Author's response to reviews

Title: Do inter-hospital comparisons of in-hospital, acute myocardial infarction case-fatality rates serve the purpose of fostering quality improvement? An evaluative study.

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Author's response to reviews: see over
Dear editor,

Herewith we submit the revised manuscript entitled “Are in-hospital acute myocardial infarction case-fatality rates useful as a quality indicator? An evaluative study.”

Taking into account the remarks by the reviewers numerous changes have been made.

We give here the main of them:
1) The title has been changed, in line with the reviewer’s comments, into “Do inter-hospital comparisons of in-hospital, acute myocardial infarction case-fatality rates serve the purpose of fostering quality improvement? An evaluative study.”.
2) Abstract: less emphasis is laid upon the lack of accuracy and of completeness of the data and more on the quality-improvement “environment” in which the in-hospital acute myocardial infarction case-fatality rate has been implemented. We also provide some of the main results.
3) In the Background a paragraph has been devoted to the concept of accountability and how the indicator fits into it. Also a brief description of the Belgian context is given and the aims of the study accordingly have been revised.
4) In the Methods section and in line with the reviewers comments, the paragraph about the MONICA project has been revised and included in the “data source” subsection, a subsection “Definition of the study population” has been added, the subsection design has been revised, subsections “Statistical methods” and “Feedbacks” have been added.
5) A sentence regarding the approval for the use of the data used in this study is added: “The study being (1) of a retrospective, non-interventional type and (2) anonymous with respect to both hospitals and patients, no approval by an ethics committee is required under the Belgian law.”
6) The Results section has profoundly be reorganized:
6.1 In the subsection “Patient and hospital characteristics by level of care” an extension of the statistical testing has been carried out
6.2 The section “Completeness and accuracy of the data” has been renamed “Comparison between MCD and MONICA” because some elements of the analysis of the MCD data are related to these topics. Data about PTCA and old myocardial infarction have been added into the comparison.
7) The discussion section has been subdivided into sections “Data quality of the MCD”, “Statistical modeling” (a completely new subsection), “Inter-hospital comparison” and “Quality improvement” (a completely new subsection).

Point-by-point response to the concerns:

1. Reviewer E. DeLongh

However, as currently written, the manuscript lacks sufficient detail and some of the presentation is confusing at times. For example, the MONICA study is referenced as a registry, and diagnostic criteria are given, but there is no description regarding the richness of the database.
We have reformulated the section on the MONICA study lines 174 to 205 and adopted the MONICA nomenclature as provided in the literature. We also give an overview about the richness of the MONICA database.

It would have been good for the authors to indicate briefly how well actual baseline covariates are captured in the MONICA registry. One might have expected the authors to approach the issue of confounding through a statistical model that adjusts for the covariates in the MONICA database and then comparing to the results obtained from the discharge database. However, it is not clear whether sufficient detail is included in the MONICA registry.

As explained on lines 202-205, due to privacy regulations and agreement with the registering hospitals we were not able to compare the MONICA database and the MCD neither on individual level nor on hospital level. Further, the common variables between MONICA database and MCD are very few and consist of cases, fatalities, age groups and gender, PTCA and whether it was a first or recurrent event. Due to the small numbers of observations, which would lead to too large confidence intervals around the estimators, the untraceable differences in numerator and denominator of the AMI-CFR in both datasets and the relative paucity of the clinical details in the MONICA database, we confined ourselves to compare the number of occurrences and fatalities in both databases.

Although this reviewer may be misinterpreting the methods, which need more specific explanation, it appears that the authors are arbitrarily designating an interval around 1.0 for a risk “departure” (the calculation of RR is referenced in a medical journal but not explained) that should not be interpreted and otherwise simply using the significance of a crude risk ratio as strong, moderate, or weak, evidence of superior or inferior quality. The rationale for this interval is unclear.

In the section “Design” (lines 229 to 246) the rationale of the interval around 1.0 is further explained and has been reformulated as the “inconclusive zone” instead of the “zone of non-interpretation”. The RR is explained on lines 236-238 and its computation is given in the section of the “statistical methods” (lines 270-302).

Additionally, the aim to assess the completeness and accuracy of discharge records seems to be relatively superficially approached. There appears to be no patient-specific matching of data, or even of numbers of patients recorded by the two datasets for each hospital.

We acknowledge the superficial character of our assessment. However, as explained on lines 203-25, due to privacy regulations and agreement with the registering hospitals we were not able to compare the MONICA database and the MCD neither on individual level nor on hospital level. In addition to the first submission we now provide data regarding the carrying out of PTCA and whether it was a first or recurrent event (lines 436-450). We provided additional elements of weaknesses in the data quality in the
sensitivity and transfer analyses. Finally we devoted the first subsection of the Discussion to the “Data quality of the MCD”.

Minor comments:
p. 5, bottom of page and p. 6, top of page: The text here implies that the distinction between STEMI and non-STEMI was not available during the period of this study, but the manuscript includes these in Table 1. This paragraph is confusing.

This paragraph has been reformulated as follows:” At the time the study data were registered and coded by the hospitals, the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) did not distinguish between STEMI and NSTEMI, but as from October 2005 new ICD-9-CM regulations provide guidance to do so[21]. Herein STEMI is coded as 410.0-6, 410.8; NSTEMI as 410.7; and AMI “Not Otherwise Specified” (AMI-NOS) as 410.9. It became then possible for one of the authors (NT) to recode a posteriori the data in terms of STEMI or NSTEMI. ”

p. 7: This paragraph claims that the study will assess the completeness and accuracy of discharge records, but hasn’t yet introduced the other dataset against which the comparison will be made leaving the reader to wonder how this task will be accomplished.

This paragraph has been transformed into “In this study we explore the AMI-CFRs’ potential as a quality-improving tool. More precisely we aimed (1) to evaluate to which extent Belgian discharge records allow the assessment of quality of care in the field of AMI, (2) to determine the existence of inter-hospital differences in AMI-CFR and (3) to compare outcomes according to type of hospital.” We now introduced the datasets against which the MCD are compared in the Methods section and state that the MONICA registries are considered the standard against which the MCD are judged.

p. 10: The calculation of the RR might have been briefly described, rather than referencing a journal article.

The calculation of RR is given in the section of the “statistical methods” (pages 13-14).

p. 10: Presumably part of this effort is to promote quality improvement; excluding transfers out from analyses would seem to defeat the purpose, as it would encourage hospitals to transfer out patients about to die. This concern has been taken into account regarding the hospitals in which those patients are “transferred in”. On lines 294-297 we introduce the two types of analysis: “a first one wherein transferred-out cases were excluded and a second one with exclusion of all transferred cases.” In the discussion section (lines 618-624) we give the rationale of this double approach, and on line 655 we argue “Finally, our analyses revealed important inter-hospital
differences in medical practices but do not seem to indicate a systematic, early discharge practice of “patients about to die” in any hospital, intended to diminish its AMI-CFR. Also, the AMI-CFR of the hospital, admitting transferred out patients, seems to be protected to a certain extent by the modeling of shock, age group, gender and co-morbidity of this type of patients. “

Results section: It is not clear which dataset is being referenced in much of what appears in this section. This section is now introduced with the wording “The MCD dataset…” (line 377), we also changed our text accordingly in the transfer section line 452

P. 13, reference to Table 2: This reviewer could not find the “54 out of the 190” cases in the Monica registry. Table 2 now includes these cases in the column labeled “<1h”

Table 1: The table lists case fatality rates for males and for those with shock; for completeness, these rates for females and non-shock patients should be given. Also, hospital volumes are not mentioned, while CCI and LOS don’t present much information and could be relegated to the te
Table 1 has accordingly been revised

2. Reviewer Kuo-Piao Chung

It is an interesting article regarding AMI case-fatality rates. However, there are three major and three minor concerns as well as optional comments for the manuscript.

Major concerns

1. The title of the manuscript was not fitted well with four research aims and overall text. Do you intend to argue that in-hospital AMI-CFR is not a good quality indicator, but intermediate outcome of death within 28 days by empirical data instead? Is your focus on data quality for AMI-CFR hospital comparison? Please try to align your title, specific aims as well as overall text. For example, “Screening of hospital quality of care by using different data sources for AMI-CFR. “

We intend to examine to which extent an internationally used quality indicator indeed may foster quality initiatives in a local context and if it an inter-hospital comparison really enables to assess the quality of AMI care. Therefore, the title has been changed into “Do inter-hospital comparisons of in-hospital, acute myocardial infarction case-fatality rates serve the purpose of fostering quality improvement? An evaluative study.”
We further reformulated our study aims as follows: “In this study we explore the AMI-CFRs’ potential as a quality-improving tool. More precisely we aimed, by determining the existence of inter-hospital differences in AMI-CFR, (1) to evaluate to which extent
Belgian discharge records allow the assessment of quality of care in the field of AMI, and (2) to identify starting points for quality improvement. “

2. The research questions are not well specified in background which could impact on the significance or contributions of this article. The gap of knowledge or research focus should be specified more concrete. If AMI-CFR was a well-established indicator, what else can be added for your study? It is not possible to support a quality indicator by data-driven only if data quality was still an issue. The evidence-based medicine and clinical practice guideline should be the rationales behind. Data can show the existence of variation which might be evident for improvement in the future.

In the first paragraph we state the importance of the guidelines and of report cards (lines 77-79) in attempts to reduce AMI-CFRs and have thoroughly revised the discussion, introducing a section on Quality Improvement, mentioning the importance of EBM in quality issues (lines 672-674). We devote now a paragraph to the concept of accountability and public reporting of comparative information as quality improving tools, provided the data are qualitatively sufficiently good (lines 126 to 133). We further devote a paragraph to the Belgian context (lines 135-141), introducing the research questions.

3. On page 7, the second aim needs to be elaborated. Do you mean “its” by data (hospital discharge records) or by indicator (AMI-CFR)?

We reformulated our study aims as follows: “In this study we explore the AMI-CFRs’ potential as a quality-improving tool. More precisely we aimed, by determining the existence of inter-hospital differences in AMI-CFR, (1) to evaluate to which extent Belgian discharge records allow the assessment of quality of care in the field of AMI, and (2) to identify starting points for quality improvement. ”

The result of table (table 2) and explanations were not clear enough to provide evidence for assessing the completeness and accuracy of Belgian discharge records. There is no standard for comparison, no test statistics, nor did the data provide information directly.

Those research aims need to be considered once again.
The table has been revised. The standard for comparison has been defined to be MONICA, stated explicitly on lines 189-190. Test statistics are provided on lines 423-434. We further provided comparative data regarding “old myocardial infarction” and PTCA (lines 436 to 450) showing significant - we computed 95% confidence intervals around a single proportion - differences in completeness and accuracy between MONICA and MCD.
The transfer issue as well as the sensitivity analyses point in that same direction of lack of completeness and of accuracy.
Minor concerns

1. Using CCI as a variable for risk adjustment was not good enough. It considers not severity of disease, but comorbidity instead. Please add or discuss it into the limitation part or provide discussion in manuscript.

We clarified this issue as follows: “…we carried out two types of main analyses: a first one wherein transferred-out cases were excluded and a second one with exclusion of all transferred cases. In each analysis, adjustment was made for five-year age groups, gender, per-semester evolution of the AMI-CFRs, and shock.” (see lines 294-297)

We further discuss our risk-adjustment and provide the C-index of our models, which are very comparable to those of a study evaluating five risk scores. (see lines 586-593)

2. Definition of AMI-CFR on Page 6, 2nd paragraph was inconsistent with page 9, 1st paragraph. Please modify your wording to avoid confusion.

We extended page 9 1st paragraph as follows:” In the framework of routine analyses of the MCD, for reasons of monitoring over the years, and to comply with the OECD requirements, we preferred to stay in line with the AHRQ model, adopted by the OECD, recognizing the difference in definition of in hospital AMI-CFR between MCD and MONICA. However in Belgium, this difference leads to the very small 0.5% difference in AMI-CFR[1]. ” (see lines 197-203)

3. Please provide note or change the table contents for “No transfer out” and “No transfer” into “Exclude transfer our”, “Exclude all transfers”. In addition, the meaning of “departure” was not self-evident in table.

“No transfer” has been changed in “Exclude all transfers”

4. Please specify your definition of AMI-CFR with numerator (F1 or F1 + F2) and denominator (F1 + F2 + NF1, F1+F2+NF1+NF2). Do you calculate more than one kind of definition?

This definition has now been specified as follows “For the years 2002-2004 and for the age groups between 25 and 74 years, we compared the MONICA hospitalized fatalities (fatal definite (F1) + fatal possible (F2)), the numerator of the AMI-CFR, and MONICA hospitalized cases (non-fatal “definite” (NFl) + “possible” (NF2) + fatal “definite” (F1) + “possible” (F2)), the denominator of the AMI-CFR, with respectively the AMI fatalities and cases in the same age groups of the MCD.” (Lines 191-196) The variable providing the degree of certitude of a diagnostic being badly filled out in the MCD, we were able to calculate only this kind of definition.

Discretionary comments

1. Indicator development from data-driven is possible, but not popular. Expert consensus combine with evidence or guideline, such as Modified Delphi Technique, is popularly adopted.

Our intention was not to develop an indicator but to apply and evaluate the use of an elsewhere developed and internationally applied indicator into the Belgian situation.

We recognize and explicitly refer to EBM as a necessity in indicator development (lines 672-674 and 695-697)

2. The reference in manuscript could be updated a little bit if possible. More
newly articles could add values to this manuscript. We updated the manuscript with more recent articles (7 articles of the years 2008 to 2010) and further provided articles underpinning statements regarding accountability, public reporting and statistical methods [1-22]:

Added References


