Dynamic consent and personalised medicine

Dynamic consent has the potential to facilitate personalised medicine delivering on its goals

In Australia, guidelines for ethical conduct of human research are defined in the National Statement on Ethical Conduct in Human Research, which states: "consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it".[1] The conventional one-off approach to consent aims to encompass all aspects of the proposed research. An expectation exists, however, that consent is specific, and obtained after a participant has gained a thorough understanding of the project's aims, methods, risks and benefits. Participants should also have the right to revoke their consent and withdraw from any or all aspects of the project.[2]

Biobanking specimens for future use in currently unplanned (and often unforeseeable) future research exemplifies challenges for conventional consent.[2,3] One approach is "broad" or "unspecified" consent, where participants consent to their samples being used based on a description of the overall goal of the research, with an explanation of governance processes in place for making decisions about its direction, and examples of potential projects. It is debatable whether participants can be considered to be informed under these circumstances;[2-5] nevertheless, empirical evidence indicates that the Australian community is receptive to this pragmatic approach.[6-8]

Another approach is "metaconsent", where participants decide on their mode of consent (eg, specific, broad/blanket), which may be stratified, for example, by data type (eg, genome sequences, health records, imaging) or funding source (eg, publicly funded or commercial).[5]

Dynamic consent was conceived as another alternative to broad consent for biobanking,[2,3,9] but it is applicable more broadly.[10] Dynamic consent uses a web-based platform that can be accessed by the public, research participants and researchers to enable participants to provide consent and indicate their preferences for research involvement.[11-16] In fact, dynamic consent platforms are not just for consent, but also provide general information, often in a range of formats (eg, audio, images, video) about the aims and methods of the research program.[14-16] Dynamic consent can support specific consent, broad/blanket consent, and metaconsent.[11,17] Participants can use the dynamic consent platform to indicate preferences for types of research participation, mode and frequency of communication, as well as preferences for what type of data can be shared and with whom.[11,12] A dynamic consent platform typically provides registered participants with a personal portal to gain up-to-date information about projects they have enrolled in, and allows them to modify their consent to existing projects and to consent to participation in new studies.[14-16]

Privacy and security in dynamic consent

Privacy and security of personal data are consistently identified as major concerns of research participants,[13,14,18] and failure to convince the public to trust that they are adequately protected often results in project failure.[18] Dynamic consent platforms provide researchers with robust technological and governance protections, often using novel solutions to protect privacy and enhance security through access restriction, pseudonymisation, encryption, data separation, audit trails, and blockchain technology.[14-16] This is important in Australia, where regulation of data sharing is a mix of common law, legislation, guidelines (ie, the National Statement on Ethical Conduct in Human Research)[1] and codes of practice, with variation between jurisdictions. It has been argued that within this environment, trust shifts to researchers and clinicians.[19]

By providing ongoing opportunities for participants to determine how their data are used and protected, dynamic consent has the capacity to enhance trust and public license for research, improve participants' experience in longitudinal research, enhance their engagement with research, and thus improve research outcomes.[9,11,12] In this way, dynamic consent overcomes barriers to effective research by generating the necessary public trust through transparency of data management and sharing, and increased communication with participants.[9,11,12,14,16,18,20] Transparency about the use of their data, as well as communication and engagement opportunities offered by dynamic consent are valued by research participants and have been shown to enhance participants' autonomy and engagement with research.[9,12,18,21]

Research participants as partners in dynamic consent

Projects using dynamic consent often place participants at the centre of the research, actively involving them in decision making throughout the

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project in study design, development, reporting and management, thereby emphasising their role as research partners rather than participants or subjects[15,16] and ensuring the research continues to focus on areas of importance to them. Even developing the dynamic consent platform itself can be participant-driven, with major design changes stemming from participant requests.[15] Particularly successful dynamic consent platforms embed robust community engagement models, both face-to-face and online, and consider increasing community awareness of health and closer collaboration between researchers, clinicians and research participants as a project aim.[14-16,22]

The granularity of consent enabled by dynamic consent platforms is particularly relevant to precision medicine and genomic research projects. Indeed, it has been argued that dynamic consent is necessary for personalised and precision medicine to achieve its goals.[23,24] For example, the dynamic consent platform CTRL has recently been developed for the Australian Genomics study.[21] Participants are invited to register for CTRL after they provide written consent to the study during a face-to-face recruitment meeting. The use of CTRL allows participants to update their consent for the study and for potential future uses of their data, as well as to receive information about study progress and communicate with the study team. User experience and usage data from CTRL will be collected and used to evaluate the effectiveness and utility of dynamic consent in ongoing studies.[21]

Strengths of dynamic consent studies

Empirical evidence demonstrates that successful dynamic consent implementation can enhance patient engagement and facilitate recruitment, management and retention of research participants.[10,14,15,20,22] Dynamic consent has been shown to address the substantial problem of under-representation of marginalised communities in research.[22] Locally, concern about specific harm and remote location has previously resulted in under-representation of Indigenous Australians in genomic research.[25] Dynamic consent has the potential to be part of the solution to this problem. Dynamic consent platforms reduce geographical limitations on participation, which are otherwise a major barrier to rare disease research where relatively small numbers of potential participants are geographically dispersed. For example, in the All of Us precision medicine program, over 175 000 participants contributed biospecimens in 14 months, data from electronic health records were collected on more than 112 000 participants, and more than 80% of participants were from groups typically under-represented in research.[22] Digital engagement is also beneficial when face-to-face appointments are limited because of COVID-19.

Challenges and limitations of dynamic consent

There is no ideal dynamic consent platform at present. A review of the concept of informed consent in the context of population-level genome sequencing research evaluated five currently used systems and found that dynamic consent platforms were important for achieving the respective project goals, but identified limitations.[13] There were insufficient mechanisms for assessing whether participants have understood what they are consenting to before allowing them to consent, lack of functionality for participants to choose their preferred level of consent, and failure to allow participants to decide whether they wanted to receive individual test results.[13] These findings highlighted the need for a framework to guide the implementation of dynamic consent in precision medicine.[13]

As dynamic consent is a technological solution, it contains an inherent risk of exacerbating the digital divide between those who have access to relevant technology and those who do not, which could undermine its potential to enhance research participant diversity. Thus, evaluation of dynamic consent implementation should use inclusivity as a metric of its success.[20]

Developing, maintaining and governing dynamic consent systems safely, securely and ethically also has a significant cost (eg, funding, labour and expertise).[5,12,13,17,26] Most existing dynamic consent platforms have been developed through ongoing multidisciplinary collaboration with developers working closely with patients, researchers and clinicians to gradually update and maintain the platform, ensuring that the system meets the needs and ethical considerations of all of its users.[15,16] This means that using a dynamic consent platform is inaccessible for projects without significant funding allocated to its development.

Summary and next steps

Dynamic consent has the potential to increase participant recruitment, reduce attrition, increase engagement and satisfaction with research, improve communication, build trust, increase inclusivity of research, improve participants' understanding of research, and even increase health literacy.[9,11,12,20] While there is evidence in support of these objectives being met when dynamic consent platforms have been used, further empirical evaluation is required.[10,26] Ideally, this should be based on clear enunciation of the theoretical underpinnings that suggest dynamic consent will increase participant trust in research.[26] A framework for dynamic consent evaluation and reporting, building on existing theoretical conceptions of informed consent, has recently been proposed.[26] In this framework, a set of core outcomes should be developed to ensure consistent measurement and reporting of dynamic consent studies, potentially to be evaluated in randomised controlled trials where participants are randomised to either traditional paper-based or dynamic consent. Adoption of these enhanced evaluation methods would support robust assessment and reporting of outcomes of dynamic consent platforms, and over time would contribute to the development of a theoretically justified evidence base for their implementation.[26]

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