CASE STUDIES

Health literacy and consent forms: librarians support research on human subjects

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Poorly written consent forms could have negative consequences on participation in and outcomes of a research study. To help campus researchers use best practices in health communication with human subjects, librarians began teaching health literacy workshops and providing a consent form review service for principal investigators. Workshops have been well attended, and use of the editing service is growing. The library has become an important resource on campus for matters of health literacy and clear health communication. By assisting faculty in communicating clearly with research subjects, the librarians have contributed to university research efforts.

INTRODUCTION

Poorly written consent forms could have negative consequences for researchers and clinicians. A consent form that is too difficult to understand could influence an individual's willingness to participate in a study. A consent form that is difficult to understand could also influence the outcome of a study by causing confusion on the part of research subjects, leading to failure to adhere to the protocol directions [1] and raising the question, ''Could subjects' level of health literacy affect the outcome of a study?''

The problems of poor readability and complexity in consent forms have been documented in the literature since shortly after the development of federal policies protecting human subjects in the 1960s [2]. In 1978, Grundner noted that ''Consent is worthless unless it is an 'informed consent,' and 'informed consent' is not possible without subject understanding. While there remain many complicated problems involved in securing subject understanding, we must not allow the unreadability of the consent form to be one of them'' [3]. In 1980, Morrow expressed concern that informed consent documents might not be understood by a substantial portion of patients who sign them. In a study of sixty consent documents that were tested for readability and grade level, he found that the average document was at the ''difficult'' level, comparable to material in an academic medical journal [4]. The authors' experiences as medical librarians confirm this reading level of consent forms. This paper describes two initiatives that the authors have undertaken to assist investigators in writing consent forms that can be read by a majority of their research subjects: a health literacy class and an institutional review board (IRB) consent form review service.

The University of Maryland is an academic health sciences institution in Baltimore, where research plays a key role. Faculty in the schools of dentistry, medicine, nursing, pharmacy, law, and social work generated $529.1 million in extramural funding in fiscal year 2012. Research studies on humans account for a large portion of the funding. Librarians at the Health Sciences and Human Services Library (HS/HSL) have served as nonscientists on the university's IRB since 2001. This service to the university provides an opportunity for librarians to work closely with faculty and staff in a variety of ways related to human protections and human subjects research. Two of HS/HSL librarians' goals are to contribute to patients' understanding of health concepts and to raise faculty awareness of health literacy issues.

Human subjects research on campus is overseen by the Human Research Protections Office (HRPO). The HRPO provides support for the IRB, which provides ethical and scientific oversight for research conducted on campus. The beginning of the HS/HSL librarians' service on IRB panels coincided with a rising awareness of health literacy in the United States. Research was beginning to establish a relationship between health literacy and health status and the importance of using clear language in consent documents to encourage compliance with research protocols [5]. However, the literature has indicated that IRBs typically do not emphasize readability of consent forms when issuing instructions on how to review research protocols [6]. These conclusions were consistent with how the university's IRBs were operating.

HEALTH LITERACY INSTRUCTION

HS/HSL librarians began offering a workshop, initially called ''Health Literacy and the Consent Form,'' in 2004. The class was part of a series of free workshops that the library offers each semester. Based on the success of that class, a librarian was asked to present the same information in a grand rounds session, called ''Patient Health Literacy & the Consent Process.'' The session was attended by more than 30 clinical and research faculty and resulted in over a dozen requests to offer the class to entire divisions or departments. Librarians have continued to offer this workshop, though its content has evolved over time, and it is now called ''Communicating with Patients.'' This 90-minute class includes a review of health literacy in the United States, implications of low health literacy on patient behavior,

EC A supplemental appendix is available with the online version of this journal.

Figure 1
Classroom exercise

Directions: The following information is written at a 15.9 grade level, contains a number of passive sentences, and has a reading ease score of 28.7. Please apply best practices in clear health communication to make this information easier to read and understand. Remember to consider font style, sentence length, the use of white space, and lists and illustrations when possible.

How is diabetes treated?

Everyone who has diabetes should be seen at least once every six months by a diabetes specialist (an endocrinologist or a diabetologist). He or she should also be seen periodically by other members of a diabetes treatment team, including a diabetes nurse educator and a dietitian who will help develop a meal plan for the individual. Ideally, one should also see an exercise physiologist for help in developing a physical activity plan and, perhaps, a social worker, psychologist, or other mental health professional for help with the stresses and challenges of living with a chronic disease. Everyone who has diabetes should have regular eye exams (once a year) by an ophthalmologist to make sure that any eye problems associated with diabetes are caught early and treated before they become serious.

best practices for clear communication, and assessment tools and other resources. More than 400 people have attended the sessions as of May 2013.

The class also includes a hands-on exercise where attendees have the opportunity to use tools that are introduced in class to put paragraphs of medical jargon into plain language (Figure 1). This is often the attendees' favorite part of the class.

Class evaluations have been positive overall. Responses to the question ''What are the most significant things that you learned during this session?'' include:

The prevalence of health illiteracy and how much it can affect a patient's understanding of treatment and/or compliance with a self-care/medication regimen.

Most medical documentation is too complex for the average person to understand.

How well my patients understand the information I give them directly depends on how well I communicate it to them.

How to create documents and check for reading level/reading ease.

Various tools like Ask Me 3 and REALM.

The Microsoft Word reading level and reading ease assessment feature.

The ''Define'' feature on Google.

Responses to the request for additional comments include:

HS/HSL should offer a separate class specifically on verbal communication.

The workshop should be required for anyone involved in the consent process.

Spend more time covering the tools available to help with clear health communication.

Workshop attendees are guided to the library's LibGuide, ''Health Literacy Resources'' <http://guides.hshsl.umaryland.edu/healthliteracy>, and librarians point out a few of the best tools listed there. A recent comment accurately noted that ''there was no discussion of the intersection between health literacy and organizational liability.'' HS/HSL librarians plan to use this suggestion as an opportunity to work with members of the Office of Risk Management in the medical center.

INSTITUTIONAL REVIEW BOARD CONSENT FORM REVIEW SERVICE

The success of the literacy classes encouraged HS/HSL librarians to take further steps in working to promote health literacy. Most recently, staff have developed the consent form review service, which began in February 2011, when a librarian took note of complaints by fellow IRB reviewers about the difficult language in most of the consent forms submitted to the board. Since 2009, principal investigators applying for IRB approval are required to submit consent documents written at the seventh-grade level. They are rarely able to meet this stringent requirement. While there are links from the IRB website to outside resources to assist investigators in writing an appropriate consent form, they are primarily guidelines and templates. Providing assistance with creating readable forms presented another opportunity for librarians to work with principal investigators. HS/HSL librarians proposed a free review service for investigators where trained librarians and paraprofessionals would simplify the language of a consent form prior to its submission. Presentation of the idea to the HRPO received an enthusiastic reception.

In response, HS/HSL librarians developed a request form for the IRB consent form review service <http://www.hshsl.umaryland.edu/assistance/research_consent.cfm> and added it to the library's Reference and Research Services web page. A link to the service was also placed on the HRPO ''Investigator Toolkit'' page. The online form requires submission of basic information, including affiliation, status, contact information, and ''need by date.'' There is a place to attach drafts of consent form documents being submitted for review and a pledge to return the edited document within three business days. Each submission generates an email to reference staff, who divide the work among themselves.

Training and publicity

HS/HSL librarians determined that all reference staff, including paraprofessionals, were qualified to review the submitted consent documents, based on their demonstrated excellent oral and written communication skills at the reference desk and completion of college-level coursework. To launch the service, a librarian with many years of experience serving on the IRB provided an introduction to best practices

for health literacy to three paraprofessionals and two reference librarians. Ongoing training sessions for reviewers are similar to the workshops that librarians offer to patrons, with the emphasis placed on best practices for clear communication, assessment tools, and other resources. Part of the training includes time to practice simplifying language in writing samples from actual consent documents. Training workshops have continued as new staff are added to the service.

Library staff use a variety of methods to publicize the consent form review service, including the library's Facebook and Twitter accounts, website, electronic newsletter, and digital displays. More targeted publicity aimed at principal investigators is done by librarians who serve on IRB panels.

Challenges to providing the service

Between February 2011 and July 2013, HS/HSL staff reviewed twenty-five consent forms from eighteen individuals. Providing the consent form review service to the university research community presents reference staff with a number of challenges, the most notable of which are the time commitment required, the difficulty of simplifying scientific language, and the difficulties in finding time to establish an author-editor dialogue.

Time commitment. The time commitment needed to edit the documents has proved greater than anticipated. An average consent form submission is nine pages long, and it is not uncommon for researchers to submit consent forms with reading levels at grade fourteen or higher. Reducing the reading level of these documents to meet the campus HRPO's mandate of grade seven or below requires significant editing or even rewriting. HS/HSL staff must balance this editing work with their other job responsibilities and their daily shifts at the reference desk. While it is stated that the reference department will return the forms within three business days, staff generally have a little more time, as the ''need by'' dates that researchers indicate on the request form tend to be about five business days from the date of submission. This leeway is beneficial, not only for reviewing long or difficult consent forms, but also for times when HS/HSL staff have to accommodate staff vacation or sick days, busy periods at the reference desk, and other library projects that compete for staff time. Although staff members are currently able to meet all submission requests by their deadlines, the service is gradually becoming more popular. HS/HSL librarians anticipate that an increase in the number of requests for this service could affect the ability to fulfill them in a timely manner.

Scientific and legal language. Research consent forms, although intended for a lay audience, are typically written using scientific and legal language. Researchers describe the purpose and procedures of a scientific research study with the goal of providing adequate disclosure for the legal consent of study participants. The constant challenge of consent form review is to improve readability by clarifying both scientific and legal terminology. When simplifying professional discourse, there is always a risk that meaning will be changed or nuance lost as common language is substituted for subtler, more detailed professional language. With consent forms, however, this loss must be weighed against the benefits of communicating essential study information to readers with low literacy. For particularly difficult or high grade-level forms, an HS/HSL staff member will alert the researcher by email that subtle meanings and distinctions may have to be sacrificed to simplify the document.

Author-editor dialogue. Another significant challenge is that library editors have limited dialogue with the consent form authors. Primary contact is made electronically: the researcher uploads a document to a web form to submit it, and a librarian returns the edited file as an email attachment. The exchange occurs at arm's length. In some ways, this is helpful to the review process, because the staff member approaches the consent form as a study recruit will—with no prior knowledge of the research. However, HS/HSL staff must also make judgment calls in reviewing the forms. Reviewers cannot always intuit the author's rationale for including content. HS/HSL staff rely on Microsoft Word's Track Changes feature when making edits. When the basis for the inclusion of extremely detailed information is unclear, staff uses margin comments to ask the author to consider its necessity. Margin comments sometimes serve as author-editor dialogues. The edited version is presented as an option, with the investigator making the final decision on which changes to accept.

OUTCOMES

Of the 18 individuals who have used the service, 12 (67%) are faculty at the university and the remaining 6 (33%) are members of the staff. The primary user affiliation has been from the school of medicine, at about 60%. Remaining clients have been from the schools of social work, pharmacy, and dentistry.

In 2012, HS/HSL librarians began sending a satisfaction survey (Appendix, online only) to those who have used the consent form review service. As of July 2013, seven responses have been received, all of them positive. Survey respondents selected ''simplified terminology'' as the most beneficial change made to the consent forms. All users indicated that they would recommend the service to colleagues. One respondent said she would use many of the librarian's suggestions on future consent forms, and another asked to meet with the reviewer to learn more about best practices for clear communication. HS/HSL librarians will continue to survey all users of the service.

The initial health literacy instruction efforts have led to a close working relationship between the HRPO staff and the librarians who work as liaisons to the

medical school. A librarian was asked to present ''Utilizing the Medical Literature to Prepare a Research Protocol,'' another grand rounds session that covered how to do a comprehensive literature search. A librarian trained the HRPO analysts to search PubMed, Science Citation Index, and Embase and established literature searching guidelines that investigators must follow when submitting a new research protocol. Librarians were asked to participate in the evaluation of the HRPO by the Association for the Accreditation of Human Research Protection Programs, the accreditation board for human research protection programs. A librarian also demonstrated to the members of all four IRB panels how to read a consent document from the research subject's perspective. Since the training, librarians have observed that many more IRB members, who are primarily medical school faculty, have paid closer attention to the readability of the consent forms.

CONCLUSION

The work that HS/HSL librarians have done on behalf of clear health communication has been very satisfying. It has increased the library's visibility on campus, facilitated new relationships with faculty and administration, and given reference staff some challenging projects to work on. The authors hope that research subjects have benefited from these efforts as well.

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Innovative information service development: meeting the information needs of an interdisciplinary, cross-sector research complex

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Question: How can a team of health sciences librarians effectively meet the diverse needs of a new research complex?

Setting: A satellite location of an academic health sciences library that spearheads information services for an interdisciplinary, cross-sector research complex provides a case study.

Methods: The health sciences library established a library space at a new research complex that combines the services and expertise of a bioinformationist, translational research librarian, and public/private partnership librarian. The focus is on integrated information services, and the librarians serve as a boundary-spanning unit within the research complex.

Results: The colocation of the library with research cores and other units at the research complex has led to the creation of new partnerships and deepened existing ones.

Conclusion: Meeting the information needs of a diverse population requires a multifaceted approach to providing information services, and librarians must proactively seek out opportunities to establish meaningful collaborations.

INTRODUCTION

The Taubman Health Sciences Library (THL), a division of the University Library (MLibrary) at the University of Michigan (UM), has adapted quickly to changing information needs in the ever-evolving information landscape of the health sciences. The university demonstrated its commitment to bridging academic research and entrepreneurial opportunity through its 2009 acquisition and subsequent development of the North Campus Research Complex (NCRC). To enhance the synergistic relationship between the university, library system, and diverse population at the NCRC, THL established MLibrary@NCRC, an innovative library focused on access to information and integrated services. This article describes how MLibrary@NCRC integrated multiple