

Expert Panel Report

REPORT FROM THE PANDEMIC INFLUENZA PROJECT *EXPERT PANEL MEETINGS*

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Introduction

With avian influenza endemic in Asia, Europe, and Africa, the threat for a human pandemic outbreak is expected and cannot be ignored. The United States has begun preparing for a potential influenza pandemic in order to build resilience to this potential disaster. Federal, state, and local entities vary in their level of preparation.

With an influenza pandemic come severe economic consequences and heightened threats to human health and security. Inevitably, the virus will cause illness, disability, and death in humans while potentially destabilizing populations in several countries. This presents a need for ethical, socially-just decision making within defined parameters at various points during the lifetime of a pandemic. Incorporation of ethics will influence pandemic planning efforts and bring together the scientific dimensions and the ethical values and principles of planning assumptions.

In August of 2007 under contract with the Indiana State Department of Health (ISDH), the Indiana University Center for Bioethics (IUCB) provided to the ISDH a set of Technical Advisory Documents (TADs) concentrating on ethical issues that may arise in the event of an influenza pandemic. The TADs focused on four key topics: (1) altered standards of care (2) triage (3) vaccine and antiviral allocation and (4) healthcare workforce management. A framework of seven ethical points was presented that the Center believes the State should consider when formulating policy in response to an influenza pandemic. These seven points include: (1) consistency with the Mission of ISDH and other

healthcare organizations in general; (2) transparency; (3) public accountability; (4) responsiveness; (5) proportionality; (6) reciprocity; and (7) uniformity of implementation.

Since that time, experts have added to the literature and policies that shape pandemic influenza planning and the ISDH has once again contracted with the IUCB to update the TADs according to current thinking. In order to do that, IUCB engaged expert panels to review each of the TADs and develop case studies to illustrate how the recommendations in the TADs could be applied. IUCB has much experience in conducting expert panels that engage members of the community. The feedback gained from these panels of experts in public health, medicine, and health policy would lead to effective revision of the TADs.

Expert Panel Goals

The Indiana University Center for Bioethics convened expert panels for each of the four topics of the Technical Advisory Documents (TADs): altered standards of care, triage, vaccine and antiviral allocation, and healthcare workforce management. The goal of each meeting was to assess the relevance and applicability of the recommendations put forth by the TADs. Participants were encouraged to apply the seven ethical points and assess the feasibility of the recommendations by examining case studies intended to portray real world ethical dilemmas. Engagement from the public was critical for each panel to learn the full ethical and social implications of pandemic influenza preparedness and planning.

Participants

From February to May of 2008, six expert panels were convened to discuss the applicability and feasibility of the four TADs. Two sessions were held for each of the panels, vaccine and antiviral allocation and healthcare workforce management. One session was held for each of the other two panels, triage and altered standards of care. Participants from many fields across the state of Indiana were sought and invited to join the panels. Healthcare and legal professionals, business and community leaders, public safety and service leaders, teachers, students, and the media were represented. There were no prerequisites for participation in the expert panels, and few members had educational or professional training in bioethics.

The panels were not intended to be exclusive but efforts could not be overly exhaustive: we could not recruit more than fifteen participants for each panel due to limited facility space. Furthermore, it was felt a panel larger than fifteen members might limit effective discussion. Email and word-of-mouth were successful methods in extending invitations to participants. Participation was voluntary and strongly encouraged. Each meeting was held in Indianapolis, at the IUCB. This location made it difficult for some participants, who came from the most distant parts of the state. Panelists who could not attend contributed through email. Each meeting drew between three and eleven participants as expected. A total of thirty-seven participants were involved in the expert panels.

Process

Six meetings were held, each lasting between two and three hours. In preparation for each meeting participants were asked to review the relevant TAD, Executive Summary, and Ethical Points to Consider documents. Each meeting began with a brief overview of the IUCB pandemic influenza project followed by a direct transition to the recommendations for the TAD under analysis. Panelists were prepared and fervent scrutiny of each recommendation occurred. Following discussion of the recommendations, possible case studies intended to depict ethical dilemmas of a pandemic influenza were proposed. At each meeting additional handouts (e.g. IUCB internally prepared background information on TAD topic and external sources from the CDC and HHS) were provided and notes were taken to preserve the discussion.

Final revisions of the recommendations of each TAD were made after the expert panel meetings and redistributed to the panel participants for review and comment. This process ensured that all changes made to the recommendations captured the discussion and intention of the panelists.

Purpose of the Paper

Each panel successfully achieved its goal, to critically analyze and discuss the feasibility of implementing the TADs. The purpose of this paper is to capture a summary of the discussions and the panelists' proposed changes for each original recommendation.

Outcomes

Expert Panel on Altered Standards of Care

One panel was convened to assess the ethical issues of implementing altered standards of care, primarily regarding healthcare delivery in the event of an influenza pandemic. The group consisted of legal professionals, emergency preparedness officials, and a physician from the Indiana University School of Medicine. Panelists engaged in rich discussion of the five recommendations and provided careful criticism of each.

Recommendation 1: The State of Indiana should develop a protocol for altered standards of care, which would take effect for all healthcare institutions upon the declaration of a statewide pandemic influenza emergency by the Governor. This protocol should specify those healthcare professionals affected by this protocol and would include legal protections for healthcare providers and institutions.

The first concern panelists expressed for Recommendation 1 was identification of triggers for declaration of a statewide pandemic influenza emergency. Panelists wanted to know what events in a pandemic influenza would prompt the Governor to declare an emergency, and panelists recommended the State to identify such triggers prior to their occurrence. The second and greater concern of panelists was whether the recommendation offered a false promise for legal protections for healthcare providers and institutions. Healthcare providers on the panel questioned what, exactly, they would be protected against and to what extent the State would provide immunity

for practicing altered standards of care, after the Governor's declaration of an emergency. It was advised that "would include legal protections" should be amended to "should include legal protections."

Recommendation 2: The State should begin immediately to engage owners/administrators of all healthcare facilities in discussions about the impact of a statewide protocol for altered standards of care, including the selection of alternate care sites. All efforts should be made to agree to these changes by consensus and partnership.

Panelists were satisfied with this recommendation and provided no further changes. Discussion centered on fair selection and compensation of potential alternative sites for care, considering ease and access of site for citizens, and emphasized the need to develop partnerships among hospitals, insurance companies, and state healthcare associations.

Recommendation 3: The State should design, develop, and maintain a database of healthcare workers and encourage all healthcare institutions, including professional schools, to identify potential healthcare workers and register them into this database prior to the pandemic.

Panelists agreed that development of a database was necessary for the State to complete prior to an influenza pandemic. It was also encouraged that the State update the list often and ensure all registered healthcare workers have the appropriate qualifications and skills. Panelists also called for future discussion on emergency credentialing and temporary licensing of potential healthcare workers.

Recommendation 4: The State should ensure that a comprehensive program is developed and implemented to provide all healthcare workers with adequate training and information regarding pandemic flu and their anticipated responsibilities.

All panelists agreed with this recommendation and stressed the need for education of all healthcare workers including but not limited to clinicians, residents, medical students, nursing students, paramedics, and pharmacists.

Recommendation 5: The State should establish minimal standards for modified documentation procedures which can be implemented efficiently at the time of the pandemic for all healthcare institutions, mortuaries, and other organizations.

Panelists expressed concerns that adhering to present documentation standards would be cumbersome during an influenza pandemic. Members stressed the need for hospitals to develop altered documentation standards for intake procedures and encouraged hospitals to develop a minimum dataset for uncomplicated and efficient daily review of patients. Panelists were aware that minimum documentation standards would differ among hospitals and alternative care sites, and for that reason, they proposed the State provide guidance on developing minimal documentation standards, rather than creating a blanket set of standards to cover all institutions, mortuaries, and organizations around Indiana.

Expert Panel on Vaccine and Antiviral Allocation

The panel was comprised of clinicians and individuals in public health, brought together in two sessions to discuss the ethical implications for the two recommendations of this TAD. In general, all panelists were apprehensive about obtaining and securing an adequate amount of vaccines and antiviral medications in the event of a pandemic.

Recommendation 1: The Indiana State Department of Health should adopt a system similar to the California Department of Health Services vaccine and antiviral agent prioritization plans and construct a prioritization list based on its implementation.

Panelists discussed the ethical implications of the State adopting a rank-order prioritization scheme for vaccines and antiviral medications. Prioritization schemes developed by California Department of Health Services and the Department of Health and Human Services (HHS) were considered. Panelists did not favor one scheme over the other and attempted to combine the two. Members encouraged the State to clearly define its sub-populations just as California did and additionally, to adopt an allocation methodology similar to the HHS's. Panelists believed that consideration of both schemes would ensure fair distribution of vaccines across the population.

Recommendation 2: The Indiana State Department of Health should develop an education module for county health departments regarding the criteria by which the prioritization plan is developed, and counties should be instructed

as to how prioritization decisions will be made.

The panel supported the general context surrounding the education and dissemination of information for vaccine prioritization, although the wording and target of this recommendation were criticized. For example, “toolkit” and “program” were preferred over “module.” Regarding the target of the educational effort, the panel recommended that the education pieces and prioritization plans should reach other authorities in addition to county health departments (e.g. Emergency Management Agency, local health departments, first responders, professional organizations, and security forces).

In addition to Recommendations 1 and 2, panelists emphasized the need for IUCB to create a new recommendation to address allocation strategies of antiviral medications. The discussion focused on the question of whether medication should be used for treatment or prophylaxis, in part because prophylaxis requires four times the number of pills as does treatment. One panelist argued that “prophylaxis with the antiviral drug, oseltamivir (Tamiflu), would be more successful if there were enough, while treatment with oseltamivir might be a waste of a scarce resource because no benefit would be seen if given more than forty-eight hours after symptoms started,” therein reflecting that the medical system will be stressed in the event of a pandemic and patients are not likely to present for medical attention within the critical first 48 hours. In the end, panelists came to the conclusion that due to the limited supply of antiviral medications, emphasis on prophylaxis would diminish the supply more quickly at the

expense of those infected. Treatment, on the other hand, would maximize utility of the medication. Panelists also recommended the need for a triage scoring tool for distribution of antiviral medications. This tool would be based on physiological data, and the responsibility would lie with supervisors, not the treating physicians, to decide who would receive the medication.

Expert Panel on Healthcare Workforce Management

A diverse group was convened in two sessions to discuss the ethical implications that arise for healthcare workers during an influenza pandemic. Legal professionals, public safety officials, leaders of healthcare agencies, clinicians, human resource specialists, and ethics advisors of healthcare institutions were convened to achieve a broad perspective.

Recommendation 1: The State Department of Health should identify and designate healthcare workers, both professional and nonprofessional, deemed to be critically necessary during a pandemic.

The members felt it would be more appropriate for the State to work with healthcare organizations to identify a list of healthcare workers necessary during a pandemic rather than assume the responsibility itself. Panelists felt healthcare organizations would be better suited to reach more healthcare workers to determine who would be critical and in general, felt this would result in a better communication process. Furthermore, panelists were open to a mathematical model, similar to the vaccine prioritization schemes, to identify critical health-

care workers. The group was particular about the wording of this recommendation and suggested that “professional and non-professional” be changed to “clinical and non-clinical” to include those individuals who are necessary to health-care operations but who do not have a clinical focus.

Recommendation 2: The State of Indiana and healthcare organizations should plan an influenza response on the premise of high expectations for workplace continuity for professional healthcare staff. Efforts should be made to educate fully all healthcare workers, professional and nonprofessional, about the nature of pandemic influenza, and all should be encouraged to develop personal pandemic plans. Professionals additionally should be informed of their professional ethical responsibilities. Efforts should also be made to emphasize each nonprofessional worker’s vital role in the pandemic response.

Panelists were satisfied with the content of this recommendation and the attention placed on a “high expectations, no punishment” approach. The group felt this was the best way to encourage healthcare workers to report to work during a pandemic. Additionally, panelists felt strongly about the responsibility of educating all healthcare workers and suggested the State create informative tools and identify methods of education and personnel responsible for educating providers. The members suggested one way to ensure healthcare providers become educated about the nature of an influenza pandemic is to make professional licensure dependent upon completion of a pandemic training program. Again, the group was particular about the wording of this recommendation and suggested

that “professional and non-professional” be changed to “clinical and non-clinical”.

Recommendation 3: The State should set and communicate expectations that healthcare institutions have adequate supplies of appropriate medical equipment (as defined by the State), prophylaxis, and related material and that these institutions ensure these supplies be made readily available to all critical personnel expected to interact with patients. Healthcare institutions should be expected to inform the relevant county and State health officials of the extent to which they are able to meet these expectations.

Expert panel members believed that in addition to ensuring an adequate allotment of supplies to healthcare facilities, the central theme for this recommendation is the need for clear, efficient modes of communication among counties, healthcare organizations, healthcare facilities, and the State. Members felt that large gaps exist in current communication processes for healthcare expectations between counties and between hospitals and healthcare facilities. It was suggested that the recommendation be updated to make certain the State identifies routes of communication.

Recommendation 4: The State should provide guidance to healthcare institutions in the development of fair and responsive policies for developing incentives for presenting to work, as well as determining sanctions for noncompliance with expected responsibilities. By “clear policies” we mean that an institution should describe whether some or all workers may be permitted to be absent; whether workers may use ac-

crued leave/vacation time; and whether sanctions will be applied to workers who elect to be absent without acceptable reasons.

Considering an earlier recommendation (Recommendation 2), panelists felt that the “high expectations, no penalties” approach was not enough to entice health-care workers to present to work in the event of a pandemic. It was agreed that the State should not provide guidance on developing sanctions but instead provide guidance for developing incentives for reporting to work. The human resource specialists of the panel advised that for healthcare facilities to develop incentives would require additional thought and the advice of many individuals including human resource managers, institutional stakeholders, and legal counsel. Another concern was the potential for confusion among employees transitioning between alternative care sites, and the sharing of employees between facilities as the latter addressed the workforce shortage during a pandemic. The panel recommended that the State work with insurance companies and specialists to find ways to reimburse providers, healthcare facilities, and organizations.

Expert Panel on Triage

A group of clinicians with backgrounds in pulmonology, emergency medicine, and intensive care was an appropriate composition for this panel to address the topic of triage and careful prioritization of scarce resources for patients.

Recommendation 1: The Indiana State Department of Health should adopt the New York State Workgroup’s (2007) protocol, which rejects the consideration of social role and age as triage inclusion

and exclusion criteria in favor of a system of allocation based solely on physiologic prognosis.

Specifically, the New York State Workgroup adopted the Sequential Organ Failure Assessment (SOFA) prognostic scoring system to determine an individual’s triage status. Panelists agreed that effective triage protocols use predictive systems based on acute physiology such as SOFA or APACHE. The group accepted the ethical implications of the recommendation but expressed the need to develop an additional triage method for the pediatric population, also to be based on physiological prognosis. Importantly, the group did not reach consensus on whether to consider age as an inclusion or exclusion criteria for triage allocation decisions. Panelists contended that age is a recognized clinical factor. Additionally, panelists maintained that treating clinicians would refuse to use triage protocol that excluded age. Panelists felt that the State should give greater consideration to age as a clinical factor in evaluating patients for medical attention.

Recommendation 2: The Indiana State Department of Health should encourage all acute care facilities to adopt a common procedure for addressing how to allocate scarce resources when two (or more) patients arrive at an acute care facility with identical prognoses, and there are insufficient resources to treat all.

Panelists appreciated the sensitive implications of this recommendation. In the event of a tie between two or more patients, the panel advised the development of multilevel triage criteria as an additional tie breaker, which would incorpo-

rate other prognostic scoring methods such as APACHE, which does include age as an inclusion or exclusion criteria. Members cautioned, though, that using another scoring method as a tiebreaker might not be consistent with previous recommendations of the TADs.

Recommendation 3: The State should require all acute care facilities to adopt a common procedure to conduct a daily retrospective review of all triage decisions in order to identify flaws in the protocol and to provide accountability.

Panel members were particular about the phrasing and felt that the extent of this recommendation was limited. First, it was advised that “identify flaws in the protocol” be amended to reflect a more positive statement, “identify opportunities for improvement.” Second, the panel felt the recommendation was incomplete and further clarification was needed to describe the purpose and scope of daily retrospective review. Panel members believed that daily review should occur at the State and institutional levels. All triage review and history would be housed in a central database maintained by the State. Panelists concurred this synchronization of data would be an effective method to identify needs and areas for improving protocol to provide the best care throughout the state. Panelists recommended that all healthcare institutions including outpatient, long-term care facilities, and alternative care sites be included in any database or tracking system.

Conclusion

Many issues were considered during the deliberation of ethical implications that could arise in the event of an influenza

pandemic. The panels provided intense discussion and broad input representing many perspectives. The points of debate from the panels illustrated that the issues posed by a pandemic would likely be difficult to grasp and measure. Overlying all the discussion is the recognition that several unknowns related to the nature of an influenza pandemic still exist, including the exact nature of the virus, efficacy of antiviral medications, lag time until available effective vaccine, and public and professional response to the pandemic. Hopefully, the utility of these recommendations will provide reassurance and an adequate foundation for on-going planning efforts.