Author's response to reviews

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

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Author's response to reviews: see over
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Dear Iratxe Puebla,

Thank you for the opportunity to make further revisions to our paper titled *Functional Status Decline as a Measure of Adverse Events in Home Health Care: an observational study*. We value the comments that the reviewers have made and believe that we have accommodated all the outstanding issues. We have bolded text in the manuscript for which changes were made. To follow is our reply to the reviewers’ comments.

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.**

While we are thankful for the reviewer’s comments and have attempted to make further clarifications, the use of adverse events as a marker of quality is standard practice in the international literature. Of course, we are not claiming that our results are generalizable as the data come from the largest home health care agency in the US; this has been stated in the limitations. We added additional comment on this issue of stability related to size in the limitations. As a final sentence, we address the larger question raised by the reviewer about variations in quality of care and external processes of validation. More generally we feel that use of declines in functional status are appropriate as previous research has shown declines in functional status to be among the most reliable outcome measures in the OASIS (Madigan and Fortinsky, 2004; Hittle et al.2003; Madigan and Fortinsky, 2000).

2. **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.**

The reviewer makes an interesting comment here, but we are working within the institutional and historical constraints of the Centers for Medicare and Medicaid in the US. We fully agree that the current measure is not optimal, hence our paper. The issue with smaller adl declines is that home health care agencies employ heterogeneous populations and is not uncommon for a variety of professionals/ paraprofessionals to provide care and give assessments. A one-unit decline may be too prone to variability in human judgement and hence, measurement error. We have added more content to this effect under the section titled Dependent variables.

3. **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.**

While we agree a multi-nominal model would have been preferred, it also has to be statistically specified. We did some explorations in this area, but the regression could not be estimated or failed to converge. We also worked with HLM modeling, but this too did not converge. We have added content relevant to this point.
4. 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.

While we see the reviewer’s point here, the link between adverse events and quality is not only common practice (with literally many hundreds of papers in the literature), but it is required by the US federal government. Since quality is a latent construct for which no gold standard exists, quality research by nature, relies on surrogates which are often adverse events. Functional decline is unique since most studies focus on mortality (Aiken et al. 2002; Krumholz et al. 1999; Iezzoni et al. 1996; Normand et al. 1995) or group all adverse events together as one index (Bridges et al. under review; Geraci et al.1993). Mortality or unexpected death may not be appropriate for quality research in home health care as it is too rare an event. Additionally, an index comprised of all 13 possible CMS defined adverse events may not identify the appropriate risk factors as the events are quite varied. The public reporting of the discrete functional status measures does use a risk adjusted approach; we have included additional information on this in the background information specifically to address the reason why the adverse events are not risk adjusted by CMS.

5. If they are rare, the events might be quite unstable and at any given point unfairly label an agency.

The reviewer is correct, and this is common knowledge in the literature and in practice. Stability is demonstrated by the comparable rates over time for all three indices as the study was conducted for the same six-month period, one year apart. This was done to eliminate any potential seasonal bias. As well, in the limitations and final section we identify that the limitation based on the use of one agency requires additional research.

6. 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.

The reviewer makes a good point. Indeed, this is just a beginning look at the complex issue of developing a quality measure. Current national studies rely on the conservative definition of adverse events. Despite being a first step, this is a very important smaller study, without which, larger national studies would be very difficult. Text in the manuscript has been added to emphasize that this study is a first step in questioning these adverse event indicators.

Thank you for your time and consideration,
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