Joint replacement **O**utcomes in **I**npatient Rehabilitation Facilities and **N**ursing **T**reatment **S**ites (**JOINTS**)

RESEARCH PLAN

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The National Rehabilitation Hospital (NRH) Research Division and its partner, the Institute for Clinical Outcomes Research (ICOR), are pleased to work with the IRF and SNF industries in examining the post-acute management and treatment of patients with hip and knee joint replacements in inpatient rehabilitation facilities (IRFs) and skilled nursing facilities (SNFs). This work is being funded by the HealthSouth Corporation [and to be named partners] as part of thier commitment to a full and open inquiry on the relative strengths of IRF and SNF rehabilitation for patients with joint replacements. This study comes at a propitious time given the stepwise enforcement of the 75% rule by the Centers for Medicare and Medicaid Services (CMS) and the desire of the rehabilitation industry to determine which joint replacement patients are best served in various settings of care.

The 24-month study will be conducted in three overlapping phases:

- **Phase 1**—a 4-month ramp-up period for the recruitment of study facilities, the formation of the Clinical Practice Team (CPT), the refinement of data collection protocols, institutional review board (IRB) approvals of study protocols,[*] and the formation of the study's Policy Advisory Panel (PAP).

- **Phase 2**—a 15-month data collection and preliminary analysis period that includes the presentation of initial findings in Project Month 16 (12th month of Phase 2).

- **Phase 3**—a 9-month data analysis, dissemination, and utilization phase that overlaps with Phase 2.

The study will entail the participation of 1,400 IRF patients and 1,400 SNF patients drawn from 20 geographically diverse facilities—8 IRFs and 12 SNFs. We will later propose a **Phase 4** study that will address the cost-effectiveness issues related to IRF and SNF rehabilitation for patients with joint replacements. This phase may overlap with Phase 3.

STUDY QUESTIONS

1. ***What are the characteristics of joint replacement patients (DRGs 209 & 210) served in IRFs and SNFs? How are they similar or different?***

   We need to know if there are systematic differences among joint replacement patients served in both settings and take these into account when evaluating outcomes and cost effectiveness as outlined below. See also Question 6.

2. ***How are the interventions and processes of care for joint replacement patients different in IRFs and SNFs?***

[*] IRB approvals for the protection of human subjects and HIPPA compliance.

How can we best characterize the differences in the care received in an IRF vs. a SNF? What makes the care in an IRF and a SNF different? What do they do similarly and what do they do differently? Consider all interventions, e.g., nursing services, physician interventions, physical and occupational therapies, nutritional support, medications, passive motion exercises, weight-bearing exercises. Also consider timing, intensity, frequency, and duration of therapies.

3. ***What specific interventions or combinations of interventions in IRFs and SNFs make the biggest difference in outcomes for joint replacement patients taking into account patient differences?***

   The relevant outcomes for this study include: (1) the onset of complications during the course of treatment, (2) change in severity of illness from admission to discharge, (3) discharge destination (including unscheduled discharges to acute care), and (4) change in functional status from admission to discharge. We will consider (5) rehospitalizations or readmissions in the first 3-6 months following discharge from post-acute care, as part of the Phase 4 cost-effectiveness analyses to be addressed later.

4. ***Which joint replacement patients do better in an IRF and which do better in a SNF?***[†]

   How can we best characterize the differences between patients who do better in one setting or the other? How can these characterizations assist in developing post-acute placement criteria and in characterizing the patient mix that should be used in defining an IRF pursuant to the 75% rule?

5. ***What is the relative cost-effectiveness of IRF and SNF care for joint replacement patients?***

   For which patients is it more cost-effective to be placed in an IRF and which patients in a SNF taking into account outcomes both at discharge and rehospitalizations during the first 3-6 months following discharge? This will be addressed in a later Phase 4 study.

6. ***Are comorbidities***[‡] ***among joint replacement patients an adequate indicator of additional medical need during the rehabilitation process? Can a severity-of-illness measure serve as a better indicator of medical need? Are patients with greater medical needs served better in an IRF or a SNF?***

   Do comorbidities or a severity of illness indicator have better predictive validity in terms of service utilization, costs, and outcomes? The element of costs will be addressed in Phase 4.

7. ***Can we design a more efficient course of rehabilitation interventions for joint replacement patients in IRFs and SNFs to reduce the length of stay and costs?***

[†] Note the question is not whether joint replacement patients do better in IRFs or SNFs. That is an either/or question. We want to proceed on the assumption that some patients do better in one setting and some do better in another. It may well be possible that joint replacement patients do better consistently in one setting versus another and this study may actually conclude with such a finding.

[‡] These include both comorbidities recognized under the IRF-PPS and other comorbidities not specified in the IRF-PPS.

BACKGROUND AND SIGNIFICANCE

Over the last decade (1994-2003), the number of joint replacement patients discharged from acute care hospitals increased 51%, from 241,410 to 364,824 patients.[§] Many of these patients have found their way to one or more post-acute settings. Today, patients with hip or knee replacements comprise the single largest patient group served by IRFs. In FY 2003, according to the GAO, IRFs served 121,528 joint replacement patients—24% of all patients seen in an IRF.[1] In 2003, SNFs served 106,981 joint replacement patients.

The admission of joint replacement patients to IRFs remains controversial for reasons related to an IRF's compliance with CMS's 75% rule—the principal criterion in defining an IRF. To qualify as an IRF, as distinct from an acute care hospital—and therefore exempt from the acute hospital Medicare DRG payment system, 75% of an IRF's patients previously had to come from 10 conditions specified in federal regulation. In 2004, CMS refined the original list of 10 by eliminating the 10th group, "polyarthritis," and replacing it with 4 arthritis-related conditions creating a list of 13 impairment groups (9 original groups + 4 new groups created from the polyarthritis group. While the list appears to be an expansion, it effectively narrows the kinds of patients who can be served in an IRF and still meet the 75% rule.

At issue, for purposes of this study, is Group 13, the joint replacement group. The definition of this group now includes extra criteria that limit the types of joint replacement patients that enable an IRF to meet the 75% rule. Group 13 patients are limited to joint replacement patients who (a) "underwent a *bilateral* hip or knee replacement surgery during the acute hospital admission immediately prior to their admission to an IRF," (b) are extremely obese with a BMI of 50 or higher, or (c) are over the age of 85. In other words, joint replacement patients are limited mainly to those with bilateral replacements and those with unilateral joint who meet one of the last 2 conditions.

In FY 2003, according to the GAO, only 13% of all IRF joint replacement patients met the new more limited criteria mainly because most joint replacement patients had unilateral replacements instead of bilateral replacements. Joint replacement patients, however, can be considered as meeting the 75% rule if they also have a comorbid condition that is on the list of 13 primary conditions. Some 51% of all IRF joint replacement patients had either a primary or a comorbid condition that was on the list of 13 conditions. Joint replacement patients, according to the GAO, comprised 31% of all IRF patients (from all impairment groups) who did not have a primary or comorbid condition on the list of 13 impairments in the 75% rule in FY 2003.[1]

In developing and refining the 75% rule, CMS implicitly assumes certain joint replacement patients may be served better in other less-intensive and less expensive post-acute settings—in a SNF, at home with home health care, or in an outpatient setting. Of these various settings, SNFs are most often considered a potential substitute for more intensive IRF-level care. At present, we know that SNFs provide less intensive care at a lower cost to the Medicare program with generally longer lengths of stay. But we do not know whether SNFs or IRFs serve a different mix of joint replacement patients or which produces better case-mix adjusted outcomes and better outcomes relative to costs.

[§] Data furnished by HealthSouth pursuant to an analysis of MedPAR data.

In examining differences between IRFs and SNFs, we first need to know whether there are material and systematic differences in the characteristics of the lower-extremity joint replacement patients served in these two post-acute settings (**Question 1**). This question is being partially addressed in another HealthSouth commissioned study, but we believe that we need to probe more deeply—by also looking further at severity of illness—in order to adequately take into account the differences in outcomes and costs in IRFs and SNFs. This study uses a sophisticated severity-of-illness measure that enables researchers to characterize severity beyond traditional methods.

In examining the differences in outcomes and costs between IRFs and SNFs, we also need to be able to characterize the differences in the care received in these two settings (**Question 2**). One needs to look at all interventions and processes of care from basic medical support to individual therapies. Moreover, one needs to characterize these differences in terms of *timing, intensity, frequency, and duration.* Without these characterizations, both settings remain black boxes and prudent purchasers, both government and health plans, cannot fully know what it is that they are purchasing. Nor can they discern the active (vs. inactive) ingredients in the IRF and SNF rehabilitation processes that shape outcomes (**Question 3**). Purchasers and providers alike need to know which clinical activities and interventions make the biggest difference for which patients and in what settings are these activities and interventions are most likely to be found. ***It is not enough to say one setting is more effective than another without stating what it is about that setting that accounts for difference.***

We believe that asking whether joint replacement patients do better in IRFs versus SNF is asking the wrong question. ***Instead, we need to ask which patients do better in an IRF and which do better in a SNF*** (**Question 4**)? We start with the presumption that neither setting has an exclusive franchise in this area. Our research may find that one setting or the other does have consistently superior outcomes across all joint replacement patient subgroups but this remains an unknown at this time.

Outcomes eventually have to be evaluated relative to costs (**Question 5**). SNFs have a priori advantage here given their lower cost structure. In those instances, where IRFs provide superior outcomes, one still has to ask whether the additional costs of IRF-level care are worth the outcome. Moreover, one needs to consider both the costs of the post-acute stay and the cost of subsequent health care utilization, particularly unplanned rehospitalizations, in the period following discharge from a post-acute setting—in order to obtain a more complete picture of all post-acute related costs. At this point, we do not know whether similar SNF or IRF patients have different cost experiences in the post-discharge period. We are also faced with the issue of how society values an outcome and the relative costs associated with an outcome. The answer to these questions may vary with the outcome in question. Some outcomes, such as discharge-to-home and rehospitalizations, have an intrinsic economic component and may be valued differently than gains in functional status from admission to discharge. From the standpoint of IRFs, the cost-effectiveness issue is material only if it can be shown that IRFs provide superior case-mix adjusted outcomes. Hence, we have reserved addressing this issue until a later phase and will not be addressed in the study' first 3 phases.

Often, we find that impairment or principal diagnosis is not an adequate indicator of medical need or an adequate case-mix adjuster (**Question 6**). As a result, we turn to the presence

of comorbidities[**] as a surrogate indicator of medical need or medical acuity without adequate empirical evidence as to their actual impact on care management and outcomes. The ability to control for patient differences often pivots on our ability to take into account important differences in medical acuity or severity. Medical rehabilitation has both a medical and a rehabilitation component and the field has, relative to its efforts to measure function, neglected measuring the overall medical acuity of the patient. Identifying and counting the presence of all comorbid conditions has become increasingly important in rehabilitation health policy: in rehabilitation payment policy (the IRF-PPS), in characterizations of medical necessity for rehabilitation care, and in the 75% rule. All incorporate the presence of all comorbid conditions as an important consideration without adequately determining their validity in predicting resource consumption and outcome. This study addresses this indicator of patient need by comparing the predictive validity of comorbidities with a finely-grained severity-of-illness measure in evaluating service utilization and outcome.

In the course of this study, we may well find that some IRFs and SNFs provide certain patients with an especially efficient and effective course of treatment that, if it were to become the standard of care, would be far more effective and cost-effective than care commonly provided in most IRFs, SNFs, or both (**Question 7**). With large sample sizes, we stand the chance of uncovering exemplary practices in IRFs or SNFs or both, some of which may be clinically counterintuitive or run against conventional wisdom. This has been the case in previous studies of the kind being conducted here. ***One of the main benefits to facilities participating in this study, both IRFs and SNFs, is the opportunity to uncover exemplary processes of care that can enhance the quality and efficiency of IRF or SNF care or both.***

Until very recently, there were "no studies of outcomes of lower extremity joint replacement across post-acute sites."[2] Previous studies comparing IRF and SNF outcomes have been largely limited to stroke and hip fracture. These studies found that compared to SNFs, IRFs generally provide superior outcomes for stroke patients in terms of functional gain, return to community, and post-discharge mortality. The evidence with hip fracture rehabilitation patients, however, remains mixed: Some studies show that SNFs do better on select outcomes; some studies show little or no difference, some show that IRFs do better, and still others show that SNFs do better with some patient subsets while IRFs do better with others. Many of the studies to date on post-acute stroke and hip fracture rehabilitation include important qualifying statements about potential selection biases, the comparability of the IRF and SNF study groups, the post-discharge window of observation, and other study limitations. Because of the significant clinical differences, the results of these stroke and hip fracture studies do not generalize to joint replacement rehabilitation.[3 4 5 6 7 8 9 10]

The MedPAC-RAND study

The only study to date on outcomes of joint replacement patients across post-acute sites is the recently complete RAND Health study completed for the Medicare Payment Advisory Commission (MedPAC).[11 12] Using only administrative data[††] on 426,000 acute care discharges from January 2002 to June 2003, RAND sought to determine differences between joint replacement patients discharged to home (N=149,000), an IRF (N=149,000), or a SNF

[**] These include both comorbidities recognized under the IRF-PPS and other comorbidities not specified in the IRF-PPS.

[††] Examples of administrative data include MedPAR, Medicare claims data, MDS, and IRF-PAI.

(N=128,000) in terms of their characteristics, outcomes, and Medicare spending. The study found that SNF patients were older and had more comorbidities and complications, and that IRF care costs were considerably higher than SNF care or home care costs. The study's cost findings were incomplete, however, since they were limited to Part A expenditures and did not include Part B payments for physician services and outpatient therapy services within a given episode of care.

The MedPAC-RAND study is especially guarded with respect to outcomes. RAND limited its analysis to mortality and post-discharge institutionalization but suspected the presence of selection biases for which it believed it was not able to control adequately through instrumental variable analysis. Selection bias is a potential problem when using administrative data sets that do not contain adequate patient severity data—or links to such data—that allow one to control adequately for patient differences among those going to different settings of care.

Most disappointing, according to the authors, was their inability to address their preferred outcome, namely, functional status: IRFs and SNFs use different functional assessment measures and administer them at different points in time. Despite these constraints, researchers did try to make some comparisons on select variables (e.g., walking, transferring) and select patient subsets where limited comparability was possible. Researchers found that "[among] patients who were discharged at 14+ days, 1% of IRF patients were walking independently at admission but 76% were walking independently at discharge." Comparable findings among SNF patients were 9% and 31% respectively.[13] Researchers did not include functional variables in their multivariate analyses because they "felt they were too inconsistently measured across IRFs and SNFs to be treated formally as outcomes."[14]

Using only administrative data severely limited RAND's ability to address key study questions despite large numbers of patients these administrative data sets offered. Researchers conclude by noting that they needed "three additional types of information:" (1) measures of "real resource use across sites of care rather than measuring only Medicare payments," (2) "a method for evaluating the trade-off between better outcomes and higher costs," and (3) better measures of outcome, including a measure of functional status that was captured consistently across all discharge settings."[15] RAND researchers might have added a 4th data need, namely, better measures of patient severity and thus be less reliant on instrumental variables to control for patient covariates resulting from selection effects.

This study addresses these limitations by collecting clinical data not available in administrative data sets. This study will (1) provide far more in-depth information on resource utilization (especially with regard to physician, nursing and therapy services), (2) propose a Phase 4 plan to evaluate the trade-offs between higher costs and better outcomes, (3) address the inconsistency of functional assessment measurement across care settings, and (4) provide far more detailed information about patient characteristics and severity to control for patient differences that might arise from selection effects. In short, this study is a natural successor to the MedPAC-RAND study and provides solutions that overcome its inherent limitations.[‡‡]

A recent review

[‡‡] This research plan was conceptualized prior to the release of the MedPAC-RAND report on June 15, 2005. The MedPAC-RAND report provides an important baseline for this study.

A recent review of the state of the science in rehabilitation relative to CMS rule making argues that, for joint replacement patients, "[t]he majority . . . can go directly home [from acute care] and inpatient rehabilitation does not yield superior outcomes overall."[16] The key qualifier is "overall." Within this broad group of patients are subsets that probably can benefit from either IRF or SNF level care or care in other settings. The authors[§§] of the paper go on to state "the burden of proof is on rehabilitation providers to demonstrate that there is any subpopulation of these patients for whom inpatient rehabilitation is clinically necessary and cost-effective." The authors also exhort providers to identify "the optimal timing, intensities, and durations of rehabilitation services for different populations of patients" and conduct research to identify ways in which "rehabilitation services can be most effectively and efficiently delivered." The aim of this study is to identify these subpopulations, determine the interventions or combinations of interventions associated with superior outcomes, and locate the settings associated with these interventions and outcomes.

To date, the common denominator across all 7 study questions is the quest for evidence-based practice in joint replacement rehabilitation. This evidence is lacking, and where it does exist, it is rarely in a form that can answer the questions that dominate the present post-acute rehabilitation environment especially with regard to the 75% percent rule and the IRF-vs.-SNF debate in post-acute care.

METHODS

Overall approach

We will use a methodology known as clinical practice improvement (CPI) to answer the study's principal research questions. In the narrowest sense, only Question 7 is a clinical practice improvement question but, as a method of inquiry, CPI is especially well suited to answer the study's principal research questions. CPI is a type of observational cohort study that entails the acquisition of both prospective and retrospective data. It does not disrupt the natural milieu of the treatment setting. CPI offers a naturalistic view of rehabilitation treatment by examining what actually happens in the care process. It does not alter or freeze the treatment regimen to evaluate the efficacy of a particular intervention as in the case of a randomized controlled trial. CPI captures the breadth of patients, interventions, treatments, and their interactions within the rehabilitation setting. The CPI approach also offers the advantage of large numbers—numbers that often cannot be attained in a randomized controlled trial (RCT) constrained by stringent selection criteria. The CPI approach controls for patient differences by taking into account important patient covariates such as severity of illness and functional status. Moreover, CPI's detailed data on interventions allow researchers to zoom in on the most meaningful level of resolution regarding the types of care rendered—consistent with current knowledge and the insights offered by clinical participants. Thus, the CPI approach can answer study questions and hypotheses initially at a fairly basic level of resolution but also allows drilling down into the data with the help of additional insights offered by a multi-disciplinary clinical practice team.

[§§] One of the three authors is the director of NIH's Center for Medical Rehabilitation Research (M Weinrich) and another is or was a CMS senior staff member who had a major rule in the design and selection of prospective payment systems for post-acute care (T Hoyer).

CPI overcomes many of the limitations of traditional types of observational studies by the manner in which it creates a comprehensive database of patient characteristics, disease-specific physiological severity of illness measures, therapy interventions, medical and nursing procedures, and outcome data, so that most covariates can be addressed in analyses. Accepting a priori that potential confounding variables should be identified and measured–rather than eliminated–allows for a richer study. Naturally occurring variation becomes a benefit for finding effects, rather than an error term that masks them. Once a CPI study is underway, few potential participants are excluded, as the study is structured to capture differences, rather than be confounded by them. This inclusiveness allows greater generalizability and greater ecological and external validity of findings. Details of CPI methodology and how we will use CPI methods (including measuring severity of illness and documenting treatment details) to study individuals with joint replacements are described below.

CPI methodology uses data from natural settings to describe the content and timing of the treatment to determine those medical procedures and therapy interventions that are associated with better outcomes. One hallmark of the CPI process is the manner in which it can carefully disassemble each component of the joint replacement rehabilitation process and then determine how and to what degree each component—individually and in concert with others—contributes to outcomes, taking into account patient differences. The process for implementing a CPI study can be summarized as follows:

1. ***Establish a multi-site, multi-disciplinary Clinical Practice Team*** composed of each facility's site director (medical director or lead researcher), lead clinicians from each discipline at each facility (e.g., nursing, physical therapy, occupational therapy), and the NRH-ICOR project team (with expertise in severity of illness measurement and CPI). The Clinical Practice Team (a) refines patient selection criteria, (b) identifies and defines outcomes of interest, (c) proposes hypotheses for testing, and (d) provides leadership and guidance through all analyses. The Clinical Practice Team fosters trans-disciplinary communication and training across traditional scientific and clinical boundaries. A key advantage of the CPI approach is the manner in which it garners clinical staff support needed to sustain project momentum, enhances project ownership, and increases staff commitment to the dissemination and implementation of findings.

2. ***Engage clinicians of various disciplines from participating centers*** in an iterative process of (a) defining key patient characteristics presumed to affect outcomes and/or effectiveness of therapies, (b) identifying and defining individual components of each discipline's care process, (c) creating discipline-specific documentation tools to quantify the delivery of those components, and (d) incorporating documentation into routine facility practices. The clinicians build on theoretical understanding, research evidence to date, existing guidelines, and clinical experience to select factors that may influence outcomes.

3. ***Collect detailed patient, process, and outcome data using the discipline-specific documentation tools and the medical record.*** Multiple quality assurance methods are utilized, including training, internal reliability testing, and external review of quality assurance processes.

4. ***Test a priori research question or hypotheses using multivariate analyses***, including hierarchical models, multiple regression, analysis of variance (ANOVA), logistic regression, and other methods consistent with the measurement level of predictor and outcome variables.

5. ***Use risk adjustment*** to take into account each patient's co-morbidities and severity of illness. CPI projects use the Comprehensive Severity Index (CSI) as the primary, though not exclusive, severity adjustment measure. CSI is an age- and disease-specific measure of physiologic and psychosocial complexity based on over 2,100 signs, symptoms, and physical findings presented by the patient.

6. ***Generate and test post-hoc hypotheses.*** There is successive testing of hypotheses based on questions that originally motivated the study, previous studies, and new hypotheses proposed by the Clinical Practice Team.

7. ***Develop recommendations for clinical practice and policy*** relative to the questions that motivated the study. Propose new interventions and randomized clinical trials if and where needed.

8. ***Disseminate findings and recommendations*** via peer-reviewed journal articles, professional conferences, and print and electronic media for policy makers, practitioners, and consumers.

We will build on the recently completed stroke rehabilitation study in which we used CPI methods. More specifically, the Clinical Practice Team will evaluate and modify the point-of-care documentation instruments used in the stroke study especially with respect to the documentation of nursing, PT and OT services.

We will propose a cost analyses module to the CPI study to address the study's Phase 4 cost-effectiveness issues mentioned earlier. We will propose two or more alternatives approaches depending on how the cost-effectiveness issues are framed.

Study group

The study sample will consist of 2,800 joint replacement patients treated in IRFs (N = 1,400) and SNFs (N=1,400). To acquire a study group of this size, we will need to recruit approximately 8 IRFs and 12 SNFs located in geographically diverse regions of the nation.

Patients will be enrolled in the study if they:

1. Are 21 years of age or older,
2. Received a hip or knee replacement of any type for any reason, and
3. Admitted from any source.

To be included in the study's database, the above enrollment criteria need to be met. In addition, patients also must:

4. Have a minimum rehabilitation length of stay (LOS) of 3 days, and
5. Have complete admission and discharge FIM data.

We will not exclude low-frequency hip or knee replacements, e.g., bilateral replacements, combined hip and knee replacements (same side or opposite sides). We will exclude other types of joint replacements such as shoulder and ankle replacements since the rehabilitation for these patients is quite different. For most study patients, the joint replacement will be their first, but

with the aging of the population, revisions are becoming more common. According to the MedPAC-RAND report, 4.8% of IRF and 6.3% of SNF joint replacement patients had a revision.[17] The study sample will include both Medicare and non-Medicare patients.

The newly formed Clinical Practice Team (CPT) reviewed the study's original enrollment and inclusion criteria and has recommended the criteria as outlined above. The Project Team and the Clinical Practice Team have debated at length whether hip replacements subsequent to a hip fracture should be included in the study. The consensus is that hip fracture patients who have had a joint replacement should be included. Although the treatment of elective and trauma-induced joint replacement is different, the CPT believes that both needed to be captured in order to determine which groups might be served better in one setting versus another. Including hip fracture patients will ensure that the study will capture a picture of the frail elderly with multiple comorbidities that may be most difficult to treat. In many of these patients, replacement is preferred to joint repair in order to mobilize patients more quickly after surgery.

Current practice patterns also factored into the study selection criteria. The 3-day minimum LOS coincides with existing FIM documentation guidelines. If the LOS is less than 3 days, there is no discharge FIM. The study's original patient selection criteria excluded patients who had an interrupted rehabilitation stay of more than 3 days. The CPT determined that a patient should remain in the study if he or she returns to the participating facility as part of the same episode of care regardless of the duration of interruption.

One of the challenges facing this study is that the mix of joint replacement patients seen in IRFs and SNFs may be changing over the course of the study as IRFs limit the kinds of joint replacement patients they are admitting in order to comply with the step-wise implementation of the 75% rule. This may also be occurring because fiscal intermediaries (FIs), apart from the 75% rule, are refining or revising the medical necessity criteria that determine whether a joint replacement patient should be admitted to an IRF. These changes in the larger environment may affect the mix of patients in the study, may limit the size of patient subgroups to be studied, and may make it more difficult for the study to make accurate representations about the kinds of patients seen in IRFs and SNFs over time.

The Project Team will address these issues with members of the study's Clinical Practice Team to ascertain how their facilities are being affected by these changes and the probable impact of these changes on the study. The Project Team will also address this issue with the Policy Advisory Panel in its first meeting to be conducted during the Phase 1 ramp-up period. This study will take full cognizance of the larger policy environment and how it may impact of study group selection and industry practice patterns.

Sample size and power calculations. Sample size was determined using Cohen's recommendations for modeling the magnitude of effect size.[18] In some research (e.g., studies conducted in applied settings or new areas of inquiry), effect sizes may be small because the phenomena under study are not under good experimental or measurement control. The smaller the effect size, the larger the sample required (other parameters being equal) to detect significant differences. Cohen recommends that power calculations be performed assuming small, moderate, and large effect sizes based on the proportion of variance accounted for in the dependent variable.

Using these concepts and tables provided in Cohen, a sample of 2,800 subjects will have at least 80% power (with Type 1 error of $p<.05$ (2-tailed test)) to detect small effects (effect size of 0.15) of the predictor variables on outcomes. The sample will allow us to detect differences in mean values of continuous outcomes that are 0.15 standard deviation units, and differences in discrete outcomes of 4% to 8%. For regression analyses, independent variables that predict about 2% of the variance in outcomes will be detected. When analyzing subgroups of patients within e.g., levels of severity of illness, more than 300 subjects are expected in most groups, which will allow detection of medium sized effects (effect size of 0.30) with at least 80% power (with Type 1 error of $p<.05$ (2-tailed test)). Models for these sub-analyses will be sensitive to differences in mean outcomes that are 0.3 standard deviations, or between 8% to 15% differences in rates of an outcome.

Representativeness of the sample. The proposed study group constitutes a convenience sample based on the willingness of facilities to participate and, as such, there is naturally a concern that the sample may not be representative of all joint replacement rehabilitation patients and thereby limit the generalizability of the study's findings. Ideally one would like to have a national probability sample of joint replacement patients but such a sample makes it difficult to acquire the depth of information being sought in this study.

The sample, nonetheless, will be a geographically diverse one that will assure a reasonable degree of practice variation. The Project Team will select facilities from each of the 4 major Census regions. Where multiple sites are to be selected within a region, we will also consider the population and facility distributions among the 9 Census divisions. (See **Appendix A** for a description of Census regions and divisions.) More importantly, we propose to compare the study group to one or more known national samples of joint replacement patients using IRF-PAI data, SNF-MDS data, or MedPAR data in order to determine the representativeness of the study group and the generalizability of the study's findings. We will consider reweighting the study sample in the data analyses if there are significant differences with known national samples—unless the implications of the differences can be quickly or adequately ascertained.

Facility recruitment. HealthSouth will commit to the participation of 2-4 IRFs from geographically diverse areas of the nation—possibly up to one from each Census region. The Project Team, working with the NRH and HealthSouth leadership teams and with the American Medical Rehabilitation Providers Association (AMRPA), will recruit 4-6 additional facilities. The Project Team will work with the American Health Care Association (AHCA) and the American Association of Homes and Services for the Aging (AAHSA) as well as with its own contacts in the SNF industry to recruit up to 12 geographically diverse SNFs. The Project Team will designate additional facility selection criteria. Participating facilities should represent the gamut of practice and not just the "best-of-breed" in each category.

Patient information. Each participating facility will collect data on qualifying patients consecutively as they are admitted to the facility. As in prior studies of this kind, it is not necessary to obtain individual patient consent because:

1. The study does not introduce a new intervention or test;
2. The study only documents current practice as provided by therapists, the medical record, or existing databases;
3. The study deidentifies all data for both patients and clinicians;
4. The study does not obtain post-discharge follow-up data directly from individual patients.

5. There is a high likelihood that if all individuals are not included in the study that a bias would occur that would jeopardize the study

By not having to obtain individual patient consent, study participants can be identified quickly as they are admitted and extensive resources do have to be deployed to explain the study to each prospective patient. This will enable the Project Team to achieve target numbers of patients more quickly.[***]

Selection bias. One concern that researchers have in comparing differences in patient outcomes across settings of care is that the differences in outcome may be due to unobserved differences among patients that stem from how patients were selected into facilities. Researchers will sometimes try to correct for this by using what is called instrumental variable (IV) analysis. In the MedPAC-RAND report cited earlier, for example, researchers tried to model patient selection bias by considering the geographic availability of a type of site relative to where the patient lived on the assumption that geographic proximity would shape referral patterns and patient choices. Selection bias is especially a problem with administrative data sets (such as those used in the MedPAC-RAND study) where patient-level data with respect to severity and other factors are likely to be less complete. Although we cannot eliminate all selection bias, we believe that the data set proposed here will be much more complete—if not exhaustive—with respect to patient characteristics leaving much less variance in outcome unexplained due to patient differences. In later sections we outline the detailed severity adjusters to be used in this study.

Study variables

The multi-disciplinary Clinical Practice Team will suggest, discuss, and reach consensus on a defined set of patient, treatment, and outcome variables. This process will begin with a systematic review of variables used in other CPI studies, especially the Post-Stroke

Table 1
Examples of Data Elements for the Joint replacement Study

Selected Patient Premorbid Characteristics
Demographics (race, age, gender, education, marital status, employment)
Smoking status/history
Prior substance abuse
Arthritis-related history
Psychiatric history
Pre-surgery functional independence

[***] Only the local facility will know the identity of the study patient. Each patient will be assigned a study ID number and only the local facility will be able to link the study ID number with an individual patient. In Phase 4, the cost-effectiveness study to be undertaken later, it may be necessary to use identifying information from the local facility in order link project data with Medicare administrative data to determine the incidence of post-discharge readmissions and rehospitalizations. If this identifying data should be needed to link clinical and administrative data, it will be done preferably in a manner such that the patient will remain known only to the local facility and unknown to members of the Project Team (e.g., through encryption). In any event, such linkage will be fully IRB and HIPAA compliant.

Pre-surgery living situation
Selected Patient and Severity Characteristics
ICD-9 Diagnosis Codes including co-morbidities and complications
Comprehensive Severity Index
Acute care length of stay
FIM Motor & Cognitive at admission
Selected Rehabilitation Intervention Data
Physician interventions, e.g., family interactions
Physical Therapy, e.g., gait training, stair training
Occupational Therapy, e.g., dressing, community integration
Medications
Pain management
Nutrition
Selected Medical Course Indices
Vital signs – high/low for each day
Lab test results
Outcome Variables
Complications
Change in severity of illness from admission to discharge
Change in functional status from admission to discharge
Discharge location

Rehabilitation Outcomes Project. A review of joint replacement-specific variables will begin at the first project meeting and will continue via telephone conference calls during the project's first few months in Phase 1. Table 1 provides a sample listing of the study variables and data elements.

Patient variables (including severity-of-illness). Patient characteristics will be included based on previous research indicating their importance in this or other populations. The Clinical Practice Team will identify other joint replacement-relevant patient variables to include in the data collection instruments.

A critical variable in CPI studies is the measure of how ill or acute the patient is at various times during the study period. Clinicians and researchers believe (supported by analyses of our stroke rehabilitation database) that complications and co-morbidities have an independent effect on rehabilitation resource utilization and outcome. The CSI will be the primary severity adjustment method. CSI, developed over 20 years by Dr. Horn and her colleagues (initially at The Johns Hopkins Hospital), defines severity as the physiologic and psychosocial complexity presented to medical personnel due to the extent and interactions of a patient's disease(s).

CSI is age- and disease-specific, and independent of treatments. The CSI provides an objective, consistent method for defining patient severity of illness levels based on over 2,100 individual signs, symptoms, and physical findings related to a patient's disease(s), not just on diagnostic information (ICD-9-CM coding). There are over 5,600 disease-specific CSI criteria sets. CSI has been validated extensively in many inpatient, ambulatory, rehabilitation, and long-term care settings since 1982.[19 20 21 22 23 24]

The CSI incorporates disease-specific severity algorithms and produces a 4-point measure as well as a continuous measure (0 to no upper limit) for each of a patient's diagnoses. It also produces an overall 4-point score and an overall continuous score that reflect interactions of diseases. To produce these measures, ICD-9 CM codes (principal diagnosis and comorbidities) entered into the CSI software generate specific, disease-oriented questions. A trained data collector finds answers to these questions in a patient's medical record. These responses produce a highly sensitive measure of severity that could not be produced by using diagnosis and/or procedure codes alone or by using a limited, fixed set of physiologic criteria independent of the underlying diagnoses.[25 26 27 28] The more abnormal the signs and symptoms, the higher the score, with Level 4 signs and symptoms being catastrophic, life threatening, or likely to result in organ failure. Level 1 indicates a mild form of disease. The CSI will allow us to separate the severity of illness of the joint replacement from the severity of illness of all other injuries, complications, and co-morbidities.

The CSI also indicates whether a diagnosis is present on admission or not; hence, one can identify complications, such as infections, that occur after admission and can determine how severe they are by their disease-specific maximum severity score. Horn's research has found that patients who are sicker on admission are more likely to get infections and other complications during the hospital stay, and also are more likely to have their comorbidities worsen after admission. The CSI software can track these outcomes. CSI data will be obtained for three different time periods of the patient's stay:

- The **'admission CSI'** review includes all data from the first yet-to-be determined hours of the IRF or SNF stay. It assesses how sick the patient is on admission to the facility.

- The **'discharge CSI'** review assesses the extent to which abnormalities have been resolved, and reflects information from the last pre-determined hours before discharge.

- The **'maximum CSI'** review uses data from the entire stay, including the admission and discharge review periods. It measures the most aberrant findings, regardless of when they occur.

Process variables. Another component of the CPI methodology is process, which refers to the care the patient receives. It addresses all interventions and management strategies. Previous experience tells us that many intervention and management strategies are well-described in traditional facility documentation processes. However, exact descriptions of specific types and duration of activities/interventions performed within therapy sessions are not included in traditional documentation. Thus, we will collect process variables in 2 ways: from therapy intervention documentation forms revised for this study and from chart review.

1. Therapy intervention documentation. We will refine intervention documentation forms developed and used in the stroke rehabilitation CPI study rather than creating such forms

from scratch. This refinement will be responsive to the clinical issues that dominate joint replacement rehabilitation. As an example of a therapy intervention documentation form, see the physical therapy form in **Appendix B**. This form allowed recording of time spent on specific functional activities (sitting, transfers, sit-to-stand, pre-gait, gait, advanced gait, community mobility, etc.) and interventions (balance training, postural awareness, proprioceptive neuromuscular facilitation, neuro-developmental therapy, gait with body weight support, cognitive training, etc.) used within each activity. The PT form also captured time spent on formal assessment and worksite evaluations. Group therapy was recorded and included number of patients, therapists, and assistants involved in the group. The experience gained from the stroke rehabilitation study will inform our development of documentation procedures specific to joint replacement. This will be a major activity in the first few months of the study. ***The point-of-care intervention documentation in this study will be limited to 4 main disciplines—physician, PT, OT, and nursing.***

2. Chart review. The Clinical Practice Team will identify and define study-specific process data elements that are collected (along with patient severity and other information) from chart review following patient discharge. Examples of process variables include medication data and nutrition information. As stated above, these process variables identified by the Clinical Practice Team are in addition to information on therapy intervention documentation forms. We will also include all data from the IRF-PAI and the SNF-MDS.

Outcome Variables. The study will initially focus on four outcomes: (1) the change in functional status as measured by the Functional Independence Measure (FIM) from admission to discharge, (2) change in severity of illness from admission to discharge as measured by the CSI, (3) the onset of preventable complications, and (4) discharge destination, i.e., home, assisted living, institutional care, and acute care. The Project Team, in concert with the Clinical Practice Team (CPT), will refine these outcome variables during Phase 1, the study's 3-month ramp-up period. For example, the CPT will identify the sentinel complications to be tracked (e.g., DVTs, infections). The CPT may expand beyond the initially-defined outcome variables or endpoints. In the cost analysis, reserved for Phase 4, we will examine all health care utilization (e.g., use of home health care) with a special focus on rehospitalizations and readmissions to acute care after discharge from an IRF or a SNF.

In looking at change in functional status from admission to discharge, one of the most vexing issues is that IRFs and SNFs use different functional assessment instruments: IRFs use the Functional Independence Measure (FIM) embedded in the IRF-PAI and SNFs use the Minimum Data Set (MDS) 2.0, a portion of which addresses domains included in the FIM. We considered multiple options. First, we considered the option of creating a crosswalk between the FIM and the MDS and reviewed several past and present attempts at creating a crosswalk. We concluded that past item-by-item attempts were not successful[29 30 31] and that newer attempts using item-banking techniques are more promising but will not be ready for quite some time.[†††] We also considered using a third instrument as a bridge between the FIM and the MDS. The Barthel Index has been used for this purpose—albeit with reservations as in the recently released MedPAC-RAND report.[32] The MedPAC-RAND study did so but expressed reluctance to use it

[†††] Based on personal communications with researchers at the Rehabilitation Institute of Chicago (T Malison) and the University of Florida (C Velozo).

as a sound outcome measure. Other researchers have used the "Barthel bridge" as a patient covariate, not as an outcome measure.[###]

To complicate matters further, IRFs and SNFs use different time points: IRFs collect FIM data upon admission and discharge; SNFs collect MDS data on the 5th and 14th day after admission. Moreover, the FIM reports on the patient's most dependent behavior while the MDS reports the patient's usual behavior.

Considering these complications, we opted to apply the FIM at admission and discharge in both IRFs and SNFs. The FIM is the more parsimonious of the two instruments and is reported to have better measurement properties. This places an extra burden on SNFs who will have to collect FIM data in addition to MDS data they already collect. Some SNFs with substantial rehabilitation capacity already use the FIM or have used it in the past and are familiar with it. We believe that administering the same functional status instrument at similar time points will greatly enhance the creditability of the findings.

Data collection

All HIPAA guidelines will be followed for collection and use of data. A HIPAA waiver will be obtained and used to disclose data collection from medical records. This study will not obtain an informed consent during the course of this study. This is in order to exam the full spectrum of Rehabilitation for the individuals that have had a joint replacement. The study is observational only and the course of the individuals care will not be altered in any way due to the study. In addition, there is a high likelihood that if all individuals are not included in the study that a bias would occur that would jeopardize the study.

The CSI software system will be the central repository for all project data, as it includes the CSI severity system described above (standard for all CPI projects due to its disease specificity) and contains auxiliary data modules (ADMs) that are built to accommodate project-specific information such as the intervention and chart review data. For this project, there will be one ADM that includes patient, process (e.g., intervention documentation data), and outcome variables. The development process for each variable type is described below.

All data are entered into the CSI Software System and identified by Study ID number only. Periodically throughout and at the completion of the data collection effort CSI data are harvested from each facility's CSI database where data files are encrypted using OpenInsight's(R) proprietary record-storage algorithms. Data files are transferred electronically to ISIS/ICOR using remote access software with 128 - 256 bit SSL encryption, such as 3amLabs' LogMeIn IT Reach.

[###] Based on personal communications with researchers at the University of Colorado Health Sciences Center (A Kramer).

When all data from all sites are received they will be merged into a comprehensive database. At this point, each site will be assigned a unique number, which precedes the Study ID number of each record from that site. Each site will be told its number but not the numbers of the other sites. The patient identifier data will be sequential numbers from 1 to 200 given to each of the study patients from each site; patients cannot be identified directly or through identifiers linked to the patients.

The entire CSI database will then be exported to a SAS program for analysis. Each site retains ownership of its data and has licensed to ISIS the right to use the collected data from this project. The sites where the data are collected will remain unidentified in any report or publication, and ISIS holds all patient and provider information in confidence.
ISIS/ICOR occupies approximately 2700 sq. ft. of modern, locked, wheel-chair accessible office space in Salt Lake City, UT, located in Suite 100 at 699 East South Temple. ISIS/ICOR has a computer network (LAN) with high-speed DSL Internet connection, a data transmission security protocol, and automatic nightly data backup protocol; it also has modern workstations and laptop computers, back-up devices, and laser printers.

Clinical data collection will be 3-pronged.

1. **Point-of-care documentation** will be acquired during each PT and OT encounter with a joint replacement patient to capture information not currently collected in the course of care. Typically, patient assessment information is well documented; however, detailed information about therapy-specific activities and interventions within activities are not documented consistently. For example, we will want to know how much time is spent doing advanced gait activities and what interventions (balance training, strengthening, perceptual training) are done within the gait activity. In addition, nurses and physicians will complete a point-of-care intervention documentation form to capture interventions and patient-related activities that are not documented typically. Examples of these types of data include reinforcement of therapy interventions and frequency of teaching sessions (nursing) and details of family or provider conferences (physician). See **Appendix B** for example of the specific documents. **The information that will be collected as part of the point-of-care documentation falls within the existing job description of the clinician and only requires orientation to the format of the document. Each site will utilize this form as part of their standard practice for all individuals that are admitted status post hip replacement surgery.**

At the beginning of the data collection phase of the study, each project site will identify a PT, OT, and nursing leader to be that discipline's Lead Clinician for the project. Two of these individuals from each site will attend a training session at NRH that will be conducted by the NRH Data Quality Coordinator and by the study's Site Coordinator. Ideally, we would also want a lead physician from each site to participate in the training session. This may be difficult because many physicians are private practice physicians who have admitting privileges but are not employees of the IRF or SNF. The Clinical Practice Team will develop proposals on how best to train participating physicians.

The train-the-trainer orientation session will enable Lead Clinicians to conduct subsequent discipline-specific training programs for their colleagues to teach them how to use the intervention documentation. It will also establish a consistent approach to validate the accuracy of form completion within each facility. A training manual will contain instructions for intervention documentation, definitions for all terms used, and case scenarios that depict how documentation is to be completed. Clinicians at each participating facility will use the newly-

established documentation process as they document care for each patient encounter. Based on past experience, we estimate that, once the clinician becomes familiar with the form, it will take a PT, OT, or nurse about 2-3 minutes to complete a form and it will take physicians about1 minute. Clinicians will place completed intervention documentation forms in the chart so that they are available for retrospective chart review data collection (see below).

2. Retrospective chart review data collection will be conducted after patient discharge. Each site will assign or hire a staff member to perform chart abstraction using the CSI software system described above. These staff will attend a 4-day training session that will include both didactic and practice sessions. Based on previous experience in the stroke rehabilitation project, we anticipate that chart abstraction will require about four hours per subject.

3. Functional status will be measured using the Functional Independence Measure (FIM) embedded in the IRF-PAI. This data collection is standard practice in IRFs but will be an additional effort in all or some of the participating SNFs. If participating SNFs are collecting FIM data currently, we will verify that it is the up-to-date version that is being used in IRFs today. We are exploring two options to obtain these data on admission and discharge from SNFs that do not collect FIM data currently: train on-site personnel to collect FIM data for each study patient or have FIM-trained personnel visit the facility to collect the data. We anticipate the decision of which option to use will be made in conjunction with each participating SNF; some may prefer to collect their own data; others may wish to have it done by outside personnel. In both IRFs and SNFs, the data abstractor will transfer FIM data into the CSI software system during retrospective data collection.

Quality assurance procedures. Quality assurance procedures will be performed for the point-of-care documentation, retrospective chart review, and functional status data.

1. For **point-of-care intervention documentation**, each site will follow the process outlined during the Lead Clinician training session at NRH. Auditing procedures will include having two therapists observe a patient session and document the session on separate treatment forms. Results will be compared and differences will be identified, discussed, and harmonized. These results will also be reported to the project's Site Coordinator and Data Quality Coordinator at NRH, who will monitor trends in reliability issues for treatment documentation at each site.

2. For **retrospective chart data collection**, each chart abstracter will undergo reliability testing following the 4-day CPI training session conducted by ICOR staff. This reliability goes beyond internal data editing features of the CSI software and ensures complete and accurate data collection. Reliability monitoring will be conducted for each data collector after the first four charts are completed and again after 25 charts. To ensure that data collection accuracy is maintained throughout the project, reliability testing will occur periodically depending on facility sample size. Reliability charts will be selected randomly from cases rated. Charts will be blinded of confidential patient and clinician information and sent to the ICOR office where an ICOR reliability team member will re-abstract each chart. A 95% agreement rate between the chart abstracter and ICOR staff will be required for each reliability test.

3. For **functional status data collection** we will establish a consistent procedure for FIM data collection that is done by facility personnel and by outside personnel for participating

SNFs. NRH will provide guidance about how FIM reliability is done typically in an IRF and similar processes will be applied to SNFs.

ICOR will maintain a comprehensive project database containing all patient and clinician data. All data will be checked upon receipt for completeness and accuracy (e.g., sensible value entries such as dates within the study time period and sequential timing of linked process steps). Data will be merged into a comprehensive database when data collection is complete. Each site will be assigned a number, which will precede the Patient Identification Number of each record from that site. Each site will be told its number but not the numbers of other sites. Patients and clinicians will not be identified in the project database, which will contain only HIPAA limited data set information.

Analysis plan

The ICOR team will perform all analyses, which will be directed by the PI, Co-PI, and members of the multi-disciplinary Clinical Practice Team. These researchers and clinicians have the fundamental knowledge and experience treating patients with joint replacement to know when associations are clear or whether additional explanatory variables are needed. Clinical strengths of the Clinical Practice Team combined with CPI experience and analytic strengths of the NRH/ICOR Project Team will result in clinically meaningful, statistically sound data analyses.

Management of missing data and outliers. When data are missing, we will make one or more adjustments depending on the variable and its intended use in the analyses. Sometimes we will categorize values simply as "unknown" (and still include the variable in the analysis as a dummy variable representing the missing category); sometimes we will delete patients with missing data from some analyses; and sometimes we will be able to collapse continuous variables with missing data into categorical data and place the cases with missing information for the continuous variable into a category using corroborating data. For example, we may not always have a patient's Body Mass Index, but we may have other weight- and height-related information (e.g., an order for a bariatric wheelchair) that may allow us to categorize a patient broadly, e.g., as overweight or obese. When missing data are material, we will also examine whether patients with missing data are substantially different from the rest of the study group, and will adjust accordingly. To exclude unrealistic values and obvious outliers from the analysis, we will set ranges for some variables. Values beyond set ranges will be considered improbable and will not be used in the analysis.

Preliminary data analyses. The first phase of analysis will use descriptive statistics to examine frequencies of categorical patient, treatment, and outcome measures, and average, median, quartiles, and amount of variation (standard deviation and range) for continuous measures. We will conduct bivariate analyses to test the relationship between each candidate predictor (including IRF vs. SNF) and other predictors and outcomes. For discrete variables, we will create contingency tables and will use chi-squared tests, Fisher's Exact tests, or Wilcoxon tests or Kendall's tau (for ordered categories) to determine significance of bivariate associations. We will also use categorical analysis of variance to determine the proportion of variation in outcome explained by each predictor including setting of care (IRF vs. SNF). For continuous variables with normal distributions, Pearson correlation, 2-sample t-tests, or analysis of variance will be used. For continuous variables with non-normal distributions, non-parametric tests will be used including Spearman correlation, Wilcoxon rank sum tests, or Kruskal-Wallis tests. A two-sided p value <0.05 will be considered statistically significant.

Analyses related to study questions. It is assumed in some quarters that joint replacement patients in IRFs and SNFs are similar. Using appropriate bivariate analyses, we will compare the patients in both settings in terms of age, gender, time from surgery to rehabilitation admission, functional status and severity at admission, and a host of other demographic and clinical variables identified by the Clinical Practice Team (**Question 1**). Averages and percentages may mask important differences, so we will examine whether certain subsets of patients cluster in one setting versus another. Understanding these patient differences are important in developing the regression models to determine the independent effects of facility type on outcomes.

A concern for study investigators is that referral patterns to IRFs and SNFs may be changing because of the gradual enforcement of the 75% rule and the use of medical necessity criteria by fiscal intermediaries. This may make the patient populations in both settings more different than before. Fortunately, multivariate analyses using detailed data about patient characteristics as outlined earlier will enable us to sort out the specific contribution of patient differences to the study's primary outcomes.

There are many ways in which to characterize the interventions and processes of care in IRFs and SNFs (**Question 2**). We make a distinction between the *activities* (e.g., gait) that a patient participates in and the *interventions* used (e.g., parallel bars). We can examine the timing, frequency, intensity, and duration of various activities and interventions. We can also examine by 3- and 6-hour blocks of treatment time or any other meaningful block of time. How we ultimately characterize the differences in IRF and SNF processes of care will depend, in large part, on the frequency distributions, observed patterns of care, and the advice of the Clinical Practice Team. Again, appropriate bivariate analyses will be used here.

We will use both bivariate and multivariate analyses to answer the study's remaining research questions (**Questions 3-4, 6-7**). In examining outcomes, we will perform hierarchical and least squares regression for continuous outcomes of FIM scores and severity of illness, and logistic regression for dichotomous outcomes created from information on complications and discharge location. These two types of regression analyses will be performed on the SNF patients alone, on the IRF patients alone, and on the dataset combined. The analyses will be used to identify patient, and treatment variables that are associated with better rehabilitation outcomes in each setting. In these regressions we will include patient characteristics, such as severity of illness, age, gender, race, type and number of joints replaced, the setting of care, and individual treatments and combinations of treatments. In all multivariate analyses, a p-value of $<0.05/m$ (Bonferroni correction: m is the number of independent variables in the model) will be considered to be significant. Two-way interactions can be included and tested along with non-linear variables suggested by the Project Team and Clinical Practice Team.

Using suggestions from the multi-disciplinary Clinical Practice Team, potential predictors will be allowed to enter the models. Those that are not statistically significant will be deleted sequentially from the full model. Excluded variables can be reintroduced at various stages of model development as decided by the Project Team but final models will include only statistically significant variables. Two-way and higher order interactions can be included and tested along with non-linear transformations of variables suggested by the Project Team. Regression analyses will allow us to examine the extent to which various process/treatment steps

and facility variables are associated with outcomes, controlling for severity of illness and other patient factors.

Analyses within subgroups of patients can clarify associations found in regression analyses using larger samples of patients. For example, one might perform analyses with patients receiving hip joint replacement to control for differences from patients with new knee joints. A sample of 300 or more patients will allow up to 30 predictors in models without being over specified. Using a 10:1, cases-to-variables, ratio helps to avoid spurious correlations/ associations. Because we have so many variables to use as possible predictors, variables will be grouped (e.g., patient variables as a group) and significant variables from each group will be included in the final models**.**

When we perform patient-level regression analyses, we first will allow patient characteristics to enter in order to determine the amount of variation in outcomes due to differences in patients. Next, we will add treatment variables to determine the amount of variation in outcomes due to differences in treatments delivered while controlling for patient differences. In the next step, we will add interaction variables. Only later will we include facility variables, because if facility variables are significant, they do not tell us what to do to improve care. We cannot send all patients to one facility. CPI analyses first examine variation due to patient and treatment factors and their interactions, which give information about what treatments are better and for whom. After including patient and treatment variables, we will include facility variables to determine if there is any additional variation explained by facility variables that has not been captured already with the significant patient and treatment variables included in the models. We will then repeat the regression analyses using hierarchical models to determine if we find significant "among-site" components of variance and if we lose any significant patient or treatment variables in the hierarchical models.

Hierarchical analyses address the fact that patients are treated in 20 facilities, which may affect the independence of observations. We will include facility descriptive variables or facility dummy variables in the regressions. Site effects, which could be influential as determined by hierarchical models, may already be accounted for in the detailed patient and treatment predictors. Researchers rightfully worry that patient observations may be correlated within a setting or that treatments may be correlated within a setting; independence of observations is the basic issue. We will perform hierarchical analyses to be sure that the significant variables remain significant and in the same direction for both ordinary and hierarchical regression.[33]

A CPI study collects detailed data on all factors that may influence outcomes for a specific group of patients. We attempt to capture variables at the patient level that may differ across sites. As a result, in our work to date, we have collected very detailed patient-level data about severity of illness, levels of impairment, and many other patient factors; we have collected details about all interventions including those used at every therapy session performed by each type of therapist, all medications, all nutrition support, etc., and all recorded by time and date. Hence, any differences in patients and treatments among the participating sites are likely to be captured in the detailed patient and intervention data used in our study analyses. Using this level of detail helps to make observations within facilities less correlated in regression analyses.

Past analyses of CPI databases have routinely included both hierarchical and non-hierarchical multivariate analyses to predict outcomes, but we have never found differences in the significant factors identified by the two approaches. The absence of a difference may be due

to the detailed manner in which CPI data account for patient differences, including physiologic severity of illness information, and treatment differences at the level of detail of each treatment performed, with both time and date recorded.

Regression coefficients and odds ratios on the independent variables will be used to quantify the magnitudes and directions of effects of each predictor variable on outcomes. Before we start this analysis, we will use pairwise correlations to explore associations between our independent variables (colinearity), and will delete one of each pair of highly correlated independent variables ($r > 0.75$).

For logistic regressions, we will assess discrimination by using the area under the receiver operator characteristic curve (c) to evaluate how well the model distinguishes patients who did not achieve a specified outcome from patients who did achieve the specified outcome. Values of c that are closer to 1 indicate better discrimination.[34] In addition, the Hosmer-Lemeshow goodness-of-fit test will be used to evaluate the degree of correspondence between patients' estimated probabilities of developing the specified outcome and the actual development of the specified outcome over groups spanning the entire range of probabilities (calibration). Hosmer-Lemeshow p values that are closer to 1 indicate better fit. R^2 will be used to evaluate proportion of variation in continuous outcomes that is explained by the model. R^2 values closer to 1 indicate better models.

Artifactual relationships are always possible in regression analyses. However, in CPI methodology, analyses are not performed by including all possible variables and seeing what is significant. Instead, analyses are led by the Project Team working with the multi-disciplinary Clinical Practice Team using theory, research evidence to date, existing guidelines, and real-world clinical experience. Although the majority of findings are not surprising, some significant findings may be surprising; they lead to more detailed analyses. We then perform various types of sensitivity analyses by including additional possible confounders, examining subsets of variables and patients with specific characteristics, and looking at multiple different slices of the data in order to determine if the surprising findings persist. After we exhaust all suggestions from clinicians as to what might explain the surprising associations, and if the findings persist, then we feel more confident that the relationship is not an artifact. Of course, we will find significant patient characteristics or interventions only if some patients have them. And clinicians who use the surprising significant interventions can speak to their effectiveness from personal experience.

In the CPI methodology not all possible associations can be articulated at the onset. The CPI process depends on the ability to define identified outcome measures and control for possible covariates (patient factors) in order to identify best treatments. While the investigation is governed by the proposed study's broad hypotheses, CPI is also a discovery process based on post-hoc analyses suggested by clinical professionals with fundamental knowledge of patient and treatment issues. Data collection questions and analyses will be processed regularly with the Project Team. All analyses are discussed until the Project Team is satisfied that study questions have been addressed fully and findings are based on the most valid interpretation of the data. CPI is an innovative approach to understanding the impact of specific rehabilitation interventions and site of care on joint replacement outcomes. CPI uses both existing research findings and practicing clinicians' expertise to define the elements and analyze the data to capture the complexity of the rehabilitation process. Preliminary findings from the Stroke

Rehabilitation study show quite clearly that CPI methodology can succeed in opening the black box of rehabilitation to scientific inquiry.

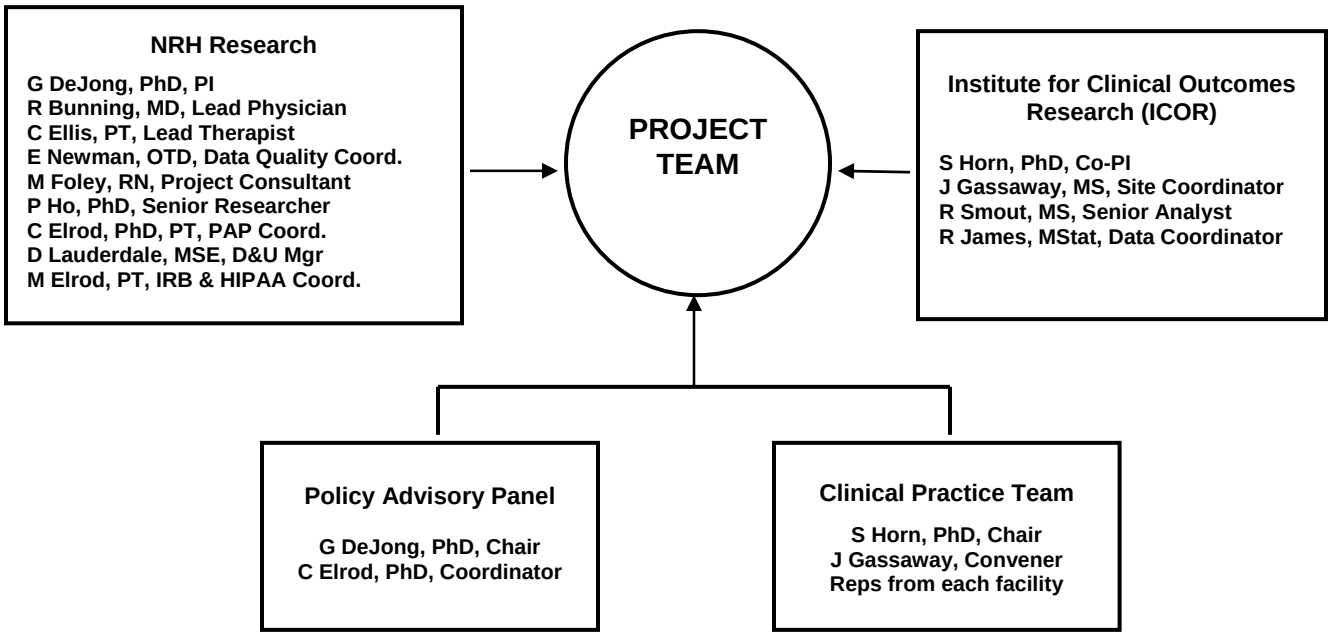
PROJECT ORGANIZATION

The proposed study is a multidisciplinary collaboration between (1) two research organizations, i.e., **NRH Research** in Washington, DC and **ICOR** in Salt Lake City, UT **(**the **Project Team**); (2) the **Clinical Practice Team** comprised of clinicians from each of the participating facilities; and (3) the **Policy Advisory Panel**. NRH Research is the lead organization for this study. The relationship between these entities is depicted in Figure 1.

Project Team

The intellectual leadership for the project will come from the Project Team members listed in Figure 1. This project essentially carries forward the same core project team (DeJong, Horn, and Gassaway) that developed and executed the original Post-Stroke Rehabilitation Outcomes Project referenced elsewhere in this document—with the addition of several other members identified above. The Project Team's membership will fluctuate with the analytical and logistical needs of the study as it progresses through its 3 phases.

Figure 1—Collaborating Organizations & Principals



In addition to its intellectual leadership role, The NRH team will provide overall administrative leadership for the project, e.g., institutional review board (IRB) clearances, HIPPA clearances, subcontract arrangements with ICOR, organizing the meetings of the Policy Advisory Panel, arranging travel for meetings, submission of progress reports. NRH Research Division is fully equipped to facilitate this administrative role. The ICOR team of Horn, Gassaway, Smout, and James will provide overall management of project data including data collection, cleaning, editing, and the creation of specific data files needed for the proposed data analyses. ICOR will initiate a subcontract with each participating facility. In her role as study

site coordinator, Ms. Gassaway will work closely with the Clinical Practice Team representing clinicians at the participating IRF and SNF sites from which the study data come.

The Project Team will meet as needed to prioritize project tasks, monitor project progress, identify issues for the Policy Advisory Panel and Clinical Practice Team, follow up on Policy Advisory Panel and Clinical Practice Team recommendations, and prioritize data analyses in keeping with the study's research questions and post-hoc hypotheses. During the data analysis phase of the study, the Project Team will identify ways in which the data might be partitioned, identify the variables to be included in the analyzes, address any residual missing data issues, address confounding variables, identify data issues to be addressed in the teleconference meetings with the Clinical Practice Team, and prepare policy and practice implications for consideration by the Policy Advisory Panel. Also, the Project Team will take the lead in writing the manuscripts for presentation and publication, preparing successive iterations of each manuscript, and invite members of the Clinical Practice Team to participate actively in manuscript preparation.

Clinical Practice Team

The Clinical Practice Team consists of representatives from each of the participating IRFs and SNFs. The team consists of clinicians directly involved in the provision of rehabilitation services for patients with joint replacement. Each facility will designate a lead clinician who will serve as the local site director for the study (e.g., the lead physician, unit manager, or case manager responsible for orthopedic rehabilitation) and will organize a local multidisciplinary team to implement the study at the site. The Clinical Practice Team will have one **2-day face-to-face meeting** at the beginning of the study. The purpose of the meeting is to provide an orientation to study research questions and methods; review data collection instruments, protocols, and quality control measures; and lay out the expectations for each site.

Thereafter, the Clinical Practice Team will **meet weekly by teleconference** until data collection is completed and data are analyzed initially. Toward the end of the data collection period, elements of the Clinical Practice Team will assemble for a second **2-day face-to-face meeting** to review initial findings and chart future analyses. Thereafter, it will **meet bi-weekly** until the study is completed. We have used this approach in previous CPI studies and have found that regular meetings remain essential to building a sense of ownership and camaraderie, complying with study protocols, and interpreting study findings. CPI is very much a bottom-up approach in which front-line clinicians are seen as the experts in providing guidance for the study. The Clinical Practice Team has proven essential to achieving local buy-in and commitment.

Given the number of sites involved and in the interest of facilitating communication across sites, NRH Research will **establish a listserv** and/or **website** that will provide an electronic forum for sharing study news, for disseminating Clinical Practice Team decisions, and for reporting overall study progress. The listserv will also allow interactions among clinicians from different sites, and provide a forum for asking technical questions and sharing creative solutions. This will not be a substitute for the Clinical Practice Team where the key decisions about study protocols and data collection will be made. Nor will the website or listserv be a substitute for other project communications with local sites. Instead, the listserv and website provide additional forums for participating clinicians to raise questions and obtain answers. Recurring questions will be consolidated into a list of FAQs—frequently asked questions, along

with their answers, that will be posted on the website. Because not all sites and clinicians necessarily have routine access to the Internet, these supplementary electronic communications vehicles cannot be considered a substitute for other communications with local sites.

We will also make a portion of the website accessible to outside groups and stakeholders who want to know more about the study. Items to be considered for outside consumption include an executive summary of the research plan, a list of Policy Advisory Panel members, Panel recommendations, study publications, and key study findings as they become available.

Policy Advisory Panel

To facilitate acceptance of study findings within the larger health policy community that shape rehabilitation payment and practice, we will create a policy advisory panel consisting of health policy and rehabilitation stakeholders. Table 2 lists the organizations and types of experts that we believe have important contributions to make to the project and will be invited to participate. NRH Research will recruit members to serve on the Policy Advisory Panel and will work with study sponsors, trade associations, and other networks in the recruitment process.

Table 2
Policy Advisory Panel

Organization
• Centers for Medicare & Medicaid Services (CMS)
• Medicare Payment Advisory Commission (MedPAC)
• National Center for Medical Rehabilitation Research (NCMRR)
• National Institute for Disability & Rehabilitation Research (NIDRR)
• Agency for Health Care Research & Quality (AHRQ)
• American Medical Rehabilitation Providers Association (AMRPA)
• American Hospital Association
• Association of Rehabilitation Nurses
• Federation of American Hospitals (FAH)
• One or more consumer organizations, e.g., Arthritis Foundation
• American Health Care Association (AHCA)
• American Association of Homes and Services for the Aging (AAHSA)
• American Occupational Therapy Association
• American Physical Therapy Association (APTA)
• CARF
• JCAHO
• Am Academy of Physical Medicine & Rehabilitation (AAPM&R)
• American Congress of Rehabilitation Medicine (ACRM)

• Private payer or health plan
• Uniform Data System
• Orthopedic physician group
• Academic or independent health policy person

The Policy Advisory Panel will have two in-person meetings—at the outset of the study and after the initial data analyses are completed in Month 16. At the outset of the study, the Project Team will orient the Panel regarding the purpose and scope of the project and invite comments about the overall direction and methods used. These comments will be reviewed by the Project Team with the Clinical Practice Team and communicate back to the Policy Advisory Panel. The Project Team will also identify changes in the policy environment that may affect study design and seek Policy Advisory Panel members how best to address these changes.

At the conclusion of the initial data analyses, the Project Team will share study findings with the Policy Advisory Panel. The Policy Advisory Panel will identify implications of the findings for policy, practice, and further research where needed.

It may also be necessary to convene the Policy Advisory Panel one or more times by teleconference in the interval between its first and second in-person meetings. We anticipate that there will be some vexing issues with major policy implications for which the Project Team will need the Policy Advisory Panel's advice. For example, not all rehabilitation outcomes are equal and the relative effectiveness of one setting of care versus another may vary with the outcomes under consideration. The Project Team may need to obtain the Panel's views about how to rank these outcomes. Project Team may need to obtain the Panel's views in planning the study's Phase 4 cost-effectiveness analyses given the different approaches that can be taken.

Timeline (See Figure 2)

Figure 2—Timeline for Joint Replacement Rehabilitation Study

Project Task	Month																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Phase 1: Ramp-up (4 months)																								
Recruit IRFs and SNFs																								
Develop & execute individual facility agreements																								
Revise point-of-care data collection instruments																								
Submit study protocols for IRB & HIPPA approvals																								
Design ADM																								
Organize Clinical Practice Team (CPT)																								
Conduct 1st in-person CPT mtg																								
Pilot test point-of-care data collection instruments																								
Designate local site data collection manager																								
Conduct 1-day training mtg of lead clinicians																								
Conduct 4-day training session for chart reviewers																								
Develop/implement listserv and project website																								
Recruit & assemble Policy Advisory Panel																								
Conduct in-person Policy Advisory Panel mtg																								
Phase 2: Data Collection (12 months)																								
Collect inpatient data																								
Conduct weekly teleconference mtgs with CPT																								
Enter, clean, & edit inpatient data																								
Assemble descriptive statistics & freq. distributions																								
Conduct case-mix adjusted bivariate analyses																								

Conduct case-mix adjusted multivariate analyses																									
Assemble & present initial study findings[§§§]																									
Conduct 2nd in-person CPT mtg																									
Phase 3: Analysis (10 months)[****]																									
Continue with bivariate & multivariate analyses																									
Conduct biweekly CPT teleconference mtgs																									
Prepare manuscripts for presentation & publication																									
Prepare cost-effectiveness study plan																									
Present to professional meetings																									
Revise & resubmit manuscripts for publication																									

[§§§] Key time point.
[****] Overlaps with Phase 2

KEY STAFF

From NRH Research:

Gerben DeJong, PhD (PI) is a senior fellow with the NRH Research Division and is awaiting reappointment as a professor in the Department of Rehabilitation Medicine at Georgetown University's School of Medicine where he previously held an appointment in the Department of Family Medicine for 14 years. He rejoined NRH in late 2004 after a 2-year stint with the University of Florida. Dr. DeJong previously served for 16 years (1985-2001) as NRH's first Director of Research and as the Founding Director of the NRH Center for Health & Disability Research. During his tenure with NRH, Dr. DeJong also served as the Co-director of the NIDRR-funded Rehabilitation Research & Training Center (RRTC) on Managed Care & Disability (1997-2002) and as the Director of the RRTC on Medical Rehabilitation & Health Policy (1993-97). Dr. DeJong is the author or co-author on more than 200 papers. He served as a Co-PI with Susan Horn, PhD on the very successful and large multi-site Post-stroke Rehabilitation Outcome Project (PSROP) that in many ways serves as a precedent for the current study.

As PI, Dr. DeJong will provide overall leadership for the study, participate in the analyses of study data, meet with the Clinical Practice Team, work with the Policy Advisory Panel, supervise the project's administrative tasks (e.g., IRB process), contribute to the production of manuscripts and in other project materials, monitor study progress, and serve as the interface with the sponsoring organization, HealthSouth.

Robert Bunning, MD (Lead Physician) is board certified in Internal Medicine and Rheumatology. He has been the Arthritis Rehabilitation Program Director and the Orthopedics Program Director at NRH for 20 years. He is a Fellow of the American College of Rheumatology and the American College of Physicians. He is the former president of the DC Rheumatism Society and served three years on the executive committee of the American College of Rheumatology section on Rehabilitation. He was appointed Associate Medical Director of National Rehabilitation hospital in September of 2004.

As the study's lead physician, Dr. Bunning, will assist in the design of the physician point-of-service documentation. He will identify the pertinent issues to be addressed and help to answer questions that may arise from other physicians participating in the study. Dr. Bunning will bring his expertise in arthritis, joint replacement, and rehabilitation. He will participate in meetings of the Clinical Practice Team and the Policy Advisory Panel. He will participate in the analyses of study data and contribute to the study's reports and publications.

Cathy Ellis, PT (Lead Therapist) is the Clinical Director of NRH's Musculoskeletal Program and is NRH's director of physical therapy, occupational therapy, vocational rehabilitation, therapeutic recreation and clinical rehabilitation engineering at the NRH. She has practiced at the NRH since 1985. Over the last several years she has served as APTA's member representative to the Medicare Negotiated Rule Hearing on Payment for Prosthetics and Certain Custom Fabricated Orthotics. She currently serves on the CARF Board of Trustees.

Ms. Ellis will contribute her first-hand knowledge about the clinical management of joint replacement patients. She will work with Dr. Newman and others in revising the point-of-care documentation forms, participate in the training sessions aimed at lead therapists from other

sites, and participate in the deliberations of the Clinical Practice Team in refining patient selection criteria, propose solutions to vexing data collection challenges, and in analyzing study findings.

Elizabeth Newman, OTD, OTR/L (Data Quality Coordinator and **Research Therapist),** is currently the Occupational Therapy Rehabilitation Manager for Inpatient Rehabilitation programs at the National Rehabilitation Hospital. Dr. Newman provides overall leadership for the OT Service at NRH and within the larger NRH system. She is responsible for daily operations of the OT service as well as coordination of OT staffing and practice at NRH. She also coordinates NRH FIM data collection and is intimately familiar with functional assessment issues. Dr. Newman has over 20 years of experience in post-acute rehabilitation. She recently completed her doctorate in occupational therapy from Rocky Mountain University of Health Professions in May 2005. She has a MS in OT from Thomas Jefferson University. She serves on the AOTA Annual Conference Planning Committee.

Dr. Newman will serve as NRH's lead OT for the study and serve as the study's data quality coordinator. She will also work with the Clinical Practice Team in addressing patient selection issues and revising the stroke point-of-care documentation instruments for use in this study. Dr. Newman will work with Ms. Gassaway (the study's site coordinator) and Ms. James (the study's data coordinator), in developing training materials and in conducting the training session of lead clinicians from all the study sites to be held at NRH. As the study's data quality coordinator, Dr. Newman will work closely with both Ms. Gassaway and Ms. James in answering questions from clinicians at participating sites, making sure that data are collected consistently across sites, and in identifying non-probable values. She will work with the ICOR team in developing auditing protocols needed to assure consistent reporting of intervention and functional assessment data. As a research therapist, Dr. Newman will also participate in the analyses of study data and preparation of reports and papers for publication and dissemination.

Mary Foley, RN (Project Consultant) is the Assistant Vice President of Care Management at NRH. Ms. Foley is a certified rehabilitation nurse with over 20 years experience in rehabilitation. Ms. Foley came to NRH as a liaison nurse evaluator assessing patients for admission to rehabilitation. Since the late 80's, she has also served as NRH's Director of Admissions overseeing the clinical and financial clearance of patients for admission. Ms. Foley is also responsible for physician relations management and utilization review. Over the last few years, she has also work with industry leaders in addressing PPS rules and the 75% rule.

Ms. Foley will bring her expertise in rehabilitation nursing, rehabilitation care management, and post-acute payment systems. She will bring her knowledge of joint replacement patient referrals to post-acute care, industry practice patterns, the role of fiscal intermediaries in shaping post-acute placement decisions, and industry data systems (e.g., IRF-PAI, SNF-MDS). Ms. Foley's knowledge of industry- and patient-level practice patterns will provide a real-world perspective to the study's research design, data collection processes, and data analyses. She will participate in the deliberations of the Clinical Practice Team and the Policy Advisory Panel as needed.

Pei-shu Ho, PhD (Senior Researcher) is a health services researcher with interests in health access and outcomes for vulnerable populations, particularly the elderly and adults with

physical disabilities. She has extensive experience in working with large research databases. Her recent work includes examining the impact of exercise/physical activity on secondary conditions among adults with spinal cord injury, the risks of falls among adults with functional limitations, and the evaluation of care quality of a managed care plan of adults with physical disabilities. Dr. Ho has been involved in health systems outcome measurement and is familiar with post-acute outcome measures.

Dr. Ho will be responsible for helping to determine the generalizability of study findings by comparing the study sample to other known national data sets, e.g., IRF-PAI, MDS, eRehab, and comparing the facility sample to other known national databases such as OSCAR. She will assist in the design of the Phase 4 cost-effectiveness analyses, participate in the analyses of study data and interpretation of study findings, and participate in the preparation of study reports and publications.

Cathy Elrod, PhD, PT (Policy Advisory Panel Coordinator) is a physical therapist and health policy analyst. She received her MS in Physical Therapy from the Medical College of Virginia in 1993 and worked as a physical therapist at the Medical University of South Carolina (1993-1997). In 1999, she joined Marymount University's Department of Physical Therapy where she served as an assistant professor while pursuing her doctoral studies in public policy at George Mason University's School of Public Policy. She completed her PhD in 2005. She remains active in the Virginia chapter of APTA. Dr. Elrod will assist Dr. DeJong in the recruitment of Policy Advisory Panel members, organizing the Panel's meetings, and summarizing Panel recommendations.

Donal Lauderdale, MSE (D&U Manager) is Research Information D&U Manager at NRH where she has played a central role in defining knowledge translation as a discrete program function at NRH. She has over 20 years experience in health information systems and management and most recently served as program manager for the NIDRR-sponsored RERC on Telerehabilitation and the DoD-funded Assistive Technology Research Center.

Ms. Lauderdale will organize the study's listserv, work with the project coordinator in recruiting facilities to participate in the study, facilitate the dissemination of study findings and recommendations through newsletters, consumer outlets, and other media. In this latter capacity, she will also work with the communication resources of HealthSouth and those of the stakeholder organizations represented in the study.

Mathew Elrod, PT, Med, NCS (IRB & HIPAA Compliance Coordinator), is a physical therapist and Programs Coordinator for the NRH Research Division. Mr. Elrod has work in multiple health care settings—acute care hospitals, a rehabilitation hospital, and an outpatient clinic. He came to NRH in1997. Mr. Elrod coordinates clinical research activities and serves as NRH's principal liaison with MedStar's Institutional Review Board (IRB). He is currently active the APTA and serves as the Chapter president for the District of Columbia.

One of the major challenges at the outset of the study will be the need to obtain the necessary IRB and HIPAA approvals related to the protection of human subjects and information privacy involving as many as 20 sites. Mr. Elrod will spearhead this process as he does for other NRH research studies. He will coordinate with the MedStar IRB any other IRBs that may govern the participation of local sites. Mr. Elrod will identify the information and compliance

requirements of individual sites and identify the most efficient process by which approvals and compliance can be achieved across all sites. His participation will be particularly intense during the study's Phase 1 ramp-up period and then again on the 1-year and 2-year anniversaries of the initial approvals when IRBs normally require a study progress report—even after data are collected and data analyses continue. He will also coordinate the close-out report that must be submitted to IRBs.

From ICOR:

Susan D. Horn, PhD (Co-PI) is Senior Scientist with ICOR and Vice President for research for International Severity Information Systems, Inc. (ISIS), Adjunct Professor in the Department of Medical Informatics at the University of Utah School of Medicine in Salt Lake City, and Visiting Professor, School of Nursing, Vanderbilt University in Nashville, TN. Dr. Horn was a faculty member at The Johns Hopkins University in Baltimore for 24 years where she conducted research, taught biostatistics and health services research courses, and directed the RWJF Program for Faculty Fellowships in Health Care Finance. Work begun in 1979 on issues of illness severity formed the basis for the CSI proposed for this study. Dr. Horn has conducted numerous CPI and cost-containment studies. She has authored over 140 publications on statistical methods, health services research, severity-of-illness measurement, CPI, and quality of care. Dr. Horn was PI for the NIDRR-funded PSROP. As Co-PI, Dr. Horn will head the ICOR team, chair meetings of the Clinical Practice Team and work closely with Dr. DeJong in all phases of the project including data analyses, meetings of the Policy Advisory Panel, and dissemination of findings.

Randall J. Smout, MS (Senior Analyst) is a senior analyst at ISIS/ICOR. For the past 6 years, he has been involved in 10 or more CPI studies ranging from abdominal surgery to bone marrow transplantation, and most recently, stroke rehabilitation. He is an expert SAS programmer. Mr. Smout will be the project's principal data analyst. Mr. Smout is a suburb research database manager who is capable or organizing several large research databases concurrently. He is able to present alternative approaches to the analyses of data to clinicians and investigators in helping to structure future analyses and findings. He was also a major contributor to the PSROP and the many manuscripts that resulted from it.

Julie Gassaway, MS, RN (Site Coordinator), is the Director of Projects and Product Development at ISIS/ICOR and has served as the project coordinator or site coordinator for the several large CPI studies including the PSROP. She will convene the Clinical Practice Team and organize its weekly conference calls, and summarize its findings and decisions as the study progresses. In previous CPI studies, Ms. Gassaway has been especially instrumental in developing strong working relationship with clinical representatives at participating study sites. Ms. Gassaway has been involved in severity measurement and CPI studies for over 15 years.

Organizational Capabilities

The lead organization for the proposed study is the **National Rehabilitation Hospital** (**NRH**) **Research Division**. The NRH Research Division serves both as the research arm of the National Rehabilitation Hospital and the rehabilitation research arm of the **MedStar Research Institute** (**MRI**). NRH is one of 7 hospitals in **MedStar Health**, a not-for-profit, community-

oriented health care system located in the larger Baltimore-Washington. MRI serves as the lead research organization for the larger MedStar Health system and works closely with the research programs associated with all MedStar subsidiary hospitals and facilities such as NRH.

National Rehabilitation Hospital (NRH)

NRH is a private, not-for-profit facility with 128 licensed beds located in Northwest Washington, DC. NRH's rehabilitation services are designed to meet the needs of individuals with disabling injuries and illnesses such as stroke, head and spinal cord injuries, arthritis, amputations, joint replacements, post-polio syndrome, multiple sclerosis, chronic pain, back and neck pain, occupational injuries, cardiac disease, and other neurological and orthopedic conditions. NRH is listed in *U.S. News & World Report* as one of the nation's top 15 hospitals for medical rehabilitation. NRH also operates all of MedStar Health's rehabilitation programs at 7 hospitals and 34 outpatient rehabilitation clinics. NRH and its larger network of affiliated programs serve as a significant resource for the recruitment of participants for NRH clinical trials and research studies conducted by the NRH Research Division.

The **NRH Research Division** conducts clinical and health services research designed to enhance human performance, promote independence, maintain health, and lead in the creation of evidence-based rehabilitation practice and health policy. Established in 1986, the NRH Research Division is largely funded with grants from NIH, NIDRR, DOD, AHRQ, CDC, foundations, state government, and private sources. The NRH Research Division has close ties with Georgetown University, particularly the Departments of Rehabilitation Medicine and Neurology. Senior NRH researchers have their academic appointments at Georgetown University.

The NRH Research Division's administrative core provides logistical and grant/contract management support. The administrative core works closely with the grants management, financial, and human resource staffs of both NRH and the MedStar Research Institute (MRI). The Division's D&U core provides novel ways to assist investigators in disseminating research findings and translating those findings into practice and policy. A significant part of the coordination of the proposed project occurs at-a-distance via teleconference. NRH is well-prepared to provide support in this area with through its new, 500-square-foot conference center that allows multi-media consultation using a full array of broadband wired and wireless technologies.

The **MedStar Research Institute (MRI)** is the research arm of the larger MedStar Health system. MRI provides administrative support for 600 projects across the MedStar system. Its facilities include an 8,000-volume library, 600 journals, a statistical analysis and computing center, research poster design and production, financial administration, and a fully-accredited IRB. MRI also arranges for volume purchasing of software licenses, subscriptions (including over 100 full-text online medical journals), on-site employee training, and office equipment leasing.

MRI operates a fully accredited Institutional Review Board (IRB). It has a Federal-Wide Assurance from the Office for Human Research Protections (OHRP). All research conducted within MedStar Health requires prior approval by the IRB before research activities can be

initiated. The MRI IRB also requires that each researcher attend an annual training session that covers the federal regulations of conducting human subjects research.[††††]

Institute for Clinical Outcome Research (ICOR)

The Institute for Clinical Outcomes Research (ICOR) is a division of International Severity Information Systems (ISIS) located in Salt Lake City, UT and Annapolis, MD. ISIS/ICOR is located in modern wheelchair-accessible office space that includes the full array of IS technologies and software expected of a contemporary research enterprise.

ICOR has completed over 20 large CPI studies during the past 10 years and has more than 25 years experience in developing severity-of-illness instruments. ICOR has conducted studies on IRF stroke rehabilitation (N = 1,400), long-term care pressure ulcers (N = 2,490), CABG surgery (N = 2,300), pediatric asthma and bronchiolitis (N = 2,000), caesarean section (N = 1,800 deliveries), hospice care (N = 1,800), ICU care (N=16,000), pediatric severity-of-illness (N = 18,000) patients, managed care outcomes (N = 13,000 patients). These studies were funded by government agencies, foundations, health care organizations, and pharmaceutical groups. In all of these projects, ICOR performed the tasks described in this proposal by partnering with other researchers and health care organizations. ICOR staff have skills in nursing, medicine, study design, data collection software design, medical informatics, data processing, statistics, analysis, and project administration. CPI studies are only possible when these skills are linked with the clinical knowledge and skills of collaborating organizations.

HUMAN SUBJECTS

This study is an observational cohort study of existing practice in order to identify differences in practice and how these differences, controlling for patient covariates, are associated with patient outcomes in two post-acute settings of care—skilled nursing facilities (SNFs) and inpatient rehabilitation facilities (IRFs). The study does not introduce or test a new intervention nor does it attempt to change any existing practice over the course of the study.

The study draws on the patient medical record and supplements medical record data with point-of-care data completed by the treating clinician to ascertain the actual character of care provided in terms of frequency, timing, intensity, and duration.

The only risk to the patient is the possible breach of confidential or protected health information (PHI). To guard against such a breach, personal identifiers will remain with the participating facilities and patient-level data to be included in the study's database will be stripped of personal identifiers. Each patient will be assigned a consecutive study identification (ID) number preceded by a code for the post-acute facility to which the patient was admitted. The on-site data manager will keep a log of patients, their study ID and medical record number.

[††††] In addition to its grants management functions, MRI also has its own portfolio of research studies and on-staff investigators. MRI has nationally recognized researchers in many clinical specialties dedicated to the advancement of knowledge through research for clinical application and health planning. MRI has earned a national reputation of research excellence through leadership roles in NIH projects such as the Women's Health Initiative, Diabetes Prevention Program, Strong Heart Study, WAVE trial, National Cancer Institute trials, and Genetics of Non-Insulin Dependent Diabetes (GENNID).

This log will not leave the facility and only the data manager or site director will be able to retrospectively relink the study ID with a particular patient.

No patient can be identified in the study database. Only the study ID will be known. All study data will be stored in a password-protected database located in a locked project office.

The treating facility will not be identified in the data analysis except by code and will not be identified in any publications that result from the study.

Risk/benefit

Again, the only risk of the project to human subjects is the accidental or unauthorized disclosure by the Project Team. The likelihood of such disclosure of this patient information is extremely low. If this information were accidentally disclosed, the seriousness of risk would be minimal because these data will not include personal identifiers that would allow an unauthorized individual to link these data to an individual patient by name unless they had access to the key that matched study ID number to individual patient record at a local site. This key will be maintained by the local site and, again, all patient identifiers are located only at the local study site.

The benefits of the study will accrue to future patients, not to study patients. Future benefit will accrue when best practices that are uncovered in this study are incorporated into actual policy and practice. Benefits to future patients include more appropriate post-acute placement, fewer medical complications, higher functional outcome at discharge, and greater independence in family and community life. The project will enhance the ability of policy makers and clinicians to make better post-acute rehabilitation placements and treatment pathways.

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