Improving Iowa Research Network Patient Recruitment for an Advance Care Planning Study

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Abstract

Introduction/Objectives: In February 2019, recruitment began in Iowa Research Network offices for a Patient-Centered Outcomes Research Institute (PCORI) funded Advance Care Planning (ACP) study to be conducted in 7 primary care practice-based research networks across the United States and Canada. The main study trained clinicians and nursing staff in serious illness care conversations and requested they refer eligible patients. Eligible patients were those with serious illness or frailty expected to live 1 to 2 years. Clinicians indicated it was difficult to identify eligible patients. This study aimed to find better methods for increasing patient recruitment for the ACP study. Methods: Research staff brainstormed and implemented strategies to increase patient referrals from clinicians. Participating offices used Epic for their medical record and the Gagne Index was used to generate a list of eligible patients in Epic SlicerDicer. When patients from the Epic SlicerDicer report appeared on the schedule, clinicians and nursing staff were notified that they might be eligible for ACP. Clinicians and nursing staff were asked to complete a survey identifying their perception of implemented strategies. A Wilcoxon signed-rank test was conducted to compare referral numbers before and after the Gagne Index/Epic SlicerDicer intervention. Results: Seven clinicians referred patients prior to and 11 after the Gagne Index/Epic SlicerDicer intervention. Clinicians referred a total of 120 patients; 31 patients prior to and 89 patients after the Gagne Index/Epic SlicerDicer implementation (P = .002). Survey results indicated that several strategies facilitated clinician referrals, including patients identified as potentially appropriate on the schedule, quarterly meetings with researchers, and e-mails with a list of potentially eligible patients. Conclusions: Notifying clinical staff about potential study participants increased patient referrals in this ACP study. Research staff must have time, funding, and patience to support clinical staff who are expected to refer patients to studies.

Keywords

family medicine physician, recruitment, advance care planning, practice-based research network, epic SlicerDicer

Introduction

Historically, clinical trials involve researchers approaching subjects about potential participation in a study. Some clinical trials involve staff from primary care offices in patient recruitment. A primary care office is the setting where physicians are trained and skilled in providing continuing care including but not limited to counseling, disease prevention, health maintenance, and patient education. It is an ideal setting for a relationship between the clinician and patient to form, which translates into improved clinical care and population health.1 Because of this relationship, physician or clinical/office staff referral of patients for clinical studies can be beneficial. However, it also adds another layer of difficulty to recruitment. For successful recruitment through primary care offices, traditional workflows must be adjusted for both research teams and clinicians.

In March of 2019, recruitment began in the Iowa Research Network (IRENE) for a Patient-Centered Outcomes Research Institute (PCORI) funded Advance Care Planning (ACP) study.
Care Planning (ACP) study to be conducted in 42 primary care offices across 7 practice-based research networks (PBRNs) in the United States and Canada. Advance care planning is “a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care. The goal of advance care planning is to help ensure that people receive medical care that is consistent with their values, goals and preferences during serious and chronic illness.”2 The main ACP study trained clinicians and nursing staff in serious illness advance care planning conversations according to the Serious Illness Conversation (SIC) guide developed by Ariadne Labs3 and requested each office refer 30 to 40 eligible patients over an 18-month time period. Eligible patients must (1) be seriously ill or frail, (2) be expected to live 1 to 2 years, and (3) have participated in an advance care planning conversation with trained clinicians and nursing staff. Additionally, eligible patients were required to be community dwelling and have the cognitive abilities to consent to participate in the study. Initially, recruitment was slow. Clinicians and nursing staff expressed that it was difficult to identify and recruit eligible patients.

Three participating IRENE offices used the electronic medical record, Epic. Staff from these offices indicated that it would be helpful if the researchers could identify potentially eligible patients who were scheduled for upcoming office visits. The purposes of this study were to (1) assess whether marking patients on the office schedule for clinicians using the Gagne Index (a validated mortality prediction tool)4 and Epic SlicerDicer (an electronic medical record tool to generate customized patient data reports) increases patient referrals and (2) assess clinician and nursing staff perceptions of implemented strategies to increase their referral of potential subjects.

### Methods

Institutional review board (IRB) approval was obtained for both this study and the main PCORI-funded ACP study. For the main ACP study, 7 PBRNs across the US and Canada were each asked to recruit a total of 42 offices.4 The offices from each PBRN were randomized to 1 of 2 study arms: the clinician-focused Serious Illness Care Program (SICP) or the team-based SICP. Clinician-focused offices were to have only clinicians participating in the SIC. Team-based offices had clinicians, nurses, and medical assistants participating in the conversation; therefore, more clinical staff were enrolled and trained in team-based offices. After having a SIC with patients, clinicians were expected to spend approximately 5 minutes introducing the study to eligible patients. If patients were agreeable, clinicians provided patient names and contact information to the research team for consent and survey completion. Clinicians from each office were expected to refer approximately 2 patients per month for the initial recruitment period of 18 months for a total of 30–40 patients. Each office was asked to recruit a total of 30 patients (180 per PBRN) who consented and completed the baseline and 6-month surveys.

From 3 IRENE PBRN offices, 25 clinicians and nursing staff were trained to have SICs and refer patients to the study. Recruitment was slow in the beginning, and in June of 2019 only 19 patients had been referred by clinicians to the IRENE research team for potential participation (see Table 1).

IRENE research staff were concerned about study enrollment and conducted the study protocol as planned, including quarterly in-person office meetings and regular office contacts. During a quarterly meeting, 1 clinician participating in the study mentioned that EPIC SlicerDicer, a self-service query tool, was in pilot mode and available for staff use to potentially identify patients for referral to the study.

Clinicians also mentioned uncertainties about which patients to involve in ACP conversations. Because of these uncertainties, the research team reviewed the literature regarding prognosis to attempt to find a prognostic index to aid clinicians in determining which patients should be considered for the ACP conversation.6 From their scoping review of 17 unique prognostic indices for 6-month to 5-year all-cause mortality in community-dwelling adults, the research team decided to use the Gagne Index, which was created with community-dwelling adults 65 years and older for an all cause 1-year mortality.7 The Gagne Index was convenient as International Classification of Diseases and Related Health Problems-10 (ICD-10) codes were available for programming in Epic’s SlicerDicer, which allowed the

### Table 1. Monthly Patient Referral Numbers by Office.

| Offices | 1/19 | 2/19 | 3/19 | 4/19 | 5/19 | 6/19 | 7/19 | 8/19 | 9/19 | 10/19 | 11/19 | 12/19 | 1/20 | 2/20 | 3/20 | 4/20 | 5/20 | 6/20 | 7/20 | Total |
|---------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| A       | 0    | 0    | 0    | 1    | 2    | 0    | 0    | 0    | 1    | 1    | 3    | 1    | 6    | 4    | 1    | 1    | 11   | 3    | 2    | 37   |
| B       | 0    | 0    | 1    | 1    | 1    | 0    | 0    | 0    | 3    | 2    | 0    | 3    | 4    | 0    | 2    | 2    | 4    | 7    | 3    | 33   |
| C       | 0    | 0    | 0    | 2    | 2    | 9    | 3    | 0    | 0    | 8    | 4    | 3    | 1    | 4    | 7    | 0    | 3    | 4    | 0    | 50   |
| Total   | 0    | 0    | 1    | 4    | 5    | 9    | 3    | 0    | 4    | 11   | 7    | 7    | 11   | 8    | 10   | 3    | 18   | 14   | 5    | 120b |

*aIRB not approved by central IRB.

*Goal: 30 to 40 patients referred per office.
research team to customize searches based on the Gagne Index components. Gagne Index components include medical diagnoses such as alcohol abuse, congestive heart failure, liver disease, and weight loss. After limiting the SlicerDicer report to a specific office, 20 reports were generated for each of the Gagne Index medical diagnoses. Those reports were exported, compiled, and imported into the statistical package SPSS, where the appropriate weight for each medical diagnosis was calculated and a mortality risk score was generated for each patient. Participating clinicians each received a secure e-mail with an Excel document that included all patients that appeared on the SlicerDicer list for their specific office. Mortality risk ranged from 2.4% to 46.8%, and each list included between 2000 and 3000 patients. The Excel file was sorted so that patients with the highest mortality risk appeared on top.

During subsequent quarterly meetings, clinicians indicated that the Excel lists were cumbersome. They asked if the patients included on the Excel lists could be marked on the upcoming office appointment schedule. The University of Iowa Privacy Officer was consulted to determine whether research staff could make notes on the electronic medical record. While waiting for approval from the University of Iowa Privacy Officer, nursing staff made notes on the electronic medical record.

The research team e-mailed patient names to clinicians and nursing staff at Office A starting on November 4, 2019. At offices B and C, nursing staff indicated they could use the Excel list to mark upcoming patients on the office schedule. Nursing staff were not required to have permission from the UIHC Privacy Officer to mark on the schedule, meaning those offices could move forward with patient identification on the schedule immediately. A nurse manager marked patients for Office C starting on September 29, 2019. However, this nurse manager marked all patients that she found on the list, even if the mortality risk was lower than 14.6%. Although Office B also indicated they had staff that could mark on the schedule in October of 2019, it was later discovered that staff were not marking potential patients on the schedule as planned. Once the Privacy Officer approved and Epic write privileges were granted in December of 2019, a research staff (MES) made notes each week for the upcoming scheduled patients at all 3 offices.

Descriptive statistics were calculated for the questionnaire responses and number of patient referrals from February 11, 2019 through July 31, 2020 for the ACP study. A Wilcoxon signed-rank test was conducted to compare patient referral numbers before and after the Gagne Index/Epic SlicerDicer intervention implementation. The patient referral time period was approximately 9 months before and 9 months after the Gagne Index/Epic SlicerDicer intervention. When running the before and after recruitment numbers, we controlled for timing of the Slicer/Dicer intervention and the number of clinic sessions per clinician since the intervention was not implemented at the same time in each office. All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Seven clinicians referred patients to the study prior to and 11 clinicians referred patients after the Gagne Index/Epic SlicerDicer intervention (see Figure 1). Clinicians B-2 and C-4 did not refer patients before or after the intervention. Clinicians referred a total of 31 patients to the study prior to and 89 patients after the Gagne Index/Epic SlicerDicer implementation. The medians before and after the intervention were 0.8 and 3.2 patients per 100 clinic sessions, respectively (P = .002).

Fourteen (70%) of 20 potential clinicians and nursing staff respondents responded to the survey. Eleven (79%) of survey respondents were female. Respondents had a mean of 13.7 years of practice in their current profession. Respondents indicated that patients identified as potentially eligible noted on the schedule, quarterly meetings with the study team, and e-mails with a list of upcoming patients from the SlicerDicer/Gagne List facilitated referrals. Barriers to recruitment included uninterested patients, ineligible patients, and lack of time for ACP. See Table 2 for complete survey results.

Clinical trials often have difficulty attaining their target sample size, which jeopardizes the integrity of study findings. In an early review of 41 clinical trials, approximately two-thirds of the studies did not achieve their target patient sample size.7 This held true for our study, despite the fact that recruitment goals were relatively modest and there
were many modes of communication by research staff to office physicians and staff. Research has been conducted testing electronic medical record alerts to encourage physicians to consider patients for specific research trials. In 2005, an electronic medical record clinical trial alert (CTA) was implemented in selected outpatient clinics at a large academic health center in the United States after 12 months of recruitment through physicians via posters and physician in-service. The CTA resulted in a significant increase in referrals after alert implementation (5 before and 42 after).8

Even though alerts are available to enhance physician recruitment of subjects, numerous barriers continue to hinder recruitment; these include competing research trials, lack of time, under-resourced staff, workload, trial-specific requirements, inadequate research experience and training of physicians, lack of financial incentive or rewards, and clinicians viewing trials as criticism of their current practices.9-11 Furthermore, as can be seen in our study where physician members of PBRNs were involved in recruitment, an electronic alert may not be feasible since offices have different electronic medical records and centralized research staff may not be able to gain permission to access a specific office’s medical record for recruitment purposes. Much training and support are necessary if clinicians and nursing staff are asked to recruit patients for trials, and they must be willing to approach all eligible patients.12 Notifying clinicians and nursing staff about patients who were potentially eligible for an advance care planning study led to a statistically significant increase in patient study referrals per clinic session for our ACP study.

Most patients identified as potentially appropriate for our study were not ever referred to the study. Previous research indicated that under-resourced staff, workload, competing trials, ability of health care workers to explain studies to patients, and uninterested patients were all barriers to study recruitment.9 A plethora of research indicates that limited time was a major barrier for trial recruitment.9,11,13 Clinicians and nursing staff participating in this study indicated that some patients identified by the research team were inappropriate, some patients refused to participate, and sometimes the clinicians and nurses did not have time to address ACP. Patients that appeared to be appropriate for ACP based on the Gagne mortality risk index did not always meet study eligibility criteria.

A subset of patients were identified via e-mail to the clinician or with a note on the schedule by the research team 4 or 5 times prior to study referral by clinicians or nursing staff. Many reasons could be identified for why clinicians may not refer a patient the first time they were notified the patient might be appropriate for ACP. For example, the patient may have been appropriate for ACP, but the encounter was inappropriate or the clinician may have run out of time.

Finally, clinical staff have competing demands and may forget about studies. Clinical staff participating in our study admitted during quarterly meetings that they did, at times, forget about our study. Therefore, regular communication
with as many participating staff as possible is crucial when clinical staff are involved in study recruitment.

**Limitations**

There are several limitations to this study. Because the overall goal was to increase patient recruitment, implementation of strategies occurred as needed and it was not possible to determine with certainty which strategies, if any, increased patient referrals to the study. The clinician and nursing staff survey provided researchers with valuable information as to which strategies clinical staff perceive to be beneficial for study referrals and recruitment. The survey results indicate that multiple strategies facilitated referrals, some of which, including EMR alerts\(^5\) and effective communication with the study team,\(^14\) have also been identified in previous research.

There were a small number of participating clinicians in this study, and they were not equally invested in recruitment. One clinician participating in the study was also a member of the research team, and most of the early referrals from that office came from her. One trained clinician left her practice before recruitment ended, and 2 clinicians were trained a few months after recruitment started. Participating clinicians had different patient panels, and they all spent different amounts of time in clinic. Some clinicians were out for extended vacations, maternity leave, or illness, and some clinicians had other responsibilities and were only in clinic part-time.

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**Table 2. Clinician and Nursing Staff Perceptions of ACP (n = 14).**

| Questions                                                                 | n (%) |
|---------------------------------------------------------------------------|-------|
| ACP is part of my routine:                                                |       |
| Always/usually                                                            | 2 (14) |
| About half the time                                                       | 3 (21) |
| Seldom/not at all                                                         | 9 (65) |
| Estimated percentage of time SIC guide is used:                           |       |
| 0-25%                                                                    | 7 (50) |
| 26-75%                                                                   | 5 (36) |
| 76-100%                                                                  | 2 (14) |
| Estimated percentage of patients per clinician who had SIC referred to study: |       |
| 0-25%                                                                    | 4 (29) |
| 26-75%                                                                   | 3 (21) |
| 76-100%                                                                  | 6 (43) |
| Estimated number of unique patients per clinician the SIC guide was used with: |       |
| 1-10                                                                     | 10 (72) |
| 11-20                                                                    | 3 (21) |
| 21+                                                                      | 1 (7)  |
| Factors that hindered clinician referrals to the study:                   |       |
| Patients were not interested in participating in the study                | 11 (55) |
| Patients did not meet eligibility requirements                             | 8 (40) |
| I did not have time to use the SIC guide                                  | 7 (35) |
| I forgot about the study                                                  | 4 (20) |
| It did not fit in our clinic workflow                                     | 4 (20) |
| I was uncomfortable with the SIC guide                                    | 2 (10) |
| Turnover in clinic staff                                                  | 1 (5)  |
| Not enough clinicians/team members trained to use the SIC guide           | 1 (5)  |
| Not enough clinicians/team members participating in the study             | 1 (5)  |
| Strategies that facilitated clinician referrals to the study:              |       |
| Patients identified as potentially eligible noted on the schedule         | 10 (50) |
| Quarterly meetings with the study team                                    | 8 (40) |
| E-mail with full list of patients from Slicer Dicer/Gagne List            | 4 (20) |
| E-mails with list of upcoming patients from Slicer Dicer/Gagne List       | 4 (20) |
| Sense of obligation                                                       | 3 (15) |
| Food/treats provided by study team                                        | 2 (10) |
| Patient identification handout                                            | 2 (10) |
| Office specific patient brochure provided by IRENE                         | 2 (10) |
Conclusions

Notifying clinical staff about potentially eligible study participants increased patient referrals in this advance care planning study. Involving clinicians and nursing staff in patient recruitment for a study is difficult, especially if research staff do not work in the office. Study planning should include significant research staff time to support and encourage clinical staff as they refer patients to the study. It takes time for workflows to change and allow recruitment to get “off the ground,” so study protocols and timelines must allow an adequate length of time for recruitment. More research should be conducted to determine whether assisting clinical staff with identification of appropriate patients can increase patient referrals to trials.

Authors’ Note

All statements presented in this publication, including its findings and conclusions, are solely the responsibility 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.

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Trial Registration

NCT03577002 (https://clinicaltrials.gov/ct2/show/NCT03577002)

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References

1. Sellors J, Cosby R, Trim K, et al. Recruiting family physicians and patients for a clinical trial: lessons learned. Fam Pract. 2002;19:99-104.
2. Sudore RL, Lum HD, You JJ, et al. Defining advance care planning for adults: a consensus definition from a multidisciplinary Delphi Panel. J Pain Symptom Manage. 2017;53:821-832.e1.
3. Bernacki R, Hutchings M, Vick J, et al. Development of the Serious Illness Care Program: a randomised controlled trial of a palliative care communication intervention. BMJ Open. 2015;5:e009032.
4. Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64:749-759.
5. Totten AM, Fagnan LJ, Dorr D, et al. Protocol for a cluster randomized trial comparing team-based to clinician-focused implementation of advance care planning in primary care. J Palliat Med. 2019;22:82-89.
6. Kim P, Daly JM, Berry-Stoezlle MA, et al. Prognostic indices for advance care planning in primary care: a scoring review. J Am Board Fam Med. 2020;33:322-338.
7. Charlson ME, Horwitz RI. Applying results of randomised trials to clinical practice: impact of losses before randomisation. Br Med J (Clin Res Ed). 1984;289:1281-1284.
8. Embi PJ, Jain A, Clark J, Bizjack S, Hormung R, Harris CM. Effect of a clinical trial alert system on physician participation in trial recruitment. Arch Intern Med. 2005;165:2272-2277.
9. Duncan M, Korszun A, White P, Eva G; SURECAN Investigators. Qualitative analysis of feasibility of recruitment and retention in a planned randomised controlled trial of a psychosocial cancer intervention within the NHS. Trials. 2018;19:327.
10. Rahman S, Majumder MA, Shaban SF, et al. Physician participation in clinical research and trials: issues and approaches. Adv Med Educ Pract. 2011;2:85-93.
11. Spaar A, Frey M, Turk A, Karrer W, Puhan MA. Recruitment barriers in a randomized controlled trial from the physicians’ perspective: a postal survey. BMC Med Res Methodol. 2009;9:14.
12. Donovan JL, Paramasivan s, de Salis I, Toerien M. Clear obstacles and hidden challenges: understanding recruiter perspectives in six pragmatic randomised controlled trials. Trials. 2014;15:5.
13. Sahin D, Yaffe MJ, Sussman T, McCusker J. A mixed studies literature review of family physicians’ participation in research. Fam Med. 2014;46:503-514.
14. Raferty J, Bryant J, Powell J, Kerr C, Hawker S. Payment to healthcare professionals for patient recruitment to trials: systematic review and qualitative study. Health Technol Assess. 2008;12:1-128, iii.