based Smoking Cessation Tool for Shared Decision Making

Corresponding Author:
Charles R. Doarn, MBA
Professor
Family and Community Medicine
University of Cincinnati
231 Albert Sabin Way
MSB 4453B
Cincinnati, OH 45267-0582
E-mail: charles.doarn@uc.edu
Abstract

Background: Smoking is the leading preventable cause of morbidity and mortality in the U.S., killing more than 450,000 Americans. Primary care physicians (PCPs) have a unique opportunity to discuss smoking cessation evidence in a way that enhances patient-initiated change and quit attempts. Patients today are better equipped with technology such as mobile devices than ever before.

Objective: To develop and evaluate an evidence-based smoking cessation application (app), for use on a tablet computer to optimize interaction between PCPs and their patients who smoke.

Design and Approach: A group of interprofessional experts developed content and a graphical user interface for the decision aid and reviewed these with several focus groups to determine acceptability and usability in a small population.

Results: Using a storyboard methodology and subject matter experts, a mobile app, e-Quit worRx™, was developed through an iterative process. This iterative process helped fine tune the content and ergonomics of the app and provided valuable feedback from both patients and provider teams. Once the app was made available, other technical and programmatic challenges arose.

Conclusions: Subject matter experts, while generally amenable to one another’s disciplines, are often challenged with effective interactions, including language, scope, clinical understanding, technology awareness, and expectations. The successful development of this app and its evaluation in a clinical setting highlighted those challenges and reinforced the need for effective communications and team building.

Keywords: m-Health, application development, smoking cessation, shared decision-making, primary care, decision aid
INTRODUCTION

Smoking is the leading preventable cause of morbidity and mortality in the U.S. [1]. Each year, smoking kills nearly 450,000 people in the U.S. and costs almost $100 billion in healthcare costs and productivity losses. An estimated 19% of adults in the U.S. smoke [1]. Although numerous interventions improve the likelihood of successful smoking cessation and the resulting health benefits [2], most smokers relapse or require several interventions and attempts before staying quit [3]. Primary care physicians (PCPs) have a unique opportunity to discuss smoking cessation evidence in a way that enhances patient-initiated change [4] and quit attempts [5]. Unfortunately, while current guidelines summarize the comparative effectiveness of available smoking cessation medications, counseling techniques, and other methods [6], physicians discuss cessation with smokers infrequently and underutilize tobacco cessation medications [7,8].

Methods that allow physicians to conduct more frequent, efficient tobacco counseling are necessary to disseminate smoking cessation evidence [9-12] and could have a substantial impact, as even brief counseling by a PCP can increase the likelihood of smoking cessation [4]. Decision aids are a method that can assist clinicians and patients in finding motivating, personally effective quit strategies that can be integrated into physician offices where patient-provider discussions about smoking cessation typically occur.

Use of a hand-held electronic tool can increase physicians’ comfort with cessation counseling [13]. Furthermore, shared decision-making (SDM) has the potential to engage and inform patients and improve quality of care, especially when combined with decision aids and health information technology (HIT) tools [14]. Tudor-Sfetea et al. evaluated mobile health (m-Health) apps in the context of smoking cessation [15]. This study demonstrated preliminary
changes in smoking behavior as a result of using Quit Genius or Smokefree, two smoking cessation mobile apps in the United Kingdom.

With so many options for cessation support, it is important for clinicians to personalize evidence-based interventions that are both useful and appealing to patients. During primary care office visits with competing priorities [16], applying patient-centered outcomes research (PCOR) for any given problem can be challenging. To address these opportunities and challenges, we developed an iPad/tablet-based m-Health decision aid application (e-Quit worRx™) to assist PCPs in disseminating PCOR evidence about smoking cessation options and engage in SDM.

**Methods**

The primary objective of this research effort was to develop an acceptable and easy-to-use smoking cessation decision aid that incorporated PCOR evidence into an m-Health tablet-based application called e-Quit worRx.

**Project Team**

An interdisciplinary team of subject matter experts (SMEs) was formed to complete this project. These experts included specialists in primary care, smoking cessation and social work, health information technology and m-Health, app development and computer programming, and qualitative and primary care practice-based research.

**Conceptual framework**

This project was guided by a conceptual framework grounded in SDM and behavioral theories of smoking cessation (e.g. stages of change and the 5As – Ask, Advise, Assess, Assist, Arrange) (Figure 1). We adapted frameworks developed for primary care for smoking cessation counseling [17] and for SDM such as those used in colorectal cancer screening [18] to create a conceptual framework to guide the study innovations, intervention, and outcomes. We aimed to
combine theory-driven aspects of smoking cessation (e.g. stages of change, self-efficacy, etc.) with iPad-based interactive, tailored delivery of PCOR evidence to smokers at the point-of-care (their PCP’s office). The overall goal of the decision aid was to provide evidence-based and patient-centered smoking risk and cessation information to patients. Once developed and acceptable to patients and physicians, the decision aid would then be introduced into a routine office visit while minimizing physician and office staff training and ongoing time commitment.

**Project Design**

The project was completed in three phases as depicted in Figure 2: (1) development of a storyboard of app content and flow and initial app version; (2) evaluation of the app at various development stages with physicians, medical staff and patients through an iterative process and app refinement; and (3) clinical pilot testing of the app with patients in the PCPs office. The third phase will be reported in a separate manuscript.

**Phase 1: Content Development, initial feedback, and Storyboarding**

Development of a new task or device often is conceptualized through the use of storyboarding [19]. Some processes of app development, that are Web-based, have recently been patented [20]. Iqbal et al., lay out some of the requirements for engineering practices of mobile application development [21]. This process, while challenging, provides an excellent tool for development teams to understand what the final process or device should look like and how it works. The entire research team laid out a storyboard for how the app should flow from a physician and patient perspective. The assembled team was also aware of the wide expertise it brought to the development phase.

One of the steps in the storyboarding process is to provide input on the how the user will interface with the app. Human factors and ergonomics play a role as well. To accomplish this, separate focus groups with patients and smoking cessation experts were held as well as
individual interviews with PCPs and medical support staff. The goal of these initial sessions was to understand what stakeholders wanted and needed to be included in a clinical encounter for smoking cessation. These interviews addressed, as appropriate, previous smoking attempts, previous and desired communication about smoking, use and comfort with electronic media, and knowledge and comfort with evidence-based smoking cessation tools.

Clinical evidence-based content for the app development was obtained in large part from the Smoking Cessation Guidelines for Clinicians [6] and Cochrane reviews [2]. In addition, the CDC’s smokefree.gov website [22] and incorporation of feedback from focus group interviews as well as knowledge from the scientific literature in the following: (1) PCOR studies in the areas of primary care [4, 23-25], (2) smoking cessation medications [26], (3) m-Health tools [27-30], and (4) decision aids [31].

**e-Quit worRx Coding and Design**

The team used an iPad platform (iPad 2, Apple, Cupertino, CA), using iOS 7, as the user interface for our decision aid. Code for the app was written in Apple’s Xcode software on a MacMini using the Swift programming language. Two master level students from the University of Cincinnati’s computer science program worked with the team to write the code. Code versions were archived in Github. Prototype app versions were tested on three iPad2 devices.

**Phase 2: Iterative Usability Testing with Stakeholders and End-Users**

Once a prototype app (version 1.0) was complete, a second round of key informant interviews was completed with patients, clinicians, and clinical support staff. These interviews focused on usability and included a modified system usability scale as well as a semi-structured questionnaire [32]. Interviews touched upon participants’ experiences using the app, recommendations for modifications, and evaluations of specific app components. Initial rounds
of testing used concurrent think aloud techniques to elicit real time feedback and emotional responses. Later rounds of testing used retrospective think aloud techniques to assess important metrics such as accuracy and time needed to complete tasks on the app.

**Participants**

This study was approved by the University of Cincinnati IRB (ID 2015-0880).

For the first two phases, described in this manuscript, our team sought feedback from and recruited key stakeholders including patients and primary care physicians and primary care office staff (nurses, medical assistants and office managers) ranging in their comfort and familiarity with technology. We also sought feedback from an interdisciplinary team of faculty and staff from our university with expertise in addressing tobacco cessation.

Patient participants were recruited from the target practices for the eventual pilot trial and recruitment guidelines were in line with previous similar studies [23]. Participant recruitment for the clinical phase will be addressed in a separate manuscript. Non-patient participants were recruited using the snowball technique, beginning with physicians and experts known to the research team, who were then asked to recommend others who could speak on the topic of interest, and so on.

A mixed methods approach was incorporated for app design. The primary outcome was to determine usability. Data sources included qualitative feedback from semi-structured interviews and focus groups with key stakeholders, System Usability Scale (SUS) results, and feedback and discussions among our research team members. Interviews were conducted until saturation was achieved - no new ideas were being brought forward. The stakeholders included ten patients, seven clinical support staff members (medical assistants, nurses), eight PCPs (physicians, advanced practice nurses), and nine smoking cessation experts.
RESULTS

Stakeholder feedback was obtained iteratively prior to the first app version and with each of five app versions (Table 1). During each increment, changes were made in app content, appearance, and flow based on feedback from the focus groups with changes between versions ranging from relatively minor content revisions or additions to major changes to the GUI. Figure 3 contains representative screenshots showing how the app content and appearance changed version to version.

Readability

Testing of version 2.2 produced feedback that the literacy level was too high for the clinic populations we serve. A literacy evaluation revealed that our initial text averaged a 7th grade reading level. Between app versions 2.2 and 2.3 we made text edits screen-by-screen focusing on improving readability and we reduced the average to a 5th grade reading level (Figure 4).

Usability

Usability, as assessed with the System Usability Score (SUS), increased with each version for a final of 90/100, above 65 considered “usable” (Figure 5). After iterative usability testing, a final app version was ready for pilot testing in the clinical setting.

Description of e-Quit worRx

The app-based decision aid ‘e-Quit worRx’ has several key components, including collecting (1) a comprehensive smoking history, (2) personal reasons for and against smoking, (3) barriers and facilitators to quitting, (4) describing treatment options, including their level of evidence, risks, and costs, and finally (5) summarizing content to aid in SDM. The graphical user interface (GUI) was unidirectional but used branching logic based on user input. The app begins with a splash screen followed by a secure login screen so that user data was encrypted on the device.
The app was designed to personalize users’ examination of the positive and negative effects of smoking and increase their knowledge of smoking cessation treatment options.

Treatment options included first line medications, therapy including local available cognitive behavioral therapy (CBT) providers, and other treatments such as telephone quit lines and m-Health tools.

A summary screen is saved, entirely customized to an individual’s input, to facilitate discussion with their PCP. The summary screen includes personalized information derived from their responses. In addition to summarizing their personal considerations about the pros and cons of smoking, it summarizes interest in the various cessation aids. The app includes a provider input screen, where a plan is selected, and an exit interview to be completed by the research team after the clinical encounter.

The app collects basic demographics, including race, sex, income, age, frequency of smoking and desire to quit for control groups and intervention groups but was designed to collect much more detailed information from intervention subjects.

User input, including audio capture from the exit interview, is temporarily stored on the device in an app-based database until the session is complete. Data is then uploaded wirelessly to a Health Insurance Portability and Accountability Act (HIPAA)-compliant Research Electronic Data Capture (REDCap) database whose redundant servers were housed at Cincinnati Children’s Hospital Medical Center.

Summary

A user friendly and acceptable iPad app-based decision aid for use in primary care offices was created. The design process presented several challenges (Table 2) including navigating requests to our coders for repeated changes to both content and design, resolving conflicting feedback from our diverse group of stakeholders and even within our study group, realizing the
time-intensity of editing content and code, and integration into a clinical setting. We observed challenges between engineers and physicians that required management and interaction to remain on target.

**Limitations**

Our study had a few predicted and unforeseen limitations. We were not, as we had foreseen, able to fully integrate the app into the EHR so that patient selections and chosen interventions would populate into the medical record. After discussing with our Health IT Department, both our timeframe and budget were far too small for this.

We were able to integrate into the clinic sites in several ways. We gained access to the network and Internet connection, allowing real-time secure data transfer to our database. We enabled automated Health Insurance Portability and Accountability Act (HIPAA-compliant) e-mail messaging to patients at the end of the session summarizing interventions chosen, and we built new matching templates (i.e. SmartPhrases and a SmartSet order set) for our EHR so that providers could quickly copy over patient selections from the study. Finally, though the existing clinic printers could not be used to print from our app, we placed AirPrint enabled printers at each site to allow printing summaries for patients and PCPs.

Another limitation was that we were unable to create a generic enough application framework so that clinical content could be swapped out to create decision aid apps for other clinical scenarios, diabetes medicine selection for example. This was an initial goal, but during the app design process, we made a decision to choose personalization for the patient over future generalizability.

We also discovered not only would much more work have to go into making our iPad app compatible with iPhones or even Android devices, but we had to pick landscape or portrait display on the iPad instead of allowing the user to decide to ensure the app displayed correctly
on the screen. Making the display orientation neutral would have required more programming time than allowed for our study.

**DISCUSSION**

m-Health is no longer a novel approach or tool for healthcare. Tools have been developed and tested for smoking cessation [15,23-26] and other clinical conditions. Today, patients are more engaged in the management of their health than ever before. SDM tools are important in the management of disease and some healthcare is actually moving toward the patient-centered home [33-35]. Acceptance of computer-based tools in addressing patients’ needs whether in the home or exam room are more acceptable today as well [36-37]. Bashshur et al. report on empirical foundations on telemedicine intervention for chronic disease management [38].

Development of m-Health solutions are time consuming and challenging. The life cycle of such devices are short lived and must be upgradeable with changes in software versions, operating systems, and consumer needs. Nevertheless, healthcare will continue to integrate technologies like e-Quit worRx into the management of a patient’s health.

**Acknowledgments**

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**Declaration of conflicting interests**

The authors declare that there is no conflict of interest.
References


Figure 1. Conceptual Framework for Shared Decision Making Using an App for Evidence-Based Smoking Cessation
Figure 2. Study flow and app design process

- **Lit Review**
  - 5 AS: Ask, Advise, Assess, Assist, Arrange
  - Smoking history
  - Motivational interviewing
  - Comparative effectiveness
  - Patient centered shared decision making

- **Draft App**
  - Feedback:
    - Team members
    - Smoking cessation experts
    - Patients
    - PCPs and staff

- **Prototype App**
  - Usability testing feedback
    - Smoking cessation experts
    - Patients
    - PCPs and staff

- **Production App**
  - Controlled Pilot study
    - 3 primary care offices
    - 72 Patients
    - After visit patient debriefing
    - Clinic staff debriefing
    - 12 week follow up call
Figure 3. Development of select e-Quit WorRx screenshots from Grant Concept, to Storyboard, through iterative App versions

<table>
<thead>
<tr>
<th>Grant concept</th>
<th>Patient Feedback</th>
<th>Method Selection</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>So, it sounds like you...</td>
<td>Ways people quit</td>
<td>Summary Report Screen</td>
<td></td>
</tr>
<tr>
<td>Aren’t quite ready</td>
<td>Call today</td>
<td>Reasons i smoke:</td>
<td>Leave likely to help:</td>
</tr>
<tr>
<td>Are thinking about it</td>
<td></td>
<td>Tobacco use</td>
<td>Never</td>
</tr>
<tr>
<td>Are ready to quit</td>
<td></td>
<td>戒烟</td>
<td>Never</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storyboard</th>
<th>Method Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your personalized feedback from e-Quit WorRx</td>
<td>Ways people quit</td>
</tr>
<tr>
<td>Your screen will present a summary of your responses and next steps to create a plan with your doctor to develop your personal action plan.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>App version 1.0</th>
<th>Method Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your personalized feedback from e-Quit WorRx</td>
<td>Ways people quit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Version 2.4, Final</th>
<th>Method Selection</th>
</tr>
</thead>
</table>
**Figure 4.** Grade level (left scale) and Reading Ease score (right scale) for app version 2.2 (left) and 2.3 (right)
Figure 5. System Usability Score across app versions
Table 1: Themes from qualitative analysis of focus groups and usability testing

<table>
<thead>
<tr>
<th>App Development</th>
<th>Theme</th>
<th>Representative Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>Present treatment options in the app</td>
<td>Present different treatment options, main risks of things, like with Chantix it is a plus and minus because it is actually very good at helping some people but it can have some nasty side effects.</td>
</tr>
<tr>
<td></td>
<td>Present cost in the app</td>
<td>There was a cigarette calculator thing that I went online and you put in how many years you have smoked and how much and with that you could have bought a luxury car with all that money. Something along those lines.</td>
</tr>
<tr>
<td>Physicians</td>
<td>Gauging their readiness</td>
<td>I do not necessarily go through the formal stage criteria but after 20 years you have some idea of what phase someone is in. That helps to see if they are ready to quit-something like that.</td>
</tr>
<tr>
<td></td>
<td>Time to complete the app information</td>
<td>If you are delaying my visit because they are out there filling this thing out and we are calling them and they are not done with their survey, then it would be a problem. Has to be done in waiting room or exam room before I get there.</td>
</tr>
<tr>
<td>RN’s and Medical Assistants</td>
<td>What’s worked in the past and what hasn’t would be helpful</td>
<td>I say the doctor has lots of materials and I ask them what they have been trying to do, what worked and what did not, it would be helpful to know that about the patient.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>App Testing</th>
<th>Theme</th>
<th>Representative Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>Visual and ease-of-use</td>
<td>More uniform text style, better contrast, too dark of a background, visually challenging-just kind of drives me crazy, lots of mental gymnastics that make you leap back and forth.</td>
</tr>
<tr>
<td>V2.1</td>
<td>Customized feedback and knowledge</td>
<td>I could tell that the feedback was customized at the end, kind of surprised, and I liked increased knowledge about cost of smoking and personal barriers to quitting.</td>
</tr>
<tr>
<td>Physician</td>
<td>Evidence based methods</td>
<td>Evidence-based methods are helpful, pros and cons, cost is helpful</td>
</tr>
<tr>
<td>V2.3.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V2.3.1</td>
<td>Saves time for visits about smoking or patient wants to discuss smoking</td>
<td>Cuts back on me asking all the questions, gives you some tools that might be helpful, and app is a conversation starter</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Medical Assistant V2.3.1</td>
<td>Time for filling out app</td>
<td>It was not disruptive, It went well and we still stayed on schedule</td>
</tr>
</tbody>
</table>
Table 2. Challenges by area: e.g. Content, Feedback, Coding/working with engineers, HIT integration

<table>
<thead>
<tr>
<th>Topical Area</th>
<th>Challenge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content development</td>
<td>1. Deciding what evidence to include when literature is conflicting</td>
</tr>
<tr>
<td></td>
<td>2. Time consuming edits of text screen by screen that required medical knowledge</td>
</tr>
<tr>
<td></td>
<td>3. Fidelity of detail on smoking cessation – physician vs patient confusion to the end user</td>
</tr>
<tr>
<td>Feedback</td>
<td>1. The process was iterative and feedback was influenced by level of understanding</td>
</tr>
<tr>
<td></td>
<td>2. Technical prowess</td>
</tr>
<tr>
<td></td>
<td>3. Visual appearance and appeal of the app</td>
</tr>
<tr>
<td></td>
<td>4. Too many colors and busyness of screen make is chaotic</td>
</tr>
<tr>
<td></td>
<td>5. Compromising when feedback from different sources conflicted</td>
</tr>
<tr>
<td>Coding and working with programming engineers</td>
<td>1. Challenging dialogue between medical and engineering/computer programming personnel</td>
</tr>
<tr>
<td></td>
<td>2. Acceptability of multiple iterative change requests vs desire of programmers to get a full request, complete it once and be done</td>
</tr>
<tr>
<td>Health Information Technology and clinical integration</td>
<td>1. In ability to fully integrate with electronic health record (Epic) at clinical sites to update patient’s record</td>
</tr>
<tr>
<td></td>
<td>2. Network access at clinical sites – workaround devised</td>
</tr>
<tr>
<td></td>
<td>3. Printer access – had to purchase new printers</td>
</tr>
</tbody>
</table>