Author’s response to reviews

Title: Intra-cluster correlation coefficients in adults with diabetes in primary care practices: The Vermont Diabetes Information System Field Survey

Authors:

   Benjamin Littenberg (benjamin.littenberg@vtmednet.org)
   Charles D MacLean (charles.maclean@vtmednet.org)

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Author’s response to reviews: see over
Title: Intra-cluster correlation coefficients in adults with diabetes in primary care practices: The Vermont Diabetes Information System Field Survey

Response to Reviewers’ reports

Version: 1 Date: 6 January 2006
Reviewer: Patty Chondros

1) Pg 2: The term “clustered studies” in the first line of the abstract may also imply that multiple studies are clustered rather than its intended meaning where the study design involves recruiting individuals from within clusters. Need to modify wording to eliminate any ambiguity eg cluster-based studies or cluster sample study designs

Done

2) “To the extent that patient characteristics are independent of cluster, the effective sample size will be close to the number of subjects”. Need further clarification on the number of subjects, do you mean the number of subjects required for a cluster-based study?

Done

3) “The inflationary factor, sometimes called the design effect, is a function of how much correlation there is within each cluster. This clustering can also be quantified by the intra-class correlation (or intra-cluster correlation) correlation coefficient” Suggest changing the wording “This clustering can also be quantified” to “This correlation is known as the intra-class correlation (or intra-cluster correlation) correlation coefficient”

The inflationary factor we describe is not identical to the ICC. This is discussed in discussion paragraph 2.

4) Pg 5 Functional status and Depression, first line Add “Health Survey” to the description of the SF-12 ie “Medical Outcomes Trust SF-12 Health Survey”.

Done.

5) Describe in more detail which methods/formulas were used to calculate the ICC and standard error of the ICC for the continuous and binary variables.

Done.

6) Generally avoid using the word “clustering” to describe the degree of the correlation within clusters. All participants are clustered within a practice, however the degree to which their characteristics are similar or dissimilar within the clusters is measured with the ICC.

Done

Pg 6, first paragraph. -Change the wording of “within practice clustering” to “within practice correlation”.

Done
- Wording “also among the most clustered” is incorrect. Suggestion “also had high ICCs ranging between X and Y compared to the other variables”.

Done.

-Last line “...appears to vary importantly across practices” – How do they vary importantly across the practices? What is the range of ICC?

Done.

- Pg 6, 2nd paragraph: Revise wording for “were clustered within practice” . Suggestion “had relatively higher ICCs”

Done.

-Pg 7, 1st paragraph: “Health literacy is a substantial ... with little clustering within practices” –Not sure what this statement means? Please clarify or revise the sentence?

Revised

7) Pg 7, Last paragraph: Need to revise sentence “the impact of clustering on sample size appears to be a relatively small effect”. The impact on the sample size can have a great effect even with a relatively small ICC. Even with an average cluster size of 14.5, the design effect (deff) is 1.68 for an ICC of 0.05 and the deff=1.14 for an ICC of 0.01.

Revised

8) Pg 7, paragraph 2: “clustered studies” See comment 1

Done

9) Pg 7, paragraph 2: “If the average cluster contains m subjects” Need to revise the wording. Suggestions: “If the average cluster size is m” or “the cluster contains on average m subjects”

Done

10) Pg 7, paragraph 3: Suggest changing sentence “unless they happen to have the same cluster sample size (which is extremely unlikely)” to “unless they have the same mean cluster size as this study”.

Done

11) Pg 7, paragraph 4, beginning of first sentence: Suggest including ICC at the beginning of the paragraph ie “These ICC estimates...”

Done

12) Pg 7, paragraph 4. Provide a brief description of the clusters ie GP practices in the results section (eg median and range of the number providers per practice, sex, age of providers etc). If published elsewhere, then reference the information regarding median number of providers per practice in the discussion.
We have added information on the size of the practices, but do not have access to data on the gender or age distribution of the providers.

13) Complications of diabetes: Are estimates given in the table for complications of diabetes the mean number of complications or the percentage of participants with the complication? If percentages are given, need to add (%) to each complication for clarity.

Percentages. Revised.

14) Also, add footnote to table 1 describing that unless otherwise indicated the mean is presented for the variables.

The heading of the column covers this issue.

15) What is the range of values applicable for each of the "Audit of diabetes - dependant Quality of Life" variables?

We have added a line with this information.

16) Pg 8, References: Need to correct the initials of first author for the first two references from DM to SM.

Done

1) Pg 3 Demographics and social and economic characteristics: Include the $US to the $ to the income groupings

Done

2) Table 1: Health insurance: Are the 4 types of health insurance mutually exclusive or can individuals have more than one insurance type? Add a brief explanation either in footnote of table or in methods section describing the health insurance types to clarify the different insurance types for readers not familiar with the US health system.

Done

3) Also consider including the precision of the estimates (eg 95% Confidence interval for population ICC: ICC +/-2xSE) when interpreting the estimated ICCs.

Done.

4) For comparative purposes in Table 2, the authors may also be interested in a paper recently published with estimates of ICC for middle aged and older adults in primary care in Australia and New Zealand. Elley CR, et al. Designing Cluster Randomised Trials in Primary Care and Residential Care: Intraclass Correlation Coefficients for Sample Size Calculation. Aust N Z J Public Health 29(5): 61-467 (2005)

We have added this material to Table 2.
Abstract line 2: ‘outcomes’ should be used instead of ‘variables’

We chose “variables” because many of them, such as literacy and comorbidity, are not strictly “outcomes.”

Abstract line 5: the figure of 8,808 is a bit misleading as most ICCs were estimated from a subsample of about 1,000 which based on a response rate of 64%. These points should be included in the Abstract.

We have eliminated the number from the abstract.

Abstract, line 9: ‘ICCs varied widely’ -describe the distribution using median and range or interquartile range. This should be done separately for continuous and binary variables (see below).

This is material is now in the results section, but we do not think the subgroup results warrant presentation in the abstract.

Also ‘likelihood of’ should be ‘proportion with’.

Done

Background, line 5: ‘will be in error’, state what the nature of the errors will be.

Done.

line 14, ‘inflationary factor’ should be ‘variance inflation factor’

We are not referring to the variance inflation factor here, but rather the design effect.

2. In the methods section, it would be worth describing the health care context in more detail for an international readership. How were the primary care practices sampled? What are the practices like? For example, how many doctors, nurses or other health professionals are present? What is the nature of the relationship of the patients to the practices in terms of long-term registration or receipt of care? Do the practices provide most diabetes care or do patients also attend specialist clinics for diabetes screening activities? Are the practices urban or rural?

We have expanded the description of the practices.

3. The measures used are generally clearly described. However, it is not clear whether the blood analytes were estimated from a specially taken sample or whether routine clinical measurements were used.

Tests were ordered by the primary care provider when clinically indicated.

Was the blood sample taken fasting?
Triglycerides were measured in the fasting state. The other specimens were not specifically collected while fasting.

4. The section on statistical analysis needs to be expanded. An algebraic definition of the ICC should be given. The estimation method used should be stated (was one way analysis of variance used?). A word of justification for applying this method to binary outcomes should be given. What method was used to estimate the SE. Presenting confidence intervals for the ICC would be more relevant. How did the authors deal with missing values, departures from normality, and ordinal variables?

We have added a description and reference for the methods used.

5. In the Results section, data for the binary outcomes should be separated from the continuous outcomes as completely separate Tables. The SD should be given for the continuous outcomes. For both continuous and binary outcomes, the number sampled per practice should be presented in the Tables as no (n-nought).

We found that separating the tables by variable format (categorical vs. continuous) appeared artificial and made the tables much harder to understand and use. Since we provide standard error and sample size, we elected not to also include the somewhat redundant standard deviation as it is easily calculable from the data provided. Likewise, the mean number sampled per practice is easily found by dividing N by 73.

It seems strange to see the data presented for demographic and economic variables as these are unlikely to be considered as potential outcomes for a study. If they are to be included then this should be justified.

Although demographics cannot be outcomes, they nonetheless may be the subject of data collection. We think that the analysis of economic variables (which have been the outcomes of many thousands of studies) need not be explicitly justified, either.

The text associated with the results includes some discussion.

This material has been moved into the Discussion section.

6. The Discussion could be extended with reference to other recent papers, including the following papers and the references cited in them:

Done.

Campbell et al suggest that ICCs are higher for process measures than for outcomes. Is this confirmed in the present data?
We see a similar pattern and have added some comment to the discussion.

We showed that there is an association of ICC and prevalence for binary data. Is this confirmed?

Yes it is and this material is added. Because we had relatively few prevalence values above 50%, we did not divide them into tertiles as previously reported. Rather, we assessed correlation.

What were the effects of adjusting for variables such as age, sex and socioeconomic position.

Such an analysis was not done. We believe the paper is complicated enough as it is and that such an analysis would not meet our primary goal.

How generalisable are the estimates between health care systems?

We have no data to illuminate this issue.