Creating Engaging Trial Alerts

The Application of Quality Function Deployment as a Design Tool for an Interactive Database

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Abstract: This paper describes student research exploring the application of Quality Function Deployment to the design of an interactive database. The aim of this research is to identify visualization and interaction ideals within the context of a physician's cognitive and environmental influences when receiving a Clinical Trial Alert. Through the collaborative efforts of physicians and designers in conjunction with an unambiguous research method, user requirements may be identified at the front end of the design process. The resulting quantitative and qualitative data will uncover factors that inform the design of a graphical user interface, the motivating factors for physician response, and opportunities to convey multiple layers of information. It is hoped that this early identification will lead to accelerated progress in the design of the Clinical Trial Alert system.

Key words: Quality Function Deployment, medical, graphical user interface, clinical trial

1. Introduction

From cancer drugs to medications for AIDS patients, Clinical trials are a vital component in the advancement of medical treatments. Human participation is a mandatory requisite in gaining approval from regulatory bodies. Acquiring candidates for trials, however, is a difficult proposition. Sponsors carry the burden of finding enough eligible participants to prove the safety and effectiveness of the treatment, while constrained by a window of opportunity that allows them to recoup the significant investments made in research and development. Newspaper and radio advertisements are only moderately successful in finding willing candidates; of those who respond, only a fraction may be eligible for participation. Physicians are requested to keep their eyes open for potential candidates for trials, but the constant activity in clinical practice often obscures opportunities to match potential participants with relevant trials.

Electronic Health Records (EHRs) are providing new opportunities for the advancement of clinical research. A system is under development that utilizes existing EHRs to match potential candidates with clinical trials at the point of care. During a physician's encounter with the patient, information is gathered and submitted within the EHR. The Clinical Trial Alert (CTA) is triggered within the framework of an EHR when designated eligibility criteria are met. This system alerts the physician to the patient's potential eligibility for one or more clinical trials, at which point the physician may choose to respond and attain the patient's consent to be contacted by the sponsor.

As part of ongoing research at the University of Cincinnati, a research team comprised of graduate students in the Master of Design program collaborated with Dr. Peter Embi, MD, MS, Assistant Professor in the College of Medicine. The goal for the students was to create a graphical user interface that would increase the quantity of physician responses to Clinical Trial Alerts, ultimately increasing patient recruitment and enrollment. The student's participation in the CTA project was intended to be a vehicle for instruction in the use of Quality Function Deployment as well as a practical application of Visualization Theory. As such, given the constraints of time and personnel, some research methods were condensed or hypothesized.

Quality Function Deployment (QFD) is a structured approach to defining customer needs or requirements and translating them into specific plans to create products to meet those needs. Direct discussions, interviews, and surveys are a few of the ways that the "voice of the customer" may be understood. The voice of the customer is directly applied to the formulation of customer/user requirements. QFD's most conspicuous tool is the "House of Quality" product planning matrix. This matrix enables researchers to evaluate individual design concepts against customer/user requirements. A numerical value is then applied to the requirements so that they may be prioritized according to significance. It is important to note that QFD is not synonymous with the House of Quality matrix; QFD's value, rather, lies in the process of communicating and decision-making of which the matrix is but a component.

2. Hearing the Voice of the Customer

After an explanation by Dr. Embi about the existing CTA tool and the research behind its development, team members set about their own research into the issues surrounding the CTA. These areas included:

- Context of use
- Benchmarking
- Market Research

This initial research created scaffolding around which the customer/user requirements would take shape.

2.1 Context of Use

Team members plotted a timeline of the physician's workflow from the time of arrival at the workplace until the close of work for the day. This research surveyed the physician's interaction with the computer, office personnel, and patients. It also followed the progression of the patient's EHR from the time of the patient's arrival until the completion of the patient's record for that visit. Other personnel such as nurses, physician's assistants and other office personnel who interact with patients were included in this workflow in order to explore the possibility of secondary respondents to the CTA.

2.2 Benchmarking

Similar products such as survey websites and EHR databases were assessed to identify possible strengths or weaknesses in user interaction. Motivating factors for response were also considered to explore possible methods for, and the appropriateness of compensation for physician respondents.

2.3 Market research

An interview was arranged with a panel of three practicing physicians who would receive or have received a clinical trial alert during the course of a patient encounter. This panel identified several key issues associated with the existing CTA system. They also provided valuable insight regarding physicians' work habits, preferences for communication, and motivation for responding to CTAs.

3. User Requirements

The team's findings from these three areas resulted in identification of twelve key user needs. These findings were presented to Dr. Embi, the project lead. Since this research was initiated as an academic exercise, in lieu of the time, expense and challenges associated with selecting a statistical sample of users, and because of Dr. Embi's practical knowledge and experience with physicians and their environment, he was asked to "stand in" for 100 physicians and rank each of the users' needs on a likert scale. This ranking would assign each requirement a value on the House of Quality matrix. The user requirements (in order of importance) dictate that a CTA system must:

1. Provide alert task next steps that are:
    a. user-friendly
    b. easy to understand
    c. intuitive
2. Pull information forward so physicians don't have to look for information
3. Help manage patient participation as well as patient and physician expectations over multiple trial possibilities
4. Inform physicians of information about the results of trials
5. Draw attention of physicians in sub-specialties with relevant alerts
6. Be integrated with the existing workflow
7. Enable physicians to know they are contributing to learning within the healthcare community
8. Keep physicians moving forward in the clinical process and add to their progress in administering patient care
9. Allow other people to benefit from information gathering, interaction with clinical trial alerts
10. Be fun/entertaining during interaction
11. Anticipate what physicians are going to do and/or let the physician know when the alert is about to come up
12. Add value to the data recording process

4. Design Concepts

Team members generated twenty design concepts to address these user needs. Some concepts addressed multiple needs; some only addressed an individual need expressed as a component of the system. They evaluated 12 user requirements against these 20 design concepts.

In order to evaluate each concept, a single question was posed to frame the concept against the user requirement. This question asks: “To what degree does this concept address the corresponding user requirement?” The question prompted a quantitative response by group members. A value of 9, 3, or 1 was assigned to represent a strong, moderate, or weak positive relationship respectively. The variance in numbers was intended to suggest a clear delineation of the concept’s relevance to the requirement. 240 individual decisions were made to enable ranking of the concepts and facilitate the transformation of qualitative information into quantitative data. (See Fig. 1) Mathematical calculations were then applied to the fields on the House of Quality matrix. These calculations accounted for the importance of rank among design requirements, the design/requirement relationships, the importance of those relationships, and weighted values applied to some requirements.

The results from the House of Quality matrix informed the team’s decisions concerning which design concepts held the most promise and should be developed further. The most promising concepts are listed below. The title of each concept is followed by a brief description.

1. Patient eligibility quantification: Graphically show a patient’s eligibility for the trial by showing percentages or icons.
2. Interactive CTA system: The system sends pre-alerts to the physician's email, voice mail or pda.
3. Clinical trial timeline: The physician can view information about how the trial is progressing or the status of the trial.
4. Physician-customized CTA: The physician determines when the alert pops up and may customize the interface.
5. Physician preference quantification: The CTA is ranked and ordered by its relevance to the physician's specialized field.
6. Icon attentive pop-up alert: An icon pops up rather than the entire dialog box.
7. Unfolding information tree: More information unfolds when a field is clicked or rolled over by the cursor.
8. Breathing icon delay: After “Wait” is selected, the window minimizes to button or light that glows in intervals to remind the physician that a CTA is waiting in background
9. Pre-alert notification: An alert becomes visible as soon as patient information is accessed.
10. Single button screens: Only one click per screen is required to move forward.
11. Social responsibility motivator: The physician is reminded of the illnesses that are being addressed through clinical trials.
12. Variable physician response: The physician can choose to respond “now”, “later” or “refuse" the alert.

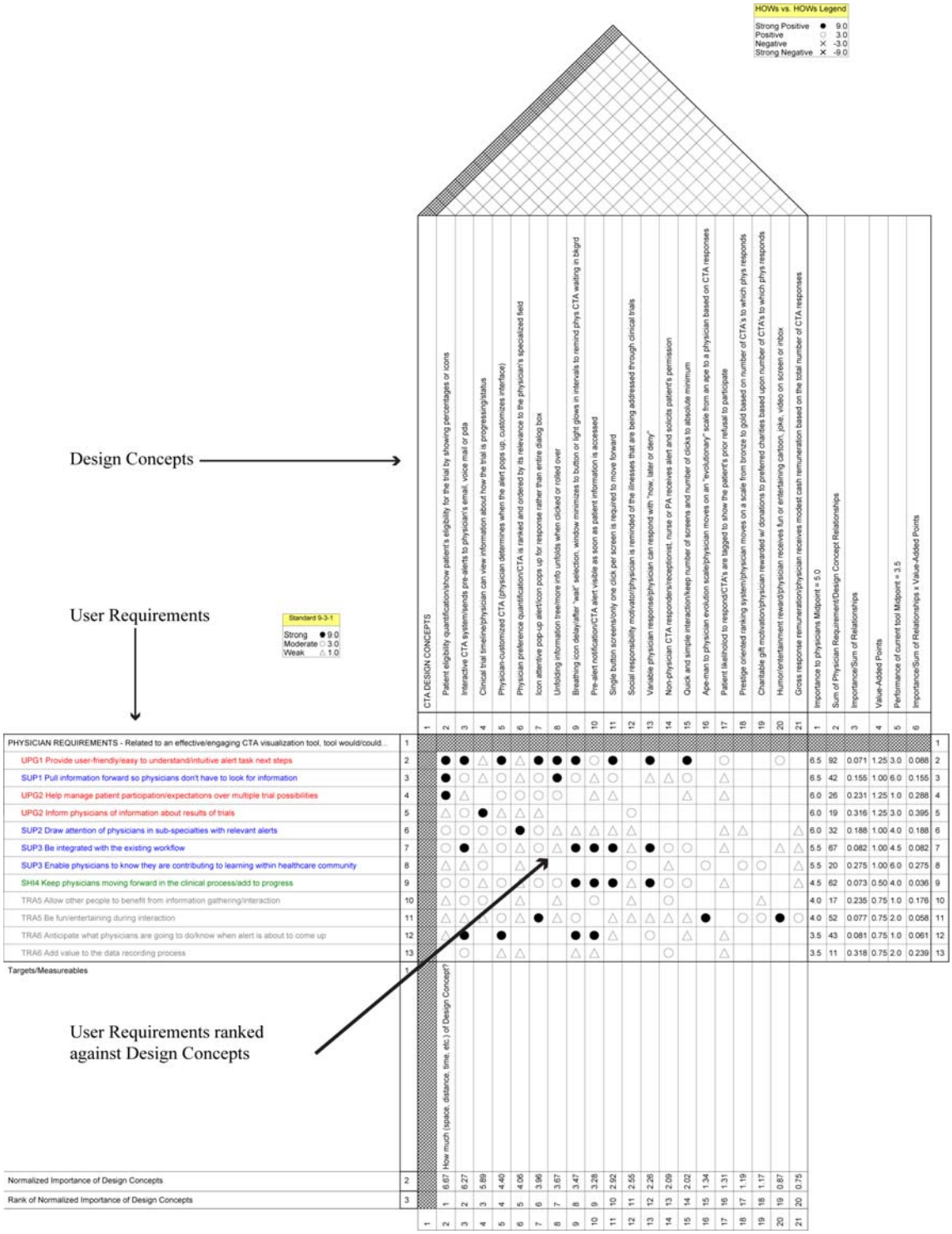

Fig. 1 House of Quality Matrix

5. Results

The use of Quality Function Deployment served to propel the design team toward productive solutions quickly. The initial phase of Quality Function Deployment created a structure by which researchers could identify key areas impeding physicians from responding to a clinical trial alert. These took the form of motivational barriers as well as time constraints and information/workflow interruptions.

The resulting design concepts seek to provide enhanced functionality benefits that may address motivational and precognitive issues facing physicians under time constraints. The new design may in turn remove emotional or fatigue-oriented barriers to a physician's willing response to a clinical trial alert, thus resulting in greater physician response and ultimately patient participation in clinical trials, leading to safer and more confident use of new products for medicine.

The quantitative analysis provided unambiguous data by which objective decisions could be made about individual concepts. As a result, more time was spent on the most promising concepts and components. The enhanced efficiency facilitated more productive subsequent collaboration with the lead researcher, advancing the project toward the exposure of deeper design issues so that they could be addressed before the end of the educational period. Even though some allowances were made to keep the education process moving forward for the students, the net result of the exercise proved to be sound through the execution of the development process. The marked difference between the existing system and the design concepts are a result of focused application of research methodologies to clearly identified user requirements. (See Fig's 2 - 3.1)

The project lead concurred that the concepts presented by the student research team addressed key user needs that were previously not met, and exposed some needs that had previously not been identified. The adoption of QFD has tangibly contributed to the conceptual design of a system for generating and delivering Clinical Trial Alerts.

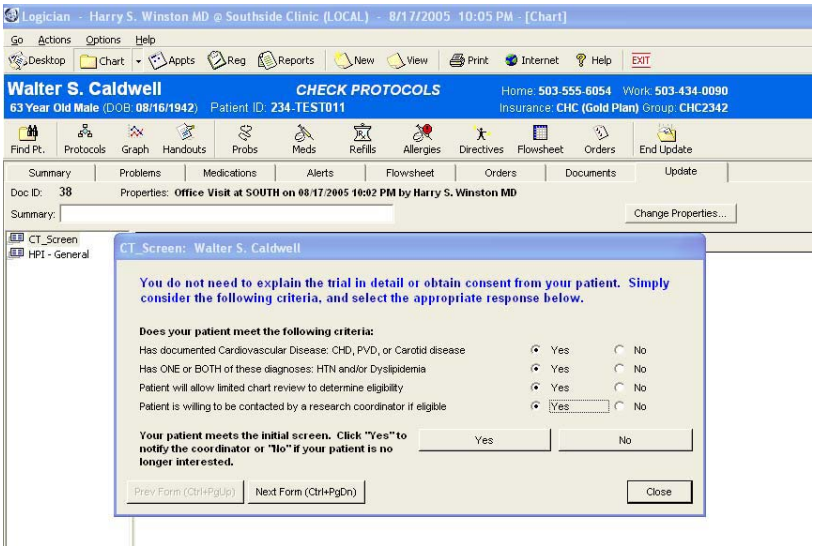

Fig. 2 Existing CTA Screen

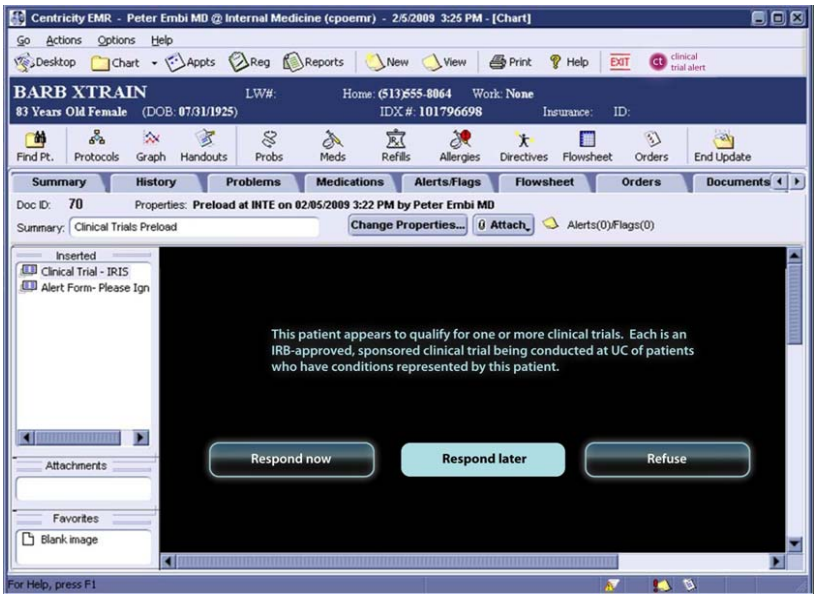

Fig. 3 Conceptual trial alert screen offering flexible response options

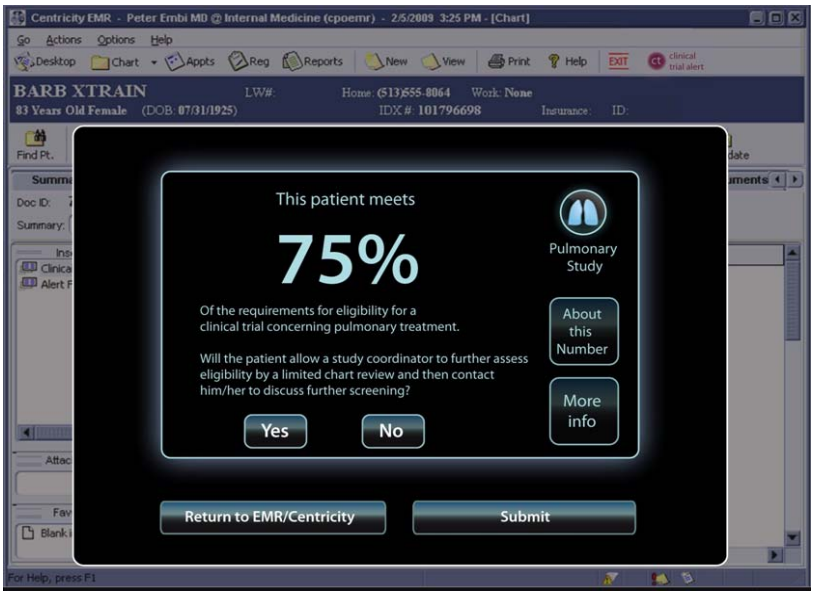

Fig. 3.1 Conceptual trial alert screen indicating patient eligibility, trial category and unfolding information

6. References

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