Author's response to reviews

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

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Author's response to reviews: see over

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 thank you for Akria Akabayashi's review of the above manuscript. We thank him for the time and effort he took with the review. Herein, we will attempt to respond to his concerns with this manuscript, and to the issue of whether or not this ought to be considered a Debate article or rather a Country Report.

We will respond to each of his comments in turn.

1) This paper comprehensively presents an ethical framework for decision-making during an influenza epidemic, a topic on which little research has been done to date. However, it is unclear whether this paper describes empirical or normative research. The conclusion contains information drawn from observation, suggesting that this work is empirical, but the description of the research methods is inadequate for an empirical study.

If this study was normative, the authors cannot justify their arguments merely by stating their position (Tables 1 and 2). For a normative study, one must explain the grounds to justify the value of experiences instead of going on and on about how the two tables derive from experience. Normative research in general requires a clear justification of all decisions, but the authors frequently fail to provide such justification.

We claim a legitimate scholarly difference of opinion about the classification of bioethics research into empirical and normative kinds, in that we reject the dichotomous approach which is implied here that research must be either empirical *or* normative. While this has certainly been the case traditionally in bioethics, there is now a growing body of literature which demonstrates how empirical approaches to bioethics contribute to the normative justification of research, and that the distinction between the empirical and the normative is collapsing [1-4].

We emphasize again the significance of the fact that this was an actual engagement of ethics in a planning process, and the consultation with and vetting by stakeholders provides discursive legitimacy to the ethical framework. Thus, we "go on and on" about how the values were derived from experience because we believe that the experience of being involved in pandemic planning throughout the development of the framework

provides partial normative justification for the inclusion of the values, along with the discursive justification that is provided by the literature review, i.e. a community of scholars have previously articulated and generally accepted most of the values in the framework. This was not, however, an empirical study in the traditional sense. This ethical framework is a hybrid of empirical and normative approaches and is not so much simple research but an engagement of ethicists with pandemic planning and the incorporation of that work into actual pandemic plans. In some sense, then, the work is neither and both empirical and normative. What is unique is the way in which the values' relevance to pandemic planning has been articulated and the way in which pandemic planners have vetted and discursively legitimized the values' inclusion in the framework.

We feel we have adequately articulated this in the manuscript where we have stated the following (in a section that was added in response to Emanuel's previous review):

> "The intention of this section is not to systematically derivate 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. 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 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"pg. 6.

2) For instance, while discussing the ethical processes, the authors use the framework of Daniels & Sabin, yet fail to give any real reason as to why it was chosen (besides stating that is useful). One can't help but feel that the authors used it without fully considering its implications first.

We accept that the choice to use Daniels and Sabin's framework for the procedural aspects of the ethical framework appears arbitrary. However, the decision was based upon the fact that co-author Dr. Gibson has used it extensively in her own work, and because an extensive literature has developed around Daniels' and Sabin's accountability for reasonableness framework. The Daniels and Sabin framework has broad applicability across institutional settings and priority setting situations [5-12]. Because the Daniels and Sabin framework applies deliberative theories of democratic justice to the specific problem of health care priority setting, and because it is unique in this regard, we felt it promoted the kind of fair deliberative approach to pandemic planning that the ethical framework intends to promote. Recall that we argue that the ethical framework is intended to promote debate and deliberation through a process that also promotes fair

engagement of stakeholders (see manuscript page 9). We have therefore added to the paper an explanation for the choice to use the Daniels and Sabin framework on page 10:

> "Ethical processes
>
> In planning for and throughout a pandemic influenza crisis, difficult decisions will be made that are fraught with ethical challenges. Our framework around ethical processes is based upon the "accountability for reasonableness" model developed by Daniels & Sabin [13] and adapted by Gibson, Martin & Singer [14]. This model provides a useful way of identifying the key elements of ethical decision-making processes. An extensive literature has developed around Daniels' and Sabin's accountability for reasonableness framework. The Daniels and Sabin framework has broad applicability across institutional settings and priority setting situations [5-12]. Because the Daniels and Sabin framework applies deliberative theories of democratic justice to the specific problem of health care priority setting, and because it is unique in this regard, we felt it promoted the kind of deliberative approach to pandemic planning that this ethical framework intends to promote. Table 1 outlines the characteristics of an ethical decision-making process. Stakeholders will be more able to accept difficult decisions during a pandemic influenza crisis if the decision-making process has, and is perceived to have, ethical legitimacy."

3) The authors also fail to justify their choice of the 10 ethical values. They merely state that eight used by the Toronto University Center for Bioethics were used plus two that were added after discussion with other researchers. The authors neither give a reason why the original eight were chosen nor explain the need to add two more.

We have added to the manuscript further explanation for the inclusion of the values in the framework. Firstly, see above response for an explanation of why we use the procedural values from Daniels and Sabin. Secondly, the Joint Centre for Bioethics work on the ethics of SARS has explained further and been referenced on page 11:

> "The values identified in our ethical framework were based initially on previous work on ethics and SARS at the University of Toronto Joint Centre for Bioethics (JCB). This work was funded by a Canadian Institutes of Health Research grant in 2004 through 2006 and has led to several key publications on the ethical dimensions of SARS [15-19]. In particular, Singer et. al., in their seminal British Medical Journal article begins to identify key ethical values that were of relevance during the SARS epidemic in Toronto. These values were then further articulated by our working group and adapted for the pandemic influenza planning context. Through a discursive process of stakeholder consultation with public health specialists, ministry officials, S & W's pandemic influenza committee, and the clinical ethics group at the JCB, we augmented the values to include two new values (stewardship and trust [20, 21]) and refined the definitions of each value in

light of the anticipated demands of a pandemic influenza crisis compared to a hospital-based epidemic such as SARS."

We again point to the response given in (1) above that concerns the normative justification for the values and the aims of this paper.

4) Furthermore, the authors' review of the literature on decision-making when faced with an ethical dilemma in public health is insufficient. Kass (2001) and Childress et al. (2002) have published studies on this same topic. In general, one should address why the frameworks presented in these previous studies are inadequate and state how the present research would contribute to the literature.

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Again we have a scholarly disagreement with Professor Akabayashi. There was no lack of consideration of these frameworks. In fact, one of the authors (Dr Ross Upshur) had published a framework for public health ethics that predates both the Kass and Childress papers by several months [22]. While there are overlaps between Dr Upshur's framework and that of Prof.'s Kass and Childress et al., it is in fact Dr Upshur's framework that informs the discussion of the public health ethics aspects of this pandemic framework. Most importantly, the Kass framework is about the evaluation of a public health program. The response to a pandemic entails more than the involvement of public health and will not be programmatic in the sense that a prevention program or screening program would be. Hence the Kass framework is not appropriate for a pandemic response.

The Childress paper raises similar issues to the Upshur paper with the exception of a criterion about effectiveness. This is an important issue in public health ethics that does not need to be decided in the current paper, but simply put, the broad uncertainties associated with a novel influenza virus make the guarantee or reasonable probability of the effectiveness of the response to the pandemic moot. A similar issue faced decision makers in SARS. Thus Upshur argues for precaution as an important principle, precisely because uncertainty or lack of knowledge of what is optimally effective should not necessarily constrain public health action.

Furthermore, the ethical dilemmas facing pandemic planners are not just public health dilemmas—they are also clinical and organizational ones. This is why we describe the formation of the working group in detail, and outline the role that clinical, organizational and public health ethics played in the development of the ethical framework. Indeed, our experience has been that the ethical complexities of planning for a pandemic would be insufficiently met by relying solely on the literature on decision-making in public health.

5) In conclusion, I am interested in how Tables 1 and 2 were developed and find the example of SARS in an advanced country like Canada to be very valuable. However, since it was impossible to tell whether the paper was meant to describe empirical or normative research, the manuscript remains slightly thin on substance. Given that the present manuscript is inappropriate for the Debate section of the Journal, I suggest adding a subtitle like "experience in Canada" or "Canadian model" and resubmitting it as a Case Report or Country Report.

Again, we reiterate the genuine scholarly disagreement we have with the dichotomous view of research as having to be either empirical or normative (see response to point 1 above). We feel that the procedural aspects of the frameworks' development do constitute legitimate substantive content that contributes to the discursive legitimacy of the ethical framework outlined therein.

Given that the "ethical framework is intended to inform decision-making, not replace it" and that, "It is intended to encourage reflection on important values, discussion and review of ethical concerns arising from a public health crisis" (page 9) we submit that the publication of the paper itself is a part of a wider vetting and consultation process within a community of scholars that can contribute to the refinement of the ethical framework. For this reason, we feel it is important that this manuscript be considered a "Debate" article, given the provisional nature of the framework itself, and the benefit to the ethics and public health communities of furthering debate on the subject.

Finally, we feel it is important to point out to the editors that the Joint Centre for Bioethics non-peer reviewed Report entitled <u>Stand on Guard for Thee</u>, which is also based on the work on ethics in pandemic influenza planning at the Joint Centre for Bioethics, has had a significant global impact. That report was released shortly after this paper was submitted to BMC and in that time its uptake has been wide and significant. A few of the main areas of impact have been:

1. the WHO has used it to inform the development of their working groups on ethics for pandemic planning
2. The New Zealand National Ethics Advisory Committee (NEAC) document <u>Ethical Values for Planning for and Responding to a Pandemic in New Zealand</u> states that it was greatly informed by the Joint Centre for Bioethics work
3. The Irish Council on Bioethics has reviewed the document and called it "excellent"
4. The authors of this paper have presented in North Carolina, Washington DC, Paris France, and Geneva to governments and pandemic planners, and
5. Jaro Kotalik, in a literature review on ethics and pandemic planning commissioned by the Swiss National Advisory Commission on Biomedical Ethics reviews the <u>Stand on Guard for Thee</u> document at length.

In addition, there has been wide spread international interest in the document at the policy and regulatory levels of government. While we have taken seriously the feedback

we have received from our peer reviewers, we can only hope that a peer reviewed publication could have such an impact.

We hope that the editors will recognize the significance of the work described in this manuscript, and see the merit of publishing a paper which has the potential to fill a significant gap in the academic literature on the ethics of pandemic planning.

Sincerely yours,

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For: Karen Faith, Jennifer Gibson and Ross Upshur

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