

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

**EXECUTIVE SUMMARY**  
**Policy Advisory Panel Meeting**  
**September 27, 2005**  
**Washington, DC**

The National Rehabilitation Hospital hosted the Policy Advisory Panel meeting on September 27, 2005 in its Telehealth Center. All participants received a briefing book prior to the meeting that provided the motivation for the study, the project Research Plan, and pertinent background materials.

**MEETING PARTICIPANTS**

**PANEL MEMBERS AND THE ORGANIZATION EACH REPRESENTS**

**Rochelle Archuleta, MBA, MHSA**  
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**Susan Klanecky, RN, CRRN**  
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**Barbara Braun, PhD**  
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**Christine MacDonell**  
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**Melinda Beeuwkes Buntin, PhD**  
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**Trudy Mallinson, PhD, OTR/L, NZROT**  
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**Michael Munin, MD**  
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**Michael Weinrich, MD**  
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**Carl Granger, MD**  
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**Unable to attend:**

**Callahan, Leigh, PhD**  
Arthritis Foundation

## **PANEL OBSERVERS AND THE ORGANIZATION EACH REPRESENTS**

**James Bowman, MD**  
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**Ruth Brannon, MSPH**  
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### **PROJECT STAFF - NRH**

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### **PROJECT STAFF – ICOR**

Susan Horn, PhD, Study Co-PI  
Julie Gassaway, MS, RN

## **MEETING GOALS**

1. Familiarize multiple stakeholders in joint replacement rehabilitation with the JOINTS project;
2. Review JOINTS project objectives, study design, and timeline;
3. Enable Panel members and observers to ask questions of the Project Team regarding objectives and design; and
4. Enable Project Team to obtain advice from Panel members and observers regarding study design issues, the larger policy environment, and project communications.

## **KEY RECOMMENDATIONS**

1. Implement a follow-up study for patients who have been discharged from the SNF or IRF.
2. Use outcome variables in the follow-up study to ensure that data points are consistent with what was collected in the primary study so that comparisons can be made

appropriately (although some outcomes upon discharge may not be equally relevant at follow-up).

3. Request from CMS a waiver from the “75% rule” and from the local coverage decisions (LCDs) of Medicare fiscal intermediaries for patients enrolled in this study.
4. Clarify patient inclusion/exclusion criteria especially with respect to the inclusion of hip fracture patients who have joint replacements.
5. Weigh the facility selection methods to maximize the ability to generalize conclusions to the larger IRF/SNF joint replacement rehabilitation population.

## **DISCUSSION**

### **Introductions**

Dr. DeJong, the study’s principal investigator and Panel chair, welcomed Panel members and observers and thanked them for their willingness to contribute to a project that seeks to establish a firmer basis for future policy making with regards to joint replacement rehabilitation. Each panel member outlined the stake that his or her organization has in the study. The Panel’s diversity was designed to elicit all relevant perspectives and provide greater project accountability and transparency as part of an open, no-holds-barred inquiry to determine optimal treatment approaches and the settings of care for different types of patients with joint replacements. The study seeks to provide objective practice-based evidence that can lead to evidence-based policy decision with respect to the post-acute placement and rehabilitation of patients with joint replacements.

Dr. DeJong proceeded to frame the issues, outline the study’s approach and methods, and analysis plan. He noted that the project responds to CMS’s call for more publicly and privately sponsored studies that will lead to more informed policies and practices with regard to post-acute rehabilitation.

### **Study Methodology**

This project uses a “clinical practice improvement” (CPI) methodology, a practice-based evidence approach that captures in-depth, comprehensive information about patient characteristics (including clinical signs and symptoms), rehabilitation processes of care, and rehabilitation outcomes. Combined, these data will enable investigators to characterize the process of care in different settings of care and ascertain the contribution of individual rehabilitation processes to outcomes taking into account patient covariates.

The CPI approach offers a naturalistic view of joint replacement rehabilitation treatment by examining what actually happens in the care process. It does not alter the treatment regime to evaluate efficacy of a particular intervention. Moreover, CPI’s detailed data on rehabilitation interventions will allow researchers to drill down to the most meaningful level of resolution regarding the types of care rendered—consistent with current knowledge and insights offered by

team participants.

### **Panel comments**

- For results and recommendations to be accepted by policymakers, we need to be sure that the methodology is something that everyone will accept.
- Consider use of a randomized controlled trial (RCT) and enroll patients while still in acute care.
- Agreed that CPI, although not an RCT, is an appropriate and acceptable method for use in this study. CPI looks at actual patient care and is a good way to discover best practice.

### **Panel suggestions**

- Make sure that severity adjustment using the Comprehensive Severity Index (CSI) and functional status accounts for patient variability.
- As the study progresses, watch for key variables that may differ greatly between treatment sites; may need to match samples on key variables or ‘stratify recruitments.’
- While methodology will capture what is occurring during therapy, try to capture what happens during other parts of the day (i.e. patient staying in bed).
  - Consider use of step monitors to measure non-therapy ambulation

### **Institutional Review Board (IRB)**

The Project Team anticipates that the study will obtain an expedited Institutional Review Board (IRB) approval, which includes a waiver of the requirement for obtaining informed consent. The study is a quality improvement effort; no new treatments are introduced. The research involves no more than minimal risk to subjects and the likelihood of harm/discomfort is no greater than what patients would ordinarily encounter during routine clinical care. Rights and welfare of patients are not at risk. In addition, the project team will not be interviewing patients and patients will have no contact with members of the research team. See additional comments pursuant to proposed follow-up study.

### **Facility Selection**

The briefing book provided Panel members with the factors that inform the study’s selection of SNFs and IRFs. Due to the nature of the study, the study does not seek to achieve a national probability sample but does try to capture diversity of practice by selecting facilities based on geographic diversity, Medicare certification, for-profit and non-profit status, and volume of joint replacement patients. The study seeks to enroll facilities with at least 200 joint replacement

patients annually. Due to the high-volume criteria, the project team has concerns about including only the ‘best-of-breed’ facilities although such facilities are more likely to produce best practices in both settings and, any selection bias, that may exist will not favor one type of facility over another.

A major strength of the CPI model is that it is patient-based, rather than setting-based. The Project Team aims to determine what treatments result in best outcomes for specific types of patients. Treatments may be similar or different among and within treatment settings.

#### **Panel comments**

- Agree with obtaining geographic diversity.

#### **Panel suggestions**

- Be clear about facility characteristics and how they are similar/different from the larger IRF/SNF population to address concerns about selection bias.
- Be aware of non-clinical decisions that influence placement into facilities (e.g., not admit obese patients, no IRF close to patients home, etc.).
- Take into account geographic availability; consider including health networks or systems that have both IRF and SNF available.
- Consider relaxing the volume requirement (200 patients/year) to include smaller facilities, which may help to diversify selection.

#### **Patient Selection**

Patients with hip or knee replacement will be enrolled consecutively, as they are admitted to each participating facility.

#### **Panel comments**

- Patient characteristics for inclusion/exclusion criteria must be clearly identified.
- A common reason for hip replacement is hip fracture. Patient characteristics associated with hip fracture are very different from individuals who undergo elective surgery. Most patients with hip fractures have screw placement or hemi joint replacements.
- Hip fracture patients may be about 50% of SNF patients with hip replacement.
- Hip fracture patients count toward meeting the 75% rule.

### **Panel suggestions**

- Do not include patients with diagnosis of hip fracture even if they had a total joint replacement.
- Include patients with hip fracture but control for differences during analyses and consider excluding them for some analyses.
- Use ICD-9-CM codes to enroll patients rather than CMGs.
- Control for type of joint replacement: total vs. hemi.

### **Data Collection Instruments**

Most study data will be obtained from information contained in patients' charts. However, some information is not included in typical documentation. Most notably, details about specific activities and interventions addressed in therapy sessions and coordination of care activities by rehabilitation nurses. Thus, the study will introduce a point-of-care documentation method that promotes documentation of activities not contained typically in traditional documentation.

### **Point-of-care Intervention Documentation Tools**

Point-of-care documentation forms for joint rehabilitation will be based on forms developed previously for stroke rehabilitation and modified by clinicians who will be participating in the JOINTS study to capture treatments employed in joint rehabilitation. The Project Team suggests supplemental documentation for PT, OT, nursing, and physicians to capture information about specific treatment interventions that are not documented in traditional documentation. Burden of completion will be balanced with importance of additional information captured. The Project Team solicited comments on important supplemental elements to capture, especially for nursing.

### **Panel comments**

- The most important nursing activity for joint rehabilitation that is not contained in traditional nursing documentation is the amount of walking and transferring the nurse initiates for the patient throughout the day, which is in addition to therapy time. Education initiatives are also important.
- Completion of supplemental documentation may be challenging for bedside nurses since they are overburdened already, especially in the SNF environment.

### **Panel suggestions**

- Include a point-of-care documentation form for nursing to capture efforts to assist patients with walking and transferring, as well as education initiatives.
- Consider the experience level of nursing; advanced certification, RN, LPN, or aide.

- Capture process differences: number of staff vs. education.
- Examine facility-level characteristics:
  - Does the facility have a designated rehab unit for orthopedic patients?
  - Does the facility use a case management system?
  - What is the role of the discharge planner?
  - Staffing characteristics: could use nursing case-mix
  - Staffing ratios: number CRRNs, RNs, LPNs, and nursing aides to number of patients
- Consider use of activity monitors to capture time of ambulation per day.
- Consider use of Harris Hip and Knee scores as outcome variables (used by orthopedic community but considered quite subjective by others; many do not like).

### **Chart Review Data**

Patient (including severity of illness), process (in addition to supplemental point-of-care documentation), and outcome variables necessary to capture a complete picture of joint replacement will be abstracted from patient charts after discharge. The Project Team is assembling this list of variables, which will be reviewed in detail with the Project Clinical Team at their first meeting at the end of October. Panel had several suggestions for variables to include (see Panel Suggestions).

### **Panel comments**

- CSI, as described in Briefing Book, differentiates patients based on diseases present.
- Joint replacement field is moving toward minimally invasive procedures that may influence type of post-acute rehabilitation care.
- Mental status is important to capture as dementia, etc., plays large role in rehabilitation progress. Psychiatric measurement tools exist (in psychiatric literature).
- Consider using mediator analysis. Mediator analysis is a way to say that ‘this factor’ mediates ‘that outcome.’ Mediator analysis may be an appropriate methodology to account for the variability in facilities.

### **Panel suggestions**

- Capture the following variables regarding surgical procedure: cement-less vs. porous-coated, anesthesia (peripheral nerve vs. general), length of surgery, other surgery details, precautions for movement post surgery.

- Other variables to capture: functional status (see below), mental status, caregiver status, acute hospital length of stay, patient home location and location of IRF and SNF, body mass index, anemia, medications, home configuration, and need for physical modifications.

### **Primary Outcome Variable - Functional Status Measurement**

The Project Team investigated existing measures of functional status and found no instrument that is used in both IRFs and SNFs. IRFs use IRF-PAI FIM and SNFs use MDS. Crosswalks between the two are sub-optimal. After giving careful consideration to each, the Project Team elected to use the IRF-PAI in both settings and is now challenged with obtaining these data in SNFs.

#### **Panel comments**

- Agree that FIM is optimal approach (not MDS). It is a sensitive measure for this population. Ceiling effects may be seen if used post-discharge.
- Different IRFs obtain FIM scores differently. Some document at every interaction. Initial and discharge scores are determined by consensus or by choosing the lowest score.

#### **Panel suggestions**

- Determine how each IRF acquires and calculates FIM scores.
- Take this opportunity to train SNFs in FIM use.

### **Other Studies in Field**

The Project Team provided references to many studies in the Briefing Book and asked meeting participants if they were aware of other pertinent studies.

#### **Panel comments**

- Dr. Munin: proposed hip fracture study has not been successful in securing RCT funding
- Dr. Correa: AHRQ total knee replacement study – summary shared with Project Team; full report on Website.

### **Cost Effectiveness/Cost Analysis**

The Project Team asked the Panel for advice and what, if any, cost data should be included in JOINTS project.

### **Panel comments**

- Payment for episode is not sufficient.
- Average cost per day in IRF, SNF, hospital, ER, etc. are available.
- Length of stay is a reasonable surrogate for costs.
- Home Health coverage is included in Medicare Part A.
- Medicare Part B may be difficult to obtain due to HIPPA concerns.
- Acute hospital length of stay may be indicative of rehabilitation needs/costs.
- The driving factor for many health plans in making post-acute placement decisions is one of ‘medical necessity/appropriateness’ rather than cost-effectiveness.
- Health plans are concerned with acute length of stay, cost of rehab stay, post discharge setting, hospital readmission rates; 4 months out what are readmissions and ER visits?

### **Panel suggestions**

- Use Medicare payment data. Focus on payment, rather than cost.
- Capture use of hospitalization and ER during rehabilitation (especially in SNF) and post discharge, which can be included in follow-up study interview questions.
- Follow-up data should include adverse events, expenditures, Medicare part B data, post discharge ER visits, and return to hospital.
- Consider employer-related issues—absenteeism and return to work.

### **Waiver Request**

The panel’s briefing book included a proposed request for a temporary waiver of the 75% rule and a limited waiver from local coverage decisions for IRFs participating in this study. The overriding fear is that IRFs will alter their selection of patients because of the 75% rule and FI LCDs and thus diminish the number of patients coming to IRFs and skew the types of IRF patients seen in the study. Timeliness of the waiver is important; it would need to be accepted soon to apply to the full project. More realistically, if approved within the next six months, the waiver will help with project enrollment during the second half of the enrollment period.

### **Panel comments**

- Waiver is absolutely necessary for study to best answer the research questions.
- Waiver should be temporary and specific (time-limited period).
- Waiver will allow inclusion of patients with mental status abnormality to be treated in IRF.
- Agree that waiver can be achieved in a time frame beneficial for the study.
- Study is a beneficial way for CMS and MedPAC to get needed information, thus waiver should receive approval.
- Fiscal intermediaries that limit number of patients with total joint replacements that go to IRFs may present a bias.
- In the Medicare managed care environment on the West coast, patients with total joint replacement typically go home for follow-up, not even to SNFs.

#### **Panel suggestions**

- Perhaps full waiver of 75% rule may be too broad. Study patients that qualify for admission under the 75% rule, could still count. Only enrolled study patients would be exempt from counting toward the 75% threshold.
- Participating IRFs may need an adjustment period after the completion of the study, to allow them to adjust to the requirements of the 75% rule that had been waived during the data collection phase of the study. This time may be necessary to adjust patient referral and admission patterns.

#### **Follow-up Study**

The current study limited to the IRF or SNF stay—from admission to discharge with some acquisition of pre-admission data as recorded in the patient chart; it does not follow patients post discharge. The Project Team did not include a follow-up component initially because of the urgent nature of the project, the time delays that would be associated with obtaining informed consent to interview patients post discharge, and for lack of funding. A detailed discussion pursued.

#### **Panel comments**

- Appreciate the need to move quickly and not obtain consent for the current project.
- 20% of all joint replacement recovery occurs after discharge from IRF/SNF.
- Post-discharge follow-up is paramount.

- Administrative follow-up (no informed consent) is not sufficient.
- Follow-up measures may be a primary outcome.
- Need to have comparable measures at all points of evaluation.
- Concerns expressed regarding Project Team’s suggestion for using third party intermediary—not clearly declaring the reason for the data collection is for research; need to disclose to patient purpose of data collection; is the data set covered by the “two chains of trust?”
- Caregiver burden is a ‘cost.’

### **Panel suggestions—by topic**

#### **Time frame**

- Ideally, there should be two follow-up times: at 3 and 6 months post surgery (not post discharge). May find differences at 3 months that disappear at 6 months.
- If only able to collect information once, suggest 4 or 6 months, which would better account for time needed for recovery and final adjustments (e.g., hip precautions lifted at 4 months).

#### **IRB/Informed consent**

- Consider a third party to obtain consents.
- Obtain consent via phone prior to follow-up interview that includes permission to go back to medical records; then facility links and provides de-identified data to project team.
- Consider follow-up as a separate study.
- At issue is disclosure to patient about purposes of data use

#### **Methodology**

- Method of follow-up data collection: suggest phone or in-person interview; will depend on budget.

#### **Patient function**

- **Obtain comparable measures** of function—prior to and after surgery

- Immediate pre-op function is not optimal—has deteriorated by that time. Optimally obtain measure of function one-year before surgery.
  - Identify appropriate benchmark for pre-surgical function.
  - Be aware of differences between patient assessment of function and provider’s measurement of function.
  - Most patients with TJR want to return to normal or high-level functional activities (e.g., tennis, golf) that are not related to assistance or burden of care that can be measured through use of FIM. The FIM presents ceiling effects (see below).
  - Function has little to do with discharge destination.
- **Potential measures of patient function**
    - Do not use questions that use ‘can do more, same, less’ or use 10-point scale. Not valid or reliable.
    - **Phone FIM**
      - Suggest not use Phone FIM (IRF-PAI and Phone FIM are different instruments – no adequate crosswalk).
      - Joint replacement patients have little dysfunction that would be picked up by the FIM.
      - Ceiling effects – FIM doesn’t capture level of independence with life activities (golf, tennis, etc.)
    - **EQ5D**: European scale with 5 questions with 3 levels
    - **6MWT**: Six-minute Walk Test (timed up and go) test
      - Well-validated in literature
    - **FSI**: Functional Status Index (self-report)
      - Assesses overall function based on time needed to complete ADLs
      - Three dimensions that measure difficulty, pain, and assistance
    - **SF36 or SF12**
      - Mike Munin used in previous work – see article in Briefing Book (Tab J)
    - **Activity monitors**
      - Consider providing activity monitors to select patients to determine amount of walking.
        - ‘Excelerometer’ cost about \$400
        - Rich Macko at University of Maryland may have less-costly device
        - 1 patient wear for one week and then send to another patient
- **Panel recommendation for measure of patient function**
    - **SF36 or SF12**
      - After discussion of above functional measures, Panel recommended use of SF36, or possibly SF12 to minimize burden, and suggested further investigation of this tool.
      - Include question ‘when did you return to work?’

## Quality of Life

- Is it important to capture quality-of-life measure, participation measures, or both?
  - Many extraneous factors influence quality of life
  - Need consistent baseline and post-discharge data points
- Suggest using measure of function instead of quality-of-life measures.

### **Pain**

- Capture pain as outcome measure.
- 10-point pain scale is accepted widely and validated in literature.
- Could start with pre-determined value for before surgery: e.g., “If you were an ‘8/10’ one year ago, how would you rate pain today?”

### **Patient satisfaction and perception of care**

- May be biased toward ‘bigger and fancier’ facilities.
- Question appropriateness of this type of question in relation to primary research questions.
- National Health Care Quality Report provides general questions regarding satisfaction—Dr. Correa will provide links to AHRQ website.<sup>1</sup>

### **Other variables to consider**

- Discharge destination (including urban vs. rural-availability of services)
- Environmental barriers (e.g., stairs), living arrangements and caregiver availability
- Infection
- Contractures/manipulation under anesthesia
- Falls

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<sup>1</sup> Following the meeting, Dr. Correa provided the following web site links:

1. Links to the evidence report on Total Knee Replacement

<http://www.ahrq.gov/clinic/tp/kneetp.htm>

<http://www.ahrq.gov/clinic/epcsurns/kneesum.htm>

2. Links to Quality Measures, National Healthcare Quality Report. This includes standard questions to assess patient satisfaction. You can choose the ones that best apply to the study. See Timeliness and Patient Centered Measures.

<http://www.qualitytools.ahrq.gov/qualityreport/browse/browse.aspx?id=4994>

<http://www.qualitytools.ahrq.gov/qualityreport/browse/browse.aspx>

- Return hospital admissions and ER visits
- Deep Vein Thrombosis

**Funding Options** (The follow-up study is not funded currently)

- Funding options include partnering with pharmaceutical companies and equipment manufacturers; local insurers may also be interested for patients in their area.  
Potential contacts:
  - AHP-Association of Health Plans – Chris MacDonell will help identify contact
  - Johnson and Johnson
  - AdvaMed
  - Aetna technical assessment division - Dexanne Clohan will help identify contact

**Project Communication Plan**

The Project Team will produce and distribute an Executive Summary of meeting to all participants.

**Panel comments**

- Agree with e-mail communication to share information.

**Panel suggestions**

- Prepare a web announcement, which will facilitate recruitment.
- Prepare a one-page abstract about study.
- Share revised Research Plan with Panel members and observers; include a ‘challenges faced’ section. Highlight changes made.
- Share project progress reports with Panel members; again include a ‘challenges faced’ section.