Comparative Effectiveness and Heart Failure Readmissions

Michael Ong
October 12, 2010

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- AHRQ and Comparative Effectiveness
- BEAT-HF Trial
  - Heart Failure and Readmissions
  - Heart Failure and Variations
  - Study Design
  - Methodological Issues
AHRQ and Comparative Effectiveness

Agency for Healthcare Research and Quality (AHRQ) had $300 million of $1.1 billion of ARRA comparative effectiveness research (CER) funds
- Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE): $100 million set aside for 12 three-year awards
- $9.9 million award titled “Variations in Care: Comparing Heart Failure Care Transition Intervention Effects”
  - Started Sept 30, 2010
- Retitled by team as “Better Effectiveness After Transitions – Heart Failure” (BEAT-HF) study

AHRQ and Comparative Effectiveness

Patient Centered Outcomes Research Institute (PCORI)
- PCORI funds: $750 million per year FY 2013-2019
- AHRQ to be major distributor of PCORI CER funds

PCORI Statutory Definitions of CER
- Systematic reviews and assessments of existing and future research and evidence
- Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies
- Any other methodologies recommended by the methodology committee (still TBN)
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Heart Failure and Readmissions

- Heart failure (HF) is the medical condition most frequently associated with 30-day readmission for Medicare beneficiaries
  - HF 30-day readmission rate: 26.9%
  - All condition 30-day readmission rate: 19.6%

- About half of HF readmissions estimated to be “potentially preventable”
  - 52% get readmitted before seeing outpatient provider

Jencks, NEJM 2009; Braunstein, JACC 2003
Approaches to Reduce Readmissions

- Focus on transition period starting from inpatient discharge to outpatient care: “care transitions”

- Several approaches demonstrate reductions in resource use in randomized control studies
  - Transitional Care Model (Naylor): 30-day readmission: 13.1% vs. 26.3% for controls
  - Transition Coach Model (Coleman): AOR for 30-day readmission: 0.52
  - Project Re-Engineering Discharge (Jack): AOR for 30-day readmission: 0.72, p<0.10


Approaches to Reduce Readmissions

- Low adoption of these programs
  - Cost savings accrue to payor not providers

- Home care costs are significant cost component
  - Naylor: regular home visits plus calls by advanced practice nurse (APN)
  - Coleman: at least one home visit plus calls by APN
  - Jack: one post-discharge call by pharmacist but less effective

- Are there other options?
Telephone Intervention Without Home Visits

Telemedicine Intervention With Remote Monitoring Devices
Cochrane Meta-Analysis

- 25 studies meta-analyzed
  - 16 Telephone support studies (n = 5613)
  - 11 Telemonitoring studies (n = 2710)

- All-cause mortality:
  - Telemonitoring: RR 0.66 (95%CI: 0.54 - 0.81)
  - Telephone support: RR 0.88 (95%CI: 0.76 - 1.01)

- All-cause hospitalizations
  - Telemonitoring: RR 0.91 (95%CI: 0.84 - 0.99)
  - Telephone support: RR 0.92 (95%CI: 0.85 - 0.99)

Inglis, Cochrane 2010

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Cochrane Meta-Analysis

- HF-related hospitalizations
  - Telemonitoring: RR 0.79 (95%CI: 0.67 - 0.94)
  - Telephone support: RR 0.77 (95%CI: 0.68 - 0.87)

- Two head-to-head studies
  - Not significantly different on these outcomes

- Other outcomes
  - Subset of studies show improved quality of life, reduced healthcare costs and were acceptable to patients

Inglis, Cochrane 2010
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The five University of California Medical Centers and Cedars-Sinai Medical Center partnered together to better understand variations in HF care.

We found that there is both variation in care and in outcomes.

Ong, Circ:CVQO 2009
Predicted 180-Day Readmission Rates

- Hospital 3: 33.1% to 37.9%
- Hospital 4: 36.5% to 41.2%
- Hospital 2: 38.9% to 43.7%
- Hospital 1: 42.5% to 46.2%
- Hospital 5: 41.2% to 44.9%
- Hospital 6: 42.5% to 46.2%

Predicted 30-Day Readmission Rates

- Hospital 3: 13.8% to 17.5%
- Hospital 4: 15.4% to 19.1%
- Hospital 2: 16.8% to 20.5%
- Hospital 1: 19.8% to 23.5%
- Hospital 5: 19.1% to 22.8%
- Hospital 6: 19.8% to 23.5%
Variation and Care Transitions

- Conducted organizational survey of HF care at the six sites in 2009
  - Used taxonomy of HF interventions
  - Only one site had comprehensive activities during the care transition period due to recent grant funding

- Can care transition interventions reduce the variation between sites?
  - Interventions can reduce mortality and resource use
  - Unobservable variation in care transition activities

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**BEAT-HF: Research Project Team**

<table>
<thead>
<tr>
<th>Site</th>
<th>Site PI</th>
<th>Clinical Lead</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCD</td>
<td>Patrick Romano</td>
<td>Kathleen Tong</td>
<td>Banafsheh Sadeghi</td>
</tr>
<tr>
<td>UCI</td>
<td>Shelly Greenfield</td>
<td>Dawn Lombardo</td>
<td>Sherrie Kaplan Shaista Malik</td>
</tr>
<tr>
<td>UCLA</td>
<td>Michael Ong</td>
<td>Gregg Fonarow</td>
<td>Carol Mangione Jose Escarce</td>
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<tr>
<td>UCSD</td>
<td>Ted Ganiats</td>
<td>Barry Greenberg</td>
<td>Lorraine Evangelista Majid Sarrafzadeh Honghu Liu</td>
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<tr>
<td>UCSF</td>
<td>Andrew Auerbach</td>
<td>Michelle Mourad</td>
<td>Michael Gropper</td>
</tr>
<tr>
<td>CSHS</td>
<td>Bruce Davidson</td>
<td>Asher Kimchi</td>
<td>Jeanne Black</td>
</tr>
</tbody>
</table>

**BEAT-HF Specific Aims**

- Compare the effect of two separate care transition interventions with concurrent controls on variation in readmissions among elderly patients hospitalized with HF at the six sites

- Examine the change in variation over time in readmissions and mortality among hospitalized Medicare beneficiaries with HF at the six sites

- Compare the health benefits and costs of the two separate care transition interventions
BEAT-HF: Specific Aim 1 Trial Arms

- Care transition program modified to reduce costs
  - Substitutes planned home care visits with planned telephone monitoring calls
  - Centralizes telephone monitoring for all six sites

- Care transition program with remote monitoring
  - Substitutes planned home care visits and telephone monitoring calls with remote monitoring and prn use of centralized call center

- Usual care

Trial Design

1740 Patients Meeting Enrollment Criteria
- 1500 Patients: Enrolled
- 240 Patients: Decline
- 500 Patients: Telephone
- 500 Patients: Telemedicine

Total patients at all six sites combined
Target population

- Elderly patients (age 55+) hospitalized with a principal diagnosis of heart failure
  - Between July 2011 to December 2012 (18 months)
  - Pilot phase April 2011 to June 2011

- Exclusion criteria
  - Outside transfer patients
  - Transplant patients
  - Patients with dementia
  - Patients discharged to skilled nursing facilities
  - Patients without working telephone

Intervention:

Common Pre-Discharge Protocol

- Conducted by study nurse at each site
  - Will coordinate with and enhance existing discharge services
  - Adapts existing protocols developed for Transition Coach Program and Re-Engineering Discharge Program

- Protocol overview
  - Facilitates self-care by patient and caregivers
  - Conducts medication review and reconciliation
  - Teaches patients how to communicate their needs to different health care professionals
Telephone Intervention
Post-Discharge Protocol

- The centralized call center advance practice nurses contact patients within 3 days of discharge.

- Patients will subsequently be called at a minimum on a weekly basis for a total of at least four telephone contacts during a 30-day period.

- After the 30-day period, call center nurses will contact the patients on a monthly basis up through six months after discharge.

Telemedicine Intervention
Post-Discharge Protocol

- Patients receive prior to discharge the Guardian Phone and remote sensor devices (weight scale and a BP cuff to measure BP and heart rate).

- Following discharge, patients will be asked to transmit for six months automated biometric information and symptoms daily to the centralized call center via the Guardian Phone.

- The centralized call center advance practice nurses contacts patients within 3 days of discharge and then on as needed for six months when triggered by an alert after discharge.
Evaluation: Outcomes

<table>
<thead>
<tr>
<th>Readmissions (Primary Outcome)</th>
<th>Mortality</th>
<th>Quality of Life</th>
<th>Total Hospital Days</th>
<th>Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>3-Days</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>30-Days</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>180-Days</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

• Quality of Life measured using:
  • KCCQ = Kansas City Cardiomyopathy Questionnaire
  • EQ-5D = EuroQol Quality of Life Scale (5 questions)

Evaluation: Power

Power to detect change (type I error: 0.05, type II error: 0.2)

- 30-day readmissions: 16.3% to 11.8% (a 27.6% relative change)
- 180-day readmissions: 38.0% to 33.2% (a 12.6% relative change)
- Smaller effect sizes than seen in the Transition Coach model
  - 30.3% relative change in 30-day readmissions
  - 16.6% relative change in 180-day readmissions
Evaluation: Patient-Level

- Each patient will be surveyed by telephone at 3-days, 30-days and at 180-days post discharge
  - conducted by central survey group
  - the 3-day survey in the telephone arm is conducted by the centralized call center to minimize participant burden
  - $10 gift card for completion of each telephone survey

Patient Survey: Care Transitions

<table>
<thead>
<tr>
<th>Care Transition Improvement Domain</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Outpatient Access</td>
<td>*Days between Hospital Discharge and First Outpatient Visit</td>
</tr>
<tr>
<td></td>
<td>*Outpatient Visits</td>
</tr>
<tr>
<td>Improved Provider Communication</td>
<td>Discharge Summary Accessible</td>
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<tr>
<td></td>
<td>*Within 24 Hours of Hospital Discharge</td>
</tr>
<tr>
<td></td>
<td>*By PCP</td>
</tr>
<tr>
<td>Patient Comprehension of Care Plan</td>
<td>*Care Transition Measure Survey (CTM-15)</td>
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</table>
### Patient Survey Covariate Domains

<table>
<thead>
<tr>
<th>Sociodemographics</th>
<th>Clinical Status</th>
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<tbody>
<tr>
<td>Age</td>
<td>Functional Status (NYHA)</td>
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<tr>
<td>Gender</td>
<td>Functional Limitations</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>Comorbidities</td>
</tr>
<tr>
<td>Language</td>
<td>Clinical labs</td>
</tr>
<tr>
<td>Education</td>
<td>Ejection Fraction</td>
</tr>
<tr>
<td>Marital Status</td>
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</tr>
</tbody>
</table>

| Household Income                  | Discharge Medication       |
| Insurance                         | End-of-life wishes         |
| Employment                        | Informal caregiving        |
| Health Literacy                   | Medication use             |

### Evaluation: Organization-Level

- Monthly feedback reports to assess intervention fidelity at each site
  - implementation plans and organizational changes
  - incorporation of treatment protocols into hospital discharge planning services, and additional strategies to sustain or spread implementation
  - tracking other QI initiatives that may influence results
# Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
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<tbody>
<tr>
<td></td>
<td>Project Year 1</td>
<td>Project Year 2</td>
<td>Project Year 3</td>
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<tr>
<td>IRB Review</td>
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<td>Intervention Training</td>
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<tr>
<td>Intervention Period: enrollment</td>
<td>X X X X X X</td>
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<tr>
<td>Intervention Period: data collection</td>
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<td>Dissemination Phase</td>
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<td>All-Site Project Meetings</td>
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<tr>
<td>Progress Meetings with Medical Center Leaders and Stakeholders</td>
<td>X</td>
<td>X</td>
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</tbody>
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Methodologic Issues

- How do you compare effectiveness when there are concurrent interventions for HF care and readmissions at the six sites?
  - Topic has high interest due to expected penalties by Medicare starting 2012 for hospitals with high 30-day readmission rates for HF patients

- Related issues
  - Duplication among interventions of services?
  - Future interventions – moving target?

Ongoing Interventions: Site Example

- Inpatient Education
  - Health Literacy, Teach Back, Identify key learner, Include family/caregivers

- Discharge Planning and Collaboration
  - Home Care, Follow up Appointments, SNFs, Case Managers, Inpatient Team

- Follow Up Phone Calls
  - 2 phone calls: Day 3-4 post discharge, Within 30 days post discharge
Methodologic Issues

- Some potential approaches
  - Accounting for concurrent interventions and examining change in variation over time
  - Examining relationship between care transition measures and outcomes

Questions and comments appreciated!