Opportunities for eConsent to enhance consumer engagement in clinical trials

Enhancing clinical trial recruitment through eConsent has potential but needs more evidence of use

Consent for medical interventions or clinical research participation currently relies on the use of printed information combined with a conversation with a health care professional, which is largely undocumented. Studies have shown that few participants are truly informed at all using these traditional means, and have demonstrated that recall or comprehension of what was disclosed is poor.[1–3] Attempts to develop standardised participant information and consent forms (PICFs) that meet ethical requirements have often resulted in longer and more complex documents. While consumers have been engaged to assist with these programs, the purpose of PICFs is still too heavily weighted toward satisfying regulatory requirements rather than patient information needs. Unsurprisingly, data show that, as PICFs get longer, they are less well understood,[4,5] and there is evidence that this is one of the reasons why patients do not agree to participate in clinical research.[6]

eConsent is not simply a conversion of a paper PICF into an electronically delivered version. It also holds the promise of improving participant engagement in clinical trials through a variety of features that include:

- the use of multimedia tools to enhance comprehension;

- ready conversion into multiple languages;

- a means to track consent in a highly portable manner; and

- the opportunity to provide information in a more convenient way to persons with an inability to attend clinics.

The use of eConsent does not replace the opportunity for participants to ask direct questions to their doctor or the investigators. Moreover, in most instances, participants will still be required to make a physical visit to a clinic to receive their treatment, whereupon they can ask questions and confirm their willingness to participate.

There are relatively few studies using eConsent. In an early randomised controlled study, there was a preference for eConsent as well as improved comprehension and intention to participate in people assigned to use computer terminals rather than paper to receive information.[7] In a more recent study involving people infected with human immunodeficiency virus,[8] eConsent was found to be acceptable and had some advantages over paper information sheets. There were a majority of males included in the study (75%), and more than half were African American, with a mix of sexual orientation. Health literacy of participants was the
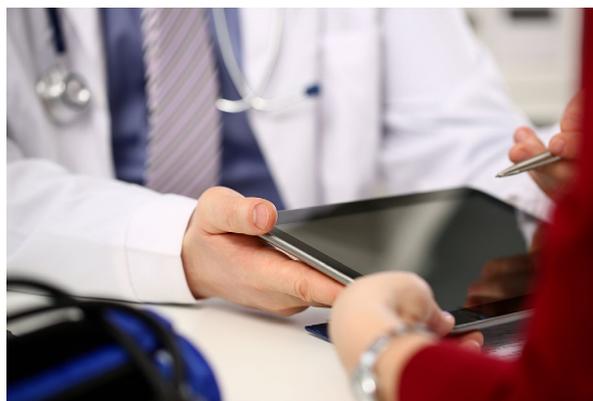
only factor that emerged as having an impact on comprehension; however, the number of participants ($n = 20$) is too small to draw statistically sound conclusions. A 2013 study tested comprehension and satisfaction when using iPads to deliver information for a neuropathy in chemotherapy study.[9] Importantly, the investigators presented the same information in both formats, but the iPad had an initial video outlining the main features of the study. They found that of the 55 patients who took part in the randomised study, there was a statistically significant association with increased comprehension in the group assigned to the iPad. The sample sizes were too small for definitive findings, but of interest was that use of the iPad did not increase likely participation rates (it was slightly lower). All participants advised that the information provided was still too complex regardless of the media used, and that simplified text, diagrams, animations and other ways to enhance comprehension are needed. A recent study reported on the TransCelerate eConsent Initiative, which employed a large survey of 3045 participants and a number of smaller stakeholder consultations.[10] While there was general support by potential participants for the use of eConsent, the survey revealed that people living in the European Union had the greatest level of discomfort with it. In this survey, they also found that people were concerned that eConsent might eliminate site/participant discussion regarding participation, even though this is not the case where it has actually been used.

In Australia, there has not been widespread use of eConsent to date. To better understand the Australian context, Clinical Trials: Impact and Quality (CT:IQ) — a cooperative funded by MTPConnect, an Australian Government Industry Growth Centres Initiative, using funds from the federal government's Medical Research Future Fund (MRFF) — set out to investigate stakeholder perceptions of eConsent and, therefore,

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to identify potential actionable insights. Chrysalis Advisory developed a survey that was sent via email to the members of CT:IQ for distribution to the wider clinical trial sector in the first quarter of 2019. A total of 179 participants completed the survey and as we used a snowball methodology, there is no denominator of persons polled. In addition, there were 19 semi-structured interviews conducted drawn from the CT:IQ membership. The majority of respondents (68%) were women, 75% were aged 40 years or over, and 80% had more than 10 years of working in trials, demonstrating considerable experience in the sector. The full report is available on the website,[11] with the questions presented on pages 58–59 of the report. The key findings are summarised in the Box.

We specifically surveyed those deploying eConsent at this stage and not the end users because we wished to understand what the sector was already doing and what the perceived barriers and opportunities were. Although only 29.2% of respondents indicated that they had any direct experience with eConsent, our survey revealed that they were overall cautiously positive toward the use of eConsent. An important finding was that there was optimism that use of electronic formats would enable participants to drive the information-seeking process in a way that best suited their needs.

The physical infrastructure, particularly in some public hospitals, was widely held as not being adequate to support eConsent uptake. Wi-Fi blind spots within hospitals were cited as a major reason for this, as well as difficulties achieving infrastructure updates within the public health system. Respondents recommended that approaches to eConsent should employ technologies that do not rely on expensive infrastructure delivered by health services. In addition, respondents indicated that, ideally, there should be a sector-wide standard for site information technology infrastructure requirements combined with clear guidance for sponsors to standardise their approaches.

A number of interviewees who had worked on trials with eConsent where sponsors had provided devices noted that the devices were clunky and prone to malfunction, which increased overall study time and burdened trial staff. Clinical trial sites often experienced sponsors insisting on their own standards, resulting in unnecessary duplication or incompatibility of instrumentation at sites. Many respondents cited that differences in the use of eConsent platforms and inconsistencies between organisations regarding eConsent compliance (eg, whether participants would be required to sign electronically, or would be able to consent by using technologies such as face recognition, fingerprint identification etc) made it difficult to adjust to the use of eConsent. Greater industry engagement and collaboration may mitigate this barrier by providing stakeholders with frameworks and support to

Key findings of the eConsent survey

Barrier	Finding
Problems with using paper-based information sheets and consent forms	• 38% of respondents thought paper consent forms were not a problem, 71.5% thought they were too long, and 62% found them too complex • 37.4% of respondents thought paper-based consent impaired participant comprehension • 67% of respondents believed eConsent would improve comprehension, although they did not believe that this would necessarily translate into greater recruitment • 59.2% of respondents believed there was a significant issue with providing adequate information to people from culturally and linguistically diverse populations and saw eConsent as a solution to this
Perception that regulators, HRECs and hospital governance offices will not accept eConsent	• 40.8% of respondents believed that ethics committees would not approve use of eConsent, 26.8% were unsure • 90.5% of respondents found it necessary to have guidelines for use by both researchers and HRECs
Patients will not be sufficiently proficient with technology or have access to suitable devices	• Certain demographics (eg, older people) were considered likely to struggle with eConsent • eConsent was likely to be well received by younger generations
Health services lack the infrastructure to deliver eConsent	• 82.7% of respondents identified a lack of IT infrastructure as a critical barrier to overcome • 59.2% indicated that the current infrastructure was inadequate, particularly within hospital sites
Difficulties with authentication of individuals and data security	• 46.3% of respondents believed there would be issues with data governance, security and privacy, but 29% of respondents disagreed with this • 59.2% of respondents felt that they would lose the ability to ensure that the person signing the eConsent was actually the participant, the remainder were undecided or felt this was not a problem
Lack of consistent practice across the sector	• 67% of respondents identified a lack of standardised guidelines as a significant barrier to success • 49.2% of respondents indicated that staff were able to manage eConsent despite the lack of training and standardised guidance
eConsent will be more expensive	• 60.3% of respondents believed that there would be a significant initial cost, which might be a barrier to uptake

HRECs = human research ethics committees; IT = information technology. ◆

implement eConsent. Furthermore, setting some national guidelines will facilitate the design, regulatory approval and implementation of strategies to adopt eConsent.

While some stakeholders identified data security as a risk associated with eConsent, others did not believe security threats were any greater than similar threats to existing digital technologies in use throughout clinical trials and the medical field more broadly. They suggested that when appropriate security systems are in place and data governance risks are managed, stakeholders were not likely to be concerned about data governance risks for eConsent. Using eConsent does not automatically mean that participants will have the ability to provide consent offsite, simply that they have access to the information offsite. This is no different from participants providing wet ink signatures offsite in terms of risk and the fact that a person comes to a clinic and accepts the study treatments is a clear demonstration of consent. Two-factor authentication processes enabled by eConsent may provide a more robust means to authenticate consent than current paper-based processes.

It was not surprising that eConsent was considered to add a cost burden over and above a paper-based approach. However, few of the respondents considered the cost savings made through enabling prior reading of relevant documentation and, in particular, the major cost savings for the site and for the participants this could potentially deliver. A respondent from a large cancer centre articulated the potential benefits by outlining how participants from anywhere outside of a 50 km radius of the tertiary centre could avoid

additional time needed in the clinic through being able to use eConsent. This centre is piloting a tele-trial model to deliver trials in non-tertiary settings and recognises that eConsent is pivotal to enabling this model, which promises to reduce the burden on patients through reducing their need to travel and to ensure that clinical trial participation is more available beyond metropolitan centres.

It appears from our survey that Australia is willing but only partially ready to implement eConsent. The pathway forward will require proactive planning, leading and managing organisational change with the creation of practical demonstration cases of the development, delivery and use of eConsent in the clinical trial setting vital to support wider adoption. CT:IQ is now looking at a program to undertake these pilot projects as part of its initiatives to enhance clinical trial capability across Australia and in other jurisdictions.

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