

Comparative Effectiveness and Heart Failure Readmissions

Michael Ong
October 12, 2010

Comparative Effectiveness and Heart Failure Readmissions

- **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)

Comparative Effectiveness and Heart Failure Readmissions

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

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, $p < 0.10$

Naylor, JAGS 2004; Coleman, Arch Int Med 2006; Jack, Ann Int Med 2009

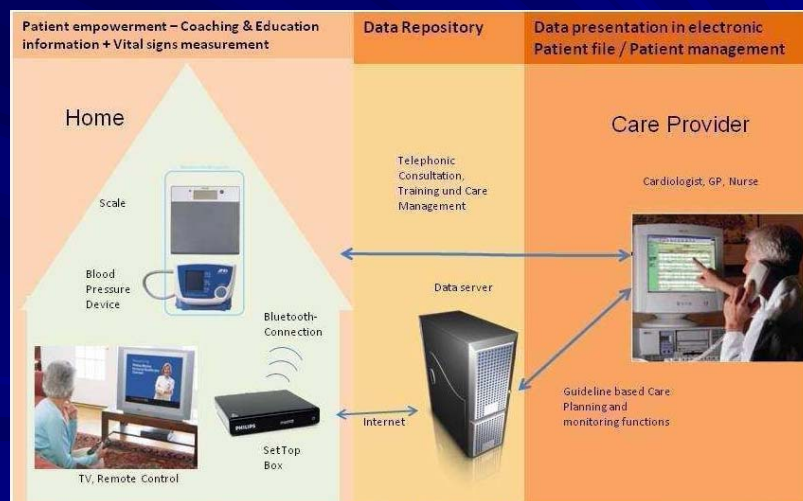
Approaches to Reduce Readmissions

- 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

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

Comparative Effectiveness and Heart Failure Readmissions

- AHRQ and Comparative Effectiveness

- BEAT-HF Trial

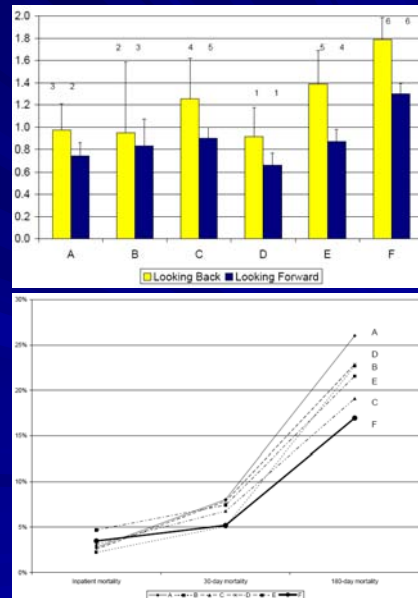
- Heart Failure and Readmissions
- Heart Failure and Variations
- Study Design
- Methodological Issues

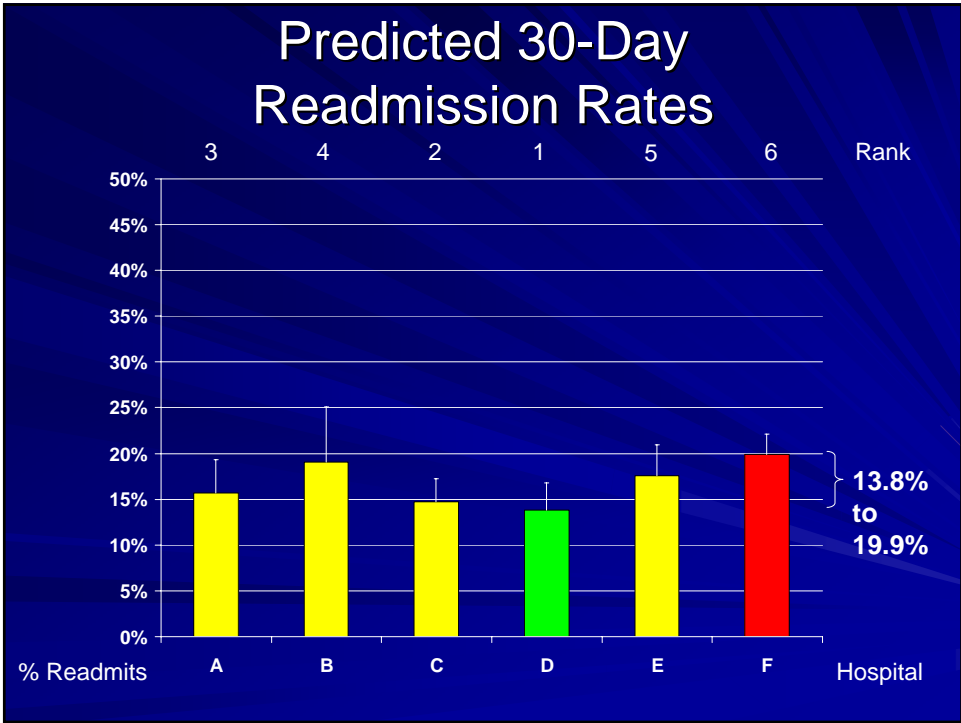
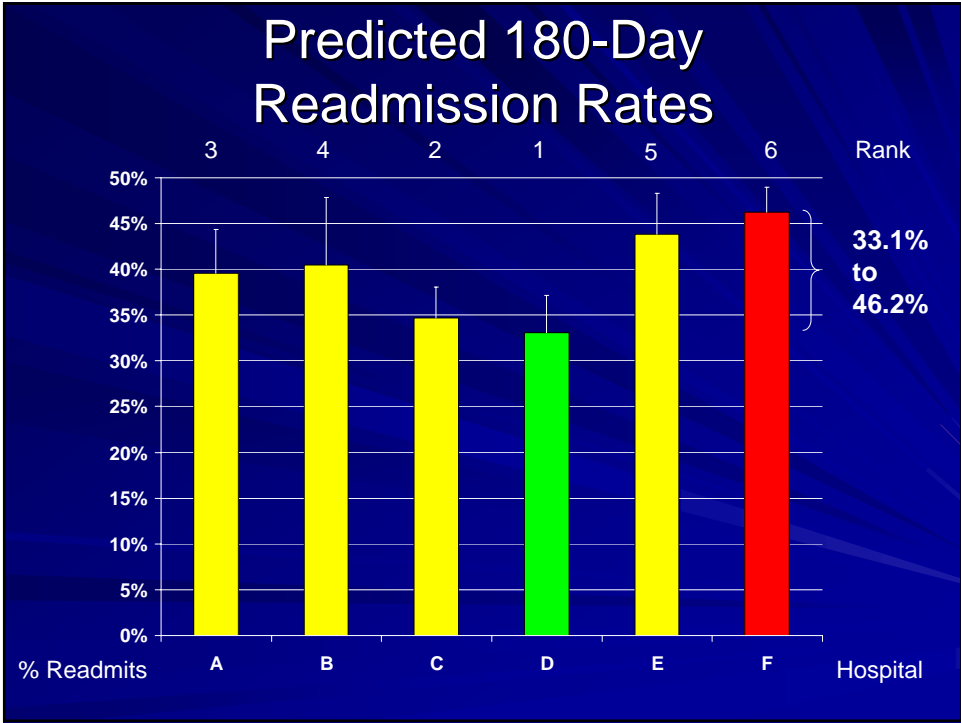
Heart Failure and Variations

- 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





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

Comparative Effectiveness and Heart Failure Readmissions

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

BEAT-HF: Research Project Team

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

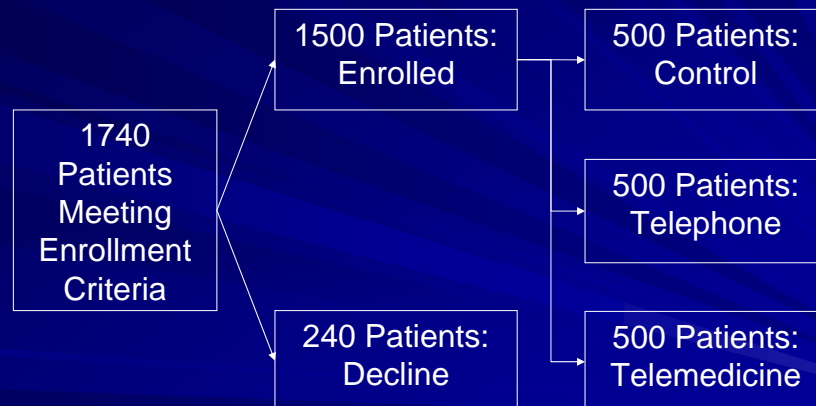
BEAT-HF Specific Aims

- 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



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

| | Readmissions (Primary Outcome) | Mortality | Quality of Life | Total Hospital Days | Total Costs |
|-----------------|--------------------------------------|-----------|--------------------|---------------------------|----------------|
| Hospitalization | | X | X | X | X |
| 3-Days | X | X | X | X | X |
| 30-Days | X | X | X | X | X |
| 180-Days | X | X | X | X | X |

- 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

| Care Transition Improvement Domain | Measures |
|------------------------------------|---|
| Early Outpatient Access | *Days between Hospital Discharge and First Outpatient Visit *Outpatient Visits |
| Improved Provider Communication | Discharge Summary Accessible *Within 24 Hours of Hospital Discharge *By PCP |
| Patient Comprehension of Care Plan | *Care Transition Measure Survey (CTM-15) |

Patient Survey Covariate Domains

- Sociodemographics
 - Age
 - Gender
 - Race/Ethnicity
 - Language
 - Education
 - Marital Status
- Clinical Status
 - Functional Status (NYHA)
 - Functional Limitations
 - Comorbidities
 - Clinical labs
 - Ejection Fraction
- Household Income
- Insurance
- Employment
- Health Literacy
- Discharge Medication
- End-of-life wishes
- Informal caregiving
- 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

| Year | 2011 | | | 2012 | | | 2013 | | |
|--|----------------|---|---|----------------|---|---|----------------|---|---|
| | Project Year 1 | | | Project Year 2 | | | Project Year 3 | | |
| IRB Review | X | X | X | | | | | | |
| Intervention Training | | | X | | | | | | |
| Intervention Period: enrollment | | | | X | X | X | X | X | |
| Intervention Period: data collection | | | | X | X | X | X | X | X |
| Dissemination Phase | | | | | | | | X | X |
| All-Site Project Meetings | X | | | X | X | X | X | X | X |
| Progress Meetings with Medical Center Leaders and Stakeholders | | | | X | | X | | | X |

Comparative Effectiveness and Heart Failure Readmissions

■ AHRQ and Comparative Effectiveness

■ BEAT-HF Trial

- Heart Failure and Readmissions
- Heart Failure and Variations
- Study Design
- Methodological Issues

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!

