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A Collaborative Clinical Trial Protocol Writing System

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Abstract

Increasing complexity in medicine has caused clinical trial experts with disparate backgrounds from multiple organizations to collaborate when developing clinical trial protocols. Although many protocol-authoring tools provide computer-based decision support to assist protocol writing, few of them provide sufficient collaboration support for a group of protocol writers. The iterative group writing activities among interdisciplinary clinical trial experts call for advanced tool support. Here we present a web-based protocol writing system with integrated support for collaborative reviewing and collaborative editing. The system uses a shared database to store threaded review comments and version information for electronic protocols. It also captures rich group event information to provide cross-activity awareness and to facilitate self-coordination within the collaborative writing team. We believe that our system can help streamline collaborative clinical trial protocol writing processes.

Keywords

Internet, Clinical Protocols, Interdisciplinary Communication, Cooperative Behavior, Awareness

Introduction

High-quality clinical trial protocols, widely utilized in medical research, are critical to conducting safe clinical trials and enabling cost-effective health care. However, many existing clinical trial protocols contain problems such as incompleteness, ambiguity, and inconsistency [1]. Most of the errors are introduced during the protocol writing process, which is often inefficient. Recent studies have shown that protocol development is a collaborative scientific writing process to achieve consensus within a group of interdisciplinary clinical trial experts [2-4]. It is an *intellective* group task involving clinical experts, statisticians, protocol editors, and regulatory affair officers [3].

Much prior medical informatics research has been done to assist in the protocol-writing task. The major efforts can fall into the following three categories: 1) Using computational model-based decision support tools to guide clinical protocol authoring, such as *PROforma [5]*, *Design a Trial* (DaT) [6], and *EON [7]* 2) Using mark-up languages or models to transfer existing free text clinical protocols into a computer-interpretable format and provide critiques to the protocol content, such as GEM [8] and DeGel [9] 3) Using a knowledge management approach to provide a structured document model or reusable text to facilitate knowledge reuse in clinical trial design, such as WITH [10]. These tools facilitate the automation, standardization, and dissemination of clinical protocol knowledge; but they have various limitations. First, most of them are designed for a single author and do not support collaborative writing activities such as group discussions, group coordination, or version control. Second, their interfaces are driven by rigorous computable models and not intuitive to clinical trial experts; this necessitates assistance from knowledge engineers, who might complicate the authoring process. Third, they do not support interactive and expressive communications required by any group-writing task, which is characterized by a high degree of ambiguity and the lack of a fixed goal [11]. Therefore, existing medical informatics tools for protocol writing mainly support human-computer interactions but ignore the aspect of human-human interactions among multiple writers.

Although many collaborative writing systems are available in the field of Computer-Supported Cooperative Work (CSCW) [12] such as Quilt [13] and PREP [14], none of them have been adopted in the group writing of clinical trial protocols. Most protocol writers rely on standard word processors and email systems to collaborate on protocols writing [3]. One possible reason is that out-the-of-box systems cannot fit into the complex workflow of the collaborative protocol writing process.

Therefore, our approach for protocol writing support is to augment the natural collaborative protocol writing process and facilitate better interactions and more expressive communications among protocol writers. Aiming at improving the quality of the resulted clinical trial protocols, we try to encourage human-centered quality control for clinical protocols by supporting multidisciplinary human clinical trial experts in iterative and collaborative protocol reviewing and revising activities, instead of relying on computer-based critiquing mechanisms. In this paper, we present an asynchronous collaborative protocol writing system that can be directly used by multiple protocol writers as a group. The asynchronous working mode is the most suitable option for clinical trial experts, who often have variable schedules. Below we first present our design methodology, including our ethnographic study methods and participatory design process. We then describe the system framework, the embedded comment model, supported writing activities, the user interfaces, and our formative evaluation results. Finally, we summarize our design and long-term goals.

Methods

System Requirements Analysis

To better understand the precise tool support needs of collaborative protocol writers, we conducted an ethnographic study at the Southwest Oncology Group (SWOG), a major adult cooperative cancer research group funded by the NCI. Our detailed study results are presented in a separate paper [3]; here are the major process problems that call for collaboration support:

- Ineffective iterative reviewing and revising
- Poor version control for evolving protocol drafts
- Challenging integration of heterogeneous input
- Insufficient feedback and awareness of group activities
- Inefficient group coordination

All of the above problems highlight the lack of awareness within collaborative writing groups. "*Awareness is an understanding the activities of others. Awareness of individual and group activities is critical to successful collaboration and is commonly supported in CSCW systems by active, information generation mechanisms separate from the shared workspace.*" [15]. Awareness happens naturally in the shared workspace; therefore, users do not need methods such as email or phone calls to notify each other explicitly. In particular, we consider cross-activity awareness missing in the protocol writing process. Cross-activity awareness is a type of awareness among collaborative writers engaged in various writing activities. For example, cross-activity awareness enables reviewers to understand the follow-up status of their comments as well as how their comments are incorporated into the new versions of the protocol; it also enables protocol editors to get immediate feedback for their writings. Current work practices support poor cross-activity awareness.

Considering the above problems, we have designed a web-based collaborative protocol writing system with embedded version control for both protocol review comments and protocols. Our design goals included: 1) to enable easy web-based protocol reviewing and editing in a collaborative mode; 2) to support comment status transition defined by protocol editors; 3) to facilitate comment-centered group discussions; 4) To enable progress tracking for protocol development. We chose to build a web-based system for several reasons. First, it is easier to prototype and to deploy than stand alone applications. Second, Internet applications enable reliable user access from anywhere and at any time .

Participatory Design

To ensure a close fit into clinical trial protocol writers' daily work practice, we used participatory design and fast iterative prototype methods [16,17]. We organized a participatory design team including three protocol writers, who were either protocol reviewers or editors, and conducted formative user evaluations throughout the whole design process. We incrementally prototyped the system by introducing each round of design to our users, eliciting their feedback, and incorporating their feedback into the next design cycle. We first proposed the system design using paper-based scenarios. For each scenario, we performed a cognitive walkthrough for our users [18]. The users could step through the actions for each task and evaluate the system usability at a fine granularity level from an early stage and at no development cost. We then built the real system based on the feedback from the scenarios. Our users have had active participation in the development process and provided timely feedback with fine details in each phase of the design. This greatly ensured the usability of the system.

Results

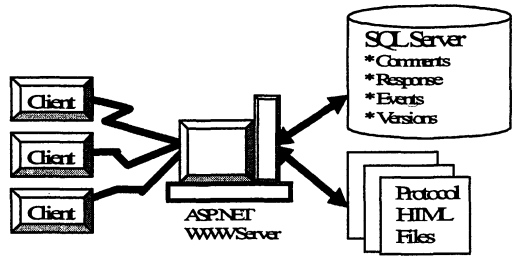

Figure 1 - System Framework

Figure 1 shows the framework of our asynchronous web-based collaborative writing system, which integrates these modules:

- Electronic protocol management with version control
- Collaborative annotation and group discussion support
- Online protocol editing support by a rich-text web editor
- Group and shared workspace awareness support

Table 1: Roles and associated activities in the collaborative writing process

Collaborative Writing Activities Roles→	Editor	Author	Reviewer	Manager
Create a new protocol: Use a protocol template to create a protocol.	X			
Edit a Protocol: Change the content of a protocol with an exclusive lock.	X	X		
Review a Protocol: Add annotations or in-text comments to protocols.			X	
Reply to comments: Add responses or discussions for comments.	X	X	X	
Track Protocol Review Progress: Browse the status of each comment and related discussions on the comment.	X	X	X	X
Track Protocol Version History: Track the evolving protocol and its version history; unresolved comments can be displayed for the current version.	X	X	X	X

Protocol writers can use web browsers to connect to the protocol server through Internet. The web server is built on Window .NET server and is connected to a SQL server database. All protocols are stored as HTML files on the server side. The database stores comments, responses to comments, version information for protocols, and user activities such as login, review, revise,

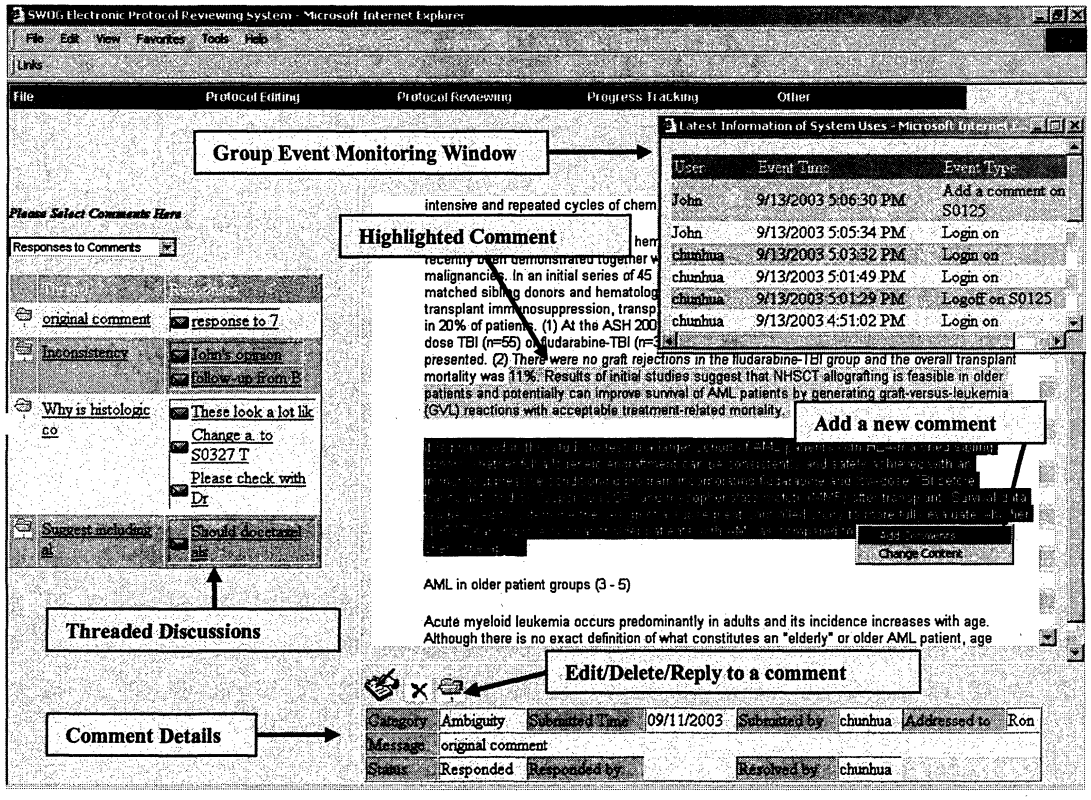

Figure 2 - Collaborative Protocol Reviewing

and logout. Each comment has a version ID, which enables the system to find context for it in an appropriate protocol draft that has the same version ID. Typically there are three roles in a collaborative writing process: 1) ***reviewer***, who adds comments to protocols 2) ***author***, who gets credit for the protocol design by contributing research ideas 3) ***editor***, who manage protocol drafts by integrating scattered inputs into a consistent document following a certain format. In SWOG, each team has only one protocol editor. All of them are called writers. Our system also supports a fourth role, a protocol ***manager***, who monitors the schedule and progress of the protocol development. Table 1 shows the writing activities supported by our system for each role.

A Comment Model and Awareness Support

Protocol review comments and version information are important messages communicated within the collaborative writing group. In the current work practice, reviewers use emails to send out comments, which are detached from protocols; but they do not get timely feedback for the status of each comment. They do not know whether or not the comments have been accepted in new versions. Reviewers have to carefully compare old versions and new versions to find differences. This process tends to be arduous and troublesome.

To solve these problems, we present a comment model with a life cycle of four status: 1) ***Unread*** 2) ***Responded*** 3) ***Incorporated*** to the new version, and 4) ***Resolved***. An editor can change the status of a comment when he or she revises the protocol. The comment model also contains rich information about protocol reviewing activities, such as the comment-maker, comment-responder, commenting-time, comment priority category, protocol context information, and protocol version information. When a reviewer makes a comment, he can also identify a group of protocol writers that he wants them to read or respond to the comment. Once these people are selected, they will be notified that a new comment is awaiting them for processing by email or when they log into the system.

By using this model, we enable writers to see how comments and protocol document drafts evolve side by side. Collaborative writers can now understand how the shared document is modified and how a coauthor's opinions are incorporated into the new versions of the document. Also, the rich information of group events around comments is very useful for group awareness support. Once comments are created or responded to, the protocol writers receive notification. When new versions are generated, protocol reviewers are notified of the changes from the old version as well as the causal relationships between the changes and the comments that apply to the previous version. In addition, the web-based protocol workspace provides shared feedback for group activities and document progress. Protocol writers using this system will use less time to understand the context of their work. The persistent awareness information kept by the system

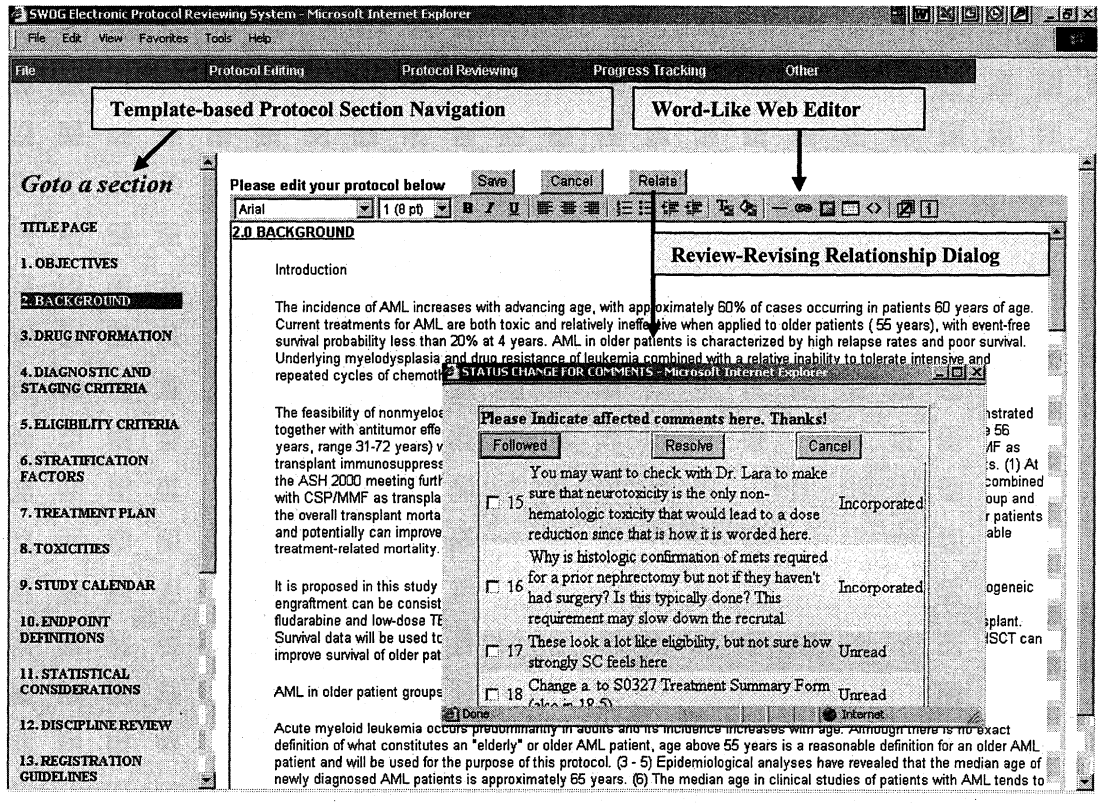

Figure 3 - Collaborative Protocol Revising

is also used to support progress tracking of the protocol. A protocol manager can browse the version history and comment status at any time during the protocol development.

Version Control

"Single scriber" strategy, where only one person in the collaborative writing group can generate and distribute a new version to the group, is a collaborative writing strategy [19]. Since our system is an asynchronous collaborative system and SWOG is used to having only one editor in each writing group, we adopt this strategy and avoid big workflow changes at SWOG. Authors can revise the content of a shared version of a protocol and save their input separately online. Only the editor is allowed to collect these inputs, compose them into a consistent draft, and publish a new version. The collaborative editing module saves protocol writers efforts in circulating drafts by email and increases the accessibility of heterogeneous input from multiple writers. When the editor updates the shared version for a protocol, an exclusive lock will be put on the protocol, other reviewers or authors cannot access it until the editor releases the lock.

User Interfaces

Examples of our user interfaces are shown in Figure 2 and Figure 3 on page 4. The major collaborative writing activities supported by our system are listed in Table 1. To minimize changes brought to users' work practice, we try to make the interface look familiar to users. As shown in Figure 2, when a reviewer wants to add a comment, he or she can simply use the mouse to select some text in the protocol, right click the mouse button, and select "Add a comment" from the popup menu. Then a window will appear with the previously selected anchor information already populated. The reviewer just needs to type a comment message, selects a comment category, and indicates who should be notified. Compared to current work practice where specifying the context of a comment is by tediously typing locations such as "section 2, paragraph 1, line 6, ..." our system provides an easier and clearer method much to the relief of reviewers. Moreover, all the online writers can immediately share highlighted comments in the protocol. If the writer selects to revise the content, he or she can edit a specific section or pinpoint a certain part of the protocol with a specific comment. Revisions will be done in a rich text web editor (Figure 3). To help writers share group information, we also open a small floating monitoring window to display recent activities in the writing group, as shown in Figure 2.

Status and Evaluation

The SWOG researchers that participated in our informal user studies of the prototype have given us positive feedback and showed enthusiastic acceptance of our system. Our next step is to have a field trial of the system at SWOG, test its usability and efficiency, and assess whether it can augment the real work pro-

cess of collaborative clinical protocol writers. Our further evaluation plan is multifold. We will evaluate 1) whether the system is generalizable to other cooperative protocol development groups, 2) whether collaboration support among human experts is more efficient than traditional computer-based decision support tools for clinical trial design, and 3) how policy, technology, and organizations might influence the adoption of collaborative systems in medicine.

Summary and Discussions

We have described a web-based protocol writing system with a focus on collaboration support for interdisciplinary protocol writers in various activities. The system design is based on a thorough understanding of the complex workflow in SWOG. It maintains the old work practices but save protocol writers time in comment editing and communication. It provides a close feedback loop for iterative protocol reviewing and revising activities. We expect to see the following advantages of this system in future evaluation studies. First, reviewers will make comments directly in the context of clinical protocols and simplify the editorial process. Second, protocol document reviewing and revising activities will be seamlessly related to each other. Third, interactions among group writers with different expertise or responsibilities will be more efficient. We hope this system can also be generalizable to other protocol writing groups. In addition, the framework used in this system is extendable. Besides providing version control for clinical trial protocols, we also plan to provide version control for evolving "clinical protocol design guidelines" or "standards," which might be reusable among different clinical protocols. Moreover, in the future, we hope this system can be integrated into existing decision support tools for clinical trial design thereby achieving a super tool that can assist protocol writers in both "human-computer interaction" and "human-human interaction" in the clinical trial design.

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