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Managing clinical research permissions electronically:

A novel approach to enhancing recruitment and managing consents

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Abstract

Background—One mechanism to increase participation in research is to solicit potential research participants' general willingness to be recruited into clinical trials. Such research permissions and consents typically are collected on paper upon patient registration. We describe a novel method of capturing this information electronically.

Purpose—The objective is to enable the collection of research permissions and informed consent data electronically to permit tracking of potential research participants' interest in current and future research involvement and to provide a foundation for facilitating the research workflow.

Methods—The project involved systematic analysis focused on key areas, including existing business practices, registration processes, and permission collection workflows, and ascertaining best practices for presenting consent information to users via tablet technology and capturing permissions data. Analysis was followed by an iterative software development cycle with feedback from subject matter experts and users.

Results—An initial version of the software was piloted at one institution in South Carolina for a period of 1 year, during which consents and permission were collected during 2524 registrations of patients. The captured research permission data were transmitted to a clinical data warehouse. The software was later released as an open-source package that can be adopted for use by other institutions.

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Conflict of interest

None declared.

Limitations—There are significant ethical, legal, and informatics challenges that must be addressed at an institution to deploy such a system. We have not yet assessed the long-term impact of the system on recruitment of patients to clinical trials.

Conclusions—We propose that by improving the ability to track willing potential research participants, we can improve recruitment into clinical trials and, in the process, improve patient education by introducing multimedia to informed consent documents.

Introduction

Recruitment of research participants is critical to the conduct of clinical and translational research; however, clinical research often is hindered by difficulties in recruiting adequate numbers of participants. Failure to recruit an adequate number of participants in a reasonable time frame increases the cost of studies [1], can reduce the power of the study to find important effects of interventions [2], and may reduce the usefulness of the study findings if standards of care change during conduct of the study or may lead to failure to complete the study [3,4].

There are a number of potential reasons for poor research recruitment. Time pressures on busy practitioners continue to increase, and clinicians report lack of time, high workload, and low practical relevance of the research as reasons for failure to recruit their patients to participate in clinical research [5–7]. At the patient level, relatively few patients report being asked by their clinicians to participate in clinical trials, but of those who were invited to participate, lack of recognition of the relevance of the study to their health problems and lack of the time required for participation have been cited as reasons for nonparticipation [8].

A number of strategies have been studied to improve clinical research recruitment, including matching recruiters to the target population, providing incentives for recruitment, and varying methods of providing study information to potential participants. A Cochrane Review of 37 well-controlled trials of approaches to improve research participant recruitment found only modest success of some of the recruitment strategies studied [9].

Advances in the electronic management of patient data have important implications for the recruitment of participants to clinical studies. Use of these data could reduce the time needed for time-consuming hand searches of clinical data to identify potentially eligible patients and allow sites to be targeted on the basis of their specific patient populations. In recent years, a number of systems have been developed to improve clinical research recruitment using data from electronic health records (EHRs). Proof-of-concept trials have demonstrated that routinely collected primary care data could be used to identify potential participants for a depression trial [10], and a chronic obstructive pulmonary disease (COPD) trial [11] had good sensitivity and specificity. Clinical trial alert systems that drew information from the EHRs have been piloted successfully to identify potential study participants at the point of care [12,13]. Another mechanism to increase participation in research is to elicit patients' general willingness to participate in clinical research. In recent years, there have been several successful efforts to create research volunteer registries using various strategies of community engagement and web-based technologies for matching research participants with

research projects [14–16]. In a similar effort to identify willing participants, many medical care facilities ask patients during hospital or clinic registration about willingness to be contacted regarding future research; typically specific clauses are checked off by the patient during the consent process for routine care [17]. Most institutions currently collect such information on paper forms that are difficult to track and are not searchable by computer systems. While there are noteworthy commercial efforts aimed at enhancing the consent process and patient comprehension using electronic methods, our work also focused on the capture of research permission data resulting from consents and making them available to researchers as searchable data elements, thus creating a virtual registry of research volunteers that can be used for recruitment into clinical trials.

Although consent to be contacted for possible participation in future research is an important consideration, consent to use electronic medical records for research also should be considered. Patients surveyed in one study were willing to allow personal information to be used for research purposes but indicated their preference to consent first [18].

We describe the Research Permissions Management System (RPMS), a new tool for electronically capturing and managing such research permissions, consents, and Health Insurance Portability and Accountability Act (HIPAA) privacy authorizations for research and discuss the potential for RPMS to promote recruitment of research participants.

Methods

The RPMS project was undertaken in South Carolina with support from a Grand Opportunity grant from the National Library of Medicine to Health Sciences South Carolina (HSSC), a statewide biomedical research collaborative of three principal research universities – Clemson University, the Medical University of South Carolina (MUSC), and the University of South Carolina (USC) – and four major health systems – Greenville Hospital System, the MUSC hospitals, Palmetto Health, and Spartanburg Regional Healthcare System. The project included collaborations with Duke University for Ethical Legal and Social Implications (ELSI) and industry partners. The project had several aims, including business process analysis, community engagement, development of a policy framework, spin-off research projects, and a software solution. About half the effort of the overall project was dedicated to the software development process, which is estimated at 12,000 man-hours over a 3-year period. This process included analytical, prototyping, and development work and was executed by a team of project leaders, project managers, and programmer analysts.

Overview

Following an agile software development methodology, our team employed the following iterative life cycle throughout the project: analysis, requirements gathering, design, development, testing, implementation, and training. The first phase of the project focused on two key areas: (1) systematic analysis of existing business practices, registration processes, and permission collection workflows in various settings at multiple institutions in South Carolina affiliated with HSSC and (2) investigative analysis of best practices for presenting information to users via tablet technology and capturing permissions and consent data

electronically. The exact details of the methods and procedures the team used are reported elsewhere [17,19,20] and are outside the scope of this article.

Analysis of existing practices and processes

The analysis of the existing processes at each location informed the team of specific areas in the patient registration process where the electronic forms best could be interjected to replace paper forms and also provided the team with a fundamental understanding of the permission collection process. The general workflow facilitated by the software product presents information to a patient or registrant, collects required checkbox selections and signatures, supports review of the information collected, and allows witness signatures. Analysis of the institutional business processes revealed other system requirements, including the ability to select appropriate forms applicable to each patient or patient visit and the need to accommodate multiple languages.

Analysis of daily processes also revealed the need to support customized extensions to the basic software in order to integrate it with existing infrastructure and tool sets at each institution. For example, integration with an institution's Enterprise Master Patient Index (EMPI) would optimize usability and allow users to search easily among existing patients. We also recognized that after the appropriate signatures and permissions had been collected, the electronic forms also should be rendered in PostScript document format, printed for patients to retain and stored in an institutional document repository.

Analysis of best practices in presentation of information and requests

The analysis of best practices investigated various methods for presenting information to patients electronically: first, for long forms by comparing scrolling pages versus presentation of the information one page at a time with the use of navigation buttons, and second, comparison of the use of a tablet-based device (Apple iPad®) versus a fixed touch-screen interface versus a traditional paper-based system. The results showed that the paginated interface was preferred by patients over the scrolling interface and resulted in fewer handling errors, such as missing a signature or initials on a form, crossing out a signature, or inability to complete a task during registration [20]. Both registration clerks and patients preferred a portable device over a fixed touch screen or paper to obtain consents. The system design also was influenced by the need for intuitive usability via tablet technology, adaptability for fast-paced clinical environments, and integration with EHR systems.

Pilot implementation

An early version of the software was piloted in selected registration areas at MUSC for 1 year following presentations and discussions with registration leadership, management, and staff. The implementation team provided user training for the new tool and offered helpdesk support for operational use and questions. We chose high-volume but low-pressure areas with several registration clerks and varied hours of operation: the central admitting area, a surgical procedures area, and the chest pain center. The central admitting area operated from 5:30 a.m. to 10:30 p.m. and has six registration points, each in a private enclosure. The daily average number of patients varied from 50 to 70. The surgical procedures area operated

from 5:30 a.m. to 2:00 p.m., and included four registration points, each in an enclosure. We informally observed that from 5:30 a.m. to 7:00 a.m., all four registration points were open and functional. However, after that time, patient flow dropped, and only two enclosures were open. The daily average number of patients varied from 25 to 30. The chest pain center operated 24 h a day, 7 days a week and conducted registrations for inpatient, laboratory, heart and vascular, nuclear stress, preoperative evaluation, pulmonary function, radiology, and transesophageal echography procedures. The daily average number of patients varied from 90 to 100. This area had 12 registration points, each in an enclosure, where the patient stood across from the registration desk to complete the registration process. Due to the limited number of iPads, observers, and training staff in all registration areas, a relatively small percentage of patients were registered using the electronic system during this test period.

Design refinements incorporated feedback and lessons learned from the pilot program, recommendations from our collaborators from the Duke ELSI, and the inclusion of rich media capability created for a video-assisted consent project at MUSC [21]. Our intent to produce an open-source software product led to the need for an underlying modular design for an extensible platform to permit customization and new functionality.

Results

The Clinical Data Warehouse (CDW) and EMPI employed in the pilot project were designed to accept data from multiple HSSC affiliates across the state of South Carolina. The data are transmitted via Health Level-7 (HL7) feeds from the source systems at these institutions over a secure end-to-end virtual private network. HL7 is a common standard for structured content of health-care data and transport of that data between different systems [22]. The data on the servers are protected further with strong firewall restrictions. The EMPI serves to match incoming patient data to existing single-patient records centrally. To be embedded fully in our institution's processes, the stand-alone RPMS software was extended to communicate with the EMPI to optimize patient lookups and to store data in the CDW. As a result, the final extended RPMS system is distributed in nature with data transmitted from source registration areas at the affiliated institutions to the centralized HSSC CDW (Figure 1). Upon patient registration at MUSC clinics, information, including demographic data, is transmitted immediately, using HL7 messages, to a central data store. The information is matched against the EMPI. After registration, the clerk moves to the RPMS interface on the tablet device and enters the visit number generated by the registration system. The system retrieves the patient information and displays it on the iPad. The clerk verifies that the retrieved information is for the correct patient and hands the device to the patient for review and consent. An electronic version of the completed and signed forms are generated dynamically in PostScript format and transmitted to the appropriate patient's folder in the institutional electronic document repository, thereby simplifying the workflow of registration clerks, since there is no longer the need to scan and store the paper forms. The signed PostScript formatted consent form is printed and given to the patient.

The research permission data are stored in the operational data store, loaded into the CDW, and associated with the patient's clinical data. The information and permissions in the CDW can be leveraged for research purposes based on clinical inclusion criteria for participation in a research project combined with patient permission status (e.g., permission to be contacted regarding future research). The data are expressed using Informatics for Integrating Biology and the Bedside (i2b2), an open-source software platform, which provides researcher-friendly clinical data exploratory and cohort discovery tools [23].

For the pilot implementation, information from several paper-based forms typically used for obtaining consent during patient registration were converted into electronic format and displayed on an iPad using RPMS. These forms included Consent for Medical Treatment, Lewis Blackman Hospital Patient Safety Act Acknowledgement, Medicare, and Tricare. Part of the Consent for Medical Treatment form is permission to be contacted for future research studies. Figure 2 illustrates the research study policy displayed on the iPad; the user is presented with an option to opt-out by touching the on-screen checkbox. During the 1-year pilot in selected clinics at our institution, 2524 patients registered using the system. Of those, 589 registrants (23%) opted not to be contacted, but the remaining 1935 patients (77%) agreed to be contacted for future research. The information collected in the pilot project was not used for recruitment purposes; the system was piloted to demonstrate proof of concept and had not been adopted.

Within the basic workflow of RPMS, the selected forms are presented to the user or patient in the order specified by the organization. The layout of the forms is optimized for a touch-screen tablet device. For example, boxes used on a paper form for patient to initial each section were converted to an 'accept' button and prolonged text sections, which require scrolling across multiple pages, were divided into discrete single-screen sections with 'Back' and 'Continue' navigation buttons. The text displayed on the screen is presented with a fixed large font. The software offers the option to display forms in multiple languages, whenever translated versions are available.

The latest version of RPMS offers new features such as support for informed consent to participate in specific research projects and consent form design tools. The form design or authoring tools allow users to create and edit their own consent forms to collect clinical or research permissions, signed consent forms, and HIPAA authorizations and to manage the consent data electronically. The platform is extensible and configurable with the ability to be used in multiple environments where patient consent is required, such as patient registration for routine care or informed consent to participate in a clinical trial. The software has been released under an open-source license [24]. We estimate that adoption of the final RPMS product by a research institution after making some enhancements to the software to satisfy local needs requires two full-time equivalent (FTE) programmer analysts for 6 months. Implementation requires workflow analysis, integration with institutional systems, and institution-specific software extensions. Maintenance requirements are estimated to be a total of 0.5 FTE for updates, patches, support, and helpdesk.

Discussion

We developed the RPMS tool to simplify collection and management of research permissions and consents that accrue to an individual through their direct and indirect interactions with the research enterprise. The captured information may be shared among organizations using the system, provided that appropriate data sharing policies are in place. For example, HSSC has a data collaboration agreement in place that allows affiliated institutions in South Carolina to share aggregate data. Current Institutional Review Board (IRB) guidelines for consenting research participants prior to use of their data or for obtaining waiver of consents still apply. RPMS allows researchers to match willing research participants to trials for which they are potentially eligible. Information can be provided directly to the patient, to the patient's care provider, and/or to the principal investigator and study personnel of an IRB-approved trial.

Recruiting participants to clinical trials is extremely challenging in the context of a busy clinical practice. Harnessing the power of electronic systems to obtain, consolidate, and organize large amounts of data is critical to achieve efficiency in clinical practice and clinical research. The ability to identify and to track patients who are willing to participate in research should facilitate research recruitment. Consumers of medical care are increasingly able to indicate their desire to participate in diverse aspects of research through a variety of new technologies and circumstances. In most hospitals, collecting research permissions is not standardized in process or content. Paper-based mechanisms of managing research permissions eventually will limit the ability of a geographically dispersed set of practices and hospitals to perform efficiently as a clinical trials network.

Studies have demonstrated that patients are more likely to participate in clinical research studies when the information is presented to them by a physician whom they know and trust [25,26]. Other studies have shown that some physicians are uncomfortable with unfiltered clinical trial alerts for participant recruitment in EHR systems [12]. One of the primary reasons that physicians participating in an automatic clinical trial alert system did not discuss clinical trials with patients who were potentially eligible was that the physician did not believe that he or she knew enough about the trial [27]. These challenges in communication and trust should be dealt with in a system-wide manner in order to realize the full potential of RPMS or a similar system in research recruitment.

Asking patients whether they are willing to participate in future research and capturing their intentions in a clinical data warehouse or other data repository is analogous to the creation of a registry of research volunteers. During the period in which the pilot was underway 77% of the 2524 patients registered agreed to be contacted in the future regarding research for which they might be eligible. Typically, such information is collected on paper, and there is no means of identifying these individuals. There were a number of challenges in deploying RPMS in busy registration areas. The deployment process involved replacing the entire paper process with the electronic system since it was impossible to separate research permissions from the entire set of clinical permissions collected during registration while preserving an efficient clinic workflow. The forms chosen for conversion to electronic delivery included the consent to treat, permission to refuse blood products, and advance

directives. Because deployment in a pilot setting was gradual, in order to preserve consistency between clinics using paper form and those using RPMS, the existing paper processes and wording had to be preserved. Despite these challenges, reaction to the new technology by personnel at MUSC has been overwhelmingly positive. Patients, registration clerks, researchers, and the hospital legal department have participated enthusiastically in testing and providing feedback on the new system [19,20]. Other challenges that must be addressed in the deployment of such an electronic system are the ethical, legal and, social implications, for example, the question of opt-in versus opt-out presentation of research-related questions to patients. The opt-out model from a de-identified biorepository has been studied at Vanderbilt [28]. At MUSC, opting out from future contact for research and from the use of de-identified discarded biospecimens for research was debated by our ethics committee, legal department, and research stakeholders. A full discussion of ethical issues, although important, is outside the scope of this paper.

One of the key features of RPMS is multilingual support, which opens avenues for adoption in international settings where multiple languages could be used for obtaining consent to participation. The authoring system in RPMS allows institutions and researchers to create forms and appropriate content based on local institutional policies, regulations, and ethical principles. This flexibility allows users to address issues related to deficits in literacy, language barriers, signature requirements, and varied workflows.

Future plans include implementation of RPMS for participant recruitment by specific investigators in more selected MUSC clinics so that we can deal with problems identified by the clinic personnel and researchers before broader institutional deployment. This next step will allow assessment of the potential impact of RPMS on recruitment of patients to clinical trials and other research studies.

The introduction of electronic media to the consent process has the potential to enhance the information presented by the addition of audio-visual content. Such educational content may simplify the increasingly complicated consent forms required for clinical studies [29].

Conclusion

In conclusion, we have developed an electronic system that leverages new tablet computing technology to simplify the collection and management of research permissions and consents. When linked to a clinical data warehouse, the system can facilitate research participant recruitment as well as the coordination and management of a clinical trials network.

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Figure 1.

Typical RPMS workflow. (a) The process starts with the patient registration. Patient demographic data are transmitted via HL7 messages to a central data store and matched against the EMPI. (b) Patient information is displayed on an iPad, and the patient is presented with consent options. (c) The consent data are transmitted to the CDW. (d) A PostScript version of the consent form is generated and stored in the electronic patient folder and may be (e) printed and given to the patient. (f) The consent data are expressed through a research query interface along with clinical data for browsing by researchers.

RPMS: Research Permissions Management System; EMPI: Enterprise Master Patient Index; CDW: Clinical Data Warehouse; HL7: Health Level 7; EMR: electronic medical record.

Consent for Medical Treatment

Permission to Contact for Research Studies

I agree to be contacted about future research studies at MUSC for which I may be eligible. I understand that if I do not want to be contacted about future research studies, I need to check the box shown below.

☐ I DO NOT agree to be contacted for future research studies.

Back Continue

Figure 2.

A screenshot of a typical research permission, which allows the user to check a box, in this case for opting out of being contacted for research.