Author’s response to reviews

Title: Emergency Department Visits and Hospitalizations by Tube-Fed Nursing Home Residents with Varying Degrees of Cognitive Impairment: A National Study

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Author’s response to reviews: see over
Dear Dr. Pala and Ms. Olino,

We would like to thank the reviewers for the helpful feedback on our manuscript. Following is a point-by-point response to each of the reviewer’s comments with notation regarding the location of the change in the manuscript and also highlighted text within the manuscript. Please let us know if there are any further questions or concerns.

Thank you again for your time and consideration!

Sincerely,

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Emergency Department Visits and Hospitalizations by Cognitively Impaired Tube-Fed Nursing Home Residents: A National Study
Caroline E. Stephens, Nathan Sackett, Prasanthi Govindarajan and Sei J. Lee

Reviewer #1 Comments:

1. The study sample includes NH residents with an MMSE score of greater than 24 whose cognitive function is normal. Furthermore, some scholars even argue that the cut-off point of MMSE score for a normal cognition could be as low as 18 if the years of schooling of a person is less than 6 years. In these contexts, the title of the paper is somewhat not appropriate in that it only studied the residents whose cognitive function is impaired.

We agree that our title suggested that we focused only on cognitively impaired NH residents. We have modified our title to, “ED visits and hospitalizations by Tube-Fed NH residents with Varying Degrees of Cognitive Impairment: A National Study”. This change has been highlighted on our title page.
2. How many NH residents are using TF? What is the percentage of NH TF residents had unnecessarily ED and hospital visits? These numbers may be informative to readers/reviewers/editors to see how important of this study is.

We agree that the number of NH residents using FT would be informative to readers. Thus, we note that prior studies suggest that as many as 34% of nursing home residents with advanced cognitive impairment have feeding tubes. (Introduction, 2nd paragraph, 3rd sentence) We also added the following statement to the Results section: “In our study, we found 3479 NH residents had feeding tubes, suggesting that nearly 70,000 NH residents in the US were tube-fed in 2006”. (noted: Results, 1st paragraph, 1st sentence).

In addition, we have revised the first paragraph of the discussion to highlight the important point the reviewer makes regarding the percentage of NH TF residents with unnecessary ED and hospital visits. It now reads: “Examining a 5% random sample of Medicare beneficiaries in 2006, we found that approximately 25% of NH residents with FTs required an ED visit or hospitalization, with 44% of hospitalizations and 24% of ED visits being potentially preventable for an ACS condition.” (noted: Discussion, 1st paragraph, 1st sentence).

3. I also assume that ED and hospital visits may be related to NH residents' health condition and the facility availability of a nursing home. In what situation did the ED and hospital visits happen? What are main causes? Such information should be taken into modeling. In the case of unavailability of some of these data, the authors should at least note them in the text.

To address NH residents health conditions, we accounted for sociodemographic characteristics (including age, sex, race/ethnicity, marital status) as well as overall health status (including comorbid conditions, ADL impairment and DNR status). Since detailed clinical information regarding the causes of ED and hospital visits are not available, we note this as a limitation (noted: Discussion, last paragraph, 2nd sentence).

4. Some typos
Abstract, Background: CI, CMS should be spelt out.
Abstract, Methods: Line 8, MMSE=0.4 should be MMSE=0-4. This is also true for the last paragraph on Page 13.

Thank you for identifying these typos – they have been corrected.

Reviewer #2 Comments:

Major Compulsory Revisions

Page 7~8 The validation of the ACS conditions is a key and most important element for this study. For the readers outside USA, a more detailed explanation regarding “using MEDPAR file and AHRQ Prevention Quality Indicator (PQI) codes or using Outpatient SAF file and AHRQ PQI codes using MEDPAR file and AHRQ Prevention Quality Indicator (PQI) codes” will be needed , especially including the information on their validity (Who and how coded them, etc).

Thank you for this helpful international perspective. We have elaborated on and substantiated the use of AHRQ’s PQI’s for determining ACS conditions based on ICD-9 codes. Specifically, we stated, “To classify visits as ACS, we used the Agency for Healthcare Research and
Quality’s (AHRQ) “Prevention Quality Indicators” (PQIs) that aim to identify ACS conditions based on ICD-9 codes. This AHRQ methodology is widely accepted and has been used extensively in previous literature as an indicator of potentially preventable hospitalizations and ED visits. These are standardized measures based on ACS condition classifications and have been validated and commonly used in prior studies of ACS acute care utilization among elderly long term care residents.” (noted: Methods – Primary Outcomes, 1st paragraph, 4th-6th sentence).

Page 8, Please inform what version of the MDS is being used. Based on this, could you please elaborate on the rationale behind the selection of these five (5) activities of daily living among the ones contained in the MDS?

We used 2006 MDS 2.0 data for this study (noted: Methods- Study Setting & Population, 1st paragraph, 2nd sentence). Since no prior investigations have specifically examined a cohort of only tube-fed residents (vs general NH population) we selected ADLs and constructed ADL categories that were both clinically meaningful and reasonably distributed across our 5% national random sample of tube-fed nursing home residents (noted: Methods – Possible Confounding Factors, 1st paragraph, 6th sentence).

Page 8, Could you please give more details on why you collapsed the total ADL score into these categories? I think there might be better ways to represent the ADL scores contained in section G of MDS than the one you have used, as it does not seem sound. If there are other experiences using this method please cite them. Otherwise, it would be better to explore other options.

As described above, since no prior investigations have specifically examined a cohort of only tube-fed residents (vs general NH population) we tried to select ADLs and construct ADL categories that were both clinically meaningful and reasonably distributed across our 5% national random sample of tube-fed nursing home residents (noted: Methods – Possible Confounding Factors, 1st paragraph, 6th sentence). Specifically, we started with splitting at 12/13 since participants who have <12 are being scored as requiring “limited” assistance with ADLs (average score of 2 across 5 ADLs), while participants who have 13+ are being scored as requiring “extensive” assistance with ADLs (average score of 3 across 5 ADLs). We felt the difference between Limited and Extensive was substantial and should be maintained in our categories. Similarly, we split at 17/18 since participants who have 18+ are being scored as “Total dependence” in the majority of their ADLs while participants who score 13-17 are being scored as “extensive” dependence. Finally, since so many of our research participants were in the 18+ group, we further subdivided this group into those who were “totally dependent” in all ADLs (20 points) versus those who were totally dependent in most ADLs (18-19 points). We recognize that we did not clearly explain our rationale for our categories. As noted above, we have added a brief clarification in the methods section outlining this rationale.

Page 15, you mention that “This study adds to a growing body of evidence documenting the potential risks and complications associated with FTs in NH residents with CI.” However, it seems this conclusion is out of the scope of the results of this particular study as there is no comparison with non-FT users and the direction of the severity of CI seems counterintuitive. A similar statement is given as “Despite such evidence, our results suggest that FT use is very common, with 46% of all NH residents with FTs being classified as having at least Severe or very severe CI (MMSE < 7).(Page 12)”
We have eliminated the first sentence in our conclusion section that the reviewer highlighted. In terms of the second sentence, we now recognize that it was unclear. We have changed it to read as follows: “Among our national sample of tube-fed NH residents, we found that nearly half were classified as having at least Severe or very severe CI (MMSE < 7)” (noted: Discussion, 2nd paragraph, last sentence).

**Minor Essential Revisions**

Page 2, “ED visits and potentially preventable ambulatory care sensitive (ACS) hospitalizations and ED visits” should better rephrased as “ED visits and potentially preventable ambulatory care sensitive (ACS) hospitalizations and ACS ED visits” to show clearly that the last ED is ACS ED as you did in the other section. (you should be consistent regarding the order and way you describe these outcomes through the paper. In some section, the order of the hospitalization and ED is different (p5)

We have corrected this wording throughout the manuscript to be consistent.

Page 3, Information on the number of “comatose” in the conclusions is redundant

We have removed this statement from the conclusions in the abstract.

[Introduction] You explained this study’s future contribution would be that “Such information may give families and providers a clearer picture of the likely burdens associated with FT use based on cognitive status and allow them to make a more informed care decision.” Please indicate what clinical conditions could be the contributions of this study clearly, such as placement of new FT tube among NH residents with CI or decision to refer to EDs.

We have added a clarification that such information may help families make a more informed care decision about initial feeding tube placement (noted: Introduction, 3rd paragraph, 3rd sentence).

Additionally, in the Discussion, you explained the influence of CI severity regarding the clinical decision by nursing staff or family. This idea is very interesting, but the rationale of the interpretation using previous studies regarding clinical decisions for old people with CI would be necessary. Furthermore, it is suggested to make a case for this study’s meaning by using previous studies about clinical decision-making aimed at older people with CI in the introduction.

We now recognize we did not support some of our possible explanations. Thus, we have added the following citations:

Perry and colleagues (2010): “Evidence suggests that a frequent precipitant for acute care transfers is dementia-related behavioral issues, which are commonly exacerbated by acute medical illness.” (Discussion, 3rd paragraph, last sentence)

Lopez (2009): “Prior research suggests that family members of NH residents with dementia are often unsure about the length and expected course of the illness and such uncertainty makes it difficult to determine whether an acute illness is part of a downward trajectory or a temporary, reversible setback.” (Discussion, 5th paragraph, last sentence)
Page 6, It should be mentioned more clearly the rationale behind the 90-day blackout window after initial NH assessment (i.e. clinical connotations, definition of long stay residents, availability of MDS assessments, etc.).

We have now clarified our rationale for this approach as follows: “Since we were specifically interested in the rates of acute care utilization by long stay NH residents, we measured outcomes after a 90-day blackout window after initial NH assessment to exclude short-stay residents.” (Methods – Study Setting & Population, 1st paragraph, last sentence)

Page 6, Please add more details on the considerations for the power calculation that led you to establish a 5% sample.

We apologize for any confusion – we did not conduct a power calculation for this study. The national 5% random sample of Medicare beneficiaries used in this study is the standard analytic file available to researchers. This 5% random sample was not derived by us – it was given to us by CMS, based on their standard sampling methodology (http://www.ccwdata.org/datadoc.php). From this sampling frame, we identified a narrower cohort of tube-fed nursing home residents (as described in our methods). We have noted the above link for the CMS standard sampling strategy (Methods – Study Setting & Population, 1st paragraph, 1st sentence).

Page 7, MEDPAR or page 8 SAF: Even it is being listed in the list of abbreviations, the first time should be spelled out in full like any other abbreviation. Otherwise, at least the way of writing the abbreviations should be consistent..

Thank you for highlighting this error – it has been corrected.

Page 8, please add a reference for “FT placement differs by race/ethnicity.”

We have added a reference [9] for this statement in the manuscript (noted: Methods – Possible Confounding Factors, 1st paragraph, 4th sentence).

Moreover, in table 1, Why are not Caucasians represented? In Methods, the classification of ethnicities with small numbers is already mentioned. Please show the prevalence of all ethnicities including Caucasians or Black as an important confounder.

Thank you for highlighting this omission. In table 1, we have now added a race/ethnicity category and listed the prevalence of whites, blacks and other according to severity of cognitive impairment. Of note, to maintain consistency with the use of categories in the table, we also added “sex” and listed prevalence rates for both males and females.

Page 13 Please refrain from mentioning the MMSE scores in the discussion section as it may lead to confusion on the actual tool being used in this particular study. Otherwise, mention again that they may be an equivalent measure (ref 24).

Thank you for highlighting this confusion. Throughout the discussion, we have now indicated the CPS score and corresponding equivalent MMSE. We believe it is important to list both scores as the MMSE is a more familiar frame of reference for readers compared to the CPS.

[Methods-Data Analysis & Table 1] The Footnote of Table 1 included “All characteristics were significantly different across all 4 levels of CL (p<.0001).” Please show the statistical tests for these p-values in Methods or footnotes of Table 1.
We have added the following statement:

“Descriptive statistics were used to characterize the sample of NH residents by the severity of their CI. Frequency, percent and measures of central tendency were employed to summarize the characteristics of the sample and evaluate the data. Frequency counts, chi-square and Kruskal-Wallis test p-values were calculated to compare the proportion of patients by the severity of their CI. Nominal variables have a chi-square p-value and ordered variables have a nonparametric Kruskal-Wallis test p-value.” (noted: Methods – Data Analysis, 1st paragraph).

[Results] The title of the table and text: Table 3 should be “Rates of Hospitalizations and ACS Hospitalizations”. However, the author wrote in RESULTS, page 11 “Table 3 shows the rates of ACS ED visits and ACS hospitalizations.”

Thank you for detecting this typo – it has been corrected (noted: Table 3 and Results, last paragraph, 1st sentence).

Discretionary Revisions

[Methods –Primary Outcomes] You defined the person-year regarding denominator of a rate as “If K5b (feeding tube present) was ‘yes’ on any qualifying MDS assessment then the resident was considered to be at risk for the above outcomes through death or the end of calendar year 2006.” In the legends of Table 2 and 3, we found “n=3479” as “person years of observation” (in footnotes). As final sample, 3479 persons were observed time at risk of events. Therefore, there is a question whether all of 3479 persons could have whole a year as their time at risk of events. If you do not show the “incident rate” in correct statistical meaning, suggested would suggest to change this expression for these outcome indicators to “proportion” or “prevalence”.

Thank you for highlighting this discrepancy and confusion. We have eliminated the incorrect reference to the number of residents in the sample in Tables 2 & 3. All residents in the sample were considered to be at risk for the study outcomes through death or the end of calendar year 2006 (noted: Methods – Primary Outcomes, 1st paragraph, last sentence). As discussed in our analysis section, since NH residents with MDS evaluations early in the year are at risk for acute care needs for a longer time period than NH residents with MDS evaluations later in the year, we included an exposure offset in our poisson models, and present our outcomes in person-years of observation with 95% confidence intervals (noted: Methods – Data Analysis, 2nd paragraph, 3rd sentence).

[Methods –Primary Outcomes] Regarding previous comment, it is better to show the definition of the time at risk of events clearly. How did you treat 2 or more ED visits and hospitalizations in 2006? Please clarify whether there is censorship of observations when the first event occurs.

We used overdispersed Poisson regression allowing us to model the number of ED visits or hospitalizations. Thus, there was no censoring.

We now reiterate our count regression methods in our results section as well as the methods section (noted: Methods – Data Analysis, 2nd paragraph, 2nd sentence; Results, 2nd paragraph, 1st sentence; Results, 3rd paragraph, 1st sentence).
[Discussion] the first half of the paragraph includes representative results in the US with this random sampling. However, these results do not address your primary objectives for this study. It would be better to answer your hypothesis first. In addition, it would be better to show these numbers; 20,000 or 30,000, as estimators with standard errors.

We have reversed the order of presentation of findings in this paragraph to first answer our hypothesis (Discussion, 1st paragraph). In addition, we now present our exact estimate or the number of nursing home residents with FT's who are comatose (20060) and the number of NH residents who were dependent in all ADLs (31700) (Discussion, 1st paragraph, 2nd and 3rd sentence). These estimates do not have standard errors or confidence intervals since they are derived from the number of participants in our study who were comatose (n=1003) or dependent in all ADLs (n=1585). Since our study was a 5% random sample of the US NH population, we multiplied these numbers by 20 to determine our national estimates. Since both the n's and 5% are exact values without statistical uncertainty, we present these estimates without confidence intervals or standard errors.