Author’s response to reviews

Title: Prospective Monitoring of Imaging Guideline Adherence by Physicians in a Surgical Collaborative: Comparison of Statistical Process Control Methods For Detecting Outlying Performance

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May 1, 2020

Re: Resubmission of manuscript Prospective Monitoring of Imaging Guideline Adherence by Physicians in a Surgical Collaborative: Comparison of Statistical Process Control Methods For Detecting Outlying Performance, MIDM-D-19-00371R1

Alison Cuff
Editor, BMC Medical Informatics and Decision Making
BioMed Central, London, UK

Dear Dr. Cuff:

Thank you for the opportunity to revise our manuscript. We appreciate the suggestions you have provided.

Following this letter are the editor comments with our responses in italics, including how and where the text was modified.
It is our hope that the revised manuscript is accepted for publication in BMC Medical Informatics and Decision Making.

Sincerely,

Michael Inadomi and Dr Khurshid Ghani
University of Michigan

1 - Please be sure to assign your manuscript to a Section/Category upon re-submission. This paper will be submitted under the category "Standards, technology, machine learning, and modeling".

2 - Please clarify in your Ethics approval and consent to participate’ section of the Declarations the reason that some practices obtained exemption from ethics approval and others required approval. One practice which previously had IRB approval under expedited review is no longer a participating MUSIC practice. Another practice has since been approved as not-regulated by their IRB. Additional File 2 has been updated to reflect these changes. The remaining two practices were approved under expedited review as having “risk [that] is no more than minimal to the human subjects”. Both practices approved through expedited review have a waiver of consent (45CFR 46 116(d)) and waiver of HIPAA authorization.

See the below addition to page 13, lines 9-20:
Those practices which were neither deemed to be not-regulated nor exempt from IRB approval were approved under expedited review as having “risk [that] is no more than minimal to the human subjects”. The practices approved through expedited review have a waiver of consent (45 CFR 46 116(d)) and waiver of HIPAA authorization. In practices in which MUSIC was deemed to be not-regulated or exempt from IRB approval, MUSIC's work in quality improvement was determined not to fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56) and thus patient informed consent is not required under those regulations. See communication from University of Michigan Institutional Review Board below:
“Based on the information provided, the proposed study does not fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56) because in this case, it is activities or procedures rather than human subjects that are the object of the study.”

3 - For all research involving human subjects, informed consent to participate in the study should be obtained from participants (or their parent or guardian in the case of children under 16) and a statement to this effect should appear in the ‘Ethics approval and consent to participate’ section of the Declarations including whether the consent was written. When reporting on such studies, individual patient data should not be made available unless consent for publication has also been obtained. If the need for informed consent has been waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this with details, including the name of the Board or a reference to the relevant legislation in the ‘Ethics approval and consent to participate’ section of the Declarations. Each IRB either determined that MUSIC's work in quality improvement does not fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56)
and thus patient informed consent is not required under those regulations, or approved practice involvement in MUSIC under expedited review with a waiver of informed consent under 45 CFR 46.116(d). Newly added supporting text has been provided on page 13, lines 9-20 (also reproduced in response to item 2, above):

Those practices which were neither deemed to be not-regulated nor exempt from IRB approval were approved under expedited review as having “risk [that] is no more than minimal to the human subjects”. The practices approved through expedited review have a waiver of consent (45 CFR 46 116(d)) and waiver of HIPAA authorization. In practices in which MUSIC was deemed to be not-regulated or exempt from IRB approval, MUSIC’s work in quality improvement was determined not to fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56) and thus patient informed consent is not required under those regulations. See communication from University of Michigan Institutional Review Board below:

“Based on the information provided, the proposed study does not fit the definition of human subjects research requiring IRB approval (per 45 CFR 46, 21 CFR 56) because in this case, it is activities or procedures rather than human subjects that are the object of the study.”

4 - At this stage, please upload your proofread manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethrough or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files. Please ensure that all figures, tables and additional/supplementary files are cited within the text. Should you wish to respond to these revision requests, please include the information in the designated input box only.