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Behavioural economic interventions to embed palliative care in community oncology (BE-EPIC): study protocol for the BE-EPIC randomised controlled trial

Ravi B Parikh,1,2 Ramy Sedhom,1 William J Ferrell,1,2 Katherine Villarin,2 Kara Berwanger,1,2 Bethann Scarborough,3 Randall Oyer,3 Pallavi Kumar,1,2 Niharika Ganta,2 Shanthi Sivendran,3 Jinbo Chen,1,2 Kevin G Volpp,2,4 Justin E Bekelman1,2

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ BE-EPIC utilises a cluster-randomised design at the physician pod-level to reduce contamination in a community oncology setting which improves external validity.
⇒ Our study incorporates behavioural economic principles that remove barriers to ordering consults in the context of clinical practice.
⇒ We use validated, patient-centric language from a standardised source to remove clinician-to-clinician variability in the introduction to palliative care.
⇒ Key limitations include (1) single-institution setting; (2) requirement for manual chart review to assess eligibility; and (3) use of default and opt-out strategies without other behavioural economic strategies.

ABSTRACT

Introduction Palliative care (PC) is a medical specialty focusing on providing relief from the symptoms and stress of serious illnesses such as cancer. Early outpatient specialty PC concurrent with cancer-directed treatment improves quality of life and symptom burden, decreases aggressive end-of-life care and is an evidence-based practice endorsed by national guidelines. However, nearly half of patients with advanced cancer do not receive specialty PC prior to dying. The objective of this study is to test the impact of an oncologist-directed default PC referral orders on rates of PC utilisation and patient quality of life.

Methods and analysis This single-centre two-arm pragmatic randomised trial randomises four clinician-led pods, caring for approximately 250 patients who meet guideline-based criteria for PC referral, in a 1:1 fashion into a control or intervention arm. Intervention oncologists receive a nudge consisting of an electronic health record message indicating a patient has a default pended order for PC. Intervention oncologists are given an opportunity to opt out of referral to PC. Oncologists in pods randomised to the control arm will receive no intervention beyond usual practice. The primary outcome is completed PC visits within 12 weeks. Secondary outcomes are change in quality of life and absolute quality of life scores between the two arms.

Ethics and dissemination This study has been approved by the Institutional Review Board at the University of Pennsylvania. Study results will be disseminated in peer-reviewed journals and scientific conferences using methods that describe the results in ways that key stakeholders can best understand and implement.

Trial registration number NCT05365997.

INTRODUCTION

Patients with advanced cancer have poor quality of life and life expectancy.1 Palliative care (PC) is a medical specialty focusing on providing relief from the symptoms and stress of serious illnesses such as cancer.2 PC can be provided in the outpatient, hospital or home-based settings.3–6 Early outpatient specialty PC has been shown to improve quality of life, improve patient-reported mood and anxiety, reduce aggressive end-of-life care and possibly improve overall survival among patients with advanced cancer.7–9 Nevertheless, most patients with cancer die without receiving a specialty PC consultation.9 Two key barriers to PC adoption include (1) inadequate identification of patients with high PC need who may need timely referral10; and (2) cognitive biases among clinicians that may preclude change from the status quo of PC referral only late in the course of illness.11 Criteria for PC referrals do exist.12,13 Pairing objective identification of appropriate patients with changes to choice architecture for clinicians may prompt greater and earlier PC referral.14 No prospective trial has evaluated whether a clinician default nudge impacts PC utilisation among patients with advanced cancer. The objective of this study is to test the impact of an intervention consisting of (1) proactive identification of...
patients who meet evidence-based criteria for specialty PC consultation, and (2) an electronic health record-based default PC referral order directed to the oncology team, on rates of PC utilisation. Our study objective is to assess the impact of an intervention consisting of default PC referral orders with an opt-out option to oncologists, based on evidence-based clinical criteria, on rates of PC referrals and utilisation among patients with advanced solid cancers. The primary study hypothesis is that default PC referrals directed to clinicians, with an opt-out option, will increase rates of PC utilisation in a community oncology setting. Secondary hypotheses are that default referral orders will improve patient-reported quality of life at 9 weeks.

METHODS AND ANALYSIS

Study overview
We describe the design and methods for a single-centre two-arm pragmatic randomised trial among approximately 250 outpatients with advanced cancer. We plan to assess the impact of an intervention consisting of default PC referral orders with an opt-out option to oncologists, based on evidence-based clinical criteria, on rates of PC referrals and utilisation among patients with advanced solid cancers.

Study setting
Recruitment for the trial is ongoing at the Ann B. Barshinger Cancer Institute (ABBCI), a large community medical oncology practice consisting of 12 physicians and 8 advance practice providers at Lancaster General Health. We plan to recruit approximately 250 patients who meet PC eligibility criteria based on National Comprehensive Cancer Network (NCCN) guidelines.15

Eligibility criteria
The study cohort consists of patients who are receiving ongoing cancer treatment or survivorship care from haematology/oncology clinicians within ABBCI (see table 1). Patients are required to have a functional telephone number. From this cohort, we recruit patients who meet one of the following guideline-based criteria for PC referral (see Participant screening section).

We exclude new patient visits, as these appointments generally focus on introductions and discussing treatment plans. We exclude patients on active interventional trials—including trials of investigational agents—because such trials generally involve frequent visits, on which layering PC may be overly burdensome to the patient. We also exclude patients who previously received PC or were enrolled in hospice care, because generally once patients are enrolled in PC and hospice, future PC visit scheduling is at the discretion of the PC practitioner. Finally, we exclude patients who receive primary oncologic care from another institution.

Participant screening
Each week, two trained clinical research coordinators (CRCs) scan the electronic health record to identify upcoming medical or gynecologic oncology appointments for patients who meet eligibility criteria with an ABBCI MD (Doctor of Medicine) or APP (Advanced Practice Provider) for the following week. From this cohort, the CRCs identify patients in both intervention and control pods with solid malignancies who are appropriate for PC referral, based on a select subset of NCCN Guidelines for Palliative Care v1.2021 (see table 2).15

Randomization
Each of the 12 medical and gynecologic oncologists at ABBCI are assigned to one of four pods, which see common sets of malignancies and have separate advance practice provider staff and patient inbox response teams. Additionally, if one clinician is away, another clinician or APP within the pod may be responsible for the management of a patient. Because of the pod-based structure in our study setting, clinician-level randomisation in our study was not feasible because of the risk of contamination—spillover of patients between intervention and control groups if a physician’s patient was managed by another physician or APP within the same pod. For that reason, we opted to randomise each of the four pods to either the control or intervention arms, in 1:1 fashion; pod-level randomisation lowers the possibility of contamination considerably. We matched pods by volume such that approximately 50% of all patients who met PC eligibility criteria were seen

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Inclusion and exclusion criteria</th>
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<tr>
<td><strong>Inclusion</strong></td>
<td><strong>Exclusion</strong></td>
</tr>
<tr>
<td>Have a functional telephone number</td>
<td>Patients appearing for a new patient visit</td>
</tr>
<tr>
<td>Receive ongoing care from haematology/oncology clinicians (physicians or advance practice providers) within the ABBCI at Penn Medicine Lancaster General Health</td>
<td>Patients who have previously received specialty PC consultation referral</td>
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<td></td>
<td>Patients who are enrolled in an ongoing clinical trial of a therapeutic agent</td>
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<td></td>
<td>Patients who receive primary oncologic care within another institution</td>
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ABBCI, Ann B. Barshinger Cancer Institute; PC, palliative care.
by two pods, and 50% were seen in the other two pods (see online supplemental figure 1). We used a random number generator to randomise one cluster of two pods to the intervention arm and the other cluster of two pods to the control arm (see figure 1). The principal investigator and primary statistical analyst are blinded to arm assignment until the trial follow-up completes.

**Interventions**

Prior to the trial, the CRC randomised each cluster of two pods in a 1:1 fashion to either intervention or usual care. Patients whose pods are randomised to the control arm will receive usual care; PC consultation will be ordered at the discretion of the treating clinician with no nudge from the clinical research staff. Patients in the control arm will still receive regular quality of life questionnaires.

For pods (and their associated clinicians) randomised to the intervention arm, the intervention consists of a clinician opt-out nudge (see figure 2). Using EPIC staff message, the CRC sends a nudge to the clinician that states that the ABBCI has identified their patient may benefit from a PC consult. Only oncologists can opt out by responding to the EPIC staff message with ‘.optout’. If the clinician does not opt out within 4 days, the CRC contacts the patient to offer PC and, if the patient agrees, places the referral order. The nudge also requests that the clinician prepare their patient for the PC outreach at the next visit.

On receiving the PC order placed by the CRC, the scheduler at ABBCI calls the patient to schedule an appointment with the PC team. Ideally, this appointment coincides with one of the patient’s existing visits.

**Recruitment and retention**

**Patient outreach for PC**

Patients who are not opted out to receive a PC consult are called by the CRC. The CRC introduces PC and asks if they are interested in scheduling an appointment (see figure 3). The CRC contacts the patient a maximum of three times if they do not answer. We prepared responses to ‘Frequently Asked Questions’ that patients may ask during the outreach call (see online supplemental table 1). The list included appropriate responses to questions such as ‘Does this mean I’m dying?’ or ‘Does palliative care equal hospice?’ If the patient accepts the referral, the CRC uses an EPIC order that triggers a phone call from schedulers on the PC team. If the patient refuses or

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**Table 2** Palliative care eligibility criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale/guideline basis</th>
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<tr>
<td>Patient has a solid malignancy</td>
<td>Prior evidence basis for early palliative care is predominantly in solid malignancies</td>
</tr>
<tr>
<td>Documented advanced solid malignancy (Stage IV)</td>
<td>American Society for Clinical Oncology (ASCO) Guidelines</td>
</tr>
<tr>
<td>Central nervous system metastasis</td>
<td>Center to Advance Palliative Care (CAPC) Guidelines</td>
</tr>
<tr>
<td>Documented ECOG (Eastern Cooperative Oncology Group) performance status &gt;2; KPS &lt;50</td>
<td>National Comprehensive Care Network (NCCN) Guidelines</td>
</tr>
<tr>
<td>Uncontrolled symptoms (ie, pain, escalating opioids, nausea/vomiting, distress, dyspnoea, delirium)</td>
<td>National Comprehensive Care Network (NCCN) Guidelines</td>
</tr>
<tr>
<td>Hospitalisation relevant to cancer or treatment or ICU admission within the past 30 days, &gt;2 emergency room visits in the last 90 days</td>
<td>National Comprehensive Care Network (NCCN) Guidelines</td>
</tr>
</tbody>
</table>

ICU, intensive care unit.
declines a referral, the CRC notes the patient’s reason, if one is offered, and thanks the patient for their time. If the patient wishes to speak to their physician before deciding, the CRC follows up with the physician to see whether the discussion was had at the visit and a referral was placed.

**Patient follow-up**

Patients are followed for 24 weeks after the index encounter. We assess completion of PC visits periodically during the follow-up period for each patient. For patients who agree to a PC consultation, a repeat prompt to the schedulers is placed if the patient does not have a PC visit scheduled within 2 weeks of accepting the referral.

**Questionnaire administration**

All patients who have a PC consultation scheduled in the intervention group and 40 randomly selected patients in the control group receive quality-of-life assessments using the Functional Assessment of Cancer Therapy-General (FACT-G) assessment. The first quality-of-life assessment takes place before the initial PC visit (intervention group) or index encounter (control group). Patients are first introduced to the study and asked if they are interested in hearing more. If not, patients are thanked for their time, and if interested, the CRC walks through a verbal consent script (online supplemental appendix A). This script notes the study’s purpose, duration and minimal risk status. If patients consent to survey administration, the CRC first administers an enrolment questionnaire (online supplemental appendix B), after which the CRC administers the FACT-G survey via telephone. If the patient does not pick up the phone call to administer the survey, the attempt is repeated three times, after which the survey attempt is classified as ‘missed’. If the patient declines to participate in quality-of-life assessment, the CRC goes over a study decline consent (online supplemental appendix C) and subsequently a study decline enrolment questionnaire (online supplemental appendix D). The FACT-G survey is repeated at 3, 6, 9 and 18 weeks (online supplemental appendix E).

**Subject compensation**

No compensation is offered to clinicians in the intervention. Patients in either the intervention or control arms who complete a FACT-G survey at 9 weeks or earlier are offered a US $50 gift card at the 9-week timepoint. The CRC delivers a gift card to each patient electronically or via their preferred mailing address shortly after they complete their 9-week FACT-G survey.

**Data safety and monitoring**

In usual care, at the time of a patient visit with a medical or gynecologic oncology clinician, clinicians may counsel patients on the availability of PC. This practice will continue in the trial, and patients are reminded that they can discuss PC consultation with their clinician at any time point. The investigators provide oversight for the study evaluation of this health system initiative. Both the PI and CRC are notified if a patient reports any concerns with the trial or the proactive outreach for PC. Responses on the FACT-G questionnaire are not automatically fed back to providers; however, the CRCs encourage patients to bring up quality-of-life concerns to their clinician. If the CRC deems that a patient response involves a life-threatening or concerning symptom, she will discuss it immediately with the patient’s oncology care team.

**Consent**

A waiver of informed consent for the delivery of the PC nudge was granted by the University of Pennsylvania and the University of Pennsylvania Institutional Review Board.
Table 3  Primary and secondary outcomes of the study

<table>
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<tr>
<th>Primary outcome</th>
<th>▶ Completed PC visits within 12 weeks</th>
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<td>Secondary outcomes</td>
<td>▶ Change in quality of life between 0 and 9 weeks (as measured by the FACT-G among patients who receive PC compared with controls)</td>
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<td></td>
<td>▶ Absolute quality of life at 9 weeks (as measured by the FACT-G among patients who receive PC compared with controls)</td>
</tr>
<tr>
<td>Exploratory outcomes</td>
<td>▶ Unplanned 30-day emergency room and hospitalisation rates (among all patients)</td>
</tr>
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<td></td>
<td>▶ Metrics of aggressive end-of-life care (systemic therapy within 14 days before death, no hospice enrolment prior to death; hospice enrolment &lt;3 days before death) among decedents</td>
</tr>
<tr>
<td></td>
<td>▶ Documented advance care planning or serious illness conversations in the outpatient medical record</td>
</tr>
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<td></td>
<td>▶ Hospice referral and enrolment</td>
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<td></td>
<td>▶ Overall survival, defined as date from enrolment to death</td>
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</table>

FACT-G, Functional Assessment of Cancer Therapy-General; PC, palliative care.

Penn Medicine Lancaster General Hospital IRBs (Institutional Review Boards), owing to the fact that this trial involves a health system initiative that would be implemented and the study is to evaluate that initiative. Prior to launching the study, the research team introduced all medical oncology, gynecologic oncology and PC team clinicians to the trial at a regularly scheduled team meeting. The PI and CRCs reviewed the design, background and desired outcomes. We obtained verbal consent from all providers to administer opt-out messages to clinicians, recruit patients into the study and administer FACT-G questionnaires at the prespecified intervals. As the study does not limit clinical care in any way, clinician consent was obtained verbally.

Patients who are selected for quality-of-life surveys are consented over the phone for administration of FACT-G surveys at baseline and at 3, 6, 9 and 18 weeks after enrolment (see online supplemental appendix A). On this call, the CRC explains the study’s purpose and minimal risks of participation (minor risk of loss of confidentiality). The CRC also notes that the survey does not impact the patient’s care and communication with their doctor, and that involvement is completely voluntary. Lastly, the CRC notes the compensation of US$50 for completion of surveys at the 9-week timepoint.

Outcomes
The primary outcome of the study is a completed visit with a specialty PC clinician (see table 3). This outcome will be derived from a manual review of the electronic health record.

Secondary outcomes include change in quality of life between 0 and 9 weeks (as measured by the FACT-G among patients who receive PC compared with matched controls), and absolute FACT-G score at 9 weeks.

Exploratory outcomes include unplanned 30-day emergency room and hospitalisation rates (among all patients), metrics of aggressive end-of-life care (systemic therapy within 14 days before death, no hospice enrolment prior to death; hospice enrolment <3 days before death) among decedents, documented advance care planning or serious illness conversations in the outpatient medical record, hospice referral and enrollment among all patients and overall survival, defined as date from enrolment to death.

Analysis plan
We use REDCap, a HIPAA-compliant and secure database tool, to track all components of the study. Descriptive statistics will be used to estimate the frequencies, means and SD of the study variables. Differences between study groups in baseline characteristics and clinical outcomes will be assessed with the use of two-sided Fisher’s exact tests and \( \chi^2 \) tests for categorical variables and independent-samples Student’s t-tests for continuous variables. The unit of analysis will be the patient.

The primary study endpoint is a binary patient-level variable indicating completion of a PC visit within 24 weeks of the clinician behavioural nudge. This analysis will be conducted as a time-to-event analysis among all eligible patients with advanced cancer. Cox proportional hazard regression analyses, adjusted for baseline covariates, will be used to examine the effect of nudges on completion of PC consultation for patients with advanced cancer. The within-pod correlation is adjusted for by including a pod-specific fixed effect. Competing risk caused by patients who die within 24 weeks or who enrol in hospice will be considered as censored in the analysis. Covariates will include patient and cancer-related variables. Patients will be followed for 24 weeks or until death or hospice enrolment. Using a two-sided type I error rate of 0.05 and a baseline PC visit rate of 20% (SD 10%), we expect a sample size of 250 patients will give us 80% power to detect a meaningful 34 percentage point response in PC visits, considering the presence of a competing risk of 6-month mortality or hospice enrolment at 20%. Given that we assumed a very conservative 50% opt-out rate, we felt that this effect size was reasonable to expect from a default intervention. In exploratory analyses, we will also analyse the impact of the nudge on PC referrals for patients who did not meet PC eligibility criteria to evaluate spill-over effects.
Quality of life secondary outcomes will be assessed using multivariate linear regression analyses. For intention-to-treat analyses, we will use the conservative method of carrying the most recent quality-of-life values forward to account for all missing data, including data that are missing owing to death.

**Patient and public involvement**

Patient participants were not involved in the development of the research question or outcome measures. Physician participants were involved in the design of the electronic health record nudge and the referral criteria; physicians were engaged in team meetings at Lancaster General Hospital to comment on these items. Physicians were also aware of the FACT-G survey and provided feedback that led to its selection as our quality of life measure.

**DISCUSSION**

Despite early PC consultations being a guideline-concordant practice, PC referral rates for patients with stage IV disease are low. Behavioural economic principles can be leveraged to address suboptimal clinician decision-making biases that influence PC referrals. In this trial, we will evaluate the impact of an intervention that utilises a default PC referral order, based on evidence-based criteria, to prompt PC visits among outpatients with advanced cancer.

This study has several strengths, including its (1) cluster-randomised design at the physician pod-level; (2) pragmatic nature that includes patients with multiple types of advanced cancer in a community oncology setting, where outpatient specialty PC availability is limited; (3) use of clinician-centred defaults that remove barriers to ordering consults in the context of busy clinical practice; (4) use of validated, patient-centric language from a standardised source to remove clinician-to-clinician variability in the introduction to PC; and (5) study of patient-centric outcomes to capture the impact of this pragmatic nudge on quality of life.

Limitations include (1) its single-institution setting and (2) requirement for manual chart review and delivery of clinician defaults; inability to incorporate other validated behavioural strategies, including accountable justification (where clinicians would be forced to explain why they are opting out of a PC referral). These technical limitations are shared across many community oncology practices; thus, despite known limitation, this study is likely to provide novel data on the impact of a low-tech strategy to guide earlier PC for a generalisable population of oncology patients.

There has been a persistent effort in oncology to address low rates of PC referrals and goal-concordant care. This trial uses a pragmatic randomised trial design to evaluate if behavioural nudges can increase PC referrals among outpatients with advanced cancer. Results from this trial may inform the design of future randomised trials testing default orders and similar algorithm-based interventions.

On completion, we plan to develop a semi-structured interview guide and conduct qualitative analysis among MD and APP participants in the trial. If successful, future directions of this work include a large, multi-health system study to test the generalisability of clinician nudges to improve PC referrals and a well-powered study to assess the impact of clinician nudges on end-of-life care utilisation and outcomes.

**Ethics**

This study has been approved by the University of Pennsylvania IRB (protocol #849498). This trial is registered with clinicaltrials.gov with the official title ‘Behavioral Nudges to Improve Palliative Care Utilization in Advanced Cancer’.

The potential risks to human subjects in this project include (1) risks of breach of confidentiality of personal health information, (2) risks of participants misinterpreting this tool as a means of quick communication with their care team and (3) risks of a breach of data for participating clinicians. To minimise these risks, our study employs numerous safeguards to protect human subjects. These include an experienced and well-trained study team, a robust informed consent process, state-of-the-art data security and ongoing emphasis that this intervention is investigational and not a replacement for usual means of communication with patients’ care teams.

**DISSEMINATION**

We anticipate collection of data for all outcomes will be complete in November 2022. In addition to presentation at scientific meetings and publication in scholarly journals, we plan to leverage resources at the University of Pennsylvania to place our results in the public domain where they can be openly discussed before any policy changes are recommended. This includes developing and implementing strategies to describe results in ways that key stakeholders can understand and implement.

**Author affiliations**

1Penn Center for Cancer Care Innovation, Abramson Cancer Center, University of Pennsylvania, Philadelphia, Pennsylvania, USA
2Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA
3The Ann B. Barshinger Cancer Institute, Penn Medicine Lancaster General Health, Lancaster, Pennsylvania, USA
4Center for Health Incentives and Behavioral Economics, University of Pennsylvania, Philadelphia, Pennsylvania, USA

**Contributors**

RBP conceptualised the study design and obtained the funding. RBP, RS, BS, RD, PK, NG, SS, KGV and JEB contributed to the development of the study design. WJF, KV, KB and GS were responsible for the development of the data collection platform, field testing of the study logistics, including clinic and subject recruitment. RBP and JC are responsible for the development of the analysis plan. RBP, WJF, KV and KB drafted the first version of the manuscript. All authors read, edited and approved the final version.

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**ORCID iDs**  
Ravi B Parikh [http://orcid.org/0000-0003-2692-6306]
William J Ferrell [http://orcid.org/0000-0001-9966-1973]

**REFERENCES**