Author’s response to reviews

Title: Designation, Diligence and Drift: Understanding Laboratory Expenditure Increases in British Columbia, 1996/97 to 2005/06.

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Author’s response to reviews: see over
To the Editors:

Re: Designation, Diligence and Drift: Understanding Laboratory Expenditure Increases in British Columbia, 1996/97 to 2005/06

Thank you for the invitation to revise our paper. We are grateful to the reviewers for their thoughtful comments, which we have used to edit the paper. The reviewers’ comments are noted in italics and our response immediately after.

Reviewer 1

1) At minimum, there needs to be acknowledgement that individuals who are classified as ‘no chronic conditions’ may happen to have chronic conditions that were out of the scope of the conditions selected by the investigators. This would include some very resource-intensive and high prevalence conditions that are not part of the BC guidelines, including but not limited to cancer, obesity, dyslipidemia, coronary artery disease.

While we acknowledge that our analysis was limited to only certain chronic conditions in our Limitations section (“our analysis of chronic conditions was not exhaustive, but rather focused only on those conditions that became the subject of incentive programs for primary care in BC” and “the “other” laboratory tests, while not guideline-recommended for these specific chronic conditions, may still be appropriate for other conditions”), the reviewer is correct and it is a point that should be addressed early in the study. Therefore, we have:

- Changed the name of the ‘no chronic condition’ category to ‘no guideline-related chronic condition’ to reflect that these are individuals who do not have the chronic conditions with guidelines that we are measuring.
- Included the following sentence in our Limitations, “Therefore individuals with other potentially prevalent chronic conditions that were outside the scope of the conditions selected for this study would be classified as ‘no guideline related chronic condition’, which limits our interpretation of people in this category.”
- Included the following sentence in our Methods section, paragraph 1, subheading Classifying Chronic Conditions, “There are other chronic conditions not included in this analysis that will
have associated laboratory tests. Increases in testing for those conditions will be captured as
general increases, since our research question is focused on testing related to guidelines” as
well as in paragraph 3, “Individuals in these groups reflect categorization based on the chronic
diseases with guidelines identified earlier, as per our research question, but may still have other
chronic conditions outside of this scope”.

2) **This is more of a limitation in interpretation than true misclassification bias but I would also like
to have seen some discussion of the threat of misclassification bias presented.**
Given the changes we made based on the reviewers first comment, we believe it also addresses this
second comment.

3) **For example, has there been any previous validation work on the codes used?**
This is an established and validated method for defining chronic conditions in our field. We have
included a reference to a study that validated this method in administrative data.
Lix L, Yogendan M, Mann J. *Defining and Validating Chronic Diseases: An Administrative Data*
Available at: [http://umanitoba.ca/faculties/medicine/units/community_health_sciences/departmental_units/mchp/
projects/media/ICD10_Final.pdf](http://umanitoba.ca/faculties/medicine/units/community_health_sciences/departmental_units/mchp/projects/media/ICD10_Final.pdf)

4) **I would also like to see greater elaboration of the issue of screening in the discussion section,
although this is briefly acknowledged.**
As the reviewer notes, the impact of screening is acknowledge in our Discussion section where we say:
“Several changes in the clinical definition and screening of chronic conditions occurred between
1996/97 and 2005/06. For example, the clinical definition of diabetes shifted from a fasting plasma
glucose level of greater than or equal to 7.8 to 7.0 mmol/L [13, 14]. For renal disease, serum creatinine
levels of 176.8µmol/L in men (eGFR of ~40 mL/min/1.73 m2 for a 40 year old man) resulting in referral
to a renal team for dialysis assessment, changed to every patient with urine abnormalities and an eGFR
<90 mL/min/1.73 m2 receiving immediate further assessment and management [15, 16]. Similarly, the
recommended screening guidelines for Type 2 diabetes shifted to begin at age 41 instead of age 46 [13,
14]. There were no major changes in clinical definitions or screening guidelines for osteoarthritis or
rheumatoid arthritis and for those conditions we see relatively stable prevalence across age groups over
time11. These changes are only two factors that may be driving the increase in treatment prevalence for
these chronic conditions, but they are surely significant ones. Once people are diagnosed with a
condition, it should be no surprise that associated health care, and particularly guideline-consistent
expenditures will follow.”

We have now included further detail in a second paragraph “There has also been a trend during this
period toward diagnosing “pre-disease” states as part of screening guidelines, and a growing demand
from patients for tests of their choosing even if the physician may not consider them beneficial. As
previously mentioned, the first screen for diabetes is now recommended at earlier ages regardless of
risk factors with a diagnosis of “impaired fasting glucose” as a “pre-diabetic” state at fasting plasma
glucose levels of 6.1mmol/L. These individuals being flagged as “at risk” subsequently require follow up
tests until the disease manifests itself [14]. So recommendations for increased population screening at
ever earlier ages and the lower threshold for these pre-disease "conditions" that then leads to increased
monitoring of individuals with no disease with testing could be another driver of the increase in other laboratory tests [14, 17, 18]. “

**Minor Revisions**

5) A minor comment, but throughout the manuscript there is inconsistency with which new paragraphs are indented.

All our beginning paragraphs under new headings and subheadings are not indented while following paragraphs are indented.

6) Under methods, subheading ‘classifying chronic conditions’, paragraphs 1 and 2. In both paragraph 1 you say “individuals with one diagnosis….” And later in paragraph 2 say “Those who received only one diagnosis”. I would be more precise with the language used as it’s not clear whether or not a diagnosis has been made. In both of these instances you are referring to ICD codes.

We have clarified our language use in this paragraph to indicate the use of the number of records for classifying a condition as follows “Individuals were counted as having a chronic condition if they had at least two records showing a diagnosis for the same condition over a two-year period” and “Individuals who had no record of a chronic condition diagnosis during the two-year period were classified in the first category. Those who received only one record showing a diagnosis for one or more conditions were classified into the “Potential Chronic Condition” group. Those with two or more records showing diagnoses for one condition (irrespective of “potential” conditions) were counted in the “one Chronic Condition” group, and so on.” This is in paragraph 1 line 12 and paragraph 2 line 3, 5 and 6.

7) Figure 1b: The title of this figure is ‘change in proportion of individuals…’ but a prevalence rate is different than a proportion. I would suggest re-phrasing the figure title to avoid the use of proportion.

For Figure 1b, we discuss the change in proportion of individuals in our results, which is not the prevalence rate discussed in Figure 1a. Therefore, the figure legend has now been changed to reflect the ‘change in proportion of individuals’ as opposed to ‘treatment prevalence’.

8) Table 2: At the bottom of the table there is a second table presented (with the subheading % growth attributable). I would suggest that this form a third table for the manuscript.

Given the limited amount of information presented in that sub-table, we have opted to leave Table 2 as it is, but we would be happy to format this as a separate table if the editors desire it.

9) Table 2: Throughout the rest of the manuscript the changes over time are increased on a relative basis, as a % change. It’s not clear to me why for the first time, data (on per-capita lab tests) are presented now as a dollar ($) change. Something to contemplate further.

We have included three additional columns that contain the percent change to be consistent as the reviewer noted.

10) Figures 2a and 2b: I would suggest that you include an endnote to make some comments regarding constant $ and age standardization.

‘Constant dollars’ has now been added into the Y-axis title of both Fig 2a and 2b as well as ‘age standardized’ into the figure titles.
11) Discussion, first paragraph: “Many factors....new screening strategies....”: presumably new screening strategies would be included within the scope of your manuscript as those who are screened would have been included based on the methods as I understand them.
Thank you, yes this is correct. Screening strategies has been removed from this sentence.

12) In the discussion section, second paragraph: I would suggest adding the word “assessment” following the word dialysis.
This word has now been added to the sentence.

13) Throughout the manuscript there is the use of the term ‘treatment prevalence’. Despite having published in this area, I must admit that I am not familiar with it. You may wish to consider providing a definition for this term early in the paper. I was able to find a good summary of the term at the Manitoba Centre for Health Policy’s website.
A definition of treatment prevalence has now been included in Methods, sub heading ‘classifying chronic conditions’ paragraph 1 line 12-15 as follows “Treatment prevalence is used here to acknowledge the limitations of administrative data in identifying the prevalence of disease. While administrative data have been shown to be quite valid in for this purpose [12], we are only counting people as having disease if they received services from a physician who recorded relevant diagnoses on a billing record.”

14) Under results, subheading demography, second paragraph: I was surprised that there wasn’t more emphasis placed on diabetes and hypertension given their prevalence. Although renal failure and dementia showed the greatest increases, at a population level, diabetes and hypertension would be expected to be a larger driver of healthcare utilization given their respective prevalence rates.
We chose to focus on dementia and renal failure in the Results because the percent increase in prevalence for both those conditions were so surprising (triple digit changes of 227.0% and 145.6%). However, we focus on diabetes and hypertension in more detail under Discussion precisely because of their higher prevalence, as the reviewer noted.

Reviewer 2

1) On page 4, the top paragraph specifies the analysis as being “1996/97” to “2005/06”. These are 1-year periods, whereas diagnosis is confirmed after examining data over a 2-year period. I find the time periods stated in the text somewhat confusing, and would liked to have seen this explained more clearly.
We explained under our Methods, sub heading Study Population, paragraph 2, line 3 that “We accessed the following files: 1) a central demographics file for 1996/97 and 2005/06 providing information on age and sex of individuals and denominator information for the analyses; and 2) the fee-for-service payment files for 1995/96-1996/97 and 2004/05-2005/06” but added the sentence “as a two year period is required to confirm a diagnosis.”

2) There is no rationale for the selection of the 2 periods of time for comparison purposes. Some context should be provided.
The year 1996/97 and 2005/06 were the earliest and latest years for which we had administrative data for this project. The time period is appropriate given that the guidelines came into place during this period as well, but as the reviewer noted, this was not indicated in the study therefore we have included the following sentence in the Methods, under subheading Classifying Chronic Conditions “The chronic conditions selected for this study were those for which specific guidelines developed by the BC Guidelines and Protocol Advisory Committee for the Medical Services Commission contain laboratory recommendations which came into place before 2006”

3) On page 5, in lines 9 to 12, the authors justify the way in which they have defined chronic conditions as being "consistent with prior research". But has the approach been validated in some more specific way? The repeated use of a method by the same research group may not be sufficient to have it accepted as good practice. This needs to be addressed.

Our answer to a similar comment raised by Reviewer 1 (Comment 3) we believe meets this concern.

4) In the top paragraph of page 6, it is suggested that "all tests" would be included. But the authors should be more specific and explain that these are the physician fees associated with the tests, and there might be other costs. In fact, some discussion of how these "other costs" might impact health expenditures should be provided.

It’s not clear to us what other costs the reviewer might be referring to, except that perhaps additional laboratory testing may also imply additional visits with physicians to order and/or to review the results of those tests. In this case we would be underestimating the cost increases associated with laboratory testing, whether those tests are for guideline-recommended tests or for other tests.

5) Lab test ordering in this study includes all physicians, regardless of specialty. I would think that the reasons for seeing a GP as opposed to a specialist especially for chronic disease management, would be different. Therefore, there might be different reasons for ordering a test, which might not be in compliance with the guidelines (but would be good practice nonetheless). There needs to be some explanation of the errors that might be being introduced by pooling all physicians.

We cannot speculate whether reasons a specialist would order a test would be different from a GP as they both would be following the same guidelines and good practice for that specific chronic condition. However, even if there was a different reason to order a test not included in the guidelines, it would be classified as ‘other tests’ and not as inappropriate use, which we discuss under our Limitations as follows “the "other" laboratory tests, while not guideline-recommended for these specific chronic conditions, may still be appropriate”.

Minor Revisions

6) In the 2nd paragraph of page 6, I would have liked to see more of a description of the "administrative fee". This section is not clear.

The administrative fee, which is the primary base fee in our analysis, is only applicable to certain tests under certain criteria and has a separate billing code that is not linked to the tests it is applied to. Therefore, we chose to treat it separately as we could not allocate it to specific tests. We have included an additional description of this in paragraph 2, line 5-8 under Methods, sub heading Laboratory Testing as follows, “The primary base fee is an administrative cost (similar to a pharmacy dispensing fee) that is applicable under specified criteria to certain panel tests performed within the same facility. It could not
be allocated to specific laboratory tests but consisted of a large portion of expenditure and therefore was treated separately.”

7) I don’t really think that the mathematical expression in the "Analysis" section represents a "framework". It is actually not even a mathematical identity. I would suggest "unpacking" this relationship and providing more detail about the elements.

We have rewritten our ‘framework’ to better represent a mathematical expression, as seen below, since omitting the per person expenditure was an inaccurate representation of our analysis:

\[
\text{Total Lab Exp} = N_c \left( \frac{S_{\text{Tests}_1}}{N_c} + \frac{S_{\text{Tests}_2}}{N_c} \right) + N_c \left( \frac{S_{\text{Tests}_3}}{N_c} \right)
\]

Additionally, our manuscript has been reformatted to conform to BMC Health Services Research journal style, in particularly, the title page has been revised to include the email addresses of all the authors and an acknowledgements section has been added to include those who have contributed to the manuscript (we have received their permission) and information on the funding sources for the authors.

We believe this addresses all the revisions suggested by the reviewer and look forward to your response.

Sincerely,

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