

JOINTS Study Research Plan

Policy Advisory Panel
September 27, 2005

National Rehabilitation Hospital
Washington, DC

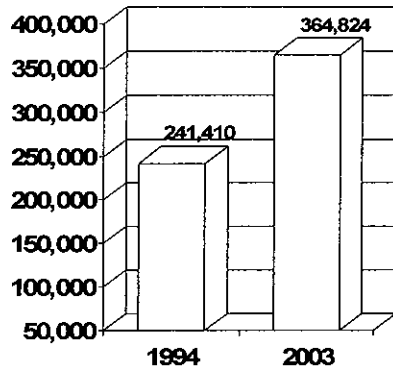
JOINTS Study

**Joint replacement Outcomes
in IRFs and Nursing Treatment Sites**

**NRH Research
Washington, DC**

**Institute for Clinical Outcomes Research (ICOR)
Salt Lake City, UT**

Framing the Issue

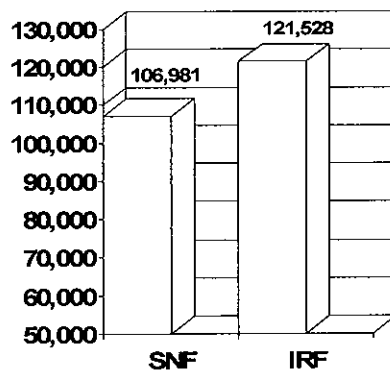


- Hip and knee replacements have increased 51% over the last decade

Source: MedPAR

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Framing the Issue



- Of the 364,824 patients who received a joint replacement in 2003, 13.5% more went to an IRF than a SNF.

• Source: GAO (2005)

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Framing the Issue

- Traditionally: SNFs vs. IRF
- Assumption: Each setting of care provides a relatively homogenous package of services.
- One setting a potential substitute for the other.

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Framing the Issue

- Comparing 2 “black boxes.”
Never really characterized differences in care between these 2 settings.
- Contrasts made: raw hours of treatment, little about content of the treatment.
- Never really characterized differences between settings in terms of type of treatment, timing, intensity, frequency, and duration.

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Framing the Issue

- Without knowing what is in these black boxes, “prudent purchasers, both government and health plans, cannot fully know what they are purchasing.”
- What are the active ingredients?
- “It is not enough to say one setting is more effective than another without stating what it is about that setting that accounts for the difference.”

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Framing the Issue

- In many ways, IRFs vs. SNFs is asking the wrong question.
- “Instead, we need to ask which patients do better in a SNF and which do better in an IRF.”
- This requires that we adequately characterize both (1) the patient and (2) the interventions associated with a given setting of care.

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What Makes this Study Different?

- Ability to more fully characterize the patient
- Ability to more fully characterize the interventions/treatments/process of care
- Not easily achieved through use of administrative databases
- Not easily achieved through patient record review

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Our Approach

Practice-based evidence (PBE)



Clinical practice improvement (CPI)

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Our Approach

□ Practice-based Evidence (PBE-CPI)

- Type of observational cohort study
- Takes advantage of the naturalistic variation in rehabilitation practice
- Large numbers
- Detailed data on patient characteristics; ability to control for patient differences
- Detailed data on treatments/interventions

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Our Approach

□ Other important PBE-CPI trademarks

- Bottom-up approach; takes advantage of front-line clinical expertise
- Trans-disciplinary Clinical Practice Team
 - Refines selection criteria
 - Identifies outcomes of interest
 - Identifies patient characteristics thought to be important
 - Defines the activities and interventions to be measured and collected

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Our Approach

- **Trans-disciplinary Clinical Practice Team (cont.)**
 - Proposes additional hypotheses to be tested
 - Develops recommendations for clinical practice and policy
 - Contributes to publication of findings
 - Stays engaged throughout the process
 - Provides clinical buy-in
 - Implement findings

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Study Group

- ❑ **2,800 patients with joint replacement**
 - 1,400 patients in SNFs
 - 1,400 patients in IRFs
- ❑ **Patient selection criteria**
 1. 21 yrs or older
 2. Hip or knee replacement (DRG 209 or 210)
 3. Did not have interrupted stay >3 days
 4. Minimum rehab stay = 4 days
 - To be reviewed by Clinical Practice Team

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Study Group

❑ Facility selection considerations:

1. Admit/discharge minimum 200 pts/yr
2. Medicare certified SNF or IRF
3. 2 SNFs or IRFs from each Census Region
4. Mix of freestandings & units (hospital-based)
5. Mix of for-profit and nonprofit SNFs and IRFs
6. Mix from managed and non-managed care markets

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Study Group

❑ Other facility selection considerations:

- Payer mix
- Best-of-breed vs. others
- Urban-rural
- SNFs that use staff therapists vs. SNFs that use contract therapists
- IRFs and SNFs that are part of the same network
- IRFs and SNFs that use some of the same staff, particularly therapy staff

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Study Group

❑ Other selection issues:

- Not a national probability sample
 - A national probability sample would not allow us to acquire the depth of data being acquired in this study.
 - Depth vs. breadth. Logistics and \$s
- Captures geographic and market diversity
- Will compare final study group characteristics to other national databases (e.g., IRF-PAI, eRehabdata, UDS, MDS)

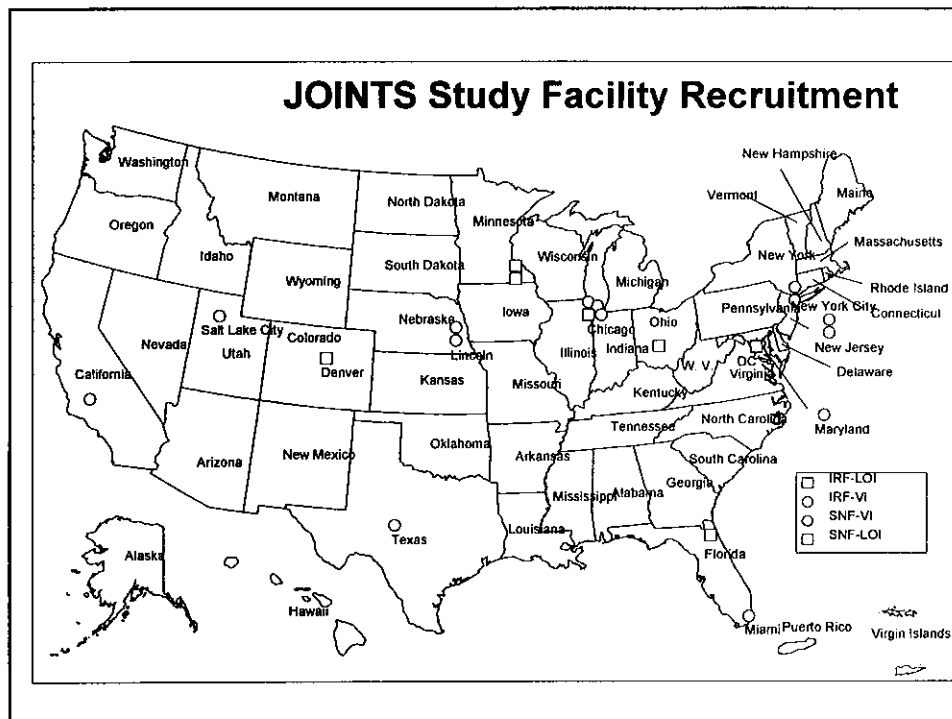
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Study Group

❑ Selection bias issues

- **Facility selection**
 - Selection bias is probably the same for SNFs and IRFs
 - Facility selection bias does not favor one type of facility
- **Patient selection**
 - Always the fear that there may be unobserved patient differences due to how patient got to a SNF or IRF
 - We will have very detailed data about patient differences (unlike administrative data that may have more limited data about patient differences).

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Study Variables

□ Patient variables

- Demographic variables
- Functional status (FIM)
- Severity of illness: Comprehensive Severity Index (CSI)
- Comorbid conditions

Study Variables

- **Severity of illness:**
 - **Comprehensive Severity Index (CSI)**
 - 2,100 signs, symptoms, physical findings
 - 5,600 disease-specific CSI criteria
 - 4-point discrete score (4=most, 1=least severe)
 - Continuous score (0 → no upper limit)
 - 'Admission CSI'
 - 'Discharge CSI'
 - 'Maximum CSI'

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Study Variables

Process/treatment variables

- Activity, e.g.,
 - Wheelchair mobility
 - Gait training
 - Community mobility
- Intervention, e.g.,
 - Strengthening exercises
 - Patient education
 - Body-weight supported training
 - Parallel bars

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Study Variables

□ Outcome variables

- Change in severity from admission to discharge
- Change in functional status
- Discharge destination

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Study Variables

□ Clinician profiles

- Limited to:
 - Staff vs. contract therapists
 - Therapists vs. therapy assistants
- Will not be obtaining other clinician data
 - Raises informed consent issues (from therapists)
 - Staff shortages, want to reduce respondent burden

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Data Collection

□ Point of care (POC) documentation

- Physician
- Physical Therapy
- Occupational Therapy
- Nursing (being reconsidered by Team)

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Data Collection

□ Point of care (POC) documentation (cont.)

- Collected at each encounter
- Training
 - 2 individuals at each site will come to NRH for training and train-the-trainer instruction
 - Training manual
 - Takes about 2-3 min (usually less) for therapist to complete POC documentation
 - Takes physician 1 min
- Quality assurance & auditing

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Data Collection

□ Retrospective chart review

- Patient, process, & outcome variables
- CSI-related data
- Each site assign or hire staff to perform chart abstraction (using CSI-driven protocols)
- Each abstractor will attend 4-day training session that includes both didactic and practice sessions.
- Reliability testing and monitoring

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Data Collection

□ Special challenges: functional status

- IRFs use IRF-PAI FIM
- SNFs use MDS
- IRFs and SNFs use different data points
 - IRFs—admission & discharge
 - SNFs—5th and 14th day
- Lack of crosswalk between FIM & MDS
- Some SNFs also use traditional FIM, not IRF-PAI FIM

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Data Collection

- ❑ **Special challenges: functional status**
 - Decision: Use IRF-PAI FIM at admission & discharge in both IRFs and SNFs.
 - Additional effort for SNFs, two options
 1. Train on-site personnel to administer FIM
 2. Outside FIM-trained personnel to visit SNF
 - FIM training and credentialing very important

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Analysis (Phase 1)

- ❑ Work closely with Clinical Practice Team made up of individuals from both SNFs and IRFs
- ❑ Question 1: Basic descriptive statistics about how similar or different patients are in both settings
 - Demographically
 - Type of replacement
 - Functionally
 - Severity of illness

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Analysis (Phase 1)

□ Question 2: Characterize the process of care:

- Length of Stay
- Type and amount of treatment
- Sequencing, timing, intensity, frequency, duration of each treatment
- Look for patterns of care
- Between SNFs and IRFs, within SNFs and IRFs, within and between patient subgroups

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Analysis (Phase 1)

□ Question 4: Determine which patients do better in one setting vs. another

- Examine how the patients who did “best” in one setting compare with those who did “best” in the other.
- Regression analyses in which setting of care is dummy variable and determine the extent to which setting explains variance.
- Pull study group apart by CMG, replacement type, age, gender, region of the country, etc.

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Analysis (Phase 2)

- ❑ Question 3: Identify the activities and interventions that make a difference in outcome
 - Examine what, as well as how much, care a patient received
 - Examine by “blocks” of care
 - Determine whether sequence or timing of care made the difference (strengthening first, then gait training?)
 - Be prepared for serendipitous findings; re-examine findings using other subsets.

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Analysis (Phase 2)

- ❑ Question 5: Determine relative cost-effectiveness of IRF and SNF care.
 - Will depend on which costs and which outcomes we consider.
 - Focus of this afternoon's discussion.

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Analysis (Phase 2)

□ Question 6: Examine the role of medical severity and need (as well as functional status)

- The use of the CSI offers an unusual opportunity
- The overlap between medical severity and functional status
- Are patients with greater medical needs served better in one setting or the other?
- How might medical severity be factored into a PPS for either setting?

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Analysis (Phase 2)

□ Question 7: Determining best practices in both SNFs and IRFs

- We expect to find some exemplary practices in both settings of care that can make care more effective and possibly more efficient.
- Assumption: No setting has a monopoly on best practices. Important lessons to be learned from both.
- Recommend validation studies and controlled trials

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This Afternoon

- Potential waiver request to mitigate potential patient selection issues
- Possible follow-up study to address longer-term outcomes
- Alternative approaches to cost-effectiveness

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Acknowledgements

HealthSouth Corporation
American Medical Rehabilitation Providers
Association
American Hospital Association
Federation of American Hospitals
National Rehabilitation Hospital

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