Participatory Design of a Collaborative Clinical Trial Protocol Writing System

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Abstract

Modern clinical trial research design often involves extensive collaborations among geographically distributed interdisciplinary protocol authoring experts; however, their collaborations are poorly supported. Concrete methods to embed social factors into design are largely unavailable and unclear. Moreover, complicated collaboration in healthcare settings makes socio-technical design even more challenging. This paper describes a hybrid participatory design method that integrates ethnographic fieldwork, role-based user advocacy, iterative prototyping, formative evaluation, and change management for the creation of a highly usable collaborative protocol writing system for a national cancer clinical trial protocol authoring organization. Usability of the system is demonstrated in the formative evaluation results. The paper concludes with a discussion about concrete approaches to participatory design and how they could reduce usability errors of healthcare information systems.

Keywords:

Participatory Design, Clinical Protocol, Socio-technical Approach

Introduction

Many researchers have realized the importance of social factors and organizational issues for system design. [1-3] However, concrete methods that account for social factors in system design are largely unavailable or have insufficient guidelines. Participatory Design (PD) is one way to approach socio-technical design. [4] It is a proactive design method that explicitly advocates active user participation throughout the design process; Unfortunately, PD has not been widely adopted in healthcare information system design. [5] The major challenges involved in PD include long prototyping design cycles, extensive investment in interactions with participants, and iterative feedback collection and incorporation. There is also no clear boundary between a participatory design stage and a real product development stage. Many other open issues like these exist that make it difficult to apply PD theory to real-world design practice. Therefore, our research has two goals: one is to explore the design space of a collaborative clinical trial protocol writing system within the Southwest Oncology Group (SWOG), and the other is to enrich participatory design theory by trying to answer these four questions:

1) How might ethnographic studies be used with participatory design methods?
2) Who best represents the users and who should be chosen as participants?
3) How can designers motivate active user participation?
4) How can we best apply participatory design to groupware, such as a collaborative writing system?

Our research has been carried out at SWOG, one of the largest adult cancer clinical trial organizations in the world. SWOG members include approximately 4000 leading clinical experts, statisticians, protocol editors, and other cancer researchers across the country. Cancer clinical trial protocols are one major product of their work, which often involve extensive collaboration among distributed interdisciplinary experts. Their current protocol writing process relies on email systems and MS Word, which are inefficient and troublesome for collaborative activities. Prior to our efforts, SWOG had tried different systems to support their protocol authoring process. However, none of those systems were effective. Our research goal is to explore how to support the collaborative work within this large virtual organization. Based on our preliminary field study results, we suggested a web-based collaborative clinical trial authoring system to SWOG. We received mixed responses: some people were enthusiastic, but others were hostile to web-based systems because a prior web-based system worked so poorly. Under these circumstances, we created a hybrid participatory design method with the hope to actively engage and motivate users in the design and to formulate the design together with users by treating them as the ultimate experts on what constitutes appropriate computer support within their context of work.

In this paper, we describe our participatory design experiences. We begin with the details of our participatory design procedure, with particular attention to the challenges brought by collaborative work practice. After that, we present a summary of research results and the major lessons that we have learned. We conclude with a discussion of how this work could enrich the participatory design methodology and inform the socio-technical design of future systems.

Design Methodology

The main phases of our design process consist of the following steps. First, we conducted an ethnographic study at SWOG and derived the current workflow model and its major communication and collaboration problems. [6] Second, we have been incrementally and iteratively carrying out prototyping designs within SWOG in collaboration with representative protocol writers. We have set up usability evaluation objectives at the outset of our system design, and have been performing formative evaluations periodically. Change management strategies have been used to negotiate with participants about the feasibility of the system to improve their work experience, the possible changes to their current work practice, and the tradeoff between the benefits and the costs of embracing new changes. We provide details of each step below.

Ethnographic Fieldwork

Our work began with a 2-year ethnographic field study to identify the essential characteristics of the current work practice at SWOG. Each SWOG clinical trial protocol takes 4 to 9 months to author and the resulting document can be 60 to 100 pages long. During a lengthy protocol authoring process, many communication and coordination activities are carried out through phone calls, emails, meetings, or circulated drafts. Data collection is challenging because protocol authors and communication data are scattered in a large space and over long time periods. Over the past two years, we have participated in some biweekly protocol review meetings, interviewed twelve protocol authors, collected protocol review comments and protocol authoring emails, and followed the development process of two ongoing protocols.

We used semi-structured interview methods [7] with snowball sampling; each interview lasts about an hour. The twelve interviewees play different roles in the SWOG collaborative protocol writing process so that we captured the process details from multiple perspectives. Below are a few questions from our interviews:

1. What are the major steps in the protocol writing process?
2. Who is involved in each step and what is their job?
3. What is the most challenging part of the writing?
4. How do protocol writers coordinate the group work?
5. What is the protocol review and revision process like?

In our interviews, we used some protocol artifacts that interviewees were familiar with to help reconstruct protocol writing scenarios and to illustrate the details of protocol writing processes. For example, when we asked question #2, we brought some old protocols that the interviewees had been involved in and let them point out the division of labor for different sections of the protocol among all the writers.

We also used a "process query" technique by asking each interviewee to draw a diagram of the writing process based on their perceptions. Interestingly, we found that the process diagrams created by our interviewees were not exactly the same. Protocol writers do not share a common view of the process, and have disparate needs of tool support. This finding alludes to the importance of involving representative participants for each writing role in the design so that we could pattern their shared needs while coordinating their individual preference in a single system. Moreover, we asked our interviewees to recall some successful experiences as well as frustrating experiences using the "Critical Incident Techniques" (CIT). [8, 9] CIT helped us get real personal experiences while minimizing interference from stereotypical reactions or received opinions.

In our interviews, one participant told us a story about one of his horrible protocol reviewing experiences, which inspired us to design the comment model in our system. He made a lot of comments to a protocol document, which was unfortunately poorly written. His intention was to be the gatekeeper of the quality of this protocol, and not to offend the author. However, the person who wrote the document and received the comments was a junior researcher and played a supportive role to his advisor, who was the real author or principle investigator (PI) of the protocol. The junior researcher did not make the changes based on the comments; instead, he forwarded all the comments to the PI and made the PI misunderstand that the reviewer was very harsh on them. This problem would have been avoided if reviewers were explicit and clear about the recipient of their comments.

We also heard similar experiences from other interviewees, such as delays in responses to comments and poor group coordination for comment addressing. We realized that it was necessary to support directed messages and notification services for comments, whereby a comment maker could specify who should be notified and who should take care of the comments within what time frame. For our system, we have created a general comment model that includes these sorts of attributes. [10]

Our interviews were complemented with observational study and artifact collection. Both approaches leveraged information gained from each other. We collected around 1,400 protocol review comments for 32 protocols and 80 emails threads by following two ongoing development protocols and participating SWOG protocol review meetings. We used the grounded theory [11] to identify the comment categories and major communication problems reflected from these comments in the collaborative protocol writing process. [6] We found that comments were essential to protocol writing processes because reviewers convey their feedback and carry out discussions or negotiations with other reviewers through comments. On the other hand, editors and authors iterate protocol document revisions based on suggestions in comments from authorities. Therefore, effective group awareness support, [12] in-situ communication, and integrated editing support around comments are what protocol writers need most. As we describe below, these results directly informed our design.

This ethnographic study provided us with an in-depth understanding of the interactions of large collaborative teams within SWOG, and particularly helped us identify the major roles in the collaborative clinical trial protocol writing process. Hence, we could recruit participants based on their roles and design our formative evaluation plan with a thorough consideration

of each role's perspective. Therefore, we think that ethnography is important and useful for carrying out "user-centered" and "work-oriented" design, especially for collaborative team work.

Role-based User Advocacy

User-centered design has been proven to help ensure the usability of a system. However, an open issue in current participatory design theory is "*Who should be the participants to represent users*?" The answer to this question is context-dependent and varies from project to project. Muller defined six approaches to selecting representative users based on interpretations from the perspectives of statistics, politics, design practice, and grounded theory. [13] Among these methods, the grounded theory approach ensures diversity among users, and the design practice approach finds the politically representative users. Since our work involves multidisciplinary users working in different roles, we wanted to combine the features of both approaches. We selected politically representative users for each role in the protocol writing process identified in our ethnographic fieldwork and made sure that they were advocates of our design. [14] The major advantage of involving user advocates is that we could augment the interactions between users and designers. User advocates can evaluate the system prototype in their real work practice and provide timely feedback to designers. Therefore, we called our approach "*role-based user advocacy*". We selected participants across three roles; we began with one protocol editor, one study coordinator, and two statisticians. Although there has been some turnover in individuals, we have kept representatives from all three roles closely involved throughout our iterative prototyping design process.

In addition, we also kept a couple of policy makers in the loop all the time. Periodically, we reported the status of the design and demonstrated the ongoing design to these policy makers. The policy makers play a "power role" over the working roles described above in that they understand the organization's culture, provide leadership, have a significant impact on the system adoption, and direct users to changes in their work practice. We found that timely communication with this "power role" is useful and important for a smooth system adoption later.

Iterative Prototyping

With a participatory design team and a set of design ideas from our ethnographic fieldwork, we began incremental and iterative prototyping. As Scacchi pointed out, the classic socio-technical design or participatory design approach does not provide the critical insights, tools, or guidelines beyond "user participation". [2] One open research question that we tried to address during this process is that, "*What counts as an active participation and how to encourage it?*" In our experience with SWOG, we solicited active participation in two phases.

First, to address the logical design of our system, we began with a paper-based mockup interface and scenarios of a new workflow. These mockups were developed using Microsoft Visio, a drawing package that helps create fake screenshots that look as if from real windows systems. Scenarios helped reconstruct worklike contexts in which users are encouraged to formulate design ideas as domain experts. We performed cognitive walkthrough on the scenarios for our participants and elicited their feedback to refine the design. [15] This process was cost-effective and enabled participants to experience and to modify potential design solutions. The mockup gave a vivid representation of the potential system outlook, and the scenarios provided sufficient details for the logical flow of functionalities to participants. Participants considered the artifacts intuitive and stimulating.

After we reached consent with participants on the interface and workflow design using mockups, we settled on the logical feasibility of our system design, and moved onto web-based prototypes to assess the technical feasibility of the potential design by considering issues such as data backend and concurrency control strategies. We went through two major rounds of system infrastructure changes. Our initial prototype used a file-based backend, which supported the old SWOG work practice of "only one editor is authorized to make changes on documents" perfectly. However, participants felt encouraged by the first prototype and were willing to try a more synchronous collaborative work mode by enabling all the authors to write multiple sections of a protocol concurrently. This new request was not supported by the file system; therefore, we changed to a database backend and modified the system accordingly. Participants provided very positive feedback on the second prototype, which remains as the current design. Web-based prototyping enabled concrete experience and modification by prospective users.

Throughout our prototyping design, we had frequent negotiation and discussion with our participants. We consulted them about the functionalities and the interface design. Our participants felt encouraged and valued as designers in this project because we incorporated many creative design ideas from them. We also felt that the iterative prototyping helped us build a mutual understanding and trust between system designers and user participants. We understood their work practice better, and they understood the technical feasibility better.

Change Management through Negotiations

A big barrier in innovation deployment is resistance to changes from users. [16, 17] Markus identified three categories of user resistance: *user-centered, system-centered, and interactional*. [18] Since participatory design emphasized the user, we focused on Markus' user-centered resistance: a resistance to innovation caused by a lack of knowledge or a reluctance to change on the users side. At SWOG we tried to minimize this resistance through frequent negotiation of possible changes with users. For example, we prepared "*What are the changes*" documents prior to each participatory evaluation session and gave participants a clear comparison of their current work practice and the potential new work practice supported by our system. We elicited their feedback and discussed the tradeoffs with them. We believe this approach worked well and also served as educational sessions that helped participants understand the system better. However,

this approach is not a panacea; change management remains a challenging problem.

Formative Evaluation

Formative evaluation is an integral part of our participatory design process. Since our design is an exploratory design, there was no prior peer system; a self-reflective evaluation is more appropriate than comparison-based evaluations. Formative evaluation throughout the design process helps us collect continuous feedback from participants as the design evolves. Our evaluation methods largely follow Kaplan's suggestions [3] from the following two aspects: 1) set up evaluation objectives from multiple perspectives and at the beginning of system design; and 2) use multiple evaluation methods.

As Kaplan pointed out, well recognized areas of system evaluation in the medical informatics literature include: (1) technical and system features that affect system use, (2) cost-benefit analysis, (3) user acceptance, and (4) patient outcomes. [3] Here we are particularly interested in evaluation areas (1) and (3); (2) and (4) would be the long-term evaluation objectives that could be carried out later. Therefore, we created a set of usability evaluation questions for these two selected areas. Below are the example evaluation questions:

1. Can our design fulfill the required functionalities that are supported by current work mode?
2. What changes will our system bring to users? Will users accept these changes?
3. Can our design address the range of problems that we observed via our ethnographic fieldwork?
4. Can our design improve the group work experiences of these users?

Following Kaplan's suggestion that evaluation should use multiple methods, [3] we integrated interviews, observations, and focus-groups to elicit feedback from our participants.

Our long-term goal is a four-staged evaluation plan, including the following steps: 1) system testing from a software engineering perspective 2) task-oriented, role-centered, and scenario-based user testing 3) small-scale field trial and 4) large scale field trial in a natural work setting. Our staged evaluation aims to keep participants closely involved in each stage of design and evaluation, and incrementally increases the degree of complexity of group interactions in different evaluation stages, so that we can keep some control and better refine the design according to feedback from participants.

Results

Requirements Specification

Iterative document reviewing and revising is the most error-prone and poorly-coordinated process in the current work practice at SWOG. We document the details of ineffective version control of evolving documents, inefficient group communication via emails, and poor group coordination in [6]. The major unmet needs of current protocol writers are: 1) awareness of the shared workspace and individual contributions to the evolving document, 2) a shared repository of documents and comments with version control for both, and 3) an integrated reviewing and revising tool that has wide accessibility.

Formative Evaluation Results

Our formative evaluations have been focused on eliciting feedback about the usability of our system in terms of our design of workflow, user interface, and system features. We found that the users liked our system design, and particularly the following four aspects of our collaborative authoring system. First, representative users liked "comment incorporating" and "notification service" very much. They all said that these features could speed up the reviewing process and help group members stay abreast of the ongoing progress easily.

Second, interoperability between the system and the old tools such as Email and MS Word was a strong requirement. Users needed smooth transition of work between two systems for the best flexibility. We also realize that this is important for any innovation diffusion. We could not force users to give up their familiar tools easily; it is better to give them more options and let themselves decide what to keep and what to use.

Third, users preferred an "all in one" design. Users liked integration. The system currently supports email, editing, commenting, progress report, document management and sharing, and many other features, which are far beyond our original intentions to strengthen the reviewing and revising activities. Users like an integrated tool where all work could be done in a single environment.

Last, "less is more" is important for work-oriented system design. Filters for information about group awareness or comments are very well received and heavily used. Most users commented that they liked to see information specific to their working document or their group and they liked direct links to selected focus without multiple page navigations.

In addition, we found that "change management" is still a challenging task. Users tended to swing between the old practice and the new workflow model. Maybe the answer to "*whether change is really necessary and beneficial*" could be only found after a field trial of the system, where cost-benefit tradeoff could be more explicitly measured. Overall, we feel encouraged by our evaluation study results. Our users so far have given enthusiastic support and positive feedback for our design. We both look forward to the next stage of field trial.

Current System Description

After several rounds of iterative prototyping and continuous formative evaluations, we have created a system that is ready for the third stage of our evaluation plan, which is a small-scale field trial by real users with real protocol writing tasks. Our research results so far consist of two parts. The first research result is a generic comment model for enhanced document reviewing and in-situ communications. [10] Based on this model, we also arrive at a web-based Protocol Collabora-

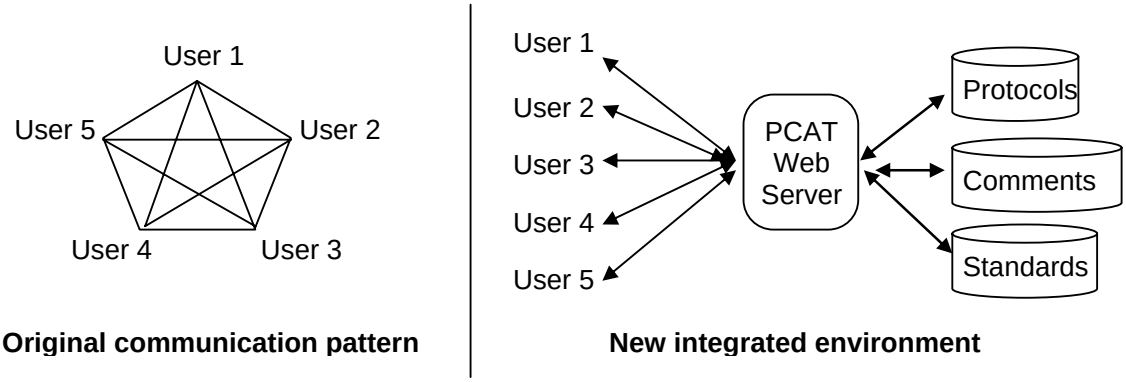

Figure 1 The SWOG communication pattern is open—users can pass the document and comments around to all team members. With our PCAT infrastructure, users have a single web portal to the evolving document as well as comments and a library of standards. Communication is still open, but all users work with the same document.

tive Authoring Tool (PCAT) that supports strengthened iterative reviewing and rewriting activities. [19]

In our PCAT system, we support a new workflow model, whose comparison with the old workflow model in SWOG is illustrated in Figure 1. Figure 2 shows a screenshot of the PCAT interface for protocol reviewers. The window is divided into three panels. The left panel displays threaded comments. The top right panel displays the text of a protocol document, where a reviewer can select arbitrary text and insert comments; the commented text is then highlighted. Each reviewer is represented with a different color. The bottom right panel displays the details of a comment, including incorporation status, the time when the comment is made, who makes the comment, who is supposed to receive the comment, and other such metadata that we describe in our comment model. [10] A comment author can edit or delete his or her own comment, and every one can attach new comments to any comment to facilitate online negotiation or discussions in the context of the shared document. Moreover, a floating window is displayed to show the recent activity of group members and to provide group awareness to collaborative protocol writers.

Discussion

One of our broad research questions is to improve the process of specifying software requirements. Currently many healthcare system designers still follow conventional requirement specification documents. The problem is that a large portion of system requirements is tacit and hard to articulate at the beginning of a system design process. As a result, the generated requirement specification documents often convey vague or incomplete system requirements, and are subject to changes over time. In this paper, we describe a hybrid participatory design method with the hope that it could lead to better articulated user requirements.

Throughout our participatory design, we found that user requirements are emergent and change often; therefore, we did not have a static requirement specification document. Instead, we had many design proposals, versioned system descriptions, notes on user feedback, design modification task lists and priority features, and notes from meetings with different stakeholders of the project. We view these artifacts as a "dynamic requirements document" that evolves over time as the project proceeds. Such dynamic requirements documents need version control and these versioned documents could provide design rationale to facilitate future system maintenance. It would be interesting to conduct further study to find out whether this kind of "dynamic requirement specification document" is generalizable to other software projects.

In health care settings, coworkers often have different training backgrounds and have different needs for a healthcare information system. Much of health care work is collaborative; thus, information systems often must be designed as groupware tools, where there are multiple types of user roles. We believe groupware systems that directly address multiple user roles have been insufficiently studied in medical informatics. Thus, we found it important to consider computer supported cooperative work (CSCW). This field offers insight into the design of groupware systems. For example, we leveraged ideas about group awareness and work coordination from CSCW. We also used the idea of "user-based advocacy" into our participatory design approach, where we included participants from all significant roles in the authoring process. This ensures that the system will include incentives for all users, rather than just for certain stakeholders.

In conclusion, we believe that role-based user advocacy, iterative prototypes, and ethnography are all integral parts to a work-oriented and user-centered design solution. We found that our hybrid design method, which integrates CSCW, participatory design, and ethnography, helped us to reduce user resistance and usability errors during early prototyping, and to arrive at a feasible and user-preferred system design. We have designed our system and applied our methodology specifically in the work setting of SWOG collaborative protocol authoring; however, we hope that our approach can be more broadly applied to healthcare groupware design in general.

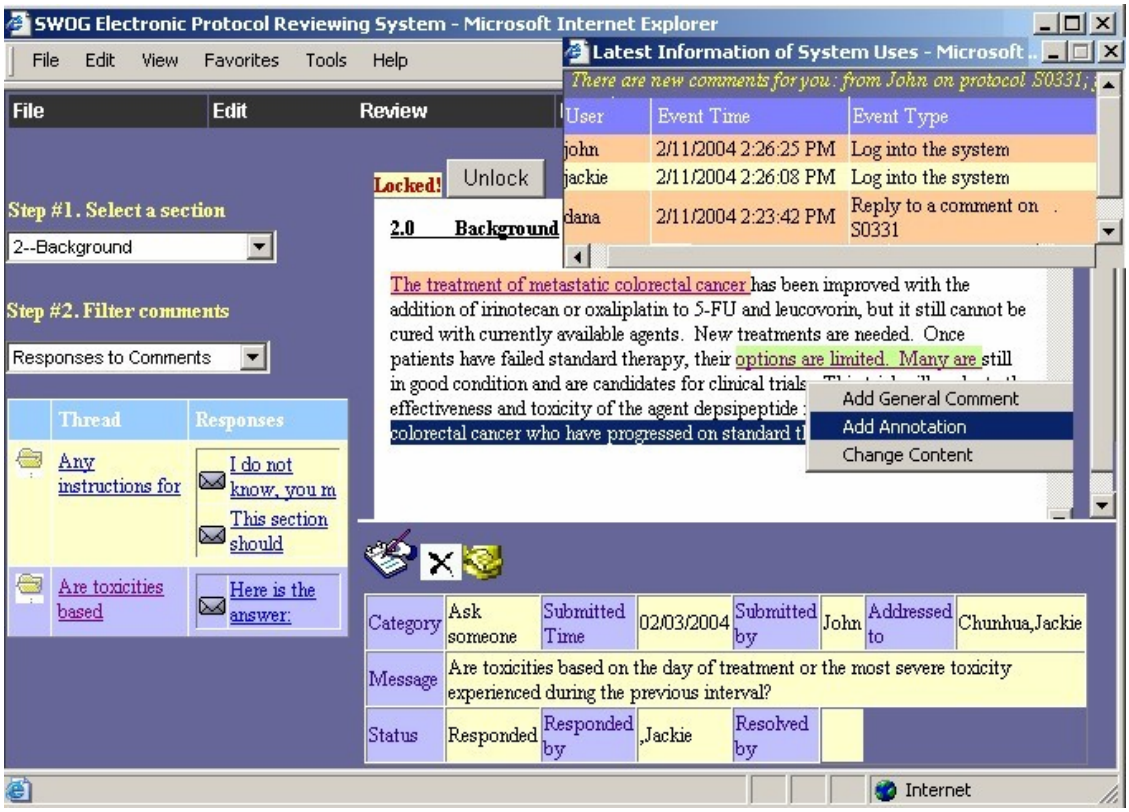

Figure 2. A screenshot of our PCAT system

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