

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	REVALIDATION AND QUALITY ASSURANCE: THE APPLICATION OF THE MUSIQ FRAMEWORK IN INDEPENDENT VERIFICATION VISITS TO HEALTHCARE ORGANISATIONS
<b>AUTHORS</b>	Griffin, Ann; McKeown, Alex; Viney, Rowena; Rich, Antonia; Welland, Trevor; Gafson, Irene; Woolf, Katherine

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Professor Mike Saks University of Suffolk, UK
<b>REVIEW RETURNED</b>	17-Oct-2016

<b>GENERAL COMMENTS</b>	<p>This is a very timely review of the process of revalidation and quality assurance in the medical profession in England, which has recently been introduced in the wake of the high profile Shipman Inquiry and the Donaldson Review. More specifically, this paper looks at the application of the MUSIQ framework to this field on Independent Verification Visits to healthcare organisations by NHS England with reference to the personal context of the Responsible Officer, the organisational context of the Designated Body, and the visit and its impact.</p> <p>On the positive side, this article helps to fill a gap in the research literature in a newly evolving area of great importance to patients and doctors alike. In conducting the original research involved, it employed a rigorous framework and was highly transparent in reporting the results using triangulated methods – thereby pointing to ways in which the system could be enhanced at an early stage of implementation. It was pleasing to hear that two positive aspects of the visits were to act as a nudge for further action and to lead to the sharing of best practice, although there clearly remain a number of shortcomings of the process which was often inconsistently applied.</p> <p>Against this, by its own admission one key limitation of the study is that it is focused on the micro as opposed to the macro level – and if this area is to be moved forward more holistic scrutiny of the revalidation and quality assurance process will be needed. Moreover, it should be made clear in the text what proportion of Responsible Officers in England responded to the initial invitation – and not just the numbers – so that the significance of the study can be better gauged. Issues of public protection and confidentiality in relation to the data accessed should also be more explicitly highlighted.</p> <p>On a more minor level, the paper needed tidying up in places, not least as regards the more consistent introduction of acronyms when they are first mentioned. There was also the occasional typo (eg p12</p>
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	<p>'except' should read 'excerpt'). It was surprising too not to see among the references Chamberlain's latest book on Medical Regulation, Fitness to Practise and Revalidation (Policy Press, 2015). Overall, though, this was a thorough and significant piece of work which should cause further reflection on the state of implementation of revalidation and quality assurance in medicine and some of the steps that need to be taken to improve the process.</p>
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<b>REVIEWER</b>	Simon Ray University Hospitals of South Manchester UK
<b>REVIEW RETURNED</b>	20-Oct-2016

<b>GENERAL COMMENTS</b>	<p>From my perspective as an NHS clinician and advocate of robust appraisal and revalidation this is an interesting paper that confirms anecdotal views of the uncertainty around the true value of revalidation. In my view the MUSIQ model is an appropriate framework for the study.</p> <p>As a non specialist I find it hard to follow the explanation of the number and timing of interviews with ROs performed in response to the 2014/5 visits and those as direct observation as part of this study - this should be clarified for a general readership.</p> <p>Table 1. How can and DB be described as a locum or have I missed something here?</p> <p>Table 2. Presumably location in the table heading is synonymous with region?</p> <p>Table 2. What is the significance of the self assessment performed by the Midlands and East - this is not referred to elsewhere in the paper</p>
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<b>REVIEWER</b>	Samantha Scallan GP Education Unit, Southampton, UK
<b>REVIEW RETURNED</b>	08-Nov-2016

<b>GENERAL COMMENTS</b>	<p>Thank you for asking me to review this paper, which describes research to explore the application of the MUSIQ model to the UK context of IVVs. The research used interviews, observation and documentary analysis to surface evidence for the effects /impacts of the use of IVVS and for the usefulness of the MUSIQ model. Themes were identified from the data and were presented in the context of the model.</p> <p>This is an interesting paper which finds a place in a growing body of research around revalidation, in this case concerning the quality assurance mechanisms. The paper is well written, clear and readable, though it is quite 'lean;' by this I mean I was left with a feeling that I could have liked to know more in several places (see below). As a piece of qualitative research, the methods of data collection and analysis are appropriate. The research process is described, though not in quite enough detail for a reader to repeat it (see below). My general comments /observations are:</p> <p>Detail in methods: in general the methods are presented, though not in enough detail to allow the reader to repeat the research. Some questions I had regarding the methods were: the nature of the semi-structured interview questions asked and how the MUSIQ model informed them; the approach to observation used; the approach to</p>
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	<p>the documentary analysis used.</p> <p>Detail in analysis: I would have welcomed more detail in how the authors balanced the three data strands and brought them together in their thematic analysis. In particular I would welcome hearing how the deductive analysis was framed (e.g. by the RQs? By the model?). What did the 'coding framework' look like? The original Kaplan et al paper presents a figure (1) which shows the model development process. Something similar for the analysis process might be helpful in sharing this detail with the reader.</p> <p>Presentation of findings: I would encourage the authors to include as many examples from their data /quotes as these help to clarify their themes for the reader, and if possible some indication of the strength of feeling for a finding amongst participants (they do this in the section on 'outcomes' which was helpful). Where quotes are appropriate to the point being made, they tend to include one quote. I did wonder if the section on 'motivation' (where appraisal is discussed) might be an area where more quotes could be added? Might there be quotes to illustrate the points for the section 'resources and data infrastructure'?</p> <p>Application of MUSIQ: given the paper was the first time the MUSIQ model had been applied to the UK QA context of visits /revalidation, I wonder if the paper might be strengthened by a discussion of the ease of translation of the model to this context /goodness of fit /areas of less good fit. The section 'original contributions' goes some way to do this, but could they say more? I also wondered how sensitive the model is to organisational differences in how the management of appraisal and revalidation is realised locally, as this may well exert a significant influence, but one that is difficult to capture.</p> <p>Conclusions: Finally, I wondered if the authors might return to explicitly consider their initial RQs in the conclusion (they state them at the end of the introduction)? This would seem to be an opportunity to revisit and evaluate whether they had been addressed.</p> <p>Overall I think this paper makes a contribution to the literature around revalidation and should be published. I hope my comments are helpful.</p>
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### VERSION 1 – AUTHOR RESPONSE

Many thanks for your helpful comments and suggestions. We are delighted to know that the reviewers think that this is timely review of an important aspect of medical revalidation as well as an interesting use of the MUSIQ framework in regulatory visits.

In addressing their constructive comments we have responded as follows:

We have referenced GMC data regarding the total number of ROs and expressed those who took part in our study as a percentage of that in order for readers to better assess the significance of the responsible officers engagement in the study

We have been more specific about how public protection confidentiality was addressed in the research and made reference to the confidentiality agreements signed between NHS England the research team.

In order to help the reader understand the number and timing of the interviews with responsible officers and observations we have added a table giving a breakdown of those.

Table 1 has been amended the column now reads 'locum agency'. This was a typographical error that has now been fixed.

Regarding table 2: location is indeed synonymous with region and we have used this term now consistently throughout. We have clarified a further concern regarding table 2 and the significance of self-assessment. The Midlands and the East carried out their own self-assessment during some of the research which we think was one of the reasons why a response rates for that area were lower than others. We included this in order for readers to understand the variance.

We responded to several queries regarding the research methods used and how the MUSIQ model informed them. We have clarified that the model was used in devising the questions to be asked in the interviews, and in identifying features of note to be investigated during the observations and documentary analysis. Similarly, we have provided further detail about how this was done in the data analysis. One reviewer asked for clarification over the coding strategy and associated framework, and we have responded to this comment by referring to Figure 2, which shows the coding framework used in the study.

In several sections of the results it was felt by one reviewer that more quotations would be valuable, in particular in the section on 'motivation' and 'resources and data infrastructure' and therefore we have added more quotes. We agree they help to provide clarity for the readership but it is always to use them in the way qualitative researchers may want without consuming all of a limited word count. We hope here we have achieved an appropriate balance.

There was a further reviewer comment about the congruence between the MUSIQ model and the IVV context to which we have applied it in this study, noting that this was the first time the MUSIQ model has been applied to the UK QA context of visits and revalidation. We have added text about the applicability of the MUSIQ framework in this context. We have also included some reflection on how the model might be modified to fit more accurately, for example by emphasising the influence of the microsystems within MUSIQ, as these exerted a significant influence in the IVV case.

In relation to our conclusions, one reviewer suggested that it might be helpful to re-state our research questions and outline how the study answered them. We take this useful comment on board and have done so, tying each research question to its corresponding conclusion in this section.

Finally, we have tidied up the use of acronyms and the various typographical errors.

We look forward to hearing from you in due course.

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Professor Mike Saks University of Suffolk, UK
<b>REVIEW RETURNED</b>	10-Jan-2017

<b>GENERAL COMMENTS</b>	This paper has been appropriately revised - and aside from a handful of minor typos is now ready for publication.
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<b>REVIEWER</b>	Simon Ray University Hospitals of South Manchester UK
<b>REVIEW RETURNED</b>	29-Dec-2016

<b>GENERAL COMMENTS</b>	I am happy with the author's response to my initial comments
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<b>REVIEWER</b>	Samantha Scallan GP Education Unit, University Hospitals Southampton NHS Trust, Southampton, UK
<b>REVIEW RETURNED</b>	18-Jan-2017

<b>GENERAL COMMENTS</b>	<p>Thank you for asking me to re-review this revised paper. It was very helpful to include a 'tracked changes' version of the updated paper as this made it much easier to follow the amendments.</p> <p>I note the authors have addressed my suggested changes and those of the other reviewers. The text has been developed and improved throughout the whole article. I found the revised paper clear, and well written. It finds a place in an emerging body of appraisal/revalidation QA literature, sets out the scope and impact of this research appropriately and provides a guide to future potential research interest.</p> <p>Finally I noted the following:  Page 37 [track changes draft]: author comment left in the text.  Page 37 &amp; 38 [track changes draft]: repeated phrase – “trawls huge numbers to catch a few” and “trawling huge numbers of doctors to catch a few” in the text.  Page 37 &amp; 42 [track changes draft]: repeated quote wording – “The more I am involved in it, the more I’ve been exposed to it, I perceive it to be of diminishing value and increasing time and effort.”</p> <p>In conclusion I think this paper makes a contribution to the literature around revalidation /quality assurance and should be published.</p>
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### VERSION 2 – AUTHOR RESPONSE

Many thanks for your positive feedback. The minor typographical errors have now been corrected and we hope this paper is ready for publication.

Page 37 [track changes draft]: author comment left in the text – now removed

Page 37 & 38 [track changes draft]: repeated phrase – “trawls huge numbers to catch a few” and “trawling huge numbers of doctors to catch a few” in the text. Removed duplicate.

Page 37 & 42 [track changes draft]: repeated quote wording – “The more I am involved in it, the more I’ve been exposed to it, I perceive it to be of diminishing value and increasing time and effort.”

Duplicate removed.