Author's response to reviews

Title: The Combined Positive Impact of Lean Methodology and Ventana Symphony Autostainer on Histology Lab Workflow

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Editor, BMC Clinical Pathology

Re: Manuscript revisions on MS 8661325412964908 - Improving productivity, quality and turnaround times in the H&E workcell through implementation of Lean process changes and the Ventana Symphony

Dear Sir/Madam:

Thank you for the very helpful comments and suggestions from the reviewers. I will respond or comment on each of their points and suggestions in detail.

What was the cost-efficiency equation, given that the automation was likely to have had real costs - at what point will the improved productivity pay back the cost of the automation described here - the authors need to use their productivity and any costing data they have to make a relevant analysis of this point.

This statement really warrants that the cost analysis be completed as part of the text or the reader will probably not consider embarking in a similar solution without knowing the cost that is just qualified as a “high cost”.

We have added to the text a description of the methods (pages 7 & 8) we used to calculate our baseline costs/slide and how those were impacted by the changed process (page 12). I was actually surprised by these numbers and checked my assumptions, calculations and such several times and thru various associates. Clearly in doing this, we have strengthened the case for our project (and perhaps that is what our administration could see as well.)

to my reading this is a report that also says that the benefits of the importation of automation into a series of steps in a laboratory are best realised by linking technical and process change. The point might be made a little more explicitly

Also it is of paramount importance for the credibility of BMC Clinical Pathology that the Ventana Symphony autostainer be assigned its real impact in the whole study.

I have added an additional paragraph (page 13) in the discussion section to attempt to make this more explicit. Obviously we did not have the means to separately assign a proportionate share of the credit to all the changes made, but I have tried to rebalance the credit such that the traditional methods are not overshadowed by the technological ones, within the context of my belief that both sorts of Lean methods/process changes are of greater benefit than one or the other alone.

To question 1 (Statistical analysis): at the bottom of Table 1 it is stated that the authors used the “two-tail t” test, but that should have been included in “Materials and
Methods”. Also the use of a parametric test like “t” requires that the data has a normal distribution and in no part of the text that issue is addressed.

I have added mention of the statistical test and it’s justification in the method’s section on pages 5-6.

To question 2 (Staff and work load): this question was not answered at all, except for writing that the laboratory has an average workload of 500 slides/day. Finished slides are not a good indication of the workload because it varies greatly depending on the nature of the tissue sample and the pathologists’ requirements. It is always necessary to evaluate the magnitude of the problem and the best indicators are workload and staff characteristics of the laboratory and neither are included.

This begins the discussion that I allude to in the manuscript elsewhere, i.e. that interlaboratory comparisons are very difficult in this arena. I have already provided some sense of the type of laboratory we are in the description of who we serve, which tells much more in itself than the number of staff or average slide numbers. However, I have also now added other clues to give this picture by giving an average number of cases/day in parenthesis, indicative of many large and complex resection cases, (page 8) and mention that the staffing was constant over the study period with the same seven employees in this work cell (page 5).

I greatly appreciate Mr. Buesa’s comments regarding productivity measurement, and appreciate his efforts to contribute to this field. I will attempt to respond and clarify our measures and metrics, which I believe will meet his concerns expressed.

“Materials and Methods” the authors write that they used the “raw blocks and slides count as tabulated monthly, combined with the worked hours” for the core activity of the lab (excluding special staining procedures). The reader has to wait until “Discussion” to find out that the productivity values presented in Table 1 (where the units are not included) refers to blocks and slides per FTE, not per worked hours. This should be stated in “Materials and Methods” and specified in Table 1.

I have added the formula used to calculate the productivity number in the methods section on page 5. As is evident, this is a number reflecting production (slides and blocks) per unit time (worked hours.) However, in an attempt to provide some measure of comparing our results with those of Raab et al, as cited in the text, I used a fixed conversion factor of 173 hours/worked FTE to convert that value to something I surmised would be comparable to what he described as a “productivity ratio” that could be used for internal comparison over time. I have attempted to query Dr. Raab more closely on the formula they used, but have not received a response as yet.

Table 1 presents a mean value of 2309 for 5 months in 2007/8 and another of 2512 for 2008/9, and consider the difference as caused by the implementation of some Lean tactics and the use of the autostainer/coverslipper but what about the overall workload of the laboratory? With this question I return to the original “Question 2” that requires
knowing the workload of the laboratory. Are the increases between 2007/8 and 2008/9 due to a concomitant increase in the workload? Did the staff change? If there was a reduction of the staff the workload (presented as “productivity”) of those remaining has to increase; was that the case? This proves the importance of answering the initial “Question 2” or defining the productivity as units of work per some unit of time.

I believe all these questions have been dealt with by the clarification of the production metric in use, the mention of the consistency of staffing in the two time periods (which made things very convenient in this manner). The seasonality of our volumes was accounted for by measuring the same months of the year, and any year over year change in volume should be insignificant given the metric of work/unit time used.

Also, from the added productivity point of view, how many additional blocks the staff is now able to handle?

This projection is evident from the calculation of the time before additional staffing would be required to maintain the takt time in the cell, based on the next limiting (capacity wise) step.

On the one hand it is written that the time the slides were available went from 12 to 4 hours and essentially consider that the role of the autostainer/coverslipper was fundamental (at least that is what can be inferred from the text).

I beg to differ on this point. The text states that “Time to first available slides decreased from a minimum of 12 hours to four hours. The primary intent of this was to provide added time for resident review of slides prior to sign-out, and was accomplished by use of a short sequence processor run for biopsy specimens arriving in the laboratory in the morning” I do not think it can be inferred from the text that the role of the stainer was in any way fundamental to this improvement. I have added some additional clarification later in this paragraph to more fully attribute other measured improvements to this change.

I think that reorganizing the way the tissues are processed to have small biopsies during the reception day instead of having them the next is the real factor in the reduction of the TAT, but tissue processing does not appear in Table 2, when it should. The authors also identify as a major bottle neck the H&E staining, when always the biggest bottle neck in the work flow of a histology laboratory is tissue processing, and in the text it is not even mentioned.

The processor schedules do contribute greatly to improved TAT, but are not the sole contributors. Table 2 reflects waiting times between value-adding steps, so by reducing the average time that a grossed sample was waiting in formalin to go on the processor by 14% is included in that table. That we were not able to decrease this value any further speaks to the fact that the contribution of the processor schedule was not the major factor in time savings. The actual time that the sample is on the tissue processor of course, is “fixed”, but adjustments in these, and use of newer methods (microwave or other) to
reduce processing times is of interest. These changes however, were not part of the study. The assertion that processing is always the biggest bottleneck is clearly an overstatement, and a confusion of in what sense we are using the term “bottleneck.” Our use of this term is in the sense that the capacity of our system limits throughput, and in this sense, our data indicates that this is the H&E staining, not the tissue processors. With several different instruments to choose from, we could start a run almost hourly if we chose or needed to. There is no problem with capacity in this area of our lab. In the sense that tissue processing is a lengthy, fixed step in the value stream, then perhaps the assertion of Mr. Buesa is correct, but immaterial to the content of the article.

Also the title refers to “improving quality” and quality is not mentioned in the whole MS.

Much as I would have liked to include more metrics on this aspect of the measured results, you are correct, and the title has been modified, and mention of quality in the discussion omitted. I appreciate Mr. Buesa’s suggested new title and have made that change. Also, the term H&E work cell is used quite a bit in the text, though some more extended areas of histology are touched upon, however, I think this tends to help people eliminate from consideration special staining, or the grossing bench, while still including work aspects like case assembly, processing, embedding and so forth, which I would include in that cell.

Again, thank you and the excellent reviewers for their efforts to improve this paper. I trust my responses have been sufficiently complete and thorough to address their concerns and suggestions.

Sincerely,

Lewis Hassell, MD