Reviewer's report

Title: Functional Status Decline as a Measure of Adverse Events in Home Health Care: an observational study

Version: Date: 4 October 2006
Reviewer: katherine berg

Reviewer's report:

General
The manuscript is now more coherent and clearer.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1. I am not completely satisfied with the response to the issues of how adverse event measures fit within a framework or how they are expected to relate to quality measures. Would not all measures be calculated at the level of a specific agency? The data used in this study are from a single agency and indeed the largest home health agency. The larger numbers of clients may permit a more stable estimate for this agency. Imagine how unstable an adverse event rate would be for a small agency. It should be clearly stated that the data from a single agency cannot be used to validate a quality measure or adverse event measure. One way of examining validity is to determine whether variation in quality indicator rates is associated with variation in quality of care as defined by external process or outcome criteria. Quality indicator rates should also be stable over time rather than random variation because agencies' current level of performance will be judged by consumers and others based on the most recent past rate. Quality measures and adverse events should be within the control of an agency. It could be argued that smaller adl declines would be more under control of an agency than such large almost "catastrophic" declines as 2 points on 3 adls. Moreover, agencies that keep patients at home to have a subsequent assessment and thus be eligible for the study, may be providing better care than agencies that send patients to hospital or have patients die. This was the reason that I had suggested a multinomial model for these competing risks. More patients were excluded due to a hospitalization or other inpatient facility than were included in the study. It is likely that these patients also had catastrophic declines in adl but they were not included in the modeling exercise. This point should at least be listed as a limitation.

In summary, I would like to see further explanation on the difference between quality measures and adverse events, how they are used to compare agencies and additional validation steps that are needed to demonstrate the validity of the ADL decline adverse event measure. Specifically, the discussion should address the issues of validity at the level of the agency. How stable are the event indicators? do they relate to other quality measures? Is it really a good idea to have adverse event indicators to reflect quality of care or would it be better to have a quality measure in this area that would be appropriately risk adjusted. If they are rare, the events might be quite unstable and at any given point unfairly label an agency. The authors state that their findings may not generalize to other agencies but do not fully explain that this study is only a first step in questioning this adverse event indicator. At the very least, further work is needed on the variation across agencies and the degree to which the variation is related to other criteria for quality of care.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests.