Author’s response to reviews

Title: “Implications of Cost-Sharing for Observation Care among Medicare Beneficiaries: A Pilot Survey”

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Author’s response to reviews:

Thank you for the opportunity to strengthen our manuscript. We appreciate your comments and recommendations and have made considerable changes to the paper.

Please see below for our responses in bold and our changes to text in italics.

Editor Comments:

There is agreement among the reviewers of the importance of the sample size and power issues that you discuss in the paper. I recommend that you consider presenting your findings as preliminary data or the results of a pilot study that can be expanded upon with subsequent data collection. There are other reviewer recommendations that can further strengthen this well written paper.

We agree that our data is preliminary and we believe that our title reflects the exploratory nature of our study.

Additionally, we have edited the abstract to reflect this:

Line 49:

Research Design and Methods: Single-center pilot cohort study

Line 57-59:
Discussion: The results of this pilot study demonstrated that cost-sharing for observation care may have unintended consequences on utilization for low-income beneficiaries. Future studies should examine this potential relationship on a larger scale.

Reviewer reports:

Ekaterina (Katia) Noyes (Reviewer 1): The authors provide empirical evidence in support of their statement that cost-sharing for observational care may have unintended consequences on subsequent health utilization for low-income Medicare beneficiaries. This study provides unique insights into patient behavior and decision-making and could have important implications for developing better, more patient-centered healthcare reimbursement mechanisms. Because of the limited study sample size (144 instead of 686 interviews as recommended based on the power calculation), I would recommend that the authors present their finding as a Debate/Controversial Issues report rather than a Research Study.

Respectfully, we disagree and maintain that our work constitutes research. However we do agree that the data derived from this pilot study are preliminary in nature.

Regardless of whether they do that or not, the authors should present a more nuanced Introduction and Discussion explaining the rationale for why hospitals may admit some patients for an observational stay rather "inpatient admission" - which is likely to do with reducing hospital risk of readmission penalty or lack of inpatient beds. Perhaps a more detailed analysis of reasons for observational admission, patient comorbidity profiles, and prior and subsequent healthcare utilization patterns could lead to potential explanations of hospital behavior. For example, an admission for an observational stay for an ambulatory sensitive or "social" condition (i.e., lack of informal caregiving for an elderly person with disability) should be analyzed and managed very differently than an admission for a true medical emergency. Also, it would be important for the readers to have an estimate of the magnitude of a bill for inpatient vs. observation stay, and the relative frequency of both types of admissions.

We appreciate this comment. We expanded the Background section to improve our explanation of the criteria for observation status, the frequency of such admissions in relation to inpatient admissions and the financial implications for patients. The decision to hospitalize a patient under observation status is that of the admitting physician and not the hospital. According to the Centers for Medicare and Medicaid, this decision should be based on the physicians best estimate of anticipated length of stay, rather than clinical metrics. Although there has been some...
speculation regarding use of observation care to avoid readmission penalties, these concerns have not been substantiated with evidence.

Please see lines 86-111 for edited text.

Peter Wushou Chang, MD, MPH, ScD (Reviewer 2): The study examined an important issue regarding cost-sharing by the beneficiaries of the Medicare in observational cost when hospitalized under Medicare Part B. The study was a polit one, with limited numbers of convenience samples. The limitations were addressed. It is recommended to upgrade the review on existing literatures on related study subjects. The authors are also encouraged to describe the quantity of cost-sharing in future studies.

Thank you for your consideration of our paper. We have included an expanded Background section in which we describe the out-of-pocket expenses for patients hospitalized under observation status.

Timothy Callaghan (Reviewer 3): Thank you for the opportunity to review "Implications of Cost-Sharing for Observation Care among Medicare Beneficiaries: A Pilot Survey" for BMC Health Services Research. This manuscript uses an original survey in Delaware hospitals to study the attitudes of Medicare patients about hospitalization under observation status and subsequent cost-sharing implications. The manuscript focuses on an interesting topic and one of growing importance as the Medicare population continues to grow. That said, I believe that significant revisions are needed to the manuscript before publication.

My primary issue with the manuscript is its sample size. While the authors are forthcoming about the pilot nature of the study - noting it as a key limitation and acknowledging that resources limited the data collection period - the generalizability of these findings is a real concern. Trying to come to any definitive conclusions from just 144 patients in two hospitals is questionable, particularly when the authors acknowledge that power analysis indicates that at least 686 participants are needed for sufficient power in the study.

The authors can and should do more to discuss how these results might change with a larger sample size and to discuss the generalizability of the results more broadly.
We appreciate the comment. We have expanded our limitations section to discuss issues related to sample size and generalizability in greater detail.

Please see lines 257-266 as below:

-In the context of this pilot study we were underpowered, and were only able to detect a potential signal regarding the direction of our findings. However, our initial sample size calculation was based on an estimate that 3-4% of patients would ration of observation care due to concerns related to cost-sharing. In contrast, we found that a substantially higher proportion would consider shortening their observation stay plan after learning about their cost-sharing obligations (34% would ask for outpatient work-up and 2% would leave AMA). Assuming our sample was generalizable, a larger patient sample could further strengthen the association that we found. However, a large study using a more representative patient sample could potentially result in a smaller effect size.

Outside of the study's small sample size, several questions arose in reading the methods used for the project. Specifically, more detail is needed in describing many of the survey questions. For example, why were the original NHIS questions condensed into dichotomous variables? Perhaps more importantly, did this happen before participants were asked the question (i.e. they answered yes/no) or after (i.e. only condensed for analysis). Similarly, you note on page 4 that questions 17-21 were demographic in nature. What demographic questions? Finally, were participants asked if they had been hospitalized under observation status previously? This could change responses to other survey questions.

Thank you for allowing us to clarify.

For the questions related to cost sharing, we retained the 4-response structure of NHIS in the survey but we created a binary dummy variable for the analysis that represented any positive response to a rationing question. We did not ask patients if they had been hospitalized under observation status in the past.

We clarified this in the methods section lines 185-192 as below:

-Questions 4-9 and 11-16, were taken directly from the 2014 National Health Interview Survey (NHIS) and addressed rationing of health services (mental health, vision care, dental, and specialist and primary care) and prescriptions due to cost in the previous 12 months. These questions were chosen to examine baseline concerns related to health care cost-sharing. The
original NHIS questions had 4 responses (Yes, No, Refused, Don’t Know); We modified this slightly by offering the responses: Yes, No, Refused, N/A. Any patient who had a positive (yes) response to any of the NHIS questions related to rationing was coded has having health-related cost concerns.

Other minor issues stood out throughout the manuscript as well:

Given the broad readership of this journal, it might be helpful early on to discuss why some patients are given hospital outpatient status instead of being treated as a hospital inpatient. This would provide helpful context to improve reader understanding of the issue.

Thank you for this comment. We expanded the Background section to address this concern as noted above.

You note early on "as more beneficiaries are exposed to Part B cost-sharing for their hospitalizations" - you should provide cites showing this trend.

We added additional text to support this claim in lines 93-98 as below

-Since this rule was enacted, hospitalizations under observation status have increased by 8%, and inpatient admissions have decreased by 2.8%.6 In addition, observation stays increased 70% from 2006-2010.3 This has been attributed in part to penalties to hospital systems for inappropriate billing for short-stay admissions5 and possibly broader cultural changes in admitting practices.7 It is estimated that approximately 25% of adult general medicine hospitalizations are observation visits.8

You note that respondents and non-respondents were similar on key characteristics except age. How do they differ based on age? This is clear in Table 1 but not in the body of the paper.

Thank you for allowing us to clarify. We edited the text of lines 196-197 as below:

Respondents were more likely to be younger than non-respondents (p=0.008) but were otherwise similar.
On page 7 in the paragraph starting with "over half of respondents" - there is an "of" included in the first sentence that should be deleted and an "of" missing from the second sentence:

This has been corrected.

The final paragraph of the discussion section (before limitations) is a bit repetitive. It could be cut considerably without any loss to the manuscript.

We appreciate this comment. We removed some repetitive text (lines 244-248) from the middle of the paragraph.

Finally, I believe that this manuscript could benefit from a more detailed discussion of directions for future research in the conclusion. While this paper’s findings related to low income patients and anticipated future behavior are interesting, it emphasizes the need for future work to study how hospitalization under observation status actually does impact future health seeking behavior. Noting the need for this future work and how your paper is a necessary first step towards that end would be valuable. Similarly, given the role for economic circumstances that you identify, future work could also benefit from exploring how variance in anticipated costs for patients hospitalized under observation status (based on condition and severity) influences anticipated and actual future behavior. This question is arguably beyond the scope of the current paper but would be worthwhile to note if adding a discussion of opportunities for future research in this area.

We agree with your statement and believe that prospective research needs to be done to further examine the relationship between cost-sharing and use of observation care on a larger scale.

We added the following lines of text, lines 250-251 & 262-264

-Future research should prospectively evaluate subsequent health utilization behaviors of patients with significant out-of-pocket costs from observation care.
As exposure to cost-sharing for observation care increases, its impact on the health behaviors, financial, and physical wellness of our most vulnerable beneficiaries remains unclear. Future prospective studies should examine this issue on a larger scale.