Developing a decision support system for tobacco use counselling using primary care physicians

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ABSTRACT

Background Clinical decision support systems (CDSS) have the potential to improve adherence to guidelines, but only if they are designed to work in the complex environment of ambulatory clinics as otherwise physicians may not use them.

Objective To gain input from primary care physicians in designing a CDSS for smoking cessation to ensure that the design is appropriate to a clinical environment before attempts to test this CDSS in a clinical trial. This approach is of general interest to those designing similar systems.

Design and approach We employed an iterative ethnographic process that used multiple evaluation methods to understand physician preferences and workflow integration. Using results from our prior survey of physicians and clinic managers, we developed a prototype CDSS, validated content and design with an expert panel, and then subjected it to usability testing by physicians, followed by iterative design changes based on their feedback. We then performed clinical testing with individual patients, and conducted field tests of the CDSS in two primary care clinics during which four physicians used it for routine patient visits.

Results The CDSS prototype was substantially modified through these cycles of usability and clinical testing, including removing a potentially fatal design flaw. During field tests in primary care clinics, physicians incorporated the final CDSS prototype into their workflow, and used it to assist in smoking cessation interventions up to eight times daily.

Conclusions A multi-method evaluation process utilising primary care physicians proved useful for developing a CDSS that was acceptable to physicians and patients, and feasible to use in their clinical environment.

Keywords: medical informatics, qualitative research, smoking cessation
Introduction

Computer-mediated clinical decision support systems (CDSSs) are software systems that match characteristics of a patient with a knowledge base of information on recommended care in order to provide patient-specific recommendations as well as other information management services. A number of CDSSs intended to support the use of clinical guidelines have improved physician adherence to guidelines, but others have been unsuccessful.

To be successful, a CDSS must work within the complex environment of ambulatory clinics where this technology interacts dynamically with clinicians, patients and existing office systems. Workflow integration is one of the grand challenges for health information technology. If physicians find these tools too difficult to incorporate into clinical workflow they will be abandoned. To avoid such problems, a CDSS should first reflect the needs and preferences of the users (e.g. physicians) and the organisational systems (e.g. ambulatory clinics) within which it works. Such a CDSS should then be introduced into clinical practice only after a rigorous schedule of iterative usability testing and formative evaluation during which the CDSS is modified to reflect the needs of the user and the demands of the clinical environment.

We followed these recommendations during development of a CDSS to assist physicians in using the United States Public Health Service (USPHS) Guideline on Tobacco Use and Dependence Treatment. This guideline recommends physicians perform the five 'As':

1. identify patients’ smoking status (‘ask’)
2. advise those who smoke to quit
3. assess readiness to quit
4. assist in quit attempts and
5. arrange for follow up.

A CDSS for this guideline could guide physicians in choosing and prescribing pharmacotherapy, facilitate referral of patients to counselling resources and provide for patients a tailored handout with this information, potentially improving adherence and effectiveness and saving time.

We employed the three-phase development process of definition, usability testing, and clinical testing recommended by Wyatt and Spiegelhalter (Figure 1). This process used a multi-method ethnographic approach that included surveys of key stakeholders, iterative usability testing with primary care physicians, validity testing and consultation with an expert panel, initial clinical testing with patients, and then pilot testing by physicians.

In the definition phase we surveyed 600 Vermont primary care and subspecialty physicians and 93 clinic office managers to determine current practice, the environment within these ambulatory clinics, perceptions of barriers to performing smoking cessation interventions and preferences among potential information management services. This paper describes the second and third phases of iterative design and testing of the CDSS, including initial clinical testing that demonstrated it was feasible for physicians to use this CDSS in two primary care clinics.

Methods

Iterative usability and validity testing

The initial prototype was developed by the Yale Center for Medical Informatics based on the responses to the surveys, on the smoking cessation resources in Vermont and neighbouring states and on the content of the USPHS Guideline. The purpose of the second phase was formative evaluation of the evolving CDSS.
Our evaluation was guided by two theories relevant to developing information technology that favor adoption by users: the Technology Acceptance Model 2 and Rogers’ Diffusion of Innovations.24,25 Semi-structured interview items were constructed to address the following attributes from these two theories of the CDSS as viewed by the physicians:

- **perceived usefulness** including job relevance and the quality of output
- **relative advantage** over their current smoking cessation interventions
- **compatibility** with clinic systems
- **perceived complexity** of the CDSS compared to other information technology and their
- **intention to use** the CDSS if it were available.

Because the small number of participants would make valid analyses difficult, we chose not to utilise quantitative measures of these perceptions. Qualitative methods were chosen to complement our prior surveys and to provide more rich, in-depth and nuanced information than a quantitative questionnaire could provide.

**Physician panels for usability testing**

The working prototype was first subjected to usability testing with three physicians active in the tobacco control community. In the second round of testing, four physicians were randomly selected from a list of primary care physicians in Chittenden County, Vermont. All seven physicians invited to participate agreed to do so. Usability testing consisted of each physician using the CDSS during hypothetical patient encounters presented by a test monitor (SC) while an observer (TWM) recorded the interactions. The testing combined three sources of data:

1. a think-aloud protocol
2. handwritten field notes during observation
3. audio taped ethnographic interviews that included
   the items derived from the two theories described above.26

These interviews and observations were analysed by two of the investigators (TWM and SC) using codes based on the two theories. Validity was addressed by reviewing our conclusions with the participants,77,28 by discussing results with expert panel members and by having one investigator (BK), who was not present at these sessions, review data analysis and interpretation. Following these analyses, we developed a list of design changes that were then incorporated into the revised CDSS used in the next round of usability testing.

**Expert panel**

We formed an expert panel consisting of three experts on tobacco use treatment, one each in behavioural counselling, pharmacotherapy and patient education, and an additional physician with expertise in ambulatory clinic processes. These individuals reviewed the CDSS’s validity as an implementation of the USPHS Guideline and provided guidance on the content and redesign of the CDSS throughout this process. We also consulted with additional individuals who had expertise in clinic information systems, Vermont’s tobacco use cessation services, readability of patient handouts and Medicare billing documentation and compliance.

**Clinical testing**

**Testing with patients**

The initial clinical testing of the modified CDSS was performed in the ambulatory clinic of one of the investigators (TWM). Once technical issues of transferring administrative data to the CDSS and printing accurate documents were resolved, the investigator used the CDSS with consenting patients identified through the clinic’s standard screening process as current or recent (within one month) smokers. Attempts were then made to interview these patients by telephone within two weeks of this visit to assess the patients’ perceptions of the encounter and the CDSS.

**Field tests in primary care clinics**

Two physicians and the staff in each of two primary care clinics agreed to field test the CDSS. These two clinics were selected because they were not involved in any other current outpatient research studies and they used a common patient administrative database program (GE Healthcare). At the end of the testing, each physician was interviewed separately by TWM using a semi-structured interview guide based on the same items as those in the usability testing. The interview was audio taped for transcription and review. The protocols for the usability and clinical testing were reviewed and approved by the University of Vermont’s Institutional Review Board.

**Results**

**Phase 2: iterative usability testing**

In our 2003 surveys, we found that 94% of the clinics had a computerised registration system, but only 20%
of Vermont ambulatory clinics had an electronic health record (EHR) into which a CDSS could be integrated,\textsuperscript{23} similar to a contemporary national estimate.\textsuperscript{29} Therefore, a CDSS intended for wide adoption would need to function in offices in which physicians might not otherwise use a computer during patient visits. However, the CDSS could potentially utilise information from a computerised administrative database. Both physicians and clinic office managers preferred that the CDSS be on a handheld computer (PDA) for both space and cost considerations\textsuperscript{23} and both groups wanted the CDSS to:

1. provide patient-specific information
2. generate tailored patient handouts
3. utilise state of residence and type of health insurance in forming recommendations and
4. document the intervention for the medical record.\textsuperscript{23}

The initial prototype of our smoking cessation PDA decision support system (SC-PDA) and all subsequent prototypes of this CDSS used a web browser on a PDA to connect via a wireless local area network to a server in a ‘client–server’ relationship. Each day, a software routine on the server pulled a flat file of data on scheduled patients from the administrative database that included the primary physician, insurance coverage, medical record number, date of birth and residence. The server also contained the CDSS algorithms based on the USPHS Guideline\textsuperscript{18} and information about local cessation resources. Based on input by the physician on the PDA screens during the patient–physician interaction, the server compiled and printed documents at the checkout station with information specific to the patient.\textsuperscript{30} Figure 2 provides a schematic of the prototype system used in the clinical testing and Figure 3 shows examples of two of the screens.

Prior research demonstrated that an active prompt to use a CDSS was more effective than a passive system relying on a physician to remember to use the system.\textsuperscript{1,2} We, therefore, designed the first prototype so that the vital signs and smoking status were recorded on a computer at intake and then communicated via the network to the physician’s PDA as an electronic prompt that would alert the physician to consider using the SC-PDA.

All seven physicians who used the SC-PDA in simulated clinical encounters provided numerous suggestions for improvements or alterations. We modified the SC-PDA in response to this feedback and that of the expert panel as summarised in Table 1.

For illustrative purposes, we review the process that led to a major revision in the SC-PDA: changing the electronic alert to a paper-based prompt to use the SC-PDA. Two of three physicians in Round 1 of usability testing had negative opinions about the electronic alert. Without an EHR in the clinic they saw no value in entering vital signs electronically other than for the sole purpose of identifying smoking status, and viewed this process as interfering with current systems for patient intake. To gauge preferences, in the second round of usability testing we presented both the electronic alert and an alternative paper-based prompt for using

![Figure 2](image_url)

Figure 2. A schematic of the final prototype that was tested in the clinical testing. Stickers on the clinic vital sign record would prompt the physician to use the SC-PDA with appropriate patients based on smoking status. The server acted as a central repository for patient administrative data and guideline information. The physician communicated with this server over a wireless network via a PDA from which additional information could be entered about the patient and through which information about patient-specific guideline recommendations and resources were displayed. The server compiled and printed patient specific documents based on these data elements.
the SC-PDA. The alternative method retained the transfer of patient administrative data to the physician’s PDA, but not the vital signs or smoking status. Instead, the clinic’s existing vital signs record was adapted to indicate the smoking status by a coloured sticker that could alert the physician to open the SC-PDA program, select the specific patient from their roster, confirm the smoking status and then proceed with the intervention. Three of four primary care physicians preferred the paper-based visual prompt because it required the least change in their clinic intake system. The fourth physician did not like either version because it was his opinion that asking about smoking status every visit would alienate patients. Based on the majority

Table 1 Major design changes in the SC-PDA resulting from usability testing

<table>
<thead>
<tr>
<th>Problem noted</th>
<th>Design alterations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Electronic alert to use SC-PDA with appropriate patients incompatible with clinic workflow and systems</td>
<td>Alternative paper-based visual prompt on vital signs sheet tested with physicians and then substituted</td>
</tr>
<tr>
<td>2 Time to obtain health history to review for medication cautions/contraindications viewed as excessive</td>
<td>Nicotine nasal spray deleted from medication choices to reduce number of screened conditions Two-stage screening to exclude common contraindications to initial medication use first (pregnant, unstable angina, serious arrhythmia)</td>
</tr>
<tr>
<td>3 Unable to cycle from ‘not motivated’ to ‘motivated’ if patient changes intention to quit during counselling</td>
<td>Button on screen recycles user back to ‘Assess’ readiness to consider quit attempt</td>
</tr>
<tr>
<td>4 Insufficient counselling guidance</td>
<td>Optional screen with prompts allows MD to provide more counselling if desired</td>
</tr>
<tr>
<td>5 Layout of tailored handouts not inviting; language at too high a reading level</td>
<td>Tailored handout scripts reviewed and edited by education and readability consultants</td>
</tr>
<tr>
<td>6 Need health record documentation that supports Medicare billing</td>
<td>The documentation note was redesigned to supplement the standard documentation of the visit and to comply with requirements for billing for tobacco cessation counselling</td>
</tr>
</tbody>
</table>
responses, we changed to the paper-based visual prompt in the subsequent prototype.

Phase 3: clinical testing

Testing with patients

Nine patients (three female; six male) were recruited to have one investigator, a physician, use the CDSS with them. Seven of the patients were current smokers and two were recent quitters. The sequence of screens appropriate for each patient’s smoking status and treatment preferences was completed in an average time of ten minutes (range 8–13 minutes). All but one of the nine patients actively looked at the PDA screens with the physician during the process. Five of the nine completed a structured telephone interview with another investigator (SC) within two weeks of the visit; one declined the interview, one did not recall the SC-PDA, and two were unable to be contacted. Four of the five interviewed patients rated the SC-PDA positively on its usefulness in assisting the discussion on smoking; the other patient was neutral and none had any negative comments about the SC-PDA or having the physician use it with them. Some stated that being able to follow the PDA screens made the questions easier to understand and facilitated their decision-making. Several design problems were discovered during this phase of the testing, and the subsequent design changes are outlined in Table 2.

Table 2 Design alterations adopted after initial clinical testing with patients

<table>
<thead>
<tr>
<th>Problem noted</th>
<th>Design alterations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 In recent quitters, no ability to increase dosage to address significant withdrawal symptoms</td>
<td>SC-PDA changed to allow physician to choose appropriate dose of nicotine products based on withdrawal symptoms</td>
</tr>
<tr>
<td>2 Prescription instructions not available at the end of the SC-PDA algorithm when most physicians write prescriptions</td>
<td>Last screen of the algorithm for each patient provides prescription instructions for recommended medications if any selected</td>
</tr>
<tr>
<td>3 If nicotine inhaler selected, physician needed to be prompted to write a script</td>
<td>Pop-up screen added to remind physician that the inhaler is not over the counter and requires a script</td>
</tr>
<tr>
<td>4 Printing order of medication instructions did not follow recommendations if two selected</td>
<td>In some patients, nicotine patch is first medication initiated, with addition of lozenge or gum only if continued strong urges. Order of medication instructions changed to correspond with this usual sequence</td>
</tr>
<tr>
<td>5 Names of several of the MAO inhibitors unfamiliar to physicians as they checked for this contraindication to Bupropion use</td>
<td>Information button allows physicians to review generic and brand names of medications with this property while in screen to review medical history cautions and contraindications to specific medication use</td>
</tr>
</tbody>
</table>

Field tests in primary care clinics

Neither of the two participating clinics had a system for identifying a patient’s smoking status. Working with the clinic staff, the process of obtaining and recording vital signs was adapted to include determination of smoking status by intake personnel and using stickers to indicate this status on the vital sign sheet. This process was implemented before any further changes were made so that adjusting to this system would be less likely to affect SC-PDA testing. After two weeks, physicians were each given a PDA and trained on the SC-PDA program in one session of approximately 60 minutes. Clinic personnel were trained on the handling of the tailored patient handouts, fax referral forms and chart documentation notes. The participating physicians used the SC-PDA during a trial period of three weeks. Each physician’s assigned PDA only displayed the patients on his or her own schedule. An additional entry labelled ‘generic’ allowed the program to be used with unscheduled patients, though without the benefit of the administrative information.

The field tests in the two clinics were completed as scheduled except for a single day when the SC-PDA was inoperative because of a server malfunction. In the physician interviews following the trial periods, the frequency of use of the SC-PDA estimated by each of the four physicians ranged between only four times in three weeks to as many as eight times in one day out of 18–20 daily patient visits, with the most cited frequencies as one and four times a day. The physician using the
SC-PDA the least stated that he had few opportunities as there were few active smokers in his panel of patients. The clinic support staff corroborated the frequency of use of the SC-PDA based on their handling of the patient tailored handouts distributed at checkout.

Two of the physicians reported that the ability to show the screens to the patient and have them ‘rally around’ the computer and follow along with the steps of making recommendations was a relative advantage of the SC-PDA over standard counselling.

‘... so it was sort of a different approach. Was not just a provider saying “look, I want you to quit”. It was a provider saying, “I want you to quit and we have this program that we’re using that could really maximize your chances at success”.’ (Physician 1)

All four physicians commented favourably on the ability to personalise both the spoken and written counselling, check for medication cautions and contra-indications, and document their services to support billing as well as insurance coverage of medications.

The two physicians in the first trial clinic found the time required to use the SC-PDA was a relative disadvantage. With probing, we learned to reduce user time by emphasising during training that the SC-PDA could print a tailored handout even if physicians chose not to do the intervention and that physicians could skip the quit date screen if they preferred. Prior to the trial in the second clinic, we adapted the training to highlight these options and eliminated a counselling selection screen. The two physicians in the second trial clinic both reported that they could use the SC-PDA efficiently. The physician in this clinic who used it the most stated;

’It actually is pretty quick and easy. I suspect that most of my interventions were in the lower end of three to ten minutes.’ (Physician 4)

This physician also commented that she would tend to bill for the service when using the SC-PDA, whereas before she had not, partially compensating for the additional time spent. Notably this physician had not previously used a PDA.

Discussion

We developed a CDSS for smoking cessation interventions hand-in-hand with physicians – the intended end users. We used an ethnographic approach in order to design a CDSS that provided advantages over how physicians usually advise patients about smoking, that was compatible with clinic workflow, and that was integrated with how physicians conduct patient visits. Through usability testing, we were better able to understand the workflow of the clinical practice, translate these preferences into the design of our SC-PDA and then implement the SC-PDA in two ambulatory clinics. This experience illustrates the value of a staged multi-method ethnographic process for obtaining detailed end user feedback during the development of health information technology.

For example, we first incorporated an electronic alert into the prototype SC-PDA because this characteristic had been associated in the literature with improvements in physician adherence. Usability testing demonstrated, however, that physicians were resistant to a different method of identifying smoking status because of its perceived impact on existing office systems. This opinion was not apparent in our surveys of physicians and clinic managers. Had we retained the electronic alert, we could have experienced multiple failed attempts during implementation. Additional problems with the SC-PDA became apparent only when using it with patients in the clinical setting.

Our pilot tests in two clinics demonstrated that physicians did use the final SC-PDA prototype in actual clinical settings, and did see a relative advantage of the SC-PDA over usual practice. The time required to use the SC-PDA is a recognised barrier to preventive care in general and tobacco counselling in particular. We took several measures to address this in our design. First, additional information about medications and counselling was provided in screens that were available if desired, but it was not necessary to work through these. Second, we acted on physician recommendations to streamline information and reduce the content and number of screens. Third, the SC-PDA could produce a tailored handout for a patient even if the physician opted not to use the intervention during a patient visit.

An unanticipated observation was that both patients and physicians saw benefits in having the patient view the screens along with the physician. This shared viewing of screen contents engaged the patient and appeared to improve patient understanding. A CDSS designed for patients to use by themselves would not capitalise on this interaction. The future development of decision support systems should exploit a CDSS’s potential for interactive, collaborative decision making.

There are limitations to this approach to CDSS development. The time-intensive nature of usability testing reduces the number of end users who can provide feedback. Those who accept an invitation to do usability testing may not be representative of other physicians. In addition, a CDSS developed through this process still may not increase guideline adherence or improve patient outcomes even if physicians use the CDSS. Clinical trials are necessary to address these questions. However, this type of CDSS development should precede any large-scale testing to avoid expensive null results from a CDSS that physicians will not use during these clinical trials.
A particular limitation to our methods was that one of the developers (TWM) recruited the physicians and clinics selected for usability testing and was present during the usability testing. However, other evaluators (SC and BK) were not involved in the SC-PDA development. Wears et al recommend that the developers of a health information technology system should not be the evaluators of the system as there is the potential for bias. The developer/evaluator may selectively record criticisms and the subjects may be less open with the developer about problems they perceive.

Conclusions

Successful integration of health information technology into clinical practice will require collaborative development of these systems with physicians, patients and support staff. The combination of multiple and iterative ethnographic methods incorporating surveys, usability testing and expert panels is feasible and useful. Through this process we avoided costly and potentially fatal errors in the design of our CDSS.

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**CONFLICTS OF INTEREST**

None.

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