

Potential Follow-up Component For JOINTS Study

At present, the JOINTS study is limited to outcomes achieved at discharge from a SNF or an IRF. The Study Team has considered, at some length, the merits of adding a potential follow-up component to examine post-discharge outcomes such as functional status, rehospitalizations, living arrangement, and social participation. Such outcomes could be evaluated at any pre-determined interval such as 3, 6, or more months following a joint replacement.

There is a keen interest within the Study Team to examine longer term outcomes in order to provide a more complete picture of the impact that SNF and IRF care may have on the lives patients with joint replacements. The study team has held back for three main reasons:

1. **Funding.** A follow-up component would add to study costs that is not budgeted.
2. **Informed consent and IRB issues.** A follow-up component may require additional informed consent from patients and delay the start of initial data collection. This could add to the refusal rate and raise selection issues due to non-respondents and individuals lost to follow-up.
3. **Timeliness.** Having to recruit patients individually to having explain the follow-up protocol would be time-consuming, add to local facility burden, and be expensive when staff time is factored in. Moreover, the study would automatically add another 3, 6, or more months to the study timeline when there is a keen interest in keeping the study on a very fast track.

We believe that there may be a way to overcome Item 2, the informed consent and IRB challenges, especially if participating facilities were to contract with a company or organization that already collects follow-up functional status and patient satisfaction data. Some facilities obtain blanket consents from patients upon admission for quality assurance purposes. The study team could request the survey organization to add questions specific to the study not already asked. To use such data, investigators would have to link data gather during the inpatient stay with follow-up data. Such linking would require use of personal identifiers although it would be possible for a local facility to do such linking without disclosing the identifiers to study investigators.

The study team has three questions for the Policy Advisory Panel:

1. How essential or important is a follow-up component to a study on joint replacement rehabilitation to study stakeholders?
2. Are there creative ways in which to address the informed consent and IRB issues that might otherwise arise and still remain very much in the spirit of existing privacy regulations?
3. If important, how could a follow-up component be supported financially?

