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Reviewer A

The authors described issues with statistical process control. Most of the discussion points are supported by surveys. Some statements are not supported by evidence with appropriate references, in particular, the association with the 'mental filter' with the laboratory errors and QC flag inattention. The authors concluded the manuscript by arguing for automated clinical decision support without appropriate evidence to support it.

Response: The paper should be an opinion piece rather than a Review as many of the human factors have not been measured in clinical laboratories at this stage. The aim of the paper was to draw attention to this source of error and a means to mitigate against it. We have modified the closing paragraphs to provide more support for automation as a solution.

Reviewer B

Thank you for taking the time to write about this important topic. Quality Control is critical to laboratory testing, and an important area for discussion.

In this “review article,” the authors define quality control, describe its components, and then make the argument that most laboratories do not properly do QC, and that there is lack of training.

Response: The paper should be an opinion piece rather than a Review.

The article then goes into a section “Lack of Adherence to protocols” which takes a somewhat historic review of reasons why humans fail. This section seems out of place in my opinion.

Response: Whilst the papers cited in this section are from the late 1990's, the more recent Surveys of Westgard and Rosenbaum suggest these same problems still exist. The work of Howanitz was very detailed and unlikely to be reproduced. We added paragraphs dealing with 'Human factors in laboratory error' and 'Evidence of human factors producing error in QC' to specifically describe the evidence.

The authors conclude that the reason QC doesn't work is because of human error. The final statement argues that automated clinical decision support is the only path forward. If this is the author's final conclusion, then an opinion article explaining what is automated clinical decision support and with supporting evidence of why it would be able to address QC human errors would be appropriate.

Response: We have rewritten the closing paragraphs to better describe automated clinical decision support.

This article is not appropriate for an article type of “review.” I think a more appropriate review topic would be a review of QC, QA, QI, QM and recent developments, clarification of the concepts and definitions (which are commonly confused). I would also recommend consider including the EPIDEM quality improvement model, which was published in the ASCP journal Lab Medicine, as it was specifically developed for laboratorians in mind (<https://academic.oup.com/labmed/article/50/1/e9/5195531>).

Response: We agree, the paper should be an opinion piece rather than a Review.

Reviewer C

This document describes the risks caused by human factors in the QC process. It is a practical article that explains common problems in real laboratories. However, there seems to be a lack of suggestions on how to solve this problem. For example, the title says, "how to improve the quality control," but it rarely says how to improve. The abstract mentioned "automating" as a solution, but there is no description regarding that in the main text.

I hope that the sub-headings will be modified to reflect the contents of the text. For example, "an understanding of error" -> "understanding the type of error."

Also, it looks like a draft version that's not finalized yet. I'd like the author to review and revise it more carefully.

Response: The aim of the paper was to draw attention to this source of error and a means to mitigate against it. We have modified the closing paragraphs to provide more support for automation as a solution. We have modified the title to better describe the article.