Author's response to reviews

Title: Prescribing Data in General Practice Demonstration (PDGPD) Project - A cluster randomised controlled trial of a quality improvement intervention to achieve better prescribing for chronic heart failure and hypertension

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Author's response to reviews: see over
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Dear Editors

Re: Manuscript 1466589465651597 - Study protocol. Prescribing Data in General Practice Demonstration (PDGPD) Project - A cluster randomised controlled trial of a quality improvement intervention to achieve better prescribing for chronic heart failure and hypertension

Margaret Williamson, Magnolia Cardona-Morrell, Jeffrey D Elliott, James F Reeve, Nigel P Stocks, Jon Emery, Judith M Mackson and Jane M Gunn

Thanks to your reviewer for his constructive comments. Please find below our responses to each of his queries, with yellow highlights indicating the new wording in the final version of the manuscript.

MINOR ESSENTIAL REVISIONS

1. It is not entirely clear when preliminary steps and step 1 (improve data quality) are carried out in the control practices. Figure 1 would imply that this is part of the intervention, but surely this needs to be done at the start of the trial in all practices, or otherwise there will be bias in patient identification between intervention and control practices. Please clarify in the text.

   Yes, practices were told to clean their data of irrelevant/outdated patient records before the installation of the extraction software and about two months before the first clinical meeting for the intervention and control groups.

   The issue has been briefly explained in page 6: “Data cleaning and recording of relevant clinical information was actively encouraged two months prior to the first clinical meeting among all practices in the study (step 1) to enable extraction of reliable information from relevant database fields.”

2. One of the secondary prescribing outcomes is mean change in blood pressure at six month intervals, but there is nothing in the protocol that states
that BP will be measured. I assume this is based on BP readings that are recorded in the record, in which case, how is it defined what counts as a six month interval? (e.g. what if the readings are 9 months apart, or 3 months?)

Each data extraction captured 24 months of GP activity in the corresponding practice. The blood pressure measurements were assumed current if recorded in the correct fields within 12 months of the data extraction at any point during the evaluation. So each extraction interval would contain data back to 24 months. Any instances of blood pressure measurement taken in that period were extracted but the most recently available in the period was used to calculate the indicator. For clarity, we have removed reference to six-month interval “Mean change in blood pressure at each interval for patients with and without co-morbidities” (page 12). We have also briefly explained this in page 13.

“The indicators were included in the study if there was evidence of their potential to improve patient care in the general practice setting, and they could be automatically extracted from general practice clinical software. Blood pressure measurements used in this study were those taken during the course of routine clinical care. All blood pressure measurements available in coded fields were retrieved at each interval but the latest available blood pressure recorded for each patient within 12 months of the data extraction was generally used to estimate the mean for the practice.”

3. Where the secondary prescribing outcomes are listed, it would be useful to refer the reader to the appendix for the description of 'prohypertensive' drug and 'drug that may exacerbate the disease' (heart failure), otherwise it is not clear what is meant.

References to Appendix 3 have now been inserted in page 12 under the relevant headings for hypertension indicator 1 and chronic heart failure indicator 2.

4. Please explain why the standard clinical outcome indicator of hospital admission for heart failure is not used in this study.

While this indicator could have been useful in measuring the impact of management, data were extracted from primary healthcare computerised systems which unfortunately are not linked to hospital admissions and do not have coded fields for hospital admission. Some records have information on referrals to hospital but this is not necessarily documented in a systematic way by GPs. To address the reviewer’s comments we have added two sentences in page 11.

“Diagnoses of hypertension and chronic heart failure were based on GP clinical decision entered in their database”. …….“The impact of the intervention is measured by two primary prescribing outcomes for each condition targeted by the intervention and five secondary prescribing outcomes relating to these two clinical topics. These were largely based on the prescribing indicators used in the feedback reports to the GPs. For details of the medicines covered see Appendix 3. Hospital admission for heart failure was not used as a clinical outcome indicator in this study because the prescribing software database does not link to the data collection for hospital admitted patients and does not contain coded fields for this information.”
5. **Worth acknowledging that with more than one primary outcome measure, the sample size really ought to be adjusted for this.**

We made calculations for several of the indicators based on the prevalence of each condition in Australian general practice. We made the final decision on the basis of the least common condition, i.e. chronic heart failure, to ensure we had sufficient power to detect any changes.

On page 14, under *sample size estimations* we have added an extra introductory sentence to clarify this: “With more than one primary outcome to be measured, the sample size required for the trial had to be powered to detect changes for the condition with lower prevalence. In Australian general practice, we applied the CHF clinical indicators as the basis of the sample size calculations (estimated prevalence: 1%-4.1% for CHF vs. 10%-44% for HT)”

**DISCRETIONARY REVISIONS**

6. **It is stated that the clinical indicators were developed in consultation with clinical experts etc. in focus groups. Is this being written up elsewhere? (in which case it would be useful to state this). The choice of clinical indicators chosen is a little idiosyncratic, and I would welcome an additional paragraph that provides the rationale for the ones that were chosen from these focus groups.**

The process of development and selection of indicators was very involved and it took six months to complete. Detailed description of the process and outcomes was the subject of a report for internal distribution only (hence no citation). We have summarized the most important aspects in page 13.

“The decision on the final indicators to be measured was made on the basis of their construct validity, face validity and operability or availability for data extraction from routine collections. Most of the suggested indicators were adopted from a previously published NPS manual¹ or NPS audits. A comprehensive review of the evidence relating to each indicator was conducted to establish construct validity. Refinement to ensure face validity was undertaken during a large workshop with GPs and other potential users. Using a simple questionnaire with a Likert scale, participants were asked to rate the accuracy of the indicators for measuring good prescribing practice, the usefulness for identifying patients receiving suboptimal treatment, and the usefulness for comparing their own prescribing practice with that of other GPs.

Final indicator definitions were decided by consensus using the above evidence during clinical reference group meetings with input from expert Australian GPs and other advisory or steering groups where necessary.”

We hope the above revisions are to your satisfaction and look forward to a rapid electronic release of the paper.

Sincerely

Margaret Williamson and co-authors