Ontario Best Practices Research Initiative (OBRI)

University Health Network

Impact of Information Technology on Research Practice:
The future of electronic data capture of participant reported outcomes

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Table of Contents

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Executive Summary

This report is an overview of the potential impact of information technology on current research practice based on work from the Consent and Data Management (CDM). CDM is a software platform for Electronic Data Collection of clinical and self-reported research data. With unique functionality for longitudinal cohort/population based studies. CDM provides for the hosting of multiple studies, each with their own protocol, study population, and research personnel.

With the emergence of new technologies and Electronic Data Collection (EDC) platforms like CDM, current concepts and practices surrounding informed consent need to be re-evaluated, and reformed once participants begin utilizing these research platforms. The nature of the conversation between researcher and participant will need to evolve to take into account the participant's increasing understanding of research and their own data. The new technology now provides functionality previously nonexistent, thus creating a shift for future systems utilized for research towards incorporating the ability for participants to dynamically and directly control their participation in a study, control access of their data by researchers, as well as control the communication between the participant and the researcher.

Specific features of EDC's of clinical and self-reported research data that impact current research practice include, but are not limited to:

- Participants register within the application and are able to perform self-report type activities;
- The granting of consent and permission to access data will be dynamic; and
- The application will be able to host longitudinal studies as well as multiple studies from researchers with no existing collaborations.

Further work is required:

- To better characterize the distinct types of relationships individuals enter into with researchers and with research platforms (data repositories, biobanks); both under what conditions these relationships do (and ought to) come into being, and how the relationships may change over time.
- To determine changes to the roles of Research Ethics Boards (REB, IRB).

Introduction

From the literature and practice there are numerous examples of how the implementation of technology can enable or promote changes to relationships and processes. This has been seen in the design and implementation of the Consent and Data Management (CDM) system, an application developed by Dr. Bombardier, Allan Harold and team at UHN. This application (research platform) has a number of innovative features that permit some insight into how research practice may change. Specific features that impact current research practice include, but are not limited to:

- Participants register within the application and are able to perform self-report type activities;
- The granting of consent and permission to access data will be dynamic; and
- The application will be able to host longitudinal studies as well as multiple studies from researchers with no existing collaborations.

Specifically, the new application will permit the research participant to directly and dynamically manage their participation, the permissions for the use of their data, and their contact with researchers. This, when coupled with the concept that participants own their data, and are only permitting researchers to use the data, is likely to lead to a significant change in the role of the participant in the research enterprise, as well as the nature of the participant-researcher relationship.

Direct and Dynamic Consent

Managing participation means that the common usage of the term consent will now be split into its two constituent parts; namely, consent to participate in the study and be subject to the procedures and interventions (if any) of the study, and what will now be a separate permission to use the data generated from the study. Consent for study participation and permission to use the resulting data no longer need be conflated into one term, but can now be more correctly treated as separate actions with separate consequences and outcomes.

This will also afford the opportunity to examine more closely how individuals actually make three very different types of decisions:

1. A decision regarding whether or not to consent to participation in a study (i.e. – enter into a researcher-participant relationship with the researcher); and
2. A decision regarding whether or not to contribute data and/or biospecimens for future research (i.e. – enter into a 'donor' or 'shareholder' relationship with a databank and/or biobank and its administrators)

3. A decision to grant permission for the use of his/her data and/or biospecimens for a particular secondary research purpose (i.e. – a future research protocol, not known to the individual at the time he/she contributed his/her data and/or biospecimens to the research platform)

In the case of the UHN CDM application there is an additional level of consent which occurs when the participant first registers in the application (#1 above). So a participant now consents to be on the research platform and be available for studies, can consent to participate in a specific study (#2 above), and can as a third step agree to specific uses of that studies data (#3 above), all of which can be changed at any time by the participant. Note that granting permission to use data is on a per study basis; the originating study would request the initial permission to access the data, any subsequent study or secondary analysis would require a new request.

It may also be appropriate to examine the term participant, as the new technology makes it possible to distinguish between participants in observational studies, from those in studies that include an intervention, and those that include a contribution of a biological sample. Other terms that may be appropriate to examine are 'subject', 'donor', 'stakeholder', 'shareholder', and 'activist' to determine whether or not these would be better descriptors for the types of relationships individuals enter into with researchers or data repositories and biobanks. Participants may actively manage their participation and data, or may wish to delegate that role to an independent decision-making authority such as a stewardship committee or access committee.

Further work is required to better characterize the distinct types of relationships individuals enter into with researchers and with research platforms (data repositories, biobanks); both under what conditions these relationships do (and ought to) come into being, and how the relationships may change over time.

Electronic Consent and Research Practice

Managing access to research data means that the participant no longer signs a consent form giving data to a researcher, which they never see again. Currently, participants are presented with choices which are pre-defined and presented in a "one size fits all" consent form. In a paper-based protocol, if a participant subsequently wished to retrieve the data, they would have to make a formal request to the study team at a given research site. When using the new technology, the participant will be able to directly give permission for access to the data, and at any time revoke that permission, or re-instate the permission, or subsequently grant permission for that data to be used in another unrelated study. Note that the participant manages these permissions directly; there is no longer any process for managing permissions that is mediated by the researcher. Similarly, if the participant does not

agree with the pre-defined consent options, should not they be able to propose their own? This is an important shift from general consent to specific permission.

The new technology now gives the participant access to, and control over, their data. But access without comprehension is meaningless. For example, the participant would need to be able to understand the individual items that make up a Health Assessment Questionnaire (HAQ) score, and what a HAQ score means, and its relevance. This new functionality and education requirement enhances the meaning of informed consent, and it is because of the requirement for informed consent that the participant must be provided with the opportunity to be educated as to how to look at data and interpret it. Again, the participant may decide instead to delegate these decisions to an independent decision-making authority rather than make the decisions themselves, and both types of behaviour must be allowed for and accommodated.

The concepts and practices surrounding informed consent need to be re-evaluated, and reformed once participants move to a research platform. For example, in the past it may not have been viable to actually test for comprehension, but the barrier to that is significantly reduced with the research platform. The nature of the conversation between researcher and participant will need to evolve to take into account the participant's increasing understanding of research and their own data. Fortunately there is a body of literature that will inform the appropriate design of this functionality.

By viewing informed consent in the context of decision-making and computer-mediated decision support, it is possible to access a large body of relevant literature, which did not exist when the fundamental human subject's protection framework and the concept and practices of obtaining informed consent for research were established.

This new technology also obviates the need for blanket or large scope granting of permissions to access data. There is no technical reason that the participant could not specify on a per item basis who may access specific data, for what purpose, and when. In other words, researchers will be required to request only the data they need, for what purpose, when they need it. There is no technical or practical reason why these requests could not route to the participants themselves for authorization prior to release of data (though other stewardship models may be developed where the participants vest a committee or other body with authority to make these decisions on his/her behalf). Furthermore, this highlights again that consent to participate in the study that originally collects data is de-coupled from permissions for the use of the data resulting from the study.

In order to support longitudinal research, as well as studies from unrelated researchers, the participant is registered in the application. In other words, while the participant may be anonymous within a study, they are known within the application, thereby creating an opportunity for

communication between participants and researchers. This establishes a 'virtual population' in a 'virtual space' where new types of conversations can take place between participants and researchers. The participant will have the ability to manage this contact with researchers. As with consumer applications, the participant will be able to specify under what terms they may be contacted. Typical uses might be requests for secondary use of data, invitation to participate in a new study, results of studies, or alerts relevant to the participant. An implication in the case of secondary use of data is that previously it was expedient for an REB to grant a waiver of consent to access data. Now there is no longer any reason why the participant couldn't be contacted to grant that permission directly.

Conclusion

In summary, should they wish, the participant can become an active partner in research due to the control of information and interaction with the researcher afforded by the application of information technology. At the same time the researcher will be required to be more precise and constrained in their requests, and to be cognizant that their access to data and participants is dynamic.

Researchers will need to increasingly include risk analysis in their protocols. If participants and their data can be dynamically included or excluded, might it put the viability of a study at risk? More speculatively, if participants with related interests are all registered on one research platform, might they organize to drive research agendas using their new role in research as a bargaining position, or on the other hand should they perhaps be encouraged to do so?

In the digital age, the general population's attitudes toward their personal data are changing rapidly. Whether it is data about their consumer preferences (credit cards, surveys, personal data lockers), their social relationships (Facebook, LinkedIn) or their general daily activity (Twitter, Pinterest, Instagram), individuals are more empowered to determine who accesses their data and for what purposes than ever. This would suggest that participants are less likely to accept the paternalistic role that has been propagated by the current human subjects research enterprise.

Further work is required to as a wealth of literature exists within the fields of social science, computer science, cognitive psychology and information systems that can inform future models and requirements for adapting to changes in research practice due to the application of new technology.

Glossary of Terms

Direct and Dynamic Consent: is informed consent given directly by a participant to manage their study related activities including study participation, permission for the use of their data, and contact with researchers.

Electronic Data Collection (EDC) System: is a computerized system designed for the collection of clinical data in electronic format.

Research Platform / Application: is software designed for internet based data collection of clinical and self-reported research data for longitudinal cohort/population based studies.

Research Practice: Research frameworks, paradigms within applied research and research ethics.