Author's response to reviews

Title: The Impact of Standardizing the Definition of Visits on the Consistency of Multi-Database Observational Health Research

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Author's response to reviews: see over
Associate Editor’s Comment:

“We have now received 2 reviews of your manuscript. Both reviewers agree that this is an interesting manuscript that offers valuable insights to the field. However, after carefully reviewing the manuscript myself and considering the reviewers’ responses, I think the manuscript could be improved with additional revisions. The reviewers’ comments are clearly articulated so I will not summarize them here, but please pay special attention to Dr. Williams request to situate your findings in the context of similar work at CISNET and Dr. Weiner's advice to provide an illustrative example that speaks to the underlying validity of the CDM."

Thank you for your summary of the comments. We have made substantial modifications to the manuscript to address the thoughtful reviewer comments. You will find our responses below.

Referee 1 – Andrew Williams:

Discretionary Revisions:
1. Describe the rationale for the standardized approach for defining inpatient visits, including the merits and drawbacks of alternative approaches. In particular, they might describe why, apart from consistency, the OMOP CDM algorithm is better than a place of service approach and a room and board code approach.

Thank you, we agree that the rationale should have been more clearly stated. A sentence was added to the end of the BACKGROUND section:

“Our main motivation for this study was to assess the impact of applying a standard visit definition to two claims databases on the prevalence of health service utilization and disease prevalence observed during inpatient encounters”

We did not evaluate the alternative approaches, but agree that should be discussed as a future direction to consider. The following was added to the DISCUSSION:

“We did not evaluate the impact of alternative algorithms that could have been considered. Further research would be required to determine if a specific algorithm had better operating characteristics than alternatives.”

2. Elaborate on their assumptions about the expected degree of consistency in prevalence under perfect measurement. Ideally the results would be interpreted with reference to an empirically-supported quantitative estimate of the expected consistency and a threshold magnitude of insufficient consistency defined with reference to a practical impact on statistical inference. Lacking an empirical basis for these estimates, the authors still might guide readers’ understanding by describing these issues and illuminating them with hypothetical examples.

Your question highlights the limitation that there is no reference to compare to and instead we had to focus on a relative comparison between the raw data and CDM data. The following statement was added to the DISCUSSION:

“It is a limitation of this analysis the lack of available reference standard to compare the prevalence estimates. The two populations are different and therefore we do not know the extent to which we could expect inconsistency. We have made the populations comparable through stratifications by age, gender, and year, but it may be underlying disease and health service utilization patterns account for differences. For these reasons, it is important to focus on
the relative comparison from the raw data to CDM-transformed data, rather than the absolute prevalence when evaluating the impact of applying a consistent algorithm across sources.”

3. Specify what they mean by “consistent” when they write that the results for “2012 were consistent with the patterns observed in both databases from 2006 through 2011” on line 201. This seems to be contradicted by the variability in the Optum data described on line 209-211.

The demographics were consistent and the inpatient visits were inconsistent. We adjusted the first sentence you refer to, to make it clearer:

“The demographic profile in CCAE for 2012 was similar to the demographic profile for Optum during the same period. The demographics in both databases were consistent from 2006 through 2011.”

We also adjusted the second sentence you referred to:

"We also found that CCAE followed the same inpatient classification pattern exhibited in 2012 among years from 2006 to 2011, while Optum varied in this classification (notably in 2008, 2009, and 2010 the percent of records classified as inpatient only in the CDM were 11.77%, 19.12%, and 14.75% respectively instead of around 3-4% as we see in other years)."

4. Offer their ideas about what determined whether a prevalence estimate became more consistent, remained essentially unchanged in consistency, or became less consistent across data sources.

First, your question made us realize we should be stressing that overall, across all conditions, the prevalences are getting more similar. We have added a sentence both to the ABSTRACT and RESULTS to highlight this finding.

“Before standardization, we found that on average each condition in Optum was 12% more prevalent than that same condition in CCAE (b=1.12); after standardization, there was only a 1% mean difference in the prevalence estimates between the two databases (b=0.99). “

In addition, in order for the reader to understanding change in consistency, as your question highlights, we believe it will be helpful to provide that information across all conditions. We point the reader to the online supplement with the following sentence in the RESULTS:

“To review the changes for all the conditions reviewed, please see the online supplement.”

5. Clarify whether the findings reported in lines 227-232 and Figure 1 are simply an expected consequence of the way the CDM algorithm excludes inpatient visits as defined in the CCAE raw data and includes inpatient visits as defined in the Optum raw data. I.e. whether this is a finding or a consistency check given the described algorithmic differences in classification approaches.

We agree this is a point that should be made clearer. In the following we augmented the first sentence and added the second:

“However, we observed the prevalence of inpatient conditions in CCAE raw was lower than the prevalence estimates from within the CDM (beta coefficient [b] = 0.94) while in Optum inpatient condition prevalences were lower in the CDM than the raw data (b = 1.06). The increase with CCAE was expected based on our how standardization method was applied to that database, but the directionality of the shift in prevalence within Optum was not prescribed by the algorithm.”
6. Give more detail in the methods and assumptions of the statistical analyses they performed and their choice of analytic approaches over other options such as measures of inter-rater agreement like Kappa.

We agree with the reviewer and have added the following paragraph to the DISCUSSION:

“This analysis provides a descriptive characterization of the impact of standardization on the prevalence of inpatient visits and associated diseases. We did not provide formal statistical test or compute measures for inter-rater agreement, but instead relied on the distribution of prevalence estimates and regression coefficients as the means of illustrating the variability observed between databases, before and after standardization. Further analysis could be performed to test the impact, and those approaches could be applied across other databases to further assess the generalizability of these findings.”

7. Situate the larger project of standardizing and illuminating definitions and assumptions in claims data that this analysis is an instance of within the context of similar efforts attempting to improve the reproducibility of findings, such as the Cancer Intervention and Surveillance Modeling Network (CISNET).

We agree this will give this paper better context so we have added the following paragraph to the DISCUSSION:

“Standardizing definitions for visits is just one example of an opportunity for improving consistency in observational research. The use of common data models in efforts such as OHDSI, Mini-Sentinel, and PCORNet present opportunities to establish shared conventions that go beyond the basic data structure and content to impart consistent interpretation of each data element within a source. Work to standardize analytical methods, as has been done by OMOP and Cancer Intervention and Surveillance Modeling Network (CISNET), is another important step in this direction. The promise of standardizing the entire analysis process, from data management through analysis execution and results interpretation, should offer the ability to simultaneously improve the efficiency, reliability, and reproducibility of research activities.”

8. Address, in the conclusions section, the fact that the results are somewhat equivocal; that standardization decreased consistency for a non-trivial proportion of conditions.

We acknowledge it in the CONCLUSION:

“While there is an increase in heterogeneity in some conditions, in general we have found that the databases became more consistent after standardization.”

In addition we hope our additions to your 4th comment above will also help the reader understand how the prevalences are changing due to standardization.

Referee 2 – Mark G Weiner:

The premise of this manuscript, that the data specification used to define an inpatient encounter type can impact the detection and rates of disease in a population, is important. The application of a standard transformation, and the display of results where differences in disease rates between data sets from two different vendors decrease after the transformation is also compelling. The authors rightfully indicate that while they are not comparing to a gold standard source of truth of the patient’s inpatient status, they would rather be consistently wrong than inconsistently right -- an important caveat that
should be stated more up front as the goal, and not just in the discussion (perhaps alluding to the distinction between a consistent definition and a gold standard truth on line 78).

Thank you for your careful read and we agree this point is important and we originally were only making it towards the end of the paper. But instead of adding something on line 78 we would like it to be part of our BACKGROUND’s closing statements:

“While there is no gold standard source of truth on a patient’s visit status, we believe that applying a consistent approach to its definition can improve transparency and reproducibility in observational research.”

While I understand the difficulty in comparing to a true gold standard, knowing that the source data that feeds both vendors' raw data sources (UB92-> Truven, UB92->Optum) is identical, I need more information about the organization and content of relevant data by these two vendors and the transform of the vendor data to OMOP, and some examples of the differences.

In the METHODS -> STUDY MEASURES -> DEFINITION OF INPATIENT VISITS IN RAW DATA section tries to highlight that even though the raw data source is the same form, the data vendors have made decisions that cause their individual datasets be different in how they are stored. Additionally, Appendix 1 provides further information about the raw data schema. However, to connect the point of the data is pulling off similar forms to this section, we have added the following sentence in the DEFINITION OF INPATIENT VISITS IN RAW DATA section:

“While the source data for Optum and CCAE come from the same forms (UB-92 and HCFA-1500) the data vendors organize the results in different ways.”

Additionally, the information surrounding the transformation can be found in the following section: DEFINITION OF INPATIENT VISITS IN CDM. The full details are found in reference #9 - Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) [http://omop.org/CDM] and Appendix 2.

The transformation seems more natural for the Truven data since both the Truven and the CDM definition of an inpatient stay is based on a revenue code consistent with an inpatient stay – like the "room and board" code. However, the intended and applied specification for inpatient status for Optum seems less related to revenue codes, and seems inconsistently described in the manuscript. The manuscript on line 71 and 72 says that Optum contains a field to indicate claims associated with an inpatient confinement,***but the inpatient classification is defined by the place-of-service.*** (presumably not a revenue code, but this is not clear). Later on (lines 152-154), the manuscript says "Any Optum records with an associated confinement identifier were considered as part of an inpatient visit unless they were identified as ER claims by the place of service field." In this latter statement the inpatient definition focuses on the "confinement identifier" where earlier it was the place of service. This discrepancy must be clarified, with quantitative results reanalyzed if appropriate. Is the "confinement identifier" a revenue code, or is it a calculated field derived by Optum based on their own algorithm? What is the revenue code in Optum that is used to anchor the inpatient status assigned in the CDM?

Thank you for pointing this out, line 71 and 72 creates confusion. We have deleted the part "but the inpatient classification is defined by the place-of-service" - this was a statement comparing the inpatient confinement field to our definition but it is not clear.
We have changed the following sentence in the METHODS -> STUDY MEASURES -> DEFINITION OF INPATIENT VISITS IN RAW DATA section to better define what a confinement identifier is.

“Any Optum records with an associated confinement identifier, and Optum derived field, were considered as part of an inpatient visit unless they were identified as ER claims by the place of service field (this was recommended as an inpatient visit definition from Optum).”

The revenue codes used to anchor Optum to inpatient status can be found in Appendix 2. However, we changed this sentence in the METHODS -> STUDY MEASURES -> DEFINITION OF INPATIENT VISITS IN CDM section to make it clearer:

“The codes for defining inpatient or ER claims in both Optum and CCAE can be found in Appendix 2.”

With the close alignment of Truven and CDM definitions of inpatient status, the stable rates of consistency seem reasonable. However, I cannot envision the nature of the scenario where the CDM labels an encounter as an inpatient stay, but the "raw" truven data does not. Furthermore, the Optum data has occurrences where the raw data labels a stay as an inpatient encounter, while the CDM does not --- a situation that never occurs with the Truven data. The variable rate of concordance between CDM and Optum recognition of inpatient status may reflect a change in their use of the "confinement identifier," though, again, that is not the intended inpatient marker based on lines 71-72. Something is clearly going on in 2009 with Optum’s definition on inpatient status!

To address your comments of consistency, which is something the first reviewer asked about, here is our reply to that first reviewer:

First, your question makes us realize we should be stressing that overall, across all conditions the prevalences are getting more similar. We have added a sentence similar to the following both to the ABSTRACT and RESULTS.

“Before standardization, we found that on average each condition in Optum was 12% more prevalent than that same condition in CCAE (b=1.12); after standardization, there was only a 1% mean difference in the prevalence estimates between the two databases (b=0.99).”

In addition, in order for the reader to understanding change in consistency, as your question highlights, we believe it will be helpful to provide that information across all conditions. We point the reader to the online supplement with the following sentence in the RESULTS:

“To review the changes for all the conditions reviewed, please see the online supplement.”

You are correct that you cannot envision a scenario where a Truven outpatient visit can become an inpatient visit. Reviewer 1 also wanted to understand this better. So we altered the first sentence and added the sentence in the comment below:

“However, we observed the prevalence of inpatient conditions in CCAE raw was lower than the prevalence estimates from within the CDM (beta coefficient [b] = 0.94) while in Optum inpatient condition prevalences were lower in the CDM than the raw data (b = 1.06). The increase with CCAE was expected based on our how standardization method was applied to that database, but the directionality of the shift in prevalence within Optum was not prescribed by the algorithm.”

Furthermore, I am curious about other differences in the nature of the inpatient admissions picked up by the CDM definition that are not part of the "raw" definition. The manuscript states (lines 265-67) that "CCAE mentions in their documentation that a small percentage of inpatient services fall into their outpatient services table when no charges are found" If these account for the extra inpatient encounters
found by the CDM definition, then what is good for normalizing diagnosis rates may not be so good for normalizing charges. The lengths of stay for these "CDM-only" inpatient encounters may also be skewed.

To your comment, we did not review length of stay in this analysis. The following sentence was added to the RESULTS:

"Also, further work should be considered to assess how standardization may impact length-of-stay and cost summarization commonly used in health economic analyses."

Bottom line is that there needs to be some illustrative examples of the discrepancies so that a reader can make a judgment about the correctness of the CDM version. It needs to be clear what is a revenue code, a place of service code and what is a derived code in the source (raw) data. Analyses of how the CDM definition of inpatient stay affects other characteristics of relevance to inpatient encounters, like charges and length of stay, should be addressed or at least mentioned.

Thank you for asking about this we think an illustrative example adds clarity on how this transformation is occurring. We refer to this figure in the METHODS -> STUDY MEASURES -> DEFINITION OF INPATIENT VISITS IN CDM section.

"Figure 1 provides an example of a claim from CCAE’s outpatient services table and how it was re-categorized to an inpatient visit."

Figure 1: Truven MarketScan Commercial Claims and Encounters (CCAE) Reclassification of a Single Patient’s Outpatient Record to Inpatient or Emergency room Visit