PRIMARY PALLIATIVE CARE FOR EMERGENCY MEDICINE (PRIM-ER)

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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
Default Approach
Goal of PRIM-ER: Provider and system change

Theory of planned behaviour

- Attitude
- Subjective Norm
- Perceived Behavioral Control
- Intention
- Behavior
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
18 Health Systems

Clinical Sites:
- Allegheny Singer Research Institute
- Baystate Medical Center
- William Beaumont Hospital
- Brigham and Women's Hospital
- Christiana Care Health Service, Inc.
- Henry Ford Health System
- Icahn School of Medicine at Mount Sinai
- Mayo Clinic
- NYU School of Medicine
- Octuman Clinic Foundation
- Rutgers University
- Ohio State University
- University of California, San Francisco
- University of Florida College of Medicine
- Trustees of the University of Pennsylvania
- University of Texas MD Anderson Cancer Center
- University of Utah
- Yale University
Cluster Randomized, Stepped Wedge Trial @ 35 EDs
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.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Instrument/Coding</th>
<th>Source</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Care Admission</td>
<td>Yes/No (Inpatient, non-palliative admission)</td>
<td>Inpatient and Outpatient Research Identifiable Files (RIF)</td>
<td>Index ED visit</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED visit</td>
<td>Count</td>
<td>Inpatient and Outpatient RIF</td>
<td>Up to 6 months from index ED visit</td>
</tr>
<tr>
<td>Inpatient Days</td>
<td>Count</td>
<td>Inpatient RIF</td>
<td>Up to 6 months from index ED visit</td>
</tr>
<tr>
<td>Hospice Use</td>
<td>Yes/No</td>
<td>Hospice RIF</td>
<td>Up to 6 months from index ED visit</td>
</tr>
<tr>
<td>Home Health Use</td>
<td>Yes/No</td>
<td>Home Health RIF</td>
<td>Up to 6 months from index ED visit</td>
</tr>
<tr>
<td>Survival</td>
<td>Days (Count)</td>
<td>Vital Status RIF</td>
<td>Up to 6 months from index ED visit or dead</td>
</tr>
</tbody>
</table>

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

1. Excludes if hospice in prior 12 months.
2. 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.
3. Facility Extraction:
   - All ED visitors 60+ years to any participating ED.
4. Excludes if transferred from SNF.
5. First ED visit to participating ED when Gagne >6.
6. Outcomes:
   - Disposition at index ED visit, healthcare utilization and survival at 6 months.

Timeline:
- 12 months prior
- Index ED visit
- 6 months post
Pilot to Implementation and Evaluation

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

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

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

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.
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
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
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
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)
### Independent Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coding</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation Period</td>
<td>Weeks from Time 0</td>
<td>Program Manager</td>
</tr>
<tr>
<td><strong>Healthcare system/ED-level variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health System</td>
<td>Allegheny, Bay Slate, 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</td>
<td>Program Manager</td>
</tr>
<tr>
<td>ED</td>
<td>1—35</td>
<td>Program Manager</td>
</tr>
<tr>
<td>ED Volume</td>
<td>30,000—49,999 visits, 60,000—69,999 visits, 70,000—89,999 visits, &gt; 90,000 visits</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Ownership</td>
<td>Nonprofit, Government, For Profit</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Emergency medicine residency training site</td>
<td>Yes/No</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Free-standing ED</td>
<td>Yes/No</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Dedicated ED social worker/care manager</td>
<td>Yes/No</td>
<td>Program Manager</td>
</tr>
<tr>
<td>US Region</td>
<td>Northeast, Midwest, Southeast, Southwest, West</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Metropolitan Status+</td>
<td>Yes/No</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Outpatient palliative care</td>
<td>Yes/No</td>
<td>Program Manager</td>
</tr>
<tr>
<td>EHR</td>
<td>Epic, Cerner, Pysis/Pulsecheck</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Trauma center</td>
<td>Yes/No</td>
<td>Program Manager</td>
</tr>
<tr>
<td><strong>Patient variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Years</td>
<td>Master Beneficiary Summary File, Base Segment</td>
</tr>
<tr>
<td>Gender</td>
<td>Female, Male, Other</td>
<td>Master Beneficiary Summary File, Base Segment</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>Asian, Black, Hispanic, White, North American Native, Unknown, Other</td>
<td>Master Beneficiary Summary File, Base Segment</td>
</tr>
<tr>
<td>Gagne index²</td>
<td>Count of conditions</td>
<td>Inpatient and outpatient RIF</td>
</tr>
</tbody>
</table>
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

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