Behavioral Nudges to Improve Palliative Care Utilization in Advanced Cancer

Study Protocol

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Outline

1. Abstract

Patients with cancer often undergo costly therapy and acute care utilization that is discordant with their wishes, particularly at the end of life. Despite early palliative care consultations being an NCCN guideline-concordant practice in advanced cancer, palliative care referral rates for stage IV patients are low. In this project, we will evaluate a health system initiative that uses behavioral nudges to prompt palliative care referrals among outpatients with advanced cancer in terms of successful palliative care referrals and downstream quality of life outcomes. In partnership with the health system, this will be conducted as a 2-arm pragmatic cluster randomized trial.

2. Overall objectives

The primary objective of the study is to evaluate the impact of sending behavioral nudges to clinicians, as compared to usual practice, on completion of palliative care referrals among patients with advanced cancer. Our secondary objectives are to identify the impact of prompted palliative care referrals on quality of life, acute care utilization, and end-of-life utilization.

3. Aims

3.1 Primary outcome

The primary outcome of the study is palliative care visits

3.2 Secondary outcomes

- Change in quality of life between 0 and 9 weeks (as measured by the Functional Assessment of Cancer Therapy – General (FACT-G) among patients who receive palliative care compared to matched controls) (**Appendix A**)
- Quality of life at 9 weeks (as measured by the Functional Assessment of Cancer Therapy – General (FACT-G) among patients who receive palliative care compared to matched controls)

3.3 Exploratory outcomes

- Unplanned 30-day emergency room and hospitalization rates (among all patients)
- Metrics of aggressive end-of-life care (systemic therapy within 14 days before death, no hospice enrollment prior to death; hospice enrollment <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
- Overall survival, defined as date from enrollment to death

4. Background

Patients with advanced cancer have poor quality of life and life expectancy.[1] Palliative care is a medical specialty focusing on providing relief from the symptoms and stress of serious illnesses such as cancer.[2] While palliative care referrals often occur in the inpatient setting for acutely ill individuals[3], early outpatient specialty palliative care concurrent with cancer-directed treatment improves quality of life and survival, is an evidence-based practice, and is endorsed by national guidelines.[4–8] Palliative care can be provided in the ambulatory, telemedicine, or home-based settings.[3,6,9,10] However, nearly half of patients with advanced cancer do not receive palliative care prior to dying.[11,12] Lack of standardized referral criteria and screening methods for palliative care contributes to underutilization. There is a high need for strategies to increase use of palliative care in oncology.[13,14]

Clinicians underutilize palliative care, initiating referrals a median of 2 months before death.[15] This *status quo bias*, which predisposes clinicians to continue current practice even if not the optimal option, may lead to delayed or missed palliative care referrals.[16] Additionally, *optimism bias,* the cognitive bias that causes clinicians to believe that their own patients are at lesser risk of negative outcomes, may cause clinicians to underestimate a patient's mortality risk or symptom burden, thus delaying palliative care referral.[17] Finally, *overconfidence bias,* the propensity to overestimate one's desired behaviors when it is not objectively reasonable, may lead clinicians to incorrectly believe they are initiating more palliative care referrals than their peers.[18]

Overcoming suboptimal clinician decision-making biases are key to increasing palliative care referrals. Principles from behavioral economics can inform "nudges" that change how clinicians receive information and make choices such as palliative care referral.[19] Default, opt-out nudges that make the optimal choice the path of least resistance can mitigate clinicians' status quo bias.[19] Reframing clinicians' prognoses by providing data-driven life expectancy assessments may combat optimism bias.[17]

Early palliative care intervention can improve quality of life for patients with advanced cancer. Outpatient palliative care is available at 98% of NCI-designated cancer centers and 63% of non-NCI centers.[20] Early outpatient palliative care concurrent with cancer-directed treatment improves quality of life, reduces symptom burden, and decreases rates of aggressive end of life care.[4,5] Nevertheless, only a minority of patients who qualify for palliative care receive it.

--References--

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5. Study design

5.1 Design

This is a 2-arm pragmatic randomized trial among approximately 250 outpatients with advanced cancer to assess response to behavioral nudges to refer to palliative care. The setting will be outpatient oncology at the Ann B. Barshinger Cancer Institute at Lancaster General Health. Eligible clinicians will be randomized in clusters by overlapping clinical team (pod) to receive default EPIC-based prompts for palliative care referral among advanced cancer patients (Arm 1) vs no intervention/usual practice (Arm 2). These nudges have been shown to positively influence clinician behavior and are often used to drive value-based oncology care; however, they have never been studied in the context of palliative care referral. The primary outcome is completion of a palliative care referral within 12 weeks of enrollment.

Following the intervention, brief REDCap questionnaires will be sent to all clinicians who participated in the trial to explore perceptions of the study intervention. This survey should take no longer than five minutes for clinicians to complete and will assess their feedback on the overall intervention in addition to specific components including automated identification of patients, receiving text and email notifications, and identifying the appropriate patients. The survey will also collect basic demographic information (age, gender, practice site, and comfort with SICs) (**Appendix 3).**

5.2 Study duration

The study is expected to begin in April 2022 and take 9 months (3 months for enrollment + 6 months total follow up) to complete. Our analysis will take place from December 2022 to March 2023.

5.3 Target population

Outpatients with advanced cancer at the Ann B. Barshinger Cancer Institute at Lancaster General Health who are eligible for palliative care (see below).

5.4 Accrual

Patients will accrue to the trial according to their clinician pod in advance of a repeat patient visit. Any eligible patient cared for by an oncology outpatient clinician will be considered eligible.

5.5 Key inclusion criteria

Patients who meet the following criteria will be eligible for the study.

- Have a functional telephone number
- Receive ongoing care from hematology/oncology services within the Ann B. Barshinger Cancer Institute (ABBCI) at Lancaster General Health.

5.6 Key exclusion criteria

- Patients appearing for a new patient visit

- Patients who have previously received palliative care
- Patients who are enrolled in an ongoing clinical trial of a therapeutic agent
- Patients who receive primary oncologic care within another institution

6. Subject recruitment

Eligible patients will be identified by a Clinical Research Coordinator in advance of a repeat patient visit with an eligible clinician.

7. Subject compensation

No compensation will be offered to clinicians in the intervention.

Patients who are administered quality of life surveys and complete a FACT-G survey at 9 weeks or earlier will be offered $50 at the 9-week timepoint.

8. Study procedures

8.1 Consent

A waiver of informed consent is requested for the delivery of the palliative care nudge. This is a health system initiative that will be implemented and the study is to evaluate that initiative. Therefore, physicians and their patients will not be consented as this is the standard of practice per the health system initiative and national cancer guidelines. Without a waiver of the consent, the initiative would still be implemented by the health system, but the study would be infeasible. There are several additional reasons why we feel a waiver of consent should be granted. First, it is not feasible to consent every physician and as mentioned this initiative would occur with or without the study of it. Second, if members of the control group were consented, this alone could change their behavior. This could potentially disrupt the design of the study and making interpretation of the findings challenging. Third, physicians are not being forced to refer to palliative care for their patients. Instead, they are receiving behavioral nudges, including default EPIC-based nudges. This is no different than standard of care in which a physician would review the same information and decide to have a palliative care consultation. The initiative is simply a reminder for the physician and makes their standard of care process easier to conduct. Finally, as part of a previous quality improvement initiative, we interviewed nearly 40 clinicians after a trial testing a clinician nudge to perform serious illness conversations. We found no evidence of harm and found that serious illness conversations were considered standard of care for patients with cancer.

Patients who are selected for quality of life surveys will be consented over the phone for administration of FACT-G surveys at baseline (prior to hospital discharge) and at 3, 6, 9, and 18 weeks after enrollment. A copy of the informed consent form is available (**Appendix B**). Those who elect not to participate will be asked to grant permission (or not) for the study team to collect limited data from them. An abbreviated Study Decline Consent form will be utilized for this purpose (**Appendix C**).

8.2 Procedures

Baseline data on oncologists and their patients at Lancaster General Health will be obtained from Penn Data Store and Clarity (Epic's data reporting database). Physician data includes demographic information (e.g. sex, type of medical degree, etc.) and may be also obtained from publicly available databases or websites online. Baseline data collected on patients will include age, gender, zip code of residence, type of cancer, Elixhauser comorbidity index, ECOG performance status, whether the patient is on active systemic therapy, and understanding of palliative care. This will be collected via the electronic health record and an in-person enrollment questionnaire **(Appendix D**) upon enrollment into the trial. Those who elect not to participate, but consent to limited data collection, will be asked to fill out a similar questionnaire including reason(s) for not wanting to participate in a de-identified manner (**Appendix E**).

Prior to the trial, staff will randomize each clinician pod in a 1:1 fashion to either intervention or usual care. The Principal Investigator (RBP) will be blinded to arm assignment. In both intervention and control arms, research coordinator staff will identify patients with advanced cancer who are actively cared for within the Ann B. Barshinger Cancer Institute system. They will then regularly review the electronic health record for eligible clinicians to identify patients with an upcoming repeat patient visit who are eligible for palliative care. Patients who are eligible will have a solid malignancy and at least one of the following five conditions: (1) Documented advanced (stage IV) solid malignancy; (2) Known central nervous system metastasis, (3) Eastern Cooperative Oncology Group performance status > 2, Karnofsky Performance Status < 50, (4) uncontrolled symptoms such as pain, escalating opioids, nausea/vomiting, distress, dyspnea, delirium, or (5) hospitalization relevant to cancer or treatment.

For patients whose clinician pods are randomized to the intervention arm, the care team pod will receive an EPIC in-basket message indicating that the patient is eligible for Palliative Care and that a default referral order has been pended for that patient. Clinicians will be given an opportunity to respond if they do not want their patient to be referred to palliative care. For clinicians who do not respond, after the allotted time, the Clinical Research Coordinator will reach out to the patient to introduce palliative care and ask if ABBCI staff can schedule an appointment. For non-English speaking patients, an interpreter will assist research staff. For clinicians who respond no, the pended order will be removed and no patient contact by the research team will occur.

For eligible patients whose clinician pods have been randomized to the control arm, no intervention will be provided. Clinicians will refer patients to palliative care based on their usual practice.

Among patients in the intervention arm for whom palliative care referral is placed, who accept for a scheduler to call them to make an appointment, a trained research coordinator will approach 40 patients as a convenience sample to administer a baseline FACT-G survey (**Appendix A**). 40 randomly selected patients, matched on categories including age category and type of cancer, will be selected from the pods not receiving the intervention. For patients that choose to enroll in the survey component, a baseline FACT-G survey will be administered prior to discharge in-person via paper or electronically. Surveys will be repeated at 3, 6, 9, and 18-week intervals by either telephone or in-person at an in-person visit. For patients that complete the 9-week survey or any survey prior, a $50 gift card will be given at the 9-week time point. Patients who miss their visits with palliative care will be contacted by the coordinator to identify why (**Appendix F**) and reschedule the appointment.

9. Analysis plan

We will 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 standard deviations 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-square 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 palliative care visit within 24 weeks of the clinician behavioral nudge. This analysis will be conducted as a time-to-event analysis among all eligible advanced cancer patients. Cox proportional hazard regression analyses, adjusted for baseline covariates, will be used to examine the effect of nudges on completion of palliative care consultation for advanced cancer patients. Competing risk caused by patients who die within 24 weeks 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. Using a longitudinal multilevel mixed-effects model with clustering by discharging clinician (intraclass correlation coefficient 0.5 based on prior randomized trial); a two-sided type I error rate of 0.05; and a baseline palliative care visit rate of 45% (standard deviation 10%), we expect that a sample size of 250 patients will give us 80% power to detect a meaningful 34 percentage point response in palliative care visits, considering the presence of a competing risk of 6-month mortality at 20%.

One secondary outcome will be (1) change in quality of life between 0 and 9 weeks (as measured by the Functional Assessment of Cancer Therapy – General (FACT-G) among patients who receive palliative care compared to matched controls. Multivariate linear regression analyses, adjusted for baseline scores, will be used to examine the effect of palliative care on completion of palliative care consultation for advance cancer patients. 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.

Other secondary outcomes will include (1) change in quality of life between 0 and 18 weeks (as measured by the Functional Assessment of Cancer Therapy – General (FACT-G) among patients who receive palliative care compared to matched controls; (2) unplanned 30-day emergency room and hospitalization rates (among all patients); (3) metrics of aggressive end-of-life care among decedents (chemotherapy within 14 days before death, no hospice enrollment prior to death; hospice enrollment <3 days before death); (4) documented advance care planning or serious illness conversations in the outpatient medical record.

For the exploratory outcome of overall survival, survival time will be calculated from the date of enrollment to the date of death with the use of the Kaplan–Meier method. Data from patients who are alive at the last follow-up will be censored on that date. A Cox proportional-hazards model will be used to assess the effect of triggered palliative care on survival, with adjustment for baseline covariates.

10. Investigators

Ravi B. Parikh, MD, MPP (Principal Investigator) is Assistant Professor of Medicine and Health Policy and Innovation Faculty at the Penn Center for Cancer Care Innovation (PC3I). Justin E. Bekelman, MD (Mentor, Co-Investigator) is Professor of Radiation Oncology, Medicine and Health Policy and the Director of PC3I. Pallavi Kumar, MD, MPH (Co-Investigator), is Assistant Professor of Clinical Medicine and Director of Oncology Palliative Care at the Abramson Cancer Center. Niharika Ganta, MD (Co-Investigator) is Assistant Professor of Clinical Medicine and Interim Chief of Palliative Care at the University of Pennsylvania. Jinbo Chen, PhD (Co-Investigator) is Professor of Biostatistics and Director of the Statistical Center for Translational Research in Medicine. Ramy Sedhom (Co-Investigator) is Assistant Professor of Clinical Medicine and Innovation Faculty at the Penn Center for Cancer Innovation. All are faculty at the Perelman School of Medicine at the University of Pennsylvania.

Bethann Scarborough, MD (Co-Investigator) is the Palliative Care Program Lead Physician at the Ann B. Barshinger Cancer Institute at Penn Medicine Lancaster General Health. Shanthi Sivendran, MD (Co-Investigator) is the Division Chief Hematology/Oncology at Penn Medicine Lancaster General Health.

11. Human research protection

11.1 Data confidentiality

Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are already in place to ensure the data are secure by using passwords and HIPAA-compliant encryption.

11.2 Subject confidentiality

Data on physicians and patients will be obtained from Epic, Penn Data Store and chart review. Any information that is obtained will be used only for research purposes and to inform the behavioral nudges described above. Information on individual patients will only be disclosed within the study team. All study staff will be reminded of the confidential nature of the data collected and contained in these databases.

Data regarding provider performance of palliative care referral are already shared among the health system and some providers and will continue to be shared as part of the trial. General panel-level statistics regarding acute care utilization at the end of life provider's deceased patient panel will be shared to outpatient providers as part of the intervention but is planned to occur regardless of trial approval as part of quality improvement efforts.

Data will be stored, managed, and analyzed on a secure, encrypted server behind the University of Pennsylvania Health System (UPHS) firewall. The primary investigator (Dr. Parikh) and statistical analyst will be blinded to the randomization schema and which groups are receiving the intervention. All study personnel that will use this data are listed on the IRB application and have completed training in HIPAA standards and the CITI human subjects research. Data access will be password protected. Whenever possible, data will be de-identified for analysis.

11.3 Subject privacy

All efforts will be made by study staff to ensure subject privacy. Data will be evaluated in a de-identified manner whenever possible. We will require time and date of appointment and zip code data of trial participants to define our exposure period and link to area-level socioeconomic data from the American Community Survey.

11.4 Data disclosure

Information on physicians and patients will not be disclosed to anyone outside of the study team.

11.5 Data safety and monitoring

The investigators will provide oversight for the study evaluation of this health system initiative. Providers will use their clinical judgment to determine the appropriateness of referring to palliative care with patients, in accordance with standard of care.

11.6 Risk/benefit

11.6.1 Potential study risks

The potential risks associated with this study are minimal. Breach of data is a potential risk that will be mitigated by using HIPAA compliant and secure data platforms for the nudge interventions (name of list platform and platform used to share info w/ MAs) and evaluation (PMACS server). As noted above, substantial data demonstrates that palliative care referrals improve patient goal-concordant care without any identified harms (despite concerns that palliative care may increase psychosocial distress, the opposite has been found), so the negative impact on patients is minimal. The FACT-G survey has been used in many trials measuring quality of life for patients with advanced cancer and no detrimental effect on patient well-being has ever been found.

11.6.2 Potential study benefits

As described in the literature, patients may have improved quality of life and better goal-concordant care when exposed to palliative care, especially earlier in their disease course. An intervention that prompts providers to refer to palliative care for patients with advanced cancer may increase the likelihood that patients get seen by palliative care. However, it is possible that patients will receive no benefit from this study.

11.6.3 Risk/benefit assessment

The risk/benefit ratio is highly favorable given the potential benefit from eligible patients having a palliative care consultation benefitting from better goal-concordant care and that efforts have been put into place to minimize the risk of breach of data.

APPENDICES

1. Sample Provider Communication

Sample timeline of provider nudge communication

7 days prior to identified patient's repeat patient visit (RPV): notification of referral sent to care team

3 days prior to RPV: opt-out period ends

Sample provider email content

Dear Dr. XXX:

ABBCI has identified that your patient [INSERT NAME] may benefit from a palliative care consultation. If you do not choose to opt out, we will reach out to the patient on your behalf to introduce palliative care and place a referral if the patient accepts.

Please prepare your patient for this palliative care appointment at your next visit.

If you wish to opt your patient out, please reply to this message with .optout

Please note that not opting out within 4 days indicates a default order.

Thank you,
Bethann Scarborough, MD

Shanthi Sivendran, MD

2. *Sample Patient Communication*

Sample timeline of patient communication

3 days prior to RPV: Study team contacts patient with introduction to palliative care

Sample patient email content

My name is XX, and I'm calling from ABBCI. Dr. [NAME] wants to include the palliative care team as a partner in your cancer care and schedule an appointment for you. You benefit when palliative care is brought into your cancer care team because they provide an extra layer of support to you and your caregivers throughout treatment.

What questions do you have for me?

Our scheduler will call you to coordinate an appointment if that is okay with you.

3. *Sample Physician REDCap Questionnaire*

Thank you for participating in this questionnaire, which should take no more than 5 minutes. You have been asked to participate in this study because you were a part of an initiative starting May 2021. As you might recall, this intervention consisted of nudges for Palliative Care referral.

Please rate your agreement with the statements using the following:
(1) Strongly disagree
(2) Disagree
(3) Neutral
(4) Agree
(5) Strongly agree

	1	2	3	4	5
Sentiment Overall					
I was satisfied with the overall experience of being involved in the study.					
Participating in the study helped me to increase Palliative Care referrals for patients.					
Identification of Patients					
It was helpful to receive names of patients who may be appropriate for Palliative Care referrals.					
The nudges accurately identified patients who were appropriate for Palliative Care referrals.					

The nudges motivated me to refer more patients to Palliative Care.					
Nudges					
I would have been more satisfied with different system of delivery than EPIC Inbox messages.					
The EPIC Inbox messages interrupted my clinical workflow in a negative way					
I opted-out of palliative care visits more often than not					
Experience					
The intervention led to more timely palliative care visits for my patients					

Please describe how the study could be improved.
[free text response]

Please tell us if you have any additional thoughts about your experience in this study.
[free text response]

Demographics					
What is your age?					
What is your gender?	Female	Male	Other		
Please select your comfort level with having a Serious Illness Conversation	Very uncomfortable	Uncomfortable	Neutral	Comfortable	Very comfortable
What do you consider to be optimal timing for Palliative Care?	At time of diagnosis	Within 3 months	At times of PC need	Following progression of cancer therapy	When out of treatment options