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Ronald O. Perelman Department of Emergency Medicine

PRIMARY PALLIATIVE CARE FOR EMERGENCY MEDICINE (PRIM-ER)

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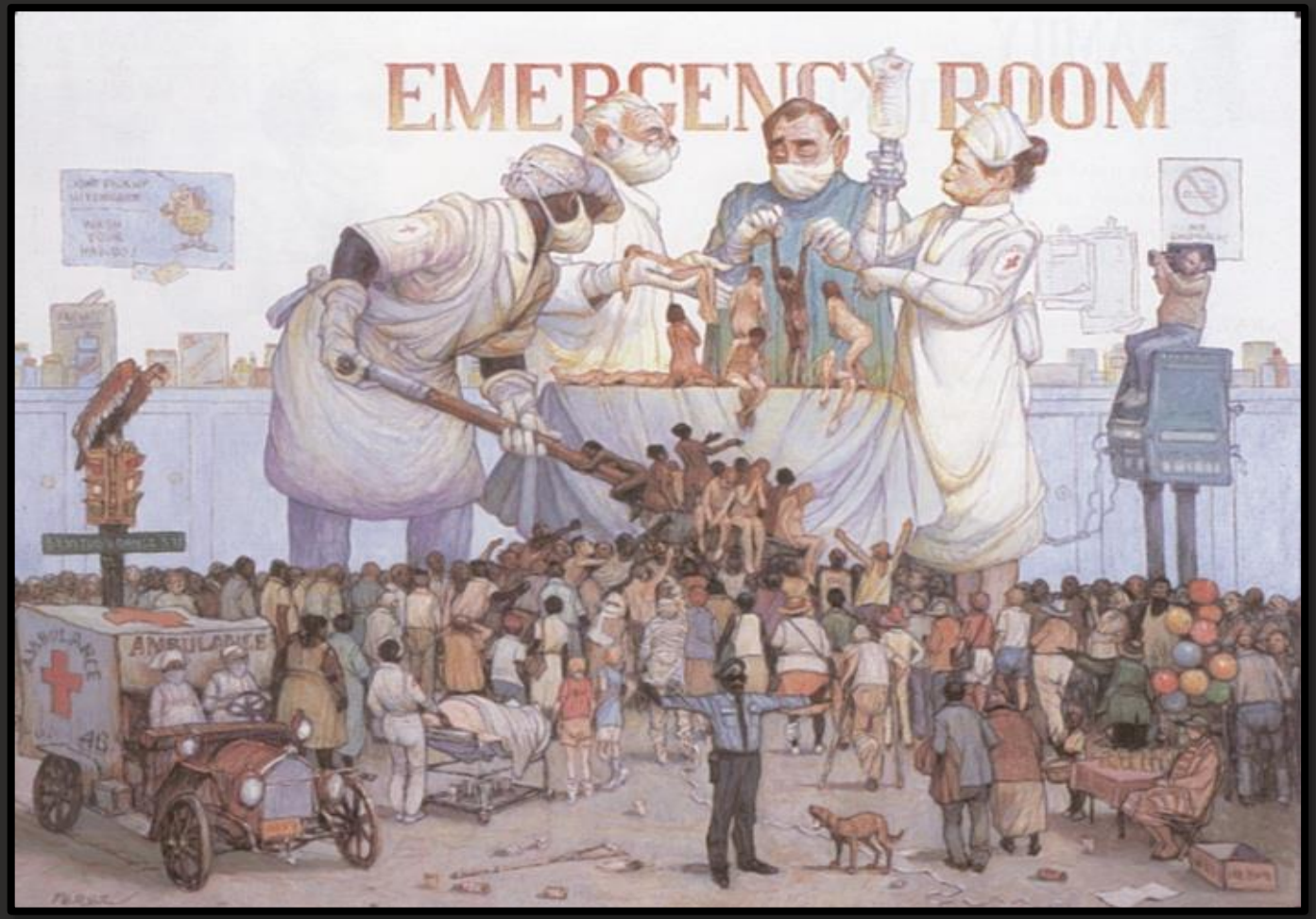

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Background and Rationale

- Increasing ED visits by older adults with serious illness
- Most prefer to receive care at home and to minimize life-sustaining procedures
- Palliative care improves quality of life and decrease health care use

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Default Approach

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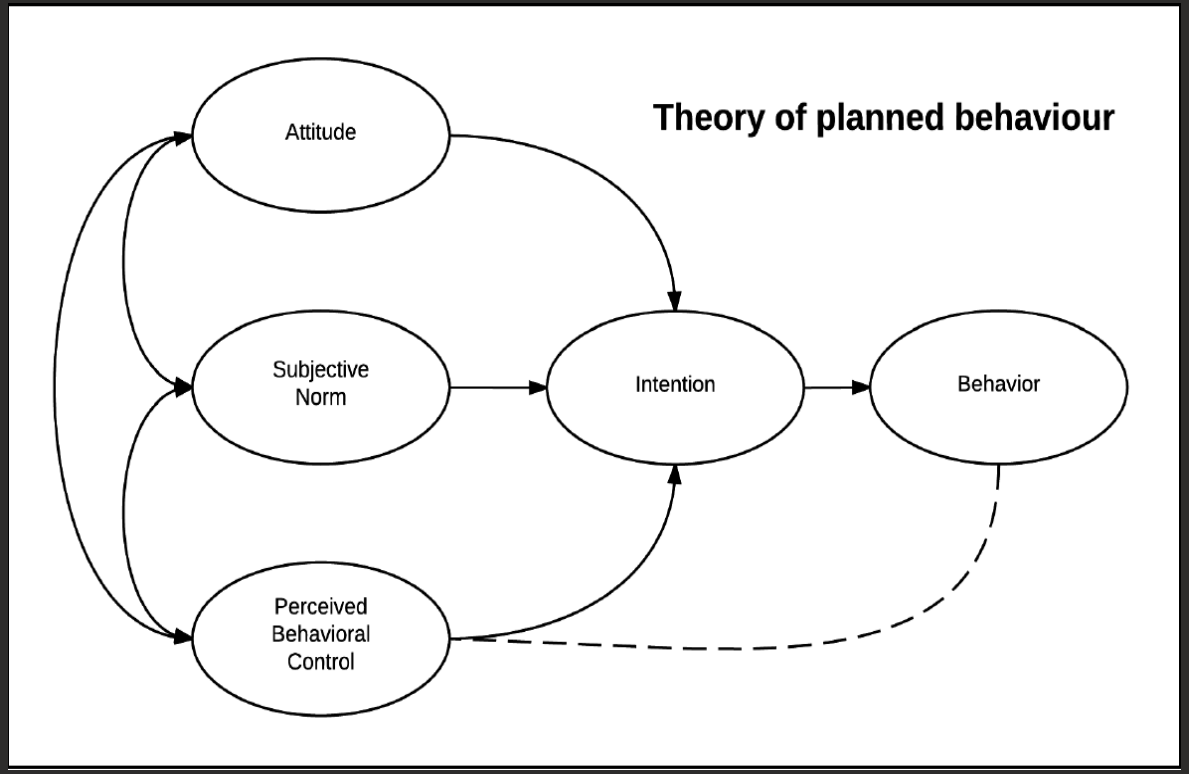
Goal of PRIM-ER: Provider and system change



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Overall Design

- Pragmatic, cluster-randomized stepped wedge design to test the effectiveness of primary palliative care education, training, and technical support in 35 EDs
- Measure the effect using Medicare claims data on:
  - ED disposition to an acute care setting
  - Healthcare utilization 6 months following the index ED visit
  - Survival following the index ED visit

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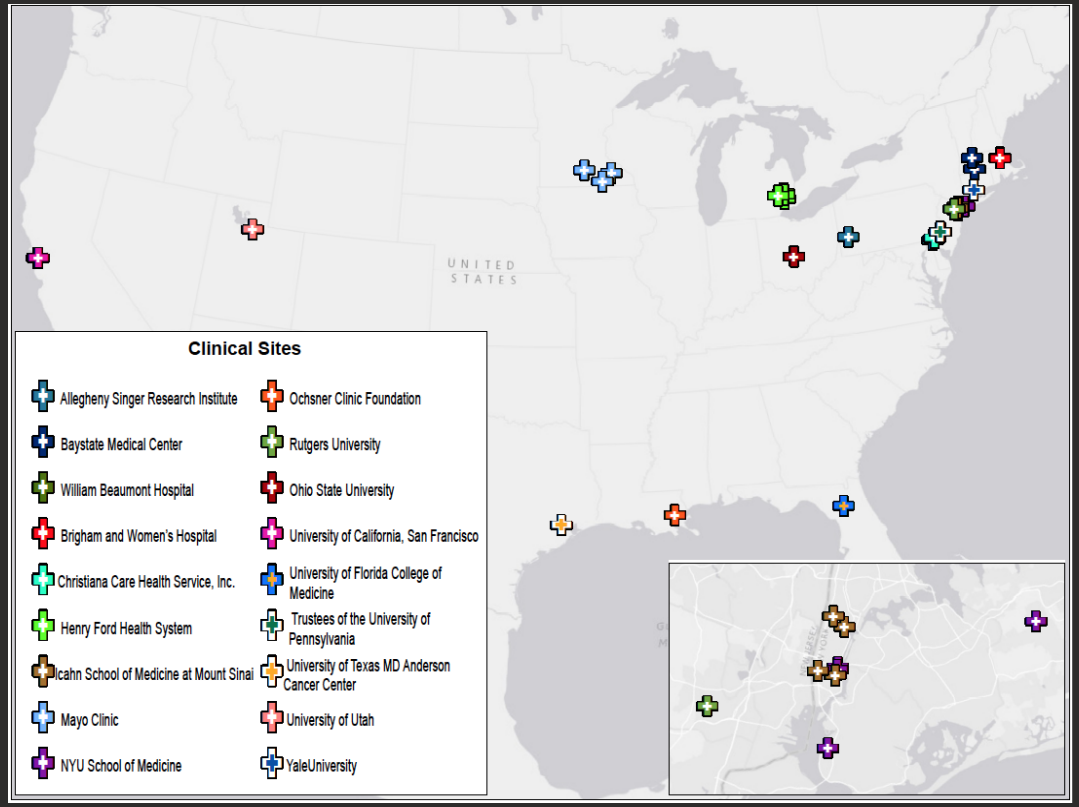
18 Health Systems



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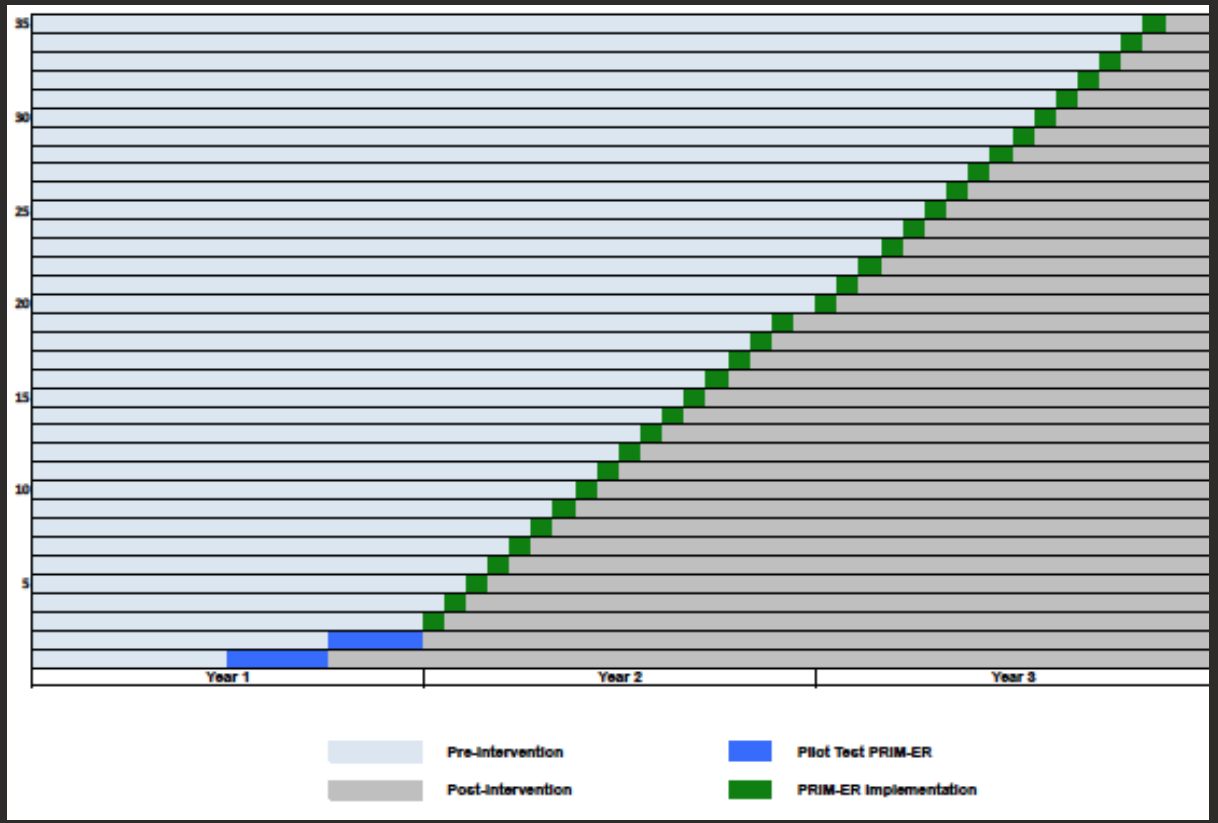
Cluster Randomized, Stepped Wedge Trial @ 35 EDs



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PRIM-ER Intervention Components

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.

SINCE 2000
ELNEC
END-OF-LIFE NURSING EDUCATION CONSORTIUM
Advancing Palliative Care

VITAL talk

EPEC®
Education in Palliative and End-of-life Care

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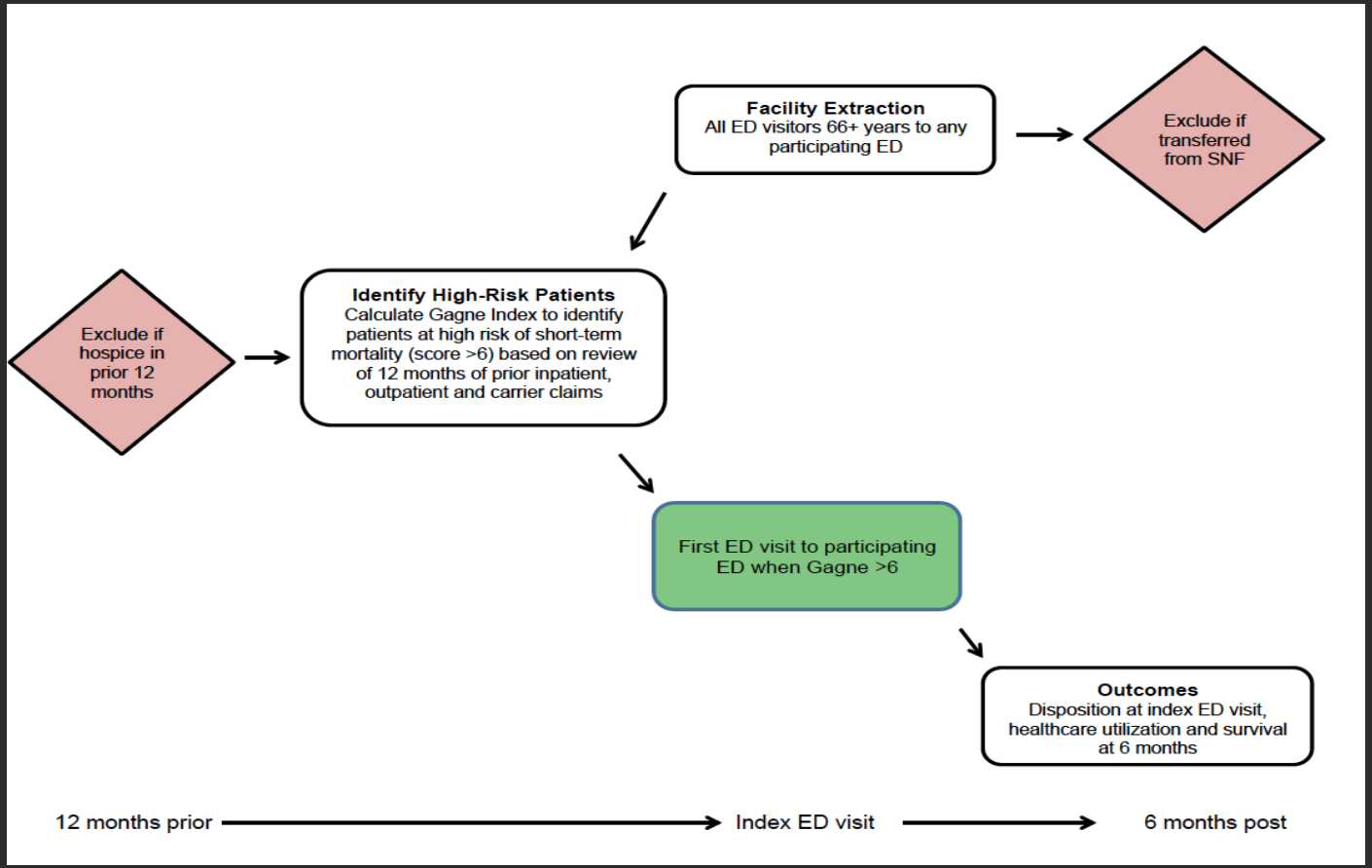
Dependent Variables

	Variable	Instrument/Coding	Source	Time
Primary Outcome	Acute Care Admission	Yes/No (Inpatient, non-palliative admission)	Inpatient and Outpatient Research Identifiable Files (RIF)	Index ED visit
Secondary Outcomes	ED visit	Count	Inpatient and Outpatient RIF	Up to 6 months from index ED visit
	Inpatient Days	Count	Inpatient RIF	Up to 6 months from index ED visit
	Hospice Use	Yes/No	Hospice RIF	Up to 6 months from index ED visit
	Home Health Use	Yes/No	Home Health RIF	Up to 6 months from index ED visit
	Survival	Days (Count)	Vital Status RIF	Up to 6 months from index ED visit or dead

*Primary and secondary outcomes to be measured as change in measures from baseline to 4 weeks post-implementation for IE phase

Evaluation



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Pilot to Implementation and Evaluation

UG3 Pilot Phase

Tailored PRIM ER to the emergency provider workforce and a more diverse ED context

- IRB approval
- Recruitment of MD & RN champions
- Finalized statistical data analysis and methods
- Finalized intervention protocol
- Finalized DSMP
- All 17 subcontracts finalized
- Tailored intervention at each individual site

UG3 Pilot Phase

Tested PRIM ER at 2 sites for feasibility, fidelity, and usability

- Developed, tested usability, and deployed clinical decision support
- Developed and deployed audit and feedback dashboard
- Clinical Decision Support Live
- Deployed EM Talk with at least 75% participation
  - 76 Emergency Providers and 100 Nurses trained @ 2 pilot sites
- Deployed ELNEC Training Modules online for nurses
- Distributed Randomization schedule and outline
- Completed all 18 Site Visits to discuss implementation

UH3 Implementation & Evaluation Phase

Implement PRIM ER in a cluster randomized, stepped wedge design in the remaining 33 EDs

UH3 Implementation & Evaluation Phase

Measure the effect of PRIM ER on

- ED disposition to an acute setting (primary objective)
- Healthcare utilization in the 6 months following index ED visit
- Survival following index ED visit.

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Strengths and Challenges

- Human Subjects
- Cross-contamination across sites
- Non-standard use of EPIC (16 of 18 health systems)
- Centralized IT support to integrate clinical decision support

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Multiple Implementation Strategies for UH3 Phase Sustainability

1. Identify and prepare champions
2. Incentives
3. Audit and feedback
4. Learning collaborative
5. System & organizational changes
   - Clinical decision support
   - Referral systems and workflow
6. Document lessons learned and provide insights to pre-implementation sites

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Data Safety and Monitoring Plan

- Minimal risk
- HIPAA waiver of authorization for Medicare Claims
- Standard reporting of related Adverse Events and Standard Adverse Events (SAEs)
- High volume of unrelated and expected SAEs (e.g., deaths)
- CMS Virtual Research Data Center (VRDC) additional protections

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Data Sharing Plan

Modalities

- Presentations at National Scientific Meetings
  - Total of 10 conferences between UH3 Years 4 & 5. Five conferences per respective year.
- Peer reviewed publications
- Epic Application Orchard
  - Portal to share informatics innovations across healthcare systems

Data to be shared

- New clinical workflows;
- Design specifications for our clinical decision support and learning management system;
- Code sets for extraction;
- Data dictionary
- Unable to extract a final de-identified dataset (VRDC)

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THANK YOU

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Independent Variables

Independent Variables		
Variable	**Coding**	**Source**
Implementation Period	Weeks from Time 0	Program 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	Program Manager
ED	1—35	Program Manager
ED Volume	30,000—49,999 visits, 50,000—69,999 visits, 70,000—89,999 visits, > 90,000 visits	Program Manager
Ownership	Nonprofit, Government, For Profit	Program Manager
Emergency medicine residency training site	Yes/No	Program Manager
Free-standing ED	Yes/No	Program Manager
Dedicated ED social worker/care manager	Yes/No	Program Manager
US Region	Northeast, Midwest, Southeast, Southwest, West	Program Manager
Metropolitan Status+	Yes/No	Program Manager
Outpatient palliative care	Yes/No	Program Manager
EHR	Epic, Cerner, Pysis/Pulsecheck	Program Manager
Trauma center	Yes/No	Program 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

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Exploratory Aim.

Determine site, provider, and patient characteristics, including the quality of implementation, that are associated with variation in impact.

RE AIM Evaluation Framework for Implementation Research

Category	Definition	PRIM ER specific measures
Reach	#, %, representativeness of individuals who are willing to participate in a given program	#, % of eligible providers invited who participate in training activity
Effectiveness	Impact of an intervention on key outcomes	Refer to Dependent Variables (Aim 3)
Adoption	#, %, representativeness of settings and intervention agents who are willing to initiate a program	#, % of eligible providers who initiate referrals to palliative care, home care, and hospice
Implementation	How closely staff members follow the program that the developers provide	#, % of sites that conduct EM Talk with high fidelity
Maintenance	Evaluating the public health impact of health promotion interventions: the RE-AIM framework	#, % of sites that continue to use the CDS system beyond intervention period

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Analytic Plan

- All analyses will be based on generalized linear mixed effect models
- Within-site correlation accounted for using the random intercept and slopes
- Primary outcome (acute care admission) will be analyzed using logistic regression model
- Secondary outcomes assessed using appropriate outcome models: Poisson, binomial (logistic), and time-to-event survival models

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