NIH Collaboratory Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

Regulatory/Ethics Consultation Call:

Primary Palliative Care for Emergency Medicine (PRIM-ER) Trial

Monday, July 16, 2018

Meeting Participants

Corita Grudzen (NYU; study Principal Investigator), MariJo Mencini (Duke), Catherine Meyers (NIH), Tammy Reece (Duke), Marcel Salive (NIH), Jeremy Sugarman (Johns Hopkins), Wendy Weber (NIH), Alexandra Bragg (NYU), Ada Rubin (NYU)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS
Review of Demonstration Project	• PRIM-ER Principal Investigator Corita Grudzen, MD, MSHS, provided an overview of the study. Briefly, PRIM-ER is evaluating the implementation of a multi-level, evidence-based educational intervention designed to provide clinicians with basic grounding in palliative care considerations. The PRIM-ER intervention utilizes widely adopted tools/curricula such as EPEC-EM[1] and ELNEC[2] and a simulation-based workshop (EM Talk[3]), as well as clinical decision support and provider audit and feedback. • **Collaborative network partners:** NYU and Rutgers University for the initial phase; expanding to 33 additional emergency departments (EDs) nationwide for years 2-3. • **Study design:** Cluster-randomized, stepped-wedge design including 35 EDs across 18 health systems. • Analysis will be performed on Medicare claims data using the Centers for Medicare and Medicaid Services (CMS) Virtual Research Data Center (VRDC).[4] The study will extract data on ED visitors aged ≥66 years and look back 1 year to identify patients	

[1] http://bioethics.northwestern.edu/programs/epec/curricula/emergency.html

[2] http://www.aacnnursing.org/ELNEC

[3] Grudzen CR, Emlet LL, Kuntz J, et al. EM Talk: communication skills training for emergency medicine patients with serious illness. BMJ Support Palliat Care. 2016 Jun;6(2):219-24.

[4] https://www.resdac.org/cms-data/request/cms-virtual-research-data-center

AGENDA ITEMS	DISCUSSION	ACTION ITEMS
	at high risk for morbidity or mortality using the Gagne index.[5] Patients already receiving hospice care will be excluded from the study. o **Primary outcome:** Disposition from ED at 6 months: acute care vs. alternative (palliative care, hospice, home care) • The PRIM-ER study will require access to protected health information (PHI) only at the NYU site. The study has been granted a waiver of HIPAA authorization and a waiver of informed consent from the NYU IRB for the Medicare claims data analysis. Patients are at high background risk for mortality and morbidity, but the study itself has been determined to be minimal risk, with breach of privacy being the only likely risk. Obtaining consent would be impracticable given the circumstances and number of patients. • There is no data use agreement contemplated. • PRIM-ER study personnel and the PI have been conducting site visits, not as a formal component of the study, but because they have proven useful for obtaining study buy-in and support from health system leadership. • It was noted that because the study intervention aims to encourage referral of appropriate patients to palliative care instead of ICUs, it will be important to frame outcomes clearly and accurately to avoid misinterpretation. The study intervention is actually a standard of care with an overall goal to align patient care plans with patient goals. Because the study outcomes of interest are things that affect patient welfare, this distinction will important.	
Status of IRB approval	• The study has been approved by the NYU IRB, which has determined that study does constitute human subjects research at the NYU site but does *not* constitute human subjects research within the other 17 health systems participating in the study. • A letter is available for sites during contract negotiations affirming the IRB approval status.	
Risk classification	• The IRB has made a determination of minimal risk for this study.	

[5] https://eprognosis.ucsf.edu/gagne.php

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Consent	• A waiver of informed consent has been granted by the NYU IRB. • A question was raised regarding whether patients were being notified that a study was ongoing. Although it was noted that individual notification seemed inappropriate, as the study was being performed with CMS datasets, others suggested that strategies such as posters or patient flyers could be used as a form of notification. It was acknowledged that post-study notification or communication about study results would most likely not be relevant to the PRIM-ER study, but plans for publication might be appropriate to include. • In response to a question about what might occur if any provider declined to participate in the study, the response was that such a scenario would most likely not come to the attention of PRIM-ER study staff.	• Two Collaboratory papers on ethical/regulatory considerations in PCTs have been forwarded to the PRIM-ER team.[6,7]
Privacy/HIPAA	• The PRIM-ER study has been granted a waiver of HIPAA authorization. • No other concerns noted.	
Monitoring and oversight	• The study has a Data and Safety Monitoring Plan that will draw on input from three experts with experience in palliative care research. NCCIH has worked with the PI in crafting the approach and it is consistent with their requirements.	
Issues beyond the study	• A certificate of confidentiality has been provided as part of the grant award. This entails obligations regarding future data use, but may not be relevant to this study.	

[6] Whicher DM, Miller JE, Dunham KM, Joffe S. Gatekeepers for pragmatic clinical trials. Clin Trials. 2015 Oct;12(5):442-8.
[7] Finkelstein JA, Brickman AL, Capron A, Ford DE, Gombosev A, Greene SM, Iafrate RP, Kolaczkowski L, Pallin SC, Pletcher MJ, Staman KL, Vazquez MA, Sugarman J. Oversight on the borderline: Quality improvement and pragmatic research. Clin Trials. 2015 Oct;12(5):457-66.

Protocol Name	*Primary Palliative Care Education, Training, and Technical Support for Emergency Medicine (PRIM-ER)*
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NYULMC Study Number	17-01790

Initial Version Date: 05/01/2018

1. Objectives

We propose the implementation and testing of a novel, highly efficient pragmatic intervention that seeks to shift the clinical practice paradigm of emergency medicine. We propose a pragmatic, cluster-randomized stepped wedge design to test the effectiveness of primary palliative care education, training, and technical support for emergency medicine (PRIM-ER) in 35 Emergency Departments (EDs). PRIM-ER includes four core components: 1) evidence-based multidisciplinary primary palliative care education, 2) simulation-based workshops on communication in serious illness, 3) clinical decision support, and 4) provider audit and feedback. These core components will be implemented in each participating health system as part of a quality improvement initiative to improve the care older adults with serious illness receive in the ED setting. In the UG3 phase of the project, we will: 1) tailor PRIM-ER to the emergency provider workforce and a more diverse ED context using an agile implementation framework approach; and 2) pilot test PRIM-ER at two sites for feasibility, fidelity, and usability. In the UH3 phase, we will: 3) implement PRIM-ER in a cluster-randomized, stepped wedge design in the remaining 33 EDs; and 4) measure the effect of PRIM-ER on aspects of: a) ED disposition to an acute setting; b) healthcare utilization in the 6 months following the ED visit; and c) survival following the index ED visit. We hypothesize that it will be feasible to test PRIM-ER at two EDs with a high level of fidelity and usability and implement at all sites. We also hypothesize that older adult visitors with serious, life-limiting illness cared for by providers with primary palliative care skills will be less likely to be admitted to an inpatient setting, more likely to be discharged home or to a palliative care service, and will have higher home health and hospice use, fewer inpatient days and ICU admissions at 6 months, and longer survival than those seen prior to implementation. Additionally, we hypothesize that sites with higher baseline ED disposition to an acute care setting and less primary palliative care knowledge and skills will demonstrate greater change after implementation.

2. Background

The high intensity of end-of-life care in the United States (US) is now considered an epic public health problem. Persons receiving many life-sustaining therapies do not appear to show a benefit of better health or longer life.[1] Emergency Departments (EDs) care for society's most vulnerable older adults who present with

exacerbations of chronic disease at the end of life, yet the clinical paradigm continues to focus on treatment of acute illness and injury. Palliative care interventions in the ED capture high-risk patients at a time of crisis and can dramatically improve patient-centered outcomes.[2,3]

Half of Americans 65 years and older are seen in the ED in the last month of life, and three-quarters visit the ED in the six months before their death.[4] Emergency care has not fully adapted to the needs or goals of seriously ill patients who prefer to have care delivered at home.[5,6] Palliative care teams are now present in over two-thirds of hospitals, as well as 98 percent of National Cancer Institute-designated cancer centers.[7] Consultation by palliative care teams, however, is typically available Monday through Friday during business hours, and palliative care teams are not routinely available to come to the ED when a patient is in crisis.

An ED visit is often described as a sentinel event signifying a breakdown in care coordination for older adults.[8,9] Since EDs sit at the crossroads of ambulatory and inpatient care, they can and often play a pivotal role in balancing the potential harms and benefits of hospitalization for seriously ill, vulnerable older adults.[10-13] Hospitalization for older adults carries significant risks such as iatrogenic complications, functional and cognitive decline, and loss of independence[14-19] but emergency providers may be unaware of safe alternatives.

Emergency medicine developed as a specialty to treat the acutely ill and injured, yet EDs increasingly care for older adults with multiple comorbid conditions who present for acute exacerbations of chronic illness. Visits to the ED by older adults are increasing both in frequency and as a proportion of all ED visits. In 2011, adults aged 65 years and older comprised 15% of total ED visits, had the highest severity of illness, and represented 44% of all admissions from the ED.[20] The number and rate of admissions to the Intensive Care Unit (ICU) by emergency providers have also increased, especially among older adults.[21] The proportion of the US population 65 years and older will continue to grow, and EDs will see an increase in both the number of older adults and the complexity of care they are required to provide.[22] The ED presents a key decision point at which providers set the subsequent care trajectory, including whether an older adult is hospitalized and to which setting. Emergency physicians can thus play an integral role in transforming care for older adults through evidence-based models of care delivery that emphasize tradeoffs between potential benefits and potential harms.[23] However, until recently, little attention has been paid to the delivery of goal-concordant care in the ED for older adults with serious illness. The default treatment plan is to deliver treatment intensive care that favor life-sustaining therapies, many of which may be contrary to what older adults desire.

3. Settings of the Human Research

The PRIM-ER quality improvement (QI) initiative will be implemented in the Emergency Departments at the following sites:

Site	Location
NYU School of Medicine	
Perelman Center for Emergency Care	New York, NY
Bellevue Hospital Center	New York, NY
NYU Langone Hospital – Brooklyn	Brooklyn, NY
NYU Winthrop	Mineola, NY
Allegheny Health Network	
Allegheny General Hospital	Pittsburgh, PA
Baystate Health	
Baystate Medical Center	Springfield, MA
Baystate Franklin	Greenfield, MA

Beaumont Health System	
Beaumont Royal Oak	Royal Oak, MI
Beaumont Troy	Troy, MI
Brigham and Women's/Dana Farber Cancer Institute	
Brigham and Women's Hospital	Boston, MA
Brigham and Women's Faulkner	Boston, MA
Christiana Care Health System	
Christiana Hospital	Newark, DE
Wilmington Hospital	Wilmington, DE
Henry Ford Health System	
Henry Ford Hospital	Detroit, MI
Henry Ford Fairlane	Fairlane, MI
Henry Ford West Bloomfield	West Bloomfield, MI
Icahn School of Medicine at Mount Sinai	
Mount Sinai Hospital	New York, NY
Mount Sinai Beth Israel	New York, NY
Mount Sinai St. Luke's	New York, NY
Mount Sinai West	New York, NY
Mayo Clinic Health System	
Mayo Clinic, St. Mary's	Rochester, MN
Mayo Clinic Austin-Albert Lea	Austin/Albert Lea, MN
Mayo Clinic Health Mankato	Mankato, MN
Ochsner Health System	
Ochsner Medical Center	New Orleans, LA
The Ohio State University	
Wexner Medical Center	Columbus, OH
Rutgers New Jersey Medical School	
University Hospital Newark	Newark, NJ
University of California, San Francisco	
UCSF Medical Center	San Francisco, CA
Zuckerberg San Francisco General	San Francisco, CA
University of Florida Health	
UF Health Shands Hospital	Gainesville, FL
University of Pennsylvania Health System	
Hospital of the University of Pennsylvania	Philadelphia, PA
Pennsylvania Hospital	Philadelphia, PA
Penn Presbyterian Medical Center	Philadelphia, PA
University of Texas	
MD Anderson	Houston, TX
University of Utah Health	
University of Utah Hospital	Salt Lake City, UT
Yale New Haven Health System	
Yale New Haven Hospital	New Haven, CT

The research component of this initiative, consisting of analyzing the Medicare Claims Database, will solely occur at the Ronald O. Perelman Department of Emergency Medicine at NYU Langone Health.

4. Subject Identification, Recruitment, and Consent

A) Methods and Procedures

This is a cluster-randomized QI initiative that will implement and test the impact of PRIM-ER in various healthcare settings. We will first develop and pilot test the QI initiative at two sites in the UG3 phase, and then use a cluster-randomized, stepped wedge design to implement the education, training, and technical support in

our network of EDs in the UH3 phase. Randomization will occur at the ED level and be done in advance by the biostatistician to determine the order in which the training will occur. The overall approach involves ongoing asynchronous learning and technical support to bolster skills, conduct interdisciplinary case reviews, and reinforce clinical pathways and protocols via provider audit and feedback. Electronic triggers for palliative care will be embedded in the electronic health record (EHR) to identify patients who may benefit from hospice or palliative care services. These electronic triggers already existing in the Perelman Center for Emergency Services EHR as part of standard, clinical workflow, but will be further tailored for each participating health system. Palliative care champions at each site will facilitate attendance at didactic and workshop sessions, disseminate information about local resources for outpatient palliative care, home care and hospice, and work with the local informatics team to reinforce protocols and implement trigger criteria to identify older adults who may benefit from further needs assessment and follow-up. Physicians and nurses will receive audit and feedback reports to monitor their performance over time, and a learning monitoring system will track participation in educational activities.

Prior to initiating this QI project, members from the palliative care team, emergency nursing, social work/case management, informatics, and ED operations from each of the 18 health systems will participate in workgroups to discuss how to best incorporate primary palliative care into the clinical workflow at each site. Pilot testing of PRIM-ER will also occur at two sites to optimize feasibility, fidelity, and usability. Emergency physicians at each pilot site will be invited to participate in usability testing of the clinical decision support (CDS) system. To assess usability, MORAE software will be utilized to perform screen captures and audio record participants verbalizing their actions, thoughts, and feelings as they progress through a simulated CDS system.

In the UH3 phase of the study, we will engage eligible providers at the 33 additional sites based on the random sequential order in which the ED implementation occurs. Throughout the duration of the project, we will actively engage each health system by providing all ED staff with audit and feedback reports to monitor their performance over time. These reports will be provided on a weekly basis during the study period, as well as incorporated into ED-specific continuous quality improvement processes. By providing this continuous and consistent feedback to ED personnel, we hope to encourage continued participation and active engagement with the initiative throughout its duration.

For the research component of the study, we will use Medicare claims of the beneficiaries in our patient cohort to measure outcomes, including ED disposition to an acute care setting, healthcare in the 6 months following the ED visit and survival following the index ED visit as a result of the intervention. The patient cohort will be extracted via the Centers for Medicare and Medicaid Services (CMS) Research Data Assistance Center (ResDAC) using a two-step process to maximize diversity, and minimize intentional or unintentional exclusions based on risk, age, health literacy, demographics, or expected adherence. First, we will provide a comprehensive list of facility codes for the 33 participating EDs. Inpatient and ambulatory claims will be used to identify community-dwelling ED visitors 66 years and over who made a visit to any of the EDs from 2 years prior to study initiation until the last day implementation day of PRIM-ER. ED claims will be identified via Revenue Center Code values of 0450-0459 (Emergency room) or 0981 (Professional fees-Emergency room) according to ResDAC. We will then examine all inpatient, ambulatory, and carrier claims for the 12 months prior to each older adult's index ED visit to calculate each beneficiary's Gagne Index, a score developed to predict one-year mortality in community-dwelling older adults.[24] The Gagne Index has been adapted from the Romano-Charlson Index and the Elixhauser system.[25,26] It calculates a score based on the presence or absence of ICD-9s from inpatient and ambulatory claims in the prior year. Beneficiaries with a one-year

mortality of at least 30% (score > 6) based on claims from the previous 12 months will be included in the analysis.

We will estimate the baseline rate of acute care admission, healthcare utilization, and survival following the index ED visit using Medicare claims data for visitors to each ED. We will use the Master Beneficiary Summary File, Inpatient, Outpatient, Home Health, and Hospice files to monitor acute care admission, healthcare utilization, and survival monthly for up to 6 months after the index ED visit to evaluate whether there is a change before and after implementation. Measurement of what will be considered the baseline rate will continue until the month prior to implementation at each site, and post-implementation rates will be considered one month after implementation and continue on a monthly basis until 6 months after the last site has undergone implementation. To reduce prevalence-incidence bias[27], we will include a roll-in period of 12 months before we begin to include baseline rates of our outcomes in the analysis. The index ED visit will be defined as the first ED visit to one of our 33 facilities during which the beneficiary has 12 months of prior inpatient, outpatient, or carrier claims consistent with a Gagne Index > 6, or >30% mortality. If a beneficiary's index ED visit occurs during the roll-in period, they will be excluded from the baseline rate calculations if they return to one of our participating EDs and would otherwise meet our inclusion criteria.

To account for primary palliative care knowledge and skills on patient outcomes in analysis, we will use survey data that assessed knowledge and attitudes of palliative and end-of-life care collected before PRIM-ER implementation from the emergency physicians, physician assistants, nurse practitioners, and nurses at all 33 participating EDs.

B) Inclusion and Exclusion Criteria

Eligible patients will include ED patients 66 years or older with serious, life-limiting illness who visited any of our EDs during the implementation of PRIM-ER. Patients must demonstrate one-year mortality of at least 30 percent (score > 6) according to the Gagne Index, a validated instrument used to measure all cause one-year mortality in community-dwelling older adults, calculated based on their prior 12 months before the index ED visit of Medicare claims. ED patients transferred from a nursing home on the index ED visit will be excluded since prediction of mortality and disposition of such patients differs from community-dwelling adults. Patients currently receiving hospice at the time of the index ED visit will also be excluded since they have already received services.

C) Number of Subjects

We expect to analyze the Medicare claims of over 57,000 patients with serious illness who have made their index ED visit to any of the 33 EDs.

D) Recruitment and Informed Consent

Medicare claims of patients 66 years and older with serious, life-limiting illness who made a visit to any of our EDs during the study period will be used to measure outcomes in our patient cohort. We will seek a waiver of Health Insurance Portability and Accountability Act (HIPAA) authorization for ED patients as this study presents no more than minimal risk and cannot be practicably conducted without the waiver given the study's geographic breadth and sheer number of participants (>57,000 eligible patients). Obtaining informed consent

for participation and use of Medicare claims from all patients in this study is not feasible and will interfere with the conduct of this study.

E) Data Analysis

a. Dependent variables

ED disposition will be measured on the index ED visit, and will be a dichotomous variable for an acute care admission (Yes/No). Acute care admission will be defined as admission to a non-palliative service, and non-acute care admission will include admission to a palliative care service or unit, discharge to home, observation (without a change to inpatient status), or transfer to inpatient or outpatient hospice.

Healthcare utilization will be measured as ED revisits (count), inpatient days (count), home health use (Yes/No), and hospice use (Yes/No) in the 6 months from the index ED visit. These will be identified through revenue codes in each site's administrative data. We developed these measures of healthcare utilization based on the *Dartmouth Atlas Decedent Cohort Care Intensity Measures* to monitor the quality of end-of-life care in Medicare patients with serious chronic illness. [28-30]

Survival will be measured in days from the index ED visit to death or 6 months, whichever is sooner.

b. Independent variables

Table 1 outlines the independent variables. Independent variables were previously assessed at the time of site implementation. Healthcare system- and provider-level variables were collected by the project manager and via a provider survey at the level of each participating ED. Patient-level variables will be assessed using the CMS Research Data Assistance Center Master Beneficiary Summary File, Base (A/B/D) Segment.

Table 1. Independent Variables

Variable	Coding	Source
Implementation Period	Weeks from Time 0	Project Manager
Healthcare system/ED-level variables		
Health System	Allegheny, Bay State, Beaumont, Brigham and Women's, Christiana Care, Henry Ford, Mayo Clinic, MD Anderson, NYU Langone, Ohio State University, Ochsner, Rutgers, Sinai, UC San Francisco, University of Florida, University of Pennsylvania, University of Utah, Yale New Haven	Project Manager
ED	1—33	Project Manager
ED Volume	30,000—49,999 visits, 50,000—69,999 visits, 70,000—89,999 visits, $\geq$ 90,000 visits	Project Manager
Ownership	Nonprofit, Government, For Profit	Project Manager
Emergency medicine residency training site	Yes/No	Project Manager
Free-standing ED	Yes/No	Project Manager
Dedicated ED social worker/care manager	Yes/No	Project Manager
US Region	Northeast, Midwest, Southeast, Southwest, West	Project Manager
Metropolitan Status+	Yes/No	Project Manager
Outpatient palliative care	Yes/No	Project Manager
EHR	Epic, Cerner, Pysis/Pulsecheck	Project Manager
Trauma center	Yes/No	Project Manager
Patient variables		

Age	Years	Master Beneficiary Summary File, Base Segment
Gender	Female, Male, Other	Master Beneficiary Summary File, Base Segment
Race/Ethnicity	Asian, Black, Hispanic, White, North American Native, Unknown, Other	Master Beneficiary Summary File, Base Segment
Gagne index[24]	Count of conditions	Inpatient and outpatient RIF
+Population estimates by MSA are based on estimates of the civilian non-institutionalized population of the US as of July 1, 2013, from the 2013 National Health Interview Survey, National Center for Health Statistics, compiled according to the 2013 Office of Management and Budget definitions of core-based statistical areas. See http://www.census.gov/population/metro/ for more about metropolitan statistical area definitions.		

c. Methods

The analytic plan accounts for the nested structure of the data, assesses normality assumptions of dependent variables, and addresses issues related to missing data, study participation bias, and baseline covariate balance. We address each of these in turn. All analyses will be conducted in R 3.3.2 (R Foundation for Statistical Computing, Vienna).

Prior to conducting the outcome analyses, we will compare patients in each ED cluster with respect to patient, provider, and facility characteristics. We will assess whether any adjustments will need to be made in the final statistical models based on whether the differences are clinically meaningful. To account for nesting in the data structure (patients nested in hospitals), we will use mixed effect multi-level models to estimate effect sizes. We anticipate two sources of variation.

The **primary outcome** is the proportion of eligible patients whose disposition is to an acute care setting (inpatient, non-palliative service). The **secondary outcomes** include healthcare service utilization in the 6 months following the ED visit and survival times following the ED visit. The health utilization outcomes include receipt of ED revisits (count), home health services (yes/no), inpatient days (count), admission to an ICU (yes/no), and admission to hospice (yes/no). The analysis of the effect of PRIM-ER on ED disposition in the context of a stepped-wedge design will be based on a Generalized Linear Mixed Model (GLMM). In particular, to assess the intervention effect, we will use a generalized linear binomial model with random site level effects. The analysis of site, provider, and patient-level characteristics that are associated with variation in impact of PRIM-ER will be based on extending the models used in the analysis plan for ED disposition, healthcare utilization in 6 months following the ED visit, and survival times to include independent variables related to the characteristics of interest.

5. Risks to Subjects

Any information collected from Emergency Department providers will be utilized solely for QI purposes and not analyzed for research.

The study involves using Medicare claims of patients in our patient cohort that contain identifiable personal health information. The largest risk to ED patients is a breach of confidentiality. This will be managed by ensuring that only qualified study team members have access to patient data; all personal identifiers will be removed after final analysis, and all reporting and/or publication of data based on Medicare claims will be in aggregate form. Study team members will also be approved by ResDAC to access the Medicare claims through the Virtual Research Data Center (VRDC), a virtual research environment allowing researchers to have direct access to approved data files to conduct their analysis within the CMS secure infrastructure. All research personnel who have access to electronic records will undergo extensive training to safeguard against

this potential risk to emergency provider, key informant, and patient participants, which will include HIPAA certification and CITI training in biomedical research and social and behavioral research.

6. Potential Benefits to Subjects

Future patients with serious illness who present to the ED may benefit from the findings of this study.

7. Protections Against Risk

Medicare claims obtained from CMS will be stored in the VRDC. The VRDC is a virtual research environment that allows researchers to have direct access to approved data files and be able to conduct their analysis within the CMS secure infrastructure. The VRDC contains its own VPN and virtual desktop. All reporting and/or publication of data will be in aggregate form. Additional protection of participant confidentiality mandated by HIPAA will be strictly adhered to.

All reporting and/or publication of data will be in aggregate form. Additional protection of participant confidentiality mandated by HIPAA will be strictly adhered to.

8. Data Collection, Safety, and Monitoring

A) Data Collection

We will estimate the baseline rate of acute care admission, healthcare utilization, and survival following the index ED visit using Medicare claims data for visitors to each ED. To evaluate the effect of PRIM-ER, we will use the Master Beneficiary Summary File, Inpatient, Outpatient, Home Health, and Hospice files to monitor acute care admission, healthcare utilization, and survival monthly for up to 6 months after the index ED visit to evaluate whether there is a change before and after implementation.

B) Provisions to Monitor Data and Ensure the Safety of Subjects

All study data will be stored and accessed via secure systems. Data will not be accessed or analyzed by individual sites; these activities will be performed exclusively by authorized individuals at the lead study site (NYU School of Medicine). Only authorized personnel who have been appropriately trained will be granted permission by the PI to access study data. A Data Safety Monitoring Plan (DSMP) will be submitted for reporting procedures of adverse events and serious adverse events.

C) Steering Committee

The PRIM-ER Steering Committee (SC) is the primary governing body of PRIM-ER. In consultation with the NIH Program Officer, NIH Scientific Officer, and NIH Collaboratory leadership, it formulates and monitors policies and procedures guiding the research activities. All major scientific and operational decisions are made by majority vote with the concurrence of the NIH Program Officer, NIH Scientific Officer, and NIH Collaboratory leadership. The Steering Committee may appoint Subcommittees and Working Groups as needed to carry out specific tasks identified by the Steering Committee. The Steering Committee will function in accordance with the Terms and Conditions of the NIH Collaboratory Demonstration Project RFA and other applicable policies of

NIH, NIA, and NCCIH. All participating PRIM-ER sites must agree to abide by the policies approved by the Steering Committee.

The voting membership of the committee is to consist of the Principal Investigator, a site Principal Investigator from each of the other 17 health care systems, the NIH Program Officer, the NIH Scientific Officer, and leadership from the NIH Collaboratory as requested. Other (non-voting) memberships also include the Program Manager and other Subcommittee and Work Group Members.

This committee will establish bylaws, policies, and standard operating procedures to govern all aspects of PRIM-ER. This committee will review and approve the collaborative research agenda as well as formulate and monitor policies and procedures guiding the research activities, review and approve procedures for data acquisition, analysis and management, oversee communication within the PRIM-ER as well as with the greater scientific community and the public.

The Steering Committee will be responsible for ensuring that there are well documented policies and operating procedures guiding all aspects of PRIM-ER activities (e.g., protocol development, review, initiation, conduct, and closure, data collection, publication, etc.) and bylaws delineating the requirements and expectations of collaborating institutions, membership criteria, review of research progress and performance, establish standards of performance, and procedures for removing institutions due to poor performance.

The Steering Committee will establish subcommittees and workgroups to assist it in carrying out its functions. The Steering Committee may meet up to four times a year.

D) Data and Safety Monitoring Plan

The PI, in cooperation with her co-investigators, the DSMB, and the IRB at NYU School of Medicine, will monitor the safety of the implemented project. The project manager will inform the PI immediately of any adverse events (AEs) that meet the collection and reporting criteria of the Data Safety Monitoring Plan (DSMP). All serious adverse events (SAEs) and Unanticipated Problems (UPs) related to study participation will be reported to the IRB and the NIA according to the criteria outlined in the DSMP. Events that might be considered AEs related to this proposal include emotional distress resulting from discussions surrounding palliative care, and any breaches in subject confidentiality. Related AEs and related SAEs will also be reported annually in the IRB for continuation or termination of the research. Given the minimal risk entailed by this project for all participating populations, we do not anticipate the occurrence of many AEs or SAEs. The PI and co-investigators will be versed in these reporting procedures, as they are currently required for all research conducted at NYU School of Medicine. All investigators and staff involved in this project have completed an extensive course and passed a certifying exam on the protection of human subjects in research. Independent Monitors comprised of a researcher in palliative care, biostatistician, and palliative care physician and content expert will monitory the data safety of this study. The study team will generate Study Reports for the Independent Monitors and will provide information on the following study parameters:

- Demographic information pertaining to patient subjects obtained in Medicare Claims.
- Stopping and reporting rules for UPs and related AEs/SAEs. A summary report will be generated consisting of the number of related AEs and SAEs by site and in total and delineated by severity.
- Any protocol deviations that have occurred since the previous report.
- Quality management activities since the last review, including frequency. A summary of findings and corrective actions taken to address the findings will be included.

- Interim analyses as requested by the IMC to assess safety concerns or study futility.

Study Report tables will be generated only from aggregate (not by group assignment) baseline and aggregate safety data for the study population.

9. Economic Impact to Subjects

There is no expected economic impact to subjects participating in this study.

10. Payments to Subjects

Patient participants will not receive compensation in this study.

11. Vulnerable Populations

Given the magnitude of the Medicare Claims Database, it is possible that adults unable to consent will be included. Since we are requesting a waiver of authorization, this should not pose any additional risk to these subjects.

Include	***Exclude***	***Vulnerable Population Type***
X		Adults unable to consent
	X	Individuals who are not yet adults (*e.g.,* infants, children, teenagers
	X	Wards of the State (*e.g.,* foster children)
	X	Pregnant women
	X	Prisoners

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Ronald O. Perelman Department of Emergency Medicine

Primary Palliative Care for Emergency Medicine (PRIM-ER)

Corita Grudzen, MD, MSHS, Vice Chair for Research, Associate Professor of Emergency Medicine and Population Health

PRIM-ER

1. Evidence-based, multidisciplinary primary palliative care education (EPEC-EM, ELNEC);
2. Simulation-based workshops on communication in serious illness (EM Talk);
3. Clinical decision support; and
4. Provider audit and feedback.

Cluster Randomized, Stepped Wedge Trial Across 35 EDs

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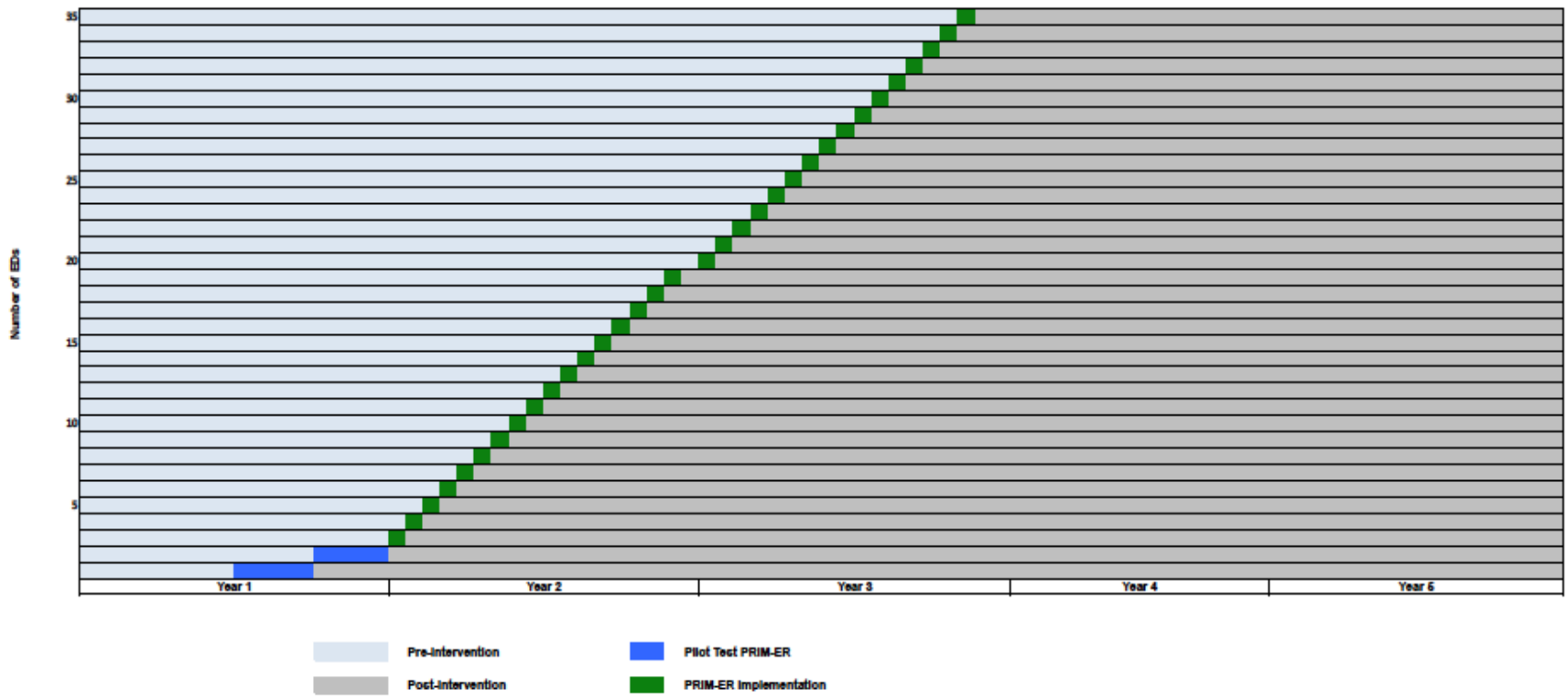

18 Health Systems

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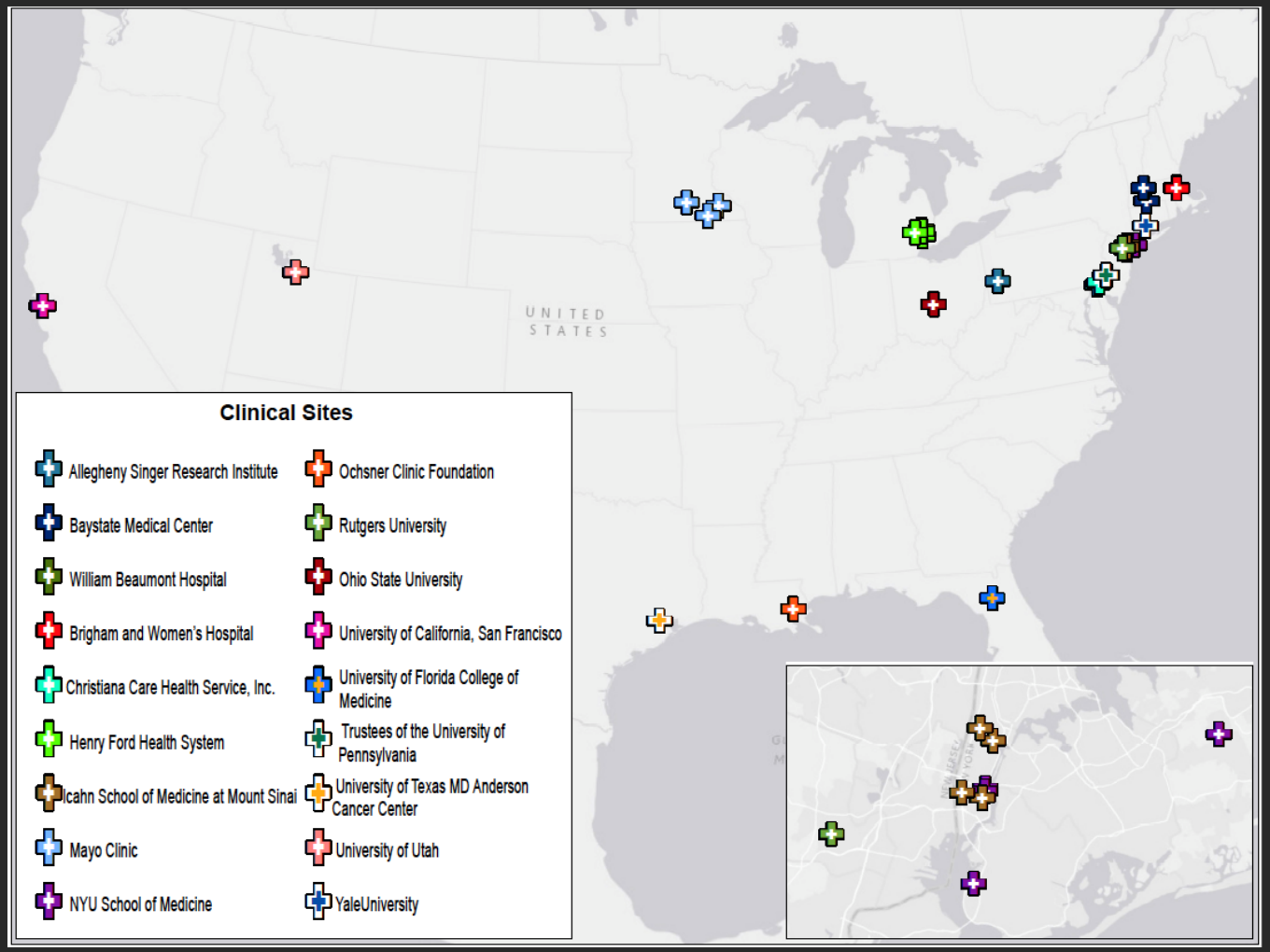

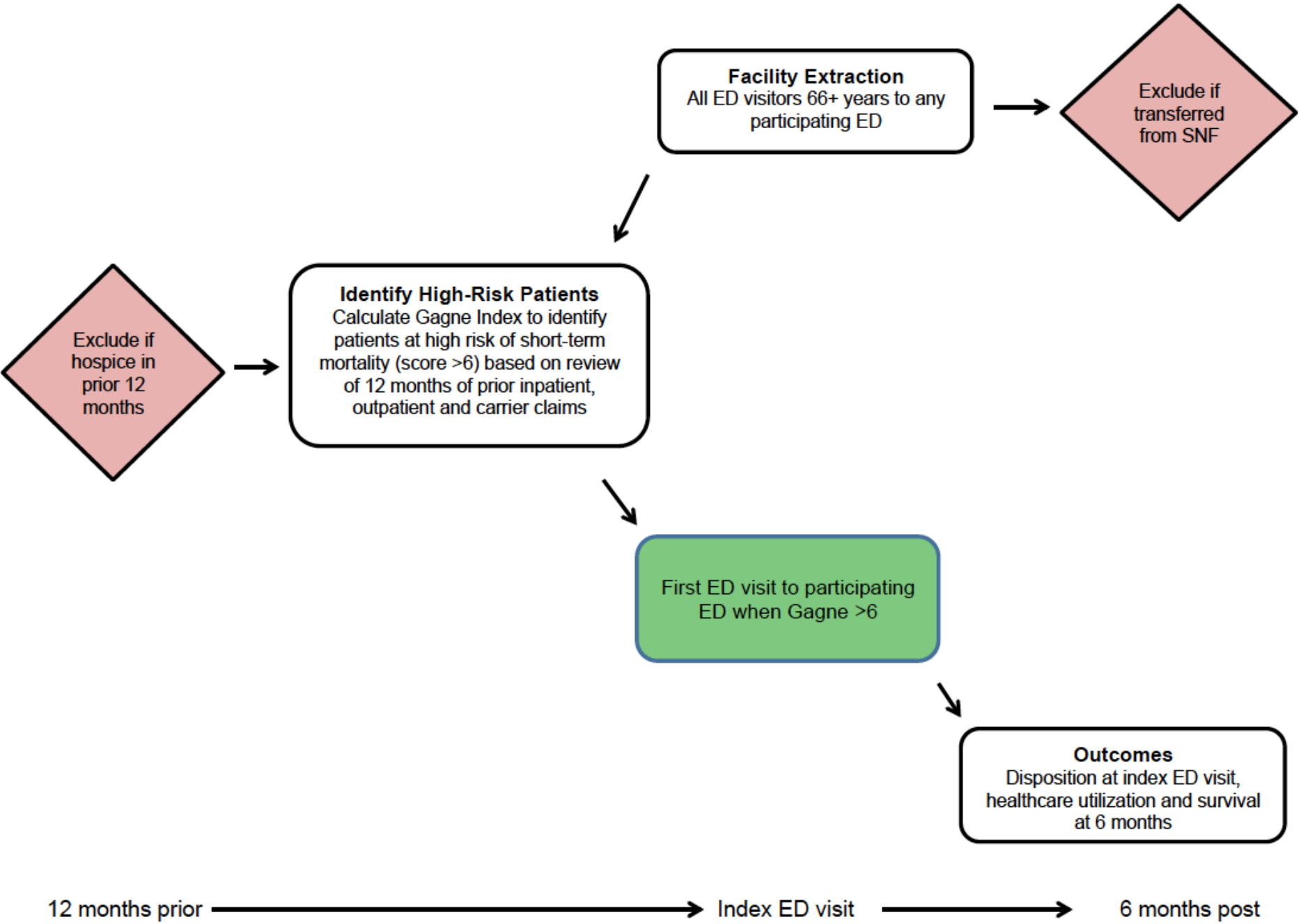
Facility Extraction
All ED visitors 66+ years to any participating ED
Exclude if transferred from SNF
Exclude if hospice in prior 12 months
Identify High-Risk Patients
Calculate Gagne Index to identify patients at high risk of short-term mortality (score >6) based on review of 12 months of prior inpatient, outpatient and carrier claims
First ED visit to participating ED when Gagne >6
Outcomes
Disposition at index ED visit, healthcare utilization and survival at 6 months
12 months prior
Index ED visit
6 months post

Protection of Human Subjects

VDRC analysis of CMS claims data

Waiver of informed consent HIPAA authorization as minimal risk and >300,000 patient participants

Intervention

Tested in the ED setting and shown to improve quality of care

No data use agreement or data sharing between prime and sub sites

Identifiable data used by local ED team only to improve quality of care