

Author's response to reviews

Title: Pandemic influenza preparedness: an ethical framework to guide decision-making

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The Editor
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Re: Manuscript “**Pandemic influenza preparedness: an ethical framework to guide decision-making**”

by Alison K. Thompson, Karen Faith, Jennifer L. Gibson, Ross E. G. Upshur

Dear Sir/Madam,

We should like to thank our peer reviewers for their comments and suggestions, and for the time and effort spent reviewing this manuscript. We are grateful for their insights and thoughtful reflections on how to make improvements. Firstly, as Angela Bate’s comments were primarily structural, we have made the changes she suggests and thank her for her careful reading and consideration of how to improve the readability of the paper. What follows is a point by point account of how and where these changes were made.

Minor Essential Revisions

1. We have followed Bate’s suggestions to the extent possible given the Debate formatting for *BMC Medical Ethics*. We have structured the main body of the paper as follows (with the appropriate font formatting):

Background

- The importance of ethics in pandemic planning

Discussion

- Development of the ethical framework
 - Formation of a working group
 - Review of clinical and public health ethics literature
 - Lessons from emergency ethics
 - Stakeholder vetting
- The ethical framework
 - Ethical processes
 - Ethical values
- Lessons for implementing an ethical framework
 - Sponsorship by senior administrators
 - Vetting of the ethical framework by key stakeholders
 - Decision review processes
- Scope of the ethical framework

Conclusions

- Cultural limitations and future directions

Summary

We have accepted all of Bate’s suggestions for discretionary revisions, and the resubmitted version of the paper has the changes highlighted for your convenience.

Discretionary Revisions

1. pg 3. the use of the word many in 'many have begun to point out...' I think is too strong as it only refers to 2 papers.

We have changed this to read "As a few scholars have begun to point out..."

2. pg 4. last paragraph – I think that there need to be a statement about fairness considerations rather than simply a quote (or as well as the quote).

We have added the following to follow the above mentioned quote on page 5:

"As we shall argue, fairness considerations are both procedurally and substantively important: there is a need for fair decision-making processes, as well as equitable distributions of scarce human and material resources."

3. pg 5. middle paragraph (start 'while there is a need ...') I am not sure this paragraph adds anything at this point – it would be better to put it in the discussion at the end especially as you refer to the work that you haven't even introduced yet.

This paragraph has been moved to page 6 under the section "Development of an ethical framework". It now begins, "One of the key lessons from the Toronto SARS experience was that health care institutions and their staff could benefit from the development of ethical frameworks for decision-making..."

4. in the section 'development of the ethical framework' I think this would benefit from being structured more clearly in terms of the steps undertaken in doing so.

As demonstrated above in the Minor Essential Revisions section this has been done.

5. pg 9. second paragraph 'some may argue ...' I think this section should go into the discussion.

This paragraph has been moved to page 12.

6. pg 11. 'proposed steps for integrating ethics ...' these read as lessons for developing a framework...

As mentioned above, we have renamed this section "Lessons for implementing an ethical framework"

7. pg 14. 'scope of the ethical framework' I found this section very lengthy and actually a distraction from the main messages that the paper was trying to convey. I think this section could be better incorporated into the discussion and shortened to draw out what the implications are for the framework of focusing on an applied approach.

This section has been shortened significantly and is now on page 15.

8. pg 16. the arguments and quotes by Kotalik. I wonder whether these arguments could be used in the background section to set up the paper. i.e. this is where the literature is currently at in terms of ethics and pandemic planning...

We have moved this section to page 3, and edited it to be more concise.

Secondly, we shall turn to Ezekiel Emanuel's report and address his points, indicating where we have made changes when appropriate. We should like to thank him for his astute comments, despite the lack of concrete recommendations on how to improve the paper. We address below the points raised in each of his paragraphs.

Paragraph 2

We found the comments submitted by Emanuel to be challenging and valuable. His comments have led us to make several changes, and point to a lack of clarity on our part about the aims of the paper. Emanuel is correct that the contribution of the paper is not in the presentation of the substantive values themselves (see Emanuel paragraph 3). The intention of this paper is not to systematically derive from normative theory the values and principles in the framework. This paper has a more narrow focus—it is an example of applied/practical ethics that attempts to introduce and articulate values that are already commonly accepted. Therefore, it is not our intention to comprehensively defend the values in the framework, but rather to show from which areas of scholarship they were drawn, articulate their relevance to pandemic planning, and to demonstrate their discursive legitimacy through a process of stakeholder engagement and vetting. To better meet these ends, we have added several references to the paper that demonstrate the general acceptance of the values in the literature, and we have clarified and stressed both the aims of the paper, and the moral significance of the stakeholder vetting process. To our knowledge, no other pandemic planning process has attempted to a) develop an ethical framework to guide pandemic influenza planning and b) assess an ethical framework's robustness and resonance in the community of its intended users. Thus, the significance of the procedural elements of the development of the framework is not to be minimized, nor are the insights we have gleaned from implementing the framework in health care organisations and in a governmental setting.

Paragraph 3

We accept that the articulation of the values and examples in the framework needed to be more thoroughly developed. We have significantly expanded on the previous version of Table 2 in which the substantive part of the ethical framework is found. In addition, we thank Emanuel for pointing out that there was a typographical error, for we did not intend to especially emphasize the value of inclusiveness in Table 1.

Paragraph 4

Emanuel raises several points which have been addressed in the expanded version of Table 2 in which the values are further "elaborated and justified", including the "overly vague" value of protecting the public from harm. We thank Emanuel for revealing to us the confusion over the

ordering of the values, and we have now listed the values in alphabetical order, for they were not intended to be in any ranked order. In addition, the ethical framework is not intended to address the overall and technical goals of pandemic planning, but rather to encourage a procedural engagement that uses the framework. Thus, it is beyond the scope of the framework to specifically address, as Emanuel suggests, “what the goals of a pandemic response ought to be.” This is not to say, however, that a procedural engagement about the overall goals of a pandemic response would not benefit from using the ethical framework to guide and shape debate.

Paragraph 5

We hope that the expanded version of Table 2 provides more clarity. However, we do not accept that it is morally significant that some descriptions of the values promote the value, and some explain how the value will be threatened in a pandemic. It was hard to determine what was behind this criticism. For example, we would argue that because the value of individual liberty is so deeply entrenched in Western clinical ethics, its positive entailments are already well understood. In settings where there is no institutional memory of how to handle pandemic infectious disease outbreaks, it is important to, as Emanuel says in the previous paragraph, “question whether individual liberty is the highest value in a pandemic situation that might kill 1% of the population and massively disrupt the health care system and economy.” For these reasons, we focus on how the value of individual liberty may be “threatened”, rather than its positive entailments. We have also provided more helpful examples in the framework, and changed, as Emanuel usefully suggests, the example for the value of individual liberty.

We are grateful to Emanuel for his helpful insights, and believe that the changes we have made in response to his comments have bettered our manuscript. Where we are unsure of his criticisms, we have attempted to provide clarification about our aims and intention, both in this letter and within the manuscript itself. As some of these involve legitimate scholarly disagreement, we hope that this paper will indeed spark wider debate where it is now lacking on the ethics of pandemic influenza planning. We again thank our reviewers for their time and efforts to improve our manuscript.

Lastly, the length of Table 2 has increased in response to our reviewer’s comments. We were unsure whether or not it can still be included in the manuscript itself, or whether it must now become an “additional file.” There was no mention about length restrictions in the *Instructions for Authors* for Debate articles. We would hope that since it is integral to the manuscript itself it can remain within the main PDF file.

We thank you for your consideration and efforts with this manuscript, and we look forward to an editorial decision.

Sincerely yours,

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For: Karen Faith, Jennifer Gibson and Ross Upshur