

Article details: 2017-0077	
Title	Manual review of electronic medical records as a reference standard for case definition development: a validation study
Authors	Tyler Williamson PhD, Rebecca C. Miyagishima MSc, Janeen D. Derochie RN, Neil Drummond PhD
Reviewer 1	Dr. Suzanne Morin,
Institution	Department of Medicine, Montréal General Hospital, Montréal, Que.
General comments (author response in bold)	<p>1. For the readership not familiar with the CPCSSN, a few sentences on its mandate, its funding and a key reference would be welcome.</p> <p>This was a recurring theme from the reviewers. We apologize for this oversight. We have corrected this in the paper and fleshed out the methods section to make this even more explicit.</p> <p>2. The methods section is extremely cursory. One has to pull out the 2014 article to better comprehend the purpose and method of the current analysis. More details should be provided in regards to period of study, cohort creation and statistical analyses.</p> <p>Again, an oversight on our part. We have corrected this in the manuscript by clearly explaining the methodology used for this study.</p> <p>3. In particular a short description on how the base EMR information differs from the CPCSSN data holdings (processed EMR data) would be warranted.</p> <p>This has been added to the introduction.</p> <p>4. There does not seem to be a new sample size calculation- then the one used in the previous paper should be described.</p> <p>The sample size was motivated by an estimation of the margin of error for the 95% confidence intervals that would be the primary measures of interest. This has been added to the methods section.</p> <p>5. It is unclear how patient demographics were considered in the analyses.</p> <p>Patient demographics were not specifically considered as part of the analytic approach. There was one statement in the original submission that suggested the contrary. We have removed this sentence and believe that this clarifies this issue.</p> <p>6. Were other records excluded because of incomplete data, other than those recorded in the previous analysis? How many records required intervention by lead author or family MD for adjudication?</p> <p>We have attempted to clarify the exclusions due to incomplete data in the paper. The number of adjudications has been added to the methods section. In total, 347 diagnoses (2.3%) were reviewed for adjudication out of the total 15,248 (1906*8) diagnoses made by the reviewers.</p> <p>7. Since the authors conclude that it is more efficient in terms of time and resources to use the CPCSSN data holdings while attaining very good validity measures, it might interesting to document how much time was saved, or how many records required reviewing by a third party, or any benefits on other processes etc.</p> <p>Unfortunately, we do not have information on exactly how much effort is being saved by the new method. However, we have conducted several validation studies and recognize that the new method offers a considerable reduction in the effort required for such validation studies.</p> <p>8. Finally, in concluding remarks, the authors might comment on what measures may be necessary to augment the validity of case definitions of diseases such as osteoarthritis and depression.</p> <p>We have added a comment about this to the interpretation. However, to be honest, we aren't entirely sure what measures are needed to augment OA and depression. Do you have suggestions?</p>
Reviewer 2	N. Nante
Institution	Università di Siena of Physiopathology, Experimental Medicine and Public Health, Italy
General comments (author response in bold)	<p>1. Abstract, "Results" section: "specificity was high for all definitions ranging from 92.6% (COPD)... In the full text Authors reported 93.3% (hypertension) and in Table 2 Authors reported 93.0% (hypertension). Could Authors verify and clarify these data?</p> <p>This was an error in the text and the table. The correct one would have been 93.0% but we have discovered that there was a rounding error and the estimate should have been reported as 93.1% in both places. Thank you for catching this typo.</p> <p>2. In "Methods" Authors don't report the period and the location in which the study was performed. Moreover, due the complex structuring of the database and the validation method, Authors should expand this part in order to facilitate the Reader's understanding.</p>

This was also noted by the other reviewer and the editorial team. We apologize for this oversight in our original version. We have corrected this in the methods section to clarify how this study was conducted.

3. "Results": "The sex of patients included in the study was reflective of the intention to over-sample older patients...". From this phrase, it is understood that the sample was not randomly selected. Could Authors better explain this point?

Indeed, there was an oversampling of those over the age of 60 and those with epilepsy or parkinsonism. This was described in the methods section but we have explained this further in a dedicated section of the methods that describes the selection of the sample.

4. "Results": "specificity was high for all definitions and ranged from 93.1% (hypertension...)". In table 2, Authors reported a specificity related to hypertension of 93.0%. Probably it is a typo or a different method of approximation. Could Author verify it?.

As we explained above 93.1% is the correct estimate and we have corrected this throughout the paper. Thank you for catching this error.

5. "Discussion", last paragraph, 7th line: "SOAP notes". The acronym is not previously reported in extenso.

SOAP stands for subjective, objective, assessment, and plan and is a commonly used method for charting in primary care. However, to make this clearer to the readers we have simply referred to this as "unstructured clinical notes."

6. "References": the total number of references is not very large. Probably because the issue is very specific. Could Authors clarify this aspect?

You are correct that we reference relatively few papers. I believe this is related to the fact that this is a newer issue which has does not have a wide literature base.