

NIH Public Access

Author Manuscript

Health Care Anal. Author manuscript; available in PMC 2014 March 14.

Published in final edited form as:

Health Care Anal. 2011 June ; 19(2): 165-179. doi:10.1007/s10728-010-0148-6.

Pandemic Ventilator Rationing and Appeals Processes

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Abstract

In a severe influenza pandemic, hospitals will likely experience serious and widespread shortages of patient pulmonary ventilators and of staff qualified to operate them. Deciding who will receive access to mechanical ventilation will often determine who lives and who dies. This prospect raises an important question whether pandemic preparedness plans should include some process by which individuals affected by ventilator rationing would have the opportunity to appeal adverse decisions. However, the issue of appeals processes to ventilator rationing decisions has been largely neglected in state pandemic planning efforts. If we are to devise just and effective plans for coping with a severe influenza pandemic, more attention to the issue of appeals processes are considered, and some suggestions are offered to help efforts at devising more rational pandemic preparedness plans.

Keywords

Appeals processes; Ethics; Justice; Pandemic influenza; Ventilator rationing

Introduction

In the event of a severe influenza pandemic, the need for life-saving mechanical ventilation will far outstrip the ability to provide it. According to planning assumptions from the Department of Health and Human Services (DHHS), in the United States alone, a severe influenza pandemic would infect 90 million people, hospitalizing nearly 10 million, with almost 1.5 million in ICU units and with nearly three quarters of a million people requiring mechanical ventilation [29]. According to Donald [15] report in the New York Times, there are 105,000 ventilators in the US, 100,000 of which are in use during a regular flu season, although these numbers are difficult to verify since there is no systematic reporting of ventilators or utilization rates and, according to McNeil, there is "a dispute between government health and security agencies about whether the size of the stockpile ought to be kept secret" that makes verification of the size of the federal stockpile difficult [15]. At the peak of a severe epidemic of moderate duration, the CDC's modeling program *FluSurge* predicts that influenza patients would require nearly twice the total number of hospital beds, twice the total number of ventilators, and over 4½ times the total number of ICU beds in the US [12].

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The effect of the material shortfall of available ventilators in a severe pandemic situation is likely to be compounded by the fact that the capacity to utilize existing equipment will be limited in such conditions. Many hospitals already function at or near their full capacity for ventilation [25]. Shortages of qualified workers to distribute and operate ventilators during a severe pandemic may also negatively affect ventilation capacity as available staff members become ill or are in the process of recovery from illness [2]. Any attempt to cope with ventilator rationing issues therefore cannot focus exclusively on the availability and distribution of machines. Attempts must also take seriously the effect of a severe pandemic, and of the response to it, on those who are required to provide care during and after the crisis.

The deficit of usable ventilators in many countries will be even more dramatic than what is predicted for the US. In addition to having fewer material resources and qualified staff in supply to cope with the increase in sick patients, low and middle income countries will likely face even higher demands during a severe pandemic than those assumed by US planners. Although the current H1N1 pandemic has not so far proven to be the sort of severe pandemic situation under discussion here, experience with it has suggested some specific ways in which other countries are uniquely affected by pandemics. For example, Dominguez-Cherit et al. [6] report that while demographic and clinical presentations of H1N1 influenza in early cases in Mexico were similar to those in other affected countries, mortality rates for H1N1 patients in Mexico were higher, citing the fact that early intervention was less common in H1N1 cases in Mexico, as well as greater air pollution, as possible explanations for the increase in severity and mortality. The H1N1 pandemic also suggests how economic and cultural considerations can lead to greater strain on medical institutions in other countries than what the US might expect to experience during a severe pandemic. For example, despite advice from the World Health Organization and other experts, economic limitations prevented some countries from instituting a national H1N1 vaccination program even though a vaccine was available, and Poland flatly rejected importing the H1N1 vaccine due to popular mistrust of claims about its safety and efficacy [9]. Were H1N1 to prove to be the sort of severe pandemic postulated by the planning assumptions discussed above, the resulting impact on deficits in usable ventilators from such factors would far exceed the effects which have been anticipated for the US and for other developed countries.

In light of such considerations, the gap between the expected supply and demand of usable ventilators requires serious forethought about how best to ration the limited supply of ventilators in severe pandemic situations. While pandemic rationing has received considerable attention, much of the discussion has focused on vaccines [7]. However, several facts about mechanical ventilation differentiate its specific planning challenges from those related to vaccines, rendering such discussions of marginal value in the context of ventilator rationing.

In comparison to ventilators, for instance, vaccines are inexpensive to acquire and easy to transport, distribute and administer to relatively large groups. Mechanical ventilation, on the other hand, is very expensive to provide and requires centralized care provided by skilled professionals. Plans for rationing and distributing vaccines, therefore, may not help address the specific challenges that ventilators present, and any cost/benefit analysis concerning who should get access to scarce vaccine likewise may not apply to deliberations about ventilator rationing. Moreover, while vaccines aim to protect both the recipients and the surrounding community from future harms by curtailing the spread of illness, mechanical ventilation focuses on saving the lives of particular individuals who are already seriously ill. Thus, the underlying concerns and justifications for vaccine rationing policies and decisions are fundamentally different from those concerning ventilators. Additionally, ventilators, unlike

vaccines, aim to save those in clear and present danger, which means that the effects of ventilator rationing decisions on particular individuals are obvious, immediate, and dramatic. Thus, particular rationing decisions are likely to take place in highly emotionally charged circumstances.

A further difference relevant to vaccine and ventilator rationing planning efforts concerns the broader conditions under which allocations are likely to be made. It is unlikely that effective vaccines will be available in the early stages of a severe pandemic. If and when effective vaccines do become available, their distribution will likely take place light of some understanding of illness patterns, and allocations can be tailored to this understanding by appropriate agencies or officials. However, in the early stages of ventilator allocation during a severe pandemic, such information will not be available and the vast majority of usable machines will not be distributed from centralized location such as a national depository. For example, while there is a national stockpile of ventilators in the US which is maintained by the Centers for Disease Control (CDC) and can be deployed to different states and jurisdictions during a state of emergency, this stockpile probably comprises fewer than 4,500 machines, or less than 5%, of the 2006 estimated nationwide total number of ventilators [2, 15]. Therefore, pandemic ventilator distribution and rationing strategies cannot rely on the sort of centralized coordination which will likely serve as the model for pandemic vaccine plans.

Discussions about pandemic rationing also must consider how arguments regarding certain prioritizations in vaccine rationing differ from those regarding ventilator prioritization. In a severe influenza pandemic, healthcare and emergency workers will face serious risks related to providing care to the ill, and losses in medical and support staff will have negative effects on the ability of the healthcare system to function in the crisis. Both reciprocity and "narrow social utility"—the usefulness of a particular person to the efforts to mitigate the effects of the crisis— may therefore justify prioritizing these groups in vaccine and antiviral rationing plans [18, 28]. But unlike a reciprocity-based prioritization of vaccines and antivirals, given the potentially serious deficits of ventilators and the geographical distribution of machines, similar prioritizations in ventilator distribution could mean that all machines would be exhausted before any other group could have a chance to get the resource. And since workers sick enough to require mechanical ventilation would be unlikely to return to work during a pandemic, narrow social utility would probably not justify prioritization in ventilator ration plans either, since providing healthcare and emergency workers mechanical ventilation would do little to curb disruptions to the infrastructure [32].

In light of these sorts of considerations, emergency pandemic plans that focus on vaccine rationing discussions but which do not address ventilator rationing specifically do little to help ensure that just and efficient practices are in place for making ventilator rationing decisions. Such plans will provide little aid or protection for the hundreds of thousands of patients in a severe influenza pandemic who will require mechanical ventilation for survival or for the healthcare and emergency workers who must care for them.

A crucial aspect of planning for ventilator rationing during a severe influenza pandemic concerns whether or not to include an appeals process through which individuals may challenge ventilator rationing decisions. Yet this issue remains largely neglected in current discussions and planning efforts. For example, an examination of the 49 available federally mandated US state pandemic preparedness plans revealed that all of the plans do address vaccine rationing and distribution and that most (43) also have plans in place for rationing and distributing antivirals.¹ But only 13 of the 49 plans mention ventilator rationing plans or indicate that some plan is to be included in the future. Of the 49 federally mandated state

plans available, then, only 5 describe guidelines or procedures for ventilator rationing. 3 of these 5 do not address the issue of appeals processes for ventilator rationing decisions at all, and one advocates for their importance but ultimately does not take a stand on the question. Consequently, only one state, North Carolina, provided explicit and specific guidance for whether or not appeals processes should be included in ventilator rationing procedures. Two sentences constituted the sum total of specific guidance on this issue within all federally mandated US state pandemic preparedness plans. They read: "There should be opportunities to revisit and revise decisions as new information emerges throughout an influenza pandemic. There should be mechanisms to address disputes and complaints; however, the extent of the review process must be balanced with the need to make quick decisions in the midst of an influenza pandemic." [21]. There is little evidence that other countries, including European Union nations, have made significant progress in providing guidance on appeals processes in their pandemic rationing plans.

If we are to devise just and effective plans for coping with a severe influenza pandemic, more attention to the issue of appeals processes in pandemic ventilator rationing planning is needed. Here, we examine the practical and ethical issues involved in including appeals processes for ventilator rationing decision-making in a severe influenza pandemic. In the following section, we outline the main arguments in support of the intuition that ventilator rationing in a severe pandemic requires appeals processes and show why each fails to establish this claim with necessity. In the next section, we outline the argument against including such processes in pandemic planning. Finally, we offer some suggestions for how to best promote the justice, legitimacy, and utility of pandemic ventilator rationing plans without requiring appeals processes.

Arguments for Requiring Appeals Processes

Justice

The main argument in support of including an appeals process in pandemic ventilator rationing plans holds that such processes are required by fairness or justice [20]. Typically, discussions concerning justice in the medical rationing context have focused on the principles that determine what counts as a just distribution of scarce resources or how allocation decisions are made [7, 24, 33]. However, such questions of distributive justice can be separated from questions about procedural justice. Regardless of which distributive principles are accepted, it is also often thought that justice requires certain mechanisms through which affected parties may challenge particular decisions. It is this notion of procedural justice which allegedly requires the inclusion of appeals processes in rationing policies and which is the focus of the discussion here.

The most influential account of why procedural justice requires appeals processes is developed by Norman Daniels [4]. According to this view, appeals processes serve important functions in rationing policies and decisions by (1) fostering democratic governance of healthcare; (2) enhancing the legitimacy of the decision-making system by ensuring that no good reasons for making a decision are excluded from the process; and (3) by promoting a fair distribution of burdens by initiating a process through which affected parties with legitimate reasons to be excluded from the general decision-making procedure may have a fair hearing on those reasons. The failure to include appeals processes in rationing policies saddles individuals with autocratic "top–down" decisions which are not always sensitive enough to the particular facts to ensure that denials of resources are made in light of all of the relevant and sometimes unique considerations of the individual cases.

¹State plans were collected July 7–9th, 2009. Plans were collected from the DHHS pandemic website (www.pandemicflu.gov/plan/stateplans.html), from various state health department websites, and by email requests to state health departments.

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Therefore, rationing decisions without appeals processes in place threaten deeply and widely shared commitments to democratic and egalitarian principles, and are less likely to have been arrived at in full view of all relevant reasons. In short, this view holds that appeals processes of some sort are necessary components for any procedurally just limit-setting policy.

There is indeed much to be said for the view that procedural justice requires some mechanisms for the review of decisions and for the participation of affected individuals in the decision-making process. But it does not follow from these requirements that *appeals processes* are necessary for procedurally just rationing in emergency situations since they do not constitute the only possible mechanisms for such review and participatory opportunities. And in dire situations, the concern to promote democratic governance of healthcare also might be thought to be less important than it is in non-emergency conditions, due to substantial limits of time or resources. Therefore, with respect to planning for severe pandemics, egalitarian and democratic considerations might be sufficiently satisfied at the stage of policy-formation and policy-adoption, and through other mechanisms such as retrospective review and improved legislation, without resorting to appeals processes.

Likewise, what counts as a "good reason" in the decision-making process, or as a legitimate reason to be excluded from the general decision-making procedure, may be altered in a severe pandemic situation. In ideal circumstances, any particular consideration which might cause an individual case to fall outside of the blunt criteria set by a decision-making system should count as a good reason to reconsider that case on its own merits as an exception to the general procedure. Thus, for example, within certain limits, the legal system allows individuals to appeal verdicts on grounds that some evidence was not available at the initial hearing or by challenging the application of the rules and procedures in the particular case given some set of unique circumstances. However, because actual conditions are not ideal, at some point in the process the opportunity to appeal on such grounds must surrender to constraints that appeals processes make on a system and, at that point, the decision must stand. As the strain on the system and the need to reach the finality of a decision increases, what should count as a good reason to allow affected parties the opportunity to trigger an appeal diminishes. In severe pandemic situations, it is possible that the strain on the system would be sufficient to entail that no particularities of an individual case justify excluding that case from the general decision-making procedure, or claiming that the system is insufficiently sensitive to all relevant facts, or diverting the use of scarce resources in order to reexamine and rectify contested decisions. In such a situation, it is not the case that good reasons relevant to the decision or legitimate grounds for making an exception to the general procedure are simply ignored. Rather, it is the case that the particularities which ordinarily count as good reasons or legitimate exceptions no longer reach that threshold. Thus, the absence of an appeals process need not constitute a system's inability to address all relevant and good reasons adequately. It is at least plausible, then, that the legitimacy of a system under dire circumstances can be maintained through other avenues than appeals processes for ensuring that all relevantly good reasons and legitimate exceptions are considered (e.g., through carefully constructed and administered triage criteria and retrospective review). Therefore, while democratic governance, legitimacy, and fairness are not irrelevant to the justice of ventilator rationing in severe pandemic situations, they do not guarantee that appeals processes are in fact necessary for just rationing in dire circumstances.

Mistrust and Historical Concerns

The sorts of issues that Daniels raises apply to systems even where the policies are consistently followed and the intentions of policy and decision makers are above reproach. However, the medical profession has been repeatedly rocked by controversies and scandals

which have undermined the public's trust [3, 13]. Groups who have been victims of or witnesses to previous abuses or unjust allocations of medical resources, such as African Americans in the US, may be unwilling to trust any system which passes "top–down" decisions about life and death. Suspicions that the rich, powerful, or well connected receive preferential treatment do, in light of all of these considerations, find real traction. Instituting an appeals processes may help quiet some of these concerns, protect the public's trust, and minimize potential future abuses [26].

Given that policy-makers and healthcare professionals depend on the public's trust, it may be argued that appeals processes are required to secure public support for any rationing program by requiring a more open decision-making process and fostering accountability within it. But as Onora O'Neill has argued, recent attempts to promote public trust in medicine and the biomedical sciences through efforts to promote openness and accountability have met with mixed success at best [23]. The focus on openness and accountability, while well-intentioned, belies the complexity of causes underlying public mistrust and may, in practice, increase mistrust.

While we should be careful not to construe this as an argument against all measures meant to promote openness and accountability, we should also be cautious of claims that mistrust in medicine can always be met with efforts to improve the transparency and accountability for decision-making. The sources of mistrust are numerous and complex, and trust lost is not easily regained. It is possible that appeals processes could help garner public support for ventilator rationing in a severe pandemic situation, but if mistrust is as rampant as O'Neill suggests, it is also possible that those processes will themselves not be trusted. Without more research, it is difficult to say just how effective appeals processes could be in winning the support of the public or of particular groups who might otherwise be skeptical of rationing policies. What we do know, however, is that previous experiences with pandemics suggests that the public is generally receptive to public health measures provided that their justification is well communicated and compliance is not sought through coercive police powers. Given these experiences, it is plausible to assume that efforts to partnership with communities may be at least as effective in securing the necessary support for rationing policies as individual appeals processes would be.

Accuracy and Quality

Another argument in favor of including appeals processes within pandemic ventilator rationing plans is based on the thought that they may help to improve outcomes. In addition to the drastic increase in patients requiring ventilation, the DHHS planning assumptions expect between a 30 and 40% drop in available healthcare workers [29]. Even in well functioning hospitals where there is no significant decrease of available healthcare workers, there is evidence to suggest that in mass casualty incidents, there is an inverse relationship between caseload and the quality of critical care, and a tendency to over-triage [8, 11]. With the disruptions to usual procedures and the ad hoc adjustments to emergency plans that may occur when healthcare and emergency workers find themselves strained and short-staffed due to worker illness and recovery from illness, it is reasonable to expect increased caseloads will have an even greater negative effect on the quality of decision-making and care. One may argue then that the inclusion of an appeals process may help to identify some of the anticipated errors by including the patient or patient's advocates as part of quality control and therefore that such processes are important for quality assurance purposes in these circumstances.

This is a reasonable position, but it is also an empirical one for which we lack good data comparing systems employing appeals processes to those employing other quality controls such as retrospective review. Without this information, it is not obvious that appeals

processes in dire situations are effective mechanisms for identifying mistakes. Clearly, more research is needed here.

Even were appeals processes useful for identifying mistakes, however, they may not be particularly useful in *correcting* them since in these circumstances it may not be ethical or even possible to rectify particular ventilator rationing even if an appeal were successful. Appeals processes can be effective quality controls only if successful appeals result in undoing inappropriate individual rationing decisions. But how likely is it that the successful appeals of ultimately warranted grievances will result in issuing ventilators to patients who were initially denied one? Given the expected major discrepancies between usable ventilator supply and demand, there simply may not be the available resources necessary to render appeals processes effective, corrective measures. In addition to material constraints which may make providing avenues for appeals ineffective, the temporal constraints on decisionmaking also raise difficulties for the claim that these processes can positively affect the quality of decisions made and care given. Depending on the speed of the process, some patients may not survive the appeal. Even if a patient was wrongfully denied access to ventilation, by the time the decision was reviewed and reversed, the patient may no longer benefit from being given access even if an available machine could be located at that point. This raises ethical questions which may even further limit the effectiveness of appeals processes as means of improving the decision-making process. If the condition of a patient who successfully appeals an initial triage decision deteriorates during the process such that she no longer meets inclusion criteria, should the wrongfully denied ventilator be provided or withheld at this point? To provide ventilation in these cases would be both ethically problematic and would undercut the argument that appeals processes improve outcomes. Finally, in light of all of these sorts of concerns, one may wonder how realistic it is to suppose that the person or persons reviewing the case are going to overturn the initial triage decision-maker's judgment in these circumstances. At the very least, much more theoretical and empirical work must be done before we can conclude that appeals processes can be effective quality control measures for ventilator rationing in severe pandemic circumstances.

Liability

Another reason why appeals processes might be thought to be important for ventilator rationing plans concerns liability issues. As the North Carolina plan notes, "If there is an adverse health outcome because of the need to ration healthcare services or the need for healthcare providers to work outside their normal scope of professional responsibility, healthcare personnel and organizations may be subject to professional liability lawsuits or other legal challenges" [21, p. 31]. Having an appeals process in place can, in some instances, resolve disputes before they end up in the legal system, and, for those that do result in legal action, the existence of an appeals process can help to establish that decision-makers acted with the reasonably appropriate amount of transparency and review. Furthermore, triage decision makers may feel less threatened to make difficult decisions which will result in patients being refused life-saving treatment, and to make them according to consistent criteria, if the threat of liability after the event is diminished [10]. Reducing the possibility of litigation may also help reduce some absenteeism by providing healthcare and emergency workers some additional protections [14].

This is an important and plausible justification for including appeals processes in pandemic ventilator rationing plans. However, there are other possibilities for at least coping with the threats of liability after the event. Enacting legislation protecting healthcare workers from possible litigation over triage decisions is one such possibility that would not contribute to delays in care. If there are good reasons to suppose that instituting appeals processes in severe pandemic ventilator rationing plans might be dangerous or unwise, then since none of

the other arguments have established that appeals processes are necessary, alternatives such as retrospective review and stronger legislation for protecting healthcare workers and their decisions from the threat of litigation ought to be preferred to instituting appeals processes. In the next section, we take up the argument that there may be such reasons.

Against Appeals Processes

Decisions whether or not to include an appeals process within pandemic ventilator rationing plans must consider the effects that doing so may have on both the quality and efficiency of the healthcare system and the safety of workers and patients. Appeals processes will shift already strained resources away from the direct care of patients. And they may do this by giving the option to those who feel that they have nothing to lose by exhausting every avenue available to receive a desired treatment. Although appeals processes generally aim at resolving disputes, in these conditions they may serve to create unnecessary and potentially hostile confrontations among staff and patients or their advocates, or within the staff itself. Without experience in implementing such plans during a severe influenza pandemic, there is little hard evidence to evaluate such claims. Nevertheless, it is over questions about safety and feasibility that the most serious objections to appeals processes in ventilator rationing plans are raised.

The few plans and independent proposals for pandemic ventilator rationing remain sharply divided, sometimes within themselves, over the potential dangers of appeals processes to the infrastructure and to patients' and healthcare workers' well-being. One of the earliest proposals for ventilator rationing guidelines, the Ontario Health Plan for an Influenza Pandemic (OHPIP) includes appeals processes, though it offers little discussion about the justification for doing so [17]. The OHPIP proposal served as a model for the influential proposal offered by the New York State Taskforce. While the New York Taskforce's proposal does call for an appeals process, it notes that doing so "will engender controversy and objections," and acknowledges that its members remained split on what sort of review process would best "serve the goal of providing a just and workable triage system" [22, p. 35]. Some Taskforce members worried that a real-time appeals process by which individual triage decisions could be challenged might create "unworkable delays" and invite "explosive debate during a time of scarce manpower and other resources," [22, p. 36] and so the issue was set aside for further discussion and the present plan offers no specific guidance on it. The guidance document offered by the Indiana University Center for Bioethics Pandemic Taskforce seconds the New York Taskforce's worries about the feasibility of an appeals process and endorses the recommendation for retrospective review but, unlike the New York proposal, the Indiana proposal does not ultimately asserts the existence of a moral requirement for allowing appeals [16]. Recommending such a procedure, it states, "would be likely to interfere substantially with the system of resource allocation," and thus it instead recommends "daily review of decisions by the central triage officials, with prospective, system-wide resolution of discrepancies which become apparent" but no avenue for challenging and correcting individual decisions [16, p. 32].

Concerns about the feasibility of instituting an appeals process are also at the core of the Task Force for Mass Critical Care Summit Meeting's proposal [5]. Relying on the model of emergency triage developed within the military and paramilitary traditions, and developed within the literature on dealing with trauma (as opposed to dealing merely with the scarcity of resources common in rationing discussions), the Mass Critical Care proposal flatly rejects the acceptability of any appeals process as antithetical to the function of the triage officer. Drawing on the command and control model of decision-making that informs this tradition, this proposal identifies the triage officer's function primarily with the effective and efficient management and oversight of clinical decisions in a time of crisis: "The triage officer is in

charge, assesses all patients, assigns a level of priority for each, and directs attention to the highest-priority patients" [5, p. 58S]. Although it notes that ethical standards exist which should govern the decisions of the triage officer and repeated review of triage operations should be conducted "to ensure "procedural justice"," this proposal holds that "appeals to the triage procedure may be impractical based on the urgency with which the allocation decisions must be made. Individual physicians, administrators, or government officials should not be able to overrule a "good faith" decision made by a triage officer in compliance with the triage process" [5, p. 62S]. In short, on this view the legitimacy and efficacy of triage decisions rests on the proven effectiveness of a command and control organization in a crisis and on an individual entrusted by the system to serve that function. Allowing the triage officer's good faith decisions to be challenged by those who stand to lose access to life-saving treatment undermines his or her decision-making authority and the ability of the system to respond to a crisis situation effectively.

While we support this proposal's claim that rationing decisions in a severe pandemic would be most effectively made by centralized triage officers, we recognize that some may prefer to leave triage decisions in the hands of individual physicians. However, although the Mass Critical Care proposal ostensibly objects to appeals processes as antithetical to the role of the triage officer, plans which would eliminate this role would not make appeals processes any less dangerous to patients and healthcare workers since the urgency of the decisions being made and the conditions under which they made are not changed by who is making it. And since the efficiency of the centralized triage officer model is achieved by eliminating other voices in the decision-making process and diminishing the complexity facing decision makers, relying on a non-centralized model may increase the likelihood that disagreements and conflicts arise as each stakeholder has an interest, and in the case of the patient's individual physician, perhaps an ethical duty to advocate for her own individual case independently of whether denying care could lead to greater benefits for other patients [27, pp. 83–84]. Thus, without here attempting to defend the claim that centralized triage officers ought to be decision makers in these circumstances, it is enough to recognize that the strains and dangers of appeals processes are greater in non-centralized decision-making systems than in centralized ones. Thus, if appeals processes are inappropriate in a command and control model, they are *a fortiori* inappropriate in a decentralized one where the problems of urgency and the difficulties associated with making life-or-death decisions in highly emotionally charged environments are only compounded by the plurality of interests and voices involved in the process.

Discussion and Suggestions for Improvement

In planning for a severe influenza pandemic, inadequate attention has been paid to the issue of ventilator rationing in general and to the issue of appeals processes to ventilator rationing decisions in particular. The unique nature of and challenges presented by ventilator rationing in a severe pandemic mean that general emergency plans or non-ventilator-specific plans will be of little use to either the patients in need of mechanical ventilation or the healthcare and emergency worker who need to care for them. Central to the justice, feasibility, and efficacy of pandemic ventilator plans is the issue of appeals processes. But while there have been some calls for requiring appeals processes in severe pandemic ventilator rationing plans, no wide consensus has emerged and little practical guidance is available.

There are two likely reasons that ventilator rationing has, in comparison to vaccine and antiviral rationing, received so little attention in state planning efforts. The first is that, as the US Government Accountability Office found, states are reluctant to take up the difficult questions of end-of-life rationing [31]. Vaccine and antiviral rationing, on the other hand, are seen as an important public health measures. That is, while vaccine and antivirals are

scarce resources that will be denied to some who might benefit or even be saved by them, their rationing aims primarily at protecting the health of the community rather than treating an already severely ill individual. Even such difficult public health concerns may be easier and less politically costly to deal with than end of life issues.

As noted above, the specific challenges presented by pandemic ventilator rationing mean that discussions and policies focused on vaccine rationing will be of limited value. But with regard to the willingness of legislators and policy-makers to address these issues, the differences between vaccine rationing and ventilator rationing should not be overemphasized. Vaccine rationing saves some individuals and not others as well, and welldeveloped pandemic ventilator plans contribute to the effectiveness and safety of the entire crisis response system. Ventilator rationing procedures may also have some, albeit very marginal, direct influence over how the disease is transmitted and progresses in the population, and ventilator plans in general will certainly have an effect on the rate at which healthcare workers operating the machines will be harmed while caring for the ill [25]. So while the problems and solutions for vaccine rationing and ventilator rationing must be recognized as different, the differences between the justification for and the implications of efforts to address those problems are less significant with regard to the willingness to address them. Legislators, policy-makers, and healthcare workers should endeavor to approach ventilator rationing under severe pandemic conditions as an important public health measure and recognize the limits and dangers of treating it primarily as an end-of-life or critical care issue [33].

The second possible reason for the remarkable differences between vaccine and ventilator preparedness is the amount of attention and aid that vaccine and antiviral state preparations have received from the federal government. As noted above, all of the state-level plans do include plans for vaccine rationing and distribution. In its 2009 report, the DHHS found that vaccine distribution was one of the areas where "major gaps" did not, in general, exist, and added that this was "no doubt...facilitated to a significant extent by repeated and substantial investments of Federal funds and technical assistance-not only annual awards for public health emergency preparedness in general since 2002 but also emergency supplemental appropriations in 2006 and 2007 that were targeted to pandemic influenza preparedness" [30, p. 43]. The federal guidelines for vaccine rationing provide states with uniform and well developed guidance for their individual pandemic planning efforts. Federally developed guidelines also provide some means of minimizing or deflecting dissatisfaction and skepticism that can frustrate local attempts to address controversial issues. The development of federal guidelines for ventilator distribution in severe pandemic situations would therefore likely prompt significant improvement in state planning efforts. Those guidelines should address appeals processes explicitly. And given the spotted history of medical rationing and allocation and the lack of trust which exists, this process should be involve a wide array of stakeholders and its justifications and implications should be wellcommunicated to the public. As an added note, the DHHS also suggests that states should consider greater cost sharing as a proven means of increasing local preparedness. This ought to be pursued by states, but given the significant costs of ventilator procurement, emphasis on increased state financial responsibility should not overshadow the role of that federally developed guidelines could play in increasing preparedness.

Federal guidelines would also help to provide further protection from liability for healthcare and emergency workers by establishing some measure for altered standards of care when the allocation of resources must shift from the current focus on improving the health or saving the life of the individual to another goal, such as saving the most lives possible (see [1, chap. 2]). However, unless specific legislation is adopted at the state and local levels, it is unclear how the courts will interpret the importance of these standards in their decisions. Legislation

should be enacted to protect healthcare workers complying with established altered standards of care from subsequent legal action.² Doing so would also eliminate one of the reasons to recommend appeals processes in ventilator plans.

While questions about the degree of danger that appeals processes actually pose to healthcare and emergency workers cannot be answered with great precision and confidence, we can reasonably expect to see an increase in errors and a decrease in the quality of care during a severe pandemic. It is possible that these problems may be even greater than those experienced during the relatively localized mass injury events and non-pandemic situations from which experience can draw. These facts do entail a need for some mechanism by which decisions can be monitored and reviewed and procedures can be adjusted. However, it is doubtful that relying on patients and their families to serve in a quality control capacity will be as effective as an institutionalized, organized, and regular retrospective review process.

Conclusion

Questions and concerns about the fairness of applying a fallible system to life and death decisions for individuals who have little or no say in the decision-making process often cannot be avoided. However, the major arguments in favor of appeals processes all fail to establish that such processes are necessary components of a reasonable, just, and effective plan for ventilator rationing in a severe pandemic. And since it is at least likely that including appeals processes in plans for severe pandemic ventilator rationing would have some non-negligible costs in safety, efficacy, and ultimately the quality of care and number of lives saved, these questions and concerns must be balanced against those potential costs. While no plan can ensure a perfect balance of all of these concerns, steps can be taken to minimize errors and potential injustices without instituting appeals processes.

Existing pandemic preparedness plans should be developed to include ventilatorspecific guidelines and procedures. These should include measures aimed at improving surge capacity as well as at providing explicit guidance for implementing triage criteria and procedures. The adoption of clear, objective, and easily measurable clinical triage criteria in these plans helps to minimize potential injustices and errors, and reduces the need for individual physician judgment in triage decisions, thus further relieving pressures to include potentially dangerous appeals processes (See, for example, [19]). Transparent and wellarticulated national guidelines reflecting these suggestions should be proposed, and state and local legislation drafted to ensure protections for both patients and healthcare providers in case of disputes over particular decisions. Plans should adopt a competent and regular retrospective review of triage decisions and allow for revisions to triage protocol in light of those reviews. If these steps are taken, pandemic planning efforts can reasonably and ethically justify not including individual appeals processes and the potential problems threaten to create. These suggestions may hopefully help chart a way for discussions toward more actionable pandemic planning which is sensitive to the attractiveness of the idea of appeals processes in medical rationing policy, but which, at the same time, recognizes the potential dangers and difficulties that appeals processes pose under severe pandemic conditions for both patients and those who must care for them.

 $^{^{2}}$ The Institute of Medicine has recently called for necessary legal protections for triage officers operating under altered standards of care. See http://www.medtau.org/pandemic/ChristianPresentation.pdf.

Health Care Anal. Author manuscript; available in PMC 2014 March 14.

Acknowledgments

This research was supported by the Intramural Program of the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH). It does not represent the views of the NIEHS, NIH, or U.S. government.

References

- 1. Agency for Healthcare Research and Quality. Altered standards of care in mass casualty events. 2005. Available at http://www.ahrq.gov/research/altstand/
- American Association for Respiratory Care. Guidelines for acquisition of ventilators to meet demands for pandemic flu and mass casualty incidents. 2008. Available at http://www.aarc.org/ resources/vent_guidelines_08.pdf
- Checkland K, Marshall M, Harrison S. Re-thinking accountability: Trust versus confidence in medical practice. Quality and Safety in Health Care. 2004; 13:130–135. [PubMed: 15069221]
- 4. Daniels, N. Just health: Meeting health needs fairly. Cambridge University Press; Cambridge: 2007.
- 5. Deverauz A, Dichter J, Christian M, Dubler N, Sandrock C, Hick J, et al. Definitive care for the critically ill during a disaster: A framework for allocation of scarce resources in mass critical care. Chest. 2008; 133:51S–66S. [PubMed: 18460506]
- Dominguez-Cherit G, Lapinsky S, Macias A, et al. Critically ill patients with 2009 influenza A (H1N1) in Mexico. JAMA. 2009; 302:1880–1887. [PubMed: 19822626]
- 7. Emanuel E, Wertheimer A. Who should get influenza vaccine when not all can? Science. 2006; 312:854–855. [PubMed: 16690847]
- Frykberg E, Tepas J. Terrorist bombings: Lessons learned from Belfast to Beirut. Annals of Surgery. 1988; 208:569–576. [PubMed: 3056287]
- Gera, V. Poland stands alone in refusing swine flu vaccines. Associated Press; Warsaw: 2010. Available at http://abcnews.go.com/Business/wireStory?id=9550082
- Hick J, O'Laughlin D. Concept of operations for triage of mechanical ventilation in an epidemic. Academic Emergency Medicine. 2006; 13.2:223–239. [PubMed: 16400088]
- 11. Hirshberg A, Holcomb J, Mattox K. Hospital trauma care in multiple-casualty incidents: A critical view. Annals of Emergency Medicine. 2001; 37.6:647–652. [PubMed: 11385336]
- Inglesby, T. Comments from Thomas Inglesby, senate subcommittee on bioterrorism and public health preparedness roundtable on "all hazards medical preparedness and response. 2006. Available at http://help.senate.gov/Hearings/2006_04_05/Inglesby.pdf
- 13. Jonsen, A. The birth of bioethics. Oxford University Press; New York: 2003.
- McGorty E, Devlin L, Tong R, Harrison N, Holmes M, Silberman P. Ethical guidelines for an influenza pandemic. North Carolina Medical Journal. 2007; 68:38–42. [PubMed: 17500430]
- 15. McNeil, D. Hospitals short on ventilators if bird flu hits. The New York Times. Mar 12. 2006 Available at http://www.nytimes.com/2006/03/12/national/12vent.html
- Meslin, E.; Alyea, J.; Helft, R. Pandemic flu preparedness: Ethical issues and recommendations to the Indiana State Department of Health. Indiana University, Center for Bioethics; 2007. Available at http://www.bioethics.iu.edu/pandemicFluPrep_2007.pdf
- 17. Ministry of Health and Long-Term Care. Ontario health plan for an influenza pandemic. 2008. Available at http://www.health.gov.on.ca/english/providers/program/emu/pan_flu/ohpip2/ plan_full.pdf
- 18. Moreno, J. In the wake of terror: Medicine and morality in a time of crisis. MIT Press; Cambridge: 2003.
- Moylan C, Brady C, Johnson J, Smith A, Tuttle-Newhall J, Muir A. Disparities in liver transplantation before and after introduction of the MELD score. Journal of the American Medical Association. 2008; 300.20:2371–2378. [PubMed: 19033587]
- 20. New York State Department of Health. Pandemic influenza plan. 2008. Available at http://www. health.state.ny.us/diseases/communicable/influenza/pandemic/plan/docs/ pandemic_influenza_plan.pdf

- 21. North Carolina Institute of Medicine. North Carolina Department of Health and Human Services. Division of Public Health. Stockpiling solutions: North Carolina's ethical guidelines for an influenza pandemic. North Carolina Task Force on Ethics and Pandemic Influenza Planning. 2007. Available at http://www.nciom.org/projects/flu_pandemic/flureport.pdf
- 22. NYS Workgroup on Ventilator Allocation in an Influenza Pandemic. Allocation of ventilators in an influenza pandemic: Planning document (2007 draft). New York State Department of Health, Pandemic Influenza Plan. 2008. Available at http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/plan/docs/pandemic_influenza_plan.pdf
- 23. O'Neill, O. Autonomy and trust in bioethics. Cambridge University Press; Cambridge: 2002.
- 24. Persad G, Wertheimer A, Emanuel E. Principles for allocation of scarce medical interventions. The Lancet. 2009; 373:423–431.
- Rubinson L, Branson R, Pesik N, Talmor D. Positive-pressure ventilation equipment for mass casualty incidents. Biosecurity and Bioterriorism. 2006; 4.2:183–194.
- 26. Saunders G. Eliminating injustice toward disadvantaged populations during an influenza pandemic. North Carolina Medical Journal. 2007; 68.1:46–48. [PubMed: 17500433]
- 27. Strosberg, M.; Teres, D. Gatekeeping in the intensive care unit. Health Administration Press; Chicago: 1997.
- Tabery J, Mackett C. The ethics of triage in the event of an influenza pandemic. Disaster Medicine and Public Health Preparedness. 2008; 2.2:114–148. [PubMed: 18525374]
- 29. U.S. Department of Health and Human Services. Pandemic planning assumptions. 2009a. Available at http://www.hhs.gov/pandemicflu/plan/part1.html#2
- 30. U.S. Department of Health and Human Services. Assessment of states' operating plans to combat pandemic influenza. 2009b. Available at http://pandemicflu.gov/professional/states/ state_assessment.html
- U. S. Government Accountability Office. Emergency preparedness: States are planning for medical surge, but could benefit from shared guidance for allocating scarce medical resources. U.S. Government Accountability Office; Washington, DC: 2008.
- 32. Vawter, D.; Garrett, J.; Gervais, K.; Prehn, A.; DeBruin, D.; Tauer, C.; Parilla, E.; Liaschenko, J.; Marshall, M. For the good of us all: Ethically rationing health resources in Minnesota in a severe influenza pandemic, preliminary report for the Minnesota pandemic ethics project. 2009. Available at http://www.ahc.umn.edu/mnpanflu/prod/groups/ahc/@pub/@ahc/@ethicsmpep/documents/ content/ahc_content_090503.pdf
- 33. White D, Katz M, Luce J, Lo B. Who should receive life support during a public health emergency?: Using ethical principles to improve allocation decisions. Annals of Internal Medicine. 2009; 150:132–138. [PubMed: 19153413]