Author's response to reviews

Title: Development and feasibility of a set of quality indicators relative to the timeliness and organisation of breast cancer care

Authors:

Marie Ferrua (marie.ferrua@igr.fr)
Melanie Couralet (melanie.couralet@igr.fr)
Gerard M Nitenberg (gerard.nitenberg@igr.fr)
Sandrine Morin (s.morin@has-sante.fr)
Daniel Serin (d.serin@isc84.org)
Etienne Minvielle (etienne.minvielle@igr.fr)

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Author's response to reviews: see over
Dear Dr Harold,

Thank you very much for your reply to the above submission. We thank both reviewers for their most helpful comments and suggestions which have been taken into account in the revised version of the manuscript. The requested changes have substantially improved the manuscript. Replies to each individual comment are given below.

We trust that this revised manuscript is now suitable for publication in BMC Health Services Research and look forward to hearing from you at your earliest convenience.

One major point suggested by both referees was to precise the number of French hospitals that were approached in our study, their case volume distribution, the presence of any cut-off and the number of non-responding hospitals. This important point has been now addressed and clearly improves the context of our study.

One other major point was suggested by G. De Bock was to discuss the content of the QIs in relation to European QIs. We have now taken this point into account, with many examples in the european (NICE, Eusoma, Duth) and US literature, with the limitations about the comparisons that could be made, the different cut-offs proposed and the potential link of the results with an accreditation process.

Yours sincerely,

Gérard Nitenberg, M.D.

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Reply to comments of Reviewer #1: Geertruida De Bock

1. I would prefer to add the patient category to the study question, i.e. “new patients with infiltrating, non-inflammatory and metastasis-free breast cancer undergoing surgery within the institution”, because this is an important focus in this question.

As suggested, we have specified the patient category in the study question (title, abstract and introduction).

2. I miss the number of French hospitals that were approached in this study and an estimate of the number of non-responding hospitals.
The main aim of this study is to assess the validity of the eight proposed QIs. As the authors define, validity is that the QI really measured what it was intended to measure both from qualitative and quantitative points of view. The measure for validity is concordance, suggesting the authors limit validity to internal validity. Given the study question, I would expect an indication of the external validity.

In the revised version of the manuscript, we have specified the number of hospitals that were approached, the number of non-responding hospitals, and the method of selection of hospitals and medical records for analysis. We have added a flowchart (Fig. 2) which gives hospital and medical record numbers from the time of the invitation to participate to inclusion and analysis.

External validity is usually considered relevant to outcome studies. We have provided reasons why we consider the external validity of our study satisfactory in a new paragraph in the discussion section.

3. The mean and SD in table 2 are difficult to understand. What is a mean score%? What is the unit? E.g. days?? The number of hospitals included esp. for Q3 and Q4 is rather low. What does that mean for the indicator?

There was a misunderstanding about this Table. Table 2 gives, for each QI, the number of hospitals included in the analysis (those with >30 available medical records), a conformity score, i.e. the mean percentage of patients with medical records that met the criteria given in Table 1, and a measure of discriminatory power (Gini coefficient).

The number and percentage of missing data have been added to the Results section. These data explain why relatively few hospitals were included in the analysis for QIs 3 and 4.

4. I miss a discussion of the content of these QIs in relation to European QIs.  
- What are the topics of QI in other countries and how does these topics related to the here presented QIs. This can be done for the NICE guidelines but also for EUSOMA guidelines.
- In a second part of the discussion the contents of the different QIs can be compared and discussed. In the Netherlands there are cut-offs for waiting times. When these are applied here, what can be concluded? Are the results from France different? The same can be done regarding the EUSOMA guidelines.
- Maybe it can be mentioned how much hospitals can could serve as a EUSOMA qualified hospital based on their scores.
- I miss a discussion on the number of hospitals that could not be included in the analysis due to low numbers of completed grids / patients.
- Further, what are / should be the implications for the hospitals of their own results?

This important and stimulating point has been now addressed and clearly improves the soundness of our results. We agree with the reviewer that the manuscript did not pay sufficient heed to the European context.

- We have alluded in the introduction and discussion to the QIs used for evaluating the quality of breast cancer care in several countries or that are advocated in European or US guidelines. Our paper focusses on the timeliness of care. We mention these QIs in the introduction and address them more fully in the discussion (e.g. UK, Netherlands). However, the different definitions used for timeliness make comparisons between our data and published data difficult.
- We discuss cut-offs for waiting times and delays. Cut-offs have not yet been introduced by the French Health Authorities but we show that there is room for improvement in France if cut-offs were used.
- We cannot calculate how many hospitals might be EUSOMA qualified hospitals based on their scores but, in the revised version of the manuscript, we mention certification of breast cancer centres (the NQMBC approach).

- The reasons for the low numbers of hospitals included in the analysis for the different QIs are now clearly explained, and the consequences analysed in the first paragraph of the discussion.

- The potential use of the comparison of results by the hospitals for their own quality improvement actions is now briefly discussed.

5. I miss a mentioning of the patient group. I miss the European context.
In the revised manuscript, the patient subgroup is given in the title, abstract and introduction. The European context is discussed at some length (see answer to point 4 above).

Reply to comments of Reviewer #2: Maria Piera Mano

1. Methods are not described in sufficient detail. For example:
   - How many hospitals received the initial approach by the study? Is their case volume distribution known? (any volume cut-off?)
   - Please provide as additional material the explanatory guide and the grid.
   - Please provide a flow chart describing the number of hospitals initially approached, compliance, exclusions (at least 30 records?).
   - Please state clearly from which number of hospitals as above described you obtained the 5215 records you started with.
   - At which stage was the 30 records criteria applied?

The revised manuscript gives all the information requested:
- The mode of selection of the participating hospitals is explained in the methods section and numbers of participating and non-responding hospitals are given in the results section. All hospitals except one complied with the minimum threshold of activity (> 30 breast cancer surgeries/year) required by the French health authorities to perform cancer surgery. This information has been added to the manuscript.
- The explanatory guide and grid are available (in French) on our website: http://www.compaghpst.fr/data/indicateurs/12_GYC_V2_Grille_de_recueil_images.pdf. This is mentioned in the manuscript.
- As requested, a flowchart (Fig. 2) giving hospital and medical record numbers is now provided. How the 5215 records were obtained is explained in the text.
- The criterion of 30 records was applied to the selection of hospitals (to be selected a hospital had to have at least 30 records for at least one QI) and, for each QI, only those hospitals were compared that had at least 30 medical records for that QI.

2. Please provide in greater detail the results of the two preliminary tests
In fact, there was one preliminary test carried out in 23 hospitals. Its objective was to assess QI feasibility. The second test assessed QI performance in a much larger panel of hospitals and compared hospitals. As requested, we have provided the available information on the results of the preliminary (feasibility) test.

3. Results: the management of missing values should be described and they should be reported.

The numbers and percentages of missing data have been added to the results section. Depending upon the QI, from 6 to 21 hospitals did not reach the threshold of at least 30 medical records to be included in the hospital comparisons (see flowchart in Figure 2). For some QIs (e.g. QI 4 and QI 5), relatively few hospitals could be included.
4. Discussion: the authors should provide brief comments on results from each of the 8 indicators. Q1 proved unfeasible because of problems in interpretation. Why not also Q2 which uses the same critical date (first appointment with surgeon)?

The discussion of the revised manuscript starts with a brief summary of the results for the 8 QIs, mainly related to the missing values, and their consequences for nationwide generalisation.

We have corrected the misunderstanding over QIs 1 and 2. These two QIs do not refer to the same item and same data.

- QI 1 was subject to misinterpretation because hospitals put a different interpretation on “time to first appointment”. In some hospitals, it was the date the patient’s medical record was created. In others, it was the date when the patient called for an appointment or the date of the GP’s letter requesting an appointment for the patient.
- QI 2 was subject to misinterpretation because it was not clear whether it referred to (i) the appointment when the decision to perform surgery was taken or (ii) to the appointment when the surgeon diagnosed suspected cancer and ordered tests before deciding to operate. After the final test and before generalisation of QI 2, we opted for option (i).