Pain Medicine

Pain Medicine 2010; 11: 575–585
Wiley Periodicals, Inc.

PRIMARY CARE & HEALTH SERVICES SECTION

Original Research Article

Evaluation of the Acceptability and Usability of a Decision Support System to Encourage Safe and Effective Use of Opioid Therapy for Chronic, Noncancer Pain by Primary Care Providers

Jodie Trafton, PhD,* Susana Martins, MD, MSc,*† Martha Michel, PhD,*† Eleanor Lewis, PhD,* Dan Wang, PhD,* Ann Combs, BA,*‡ Naquell Scates, MHA,* Samson Tu, MS,*§ and Mary K. Goldstein, MD, MS*†§¶

*Center for Health Care Evaluation, VA Palo Alto Healthcare System, Menlo Park

†Geriatrics Research Education and Clinical Center (GRECC), VA Palo Alto Health Care System, Palo Alto

‡Palo Alto Institute for Research and Education, Palo Alto

§Center for Biomedical Informatics Research, Stanford University Medical School, Stanford

¶Center for Primary Care and Outcomes Research (PCOR), Stanford University, Stanford, California, USA

Reprint requests to: Jodie Trafton, PhD, Center for Health Care Evaluation, 795 Willow Road (152-MPD), Menlo Park, CA 94025, USA. Tel: 650-493-5000 x22474; Fax: 650-617-2736; E-mail: Jodie.Trafton@va.gov.

Conflicts of Interest: Authors declare no conflicts of interest.

Abstract

Objective. To develop and evaluate a clinical decision support system (CDSS) named Assessment and Treatment in Healthcare: Evidenced-Based Automation (ATHENA)-Opioid Therapy, which encourages safe and effective use of opioid therapy for chronic, noncancer pain.

Design. CDSS development and iterative evaluation using the analysis, design, development, implementation, and evaluation process including simulation-based and in-clinic assessments of usability for providers followed by targeted system revisions.

Results. Volunteers provided detailed feedback to guide improvements in the graphical user interface, and content and design changes to increase clinical usefulness, understandability, clinical workflow fit, and ease of completing guideline recommended practices. Revisions based on feedback increased CDSS usability ratings over time. Practice concerns outside the scope of the CDSS were also identified.

Conclusions. Usability testing optimized the CDSS to better address barriers such as lack of provider education, confusion in dosing calculations and titration schedules, access to relevant patient information, provider discontinuity, documentation, and access to validated assessment tools. It also highlighted barriers to good clinical practice that are difficult to address with CDSS technology in its current conceptualization. For example, clinicians indicated that constraints on time and competing priorities in primary care, discomfort in patient-provider communications, and lack of evidence to guide opioid prescribing decisions impeded their ability to provide effective, guideline-adherent pain management. Iterative testing was essential for designing a highly usable and acceptable CDSS; however, identified barriers may limit the impact of the ATHENA-Opioid Therapy system and other CDSS on clinical practices and outcomes unless CDSS are paired with parallel initiatives to address these issues.

Key Words. Decision Support; Primary Care; Opioid Therapy; Chronic Pain; Usability

Introduction

Opioid prescribing has increased over the last decade, with per capita yearly opioid consumption in the United States increasing from under 100 mg/person to over 550 mg/person in morphine equivalents between 1997 and 2006 [1]. Despite its prevalence and increasing use, opioid therapy (OT) for chronic noncancer pain is controversial. Lack of long-term effectiveness trials [2,3] and recent increases in opioid misuse [4] and over-dose deaths [5,6] raise questions about the risks and benefits. Clinical practice guidelines (CPG) have focused on encouraging improved monitoring, and early detection and treatment of problems, conservative dosing strategies, and better patient-treatment matching to improve outcome [7,8]; however, CPGs are not consistently followed [9].

Chronic noncancer pain management is complicated and difficult even for pain management specialists [10]. Balancing the need for immediate relief with the need to minimize risks and maximize functional recovery is challenging. This challenge may be compounded in patients with mental health and substance use co-morbidities, particularly when opioid medications are included. Nonspecialist clinicians often receive little training in pain and opioid management [11] and in primary care, pain may be only one of many serious conditions competing for attention during a visit [11].

As a large primary-care centered health care system with patients who have a high prevalence of chronic, noncancer pain, mental health, and substance use problems, the Department of Veterans Affairs (VA) has recognized the importance of providing assistance and clinical decision support for primary care providers (PCPs) prescribing opioids for chronic pain. The VA/Department of Defense (DoD) CPG for the Management of Opioid Therapy for Chronic Pain [8] provided much needed guidance, but has not been consistently implemented. To encourage better application of recommended practices for opioid prescribing, the VA funded the development of a computerized decision support system (CDSS) to provide PCPs with guideline-based recommendations tailored to a specific patient during their visit. The Assessment and Treatment in Healthcare: Evidenced-Based Automation (ATHENA)-OT system [12] builds on innovations developed for the ATHENA-Hypertension CDSS [13]. Both projects use a frame-based knowledge base and the EON guideline interpreter as the underlying expert system to issue evidence-based recommendations to clinicians at the point-of-care [14]. This expert system provides a format and interface in which one can designate clinical concepts in explicit terms and use these concepts to define a system of care recommendations based on patient health care information. Benefits of this expert system include that clinical content may be updated by trained content experts rather than programmers, and that, after customizing the data extract, the CDSS is portable and can be used with any electronic medical record system. ATHENA-OT was developed for use in primary care medicine where the majority of opioid prescribing occurs.

Historically, development of medical CDSSs has neglected analysis of human-computer interactions [15], but see [16,17] for recent examples of rigorous usability testing of CDSS, despite expert panel acknowledgement that "improving the human-computer interface" is the primary challenge to designing effective decision support [18]. To maximize system impact, we integrated on-going evaluation of the CDSS into the development process. We used principles from 1) the ADDIE process, an instructional technology methodology which stands for Analysis, Design, Development, Implementation and Evaluation [19,20] and 2) Bates and colleagues' recommendations for developing a medical CDSS [21]. Following Bates recommendations, we designed a system that would appear in seconds and fit into the clinic visit when a relevant chart was opened, focus on a single main screen, and provide concrete recommended actions that a physician could implement. ATHENA-OT was also uniquely designed to provide patient specific recommendations without additional input of information [22] by obtaining patient data from the VA electronic medical record (EMR). ADDIE encourages analysis of user and system needs to inform CDSS design. The CDSS is then built, made available to users, evaluated, and redesigned as necessary. As far as we know, this process has never been followed for development of a CDSS for pain management. A recent review of CDSS for pain management found descriptions of eight CDSSs [22], but usability, including ease of use, acceptability, and clinical utility, was assessed for only two of these systems [23,24]. In only one case was this feedback used to update the CDSS [24], and in no case was additional testing conducted to determine if these changes improved usability and acceptability.

To effectively support clinical judgment, a CDSS must be optimized to be usable by the target clinicians [25]. This optimization depends on factors including integration of the system into standard clinical workflow, content utility, speed, intuitive design, and point of care delivery [21]. Our analysis was designed to identify specific problems with the CDSS interface, as well as clinicians' needs, workflow, and barriers to care that could be addressed by a CDSS.

Here we present the process and results of an iterative evaluation of the usability of ATHENA-OT, as it was designed, revised, and improved (see Figure 1 for an example of the Phase 2 ATHENA-OT graphical user interface). These evaluations not only led to improvements in the CDSS, but also identified key needs of clinicians for both integrating the CDSS into their workflow and for opioid prescribing in general. We identified limits to both the usefulness of a CDSS to guide opioid prescribing in primary care, and the ability of PCPs to follow recommended practices for opioid prescribing within the structure of current health care systems.

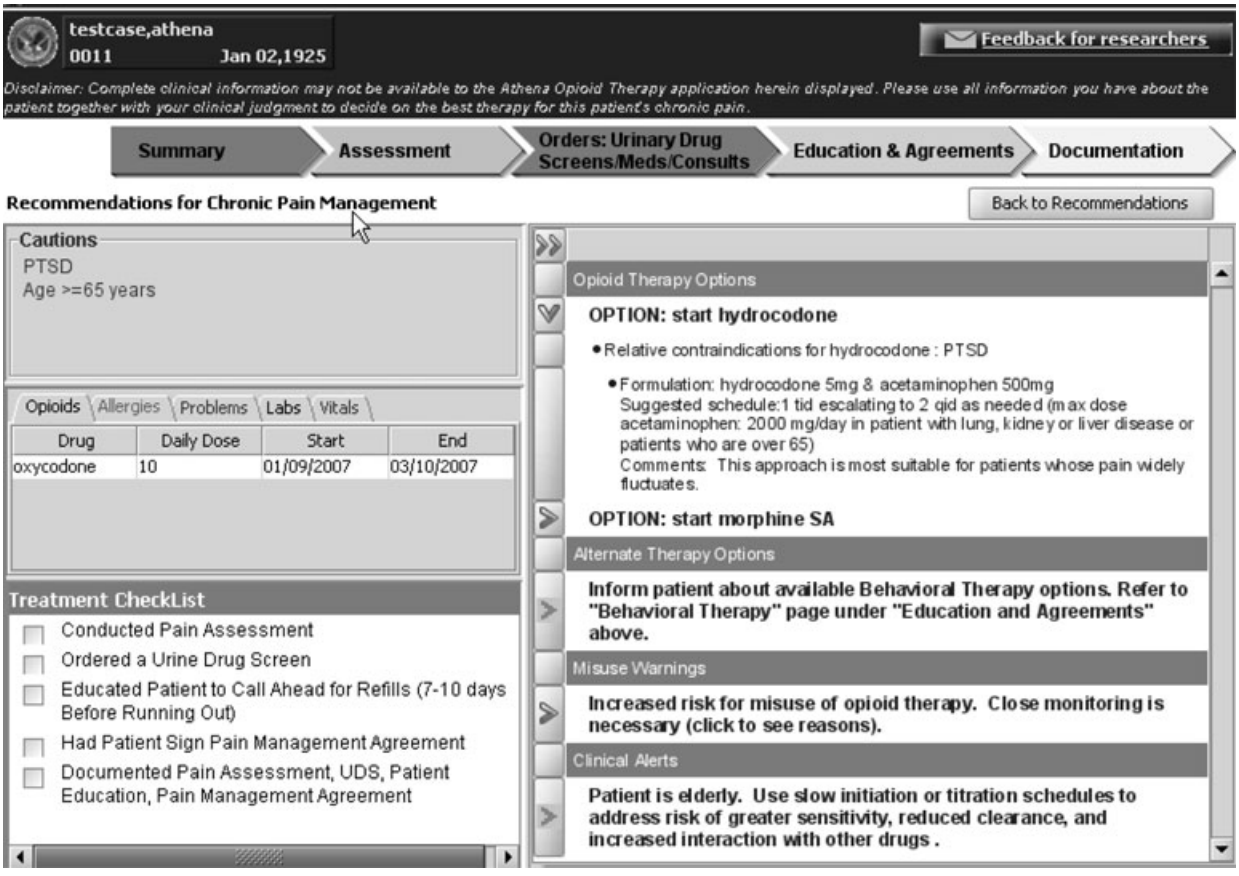

Figure 1 Main screen of the graphical user interface of the ATHENA Opioid Therapy clinical decision support system. 347 × 243 mm (600 × 600 DPI).

Methods

This study was approved and overseen by the Stanford University Institutional Review Board and the VA Palo Alto Health Care System Research and Development Committee. The patient safety features and a thorough description of the ATHENA graphical user interface (GUI, the human-computer interface which allows interaction with the CDSS via a mouse) have been described previously [12].

Evaluation and Revision Plans

Tests were conducted in two phases to evaluate the usability of ATHENA-OT in simulation-based and clinic-based settings (see Figure 2 for timeline and sequence). The phases were before (Phase 1) and after (Phase 2) deployment of a major redesign of the GUI based on feedback from Phase 1 evaluation. Simulation-based testing was conducted prior to Phase 1 clinic-based testing, and immediately following clinic-based deployment of the Phase 2 CDSS. For in-clinic testing, the CDSS was made available in local primary care clinics on November 1, 2007 and was run with on-going modifications based on feedback until March 17, 2008 (Phase 1). On March 18, 2008, a new version with a redesigned GUI was implemented in the clinics. This CDSS was made available to participating clinicians with subsequent minor revisions until June 30, 2008.

Revisions were planned and prioritized based on feedback from the usability studies, weighing consistency with CPG and the feasibility of the suggested changes. A comprehensive plan for revision of the GUI was made based on Phase 1 feedback, and additional revisions were planned and executed iteratively via system updates during Phase 2.

Simulation-Based Testing

Participants

Four VA clinicians participated in Phase 1 testing and four different clinicians plus one clinician from the Phase 1 testing participated in Phase 2. These eight clinicians were psychiatrists [3], and primary care clinicians (four physicians and one nurse practitioner). To ensure a range of perspectives, clinicians with minimal to extensive pain and addiction management expertise were included. Specifi-

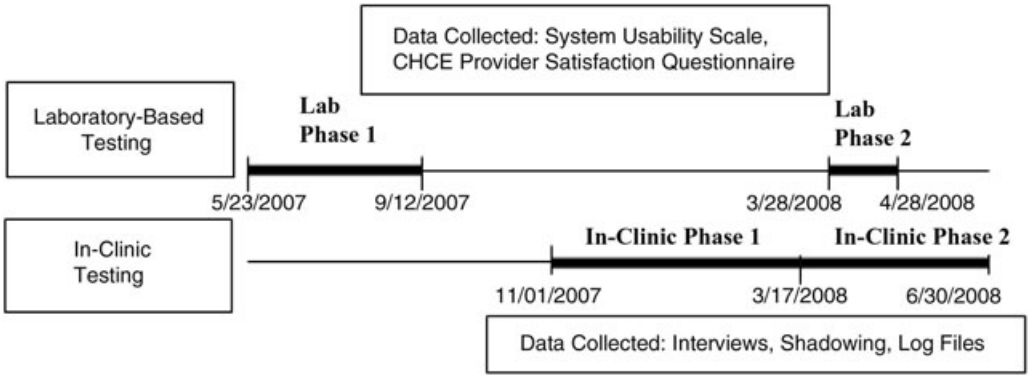

Figure 2 Timeline of laboratory-based testing and in-clinic testing. 226 × 85 mm (600 × 600 DPI).

cally, three participants had extensive expertise in pain management, and another two had extensive expertise in addiction management. All others had low to moderate experience in pain and addiction medicine. Nielsen has found that about 80% of usability issues can be revealed with five participants [26].

Data Collection

Testing generated quantitative and qualitative data from observation of clinicians' interactions with ATHENA-OT in simulated clinic visits considering patient cases requiring management of chronic nonmalignant pain. Four methods of data collection were included: 1) think-aloud protocols, 2) observation, 3) direct interviewer questions, and 4) survey instruments [27]. Each participant engaged ATHENA-OT for 45 minutes to 1 hour while reviewing 3–4 patient cases for pain management with opioids. Participants were instructed to "think aloud" while assessing each patient case and research staff recorded their interactions with the CDSS [27]. This technique is extremely valuable as it allows us to understand how participants view and navigate the CDSS as they are reasoning about a clinical case; this identifies misconceptions and problems regarding the interface. Each case was pre-selected to ensure a range of possible pain scenarios were addressed. Participants were asked for positive and negative impressions of the CDSS and recommended changes. All responses were audio recorded, transcribed, and entered into a database for analysis.

After reviewing patient cases each subject completed two questionnaires: the System Usability Scale (SUS) [28] and the Center for Health Care Evaluation adapted provider satisfaction questionnaire (CHCE-PSQ) [29]. The SUS has 10 items that provide a general measure of usability [28]. The SUS was originally validated to distinguish between difficult and easy-to-use software products [28], has been used regularly in usability testing for more than two decades, and has been shown to be superior to other available assessments for website usability testing [30]. All items were rated on 5-point Likert scales and a final score (0 [least usable] to 100 [most usable]) was computed according to instructions. The CHCE-PSQ [29] was adapted and successfully used in other local projects to assess satisfaction with informatics applications. While the psychometric properties of this survey have not been validated, the items are based on Kirkpatrick's levels of evaluation [31–33]. These have been widely used by industries developing training programs since the 1960s. This survey has eight questions scored on a 5-point scale (from poor to excellent), followed by open-ended questions.

In-Clinic Testing

ATHENA-OT was also tested during Phase 1 and Phase 2 by a group of volunteer clinicians in the primary care clinics at the VA Palo Alto Health Care System. The CDSS was automatically available to the clinicians when they opened the medical record of a patient with a scheduled visit within a 5-day window (i.e., 3 days prior to and 1 day after the visit [to allow clinicians access while reviewing cases and documenting care]). ATHENA-OT automatically displayed on the screen as the main-display page (if the patient had an active prescription for an opioid drug), or as a small rectangular "stamp" (if the patient did not have an active prescription for an opioid drug) that could be clicked on to get the main-display page.

Participants

In Phase 1 of in-clinic testing, nine physicians and one nurse practitioner had access to ATHENA-OT, and two additional physicians had access during Phase 2. Participants provided feedback on ATHENA-OT in three ways: 1) interviews, 2) direct observation via in-clinic shadowing, and 3) system use recorded in CDSS log-files [27].

Interviews. Participants were contacted periodically during both phases of the in-clinic study for feedback on the system. Due to clinician time constraints, the interviews were conducted via e-mail, telephone, or in person and typically took less than 10 minutes. Questions were open ended and focused on providers' experience with the system. PCPs were asked to report on problems they

were having, the usefulness of the system, how often they used the CDSS, and recommendations for changes or improvements.

Provider Shadowing. Three of the 12 in-clinic participants consented to being observed by a project team member during patient visits. The project team member observed 35 visits and recorded a set of pre-defined elements of the patient visit including aspects of the clinical workflow, length of visits, use of a computer during the patient visit, technical problems with the system, and how the clinician interacted with the patient EMR and the CDSS.

Log-Files. ATHENA-OT recorded the number of displays presented to PCPs and clinician mouse-clicks on the CDSS in log-files, including display of the stamp, the main display page, opening of recommendation details, and all menu items. We note that displays were made available to PCPs for all patients with scheduled visits, regardless of whether or not the patient had a chronic, nonmalignant pain problem.

Analysis of Qualitative Data

Qualitative feedback obtained from all of the above testing methods was categorized into three broad areas relevant to evaluating a CDSS based on previous research on areas central in research on usability testing [21,34,35]. These three categories are: suggestions for 1) improving the GUI, 2) how the content or design of the tool could maximize clinical usefulness, and 3) comments about integrating the tool into clinical practice. The qualitative data were independently categorized by two team members and reconciled by discussion using standard content analysis methods [36].

Results

Qualitative and quantitative feedback from the usability testing was used to evaluate the usability and acceptability of ATHENA-OT during both ongoing development and deployment, and to improve ATHENA-OT's design.

Results from Qualitative User Feedback

We elicited detailed, specific feedback on system elements to assess the success of design revisions and to help address areas where previous feedback suggested problems but not clear solutions. When prompted, providers gave detailed and specific feedback that was directly translatable into system changes. To illustrate the value of the user feedback for system redesign, we provide examples of comments about 1) the GUI, 2) clinical usefulness, and 3) integration into work practice. All participants provided feedback in all three areas. Where relevant, we explain the CDSS revisions made in response to the feedback.

Suggested GUI Improvements

Feedback on the GUI identified parts of the CDSS where the meaning of system elements or the correct method of interacting with the system was not intuitive. Where possible, these elements were modified to make their meaning or use more clear. When an understandable solution could not be identified, we added specific training on the correct use and interpretation of the CDSS element to our user training protocol.

Example 1

A user thought that the appearance of the "stamp" window implied that the patient had a chronic pain problem or diagnosis. In actuality, the "stamp" indicated that the patient had a scheduled appointment within a 5-day window and that ATHENA-OT had recommendations available should the provider consider OT for that patient. We revised the wording on the stamp to clarify this, and emphasized this point in trainings.

Example 2

Several users in the simulation-based testing did not notice the arrows under the clinical recommendations or did not realize they provided additional, more detailed information about the basic recommendation when clicked on. We addressed this in training by demonstrating the function of the arrows. Subsequent system revisions may test options to make the arrows more noticeable and intuitive.

Study subjects also provided helpful feedback on the wording of GUI elements, particularly the level of detail and vocabulary level most appropriate for PCPs. Notably, clinicians disagreed with each other and were not always internally consistent about the level of detail they desired from the system. Readability and brevity was highly valued by clinicians, however, they also wanted detailed information about unfamiliar suggestions or elements. For example, one in-clinic user commented about the Phase 1 system that "It is hard to use the tool when sitting with a patient because it is in paragraph form. It would be better if factoids or outlines and standardized approaches are numbered or outlined and in lists." In contrast, another in-clinic user stated that the system would be more helpful if it gave more detailed information on "how to switch or discontinue drugs." To address both these needs we redesigned the GUI to present brief messages indicating clinical choices or warnings that users could click on for specific instructions or greater detail. For example, the opening screen of the GUI in Phase 2 provided clinicians short options they might consider with a specific patient, such as switching medications, titrating up, or discontinuing a prescription. When providers clicked on an option, ATHENA-OT displayed detailed individualized recommendations on how to implement it, including indications and contraindications, a recommended dosing schedule and medication choice, and monitoring instructions.

Suggestions to Improve Clinical Usefulness

Subjects highlighted the need for organization, prioritization, and highlighting of information to make it more accessible and usable in a clinical environment. As one

clinician described in Phase 1 testing, "The page is too convoluted. When there are 10 different things on the screen, providers aren't going to read any of it." They requested that the most important information be highlighted and ranked in some way to enable quick scanning for the most important details. In response, we added highlighting to the patient data tables to indicate the most relevant or recent information, such as a positive urine drug screen or a current opioid prescription. We also categorized recommendations to enable easier sorting, and moved some messages from the main page into underlying detailed messages (accessed by clicking on an icon). There was no clinical justification for ranking recommendations by importance. For example ignoring either pulmonary problems or benzodiazepine dependence could result in accidental overdose and serious morbidity or even death, so it is not possible to say one is more important than the other. Therefore, we reorganized recommendations by type so clinicians could quickly find the type they desired.

Clinicians also requested tools that would document care provided rather than just assist with assessment or clinical decision-making. For example, in Phase 1 a clinician said "I would like more of the recommendations to go into a note to document what I have done with the patient." A templated pain assessment that could be written back into the medical record was the most frequently requested documentation tool, and this was incorporated into the system in Phase 2. Subsequently, a provider commented that he liked the "pain assessments which drop into notes." Similarly, several clinicians requested a clinical checklist that could simultaneously remind the clinician of standard practice recommendations and document task completion. This checklist has been implemented, but it cannot yet be written back into a note. In the lab-based usability sessions participants commonly made specific clinical suggestions, such as clarifying the wording of recommendations, cautions, and data table notation. When appropriate, we incorporated these suggestions promptly.

Comments about Integrating the Tool into Clinical Practice

Providers identified several challenges to incorporating the CDSS into clinical practice. For example, a lack of networked printers in the clinic limited the usefulness of patient handouts provided by the system. In-clinic participants identified times when software or hardware changes led to slowing of the system to the point that it was noticeable or disruptive to workflow. When possible, we addressed and corrected these problems quickly. Other systematic barriers mentioned included difficulties with provider continuity in a teaching hospital and lack of staff support for collecting urine samples for drug screening.

Some prompted and unprompted comments highlighted problems with implementing OT guidelines in primary care practice, not problems with ATHENA-OT. While identifying these problems was not a focus of our usability testing, we found that the issues clinicians brought up highlighted key problems that we encountered in designing the CDSS but that we could not resolve. For example, they wanted the CDSS to tell them whether to initiate or discontinue therapy or increase or decrease dosing rather than provide a detailed explanation of how to evaluate these potential actions. However, research has not determined when and for which patients these broad clinical decisions are associated with better outcomes; thus, neither the CPG nor ATHENA-OT attempts to guide users' choices between these options. Another common theme in clinicians' comments were concerns that it would take them longer to follow the practices recommended by the CDSS than they could currently spend on pain management in a typical patient encounter.

Clinicians' comments and concerns emphasized that PCPs face many competing time constraints that may limit their use of a CDSS for OT. While the CDSS streamlines and facilitates practices recommended in the CPG, they still require time to complete. Several clinicians commented that they liked ATHENA-OT features such as the pain assessment and other tools to assist with pain management and had no suggestions for making them more efficient, but said that they would not use them in practice because of time constraints. For example, one in-clinic clinician stated "The content seems fine. I like the resources, but again [there is] just no time with all the competing pressures to document and get the clinical reminders and notes done." Another stated "I would use [the] system if the chief told me to or if it came as a top down order. I just don't have time in the 15 minute appointment . . ." Adding an early evaluation of general problems encountered in following CPG recommendations for OT might have helped the team address these legitimate provider concerns earlier in the design process.

Results from Quantitative User Feedback

Survey Instruments

While qualitative clinician feedback on ATHENA-OT's specific features and content were key to guiding its iterative redesign, we evaluated the system's overall usability, quality, and readiness for clinical implementation with standard measures: the SUS and the CHCE-PSQ. The CDSS was rated as usable in Phase 1 simulation-based testing on the SUS. Moreover, following modifications to the CDSS based on user feedback, ATHENA-OT was rated as more usable on the SUS by participants in Phase 2 laboratory based testing (Table 1). The overall SUS score increased from 74 ($\pm$0.93) out of 100 possible points in Phase 1, and 84 $\pm$ 0.43 in Phase 2. On the CHCE-PSQ, the CDSS was rated very highly on the usefulness of the information provided (Table 1). In Phase 1, lab-based testing usefulness was rated at 4.0 out of a possible 5.0 (5.0 being "excellent") and in Phase 2 lab-based testing usefulness was rated 4.6 out of 5.0. General satisfaction measured by a holistic evaluation question increased from Phase 1 (3.7/5.0) to Phase 2 (4.0/5.0).

Table 1 Results of the CHCE-PSQ and SUS

	Round 1 (n = 4) Mean (SD)	Round 2 (n = 5) Mean (SD)	Overall Mean (SD)
CHCE-PSQ			
1. Usefulness of the information provided	4.00 (0.50)	4.60 (0.58)	4.33 (0.71)
2. Ease of understanding the information presented	4.50 (0.48)	4.00 (0.82)	4.22 (0.67)
3. Use of graphics	3.00 (0.00)	3.60 (0.58)	3.43 (0.53)
4. Improvement in patient–provider encounters	3.67 (0.19)	3.80 (1.41)	3.75 (1.04)
5. Does the DSS save time	3.25 (1.42)	3.00 (0.82)	3.11 (1.05)
6. A regular part of daily practice	4.00 (0.00)	3.60 (1.73)	3.75 (1.16)
7. Improvement in attitude toward treating patients	3.33 (0.69)	3.60 (1.41)	3.50 (1.60)
8. General satisfaction with the system	3.67 (0.51)	4.00 (0.82)	3.88 (0.64)
SUS			
1. I think that I would like to use this system frequently	3.75 (0.50)	4.50 (0.90)	4.00 (0.78)
2. I found the system unnecessarily complex	2.50 (1.30)	2.00 (0.00)	2.25 (0.83)
3. I thought the system was easy to use	4.00 (0.81)	4.25 (0.45)	4.00 (0.60)
4. I think that I would need the support of a technical person to be able to use this system	1.50 (1.00)	1.50 (0.90)	1.50 (0.88)
5. I found the various functions in this system were well integrated	3.50 (0.58)	4.25 (0.84)	3.75 (0.78)
6. I thought there was too much inconsistency in this system	1.75 (0.50)	1.25 (0.45)	1.50 (0.53)
7. I would imagine that most people would learn to use this system very quickly	4.25 (0.50)	4.00 (0.00)	4.12 (0.33)
8. I found the system very cumbersome to use	2.25 (1.26)	1.25 (0.45)	1.75 (1.00)
9. I felt very confident using the system	4.00 (0.00)	4.00 (0.71)	4.00 (0.50)
10. I needed to learn a lot of things before I could get going with this system	1.75 (0.96)	1.50 (0.55)	1.62 (0.73)

Raw scores are presented. For the CHCE-PSQ, 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent. For the SUS, 1 = strongly disagree, 3 = neither agree or disagree, 5 = strongly agree.
CHCE-PSQ = Center for Health Care Evaluation Adapted Provider Satisfaction Questionnaire; SUS = System Usability Scale.

Participants rated the ATHENA-OT system lowest on expectations that the CDSS would save time in patient visits. As noted above, the primary purpose of the ATHENA-OT system was to encourage use of guideline-recommended opioid prescribing practices, which include on-going use of time-consuming pain assessments, urine drug screening, and patient education and opioid agreements.

Another area in which the CDSS was scored relatively low compared with other questions on the CHCE-PSQ was its ability to improve patient–provider encounters and provider attitude toward treating chronic pain patients. Patients with chronic pain problems and especially patients with medication misuse problems are often considered "difficult" by clinicians, and poor communication and mutual mistrust can be a substantial barrier to using good pain management practices. ATHENA-OT was not specifically designed to facilitate patient–provider discussions other than by providing educational materials. Developing ways to use the system to improve patient–provider encounters around OT may increase ATHENA-OT's usefulness and address an additional barrier to good clinical practice. Lastly, the system was rated relatively low on "use of graphics" reflecting the systems focus on presentation of text-based recommendations.

Clinician Use of the System in Primary Care Practice

An important criteria for evaluating the acceptability of the ATHENA-OT system by providers is whether providers actually used the system during their patient encounters.

Log-Trace File

We recorded all participant interactions with ATHENA-OT during the period in which the CDSS was available in-clinic (Table 2). The 12 participating PCPs saw the ATHENA-OT full display 1,063 times for 398 distinct patients (Table 2). Of these full displays, 117 or 11% (67 in Phase 1 and 50 in Phase 2) appeared because the PCP clicked on the stamp to obtain the full display; the remainder 946 (89%) full displays appeared because the patient had an active prescription for an opioid medication. This basic interaction with the system provided exposure to warnings, recent opioid prescriptions, brief clinical recommendations, and a checklist for clinical practice. Beyond this, subjects' interactions with ATHENA-OT were selective. Subjects accessed the pain assessment, reassessment, and conversion calculator tools 36/1063 (3.4%) times, the drop-down pages with clinical and referral information 53/1,063 (5%) times, and the recommendation details

Table 2 Clinician exposure to the ATHENA Opioid Therapy system based on logged data

	Phase 1 (137 days)		Phase 2 (101 days)		Total	
	Displays (N)	Unique Patients (N)	Displays (N)	Unique Patients (N)	Displays (N)	Unique Patients (N)
Stamp display*	2,274	720	3,188	1,035	5,462	1,482
Clicked on stamp for Full display	67	64	50	50	117	113
Full display†	430	155	516	180	946	285

* Stamp display appeared when patient did not have an active prescription for an opioid drug.
† Full display appeared when patient had an active prescription for an opioid drug.

8/11,063 (0.8%) times. No one tool or information page was used substantially more than the others. In terms of performance, ATHENA-OT improved substantially over time: in February the ATHENA-OT window took 30–40 seconds to open and in April it appeared in less than 3 seconds. These improvements were achieved by altering system architecture based on feedback about in-clinic system performance.

Provider Shadowing

Between February 11 and April 24, 2008, project team members observed three clinicians conduct 35 visits. Clinic visits varied from 13 to 59 minutes and averaged 31 minutes. Observations indicated that exam rooms were set up to allow providers to easily use the computer while talking and observing the patient during the visit. In most cases, the computer was set up such that the provider could actually show the screen to patient if they desired. Two providers consistently used the EMR system during the visit, and one did not. This provider would have still seen ATHENA-OT when reviewing a chart or entering notes prior to or after a visit, but these interactions were not observed. The ATHENA-OT main display was seen by clinicians in 10 of the 35 visits; four of these patients had existing prescriptions and thus full display was triggered automatically. In these 10 visits, the time ATHENA-OT was used ranged from 3 seconds to 10 minutes.

Discussion

Usability testing and feedback led to significant improvements in CDSS design and optimized content to be of enhanced use to PCPs, our target users. Study subjects were generally positive about and satisfied with the usefulness and usability of the CDSS. After incorporating revisions suggested in our first round of testing, overall usability ratings on the SUS increased. The final ATHENA-OT was rated as highly usable: it scored 84/100 on the SUS, and SUS scores in the upper 70s to high 80s are defined as better products [37]. Clinic-based clinician testing and feedback identified GUI improvements, problems with interface design and interpretability, readability and understandability issues, and the need to highlight and prioritize specific information. It also helped to clarify the detail and reading level at which the recommendations would be most effective. Overall simulation-based and clinic-based usability testing identified distinct elements that helped improve usability and clinician acceptance of the system [27,38].

Our limited observations of clinical visits suggest that clinician practice patterns and office-settings allowed the CDSS to be used without intrusion into standard practice. These clinicians appeared to have a reasonable amount of time to use the system when needed. We note that these observations appear to contradict clinician testers' self-report of lack of time during visits, which may reflect either nonrepresentativeness of the visits we were allowed to observe, or exaggeration of time constraints by clinician testers. Clinician interactions with the system illustrated that key information must be available without requiring clinicians to click on items. The rate at which clinicians conducted additional mouse-clicks was low, as seen in evaluations of other CDSS [39]. Together, these observations suggest that ATHENA-OT could be successfully used in clinical practice to improve adherence to CPG recommendations, if implemented in a supportive setting that emphasized the importance of pain management and these guideline-recommended practices. Attention to organizational issues such as engaging end-users and addressing workflow barriers are crucial for successful deployment of clinical decision support [13,40].

Notably, usability testing also identified systematic barriers to use of recommended practices for OT that could not be addressed with a CDSS. The most consistent barrier mentioned was a lack of time and the difficulty of balancing competing clinical demands, reflecting the time-consuming nature of the CPG recommendations. A number of users mentioned that although the CDSS provided helpful information and tools, it would still take more time than they had available to follow the recommendations and thus they would be unlikely to make regular use of the system. The CPG recommends conducting a thorough pain assessment, regular urine drug screens for illicit substances and use of the prescribed medication, and conducting patient education that may include an opioid agreement. Time constraints on patient visits and the necessity of addressing multiple health concerns in addition to pain may prevent PCPs from completing these activities and therefore from using ATHENA-OT to full-

effect. An effective ATHENA-OT thus might increase the amount of time clinicians spent managing chronic pain and OT up-front. Others were disappointed that the system did not recommend a prescription when the chart was opened. Because treatment decisions are expected to be made through a shared decision-making process guided by the warnings in the guideline and by patient preferences and goals, the CPG—and thus our CDSS—focused instead on ensuring appropriate dosing levels and titration schedules to maximize clinical safety and efficacy. The desire for help with broad prescribing choices highlights clinicians' frustrations with the available evidence and a major need for research.

Regardless of whether the CDSS provides the clinician with important information, instruction, and tools, appropriate use of OT requires thorough communication between the patient and provider. This includes discussion of potentially sensitive topics such as addiction risk, mental health problems, and social situation. While the CDSS can provide prompts to talk about these issues, templates and standard questions that need to be asked, recommendations on how to address specific issues, and education materials for the patient to read, it cannot eliminate the need for this communication or necessarily speed it up. Experts are concerned that lack of thorough communication when prescribing OT may contribute to opioid misuse, increased adverse effects, and ineffective pain management, but changes in health care delivery systems will likely be required to enable thorough, consistent use of CPG-recommended practices.

Systemic barriers uncovered in testing ATHENA-OT suggest that improving clinical care may be maximized by both providing the CDSS and implementing health care system initiatives, which provide additional clinical support for recommended OT practices. This may require organizational changes to address logistical issues, in addition to changes by individual clinicians. VA has recognized this need, and is developing and implementing new, innovative primary care-based models to improve chronic pain and opioid management, including collaborations with pharmacy to manage opioid prescriptions [41], psychologist-based pain management interventions [42], and stepped care programs for depression and musculoskeletal pain [43], in addition to expanding access to multidisciplinary pain programs.

Limitations

We note that while we believe our iterative usability testing procedures represent an improvement over methods used in previous pain management decision support system development, there are limitations to our study. We conducted usability testing with a small sample and not all subjects were members of the intended end-user population. We also note that this testing does not evaluate the clinical effectiveness of the CDSS for improving guideline adherence in opioid prescribing. Also, while direct observation of clinic visits and assessment of clinician mouse clicks was helpful for obtaining a general picture of how the CDSS fit into clinical workflow, these techniques were limited in that we were not able to determine how much of the information was read or used in clinician thought processes. Post-observation discussions with clinicians would have been helpful in understanding which CDSS elements were useful during a particular visit. We note that the developers of the software were also involved in the usability evaluation. We believe this is both a strength and a weakness. This methodology allowed developers to elicit elaboration on design-relevant comments from clinician testers and helped insure that input from the evaluation was directly addressed in software revisions. However, the lack of independence of the evaluation team may have amplified response bias, potentially discouraging reporting of disapproval with the tool.

In summary, iterative testing and evaluation by end-users in a simulation-based and a clinic-based setting were crucial to developing a usable and useful CDSS that PCPs would find acceptable. Clinician evaluators indicated that the final system addressed barriers to adherence to CPG-recommended practices for OT such as lack of provider education, confusion in medication choice, dosing calculations and titration schedules, access to relevant patient information and treatment history, lack of knowledge of treatment resources, provider discontinuity, need for assistance with documentation, and access to validated assessment and patient education tools. Despite these benefits, clinician evaluators expressed concerns that the CDSS would have limited impact unless additional barriers were simultaneously addressed. Information about design level and systemic barriers to improving OT practices will be useful as plans are developed for evaluating the effectiveness and impact on clinical care of implementing ATHENA-OT as part of quality improvement initiatives in clinical settings. For example, detailed examination of how interactions with ATHENA-OT alter opioid prescribing decisions and ultimately patient health outcomes is needed to determine the clinical effectiveness of the CDSS. Study results will also be helpful as versions of ATHENA-OT for use in other clinical settings (e.g., pharmacy, pain clinics, poly-trauma units) are planned and developed. Results may also be helpful in guiding research to address questions that PCPs struggle with in managing pain and using OT.

Acknowledgments

This project was funded by Grant # TRX 04-402 entitled, "Decision Support for the Management of Opioid Therapy in Chronic Pain" and Grant # IMA 04-156, entitled "Building Expertise to Develop and Implement Decision Support Systems" from the VA Health Service Research and Development Program. The views expressed in this article are those of the authors and do not reflect those of the Department of Veterans Affairs.

References

1 Paulozzi LJ. The Epidemiology of Unintentional Drug Poisoning in the United States. Centers for Disease Control and Prevention, National Center for Injury Pre-

vention and Control; 2007. Available at: www.state-epi.org/document/audiopresentations/3_Paulozzi%20webcast%2012%2012%2007.ppt. Accessed February 1, 2010.

2 Furlan AD, Sandoval JA, Mailis-Gagnon A, Tunks E. Opioids for chronic noncancer pain: A meta-analysis of effectiveness and side effects. CMAJ 2006;174(11):1589–94.

3 Martell BA, O'Connor PG, Kerns RD, et al. Systematic review: Opioid treatment for chronic back pain: Prevalence, efficacy, and association with addiction. Ann Intern Med 2007;146(2):116–27.

4 Substance Abuse and Mental Health Services Administration. Results from the 2006 National Survey on Drug Use and Health: National Findings. NSDUH Series H-32, DHHS Publication No. SMA 07-4293. Rockville, MD: Office of Applied Studies; 2007.

5 Paulozzi LJ, Budnitz DS, Xi Y. Increasing deaths from opioid analgesics in the United States. Pharmacoepidemiol Drug Saf 2006;15(9):618–27.

6 Paulozzi LJ, Xi Y. Recent changes in drug poisoning mortality in the United States by urban-rural status and by drug type. Pharmacoepidemiol Drug Saf 2008;17(10):997–1005.

7 Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009;10(2):113–30.

8 VA/DoD The Management of Opioid Therapy for Chronic Pain Working Group. VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain. March Contract No.: V101(93)P-1633. Washington, DC: Department of Veterans Affairs & Department of Defense; 2003.

9 Bero LA, Grilli R, Grimshaw JM, et al. Getting research findings into practice: Closing the gap between research and practice: An overview of systematic reviews of interventions to promote the implementation of research findings. BMJ 1998;317(7156):465–8.

10 Passik SD, Squire P. Current risk assessment and management paradigms: Snapshots in the life of the pain specialist. Pain Med 2009;10(suppl 2):S101–14.

11 Bair MJ. Overcoming fears, frustrations, and competing demands: An effective integration of pain medicine and primary care to treat complex pain patients. Pain Med 2007;8(7):544–5.

12 Michel MC, Trafton JA, Martins SB, et al. Improving Patient Safety Using ATHENA-Decision Support System Technology: Opioid Therapy for Chronic Pain. Contract No.: AHRQ Publication No. 08-0034-4. Rockville, MD: Agency for Healthcare Research and Quality; 2008.

13 Goldstein MK, Coleman RW, Tu SW, et al. Translating research into practice: Organizational issues in implementing automated decision support for hypertension in three medical centers. J Am Med Inform Assoc 2004;11(5):368–76.

14 Tu S, Musen M. Representation formalisms and computational methods for modeling guideline-based patient care. In: Heller B, Loffler M, Musen M, eds. Computer-Based Support for Clinical Guidelines and Protocols. Amsterdam, The Netherlands: IOS Press; 2001:125–42.

15 Aigner W, Kaiser K, Miksch S. Chapter 8: Visualization methods to support guideline-based care management. In: Teije A, Miksch S, Lucas P, eds. Computer-Based Medical Guidelines and Protocols: A Primer and Current Trends. Amsterdam, The Netherlands: IOS Press; 2008:282.

16 Britto MT, Jimison HB, Munafo JK, et al. Usability testing finds problems for novice users of pediatric portals. J Am Med Inform Assoc 2009;16(5):660–9.

17 Saleem JJ, Patterson ES, Militello L, et al. Impact of clinical reminder redesign on learnability, efficiency, usability, and workload for ambulatory clinic nurses. J Am Med Inform Assoc 2007;14(5):632–40.

18 Sittig DF, Wright A, Osheroff JA, et al. Grand challenges in clinical decision support. J Biomed Inform 2008;41(2):387–92.

19 Battles JB. Improving patient safety by instructional systems design. Qual Saf Health Care 2006;15(suppl 1):i25–9.

20 Dick W, Carey L. The Systematic Design of Instruction, 4th edition. New York: Harper Collins; 1996.

21 Bates DW, Kuperman GJ, Wang S, et al. Ten commandments for effective clinical decision support: Making the practice of evidence-based medicine a reality. J Am Med Inform Assoc 2003;10(6):523–30.

22 Smith M, DePue J, Rini C. Computerized decision-support systems for chronic pain management in primary care. Pain Med 2007;8(suppl 3):S155–66.

23 Knab JH, Wallace MS, Wagner RL, Tsoukatos J, Weinger MB. The use of a computer-based decision support system facilitates primary care physicians' management of chronic pain. Anesth Analg 2001;93(3):712–20.

24 Wilkie DJ, Judge MKM, Berry DL, et al. Usability of a computerized PAINReportIt in the general public with

pain and people with cancer pain. J Pain Sympt Manage 2003;25(3):213–24.

25 Reisman Y. Computer-based clinical decision aids. A review of methods and assessment of systems. Med Inform (Lond) 1996;21(3):179–97.

26 Nielsen J. Estimating the number of subjects needed for a thinking aloud test. Int J Hum Comput Interact 1994;41:385–97.

27 Nielsen J. Usability Engineering, 1st edition. Amsterdam, The Netherlands: Morgan Kaufmann; 1993.

28 Brooke J. SUS: A "quick and dirty" usability scale. In: Jordan P, Thomas B, Weerdmeester B, Weerdmeester M, eds. Usability Evaluation in Industry. London: Taylor and Francis; 1996:189–94.

29 Kirkpatrick D. Techniques for evaluating training programs. In: Ely D, Plomp T, eds. Classic Writings on Instructional Technology. Volume 1. Englewood, CO: Libraries Unlimited; 1996:119–42.

30 Tullis T, Stetson J, authors, eds. A Comparison of Questionnaires for Assessing Website Usability. Minneapolis, MN: Usability Professionals' Association; 2004. Available at: http://www.upassoc.org/conferences_and_events/upa_conference/2004/. Accessed February 1, 2010.

31 Kirkpatrick D. Techniques for evaluating training programs. J Am Soc Train Dev 1959;13(11):3–9.

32 Kirkpatrick D. Techniques for evaluating training programs: Part 2—Learning. J Am Soc Train Dev 1959;13(12):21–36.

33 Kirkpatrick D. Techniques for evaluating training programs: Part 3—Behavior. J Am Soc Train Dev 1960;14(1):13–18.

34 Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. J Biomed Inform 2004;37(1):56–76.

35 Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: Online international Delphi consensus process. BMJ 2006;333(7565):417. doi:10.1136/bmj.38926.629329.AE.

36 Weber R. Basic Content Analysis, 2nd edition. Newbury Park, CA: Sage Publications; 1990.

37 Bangor A. An empirical evaluation of the system usability. Int J Hum Comput Interact 2008;24(6):574–94.

38 Guappone KP, Ash JS, Sittig DF. Field evaluation of commercial Computerized Provider Order Entry systems in community hospitals. AMIA Annu Symp Proc 2008;263–7.

39 Maviglia SM, Zielstorff RD, Paterno M, et al. Automating complex guidelines for chronic disease: Lessons learned. J Am Med Inform Assoc 2003;10(2):154–65.

40 Ash JS, Gorman PN, Lavelle M, et al. A cross-site qualitative study of physician order entry. J Am Med Inform Assoc 2003;10(2):188–200.

41 Wiedemer NL, Harden PS, Arndt IO, Gallagher RM. The opioid renewal clinic: A primary care, managed approach to opioid therapy in chronic pain patients at risk for substance abuse. Pain Med 2007;8(7):573–84.

42 Cucciare MA, Sorrell JT, Trafton JA. Predicting response to cognitive-behavioral therapy in a sample of HIV-positive patients with chronic pain. J Behav Med 2009;32(4):340–8.

43 Kroenke K, Bair MJ, Damush TM, et al. Optimized antidepressant therapy and pain self-management in primary care patients with depression and musculoskeletal pain: A randomized controlled trial. JAMA 2009;301(20):2099–110.