S2424CD: A RANDOMIZED CONTROLLED TRIAL OF AN INTERVENTION CALLED "ALGORITHM-ENABLED PATIENTS ACTIVATED IN CANCER CARE THROUGH TEAMS" (A-PACT) TO IMPROVE GOALS OF CARE COMMUNICATION FOR PEOPLE WITH CANCER

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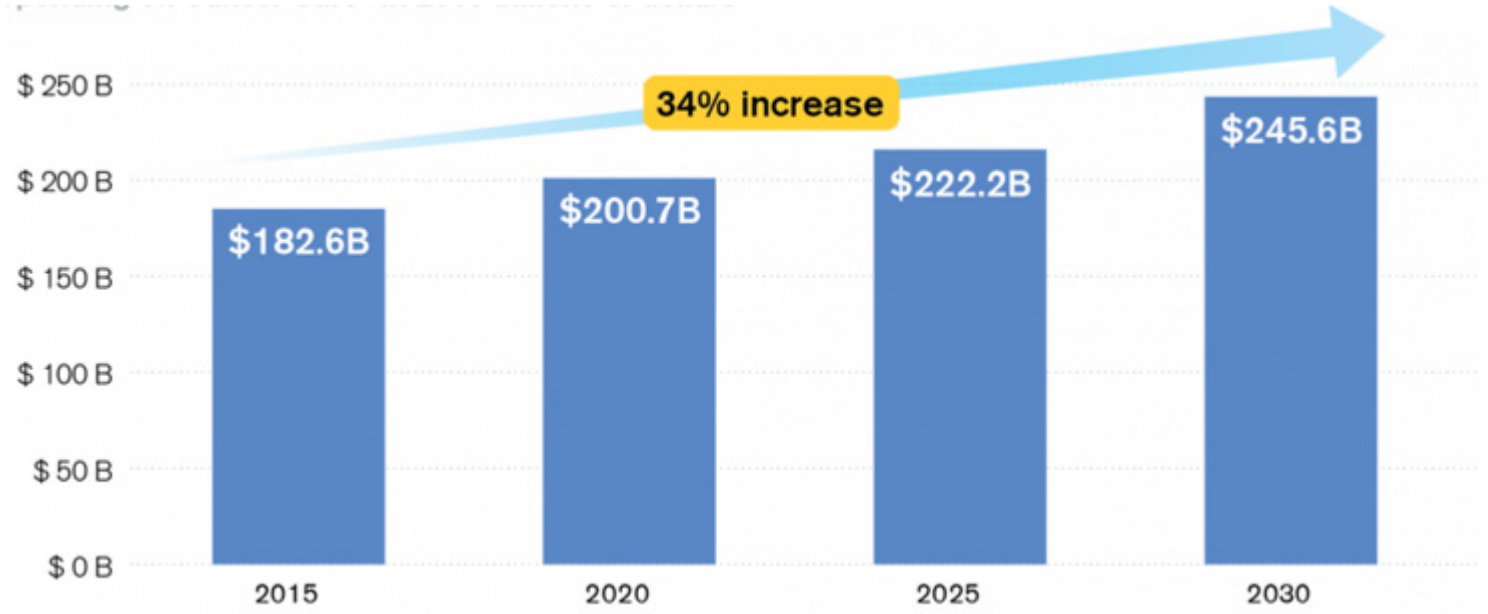
Rise in Cost ≠ Better Care

Spending on Cancer Care- in 2019 billions of US dollars



70% unaware of treatment goals[1]

90% undertreated symptoms[1]

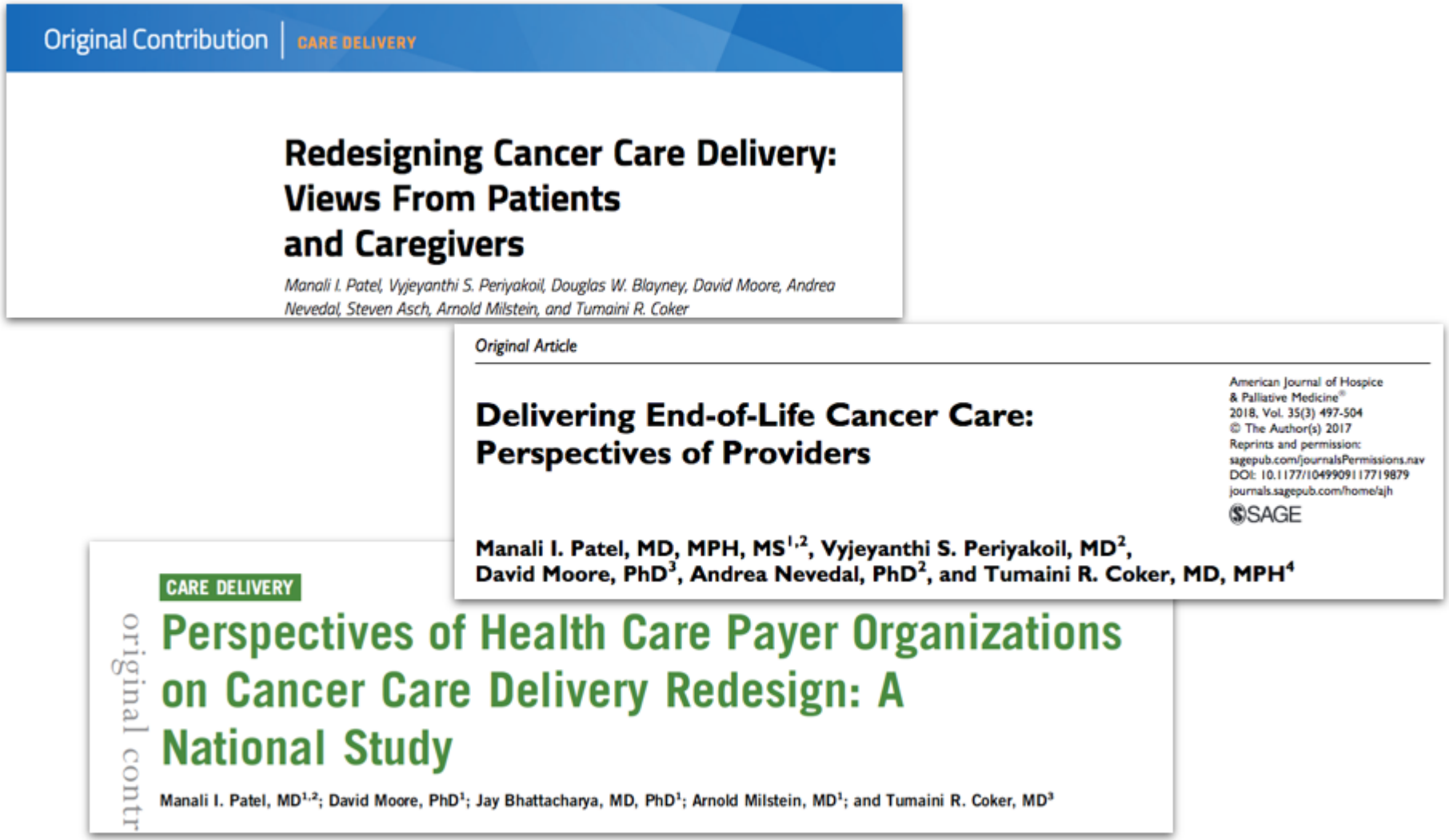
Shift in care to hospitals[2]

Shortage of professional teams[3]

Persistent Disparities[2]

[1]Mariotto, AB. JNCI 2011; [2]NCI 2016,[3] Lupa D; American Academy of Hospice and Palliative Medicine Workforce Task Force.. Estimate of current hospice and palliative medicine physician workforce shortage. J Pain Symptom Manage 2010;40:899-911

Cancer Care Delivery- End of Life Problems Across Interested Groups



Original Contribution | CARE DELIVERY

Redesigning Cancer Care Delivery: Views From Patients and Caregivers

Manali I. Patel, Vyjeyanthi S. Periyakoil, Douglas W. Blayney, David Moore, Andrea Nevedal, Steven Asch, Arnold Milstein, and Tumaini R. Coker

Original Article

Delivering End-of-Life Cancer Care: Perspectives of Providers

American Journal of Hospice & Palliative Medicine®
2018, Vol. 35(3) 497-504
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Manali I. Patel, MD, MPH, MS[1,2], Vyjeyanthi S. Periyakoil, MD[2], David Moore, PhD[3], Andrea Nevedal, PhD[2], and Tumaini R. Coker, MD, MPH[4]

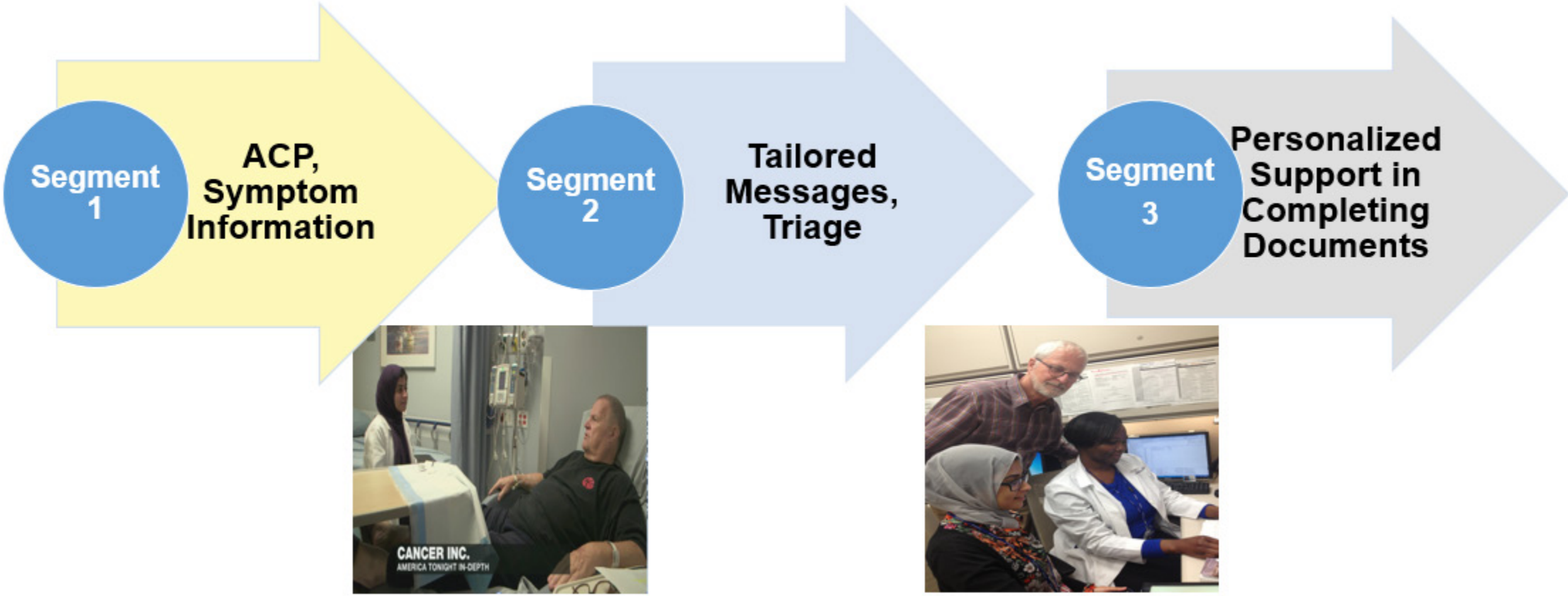
CARE DELIVERY

original contr

Perspectives of Health Care Payer Organizations on Cancer Care Delivery Redesign: A National Study

Manali I. Patel, MD[1,2]; David Moore, PhD[1]; Jay Bhattacharya, MD, PhD[1]; Arnold Milstein, MD[1]; and Tumaini R. Coker, MD[3]

Co-Developed Solutions



VA Office of Patient Centered Care & Cultural Transformation (Patel), California Health Care Foundation (Patel), NIH KL2 (Patel)
Patel et al. JAMA Oncology 2018, Patel et al. JAMA 2024

Primary Trial Results

At 6- and 15-months, intervention group as compared to the control group had:

3-fold ↑ goals of care documentation

3-fold ↑patient experience

2-fold ↑ hospice use

95% ↓ end-of-life acute care use

20% ↓ net total health care costs

Patel et al. JAMA Oncology 2018

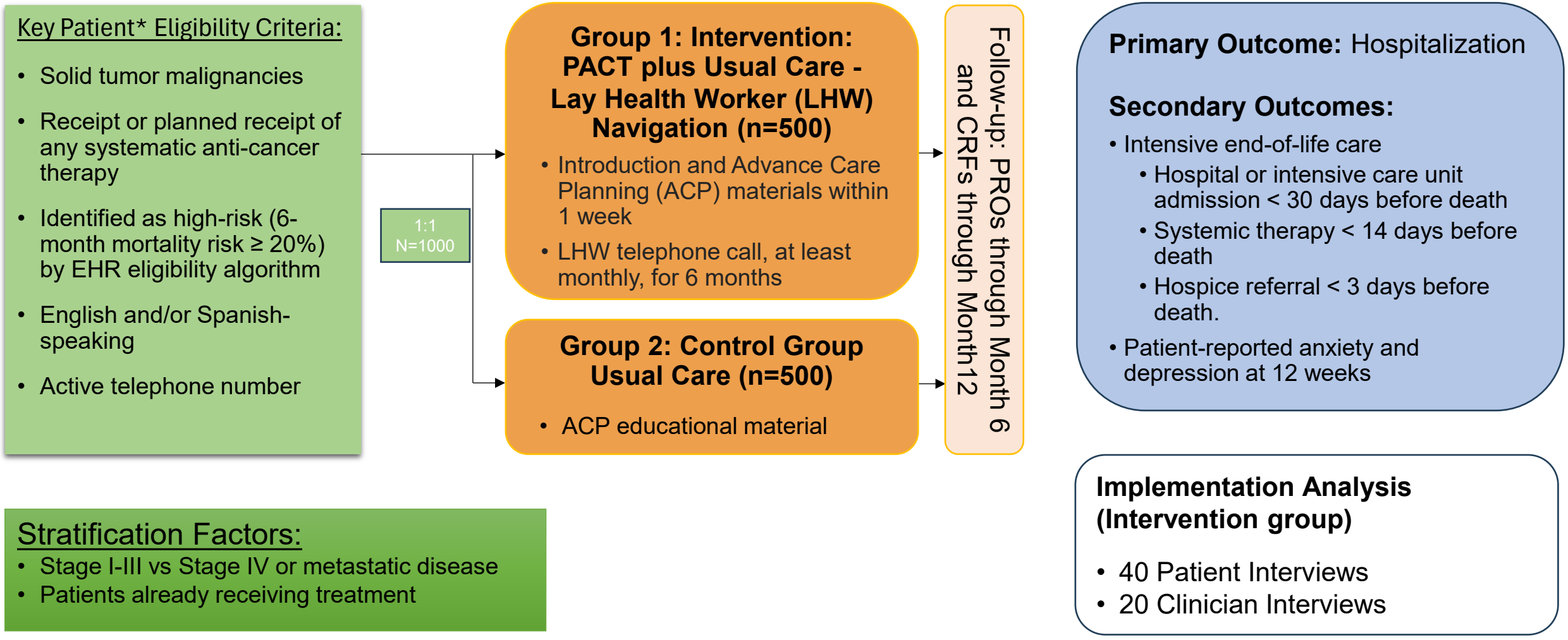
Critical evidence gaps remain. There is a need:

- For **automated tools** to identify patients with cancer who are the most appropriate for goals of care interventions
- To demonstrate that lay health worker-led goals of care interventions can improve cancer care near the end of life **in the community setting, for all patients**

S2424 Trial Aims and Objectives

- Randomized clinical trial
- Uses algorithm-driven patient identification
- Evaluates the impact of remote, lay health worker-led goals of care intervention vs. usual cancer care
- **Primary Outcome:** % with any hospitalization withing 12 months of enrollment
- **Secondary Outcomes:**
  - Any emergency department visits within 12 months of enrollment
  - End-of-life care intensity
  - Patient-reported anxiety and depression
  - Goals of care communication
- **Implementation Outcomes:** assess patient, clinician, and organizational factors that shape implementation outcomes

S2424 Trial Schema



* With consent, a subset of patients and clinicians in Group 1 will participate in process evaluation interviews.

Site Eligibility and Set up

Initial Steps:

- Interested NCORP sites complete preliminary intake survey
- Eligible sites meet with Dr. Parikh and Site IT Lead for consultation

Algorithm Set up:

- Which NCOPR site does your site belong to?
- Does your site use an electronic health record (EHR)
- Does your site have an IT or data specialist who can obtain data from your EHR?
- Does your site have any ongoing advance care planning (ACP) or goals of care interventions?

Funding Support:

- $3,000 allocation for site IT implementation, per participating site
- Budget based on estimated resource hours

Site Eligibility and Set up

Initial Steps:

- Interested NCORP sites complete preliminary intake survey
- Eligible sites meet with Dr. Parikh and Site IT Lead for consultation

Algorithm Set up:

- Weekly implementation meeting (3-4 weeks) for algorithm deployment
- Comprehensive IT requirements review and setup

Funding Support:

- $3,000 allocation for site IT implementation, per participating site
- Budget based on estimated resource hours

Site Eligibility

How to get involved?

Scan the QR code below to complete REDCap survey for eligibility status

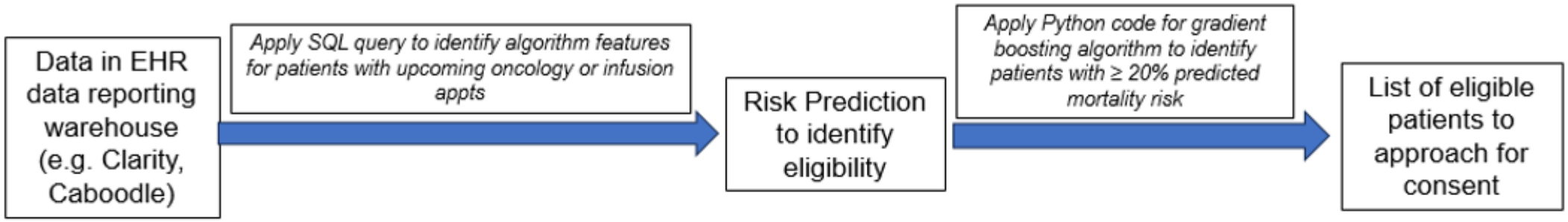
Preview of sample questions

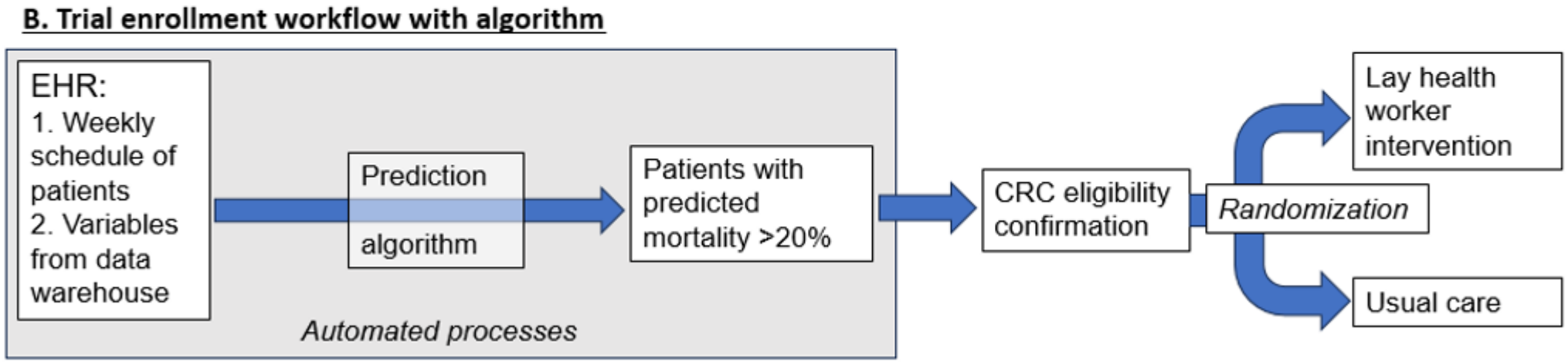
- Which NCOPR site does your site belong to?
- Does your site use an electronic health record (EHR)
- Does your site have an IT or data specialist who can obtain data from your EHR?
- Does your site have any ongoing advance care planning (ACP) or goals of care interventions?

Site Inclusion:

- Sites need to be on the same EHR system
- Site IT/Data specialist

Algorithm Workflow



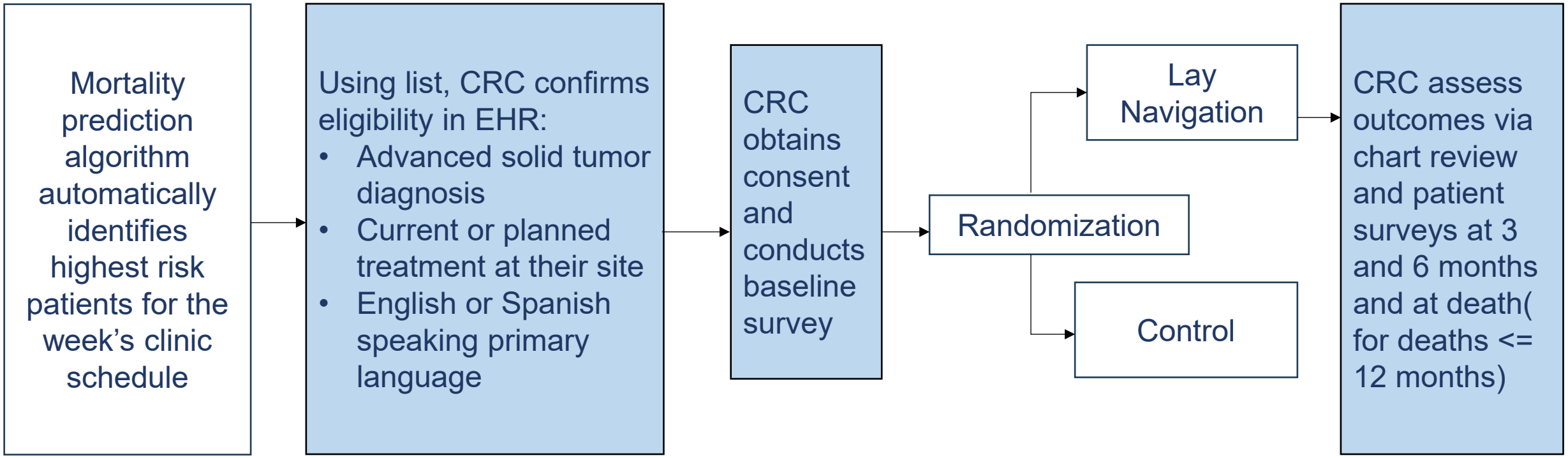


Algorithm Implementation

- Implementation Resources:
  - Comprehensive implementation guidebook available with:
    - Detail step-by step instructions for downloading data via SQL and applying the algorithm via Python
    - Environment setup requirements

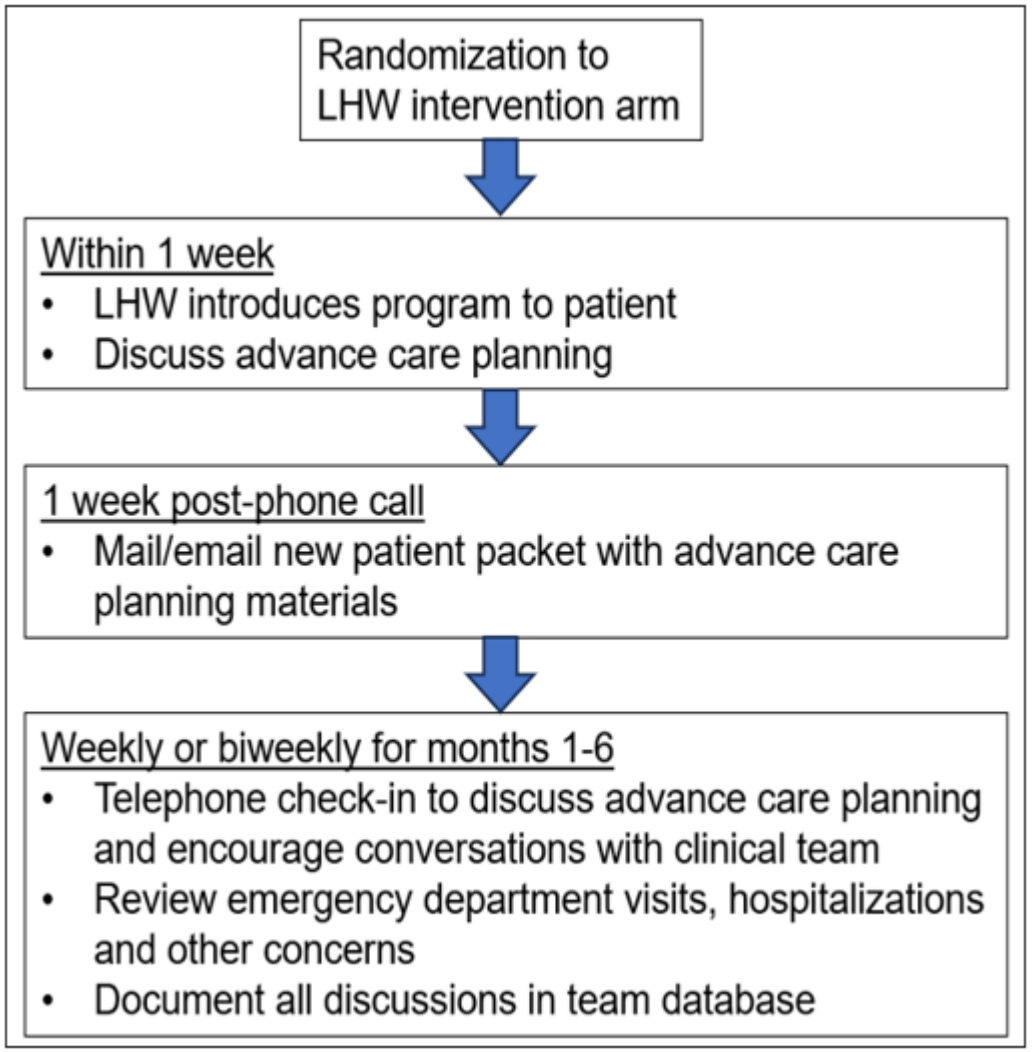
- Code Access
  - All implementation code accessible via GitHub repository
  - Repository includes documentation, example datasets, and validation tools
  - Site IT staff will contact Dr. Parikh for repository access credentials

CRC Workflow



Blue box: CRC tasks

Lay Health Worker intervention



- Navigators will be centralized, based out of Dr. Patel's center at Stanford
- Will communicate with patients on behalf of clinical sites, via telephone

Staffing

- 1.5 FTE Lay Health Workers (LHW)
- 0.50 FTE Supervisor

Assessments: Patient reports

REQUIRED FORMS / TASKS	Pre- Registration	Participant Registration/ Randomization	Month 3 (+/- 30 days)	Month 6 (+/- 30 days)	Month 9 (+/-30 days)	Month 12 (+/- 30 days)	Off Protocol
PATIENT QUESTIONNAIRES							
S2424CD Prognostic Awareness and Treatment Preferences	X		X	X			
S2424CD PROMIS® Short Form v1.0 - Anxiety 4a	X		X	X			
S2424CD PROMIS® Short Form v1.0 – Depression 4a	X		X	X			
S2424CD Heard and Understood	X		X	X			
PATIENT IMPLEMENTATION EVALUATION SURVEYS							
12-Item Acceptability of Intervention Measure				X			
15-Item Advance Care Planning Engagement				X			
3-Item Shared Decision Making				X			

Assessments: EHR-based outcomes

REQUIRED FORMS / TASKS	Pre-Registration	Participant Registration/ Randomization	Month 3 (+/- 30 days)	Month 6 (+/- 30 days)	Month 9 (+/-30 days)	Month 12 (+/- 30 days)	Off Protocol
Recent Hospitalization			X	X	X	X	
Intensive End-of-Life Care							X
Goals of Care Documentation						X	
Advance Directive Documentation						X	
Physician Order for life Sustaining Treatment Documentation						X	

Protocol Development Timeline

Item	Due Date
SWOG Statistical Protocol Review Committee (PRC) call	3/26/2025 ☑
Integration of SWOG post-Protocol Review Committee edits	4/9/2025 ☑
Submit patient-reported outcomes (PRO) forms/patient facing materials	5/1/2025 ☑
Submit protocol to Division of Cancer Prevention (DCP)	5/15/2025
Begin RAVE study build (approx. 14 weeks prior to activation)	8/15/2025
Call with study chairs to go over care report forms (CRF) draft (3 weeks post start of study build)	9/5/2025
Targeted Activation Date: Friday, November 21st, 2025	11/21/2025
NCI Operational Efficiency Working Group (OEWG) activation deadline:	1/9/2025

Benefits of Participation

Participating sites:

- Lay workers offload clinician need to initiate serious illness communication
- Ultimate decisions around care decisions remain with the clinician and patient/family
- Infrastructure to integrate lay worker into routine care, leading to downstream revenue opportunities (ACP conversations are billable by Medicare; LHW services reimbursed by Medicare starting October 2024)
- Increased but manageable palliative care volume
- Infrastructure for integrating machine learning algorithms for patient identification

To patients:

- Improved understanding in cancer care trajectory and personal goals
- Improved communication between patient and clinician team
- Improved patient satisfaction
- Improved care delivery - more palliative care, less hospitalization

Questions?

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Thank you