Using Multi-Perspective Methodologies to Study Users' Interactions with the Prototype Front End of a Guideline-Based Decision Support System for Diabetic Foot Care

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ABSTRACT

Purpose: Clinical practice guidelines are important instruments for improving quality of care; in paper form, however, they are not used as effectively as possible. In order to develop a guideline-based decision support system (DSS) prototype to help clinicians deal with diabetic patients' foot problems, we drew on methodologies from qualitative research, cognitive science, and information systems. This multi-perspective approach was intended to facilitate user-centered design and evaluation.

Methods: We employed field observations, structured interviews, and document analyses to collect and analyze users' workflow patterns, decision-support goals, and preferences regarding interactions with a DSS. Next, we aligned their requirements with sequence diagrams and followed Nielsen's heuristics to develop a DSS prototype. We then performed think-aloud analyses and used the Technology Acceptance Model to direct our evaluation of users' perceptions of the prototype.

Results: Users had a positive response to the DSS prototype in terms of its clarity of design and ease of use. They expressed a high intention of using the system in the future.

Conclusion: Applying multi-perspective methodologies is an effective way to study and design user interactions with the front end of a guideline-based DSS.

INTRODUCTION

Foot-wound infection and ulceration that may lead to the need for amputation is a major complication of diabetes. Implementing evidence-based prevention and management protocols has the potential to reduce the risk of such outcomes [1]. In 2000, the American College of Foot and Ankle Surgeons developed a guideline for diagnosing and managing diabetic foot disorders; a revised version was released in 2006 [1].

Studies have shown that implementing guidelines in the form of clinical decision support systems (DSSs) to deliver patient-specific advice at the point of care is more likely than paper-based guidelines to affect clinicians' behaviors [2]. Informatics and medical experts developing such systems need to focus on two complementary perspectives:

- Utility: Creating an executable system that is medically valid by encoding the guideline's logic in a computer-interpretable way, linking it to an electronic medical record (EMR), and executing the encoded guideline via an execution engine that draws relevant patient data from the EMR.
- Usability: Attending to potential users' needs and fitting the DSS to their workflows.

Our previous effort to develop a DSS for diabetic foot care [3] focused on adapting the American College of Foot and Ankle Surgeons' guideline to local settings and on encoding it. Drawing on that experience, we designed a tool-supported process for guideline encoding that addresses local adaptations and EMR integration. That process also includes steps for validating the guideline's clinical content [3]. However, a major obstacle to the assimilation of our system in clinical practice was that it had not been adjusted to users' needs.

In the study reported in this paper, we therefore applied qualitative, cognitive, and information systems methods to collect and analyze data on users' needs and workflows. We used that information to design and evaluate a prototype of the front end of the DSS for diabetic foot care. In order to do so, we followed a life-cycle development and evaluation approach to adapt methods drawn from multiple disciplines. In this paper we describe the alignment of our system analysis methods with the specific requirements potential users identified. This alignment process enabled us to create a DSS prototype and evaluate potential users' intentions to adopt it.

Background

In this section we review research that addresses (a) the principles leading to the successful implementation of clinical DSSs; (b) our initial work, which followed these principles, on developing a diabetic foot care DSS; and (c) approaches for user-centered design and evaluation, which we employed and extended in our project.

Principles leading to the successful implementation of clinical DSSs

Previous studies have identified several principles that may lead to the successful implementation of clinical DSSs [4, 5]. Two of the most important principles are identifying users' needs and incorporating workflow integration and timely advice. Research has also shown that such systems should affect clinical outcomes and cost reduction, and that they should be continuously maintained.

Narrowing the gaps between current realities and design conceptions is a key factor in developing successful information systems [6]. This can be accomplished by facilitating

communication between developers and users via the use of modeling methods that aid the understanding of real-world requirements; by involving "hybrid" people who are knowledgeable in both the clinical domain and organization as well as in system analysis and who may be able to bridge the gap between users and developers; and by developing the project incrementally and receiving feedback from stakeholders [6]. Rocheleau [7] stresses improvement of organizational issues (e.g., poor management, obstacles to data sharing, problems in the purchasing process) as critical for the success of information systems and as important as addressing content obstacles (e.g., poor data quality) and user-related problems (e.g., information overload).

Initial work on developing a diabetic foot care DSS

Following these design principles, we developed a DSS [3] for diabetic foot care based on a highly regarded clinical practice guideline [1]. Our previous work had focused on adapting the guideline to the local setting of family practitioners in the Israeli healthcare system and on encoding the guideline in the GLIF3 format [8]. As part of that project, we linked the encoded guideline with a diabetic foot care EMR system, developed by Eddy Karnieli. Clinicians used this system to collect data for diabetes patients' foot care and, in cases about which they had treatment questions, to communicate asynchronously with experts who could look at the data and provide answers. The encoded guideline could be interpreted by GLEE [9], GLIF3's execution engine, which traversed the encoded guideline and queried the EMR data. At decision points (e.g., "Does the patient have an infection?"), GLEE could evaluate patient data against the decision criteria and provide patient-specific advice. GLEE's stand-alone user interface (UI) facilitated communication between the guideline encoder and diabetes experts.

Two independent clinical experts validated our guideline encoding by examining the results generated by GLEE [3]. Because our previous work focused on adapting and encoding medical knowledge and on linking the guideline to an EMR system, it addressed neither clinicians' interactions with the system nor the front-end design of the UI. These aspects are, therefore, the focus of this study.

User-centered design and evaluation

User-centered design and evaluation have proven crucial for developing DSSs [10, 11] and user interfaces for other types of clinical systems [12, 13]. Reviews of user-centered design methodologies [12, 14] emphasize the value of four analytic avenues:

- Analysis of intended users' characteristics and work environments;
- Top-level functional analysis that examines users' goals, the domain structures needed for successful goal completion, and the information flows within a system;
- Analysis of the tasks users perform;
- Representational analysis, which examines the optimum information display formats (e.g., graphic display) for each task.

These studies propose general methods for collecting users' requirements. On the functional side, such methods include work domain analysis and analysis of cognitive activities. For task analysis purposes, one may employ questionnaires, surveys, interviews, observation, and laboratory field studies. The information gathered by the latter set of techniques can be reviewed with users through scenarios, task tables, and hierarchical task analysis in order to identify the tasks that may be reduced or redesigned to decrease cognitive load.

Kinzie et al. [13] suggest a life-cycle model for developing a user-centered design process; their suggestion coheres with development approaches used in information systems engineering [15]. This design process consists of the following stages:

- Data collection: Qualitative or quantitative methods are used to collect data on users' needs. Qualitative approaches include examining existing materials and sites, conducting interviews and focus groups, and observing practice; quantitative approaches include surveys and rating scales.
- Data analysis: Qualitative data are reviewed through content analysis to identify themes expressed by users. These themes are then used to formalize requirements, categorize them, and make comparisons among various respondent groups. Quantitative data are analyzed using conventional descriptive statistics.
- Requirement prioritization: This stage entails considering organizational goals, the consequences of needs not being met, and the available time, budget, and expertise.
- Defining and ranking potential high-level solutions.
- Developing a goal/task flow diagram to define the identified potential solution.

Upon completion of these stages, the content and form of the solution can be designed using storyboards and implemented via rapid prototyping that does not involve actual implementation. The cycles of prototype development, evaluation, and revision can be repeated as required.

User-centered evaluation employs various techniques, broadly categorized as inspection and usability testing [12]. Inspection methods include heuristic evaluation of user interfaces, keystroke-level modeling, and cognitive walkthroughs. Experts in human cognition and human factors engineering perform heuristic evaluations to uncover problems with user

interfaces and they make suggestions for fixing them. Keystroke-level modeling and cognitive walkthroughs are used, respectively, to assess the time required to perform specific tasks and to uncover usability issues that affect novice users' performance [16].

Usability evaluation usually involves a small number of participants and provides an important means of validating interface design decisions and testing alternative designs. Such evaluations frequently include think-aloud methods whereby users are prompted to verbalize what they are doing and thinking as they use a system.

METHODS

In order to understand users' interactions with the front end of our DSS, we used multiple methods to collect and analyze user requirements, to develop a prototype system, and to evaluate the design. The Human Rights Committee of RAMBAM Medical Center approved our research.

The life-cycle approach we used is similar to the one proposed by Kinzie et al. [13]. It combines two system-development methodologies: the Waterfall model and the prototyping model [15]. The Waterfall model begins with system analysis followed by system design; both are done using modeling methods. The system is then implemented, tested, and put into use. As new requirements arise during a system's use and maintenance, the life cycle can start and unfold again. While the system development process moves forward from one stage to the next, corrections are made to earlier phases when problems are discovered.

In our project we used the GLIF3 language and GLEE engine [8] for analysis, design, encoding, and validation of the guideline's care processes. We used Sequence Diagrams (described below) to analyze and design the DSS's interactions with users. While the Waterfall model allows ample time to elicit and analyze requirements, implementation is done only late in a system's development life cycle. As a result, not all desired changes can be accommodated and most alterations are costly. The prototyping system-development method can overcome these obstacles because it involves creating a system prototype early in the design process so that users are able to evaluate it and provide feedback before implementation occurs.

In the following subsections we provide details on the methods we used in the main stages of our DSS's development. Table I summarizes the methods we used during the stages of the system's development and evaluation.

Table I. Methods used during the DSS's development and evaluation

Stage / Method	Data collection (users' needs and workflows)	Data analysis (users' needs and workflows)	UI/ front-end prototype design	Design evaluation
Interview	M, W, UI, DS			W, UI
Observation	M, W			
Document analysis	M			
Requirement formulation		+		
Sequence diagrams		+	+	
Prototype			+	
Nielsen's heuristics			+	+
Think aloud				+
TAM				+

M: medical practice data; W: workflow data; UI: UI data; DS: decision-support goals data; +: the method was used at a certain system development and evaluation stage.

Collecting data about users' needs and workflows

We used qualitative methods – field observations, structured interviews, and questionnaires containing open-ended questions [15] – to collect data about a relatively small group of users' needs for the different perspectives defined by Johnson et al. and Zhang et al. [12, 14] and to evaluate those users' responses to our DSS prototype. First, we conducted structured interviews with five family physicians, which is the main group of potential users. Eight questions (see Appendix A) concerned users' workflows (question 1), users' preferences regarding interaction with the system (question 2), and users' goals for the DSS (questions 3-8). Additional questions (see Peleg [17]) addressed users' work practices/tasks.

To further understand users' needs and to cross-validate the collected data, we carried out a field observation of a family physician as he examined a diabetic patient's foot. During this consultation the physician "thought aloud" [18]. We also observed the work environments of all five family physicians.

Family physicians often need to consult diabetic experts or refer patients to vascular surgeons. We therefore also studied the work practices of these clinicians, and we interviewed a diabetes expert and a vascular surgeon to whom family physicians refer patients with diabetic foot problems. We further validated our collected data by studying various official documents regarding diabetic foot care issued by Clalit Health Maintenance Organization.

Data analysis of users' needs and workflows

We analyzed the data collected from structured interviews, observations, and official documents according to the four perspectives noted in Table I: medical practice data,

workflow data, UI data, and decision-support goals data. In this paper we focus on the last three perspectives.

The five family physicians often responded to the structured-interview questions with more than a simple yes/no answer; for example, two told us they wanted reminders about the data needed to calculate ulcer grades to be embedded in the DSS's data-entry interface. We collected the answers participants identified as system requirements and we recorded other requirements that were raised but that were not directly addressed by the interview questions (e.g., a recommendation that the DSS should send reminders directly to patients). We recorded these data in an Excel spreadsheet and analyzed the information by counting the number of interviewees who noted each need. When non-family physician interviewees mentioned items that might be useful for physicians, we also included those items in our data.

Our analysis also identified the elements that would be required to support the identified needs. In cases involving conflicting needs (e.g., data entry during a physical examination or after), we identified the requirements that would support the needs of the majority of clinicians. We then prioritized these requirements by dividing them into three groups: those that would be handled completely; those that would be partially supported; and those outside the system's scope (see Table II, "Level of support" column, for our rationale). We also used the summary of observations and think-aloud descriptions provided during the foot exam conducted by one of the family physicians to validate his interview answers about normal workflow and medical practices (note: we do not address the latter topic in this paper).

Table II. System requirements relating to workflow, users' system-interaction preferences, and users' goals for the DSS

Statement	Number of clinicians	Derived requirement	Level of support
Elicited from family doctors			
I don't intend to use any DSS.	1	-	-
I do/don't enter patient data during the physical exam.	3 don't 1 do	Provide decision support at one point in time after completing the physical	Full
I would like to see a short sentence rather than have a lot of interaction with the system.	4	Minimum interaction – only for decisions requiring judgment	Full
		Provide short textual recommendations	Full
I would like to be able to see the specific place in the clinical algorithm.	2	Support a UI that will show the clinical algorithm	No support – based on our assessment that this would take up too much time for a busy clinician
I would like to be reminded about data that I should be collecting.	3	The UI of the Diabetic Foot EMR system will show data to be collected	Full support by the diabetic foot EMR system
I would like to get reminders for follow-up visits.	2	Reminders for follow-up visits	Partial support – the frequency of visits will be calculated and reported. No full support due to authorization required to link to medical group's information system.
I would like the system to schedule follow-up visits.	1		
I would like to get advice about referrals.	1	Decision support for referrals	Partial support – recommendation for referral provided. No full support due to authorization required to link medical group's information system.
I would like to get advice about relevant laboratory tests.	2	Recommend relevant laboratory tests	Full
I would like the system to print patient education material.	2	Provide patient education material	Full
I would like patient historical data in tables and graphs.	3	Patient historical data in tables and graphs	No support – out of scope for GLIF-based decision support
I would like a registry of patients due for foot exams.	1	A registry of patients due for foot exam	No support – out of scope for GLIF-based decision support
Elicited from other healthcare professionals involved in diabetic foot care			
I would like explanations for the recommendations.	1	Provide explanation for recommendations	Full

Prototype design

Creating Sequence Diagrams, which are part of the Unified Modeling Language, is a way of analyzing interactions between a system and its users [19]. In our study we used Sequence Diagrams to examine interactions arising in various patient scenarios that collectively covered all parts of the algorithm in the current implementation of the DSS as well as in other proposed designs. We also used different colors to mark the types of user interactions and system actions:

- Making automatic decisions based on EMR data without involving user input;
- Displaying decision options to users;
- Receiving users' selections;
- Invoking subguidelines;
- Writing recommendations to a system buffer.

We then conducted representational analyses in order to explore the optimum information-display format for the various tasks and to consider alternate solutions. By aligning the front-end requirements with the sequence diagrams, we designed an initial version of the prototype UI. As suggested by Kinzie et al. [13], we first considered the content of the prototype and, later, its visual design. Most of the content requirements were captured by the design of the GLIF clinical algorithms.

We built the prototype as an interactive PowerPoint presentation that displays a patient's medical records and provides a link to the decision-support function. Clicking on the link displays screenshots (generated in Visual Basic) of the recommendations for the specific

patient. These recommendations were generated according to the sequence diagrams for particular patient scenarios. The UI buttons were hyperlinked to other slides in the prototype; as a result, activating a button (e.g., selecting a treatment option, clicking on an explanation button) simulated the actions that would happen in the real DSS. We used two patient cases – one simple and one complex – to generate user feedback. Finally, we prepared printouts of patient education materials and made them available when a user clicked the "Print" button [17].

Prototype evaluation

We inspected the prototype's usability using heuristic evaluation. Our evaluation was based on Nielsen's ten heuristics [20]: (1) visibility of system status; (2) match between system and the real world; (3) user control and freedom; (4) consistency and standards; (5) error prevention; (6) recognition rather than recall; (7) flexibility and efficiency of use; (8) aesthetic and minimalist design; (9) helping users to recognize, diagnose, and recover from errors; and (10) help and documentation. This step helped us to refine the initial UI design prior to usability testing.

We employed usability testing methods to obtain user feedback on the prototype; in particular, to identify the features users preferred or disliked, to clarify the reasons for their views, and to study their overall perceptions of the system and their acceptance of it. Eight physicians evaluated the UI: six family physicians (two of whom participated in the interviews to elicit user requirements, and two others who were diabetes experts), an expert endocrinologist who was also a member of our research team (Karnieli), and a general internist who was also a medical informatics researcher.

We conducted our prototype evaluation in a highly structured and carefully planned two-hour session. During the first hour we verbally informed participants about the goals of the DSS, the guideline encoding process and its execution through GLEE's stand-alone UI, and our analysis of users' needs for a diabetic foot care DSS. We also provided a short demonstration of the prototype. A brief discussion followed, during which participants expressed their views about the need for the system and tried to identify potential problems with it.

We conducted the usability study during the second hour. In order to gather individual feedback that was not biased by peer views, participants used the prototype individually (but at the same time and in the same location). We observed the participants while they used the prototype system, and we asked two of them to "think aloud" [18] (i.e., to verbalize their thoughts while working with the prototype's front end). This methodology allowed us to gain insights into participants' cognitive processes and to identify the proposed design's potential cognitive pitfalls. Users' comments and actions were mapped in order to screen elements and cognitive processes and rated according to severity from 1 (cosmetic problem) to 5 (critical). We also recorded participants' comments on the system's characteristics as well as their overall attitudes towards it (marked as positive or negative). During this encounter we also asked the participants to answer two questionnaires: one before they used the prototype and the other after. The pre-use survey (administered after they had received the overview described above) enabled us to study the variability of users' medical practices (reported elsewhere [17]).

We developed the post-use survey (see Appendix B) to help us predict users' acceptance of the proposed system design. We based it on the Technology Acceptance Model (TAM) [21], a rigorous and validated technique used to explain variances in the acceptance of information systems. TAM's simplicity makes it especially powerful. Although it is usually used to address theoretical questions, TAM's parsimony and validity make it especially suitable for practical use. We therefore adapted TAM to evaluate the potential acceptance of our DSS.

To analyze the results of the acceptance questionnaire we used the Rwg(J) [22] to evaluate the inter-rater agreement on five constructs:

- The system's usefulness;
- The recommendations' usefulness;
- The explanations' usefulness;
- Ease of use;
- Intention to use the system.

J – the number of items in each construct – was 4, 2, 2, 6, and 2, respectively. The measure of agreement is a number between 0 and 1, where 0 indicates complete disagreement and 1 indicates complete agreement. Like many other researchers, we accepted measures of 0.7 or higher as indicating agreement.

In addition to the TAM constructs of perceived usefulness, perceived ease of use, and intention to use the system, we added items that addressed users' perceptions of the prototype's explanation buttons and the validity of the system's recommendations. In order to obtain more targeted feedback, the post-use survey also contained two open-ended questions: (1) What are the positive points about the system? (2) What can be improved? We analyzed

responses to these questions together with the statements expressed in the think-aloud protocols to elicit requirements that we then categorized, as in the data analysis step, into requirements that could be supported fully, partially, or not at all.

RESULTS

Data collection and requirements analysis

Table II summarizes the data derived from interviewing and observing the family physicians. It shows the elicited requirements concerning the front end's design, the statements or observations that lead us to propose these requirements, and our prototype's level of support for those requirements. The most important requirements, stated by all the clinicians willing to use a DSS, were that users' interactions be minimized and that recommendations be summarized in short, clear text at the end of each medical exam.

Prototype design

Based on the requirements identified, we developed a vision of the system: a front end between GLEE and users that will retrieve data from the EMR and that involves minimal interaction between users and GLEE. From time to time GLEE will offer advice; the system's front end will gather these recommendations and deliver them to a user at the end of a session or when the user is required to make a decision.

We used the unified modeling language (UML) [19] sequence diagrams to analyze the order, amount, and types of interactions between the prototype, users, and EMR, in different versions of the front end. Figure 1 shows part of the Sequence Diagram of a design that entails minimal interactions, noting the different types of interactions and user actions (as

explained in the Methods section above). As the figure shows, users are required to enter only one input; the prototype system is able to make automatic decisions and select patient-specific recommendations.

To engineer the prototype supporting this interaction mode, we made the following decisions for the prototype (see Figure 2):

- The upper part of the screen indicates recommendations and the lower part indicates decisions to be made.
- Users are able to see their locations within the clinical algorithm (e.g., the text “First meeting” at the top left of Figure 2 indicates that the subguideline being executed is the first meeting with a patient and not a follow-up visit).
- Users can access explanations (e.g., why the evaluation frequency should be every 1-3 months).
- The final screen shows a “Print” button. Other screens show a “Continue” button.
- Patient education materials show recommendations, explanations for them, and references to the supporting literature.

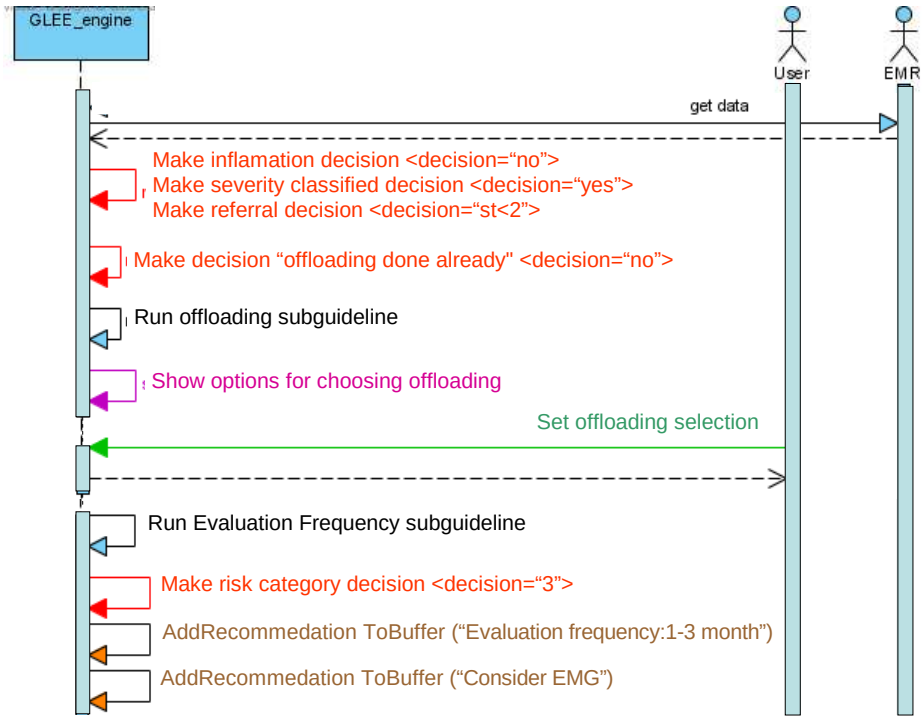

Figure 1. Sequence Diagram. Different colors mark decisions the system made without user interaction (red); options the system displayed to the user (purple); user input to the system (green); and recommendations the system wrote into a buffer that stores them until delivery (brown).

Design evaluation

Heuristic evaluation of the prototype's front end revealed a number of potential problems. Some were mainly cosmetic (e.g., changing the label from "OK" to "Close" on the button that closes the explanation window [see Figure 2]). Other problems related to mapping (e.g., between the explanation buttons and the recommendations to which they refer); consistency (e.g., in the positioning of screen elements); and lack of information on system status. A few additional problems were discovered through users' observations and think-aloud remarks and by the open-ended questions in the post-use survey (e.g., misuse of color for new recommendations, text size that was too small, and the lack of a "Save" option at the end of a

session). Appendix C lists all the positive points and problems our research elicited, along with their classification according to levels of severity and support. One problem revealed by heuristic evaluation was the lack of an "Undo" or a "Back" option in case a user wanted to cancel a previous decision. It is not easy to implement an option to revert to a previous state. However, to reduce the occurrence of errors, users need to confirm their choices by clicking a "Continue" button before they commit to their choices.

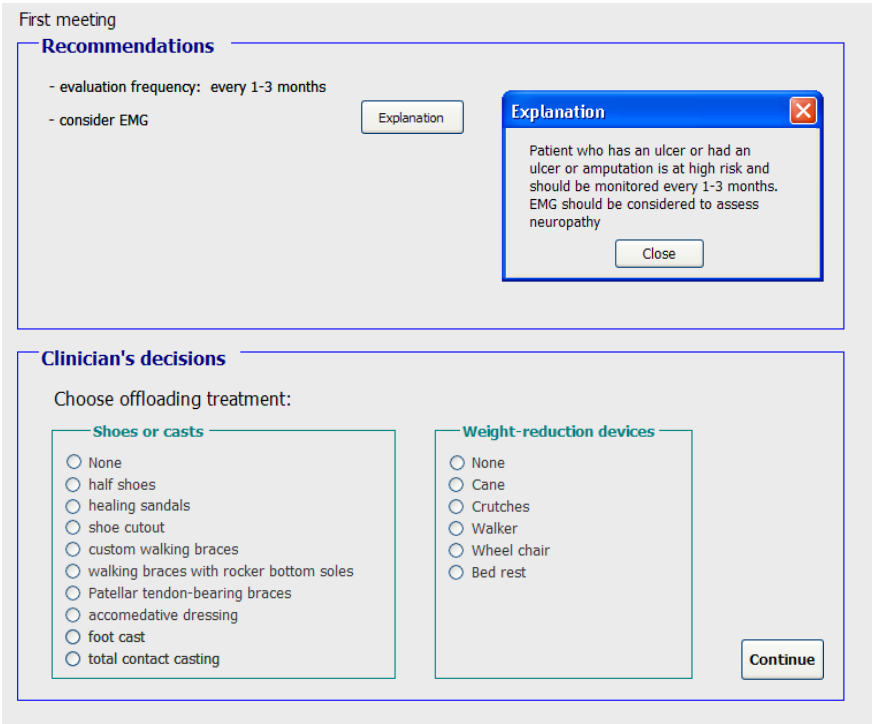

Figure 2. Design of the front-end UI (prototype).

Table III summarizes the results of the post-use survey (see Appendix B for the questions and their categorization into constructs). The inter-rater agreement was high (>0.8) for all constructs. Overall, physicians expressed highly positive perceptions of the prototype's usefulness, ease of use, and usefulness of explanations. Intention to use the system was also very high. These results were also supported by physicians' comments during the think-aloud session (e.g., "If this were an active system, I'd use it tomorrow morning."). Compared with

other measurements, the usefulness of the prototype's recommendations was perceived as lower, mainly due to physicians' disagreements with the medical knowledge of a recommendation [3] that was based not on the guideline but on the opinion of a local expert (Karnieli).

Table III. Mean scores of physicians' perceptions of the system (5-point scale: 1 = completely disagree; 5 = completely agree)

Physician #	Usefulness of recommendations	Usefulness of explanations	Perceived usefulness	Perceived ease of use	Intention of using the system
1	4.50	5.00	4.50	5.00	5.00
2	3.00	5.00	3.00	3.17	5.00
3	4.0	4.50	4.75	4.83	5.00
4	-	5.00	4.50	4.33	4.50
5	3.50	4.00	4.00	4.17	5.00
6	4.50	5.00	4.50	4.83	5.00
7	3.50	4.50	4.00	4.17	4.50
8	5.00	5.00	4.75	4.67	5.00
$R_{wg(J)}$	0.80	0.95	0.90	0.92	0.97
Mean	4.00	4.75	4.25	4.40	4.875

DISCUSSION

Our study showed that participants were very interested in a DSS for diabetic foot care. They valued its ability to assist them in deciding how to treat infections, when to refer patients to specialists, which tests to order, how to stratify risk, and how often to follow up. They liked the minimal-interaction design, the patient-education materials the prototype generated, and the availability of explanations when needed. They thought the UI was clear and easy to use and expressed a high level of intention to use the DSS in the future.

Based on these results we conclude that using multiple methods and perspectives for assessing users' needs and requirements, as well as for system design and evaluation, is a useful approach for implementing a guideline-based DSS. Like other researchers [13-15], we believe it is necessary to use a life-cycle, user-centered design approach for developing such systems. Further, we believe the process should address user requirements from multiple angles. Within this broad agreement, two aspects are unique to our approach:

- Using Sequence Diagrams to study users' interactions with the system over time when considering alternative designs;
- Using the TAM-based acceptance questionnaire for a practical evaluation of the odds of a system being accepted and used.

Limitations

In addition to its several positive results, our study has some limitations. A small convenience sample of family physicians participated in the requirements gathering and evaluation. Therefore, our results may not be representative of the entire clinician population. Moreover, we were able to observe only one family physician during our study of work practices. This was due to the fact that the opportunity to observe a foot exam is quite rare; family physicians see many kinds of patients and, when they do see diabetic patients, they do not always conduct foot exams. We therefore relied mostly on interviews to study work practices, while acknowledging that what people say about their work practices does not always correspond to what they actually do [23]. Similarly, when we used a structured interview along with a questionnaire (see question 2 in Appendix A) to assess users' preferences for interacting with the system, the preferences were described in narrative textual form to the users and only one

of the options was shown to them (via a flowchart showing the clinical algorithm). In retrospect, a better way to conduct this aspect of our research would have been to allow the users to visualize or interact with the various options before being asked to state their preferences.

Another limitation is that we assessed the DSS's usability through think-aloud protocols with only two physicians. This contrasts with Nielsen's "magic number" of five people in usability testing [24]. Nevertheless, our two think-aloud physicians allowed us to identify several important issues with the front end's design and content.

The acceptance questionnaire we used was based only partially on TAM. While it would have been valuable to confirm the reliability and construct validity of this modified questionnaire (e.g., by testing Cronbach's alpha and via factor analysis), this was not possible due to the small number of participants. We obtained face validity by having two people compare the modified questionnaire with the original TAM. Additionally, inter-rater agreement was high. Therefore, we believe it was appropriate to use the modified questionnaire to predict potential acceptance. While the use of only two perceptions – usefulness and ease of use – to gauge intent to use the system no doubt limits TAM's explanatory power, its parsimony makes it useful for practical purposes. Whether this model accurately predicted acceptance of our DSS is unknown, however, because the system has not yet been implemented.

A further limitation of our prototype evaluation methodology was that all users had been familiarized with the system during a one-hour orientation before they examined the

prototype. This knowledge might have influenced their subsequent perceptions. When the system is put into actual use, it is unlikely that users will have an hour-long orientation.

Because we were the originators of the DSS, the demand for the system and its goals did not arise from potential users or their healthcare organizations. This facet of our research likely caused our sample users to be more passive during the requirements elicitation phase. In other words, their perceptions of the system and its needs were no doubt based, to a certain extent, on what we had already demonstrated and asked. In contrast, during the evaluation of the prototype the users were much more active and provided precise feedback.

As we noted in the Methods section, our prototype simulation was not performed in a naturalistic environment [16]. As a result of this limitation, other potential interaction problems may arise once the DSS is deployed in clinicians' offices.

Future research and system implementation

Our system development methodology combined the Waterfall model [15], which places an emphasis on collecting and analyzing requirements to arrive at a system that fits users' needs, with prototyping, which provides a complementary mode of implementation that concretely supports abstract requirements and facilitates mutual understanding of requirements and their implementation by users and developers. Another perspective for system development, which we did not employ, enables goal-oriented system analysis that captures users' and developers' intentions (e.g., Tropos [25]). It would certainly be valuable to explore the added insights that might arise from such a methodology.

We are currently implementing the diabetic foot care DSS according to the feedback we received from study participants. This DSS will be linked with the diabetic foot-specific EMR at Israel's RAMBAM Medical Center. We also plan to recommend this DSS to other potential customers and stakeholders – for example, healthcare organizations in Israel and abroad – and to adapt it to and integrate it with other healthcare information systems. Our long-term goal is to evaluate the system's impact on clinical data collection, lab test orders, and patient outcomes.

Authors' contributions

Mor Peleg and Eddy Karnieli originated the idea of the diabetic foot care DSS. Together with Dongwen Wang, they developed the GLIF-encoding of the clinical guideline and its validation. Peleg and Karnieli conducted the user requirements analysis. Aviv Shachak and Peleg designed and conducted the prototype evaluation. Peleg drafted the article and all the co-authors participated in its revision and approved its final version.

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Statement on conflicts of interest

The authors do not have any financial or personal relationships with other people or organizations that could inappropriately influence their work.

Summary Table

What was already known on the topic:

- User-centered design is a well-established methodology for developing clinical information systems.
- Development of DSSs and other information systems should follow a life-cycle approach of requirements elicitation, analysis, design, implementation, and evaluation.
- Prototyping is a good approach for garnering users' feedback before final implementation.
- Multiple methodologies should be used in user-centered design.

What this study added to our knowledge:

- Sequence Diagrams enable researchers and designers to align users' interaction requirements with system designs.
- The TAM can be adapted within an acceptance questionnaire in order to evaluate the odds of a system's acceptance and use.
- Using multiple methods, including system and user-centered design, in the development of a system life cycle increases the acceptance and use of clinical DSSs.

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Appendix A: Questionnaire used to collect data on users' workflows and needs

1. At what stage during a visit do you enter the foot exam data into the EMR? Do you enter data at the end of the foot exam or during it?
2. How should the advice be delivered to the user?

   (a) an interactive flowchart showing the clinical algorithm that is traversed

   (b) a log of the clinical algorithm that was executed for the patient's data

   (c) short text summarizing recommendations, displayed at the end (or during) patient data entry

   (d) flashing recommendation that would appear during data entry
3. Would you be interested in reminders about important patient data that you did not enter and are important for decision making? If so, could you give examples for such data?
4. Would you be interested in reminders for follow-up visit? For checking laboratory data that were obtained following a visit?
5. Would you like to receive recommendations for referrals?
6. Would you be interested in automatic or semi-automatic order entry and referrals?
7. Would you like the system to produce patient education material?
8. Would you be interested in reports?

Appendix B: Post-system questionnaire

1. To what extent do you agree with the decision support given by the system to patient #1?
2. To what extent do you agree with the decision support given by the system to patient #2?
3. The explanations contributed to my understanding to a great extent.
4. It is very important to me that the system will contain explanations.
5. Using the system will help me to treat diabetic patients with foot problems more efficiently.
6. Using the system will improve the quality of care that I will provide to diabetic patients with foot problems.
7. Using the system will ease the way in which I treat diabetic patients with foot problems.
8. Using the system will make my work more effective.
9. I think that the system is easy to use.
10. I think that the system is easy to understand.
11. I think that the system is easy to learn.
12. I think that the system is complex to use.
13. Using the system requires a mental effort.
14. Using the system is frustrating.
15. If the system would be available, I intend to use it.
16. If I may have the option, I would prefer not to use the system.

Questions 1-2 regard the usefulness of recommendations. Questions 3-4 regard the usefulness of explanations. Questions 5-8 regard perceived usefulness. Questions 9-14 regard ease of use. Questions 15-16 regard intention to use the system.

Appendix C: Analysis of open-ended questions, observations, and think-aloud protocols used during users' interactions with the prototype. The statements' severity is recorded on a 1-5 scale, where 5 is most severe.

Statement	Number of clinicians	Problem's severity	Level of support
Positive statements			
Easy to use	2	NA	NA
Provides good advice	1	NA	NA
Provides references	1	NA	NA
Can help a nurse when doctor is not available	1	NA	NA
Speed is fast	2	NA	NA
Provides the bottom line recommendation	1	NA	NA
Clear	2	NA	NA
Includes an option for explanations	2	NA	NA
Negative statement (requirement for improving the system)			
No link with order entry	3	4	No support – no organizational permission
No explanations for terms	1	3	No support – decided not to be cost-effective
The guideline needs to be validated with more experts	1	5	Full support before system will be put to use
Position of explanation button is unclear	1	3	Full support
Red font is too alarming and should be changed to blue	1	4	Full support
The statement "treat myself" is not clear and should be reworded to "prescribe antibiotics"	1	5	Full support
Explanations for wrong choices made are missing	1	NA	Irrelevant requirement – the system does not permit making wrong choices
The white on orange background is not good	1	NA	No support – changes to the EMR are not part of the DSS
Improve the database	1	NA	No support – changes to the EMR are not part of the DSS
When the program ends, leave the decisions made on the bottom screen	1	5	Full support
Touch-panel should be provided	1	2	No support – decided not to be cost-effective
Font is too small and should be enlarged	1	3	Should be further evaluated with more users
Hebrew should be supported	1	4	Should be further evaluated with more users
Change color of button that links to DSS	1	1	Full support
Save button missing	1	4	Full support
Option to treat myself and refer should be supported	1	NA	Already supported by the EMR
Webcam should be supported	1	NA	Already supported by the EMR

NA: not applicable

Figure and Table Legends

Figure 1. Sequence Diagram. Different colors mark decision that the system made without user interaction (red), options that the system displayed to the user (purple), user input to the system (green), and recommendations that the system writes into a buffer that stores them until their delivery (brown)

Figure 2. Design of the front-end UI (prototype).

Table I. Methods used during the DSS's development and evaluation

M – medical data, W – data regarding Workflow, UI- data regarding user interface characteristics, DS- data regarding decision-support goals. '+' indicates that the method was used in a certain system development and evaluation stage.

Table II. System requirements relating to workflow, users' system-interaction preferences, and users' goals for the DSS

Table III. Mean scores of physicians' perceptions of the system (5-point scale: 1 = completely disagree; 5 = completely agree)