Author's response to reviews

Title: Clinically Relevant Quality Measures for Risk Factor Control in Primary Care: a retrospective cohort study

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Author's response to reviews: see over
Re: Revision of MS 2112595521121388 entitled “Clinically Relevant Quality Measures for Risk Factor Control in Primary Care: a retrospective cohort study”

Dear Prof. Giray,

Thank you for the constructive review of this manuscript and for giving us the opportunity to send a revised version of our manuscript for your consideration. We have carefully considered your comments and the good suggestions of the Reviewers to improve the manuscript. We have addressed the comments in a revised manuscript and given a point-by-point response below. All modifications are outlined below and highlighted in the manuscript Word document.

Each author has approved the revised version. We thank the Editor and the Reviewers for their comments and hope that these changes answer all the raised issues and are met by your approval. Please direct further questions or comments to Nicolas Rodondi (nicolas.rodondi@insel.ch).

Sincerely,

Nicolas Rodondi, MD, MAS
Corresponding author, contact information above
Associate Editor's comment:

Your paper was reviewed and the reviewers had several good suggestions for improvement. If you would like us to reconsider a revised version of your manuscript, please respond point-by-point to the reviewers' comments.

We thank you for your nice comment and to give us the opportunity to send a revised version of our manuscript for your journal.

Response to Reviewer #1's (Dr Asaf Bitton) comments

The paper by Weiler et al offers an interesting analysis of a retrospective cohort of 1002 patients from university-based primary care clinics in Switzerland. The authors measure proportions of patients with common chronic conditions in control, and then also add to this an assessment of whether appropriate clinical action was taken in response to the measures, and whether that resulted in potential overtreatment. They found that adding on whether clinicians responded "appropriately" to values outside the normal range significantly changed the view of whether or not clinical quality was achieved, while also not concomitantly increasing overtreatment.

1) Major Revisions:
My major feedback has to do with the overall conceptualization of the study, not its methods (which appear to be well-done). The question, to me, appears to center around the following: When evaluating quality of care for chronic conditions, should a clinician, or clinical team, get credit for trying? That may sound trite, but it is at the heart of the issue here. If, in our clinical quality measurement framework, we are looking to achieve certain thresholds of results because the epidemiological and trial data suggest better outcomes with higher levels of the population achieving those results, then then answer to this question, and the response to this study, should be negative. That is to say, it doesn't really matter, from the perspective of the end-outcome for the end-user, if the clinical team tried or took "appropriate clinical action" if the blood pressure is still 179/108mg/Hg or the LDL cholesterol is 211mg/dL because those, by and large, are dangerous values associated with harmful outcomes which the measurement system is intended to prevent, and for which the clinical team will be held accountable for not preventing.

We agree with the Reviewer that clinical studies for cardiovascular risk factors are often designed to look at thresholds. However, at the moment there is a big debate about the right threshold values at which treatment should be started and if monitoring the values is necessary, for example in hyperlipidemia (D’Agostino et al., NEJM 2014). For certain risk factors, such as dyslipidemia, trials have mainly assessed introducing a statin than reaching thresholds, as currently discussed in the new US guidelines (Stone et al., Circulation 2013). However, our concept of delivering appropriate care relies on the measurement of physician response in the face of values above normal range, because blood pressure or lipid levels of each individual patient also depend on the patient’s choices and lifestyle, that can only be influenced by the physician but not ordered. Our definition of appropriate care is not supposed to substitute for traditional and evidence-based measurements of quality of care, but to give a broader view of evidence-based care where we take into account that physicians guide patients to optimize their patients’ health more than direct it. To
give a sense of the more usual way of presenting cardiovascular risk factors, we also showed in Figure 2 the comparison between proportions of patients in control (at baseline) and proportions of patients with clinical action (in the follow-up 12 months) summing up in the term of “appropriate quality of care”.

However, if the goal of the measurement is to spur improvement and not accountability, then the allowability of the effort/other contextual explanatory factors would seem to be appropriate. This is a version of Campbell’s law, which suggests that you cannot use 1 instrument to serve 2 objectives (performance improvement and accountability) because by focusing on accountability, you corrupt the opportunity for improvement.

Thank you very much for this important point. Systematic quality monitoring is not implemented in Switzerland as opposed to many other countries. Financial incentives and annual report cards are also lacking. It has been shown that higher quality of care might be delivered when performance measures and monitoring are established (Asch et al., Ann Intern Med 2004). In our study quality monitoring was conducted only to understand where physicians might focus and improve quality of care the most, without accountability in mind. We have now cited the theory of Campbell’s law into the text (page 4, paragraph 2):

“The primary goal of new action measures is the improvement of quality of care. When focusing on accountability measures might corrupt the process of monitoring quality of care (new ref Campbell DT, Assessing the Impact of Planned Social Change The Public Affairs Center, Dartmouth College, Hanover New Hampshire, USA. December, 1976).”

What is needed, then, is a framework for understanding how and when these measures are to be used, in order to evaluate both the face validity and performance utility. If they are to be used to establish the proportion of patients at risk for a CVD event by virtue of not being in control (the true outcome here), and the clinical teams will be held accountable to that end-outcome, then it does not really matter if they took action unless it serves to reduce the proportion who are out of control. If the measure framework is intended to spur clinical performance through buy-in of the measure system and responsiveness to clinical action taken that may or may not improve the end-outcome, then it makes sense. But without a discussion of that tension, and those competing demands, it is hard to take at face level the claims made by the authors that this is inherently a better measure system and framework. The questions are: better at what, for whom, and why? Of course if you include lots of points for trying to respond to out of control values and take into view the large patient context, that will make providers look like they are "doing better" at taking care of their patients. But will that improve overall outcomes, reduce morbidity and suffering from CVD events, and reduce mortality? This study is not designed to tell us that and thus is limited.

We thank the Reviewer for these important remarks. The study is not designed to answer the questions about outcomes, morbidity and mortality reduction from CVD events or overall mortality. However, we have previously shown that treatment intensification was tightly linked to improved control of risk factor control among more than 500,000 adults with hypertension, hyperlipidemia, and/or diabetes mellitus (ref 4, Selby et al., Med Care 2009). We have now included those aspects in the limitation section (page 16, paragraph 1 and page 17, paragraph 1):
“While we have previously shown that treatment intensification was tightly linked to improved risk factor control [4], our study did not allow conclusions on morbidity or mortality of cardiovascular risk factors with regard to quality of care including action measures.”

The conclusion on pg 14 says this is a "more accurate index" but I don’t think that they have proven this contention. The authors should address head-on this philosophical and improvement challenge so that we can better understand their results and judge for ourselves whether it is, or is not, "more accurate", and if it is, what exactly it is more accurate at doing.

We adapted the conclusion and included the aspects above (page 17, paragraph 2):

“In summary, evaluating whether physicians in university primary care settings respond appropriately to poor risk factor control, in addition to proportions of patients with controlled risk factors, might provide a more clinically relevant index of quality. This might result in a broader view of the quality of care than relying solely on measures of proportions in control.”

2) Another major limitation is the exclusion of diabetic patients on insulin. These patients represent a major area of improvement (or lack thereof) and are vulnerable to clinical inertia. The authors need to better address why they excluded them.

We agree that it is a major limitation regarding diabetic patients. As patients already treated with insulin therapy had regular adjustments in insulin dosage, sometimes day-to-day adjustments, such data could not be reliably identified in the medical charts that were reviewed retrospectively (no electronic records available in these settings). Therefore, patients using insulin were excluded from the analysis of therapy modifications (page 6, line 7-8) as now better explained in the methods (page 7, 1st paragraph) and the limitation section (page 16, paragraph 2):

“Fourth, for diabetes mellitus, our measure of physician response was not applicable to patients with insulin treatment as data on day-to-day adjustments of dosages were not reliably recorded.”

3) Finally, the authors need to address on pg 9/10 the statements on how they new patients with hypertension were less likely to receive appropriate clinical action when they had other chronic co-morbidities, and how they knew diabetic patients were not more likely to receive appropriate clinical action in response to elevated A1c levels. Were these univariate correlations or multivariate models? I think they were the latter based on the tables, so it should be more clearly specified.

As suggested by the Reviewer, we have clarified that patients with hypertension were less likely to receive appropriate care at 6 months using multivariable analyses, when they suffered simultaneously from dyslipidemia or diabetes (OR 0.65 and 0.26, with increase in number of co-morbidity by 1 p for trend <0.01). Because data for 6 months were not shown, we deleted this sentence from Page 12, paragraph 1. Hypertensive patients with target organ damage were not more likely to receive appropriate clinical action in
contrast to patients with dyslipidemia at 6 and at 12 months. We clarified this on page 12, paragraph 1):

“Hypertensive patients with CAD or target organ damage were not more likely to receive appropriate clinical action in response to elevated blood pressure, than those without these conditions using multivariable analyses.”

4) Minor revisions:
pg 3: "among other differences" -- add "from US"
   As requested, we have added “from the US” (page 5, line 2)

pg 8: typo on sentence with "52-55% of patients"
   We corrected the typo (page 10).

Quality of written English: Acceptable

Response to Reviewer #2’s (Dr Lipika Samal) comments

1) The authors state the outcomes measures reported in this paper are superior to traditional outcome measures. They must support this point with data. They cannot say “we found that measuring proportions in control without evaluating whether physicians respond appropriately to poor risk factor control largely underestimated quality of care,” without proving the superiority. In other words, do these outcomes correlate with morbidity and mortality for individual patients and why should they replace current measures when considering the care provided by a physician to a population of patients?

We thank the Reviewer for this important remark on the study design. Our definition of Appropriate Quality of Care comprised the proportions of patients “in control” (defined as baseline control) and those for whom the physicians took “appropriate action measure” (defined as clinical action within 12 months, such as increase of dose, substances, etc.). We suggest that this definition gives a broader view on quality of care provided by physicians instead of the usual way of collecting the proportion of patients in control that does not take into account the situation where physicians have tried to guide their patients in the direction of better health decisions but without success, for example because of lack of adherence of the patients, as explained in our response to reviewer 1’s comment 1. We have also now acknowledged that we have previously shown that treatment intensification was tightly linked to improved control of risk factor control among more than 500,000 adults with hypertension, hyperlipidemia, and/or diabetes mellitus (ref 6, Selby et al., Med Care, 2009), but such measures have not been proven to improve morbidity and mortality yet, as now acknowledged in the limitations (response to reviewer 1’s comment 1).

We agree with the Reviewer that our study design and data cannot prove whether our definition is superior. We have therefore modified the discussion (page 15, paragraph 1):

“Simply assessing measures of cardiovascular risk factor control without action measures largely minimizes the quality of care provided by physicians and other healthcare providers. We suggest that assessment of quality of care assessment can be improved by
including of measures of therapy intensification and physician action in the face of uncontrolled values.”

2) **The abstract does not sufficiently explain the rationale for or methods of the study.**

Data are predominantly available for quality measurement and measurement of potential overtreatment in countries with quality monitoring. However no such systematic measurement schemes exist in Switzerland and most countries in Continental Europe. We added the rationale in the abstract (page 2, paragraph 1):

“Therefore we assessed physician response to control cardiovascular risk factors, as well as markers of potential overtreatment in Switzerland, a country with universal healthcare coverage but without systematic quality monitoring, annual report cards on quality of care or financial incentives to improve quality.”

3) **The definition of “appropriate clinical action” is subjective. The component parts should be examined separately, as this is a composite endpoint.**

Although our definition of “appropriate clinical action” might seem subjective, it was predefined in our protocol based on our previous publication (ref 5, Rodondi et al, Ann Intern Med 2006). However, we agree that it is important to provide the component parts of “appropriate clinical action” to the readers, as we have provided in Table 3. We could not assess the predictors of each component part, because the number of patients was too low for multivariate analyses, as we have now added to the limitations (page 15, paragraph 1):

“Lastly, we could not assess the predictors of each component of appropriate clinical action, because the sample size was too small for multivariate analyses.”

For example in poorly controlled diabetes, the total number of patients receiving appropriate clinical action at 12 months was 50.

4) **The authors state, “To our knowledge, this is the first study to document appropriate physician response to poor control of cardiovascular risk factors and potential overtreatment in a country without systematic quality monitoring.”**

Systematic quality monitoring is widely used in the US and in the UK (Fortin et al., BMC Health Serv Res 2010). We have now clarified the sentence on page 13, paragraph 2):

“To our knowledge, this is the first study in a country without systematic quality monitoring, to document appropriate physician response to poor control of cardiovascular risk factors and potential overtreatment.”

5) **The Methods section states facts about the Population in the section on Measures. Also, covariates section is disorganized and does not explain why these are being entertained as potential confounders.**
As suggested, we have fully reorganized the method section, following the suggestions of the reviewer. We have harmonized the sections by changing location of the respective parts (page 5, paragraph 3 until page 9).

6) The Results section is missing the results of the multivariate analysis.

The multivariable analysis from table 4 is now highlighted in the results with a clearer subsection title (page 11, paragraph 3):

“Multivariable Analysis of Factors Associated with Appropriate Clinical Action”

7) The Results section should clearly report the traditional quality measures, then the new outcome measures, then the Discussion should compare the two. “Suboptimal care for poorly controlled cardiovascular risk factors was provided to 15% to 62% of patients at 12 months in our study,” should come near the beginning of the Discussion section.

We agree with the Reviewer. We reorganized the result section by first reporting traditional quality measures (patients in control) (page 10, line 7-9), second appropriate clinical action measures in patients with poor control (page 10, line 12-17), and the sum of both two proportions (page 10, line 12-17). The mentioned section on suboptimal care was moved to the beginning of the Discussion (page 13, paragraph 1).

8) Table 3 seemed out of place. Please explain why it is necessary.

Table 3 gives one of the key information on the number of patients with appropriate clinical action and inappropriate clinical action, including the component parts as you suggested in your comment 3. Reporting parts of the composite outcome is suggested in reporting guidelines (STROBE Statement: STrengthening the Reporting of OBservational studies in Epidemiology. March 30, 2008. Available at: http://www.strobe-statement.org/News%20Archive.html) to help the reader understand what part contributed the most to the composite outcome. We have placed this table 3 before table 4 in which we described the factors associated with “appropriate clinical action”.

9) Figures 1 and 2 are not necessary. Appendix Table 1 is okay but the rest is not necessary.

As suggested, we have removed Figure 1 as Appendix Table 2 in order to reduce the number of figures due to space constraints for all journals. As suggested, we have replaced Appendix Table 1 by the appropriate citation (ref. 5).

Although information in Figure 2 (now Figure 1) can be gathered from other parts of the manuscript and tables, it is a straightforward and visual way to understand the concepts of patients in control (at baseline) and patients for whom clinical action was undertaken (in the follow up). The visual approach might also be more attractive for potential readers than reading the numbers from the text or a large table. If the Editor and the Reviewers feel that it does not belong in the main manuscript, this Figure could be provided as an online appendix figure.
10) Minor Essential Revisions

The Introduction and Discussion both need to be better organized. Also, there are incorrect prepositions used in several places.

Quality of written English: Needs some language corrections before being published

In addition to our response to your comments 5 and 7, the introduction and discussion sections were also restructured as requested. We would like to thank Dr Clara Podmore, MD, MPhil (MRC Epidemiology Unit, University of Cambridge, Cambridge, UK, funded by the Wellcome Trust) for editing the manuscript – as indicated in the acknowledgement section. She checked the full manuscript for English improving the manuscript. We have removed incorrect prepositions used in several places.

All changes are highlighted in the revised manuscript.