Journal of Patient Experience
2020, Vol. 7(1) 12-15

DOI: 10.1177/2374373519827029
journals.sagepub.com/home/jpx
SAGE

Online Consent Enables a Randomized, Controlled Trial Testing a Patient-Centered Online Decision-Aid for Medicare Beneficiaries to Meet Recruitment Goal in Short Time Frame

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Abstract

Online consenting allows potential participants of research projects to deliberate their participation at their own pace and may be more cost-effective than conventional approaches. Yet, online consenting is not widespread in health services research due partly to concerns about security, confidentiality, and lack of established processes. We report our use of online consenting to successfully enroll over 1185 Medicare beneficiaries in a short 9-week time frame for a research study.

Keywords

online consent, patient-centered online tool, enrollment, recruitment, Medicare Part D, technology

Introduction/Background

Online consenting allows participants to read detailed information on a study and deliberate their participation at their own pace (1). Moreover, online consenting may save time and lower recruitment costs compared to conventional approaches (2). Studies indicate that using a computer presentation of a simplified consent form can increase both understanding of the study and increase patient privacy and control (3-5). Despite these benefits and generally favorable attitudes toward the idea of completing an online consent (1), online consenting is not yet widespread in health services research due partly to concerns about security, confidentiality, and lack of established processes (6). We describe how one delivery organization in northern California used online consenting to enroll a large number of participants in a restricted time frame for a randomized controlled trial (RCT).

The online consenting process we describe was part of a study that tested an innovative, patient-centered online tool for older adults choosing among Medicare Part D prescription drug plans. Medicare beneficiaries are generally only able to change their plan during an open enrollment period (October 15 to December 7, 2016 for 2017 coverage). Thus, the research team had limited time to consent a minimum of 915 participants for the RCT. In general, older adults use the Internet at lower rates than younger adults (7), yet our organization is located in Silicon Valley where the population is well-educated with high annual household incomes (8), characteristics associated with a higher rate of Internet use (7). Since participants were testing a tool that was available only online, online consenting seemed a feasible way to reach the enrollment goal.

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Table 1. Main Concerns and Implemented Solutions of Online Consent Workflow.

Concerned Party	Concerns	Solutions
Institutional review board (IRB)	a) If there is not a researcher reviewing the consent form with a potential participant in-person, how can we ensure that participants truly understand what the study is about? b) How will we prevent complaints of unsolicited e-mails?	a) True/false questions were added to check for patient understanding of the key components of their participation. Questions needed to be answered correctly before patients could participate. b) First point of contact was postal mail
Privacy officer	The primary form of study communication was e-mail. How will we ensure that participants understand the security of unencrypted e-mails?	With the help of our privacy officer, we developed clear language to add to the consent form. Also, one of the questions to check for patient understanding (mentioned above) was regarding the use of unencrypted e-mail.
Privacy officer, information management group, research team	Our tool included a feature that uploads medication data from the medical record directly to the tool. What data are necessary to collect from potential participants and how do we collect it to ensure that the patient we invited is the patient enrolling?	Working with our information management group, we determined the data elements required for patient verification (full name, date of birth, and last 4 digits of social security number).

Methods

We modeled our online consent process from a previous study that enrolled participants via an online consent process (9). As the first study that used online consent in the health-care delivery organization, we needed to address the concerns of several parties: the institutional review board (IRB), the privacy officer, and the information management group. Table 1 outlines the main concerns and implemented solutions.

Once we had addressed each party's concerns, we used REDCap (a secure web application for building and managing online surveys and databases) to develop an Internet-based tool that we refer to as the Consent Portal (see Online Appendix for selected screenshots). Using administrative data from the delivery organization, we identified a cohort of patients likely to be eligible based on their age (65-85 years), residence in the service area, indication of active medication orders, and whose electronic health record (EHR) did not indicate that they had a different type of prescription drug coverage. We mailed potential participants an invitation to participate in the study. Those interested in participating were directed to access the online Consent Portal by entering their study ID, which was included in the invitation. The Consent Portal, housed within REDCap, was used to:

1) Verify eligibility: Patients confirmed their age, that they were the only one in the household participating, and identified their current Medicare Part D plan.
2) Obtain informed consent: Patients reviewed online consent content, and then needed to correctly answer 5 true or false questions about the study and provide an e-signature to proceed.
3) Authenticate patient identity: Patients provided date of birth, and the last 4 digits of their social security number (only patients whose information matched the information in the EHR were allowed to enroll in the study).
4) Administer a baseline survey.

We provided a phone line and e-mail address in the invitation for participants who wanted to speak to a live person. The Consent Portal was β-tested by patient stakeholders and clinic staff who estimated that it took about 20 to 30 minutes to complete. An Access database was created to track patient calls and messages, and to categorize the types of calls received. We calculated the number of participants who visited the Consent Portal, how many ultimately participated, and the number/types of patient messages received to evaluate the online consent portal. Administrative data on demographics, EHR use, and health information were also used to compare participants and nonparticipants.

Results

Mailing Recruitment Efforts

Beginning in early September 2016, 3 waves of invitations were mailed to 29 451 potentially eligible participants and 2 waves of reminders were sent to people who had not yet responded. Figure 1 shows the timing of patient recruitment, highlighting the delivery date for each wave of invitations and reminders. We originally mailed an invitation to 10 000 patients. By October 7, only 380 participants had enrolled. To reach our recruitment goal, we invited the remainder of the potentially eligible pool (19 451), dividing the mailings into 2 waves to match our capacity in responding to inquiries. The IRB overseeing this study requested that we close recruitment after reaching our pre-approved recruitment goal, which occurred in mid-November. Consent Portal use was highest at the start of 2017 Medicare Open Enrollment (the week of October 15, 2016).

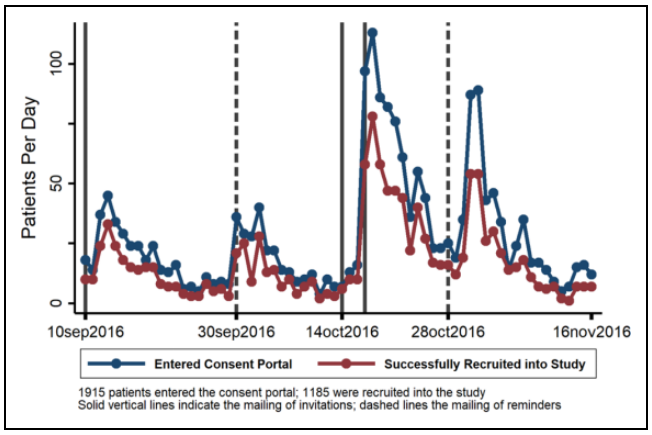

Figure 1. Timing of participant recruitment.

Patient Inquiries

By the end of Medicare Open Enrollment, we had received about 570 recorded inquiries from participants (phone, e-mail, and letters) related to the Consent Portal. Patient inquiries were grouped into the following categories:

- Information seeking/checking eligibility: 65% (n = 370).
- Trouble with Consent Portal/Browser compatibility issues: 20% (n = 112).
- Trouble with computer/no computer: 11% (n = 61). These patients were informed that they could use computers at the delivery organization's Community Health Resource Centers.
- Confused about online consent: 3% (n = 19).
- Issue with baseline survey: <1% (n = 5).

Consent Portal

An estimated 70% to 89% of participants who enrolled in the study did so entirely through the portal, without contacting the study team. (The range is driven by the number of people who contacted the study team with questions but did not provide their study ID.) A total of 1915 unique study IDs entered the Consent Portal. Of those, 320 people were ineligible and 8 did not proceed all the way through the eligibility screen (an additional 84 people were determined ineligible by a research team member either through phone or e-mail). Of the 1587 participants who passed the eligibility screen on the Consent Portal, 24.2% (n = 384) left the Portal upon reaching the first page of the consent information. Eighteen people did not participate because the information they provided did not match the EHR. Ultimately, 1185 participants successfully enrolled in the study through the Consent Portal (a 4% recruitment rate).

Participants who entered the consent portal differed from those who did not (P value $\leq .01$). For example, they were younger (72.53 vs 74.06 years), had a lower Charlson Comorbidity Index (1.01 vs 1.17 points), were more likely to have logged into their electronic medical record (EMR) within the last 3 years (94% vs 68%), sent messages through their EMR more often (6.60 vs 3.07 message strands over the last 3 years), and were more likely to be married, white, and live in an area with higher income and more highly educated residents. Participants who consented before the start of 2017 Medicare Open Enrollment did not differ significantly from those who consented during open enrollment based on these characteristics.

Discussion

Meeting our recruitment goal in the limited time frame would not have been possible using traditional consent methods. For comparison, a previous study that enrolled Medicare beneficiaries during Medicare Open Enrollment period recruited 44 participants using the traditional face-to-face consent method (10). Although consent was completed solely online, many potential participants found it helpful to connect with a live person. We were able to answer to questions about the study and troubleshoot issues with computer browsers or the Consent Portal, ensuring that patients felt confident about consenting to participate in this study.

Having a method to receive feedback from participants also allowed us to make ongoing improvements to the Consent Portal. For example, after 2 participants contacted us because they were confused about where to sign, with IRB approval, we reformatted the online consent and clearly indicated that typing their name in a designate place served as an electronic signature. Since nearly a quarter of participants who passed the eligibility screen left the Enrollment Portal upon seeing the first text-heavy consent page, a recommendation for future studies is to work with the IRB to shorten and simplify the consent as much as possible with user-friendly formatting such as bold font, color, and white space (11). Another benefit of our Consent Portal was that it included questions to test participants' understanding of the material presented to ensure that they understood key points about their participation (12).

Limitations

A study limitation is that participants were primarily concentrated in Silicon Valley, an area of higher income, education, and Internet usage. Other populations of older adults may respond differently to using an online Consent Portal. Additionally, our participants may have already been thinking about changing their plan and were therefore more likely to participate in this study than non-respondents.

Conclusions

By using online consent, we were able to enroll 1185 Medicare beneficiaries in a 9-week period. This success was due to thoughtful collaboration with patients and other stakeholders, careful planning, and user testing in the months prior to opening the Consent Portal to patients. Similar to

previous studies, we found that online consent in a study can be successfully done (3,6) even among older adults.

Authors' Note

Roman Klimke is now affiliated with John F. Kennedy School of Government, Harvard University, MA, USA.
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Acknowledgments

All statements presented in this article, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. A previous version of this article was presented as a part of a panel at the 2017 Health Care Research Network Annual Meeting in San Diego, California.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Research reported in this article was funded through a Patient Centered Outcomes Research Institute (PCORI) Award (CDR-1306-03598).

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Supplemental Material

Supplemental material for this article is available online.

References

1. Wood F, Kowalczuk J, Elwyn G, Mitchell C, Gallacher J. Achieving online consent to participation in large-scale gene-environment studies: a tangible destination. J Med Ethics. 2011;37:487-92.
2. Huybrechts KF, Mikkelsen EM, Christensen T, Riis AH, Hatch EE, Wise LA, et al. A successful implementation of e-epidemiology: the Danish pregnancy planning study 'Snart-Gravid'. Eur J Epidemiol. 2010;25:297-304.
3. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics. 2013;14:28.
4. Friedlander JA, Loeben GS, Finnegan PK, Puma AE, Zhang X, de Zoeten EF, et al. A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy. J Med Ethics. 2011;37:194-200.
5. Madathil KC, Koikkara R, Obeid J, Greenstein JS, Sanderson IC, Fryar K, et al. An investigation of the efficacy of electronic consenting interfaces of research permissions management system in a hospital setting. Int J Med Inf. 2013;82:854-63.
6. Lentz J, Kennett M, Perlmutter J, Forrest A. Paving the way to a more effective informed consent process: Recommendations from the Clinical Trials Transformation Initiative. Contemp Clin Trials. 2016;49:65-9.
7. Smith A. *Older Adults and Technology Use*. Pew Research Center [Internet & American Life Project], Washington, D.C., 2014.
8. Quick Facts. United States. Retrieved from The United States Census Bureau. https://www.census.gov/quickfacts/fact/table/US/PST0452172017. (2017).
9. Dimidjian S, Beck A, Felder JN, Boggs JM, Gallop R, Segal ZV. Web-based mindfulness-based cognitive therapy for reducing residual depressive symptoms: an open trial and quasi-experimental comparison to propensity score matched controls. Behav Res Ther. 2014;63:83-9.
10. Stults CD, Fattahi S, Meehan A, Bundorf MK, Chan AS, Pun T, et al. Comparative usability study of a newly created patient-centered tool and medicare.gov plan finder to help medicare beneficiaries choose prescription drug plans. J Patient Exp. 2018; 6: 2374373518778343.
11. Varnhagen CK, Gushta M, Daniels J, Peters TC, Parmar N, Law D, et al. How informed is online informed consent? Ethics Behav. 2005;15:37-48.
12. Rothwell E, Wong B, Rose NC, Anderson R, Fedor B, Stark LA, et al. A randomized controlled trial of an electronic informed consent process. J Empir Res Hum Res Ethics. 2014;9:1-7.

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