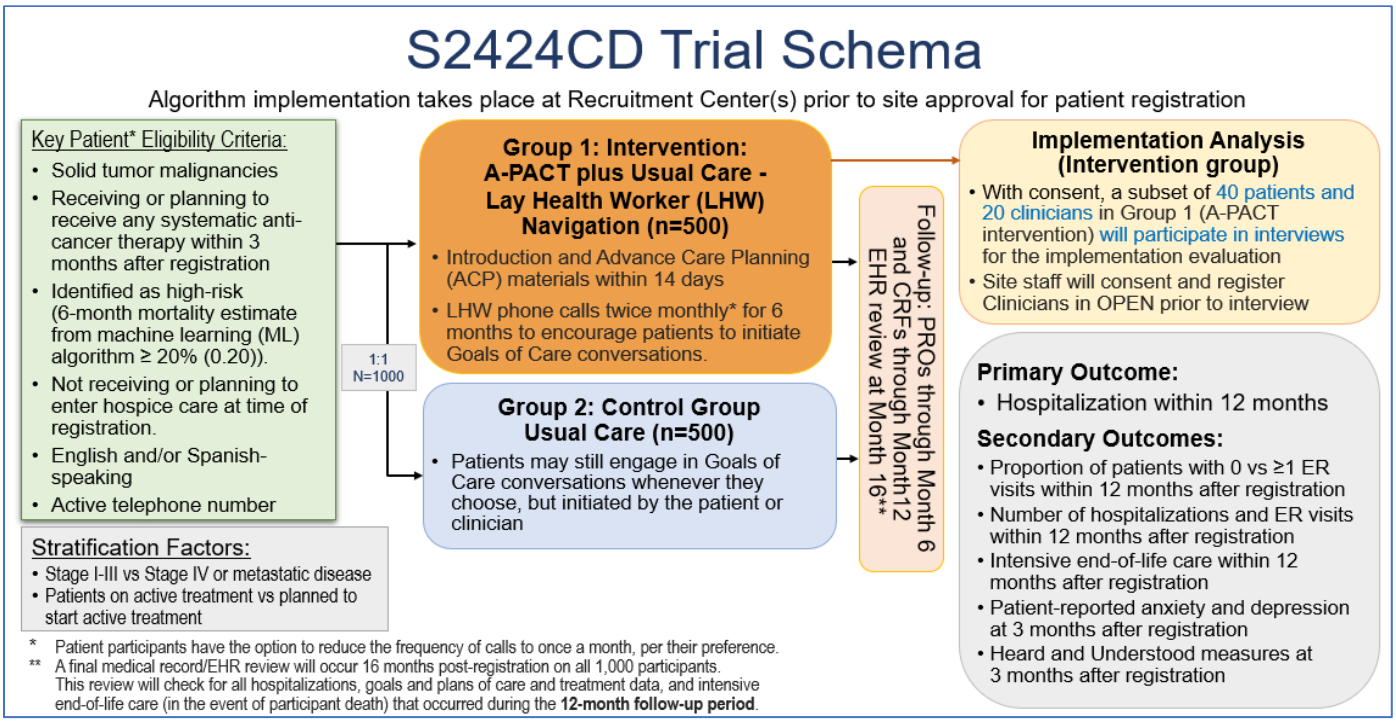
S2424CD Kick Off Meeting

April 30, 2026

SWOG Spring 2026 Group Meeting

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



Participation limited to NCORP Sites

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

Site Request: Survey to Confirm Eligibility

- To get started: Complete REDCap survey to confirm eligibility status

To get started:

Interested NCORP sites complete preliminary REDCap intake survey accessible via QR code / link below.

https://redcap.link/h6zq0fti

13 questions

To be included in a single Recruitment Center:
Affiliated sites need to be on the same EHR system

If your sites share the same electronic health record, you may fill out 1 survey for multiple sites. List each site name and each CTEP Site Code on the first page of the survey separated by a comma.

Affiliated sites that do not share the same electronic health record must *each* complete a survey

Survey questions include:

- Which NCORP site does your site belong to?
- Does your site use an electronic health record (EHR) system? (Yes/No)
- Does your site have an IT or data specialist who can get data from your electronic health record? (Yes/No)
- Does your site have a program to promote advance care planning (ACP) or goals of care communication between oncologists and patients with cancer? (Yes/No)

Electronic health record defined:
We consider sites to be sharing an electronic health record if they can view another site's patients' electronic health records and outpatient clinic schedules without submitting a record sharing request. Just because you can view a site's patients' records on an electronic data exchange platform (e.g. "CareEverywhere") does not mean you are on the same record as that site.

Site Algorithm Setup

Algorithm Set up:

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

An Algorithm Implementation Guide for IT departments, can be found at: https://github.com/HumanAlgorithmCollaborationLab/SWOG

The Implementation Guide includes:

1. A short read-me file,
2. A SQL query to extract all relevant algorithm variables from the EHR, and
3. R code for the algorithm

The time-to-implement the algorithm locally is estimated at 5-10 hours work between site IT staff and Dr. Parikh's team.

- Where the Recruitment Center is comprised of a group of affiliates that share an Electronic Health Record (EHR): **ONLY the IT department that oversees the shared EHR should be involved in the algorithm implementation process.**

After implementation is complete and verified: Dr. Parikh's office will provide an approval document to the site.

- Site must submit the approval document via the CTSU Regulatory Portal. Allow 24 hours after submission to CTSU to be able to enroll participants in OPEN.

Funding Support:

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

Study Chairs:
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Project Manager:
Ajla Pleho – ajla.pleho@emory.edu

Protocol Project Manager: Patricia O'Kane – pokane@swog.org

Data Coordinators: Manny Kharbanda and Monica Yee – cancercontrolquestion@crab.org

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

NCT # 07278739

EMORY WINSHIP CANCER INSTITUTE
National Cancer Institute-Designated Comprehensive Cancer Center

Stanford

Study Chairs:
Ravi B. Parikh, MD
Manali Patel, MD

NCORP Representative:
Jared D. Acoba, MD

Patient Advocate:
Barabara Segarra-Vazquez, DHSc

Statisticians:
Joseph Unger, PhD
Sarah Colby, MS

Data Coordinators:
Manny Kharbanda
Monica Yee

SWOG Protocol Project Manager:
Patricia O'Kane

Project Manager:
Ajla Pleho, MPH

S2424CD Trial Schema

Algorithm implementation takes place at Recruitment Center(s) prior to site approval for patient registration

Key Patient* Eligibility Criteria:

- Solid tumor malignancies
- Receiving or planning to receive any systematic anti-cancer therapy within 3 months after registration
- Identified as high-risk (6-month mortality estimate from machine learning (ML) algorithm ≥ 20% (0.20)).
- Not receiving or planning to enter hospice care at time of registration.
- English and/or Spanish-speaking
- Active telephone number

Stratification Factors:

- Stage I-III vs Stage IV or metastatic disease
- Patients on active treatment vs planned to start active treatment

1:1
N=1000

Group 1: Intervention: A-PACT plus Usual Care - Lay Health Worker (LHW) Navigation (n=500)

- Introduction and Advance Care Planning (ACP) materials within 14 days
- LHW phone calls twice monthly* for 6 months to encourage patients to initiate Goals of Care conversations.

Group 2: Control Group Usual Care (n=500)

- Patients may still engage in Goals of Care conversations whenever they choose, but initiated by the patient or clinician

Follow-up: PROs through Month 6 and CRFs through Month12 EHR review at Month 16**

Implementation Analysis (Intervention group)

- With consent, a subset of 40 patients and 20 clinicians in Group 1 (A-PACT intervention) will participate in interviews for the implementation evaluation
- Site staff will consent and register Clinicians in OPEN prior to interview

Primary Outcome:

- Hospitalization within 12 months

Secondary Outcomes:

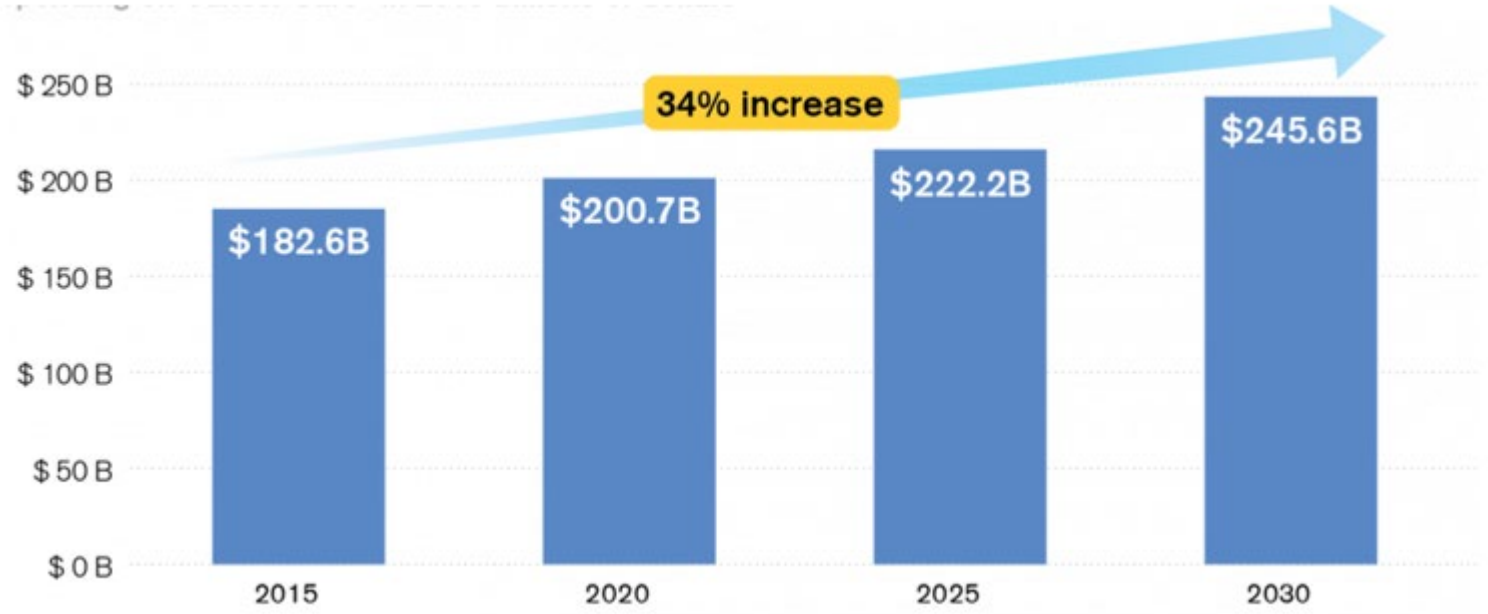
- Proportion of patients with 0 vs ≥1 ER visits within 12 months after registration
- Number of hospitalizations and ER visits within 12 months after registration
- Intensive end-of-life care within 12 months after registration
- Patient-reported anxiety and depression at 3 months after registration
- Heard and Understood measures at 3 months after registration

* Patient participants have the option to reduce the frequency of calls to once a month, per their preference.

** A final medical record/EHR review will occur 16 months post-registration on all 1,000 participants. This review will check for all hospitalizations, goals and plans of care and treatment data, and intensive end-of-life care (in the event of participant death) that occurred during the **12-month follow-up period**.

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]

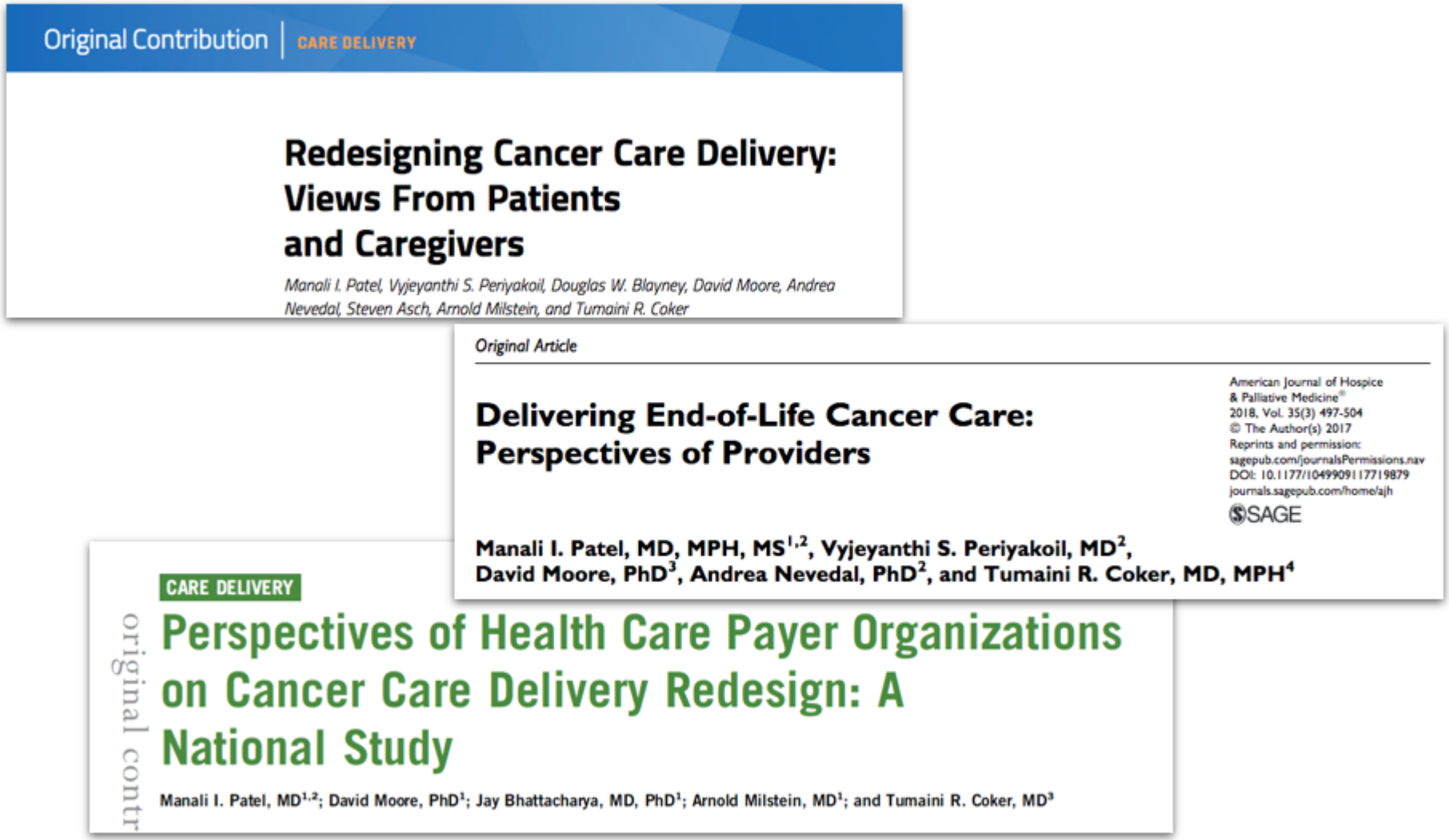
Shift in care to hospitals[2]

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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sagepub.com/journalsPermissions.nav
DOI: 10.1177/1049909117719879
journals.sagepub.com/home/ajh
SAGE

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]

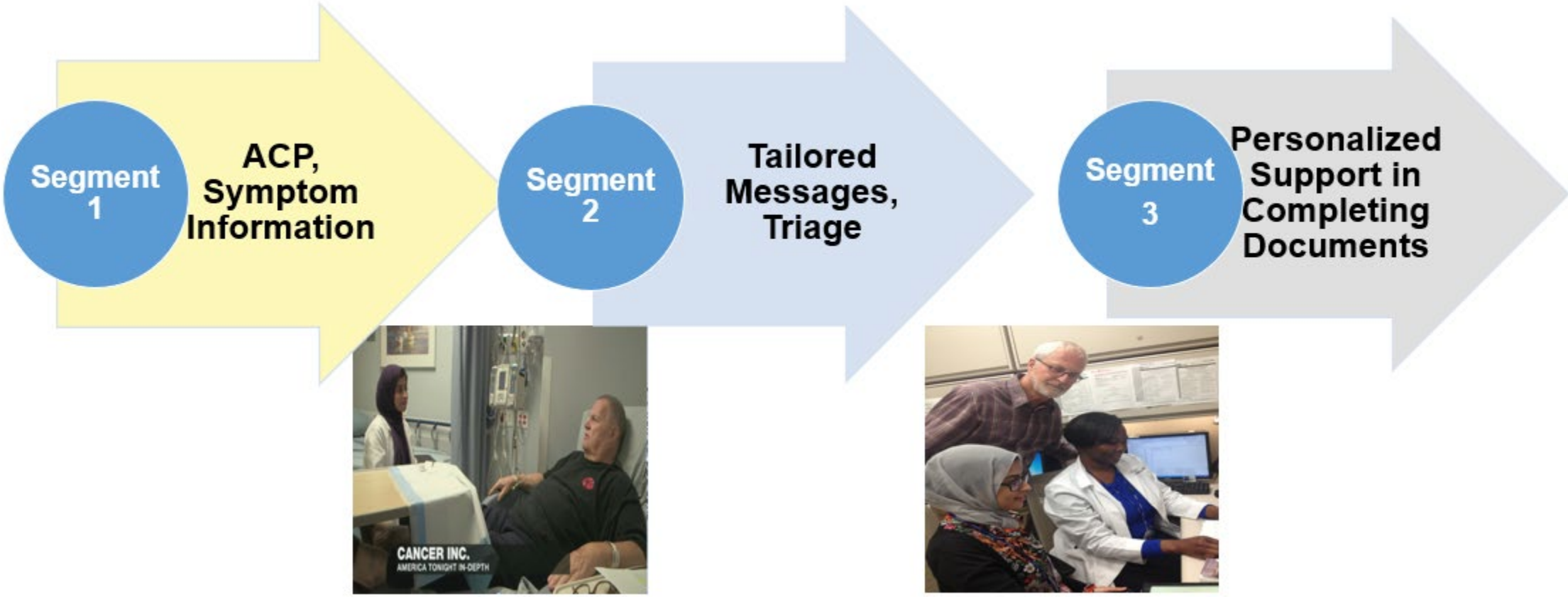
CARE DELIVERY

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**

Study Primary and Secondary Objectives

Primary Objective

- Compare the proportion of participants who have any hospitalizations within 12 months after randomization between those receiving A-PACT (intervention arm) and those receiving usual care alone (control arm).

Secondary Objectives

- Compare by arm the:
  - Proportion of participants who have any emergency department visits within 12 months of randomization.
  - Mean number of hospitalizations within 12 months of randomization.
  - Mean number of emergency department visits within 12 months of randomization.
  - Proportion of participants who report anxiety at 3 months.
  - Proportion of participants who report depression at 3 months.
  - Heard and Understood measures at 3 months.
  - To assess by arm the proportion of participants who receive intensive end-of-life care within 12 months of randomization.

Study Implementation and Exploratory Objectives

Implementation Objectives

- 40 patient interviews and 20 clinician interviews to:
    1. Quantitatively and qualitatively assess how patient, clinician, and organizational factors shape effectiveness and implementation of A-PACT.
    2. Measure feasibility of machine learning (ML) algorithm, adoption of intervention (patient enrollment), and fidelity (%of patients completing A-PACT).

Exploratory Objectives

- To assess the following in participants on the intervention arm versus the usual practice arm:
    1. Anxiety at 6 months from baseline
    2. Depression at 6 months from baseline
    3. Heard and Understood measures at 6 months from baseline
    4. Prognostic awareness and treatment preferences from baseline through 6 months
    5. Presence of Goals of care documentation in the electronic health record at 12 months
    6. Presence of Advance Directive documentation in the electronic health record at 12 months
    7. Presence of Physician Orders for Life Sustaining Treatment documentation in the electronic health record at 12 months
    8. The potential differential impact of sociodemographic factors on all outcomes.

Stratification Factors

- Patient participants will be randomized using a dynamic balancing algorithm with stratification based on 1) stage of disease (Stage I-III vs Stage IV or metastatic disease); and 2) active treatment (on active treatment at enrollment vs. plan to initiate active treatment within 3 months after enrollment).

  NOTE: Stage of disease refers to the stage of the participant's disease at the time of randomization.

Statistical Considerations

- A total of 1000 enrolled patients will provide 95% power with a type-1 error rate of 0.05 to detect an absolute decrease in 12-month hospitalizations by 10 percentage points, from 80% to 70%.
- Accrual is expected to occur over 2 years, with an estimated accrual rate of 45 pts/month.
- Patients will be followed for 16 months in order for EHR to be complete for assessment of 12-month endpoints.
- Temporary closures may occur in order to maintain a reasonable case load for the lay health workers.

S2424CD Site Eligibility, Setup and Approval Process

Why S2424CD involves a Site Eligibility and Approval Process:

- In S2424CD, both the intervention and control groups are identified by a predictive algorithm that consists of code and model weights.
- **In order for sites to participate in S2424CD:**
  The predictive algorithm must be implemented locally by site IT staff to automatically identify high-risk patients (estimated >20% risk of 6-month mortality) from routinely collected EHR data.

For Implementation of the Algorithm at the Site Level:

- S2424CD will utilize a **Recruitment Center** model for participation that is based upon site use of a shared EMR system (across sites).

  A Recruitment Center is defined as:
  - A single clinic that will be contributing patients to the study, OR
  - A group of clinics that will be contributing patients to the study that 1. belong to the same NCORP or MU-NCORP and 2. share both an electronic medical record (EMR) and clinic schedule.

Site Request, Setup, and Approval Process

Overview

Interested NCORP sites complete online survey (https://redcap.link/h6zq0fti)

- Survey response must include the name and CTEP ID for each NCORP affiliate and subaffiliate planned for inclusion in the recruitment Center.

Upon receipt of the survey:

Dr. Parikh's office contacts the site and provides next steps for algorithm implementation.

Site Algorithm Setup and Verification

(estimated total time commitment of 5-10 hrs over 3-4 weeks)

- Weekly implementation meetings for IT review and setup.

Dr. Parikh's staff conduct validation checks to verify algorithm functionality and documents approval.

Sites submit the site approval document via the CTSU Regulatory Portal.

In order for >1 clinic within the same NCORP to participate as a single Recruitment Center:
The clinics MUST share an electronic medical record (EMR) system and clinic schedule.

Site Request: Survey to Confirm Eligibility

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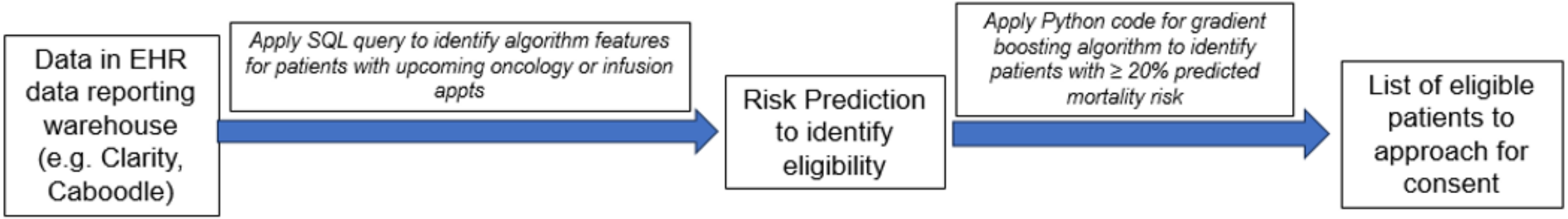
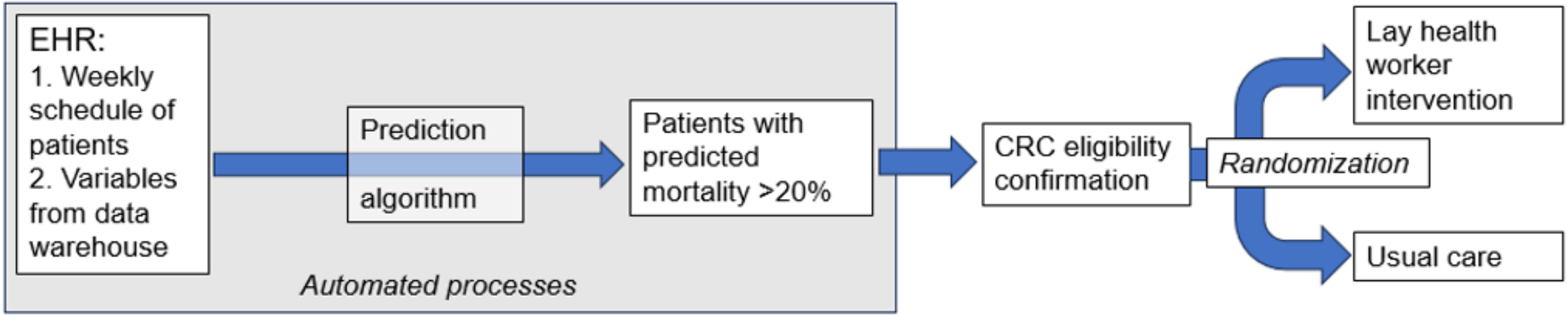
Algorithm Workflow



B. Trial enrollment workflow with algorithm



The algorithm set up extracts data from standard EHR databases (rather than requiring application installation within the EHR). All data used in the prediction algorithm can reside on sites' own local servers.

Algorithm Implementation

To set up the algorithm, IT staff at each site will undergo a brief training prior to study activation.

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

Key Patient Participant Eligibility – Disease Criteria

- Participants must have a diagnosis of a solid tumor malignancy of any stage.
- Participants must be identified as high risk, defined as having 6 month mortality estimate from machine learning (ML) algorithm ≥ 20% (0.20).
- Participants must not be receiving or have pre-existing plans to enter hospice care at the time of study registration.

Key Patient Participant Eligibility – Prior/Concurrent Therapy Criteria

- Participant must be actively receiving or planning to receive systemic anti-cancer therapy (defined as any oral, injection, or intravenous therapy against cancer) within 3 months after registration.

  NOTE: This includes chemotherapy (conventional or cytotoxic chemotherapy), hormone therapy, targeted therapy, and immunotherapy.

  NOTE: Participants are allowed to be co-enrolled on other clinical trials including trials using investigational agents.

Key Patient Participant Eligibility – Clinical Laboratory Criteria

- Participants must be ≥ 18 years of age at the time of study enrollment.
- Participants must be able to speak English or Spanish. The intervention is delivered via oral communication in English or Spanish
- Participants who can complete Patient Reported Outcome (PRO) questionnaires in English or Spanish must be willing to 1) complete PROs at all scheduled assessments (per S2424CD Protocol Section 15.3); and 2) complete the pre-registration (baseline) PRO forms within 14 days prior to registration.
- Participants must be able to provide a valid telephone number for the purpose of being contacted by the lay health worker.

No one on the study team may grant waivers to any of the eligibility criteria.

- **Refer to: https://dctd.cancer.gov/research/ctep-trials/memos/protocol-deviations.pdf**

Patient Participant Recruitment and Informed Consent

Recruitment:

- The prediction algorithm will be automated to run weekly within the Recruitment Center EHR.
- **Site research staff will** review weekly lists to confirm that the participant has a solid tumor malignancy and is on or planning to receive active therapy and **contact the prospective participant within 14 days after algorithm identification**.

Main Study Consent Covers:

- Randomization to A-PACT intervention or usual care
- 16-month follow-up with questionnaires and data collection
- Optional: Agreement to be contacted for implementation evaluation interview

Consent Options:

- In-person at clinic OR remote consent (phone/video) per NCI CIRB guidelines

Key Requirements:

- Baseline PROs completed within 14 days of consent
- Prognostic Awareness form administered FIRST and alone
- Contact preferences collected for Lay Health Worker coordination

Implementation Evaluation:

- Patient consent:
  Included as optional component in main consent
- Clinician consent:
  Separate consent by local site staff prior to interview

Identification of a Site Liaison to the Lay Health Worker – PRIOR to Patient Participant Registration

- Each site must designate one research staff member to serve as a point of contact between the site and the lay health worker in the event of suicidality or if other safety concerns are brought up to the lay health worker.
    - In this event, the LHW will immediately notify the Stanford project manager and maintain contact with the patient until the site research staff can be contacted for a warm handoff.
    - If the LHW identifies significant resistance, pushback or psychological distress, suspected harm, or if the patient reports isolation and lack of caregiver support, the lay health worker will contact the site research staff member to inform appropriate response and reporting procedures, in accordance with site protocols and IRB requirements.
- Prior to participant enrollment:
  Sites should identify the designated LHW point-of-contact and back-up point-of-contact and provide their name, role, phone number and email to Dr. Patel's team via a REDCap form, accessible from: https://redcap.stanford.edu/surveys/?s=YTTP9YN8CWECKJ8Y.
    - If the site designated LHW point-of-contact leaves the site or is no longer able or willing to be the point-of-contact, the site should designate a new LHW point-of-contact and inform Dr. Patel's team by re-submission of the above REDCap form.

Participant Registration

Timeline:

- Within 14 days of completing baseline PROs

System:

- OPEN (Oncology Patient Enrollment Network) - web-based, 24/7

Site Prerequisites:

- Active CTSU registration
- Algorithm approved by Dr. Parikh/Emory
- Approval document submitted to CTSU (allow 24 hours for processing)

Investigator Requirements:

- Active CTEP credentials
- Rostered at site
- APPs/NPs/PAs permitted to register patients

Process:

- Complete Registration Worksheet (for reference only)
- Register/randomize in OPEN → Group 1 (A-PACT) or Group 2 (Usual Care)
- Single-blinded study – See Protocol Section 7.4 (Site study team not informed of assignment)

Recruitment and Informed Consent of Clinicians and APPs

- Emory University staff will contact clinicians via email to ask if they will participate in an interview.
  - *Site NCORP administrators will be copied on all emails related to clinician interviews so that they know when to consent and register the clinician.*
- Clinicians eligible for the study will include all physicians or Advanced Practice Providers (APPs) identified in OPEN as being the “treating physician” for at least one eligible patient on the Group 1-A-PACT intervention arm.
  - Clinicians will be randomly sampled within geographic and site-specific strata, to be finalized by the study team.
  - The SWOG Statistics and Data Management Center will provide Emory University staff with a list of all physicians or Advanced Practice Providers identified in OPEN as being the “treating physician” for at least one eligible patient on the Group 1-A-PACT intervention arm.
- Recruitment will continue until the target sample of 20 clinicians is reached.
- If a clinician agrees to be interviewed, **their local site staff will administer consent and register the clinician in OPEN.**

Non-Patient (Clinician) Enrollment

Timing:

In order to avoid potential contamination, clinician interviews will be not be conducted until sites have been recruiting for approximately one year into the enrollment period.

Registration in OPEN:

- Prior to registration, site staff should verify that:
  - Clinician or APP responded positively to Emory University's email request to be interviewed,
  - Signed the clinician consent form. (Clinicians will not be providing health information, so HIPAA form is not required.)
- In the OPEN credentialing screen: Select the registration type of Non-Patient and select the applicable non-patient type 'Provider'.
- Refer to Protocol Section 13.5 for information (such as Type of Provider, Specialty) that must be entered at time of registration.

NOTE: In the OPEN registration, clinician participants will be listed as their own Treating Investigator. However, clinician participants must not consent themselves or sign their own eligibility criteria forms.

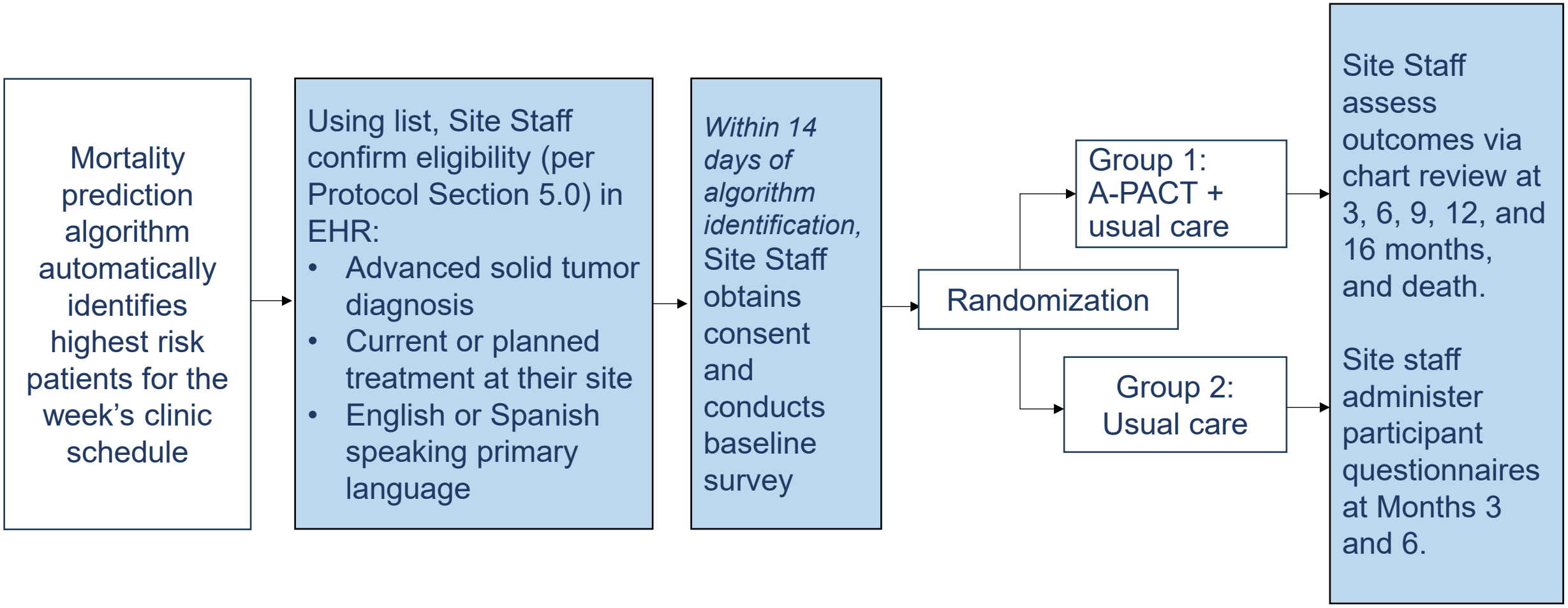
Notify Emory after completing OPEN Registration:

- Email the non-patient participant registration ID that is provided by the OPEN system upon completion of the registration to Emory University staff at: S2424CD@emory.edu, indicating that the clinician is ready for interview.

After Registration Emory Staff will schedule the interview:

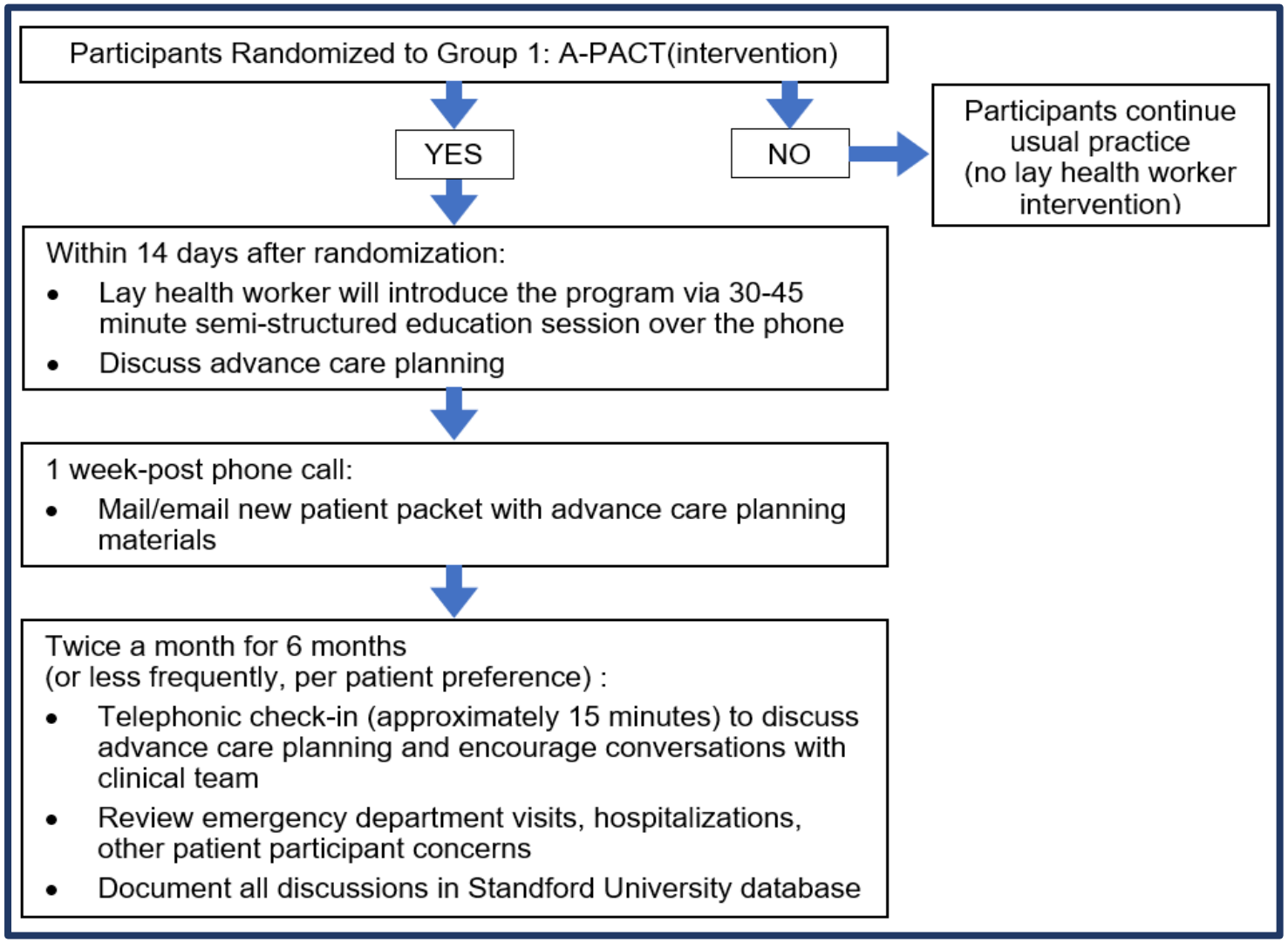
- Once Emory University staff receives non-patient registration ID, they will reach out to clinician to set up time for surveys and interview.

Site Staff Workflow



Blue box: Site Staff tasks

Lay Health Worker (LHW) intervention (Arm 1)



- LHW will be centralized, based out of Dr. Patel's center at Stanford and will communicate with patients on behalf of clinical sites, via telephone to provide tailored assistance in:
  1. Formulating health care and end-of-life care preference
  2. Completing advance directives,
  3. Guidance on how to engage in these conversations with their families and friends and their clinical teams.
  4. Encouragement to discuss these important topics with their clinical team members.
     - Initial session will be 30-45 min, then
     - 15 min phone conversations twice monthly (or less frequently per patient preference).
- LHW will contact the designated site point-of-contact if attempts to contact the patient participant are failing (defined as 3 missed calls and 3 missed emails).

Group 1: A-PACT (Lay Health Worker Intervention)

- **The lay health worker does not have direct contact with the clinical team, as the intention of the program is to encourage participants to initiate goals of care conversations with their clinicians.**
- Conversations between the lay health worker and the participants are not recorded.
- Lay health workers will log the dates and brief content of their interactions onto a secure database (at Stanford).
- Session topics are outlined in the table below.

Session number	Audio encounter	Topics covered
S1	initial	• Rapport building; Introduction; Verify mailing address • Encourage discussions of any questions; Begin to understand primary goals and patient's preferences for care • Introduce advance care planning and goals of care discussions • Begin to craft a personalized care plan based on the patient's needs The LHW will mail an Advance Care Planning brochure to patients a week post initial phone call.
S2 – 11*	Twice-monthly (or less frequently per patient preference)	• Review patient's situation since last encounter; Identify any concerns; Continue discussion about goals of care needs • Surrogate decision maker and skills in addressing with clinical team • Tailored assistance in completing any necessary goals of care and advance planning paperwork • The patient is encouraged to discuss all topics with their clinical care team At the end of each encounter, the lay health worker will work with the patient to identify any issues that need attention and make plans for follow-up at the next encounter. The lay health worker will also identify the date for the encounter for the following month until the last intervention.
S12 Study exit information	last	• Review the past conversations; • Summarize the issues • Close out the conversation encouraging engagement with all clinical care teams in all clinical encounters.

Patient Reported Outcomes

Timepoints:

- Baseline (within 14 days before registration)
- Months 3, 6 (+/- 30 days), based on the date of registration

Instruments:

- Prognostic Awareness and Treatment Preferences (MUST be given FIRST, and completed alone to prevent cross-contamination with other measures)
- GAD-7 (anxiety), PHQ-9 (depression), Heard and Understood

Completion Time:

- ~12-15 minutes to complete at each study time point.

Distribution:

- Clinic visit, mail, or secure email
- Refer to S2424CD Protocol Section 15.6 for options to complete the PRO questionnaires at home.

Return:

- Next clinic visit, mail, or secure email per institutional policy

Refused:

- Document reason on Cover Sheet, Continue study procedures (Not grounds for removal from study), Retry at next timepoint

Study Intervention Discontinued:

- Participants should continue to complete questionnaires at study timepoints regardless if participant discontinues the study intervention early per S2424CD Protocol Section 7.7.

Training:

- Site staff involved in the collection of patient-reported outcomes data should review the Patient Reported Outcome Questionnaires Training in CTSU CLASS, accessible from: SWOG Protocol Workbench.

Patient Reported Outcomes

Instrument	Timepoints	Allowable Collection Window	# of questions	Estimated time for completion
Demographics Form	Baseline only	Within 14 days prior to registration	6	3 minutes
Prognostic Awareness and Treatment Preferences	Baseline Month 3 Month 6	Baseline: Within 14 days prior to registration Months 3 and 6: ± 30 days	4	3 minutes
Anxiety – PROMIS® Short Form v1.0 – Anxiety 4a			4	3 minutes
Depression – PROMIS® Short Form v1.0 – Depression 4a			4	3 minutes
Heard and Understood			4	3 minutes

Administration timing:

- It is preferable for questionnaires to be given to the participants at the clinical visit immediately prior to the study time point or completed at home and returned at the routine clinical visit coinciding with the study time point.
- Baseline forms may be completed at home (after consent)

Implementation Evaluation Interviews: Group 1: A-PACT Intervention Only: Patient Participants

Goal: To quantitatively and qualitatively assess how patient, clinician, and organizational factors shape effectiveness and implementation of the Group 1: A-PACT Intervention.

Emory University staff will conduct implementation objective interviews with approximately 40 patient participants randomized to the Group 1: A-PACT intervention arm after the participant has completed all Month 6 study activities.

- Acceptability: Patient-reported acceptability will be measured using the 4-item Acceptability of Intervention Measure (AIM).
- Patient beliefs related to Goals of Care communication (e.g. self-efficacy and readiness) will be measured using the 15-item Advance Care Planning Engagement (ACP) survey.
- Patient-centered care: Patient engagement will be measured using a 3-item measure of shared decision making (CollaborRATE)

Instrument	# of questions	Time for completion	Timepoints
Acceptability of Intervention (AIM)	4	3 minutes	Beginning 6 months post randomization (± 30 days)
Advance Care Planning Engagement (ACP)	15	10 minutes	
CollaborRate	3	2 minutes	

Implementation Evaluation Interviews: Group 1: A-PACT Intervention Only: Clinician Participants

Goal: To quantitatively and qualitatively assess how patient, clinician, and organizational factors shape effectiveness and implementation of the Group 1: A-PACT Intervention.

Clinicians will be randomly sampled within geographic and site-specific strata, to be finalized by the study team. A total of 20 primary oncologists or advanced practice providers will be asked to complete surveys and participate in semi-structured interviews.

- Oncologist beliefs related to Goals of Care communication will be assessed using the 28-item End-of-Life Care Questionnaire (EOL-Q).
  - Upon analysis, clinicians will be described as having high vs. low rates of Goals of Care completion (~10 clinicians in each stratum).
- Organizational Climate will be measured with the 18-item Implementation Climate Scale to capture the degree to which their clinic supports use of evidence-based practices like Goals of Care communication.

Instrument	# of questions	Time for completion	Timepoints
End of Life Care Questionnaire (EOL-Q)	28	10 minutes	Month 12 (± 30 days)
Implementation Climate Scale (ICS)	18	7 minutes	

In order to avoid potential contamination, clinician interviews will be not be conducted until sites have been recruiting for approximately one year into the enrollment period.

Baseline Disease Assessment

- Upload disease appropriate source documentation necessary to support diagnosis (as per S2424CD Protocol Section 5.1a). Source documents (such as reports) must be uploaded into RAVE® via the Source document Baseline form.
- Disease does not need to be assessed or monitored over the course of the study for the purposes of S2424CD.

Study Calendar: Patient Questionnaires and Implementation Evaluation Surveys

REQUIRED FORMS / TASKS	Pre-Registration	Participant Registration/ Randomization	Month 3 (+/- 30 days)	Month 6 (+/- 30 days)	Month 9 (+/-30 days)	Month 12 (+/- 30 days)	Month 16 (+/- 30 days)	Off Protocol
PATIENT QUESTIONNAIRES								
S2424CD Prognostic Awareness and Treatment Preferences	X		X	X				
S2424CD Demographics Form	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				
S2424CD Cover Sheet for Patient-Completed Questionnaires (Completed by Site Staff at each PRO questionnaire submission timepoint)		X	X	X				
For Group 1 Participants who consent to participate in the implementation evaluation interviews ONLY:								
PATIENT IMPLEMENTATION EVALUATION SURVEYS								
4-Item Acceptability of Intervention Measure				X				
15-Item Advance Care Planning Engagement				X				
3-Item Shared Decision Making				X				

Study Calendar:
Site-Completed Forms and 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)	Month 16 (+/- 30 days)	Off Protocol
Vital Status		X	X	X	X	X		X
S2424CD Onstudy		X						
Algorithm Data		X						
Recent Hospitalizations			X	X	X	X	X	X
Intensive End-of-Life Care							X	
Goals and Plans of Care and Treatment Documentation							X	X
S2424CD Off Protocol Notice							X	X

Anticipated Adverse Events

- S2424CD is not a treatment study. No dose modification or adverse event information will be collected.

Data Submission

- The Medidata Rave® clinical data management system is to be used for all data submission. Access to S2424CD in Rave is controlled through the CTEP-IAM system and role assignments.
  - For questions pertaining to CTEP-IAM role assignments (including Rave), contact CTSU.
- Data must be submitted according to the protocol requirements for ALL participants registered, whether or not assigned intervention is administered, including participants deemed to be ineligible.
  - Participants for whom documentation is inadequate to determine eligibility will generally be deemed ineligible.
- See Protocol Section 14.0 for complete Data Submission Requirements, Procedures and Timepoints.
  NOTE:
  - **Raw algorithm data must be uploaded into Rave via the Source document Baseline Form within 15 days after registration.** The data required is stored in a file that can be found in a shared folder at each site; Submit only the rows and column headers associated with the registered participant. See Protocol Section 18.11 for more information.
  - For each PRO questionnaire administration timepoint (baseline, Months 3 and 6): the S2424CD Prognostic Awareness and Treatment Preferences form should be administered first. See Protocol Section 15.3 for more information.
  - Month 16 timepoint is for EHR review of participant records through the 12-month follow-up only.
- A printable (.PDF) version of the Master Forms Set is accessible from the S2424CD protocol abstract page on the CTSU website.

Criteria for Removal from Protocol Participation

- Patient completes 12 months of protocol participation.
- Patient death.
- The patient may withdraw from protocol participation at any time for any reason.

NOTE: Participants who discontinue or never start their planned anti-cancer therapy should not be removed from protocol participation for this reason.

<u>For Group 1</u>:

- Participants who are randomized to Group 1: A-PACT intervention will continue to receive follow-up assessments conducted by the site, even if they never connect with or participate in conversations with a lay health worker.

Documenting Discontinuation of Protocol Participation

All reasons for discontinuation of protocol participation must be documented in the S2424CD Off Protocol Notice and submitted per S2424CD Protocol Section 14.0.

NOTE:

- Research staff should only submit the S2424CD Off Protocol Notice if the patient refuses both direct and indirect follow-up on the study or in the case of patient death.
  - If the patient allows for indirect follow-up or is refusing to complete any further participant forms but will allow the site to follow them, do not submit the S2424CD Off Protocol Notice and continue to submit the site completed forms at the time points required in Protocol Section 14.0.
- If a patient cannot or refuses to complete the participant questionnaires for a study time point, this is not a criterion for discontinuation of protocol participation.
  - Do not submit the S2424CD Off Protocol Notice.
  - Submit the site-completed forms for the time point per Protocol Section 14.0, the S2424CD Cover Sheet for Patient - Completed Questionnaires documenting the reason the patient questionnaires were not completed at the time point.
  - Administer questionnaires to the patient at the next study time point.
  - See also Protocol Section 14.0 for additional follow-up and forms management information.

Patient Participant Follow-up

Participants will be followed for **12 months after registration** or until a criterion in S2424CD Protocol Section 7.8 is met, whichever comes first.

- Follow-up should continue even if anti-cancer therapy is discontinued or never received.
- Participant refuses to complete questionnaires (indirect follow-up should continue).

To ensure enough time for EHR to have complete information through 12 months, forms reliant on EHR records will be completed at 16 months after registration.

- Hospitalization, Goals and Plans of Care, and Treatment Documentation intensive end-of-life care (in the event of participant death) that occurred within the 12-month study period will be ascertained on all patients at 16 Months.
- The Month 16 timepoint will **not** involve any patient contact and it will only reflect records up to 12 months after participant registration. It is simply a delayed medical record/EHR review to ensure that the data elements of interest to this study have had time to be captured by the EHR.

Study Monitoring and Quality Assurance

- A Data and Safety Monitoring Committee will oversee the conduct of the study.
  - The Committee consists of four members from outside of the SWOG Cancer Research Network, three SWOG members, three non-voting representatives from the National Cancer Institute (NCI), and the Group Statistician (non-voting).
  - The members of this Committee will receive confidential reports every 6 months from the SWOG Statistics and Data Management Center and will meet at the Group's bi-annual meetings as necessary. The Committee will be responsible for decisions regarding possible termination and/or early reporting of the study.
  - No futility or efficacy evaluations will be conducted. The focus of these reports will be on accrual and feasibility, including feasibility of achieving adequate study power. In particular, given widely inclusive eligibility criteria and the possibility that more patients than anticipated may not achieve their primary endpoint (e.g., hospitalization), the proportion of hospitalization events on the Usual care Arm will be monitored and reported.
    - If the proportion of patients with hospitalization is lower than expected (for instance, <67%, at which point planned power would drop below 90%), an increase to the sample size or modifications to the eligibility criteria to better target individuals at high likelihood of achieving their endpoint will be considered.
- Audits will be conducted at frequency of 3 years.

Funding

Accessing the Funding Memo	CTSU website >> **S2424CD** protocol abstract page >> **Funding Information >> S2424CD Funding Sheet**

Funding Source and Study Component		Mandatory/ Mandatory Request or Event/ Optional	Study Specific Notes	Enter Date in OPEN?	NCTN Funding Amount per Patient Standard/ LAPS	NCORP Funding Amount per Patient Std/HP
Federal	Base Intervention (Non-NCORP and Standard/High Performance (HP) NCORP)	Mandatory	1	No	NA	NA
Total Potential Federal Funds					**NA**	**NA**
Total Potential Funds					**NA**	**NA**
Additional Funding Per NCORP Main Member Site						
Federal Other	Site Compensation	Mandatory	2	No	NA	$3,000

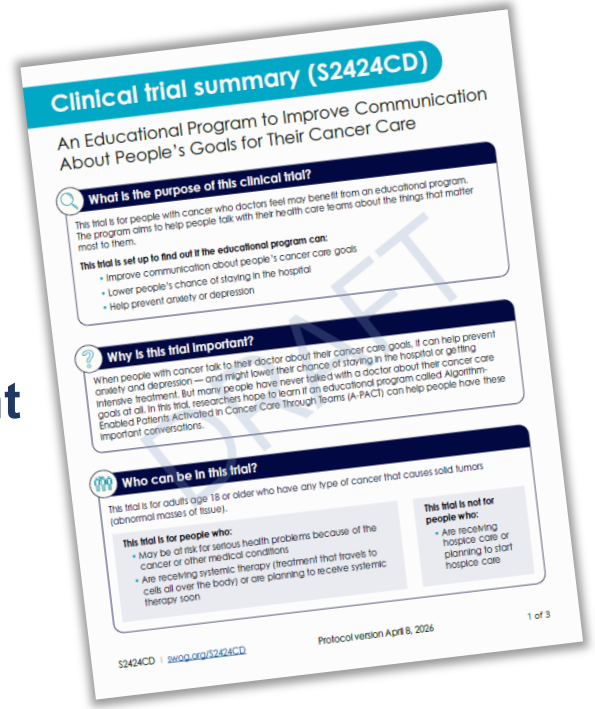
Study-Specific Notes:

1. S2424CD is limited to sites equipped to conduct Cancer Care Delivery Research (CCDR) and that have been approved by the Study Chair's office to participate in the trial. CCDR restricted funds have been distributed directly to sites and can be used to support CCDR studies.
2. Participating sites are eligible to receive start-up funding. This one-time payment per NCORP Main Member site will be triggered by the first participant enrollment onto the study under the NCORP or one of its components.

Resources and Materials — Patient-Friendly Clinical Trial Summary

The Patient-Friendly Summary is an educational tool to share key information about the trial

- Easy to understand, written in plain language
- Explains why the study is important, study treatments, who is eligible, length of trial involvement, costs, and how to learn more
- May include graphics to illustrate study design or treatments
- Translated into Spanish


Clinical trial summary (S2424CD)

An Educational Program to Improve Communication About People's Goals for Their Cancer Care

What is the purpose of this clinical trial?

This trial is for people with cancer who doctors feel may benefit from an educational program. The program aims to help people talk with their health care teams about the things that matter most to them.

This trial is set up to find out if the educational program can:
- Improve communication about people's cancer care goals
- Lower people's chance of staying in the hospital
- Help prevent anxiety or depression

Why is this trial important?

When people with cancer talk to their doctor about their cancer care goals, it can help prevent anxiety and depression — and might lower their chance of staying in the hospital or getting intensive treatment. But many people have never talked with a doctor about their cancer care goals at all. In this trial, researchers hope to learn if an educational program called Algorithm-Enabled Patients Activated in Cancer Care Through Teams (A-PACT) can help people have these important conversations.

Who can be in this trial?

This trial is for adults age 18 or older who have any type of cancer that causes solid tumors (abnormal masses of tissue).

This trial is for people who:
- May be at risk for serious health problems because of the cancer or other medical conditions
- Are receiving systemic therapy (treatment that travels to cells all over the body) or are planning to receive systemic therapy soon

This trial is not for people who:
- Are receiving hospice care or planning to start hospice care

S2424CD | swog.org/S2424CD

Protocol version April 8, 2026

1 of 3

DRAFT

We recommend a study team member review the summary with the patient as an introduction to the trial, or alongside the consent

- Also available as a PDF to be printed or shared electronically

The summary will be accessible from:

- **swog.org/S2424CD** (publicly accessible link, with printable PDF)
- Also via the S2424CD protocol abstract page on the CTSU website under Documents >> CIRB Approved Documents tab >> Support Documents filter, listed as “Clinical Trial Summary” (login required)

Additional Resources and Materials

- S2424CD Social Media Toolkit (text and graphics) will be available:
  - via the S2424CD protocol abstract page on the CTSU website under Documents >> CIRB Approved Documents tab >> Support Documents filter
  - **or** via swog.org/clinical-trials/S2424CD under “Other Study Materials” (no login)

- EMR Template will be accessible from the Documents >> Protocol Related Documents >> Education and Promotion filter on the S2424CD protocol abstract page.

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

Acknowledgements

SWOG Leadership:
Dawn Hershman, MD
Veena Shankaran, MD
Scott Ramsey, PhD

SWOG Clinical Trials Program Manager:
Sarah Cantu

SWOG Contract Attorney:
Shane Barnes, JD, LLM, MBA

Emory Project Manager:
Ajla Pleho, MPH

Contact Information

Eligibility, RAVE, Data Submission:	SWOG Statistics and Data Management Center E-mail: cancercontrolquestion@crab.org or Phone: 206/652-2267
Regulatory, Protocol, Informed Consent:	SWOG Network Operations Center E-mail: protocols@swog.org or Phone: 210/614-8808
Questions about the intervention:	E-mail: cancercontrolquestion@crab.org or Phone: 206/652-2267
Technical issues with the SWOG (ORP) CRA Workbench:	E-mail: technicalquestion@crab.org
Cancer Therapy and Evaluation Program - Identity and Access Management (CTEP-IAM) (e.g., new account requests, reset password)	https://ctepcore.nci.nih.gov/iam/index.jsp
Access to iMedidata Rave or Delegation of Task Log (DTL), Data Quality Portal questions, and Oncology Patient Enrollment Network (OPEN) questions	See Protocol Sections 14.3 or 13.5 or contact the CTSU Help Desk at: Phone: 1-888-823-5923 or Email: ctsucontact@westat.com
Algorithm Queries	E-mail: ravi.bharat.parikh@emory.edu
Lay Health Worker Queries	E-mail: manalip@Stanford.edu

Thank you!

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