Author's response to reviews

Title: Minimum volume standards in German hospitals. Do they get along with procedure centralization? A retrospective longitudinal data analysis.

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Author's response to reviews: see over
Minimum volume standards in German hospitals. Do they get along with procedure centralization? A retrospective longitudinal data analysis.

Dear Editorial Team,

Dear Mr Morrey and Mr Lambert,

Dear Mr Giray

Thank you for the opportunity to revise our manuscript. We would like to thank especially for the reviewers’ encouraging and challenging comments and suggestions. We have now incorporated the recommendations into our manuscript as far as possible.

We address their questions and suggestions quoting them in their stated order in their reviews. To contrast the quotes from our answers the reviewers’ comments are in italic type.
Referring to Mr Nobilio’s comments:

à I suggest just to try, where possible, to synthesize the text “discussion” to make it shorter.

We condensed the discussion following this discreet hint and considering Mr Böhler’s comment.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

à Pag 8, line 23: enter (table 2) after “For pancreatic intervention...”

We added the corresponding table numbers in this section.

à Pag 8, line 25 to page 9 line 1: seems to be inverted the numbering of the quintiles compared to the labels in the table 2. Indicate correctly if on 1st quintile (“Quintil 1 hospitals” in table 2) are hospitals with higher volume, obviously) instead, hospitals with lower volume correspond to “Quintil 5” in table 2...and so on also in the description of 2nd and 4th quintiles. In the text is contrary described.

Indeed, the quintile numbers were inverted which are corrected now.

à Pag 9, line 2: enter (table 3) after “For esophageal interventions...” à Pag 9, line 4: enter (table 4) after “Knee TEP interventions...”

We added the corresponding table numbers in this section.

à Pag 9, line 5: enter (tables 5, 6, 7) after “For all three transplantions procedures...”

We added the corresponding table numbers in this section.
Referring to Mrs Stitzenberg’s comments:

This manuscript is well-written and examines the patterns of care for complex surgical procedures in Germany from 2006-2010. In contrast to other countries, such as the United States, there was more regionalization of procedures in Germany, even prior to the institution of federal volume benchmarks in 2004. This is likely in part why the authors have found essentially no changes over time. It is of course interesting to note that the central government standards appeared to have no effect on actual practice. However, if there was any way the authors could examine more closely the cases that are performed at hospitals that do not meet benchmark standards, that would help us understand whether there is actually still room for improvement or whether there is a certain proportion of cases that simply cannot be regionalized for one reason or another. If there is still room for improvement, then examining those outlier cases could potentially identify targets or strategies for bringing all patients/hospitals into compliance.

Mrs Stitzenberg raises a crucial question by pointing out to study the cases in hospitals not complying with the minimum volume standards. The data available in the quality reports do not comprise individual clinical information at all. For some of the interventions with minimum volume standards hospital specific data on clinical quality indicators such as mortality or complication rates are being published starting with data for some quality indicators from 2010 on and will be available with the quality reports in more detail in the next years allowing to evaluate the quality in these hospitals.
Referring to Mr Böhler’s comments:

1. General Remarks

In the manuscript assessed for review, Werner de Cruppé and colleagues convincingly show that between the years 2006 and 2010 the introduction of nationally concordated minimum volume standards for hospitals in Germany did not lead to an increasing centralisation of the relevant interventions (i.e., transplantations of kidney, liver, and hematopoietic stem cells, total knee replacements, complex surgical interventions on the esophagus and the pancreas).

Application of minimum volume standards to health care planning and allocation is a matter of controversy in Germany and its effects are subject to scientific research in industrialised countries all over the world. It appears, however, rather difficult to prove the hypothesis underlying the introduction of minimum volume standards, i.e., that due to continuous practice medical doctors and interdisciplinary teams operating above the minimum volume limits are better trained, deliver better medical care, and reach better outcomes for their patients.

In a previous paper [Dtsch Arztebl Int 111:549-55] the authors came to the conclusion that “establishment of minimum caseload requirements in Germany in 2004 did not lessen the number of cases performed in violation of these requirements over the period 2004 to 2010”. Data presented in the manuscript under review corroborate this conclusion; the paper thus makes a significant contribution to the current discussion in Germany.

In the past, some of the authors have received research grants from the German Federal Joint-Committee and/or the Federal Ministry of Health in order to evaluate the effect of the introduction of minimum volume standards in German hospitals. The group has regularly published its results both internationally [e.g., BMC Health Services Research 2007; 7:165; DOI:10.1186/1472-6963-7-165 or Dtsch Arztebl Int 2008; 105:890-6; DOI: 10.3238/arztebl.2008.0890] and nationally [e.g., Gesundheitswesen 2008; 70:9-17 and 209-218; 2010; 72:271-8]. If baseline data presented in the manuscript under review stem from these studies, it may be appropriate to acknowledge these grants (discretionary revision; 1.1).
This study does not use any of the data made available by a grant from the Federal Joint Committee of the joint self-governing body of the German health care system for the accompanying research on minimum volume standards in 2006. For that research only quality report data from 2004 were available and used. The present study only uses data from the quality reports 2006, 2008 and 2010.

The present version of the manuscript may, however, not be easily understood by a reader who is not familiar with the organisation of the health care system in Germany. Although some of the topics listed below are covered in the authors' previous publications, the information is important for the reader and should be given in a concise way in the manuscript.

This note refers to being aware of the different knowledge international and German readers might have in understanding the subject. We do think to consider this aspect appropriately and see the absence of any such suggestion by both international reviewers as encouraging having met this advice.

The following suggestions for revision are given:

2. Background

Major compulsory revision:

2.1 The manuscript adds additional information to the authors' recent publication in August 2014 [Dtsch Arztebl Int 111:549-55; DOI: 10.3238/arztebl.2014.0549]; this publication should be mentioned and discussed in the manuscript in order to avoid any doubts regarding the possibility of duplicate publication.

We address this point at the end of the background section quoting our former publications on the subject and naming the different foci of the research questions:

In a preliminary evaluation of the consequences of the introduction of minimum volumes in German hospitals the authors reported earlier how many German hospitals performed the 5 procedures stipulated for 2004, how many complied with minimum volume standards, and indicated possible implications for geographically equal access to health care if all non-complying hospitals were excluded [46-49]. In 2014 the authors published a study updating the results on the research question how many hospitals complied with the minimum volume standards in each of the until then available hospital quality report data sets for the years
2004, 2006, 2008 and 2010 [50]. They could show that the number of hospitals not meeting the standard did not change over the years under study. The present study, however, focuses not only on the number of hospitals not complying versus those complying with the standards but investigates the research question if from a health care system’s perspective a centralization occurred over the time period from 2006 to 2010 with constant minimum volume standards (table 1).

Minor essential revision:

2.2 The part on the local follow-up study on breast cancer care in one of Germany’s federal states could be skipped.

We removed this passage and mention it only in the discussion as an example of a successful centralization.

3. Methods

Major compulsory revision:

3.1 The authors should use their data set for an additional analysis of inter-quantile changes of a given provider over years. How many providers have changed their ranking from the quantile of lower to higher case volumes and vice-versa between 2006 and 2010? How many providers did not change their ranking? These data could be used to assess the somehow unavoidable "decentralisation" that occurs in a dynamic health care system where providers may continuously "step in" (starting new activities), "stop", or "fade out" (cessation of activities).

This suggestion addresses a new research question. What are the dynamics of individual hospital volumes over the course of time? The present study focuses on centralization from a system perspective as stated at the end of the background section. Methodologically the analysis of the dynamic individual hospital perspective would be a time series analysis on the individual hospital level requiring a data linkage between the separate single reporting year data sets (2006, 2008, 2010). The single data set of each reporting year made available from the Federal Joint Committee does not provide a sound linkage mechanism as it does not account for hospital mergers and changing institution numbers. We agree that this research question is of great importance to evaluate the minimum volume regulation and its
further designing. We indeed started to address this research question in an article in press in the German speaking journal “Zentralblatt für Chirurgie” focusing once more on hospitals not complying with the minimum volume standards over the years. The results show that alongside hospitals constantly complying and those constantly not complying a third category of “changer” is of practical interest applying the respective regulations.

We had already addressed this point in our limitations. We added in the limitation section at the end of the discussion:

… The study does not investigate the temporal, intrahospital volume progression that would be of interest for individual hospital development in complementing the systemic perspective of centralization, nor …

3.2 In addition, the authors should describe the validity of self-reported data in mandatory hospital quality reports in Germany more precisely. It is difficult to understand why there is no further information on this topic beyond the statement in the last paragraph of the discussion. The authors have used these data for years and have even undertaken a survey in German hospitals regarding hospitals’ attitudes towards public reporting [BMC Health Services Research 2012; 12:378].

The mandatory hospital quality reports of each hospital in each reporting year consist of two data sets. One data set comprises the structural and some process data, which is reported by the individual hospital following standardized regulations. The reported data are completely self-reported. A second data set for each hospital provides data on quality indicators as reported by each hospital to the official external quality assurance institution “AQUA”. These quality indicator data are validated in a structured manner including different statistical checks and a random sample of hospitals where data are verified during an on-site inspection each year.

The data on minimum volume standards belong to the first data set without external validation procedure. Hospitals are obliged to report their case volumes on the minimum volume procedures in the quality reports and nowhere else as mentioned in the background section. To our knowledge neither official institutions nor
research projects have yet externally validated this part of the hospital quality report data set.

Our study on the hospitals’ perspective on the quality reports has not addressed validation criteria but usage and cost-benefit estimates.

We strongly support the necessity for a systematic study on the validation of this valuable secondary data source for the German health care system as suggested by the reviewer.

We have added a statement on the limited availability of external data validation in the background section:

Quality reports are standardized nationwide, and all hospitals are legally required to publish their quality reports following the regulations on nature, scope and data format as defined by the Federal Joint Committee [45]. The quality report of each hospital in each reporting year consists of two data sets. One data set comprises structural and process data of the hospital, which are to be reported by the individual hospital following the regulations. These reported data are completely self-reported. A second data set for each hospital provides data on quality indicators as reported by each hospital to the official federal external quality assurance institution. These quality indicator data are validated in a structured manner including different statistical checks and a random sample of hospitals where data are verified during an on-site inspection each year. The data on minimum volume standards belong to the first data set without an external validation procedure. Hospital reports are publicly available on the Internet. An electronic data set of each reporting year can be obtained on application from the Federal Joint Committee. Reports on every second year of operation were mandatory from 2004 to 2012, and annual mandatory reports were introduced in 2013. Hospital quality reports for 2012 were published in the summer of 2014.

Minor essential revision:

3.3 The source of data should be more precisely described, e.g. by citing the description of the data set according to the “Rules for Hospital Quality Reports” of the German Federal Joint-Committee.

We added a more detailed data set description in the background section.

Please see the quote under 3.2.

4. Results
Major compulsory revision:

4.1 An additional analysis of inter-quantile changes of a given provider over the years should be shown (see above, commentary to the methods section).

Please refer to our answer 3.1.

Minor essential revision:

4.2 The legends of tables 2 to 7 should list the relevant minimum volume standard (tab. 2 and 3: 10 per yr., tab. 4: 50 per yr., tab. 5 and 6: 25 per yr., tab. 7: 20 per yr.);

We added the numbers.

Discretionary revision:

4.3 In tab. 2 to 4, column 1, "quintil" should be substituted by "quintile" and in tab. 5 to 7, column 1 should show "tertile" instead of "quintil".

We corrected the words.

5. Discussion

Major compulsory revision:

5.1 The authors should add some information on the amount of improvement in outcome parameters which was expected as a result of further centralisation (for each procedure/intervention).

To our knowledge the Federal Joint Committee did not publish an estimate of the expected improvement in terms of reduced mortality or complication rates for the procedures introduced in the minimum volume regulation in the German health care system.
Minor essential revision:

5.2 The authors should reorganise the discussion of their data (and eventually divide it by single procedure/intervention) in order to focus on their main conclusion and on the reasons for it: why did centralisation not occur? It might have not been necessary (because already in 2006 there was a good baseline centralisation as compared to other industrialised countries?) or it might have been unavoidable (due to providers continuously stepping in or fading out; see above, commentary to the methods section). Or its necessity may simply not have been accepted by the stakeholders (because hospital planning is regional, regulations of self-administration are national, and the rules how minimum volume standards are determined are not transparent enough?).

Along with Mr Nobilio’s hint we shortened the discussion in the middle (page 10, line 16 to page 12 line 18) and final section (page 12 line 20 to page 14 line 3) as advised focusing on each procedure and possible aspects influencing centralization.

We hope that our revision addresses all comments appropriately and are looking forward to your response. If any further suggestions occur, please fell free to contact us at any time. Thank you once more for your helpful reviews.

Sincerely,

Dr. Werner de Cruppé