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Usability testing of Avoiding Diabetes Thru Action Plan Targeting (ADAPT) decision support for integrating care-based counseling of pre-diabetes in an electronic health record

Dillon Chrimes^{1,2}, Andre Kushniruk¹, Nicole R. Kitos³, and Devin M. Mann³

Devin M. Mann: dmann@bu.edu

¹School of Health Information Science, University of Victoria, British Columbia, Canada

²Sierra Systems Group Inc., Health Practice and IT Consulting, Vancouver-Calgary-Toronto, Canada

³Department of Medicine, Section of Preventive Medicine and Epidemiology, Boston University, School of Medicine, Boston, MA, USA

Abstract

Purpose—Usability testing can be used to evaluate human computer interaction (HCI) and communication in shared decision making (SDM) for patient-provider behavioral change and behavioral contracting. Traditional evaluations of usability using scripted or mock patient scenarios with think-aloud protocol analysis provide a to identify HCI issues. In this paper we describe the application of these methods in the evaluation of the Avoiding Diabetes Thru Action Plan Targeting (ADAPT) tool, and test the usability of the tool to support the ADAPT framework for integrated care counseling of pre-diabetes. The think-aloud protocol analysis typically does not provide an assessment of how patient-provider interactions are effected in “live” clinical workflow or whether a tool is successful. Therefore, “Near-live” clinical simulations involving applied simulation methods were used to compliment the think-aloud results. This complementary usability technique was used to test the end-user HCI and tool performance by more closely mimicking the clinical workflow and capturing interaction sequences along with assessing the

Correspondence to: Devin M. Mann, dmann@bu.edu.

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functionality of computer module prototypes on clinician workflow. We expected this method to further complement and provide different usability findings as compared to think-aloud analysis. Together, this mixed method evaluation provided comprehensive and realistic feedback for iterative refinement of the ADAPT system prior to implementation.

Methods—The study employed two phases of testing of a new interactive ADAPT tool that embedded an evidence-based shared goal setting component into primary care workflow for dealing with pre-diabetes counseling within a commercial physician office electronic health record (EHR). Phase I applied usability testing that involved “think-aloud” protocol analysis of 8 primary care providers interacting with several scripted clinical scenarios. Phase II used “near-live” clinical simulations of 5 providers interacting with standardized trained patient actors enacting the clinical scenario of counseling for pre-diabetes, each of whom had a pedometer that recorded the number of steps taken over a week. In both phases, all sessions were audio-taped and motion screen-capture software was activated for onscreen recordings. Transcripts were coded using iterative qualitative content analysis methods.

Results—In Phase I, the impact of the components and layout of ADAPT on user’s Navigation, Understandability, and Workflow were associated with the largest volume of negative comments (i.e. approximately 80% of end-user commentary), while Usability and Content of ADAPT were representative of more positive than negative user commentary. The heuristic category of Usability had a positive-to-negative comment ratio of 2.1, reflecting positive perception of the usability of the tool, its functionality, and overall co-productive utilization of ADAPT. However, there were mixed perceptions about content (i.e., how the information was displayed, organized and described in the tool).

In Phase II, the duration of patient encounters was approximately 10 minutes with all of the Patient Instructions (prescriptions) and behavioral contracting being activated at the end of each visit. Upon activation, providers accepted the pathway prescribed by the tool 100% of the time and completed all the fields in the tool in the simulation cases. Only 14% of encounter time was spent using the functionality of the ADAPT tool in terms of keystrokes and entering relevant data. The rest of the time was spent on communication and dialogue to populate the patient instructions. In all cases, the interaction sequence of reviewing and discussing exercise and diet of the patient was linked to the functionality of the ADAPT tool in terms of monitoring, response-efficacy, self-efficacy, and negotiation in the patient-provider dialogue. There was a change from one-way dialogue to two-way dialogue and negotiation that ended in a behavioral contract. This change demonstrated the tool’s sequence, which supported recording current exercise and diet followed by a diet and exercise goal setting procedure to reduce the risk of diabetes onset.

Conclusions—This study demonstrated that “think-aloud” protocol analysis with “near-live” clinical simulations provided a successful usability evaluation of a new primary care pre-diabetes shared goal setting tool. Each phase of the study provided complementary observations on problems with the new onscreen tool and was used to show the influence of the ADAPT framework on the usability, workflow integration, and communication between the patient and provider. The think-aloud tests with the provider showed the tool can be used according to the ADAPT framework (exercise-to-diet behavior change and tool utilization), while the clinical simulations revealed the ADAPT framework to realistically support patient-provider communication to obtain behavioral change contract. SDM interactions and mechanisms affecting

protocol-based care can be more completely captured by combining “near-live” clinical simulations with traditional “think-aloud analysis” which augments clinician utilization. More analysis is required to verify if the rich communication actions found in Phase II compliment clinical workflows.

Keywords

Usability; evidence-based medicine; protocol-based care; electronic health records; clinical simulations; behavioral change; behavioral contracting; healthcare providers; patient counseling

INTRODUCTION

Shared decision making (SDM) engages patient and provider in a mutual negotiation process in order to develop more tailored, achievable chronic disease management goals. Electronic health records (EHRs) have great potential for enhancing SDM; in particular, their delivery of clinical decision support (CDS) tools in somewhat protocol-based care to providers during the decision-making process may be an important platform for enhancing SDM.¹ Additionally, CDS tools can deliver evidence-based medicine (EBM) to the point-of-care, influencing the flow of the clinical encounter towards facilitation of efficient and effective healthcare.^{2,3} Patient-provider decisions are increasingly chaotic and time pressed, this limits the effectiveness of CDS tools and protocol-based care, particularly poorly designed ones that disrupt workflow or have low usability.⁴⁻⁶ Human-computer interactions (HCI) research is devoted to improving the usability and effectiveness of technologies such as CDS. A HCI research framework can uncover important design opportunities that may improve the ability of CDS to encourage SDM techniques such as goal setting, action planning and behavioral contracting.

Critical factors for effective design of CDS tools for SDM include integration with provider workflow, anticipation of provider needs through interactive HCI sequences,⁷ and a need to study the potential usability of these module types in EHR systems.^{5,8-12} Formal usability testing of HCI has begun to be considered critical to the EHR meaningful use and adoption, implementation and software lifecycles; and this clearly applies to CDS tools.^{5,13} However, SDM techniques are a new application of a CDS in real-time patient-provider interactions. Discussions and observations of usability with care providers have provided a large volume of evidence to suggest optimal system use and outcomes depend on improved usability during the EHR design process.^{11,14} Current best practices promote utilization of cognitive approaches to assess HCIs within the EHR system.^{14,15} A variety of both summative and formative user-based approaches have been employed to evaluate EHRs including “think aloud” usability testing, cognitive task analysis, and surveys.¹⁶⁻¹⁸ The “think-aloud” formative usability approach or protocol analysis, in which users verbalize their thoughts while performing pre-determined tasks within the application or CDS, is particularly well-suited to identify pitfalls to adoption prior to official software release. It integrates qualitative and quantitative analyses of direct observations of transcribed scripted provider commentary and HCI to identify surface level usability issues.^{19,20} However, this approach limits the amount of unrestricted interactions users have with the CDS and the underlying protocol of the program combined with the interface integrated architecture of the EHR

system. It does not provide a robust description of a system's influence on computer-mediated communication,²¹ and is dependent on a highly constrained simulation of patient-provider-EMR interactions.

Some groups have employed studies that measure the time to completion of set tasks as measures of usability and learnability of CDS.⁵ However, even these more unrestricted studies may have limited correspondence to live patient encounters. It is increasingly important, especially with sustained political influences on standardization of care to improve patient outcomes and reduced costs, to fully understand the usability, workflow impact and potential disruptiveness of new CDS tools prior to implementation and distribution. In this study, we evaluated a multi-disciplinary designed CDS tool, termed ADAPT (Avoiding Diabetes Thru Action Plan Targeting), using a combination usability evaluation approach comprised of patient-provider think-aloud protocol analysis with “near-live” clinical simulations to document and assess the usability and quality of patient-provider-ADAPT tool.^{22,23}

Through a process involving two usability studies, we attempted to improve the CDS prototype for integrated SDM inspired behavioral change. In the ADAPT framework and its CDS module, patients with pre-diabetes are led through a shared goal setting and action planning tool to negotiate exercise and diet goals.²⁰ This paper describes the two phases of evaluation that we conducted of the ADAPT CDS. Phase I involved usability testing in conjunction with “think-aloud” protocol analysis to assess HCI as the healthcare providers performed specific tasks following a script for invoking the ADAPT tool.^{24,25} Phase II involved a “near-live” clinical simulation to assess how providers interact with the ADAPT CDS while interviewing a simulated patient encounter to create an action plan.²⁶ We hypothesized that these methods provide complementary data; allowing a more comprehensive, “near-live” assessment of the CDS impact on clinical care.

METHODS

The multidisciplinary design of the ADAPT tool prototype, constructed as a module for EPIC EHR software interface, integrates evidence-based interventions for behavioral change with already-existing technology and is described in detail in previous publications.^{20,27} In brief, the ADAPT CDS system captured baseline levels of pre-diabetes related exercise and diet behaviors that were used to prompt SDM negotiation of goal setting/action planning encounters with their primary care provider within the EHR. Using principles of behavior change theory and protocol of the ADAPT framework, the team utilized in-depth interviews to produce a prototype diabetes prevention counseling system embedded in an EHR.²⁰ With the rough prototype in hand, the team began a two phase process to enhance the workflow integration, usability and effectiveness of the tool according to the ADAPT framework. All HCIs were observed using video and audio recording and captured on a standardized clinical workstation running Hypercam® screen recording software.

Phase I Usability testing using “think aloud” protocol analysis

Subjects—The eight subjects who participated in the “think aloud” phase of usability testing were primary care providers practicing at a general medicine clinic associated with

the hosting academic institution. The subjects were chosen from volunteers that had previously used the underlying EPIC EHR system and were not involved in prototype design or implementation for EPIC's EHR. Extent of her use in primary care varied among the subjects and no subjects had been exposed to the ADAPT CDS toolset prior to the study.

Procedure—The usability session was conducted in a typical clinic office setting. The research staff developed interview scripts for standardized ADAPT based pre-diabetes counseling scenarios with associated navigational instructions. Under instruction from the experimenter or research staff, subjects followed the scripted navigation to enter patient data, trigger the CDS alert for the ADAPT tool, review and negotiate exercise and diet action plans, and establish a behavioral contract to improve exercise/diet and reduce risk of diabetes onset. Throughout each case, subjects were prompted by the experimenter to “think aloud” or verbalize their thoughts while working through each of the CDS components (Table 1).^{15,16} At the end of each interview, the user was asked a series of follow-up questions to elicit general acceptance or dislikes to the feedback on the use, utilization, and conceptual end-user effectiveness of the tool for the main sequence interactions of exercise and diet counseling.

Data Analysis—The audio recordings of subjects were first transcribed verbatim. A log file was then created and the transcripts of providers' audio verbalizations were linked to the video recorded actions on the computer screen and onscreen end-user motions for review. The transcripts were randomly sent out to three individual coders in three iterations. This ensured that each subsample of transcripts had three coders who collectively reviewed the transcripts and annotated them three times for all possible categories. Next, these annotated transcripts were reviewed together and potential coding categories were created, compiled, and standardized. All coded categories converged into a unified coding dictionary comprised of categories and sub-classifications. Using these refined codes in each of the categories; the coders reviewed and annotated each of the transcripts together. The log files were coded for usability and workflow issues, which were identified by the reviewers (in conjunction with viewing the corresponding screen recordings) and categories were assigned to segments of the transcripts to describe these issues. In addition, use of specific components of ADAPT and its CDS components were annotated.¹⁶ Two independent coders read through the annotated transcripts of subject verbalizations and watched the corresponding video and onscreen session recordings for each case. Initial categories were refined by the coders and collapsed, resulting in the final list of coding categories. All discrepancies in the coding were resolved by discussion to achieve a consensus and form succinct terminology in the dictionary. Each coded segment of the transcribed text was categorized for: (a) the ADAPT CDS components involved (Table 1), (b) type of commentary provided by the subject (i.e. “positive”, or “negative” commentary, as judged by the reviewers), (c) usability/workflow issues as conveyed through providers' verbalizations and actions (Table 2). Frequencies of the codes tabulated for each subject were recorded for further analysis and comparison of the categories found.

Phase II “Near-live” clinical simulations

Subjects—The five subjects who participated in the “near-live” clinical simulations were primary care providers practicing at a clinic associated with the hosting academic institution. Inclusion criteria were similar to that of Phase I subjects. The subjects level of utilization of an EHR varied and all subjects had no prior exposure to the ADAPT module. The subjects in Phase II did not participate in Phase I.

Procedure—The evaluation session was conducted in a real clinic setting equipped for observation with video cameras. A research staff member was trained and served as an actor to simulate a pre-diabetes patient. Provider subjects were given background information on the “patient” before entering the clinic room and were instructed to conduct the visit as usual for a patient with pre-diabetes with the additional instruction to vocalize all issues with the ADAPT system. Visual aids to demonstrate portion size was also utilized as well as nutritional charts to give example of healthy foods. The simulated patient was equipped with a pedometer prior to the visit, which had the “simulated” number of steps this person did over an entire week. Subjects received no navigational guidance from the research staff.

Data Analysis—Audio transcripts of subjects’ verbalizations were annotated with relevant onscreen movements (e.g. menu selections, navigation, etc.) to provide an annotated log file of the provider-EHR interaction.²⁵ Three independent coders reviewed the transcripts with the screen recordings to capture the timing of specific actions during each encounter. Time stamps were generated from the raw video of user activities and entered into the transcripts. The recorded sessions were segmented into episodes representing major user activities e.g. triggering of the CDS alert, documenting patient histories, etc. The length of time and sequence of the episodes was then calculated and graphed. Time stamps generated for each activity were then extracted and compiled for time series sequencing of the EHR/ADAPT components accessed for each patient case. Individual actions performed which involved similar functions were collapsed into the final workflow components, as well as computer-mediated communication actions. Time to completion, time spent in workflow components, and time to triggering were calculated. Sequences of interaction with components were compiled and characterized for each case to assess workflow. The sequence and amount of time spent within each component were compiled to build a timeline to describe workflow during each patient encounter.

RESULTS

Phase I

A total of 8 subjects, 4 residents and 4 primary care providers, participated in the Phase I “think-aloud” usability testing. For each subject, an average of 35 codes was identified, with a range of 23 to 50 codes. Overall, there were 237 codes associated with the subjects’ verbalizations and actions, with 113 (48%) being classified as containing positive comments and 124 (52%) as being negative comments.

Component Analysis—Analysis of comments was made specifically about seven ADAPT components (Table 1), i.e. Best Practice Alert (BPA), Flowsheet (Figure 1),

SmartSet, Patient Instructions, Progress Notes, Level of Service (LOS) and Follow-Up, and Global, respectively) showed that Flowsheet and SmartSet components received the most comments of 50% and 19% of all codes or 116 and 43 code segments, respectively. Of all the ADAPT components, providers consistently indicated that they liked the Global or overall interface integrated architecture component with a positive-to-negative commentary ratio of 1.8. The BPA component had the lowest positive-to-negative ratio of 0.5. The Patient Instructions had the next lowest positive-to-negative ratio of 0.61. Eighty percent of the negative patient instructions commentary was based on workflow issues in using the document simultaneously with dialogue with the patient and that its outcome was somewhat too formal. Separately, the Flowsheet component had the most negative comments of the EHR components with a positive-to-negative ratio of 0.82. Sub-analysis showed that 70% of negative commentary was about Content and Workflow in terms of options for patient goals not showing, improved entering of the data. Subjects commented that the Flowsheet seemed too basic and only for documentation, and data entry in the comment field box was too small and hidden from view. Most subjects felt the comment box was an important mechanism for adding contextual information to the data regarding less clinical elements or conditions, such as walking to work every day or eating less at restaurants.

Providers also raised issues in navigating throughout the tool, finding difficulty in closing or bypassing the BPA, felt that the BPA did not readily convey the function of the ADAPT CDS; and lacked a functional linkage to the prescribed behavioral contract. Confusion seemed to stem from a lack of familiarity with shared goal setting and its CDS components. For example one provider stated that *“I think the Hemoglobin A1c is helpful. But I have never put in my notes the number of sweetened drinks per day like this (subject’s mouse points at 5 on the screen), nor number of steps per day (subject’s mouse points at 3000 on the screen). ‘Get off one stop early on public transport’, is that a pre-populated option?”* The SmartSet component was associated with 16% negative comments with positive-to-negative ratio of 1.26; however, unlike the flowsheet component, there was no rejection of the usability and functionality of this tool. One subject mentioned *“...they [that is the SmartSets] don’t require too much clicking [and] they are helpful.”* However, subjects felt the SmartSet was not readily intuitive for creating a behavioral contract or patient instructions. Subjects commented that the feature that allows for automatic insertion of the results of the goal setting activity into the Patient Instructions was not sufficient. Specifically, some of the goal setting data was only displayed in the Flowsheet and not in the Patient Instructions, with further information needed to complete the patient encounter. There was also a design error that limited the text length in the patient instructions and most of the text was generic and not patient specific. The positive commentary was related to the simplicity of printing the contract and providing a way for the provider and patient to finalize the negotiation and dialogue.

Coding Category Analysis—Coded segments were created from transcribed recordings. These transcriptions were used for usability issues to become identified, condensed, and then collapsed to generate a final list of heuristic categories were defined as usability, readability, workflow, content, understandability, usefulness, and navigation (Table 2). Of the seven heuristic categories, the most commentary (positive and negative) was found related

to content and workflow - representing a combined total of 60% of all comments (32%, 28% of all comments; 76 and 67 comments, respectively). The heuristic categories of navigation, workflow, and understandability were associated with the largest volume of negative comments with positive-to-negative commentary ratio of 0.36, 0.67, and 0.78 that represented ~90% of the total overall negative comments (Figure 2). In particular for workflow, a number of subjects indicated a need to improve the usability of the tool to lessen the delay in entering the patients' goals, e.g. *"I think it is reasonable to do one exercise and one diet change. The provider might start out with several options, but eventually it is about finding the balance that is reasonable."* For exercise, providers suggested the specific action plans include additional options and units displayed in the ADAPT tool as they moved through the exercise review (e.g. initial provider commentary: *"I see an [Hemoglobin] A1C with an alert value. Current activity level of 3000 [steps], not sure what that means. Get off one stop early on public transport has a Y for Yes, means that this is a goal? I don't know what that means."*) to goal setting (e.g. provider commentary: *"If that (exercise goal) is low, I would ask how they got a pedometer. But if it is 3000 [steps], and then [I'd] begin to assess why the patient does not walk very much, like is it winter or do they have arthritis that are not listed and may be missed in the initial visit."*). Likewise, there was a similar workflow issue when the diet data review was initiated by the provider. Evidence-based suggestions for how to change exercise habits were listed in the ADAPT flowsheet (Table 1). Subjects reported the need for a better flow between the types of suggested exercises suggested by the tool. Also noted were situations in the diet discussion and goal setting around eating habits, such as number of soft drinks and juices, which the providers found very useful to record. However, there were areas of the diet action planning (like reducing plate size, mealtime, and location of meals or the details of the nutritional status of food groups) that the providers found disruptive to their workflow. One subject commented that the prompted goal setting emerged "too early" during the patient encounter making the tool seem like a data collection system rather than a tool to facilitate SDM and discuss patient exercise and diet goals.

All subjects supported the use of the ADAPT flowsheet (see Table 1), which consists of an event process chain (EPC) in its sequential data entry of exercise and diet current parameters and targets (goals of the patient). Several providers commented that the tool was most useful as a monitoring tool which leveraged this core goal setting and tracking functionality. However, there were also several subjects that reported that an auto-populated data field feature would be better than the manual input option so that data entered into the system regarding the actual exercise/diet and the patients' targets would enhance the monitoring over time and save time during the patient-provider goal setting communication. Moreover, some providers stated that the patient instructions or behavior contact resembled too closely to a medical prescription. A less rigid form of monitoring was thought to be needed in setting goals of the patient's behavioral change.

Phase II

A total of 5 subjects or providers participated in the Phase II "near-live" clinical simulations. Both younger and older providers reported similar comfort level with using the EHR during a patient interaction.

Total Time—Each of the 5 providers engaged in one enacted patient counseling scenario. On average, each encounter took 14:65 minutes (range of 13:10 to 17:56 minutes) (Table 3). Providers completed the entire ADAPT patient instructions (accepted alert; used the flowsheet; and signed the SmartSet) in 100% of the cases spending on average 10.2% of encounter time directly interacting with the ADAPT tool.

Workflow—Through the 5 simulated pre-diabetes encounters, one main workflow that characterized the sequence of user interactions was identified accounting for 85% of all cases. In the enacted scenarios, all subjects followed a sequence going from flowsheet to ADAPT patient instructions from exercise to diet. Within the flowsheet activity, there was one major sequence identified from (1) agreement on exercise habits and activities to (2) diet agreement on meals per day; total daily soft drink consumption; eating at restaurants; and plate sizes and nutrition refers to using actions negotiated with the patient before the ADAPT patient instructions at the end of the encounter. However, no comparisons of other potential sequence interactions could be performed, thus we cannot be certain the prototype is ideal to reach protocol-base care related to ADAPT framework with every patient visit under multiple scenarios. Nonetheless, this sequence followed the design of the flowsheet, which purposely stacked exercise on top of diet to encourage use of the exercise tools first. Moreover, this design showed cases spent more time on diet with, 31.5% more of the time spent than exercise.

Temporal Integration—Figure 3 illustrates the sequence and duration for the characteristics of the main workflow. Time spent in the diet sequence lasted 4:16 minutes, with 54% of the time spent in simulation. The exercise portion lasted 3:17 minutes and it seemed easier for users to agree on the course of action for increasing the number of steps per week.

Communication Actions—During the patient interview there was a mix of interactions with communication/dialogue while using the tool. The raw codes derived from the transcripts proved to be very different in the usability analysis from those found for Phase I. At first, we attempted to code the simulation based on the heuristics categories developed from Phase I, but this proved to be not possible. In fact, in the simulation, the majority of workflow and use of ADAPT resided in three main dialogues: one-way for a patient or provider communicating about current or improved exercise and diet, two-way for provider-to-patient communication; and goal-oriented for a patient or provider to communicate the circumstances leading to goal setting) (Table 4). The analysis showed that due to the fact that a patient visit of avoiding diabetes Type II is significantly related to personal habits, activities and circumstances involving lack of exercise or poor diets, communication while using the ADAPT tool arose as the main driver in the co-productive patient-provider EPC sequence towards the goal of prescribed patient instructions.

We found 14 identified and condensed categories (i.e., 3 dialogues types, 7 action types, and 4 sub-actions) of the communication actions derived from the transcribed recordings that involved patient- and provider-specific dialogue and communication types to complete the patient instruction transaction from ADAPT onscreen to the patient as a behavioral contract (Table 4). Since the communication transcribed is rich and complex, the results included

examples of the different combinations of the communication actions. The communication action involving 'One-way Dialogue' (provider to patient or patient to provider) with 'Self-Monitoring' would read as: "Provider commentary: *Alright, OK so your goal [...] That would be 1400, over 1400 calories you have to eat something really good. So we can start and go from 6 to 4 [sweetened drinks] but certainly our goal would be to get it down to zero.*" Another example of 'One-way Dialogue' is with 'Support': "Patient commentary: *Yes, cutting down on soda will help reduce the risk of diabetes and the blood pressure thing?* Provider commentary: *Yeah, [you need to get] rid of the soda and doing some exercising. You know [...] I really would like to [...] you to try your best to get this done. And hopefully over time we might be able to [reduce] your medication as well.*" Furthermore, another example of the different communications is that of the combination 'Persuasive Communication' with 'Education' would be: "Subject commentary: *...it is very hard to go from where you are now to get up to 10,000 in a day or week. So I think it is something we are just going to talk about over the course of the next several months.*" An example of 'Goal-oriented' (i.e. a goal was explicitly stated) dialogue with 'Support' tool use resulted in: "Subject commentary: *Ok and so the best way for us to do it is to just talk about some of things you might do just as a part of your daily life to help you get to that. So I know you talked to our coordinator and you talked about getting off the bus or the train on stop early.*" And a simple 'Goal-oriented' dialogue was recorded as "*So if you are doing 4,300 or so right now eventually our goal would get you to take 10,000 steps per day.*"

The two-way dialogue (patient to provider and vice versa) was typically longer than the one-way and goal-setting dialogues and, in the sequence of the use of ADAPT, this dialogue occurred after one-way and usually before goal-oriented dialogue for each of the exercise and diet sequences. The two-way dialogue comprised more communication actions related to different uses of the tool simultaneously. For instance, "Patient commentary: *I don't have really that much time to walk around. I mean do I have to start walking 10,000 steps a day? How can I do it?* Provider commentary: *Right. So you are right it is very hard to go from where you are now to get up to 10,000 in a day or week. So I think it is something we are just going to talk about over the course of the next several months. And hopefully in six months from now you will be closer to that number. ... what I like to do is ... to get you up to 4800 or close to 5000 steps by the next time we meet.*" In this two-way communication example the conversation and use of the ADPAT tool resulted in 'Negotiation' and 'Response Efficacy' and 'Peripheral Attitude Shift' to 'Self-Efficacy' as the patient started to express a greater belief in their behavior change to set their own goals and demonstrate that they will monitor their progress and allow the provider to do so as well. Furthermore, the results showed that more than one communication action category occurred in a specific dialogue type; therefore, the recorded transcripts were very detailed and contained multiple categories for either the patient or provider or both simultaneously. Furthermore, the derived categories in sequence of negotiation, persuasive communication, peripheral attitude shift, monitoring, self-monitoring, response efficacy and self-efficacy directly coincide with the ADAPT framework that comprises the protocol surrounding the "transtheoretical model" of behavior change assessment of an individual's readiness to set a goal, and this case to change exercise and diet behavior to reduce pre-diabetes risk.²⁸ Lastly, the actions of

support, education, visit, and discussion were 4 sub-action categories related to the 7 communication actions.

Phase II showed rich and complex computer-mediated communication actions. These results were significantly different from Phase I but the co-productive sequence of the patient and provider working through the ADAPT components to showed that the goal of the patient instructions to establish a behavior change contract was achievable and conceptually feasibility in both phases.

DISCUSSION

The ADAPT system assessed was designed with the very specific intention to support behavioral change in patients at risk of developing type II diabetes. This can be discussed as protocol-based care and the use of the ADAPT tool provides a mechanism to realistically evaluate if this tool will be accepted in a clinical setting and that it will be used by evidence-based medicine successfully. Since the processes and outcomes were generated by a program, we observed and assessed the ADAPT tool under the umbrella of the ADAPT framework with its intention to orchestrate share-decision making (SDM) with clinical decision support (CDS) in an electronic health record (EHR). The working hypothesis was accepted in that the observations proved that the tool can be used with more positive usability than negative in the think-aloud analysis and that an endpoint of patient instructions was achieved across all providers and patients in the clinical simulation. Our assessments provide some insight in the complexities of SDM with protocol based CDS and not solely based on the EPIC vendor and developers of the ADAPT tool alone. Very few EHR systems have implemented a module combining SDM and CDS for a clinical workflow and even fewer evaluations exist of such implementations; therefore, our study was successful to investigate the usability ADAPT and evaluate its framework. In so doing, we also showed that the ADAPT flowsheet could significantly influence the workflow and perspective of the clinician, whose behavior and interaction with the patient and system was heavily shaped by ADAPT. The think-aloud results did show some frustrations in using a tool not “normally” used by providers with their patients. Moreover, the sheer richness and complexity of the communication actions found while using the tool in simulations proved that ADAPT tool caused complicated SDM to take place while achieving the goal of ADAPT. However, further analysis is required to fully comprehend the mechanisms and context causing the rich communication to occur and if the protocol behind the ADAPT tool might cause too much lengthy communication in a regular patient visit.

Our study integrated “think-aloud” and “near-live” usability approaches to improve the multidisciplinary design and refinement of a CDS system that facilitates evidence-based SDM pre-diabetes counseling.²⁰ Phase I involved usability testing, applying the well-established “think-aloud” protocol analysis method to assess human-computer interactions by having healthcare providers think aloud while using the ADAPT to complete scripted tasks.^{24,25} Phase II used a simulated “near-live” study approach to assess a more global, unstructured subject-HER interaction to characterize the functionality of the tools and the ability of providers to use ADAPT in an unscripted condition under computer-mediated communication with a simulated patient.²⁶ There were overlaps between information found

by both usability techniques and clinical simulation: each approach provided distinct insights improved the overall design and complemented our understanding of provider and the need for a multi-disciplinary framework to produce a behavior change system for diabetes prevention. Phase II also added richer contextual patient-provider interactions with different use of the tool, which included several categories in the coded transcripts not found in the Phase I think-aloud analysis. The two different types of usability analyses gave us a multi-faceted understanding of what physicians expect from CDS and how they intuitively interact with the system during clinical care in the case of diabetes prevention and control.

Some providers stated a prescription for patient instructions to change their behavior was too formal in the primary care setting. In spite of the drawback of actually using the ADAPT patient instructions for a patient visit, Phase II did reveal a correlation with communication and use of the ADAPT tool to derive the behavioral contracting, whereby the patients negotiate with their provider on setting their goals while entering of data and use of the tool supported monitoring, discussion, education or support of the behavioral change. These observations led to potential next phase of prototyping or redesign of the tool to be flexible in dealing with a variety of non-clinical aspects of poor exercise and dietary habits combined with clinical elements (conditions) that might have caused the poor exercise and diets. Additionally, Phase II was not a true natural environment; it simulated realistic use in a live clinical setting. Naturalistic or “live” testing would be the next phase to realistically evaluation a SDM CDS tool.

The usability testing of the ADAPT tool and its novel components prior to widespread release the methods employed in this study proved to be very useful.²⁹ This novelty also likely contributed to the high volume of comments about the tool content and a vast array of communication actions. However, due to the complexity of ADAPT, the think-aloud and clinical simulation were not fully integrated into the analyses. The Phase II simulation showed more detailed, complex categories than the think-aloud portion, which was expected. Additionally, both phases showed that providers had navigation problems and conflicting issues with a somewhat streamlined advancement through each section of ADAPT with print a prescription of the patient instructions to improve exercise and diet. Rycroft-Malone et al. (2010) found that standardizing care via protocols, guidelines and pathways requires mechanisms to test its context in clinical settings for patient outcomes. Our study does provide the ADAPT tool as the mechanism but the results cannot be fully integrated to state if its CDS pathway promoted better communication for SDM between the patient and provider or if it underpinned a provider’s delivery of care in forcing an ultimate end goal of behavior contracting without the complex communication actions.

Phase I extracted details of intrinsic weaknesses in the composition, content and layout of the CDS, and confirmed previously identified usability issues.^{5,8–12} Providers reported that the workflows in the flowsheet were especially cumbersome with poor content and navigation that limited the ability of the provider to know how to proceed to the next step if the patient provided a complex condition. This was particularly prominent with the transition of counseling from exercise to diet in that the transition lacked a link between exercise and diet and part of this reason could have been due to the flowsheet not showing the connection between exercise and diet. Similarly, in several negative commentaries the

lack of categories in the ADAPT tool, other than steps per day and meals at restaurants and number of sweetened drinks, was potentially overlooked by the provider because of the system layout and interface integration architecture of the flowsheet. Furthermore, discussions of plate size with the patient were viewed as an unnatural patient-provider interaction in their workflow. As a consequence, there was more time spent on the diet component compared to the exercise component. Workflow and navigation issues were the main user issues observed in Phase I, but given the artificial nature of the “think-aloud” protocol analysis approach and lack of data on provider self-directed usage of the CDS, major modifications to these areas were deferred until the more realistic “near-live” Phase II testing and simulation.²⁰

Phase II “near-live” clinical simulations focused on understanding where, when, and how providers access ADAPT in dealing with patient cases. Specifically, Phase II characterized the unpredictable aspects of use of the ADAPT that were not anticipated by the CDS designers and also identified potential disruptions caused by the ADAPT on “natural” provider workflow. Analysis of the “triggering” of the CDS and provider sequence workflow helped the development team understand previously unidentified barriers to integration of ADAPT with provider workflow and interaction sequences.⁷ Phase II testing uncovered new conflicting content issues with the workflows was not detected by Phase I testing. For example, the comment field box was hidden from view which contained extremely valuable contextual data. Additionally, the tool did not allow for more clinical discussion surrounding abnormal exercise or diet, such as patient comorbidities (e.g., arthritis or mental condition) that might hinder their daily activities. Specifically, the results showed that the ADAPT flowsheet needed a comment field near the number of steps to accurately record more contextual information about the circumstances both clinical (e.g. chronic diseases) and behavioral (e.g. 5 sweetened drinks per day). Moreover, inputs entered by the subjects in Phase II highlighted deficiencies in ADAPT’s ability to link the values of the exercise and diets of the patient to the alerts or SmartSets.

Currently, usability experts advocate using cognitive analyses of providers to assess the usability of EHRs and CDSS.¹⁴ Daniel et al listed current techniques and protocols for usability testing, arguing that “think-aloud” may provide the most information for software development.²⁴ A recent study has shown that human-computer interaction research can lead to designs of activity-based systems that change perceptions of the user to alter their behavior.²⁹ However, traditional usability testing alone is often insufficient to uncover the full spectrum of issues caused by a new CDS system. Through our two phases of testing, we have found that the “think-aloud” protocol produced a large amount of information about how providers perceive each distinct part of ADAPT and resulted in changes to streamline the use of each component. The Phase II “near-live” clinical simulations allowed us to identify and obtain details about some of the drivers behind the main issues of content, workflow and navigation. A number of studies have used either think aloud or clinical simulations to assess the impact on the development of CDS,²⁰ but this is the first study to combine their potential advantages to affect SDM around pre-diabetes in an EHR. There are websites that support behavior change in their framework but patient-provider SDM is not prevalent.²¹ In New Zealand, for example, currently CDS is used to conduct patient and provider behavioral assessments but it does not support SDM or goal negotiation.³⁰

Furthermore, we were not able to find any studies that utilized the “near-live” simulation approach or that attempted to temporally quantify dominant provider workflows as applied to behavior change SDM embedded within an EHR system prior to its release. We feel that the findings from both types of studies are critical in understanding how providers envision the integration of behavioral contracting into their clinic workflow, without which the likelihood of provider uptake would be significantly limited.

LIMITATIONS

The most important limitation is an inherent byproduct of performing usability analyses involving a tool integrated into a commercial EHR system. This limits the design ability to alter the user interface and make refinements in response to problems uncovered during usability. While Phase II was a novel “near-live” simulation, it was not a live encounter and the true usability of ADAPT in the live setting could not be fully explored by our study. The complex communication actions found in Phase II cannot be verified by a think aloud analysis and more investigation is required to determine if this communication is realistic, beneficial to patient-provider and justified to accomplish goal of the ADAPT.

CONCLUSION

Most CDS tools are implemented without robust evaluative studies to support their integration into provider workflow^{5,8,9,31} and facilitate SDM for goal setting in primary care.²⁰ This study describes a unique blend of traditional think-aloud usability testing with “near-live” clinical simulation. Using a behavioral framework designed to encourage SDM and goal setting, the usability testing successfully improved the functionality and usability of the prototype system.²⁰ However, Rycroft et al. 2010 caution the operationalization of protocol-based care and the need for a more positivism approach with empirical evidence to better understand the circumstances that might underpin clinical workflows by a program set in place. The simulation setting in Phase II provided important, often overlooked insight in to how providers would navigate, view and quickly understand the content of the displayed options or information through the EHR-CDS interface in clinical situations. Both phases of usability testing offered useful insight: Phase I assessed the overall functionality of CDS components and Phase II characterized the impact of the ADAPT prototype on clinical workflow. Phase I proved critical as the initial assessment and feedback into optimizing both the materials within and the structural components of the CDS. While there have been other studies that used multiple forms of evaluation as a basis for feedback for the development of CDS interventions^{19,32}, this is the first study to our knowledge that has attempted to synergistically apply usability testing (involving think aloud protocol analysis) and “near-live” clinical simulations for SDM and behavior change. This experience supports the growing call for more careful usability evaluations of CDS tools, particularly in SDM and other dynamic interactions involving clinical protocol pathways, prior to implementation in order to extract their full benefit.

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Highlights

- First study to combine think-aloud usability testing with “near-live” clinical simulation
- This study successfully improved the functionality and usability of the prototype system
- Successful usability evaluation of a new primary care pre-diabetes shared goal setting tool

Flowsheet Report									
Select Flowsheets to View									
ADAPT FLOWSHEET 1 [274]									
VITALS [74]									
Adapt flowsheet	Latest Ref Rng		11/7/2011	2/1/2012	2/24/2012	4/26/2012	5/4/2012	5/9/2012	
Eating out (meals/wk) - CURRENT				7	2	2	3		
Eating out (meals/wk) - TARGET				4					
Save half for later (meals/wk) - CURRENT								1	
Activity Level (Steps/day) - CURRENT				9020	12252	12619	10470	10470	
Activity Level (Steps/day) - TARGET				10000				12000	
Play Sports or Dance 2x/wk				Y				Y	
Go to Gym				Y				Y	
HEMOGLOBIN A1C	4.0 - 6.0 %		6.1 (H)	6.2 (H)				5.9	
VITALS		6/2/2011	11/7/2011	2/1/2012				5/9/2012	
BP		118/76	110/80	110/80				120/70	
Pulse		84	96	80				100	
Site			Right Arm						
BP Position			Sitting						
Temp			98.5						
Resp									
Height		65 in		65 in				65 in	
Weight		224 lbs	220 lbs	213 lbs				205 lbs	

Figure 1.
ADAPT Flowsheet.

Figure 2.
Phase I ADAPT frequency of positive and negative commentary in terms of the ADAPT component and coded heuristic categories

Figure 3.
Phase II sequence of Exercise and Diet time spent using the ADAPT tool

Table 1

ADAPT components

ADAPT components	Description of ADAPT components within the electronic health record (EHR)
Best Practice Alert (BPA)	The first triggered interaction a provider has with the ADAPT tool (designed by EPIC) is through the acceptance or deferral of the Best Practice Alert (BPA). The BPA triggers relevant information that the provider can input into the EHR module that activates the core CDS.
Flowsheet	An event-driven process chain (EPC) in ADAPT after the alert is triggered. The EPC consists of sequential exercise and diet related inputs according to actual and target (goals of the patient) exercise and diet questions by the provider. This flowsheet is a prototype with proposed functionality across EPIC's EHR product.
SmartSet	System feature that comprised a bundled order set (specific for ADAPT and the EPIC vendor) for the provider to order the appropriate prescriptions, behavioral contract while allowing for the order to be verified and electronically signed.
Patient Instructions	Output from the ADAPT flowsheet and SmartSet that gives providers prewritten instructions appropriate for the patient's current pre-diabetes status and agreed targeted exercise and diet goals for the coming months before the next visit. Also known as behavioral contract in the ADAPT framework.
Progress Notes	Patient's admission history and physical and other clinical notes in one document onscreen.
Level of Service (LOS) and Follow-up	Generic EHR system feature that allows the provider to end the patient visit with an appropriate coded level of service (LOS) and follow up for the visit.
Global	Generic system characteristics of the system that include the general functionality of the components of the ADAPT CDSS and its all-inclusive features or toolkit.

Table 2

Coding categories with examples

Code	Definition	Example coded statement
Usability	Refers to commentary on the perceived effectiveness, efficiency, and ease of use of the ADAPT Toolkit or lack thereof.	First impression is that would take a lot of education on the part of providers to get me to use this on a regular basis. Probably I would do what I usually do in my notes, like how many sodas and juices they are drinking, and how much exercise.
Readability	Refers to consistency and accuracy of the images, text, or messages.	It is interesting to me that the words are not the same. Like “reduced sweetened drinks” but this should be increased number of meals at home (points to meals at home), decrease eating out, this should be improve portion control, and this is ok “reduce alcohol beverages,” and I don’t know exercise barriers means is this increase exercise. So the wording is not consistent.
Workflow	Refers to the general sequence of tasks, triggered system events, and activities involved in a patient encounter.	...I am not sure how this interface [will work] with my work back and forth with the patient. Comment is fine, but if I can toggle well afterwards, this is problem. Plus, doc flowsheets are not something I usually work with.
Content	Refers to the extent of displayable information that is appropriate, comprehensive or missing value- added components.	If that [3000 steps per day] is low, I would ask if how they got a pedometer. But if it is 3000, and then begin to assess why the patient does not walk very much, like is it winter or do they have arthritis.
Understandability	Refers to the extent to which the text within the CDS is comprehensible by the provider to use the system features in the most appropriate way for the patient.	I think it [Flowsheet] is straightforward, which it is good. Also, it is broken up by colors, which is also good. I am not sure what to do about the ‘meals at home per day’ and I don’t know how that is going to help with my patient education.
Usefulness	Refers to the tool (and information provided by it) that is perceived as helpful in entering data, assisting with clinical decision making, and valuable for the provider in multiple use cases with patients including progressive learnability of the system.	Yes, I think it [Flowsheet] would be useful. It can be pulled up on the next column. But my question is going to be who populates this each time.
Navigation	Refers to commentary on the provider’s ability to move through the system (i.e. where to go, how to move forward or backward).	Somewhere. Oh there it [comment field box] is (pointing mouse under the comment).

Table 3

Time spent on exercise and diet section of the ADAPT flowsheet

	Average time spent (mm:ss)	Min time spent (mm:ss)	Max time spent (mm:ss)
Diet	Refers to the ADAPT sub-features and data fields populated during a sequence of questions asked concerning the current eating habits and frequencies of the patient and the way to reduce daily consumption.		
<i>Total</i>			
<i>Recommendation</i>	4.16	2.0	8.1
<i>Negotiation</i>	1.2	0.8	3.4
<i>Total Time</i>	2.0	1.1	3.2
	14:56	13:10	17:56
Exercise	Refers to the ADAPT sub-features and data fields populated during a sequence of questions asked concerning the current situation of the patient to exercise and adjust their lifestyles to improve the amount of daily exercises.		
<i>Total</i>			
<i>Recommendation</i>	3.17	1.5	3.7
<i>Negotiation</i>	1.17	0.2	2.6
<i>Total Time</i>	2.0	1.1	3.5
	14:65	13:10	17:56

Table 4

Communication actions while using the ADAPT tool

Components	Description of components within the ADAPT tool
One-way dialogue	Provider expressing concern of the patients exercise or diet with the intent to educate the consequences for lack of exercise and/or poor diet and the ability to change the patient's lifestyle to reduce the risk of diabetes. Also refers to scheduling concerns and other educative communication with the patient in terms of diabetes and improvements.
Two-way dialogue	Communication between provider and patient to fill in the exercise and diet components and discuss how to adjust their lifestyle.
Negotiation	Dialogue between patient and provider, intended to reach an understanding, resolve point of difference, or gain advantage, and to produce an agreement of the patient upon courses of action for exercise and diet.
Persuasive	Provider uses props, expresses concern of the patient's lifestyle, and mentions the somewhat social norm or an easy way to change lifestyle.
Peripheral attitude shift	The degree to which the patient changes their thoughts on the ADAPT goals and accepts the patient instructions or behavioral contract
Goal-oriented	The goal-setting element of the DPP was considered ideal in terms of logistics and efficacy for primary care and thus chosen as a core component of the EHR intervention.
Monitoring	Capacity of ADAPT to promote the provider to monitor the patient's progress.
Self-monitoring	Capacity of ADAPT to promote the patient to monitor their exercise/diet.
Self-efficacy	Describes the patients' states their level of agreement and belief in changing specific ADAPT goals via the tool.
Response efficacy	Describes the patients' response to recommended actions that will reduce the risk of diabetes
Support	Communication related to the capacity of the tool demonstrates that the patient is provided with assistance to accomplish the patient goals and behavioral change.
Education	Communication related to the value-added capacity of the tool to educate the provider and/or patient of the ADAPT system.
Visit	Communication related to the capacity of the tool to contribute to the entire patient visit as a whole.
Discussion	Communication related to the ability of format of the tool to generate discussion between the provider and patient.