Pandemic Influenza Preparedness: Ethical Issues and Recommendations to the Indiana State Department of Health

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CENTER FOR BIOETHICS

PANDEMIC INFLUENZA PLANNING:
ETHICAL ISSUES AND RECOMMENDATIONS
TO THE INDIANA STATE DEPARTMENT OF HEALTH

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Executive Summary (ES-0A-2008)

PANDEMIC INFLUENZA PLANNING:
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As of June 2008, 15 nations have reported cases of H5N1 infections, and 12 have reported fatalities. With many experts believing that the world is overdue for an influenza pandemic and that H5N1 has pandemic potential, national, state, and local governments have been in the process of developing strategies to confront this issue. In order to ensure that any such policy is acceptable to healthcare professionals and the public alike, ethical considerations must be taken into account.

In August of 2007, the Indiana University Center for Bioethics (IUCB) presented to the Indiana State Department of Health (ISDH) a set of technical advisory documents (TADs) addressing ethical issues that may arise in the event of an influenza pandemic. The topics of altered standards of care, triage, vaccine allocation, and healthcare workforce management all were addressed in these documents, each with its own annotated bibliography. Additionally, IUCB provided to ISDH an ethical framework entitled *Points to Consider*, which consisted of a set of seven ethical points that the Center believed the State should take into consideration when developing policies and procedures related to pandemic influenza response. Since that time, ethicists, researchers, and policymakers have continued to contribute to the literature and develop policies addressing ethical pandemic influenza planning. As a result, ISDH again contracted with IUCB to update the previous documents with the most current thinking on the respective topics.

In addition to including a review of the most recent literature in the updated technical advisory documents, IUCB made two further changes to TAD development process. First, the Center convened expert panels consisting of healthcare professionals, legal professionals, and other community members to review each of the TADs. [1] Based on the panel members' feedback, IUCB revised its recommendations and included

[1] A report on the use of the expert panels is available under a separate cover.

discussions on any concerns panel members expressed. The second change in the documents is the addition of case studies, which are reflective of the issues presented in the TADs and are intended to portray real world ethical dilemmas that may arise during an influenza pandemic. The solutions to these case studies are based on the recommendations provided and are presented at the conclusion of each TAD. It should be noted that the case studies may be applicable to several of the areas addressed in the four TADs, as the topics frequently overlap.

The following is an overview of the TADs. Further clarification of the recommendations and expert panel feedback are available in the respective documents.

Altered Standards of Care. Issues include the use of alternate care sites, maintaining adequate staffing, and alteration of documentation standards. Five recommendations are proposed:

1) **The State should develop a protocol for altered standards of care that would take effect upon the declaration of the Governor and include legal protections for healthcare providers.**
2) **The State should 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. Efforts should be made to agree to these site acquisitions by consensus and partnership.**
3) **The State should design, develop, and maintain a database of healthcare workers and encourage all healthcare institutions to identify potential healthcare workers and their skills and qualifications and register them into this database prior to a pandemic.**
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 influenza and their anticipated responsibilities.**
5) **The State should provide guidance on developing minimal standards for modified documentation procedures that can be implemented efficiently**

at the time of a pandemic for all healthcare institutions, mortuaries, and other relevant organizations.

Triage. The primary issue presented is whether age, social role, and social worth should be included in triage decision-making. The recommendations are:

1) **ISDH should adopt a protocol that rejects the consideration of social role and age as triage inclusion and exclusion criteria in favor of a system of allocation based solely on physiological prognosis. This triage protocol should be applied to all acute care patients.**
2) **ISDH 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.**
3) **The State should advise all acute care facilities to adopt a common procedure to conduct a daily retrospective review of all triage decisions made during a pandemic in order to identify areas of the protocol in need of improvement.**

Vaccine and Antiviral Allocation. The primary issue regarding this topic centers on how prioritization decisions should be made if there are insufficient supplies of vaccines and antivirals to meet the demand of the populations. The recommendations are:

1) **ISDH should adopt a rank-order prioritization scheme similar to those developed by the United States Department of Health and Human Services and the California Department of Health Services in order to develop a vaccine prioritization list.**
2) **ISDH should adopt an antiviral allocation strategy that places greater emphasis on treatment than on prophylaxis. Non-pharmaceutical prophylaxis, such as the use of personal protective equipment, should be emphasized.**
3) **ISDH should develop an educational toolkit regarding the criteria by which the prioritization plan is developed. This toolkit should be disseminated to all relevant stakeholders.**

Healthcare Workforce Management. Issues presented include healthcare workers' duty to care, sanctions for worker absenteeism, the use of quarantine and isolation, and the responsibilities of other vital but non-clinical employees. The four recommendations regarding these issues are:

1) **ISDH should work with healthcare organizations to identify and designate clinical and non-clinical healthcare workers deemed to be critically necessary during a pandemic.**
2) **The State should set and communicate the expectation that healthcare facilities should have adequate supplies of appropriate medical equipment, prophylaxis, and related materials and that these institutions should ensure that these supplies are readily available to all critical personnel expected to interact with patients.**
3) **The State of Indiana and healthcare organizations should plan an influenza response on the premise of high expectations for workplace continuity for clinical healthcare staff**.
4) **The State should provide guidance to healthcare organizations and facilities in the development of fair and responsive policies for reimbursement of employees, for developing incentives for presenting to work, and for determining sanctions for noncompliance with expected responsibilities.**

All recommendations were guided by the following seven ethical points put forth in the *Points to Consider* document: 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.

-- Eric M. Meslin, Jennifer M. Alyea, Paul R. Helft; June 2008

Technical Advisory Document (TAD-0B-08)

POINTS TO CONSIDER IN PANDEMIC INFLUENZA PLANNING:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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Across the globe, governments, health departments, institutions, and healthcare professionals have been preparing for a modern influenza pandemic. In general, these preparations have focused on technical issues that may arise, such as the assignment of duties and how to obtain and stockpile medications (University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group, 2005). Technical and scientific information, however, is insufficient when addressing the moral dilemmas that will arise in the event of a pandemic (Thompson, Faith, Gibson, & Upshur, 2006). For example, how will the State allocate scarce resources, approach the topic of restricting individual freedom, or ensure a policy's fairness?

Often overlooked is the importance of the establishment of ethical guidance that may assist in the development and implementation of pandemic influenza preparation and response plans. To address this issue, many efforts have been undertaken to develop ethical principles, framework, and guidance documents designed to assist in the development, implementation, and evaluation of policies that will be regarded as fair and morally acceptable by the majority of citizens in the event of a crisis (Caddy & Vergez, 2003; Centers for Disease Control and Prevention [CDC], 2007; Kass, 2001; Kotalik, 2005; Thompson et al., 2006; University of Toronto, 2005).

As in any area of public health policy that involves ethical issues and community values, making determinations about the right course of action involves a careful consideration of all scientific and medical facts coupled with ethical principles and values. On the other hand, no algorithm has yet been developed that can mechanistically make these decisions that have ethics content (Fife, Keener, Meslin, Randall, & Schiffmiller, 2004).

This document provides a middle approach, called *Points to Consider*, which has been used successfully in other areas. Though *Points to Consider* documents "are not regulations and do not have the force of law" (Nail & Aikers, 2002, p. 445), they attempt to incorporate current attitudes of government and academia (Nail & Aikers, 2002) and are typically utilized when control and evaluation policies are in their initial developmental stages (Estrin, 1990). This function is applicable to the current pandemic influenza response policies. The *Points to Consider* document is an intuitive strategy meant to provide a guide for action and is framed as a series of questions, the answers to which are not predetermined. The points are neither a set of decision rules that mechanistically resolve issues at stake, nor a set of principles whose interpretation can be manipulated by various parties to support their particular points of view. At the same time, there is (and must be) a principled basis for each of the points if the document is to be of value.

This document contains seven points that we believe ISDH should consider in the development of its pandemic influenza policies in order to ensure that any policy changes will be morally sound and acceptable to Hoosiers. It is expected that ISDH will directly refer to this document when drafting policy and when evaluating the impact of policy. It

is further expected that any policy should be consistent with this document. In this way it functions both as an ethics framework and as a method for ethical policy construction.

Points to Consider

Consistency of the Mission of the Indiana State Department of Health and the Professional Values of Healthcare in General

It is the mission of the Indiana State Department of Health to support Indiana's economic prosperity and quality of life by promoting, protecting, and providing for the health of Hoosiers in their communities and to do so via inter- and intra-agency cooperation and data-driven policy. In preparation for an influenza pandemic, everyday methods of fulfilling this mission and vision will need to be carefully reconsidered in response to shifting public health priorities. The ISDH has a public set of values embodied in its Mission and Vision Statements. Similarly, health professionals—physicians, nurses, social workers, technicians, health administrators and others—each subscribe to a set of professional standards, commitments, and ethical values inherent in their own respective practices. To the extent possible, decisions regarding pandemic influenza preparedness must be internally consistent with the respective value and mission statements of the individual groups and jointly consistent across groups.

The following questions should be addressed:

- What mechanisms will be used to provide the Indiana public with the assurance that the policy will be consistent with the principles, missions, and values of ISDH and health care professionals generally?
- What mechanisms are contemplated for attending to conflicts that may arise when the proposed policy is consistent with the values of ISDH but not other organizations? For example, what if the policy conflicts with the values of a private medical center?

Transparency

No policy can be developed, much less implemented, without an assurance that its justification and rationale have been made clear to those who will be affected by it. Maintaining transparency and open communication enhances the public's trust in the decisionmakers and may assist in achieving public compliance with control measures (University of Toronto, 2005). Policymakers' concern that openness may lead to public distress does not justify a lack of transparency, "just as a concern for a patient's anxiety would not justify not warning him of an impending stroke" (Kotalik, 2005, p. 430).

When developing a policy, the following transparency questions should be raised:

- What steps are being taken to inform the public of the policy and its implications?
- What steps are being taken to inform healthcare professionals, staff, and administrators of the policy and its implementation?

Public Accountability

It must be possible "to identify and hold public officials to account for their actions" (Caddy & Vergez, 2003, p. 29) in order to avoid an erosion of trust and transparency with the public. In the event of a pandemic influenza crisis, policymakers are obligated to include a method for ensuring that ethical guidelines and procedures are upheld (Thompson et al., 2006). Should an error or oversight occur, it is the responsibility of the policymakers to acknowledge the situation and address the public promptly in order to resolve the resulting complications. Failure to do so may result in a loss of public support and compliance.

For this reason, decisionmakers should be prepared to answer the following questions:

- What steps have been taken to prepare for a public acknowledgement of flaws in the policy and/or its implementation that may arise as the pandemic progresses?
- Who will take responsibility for such flaws or errors while addressing the public?
- What actions will be taken to ensure that the effects of any errors will be corrected and/or minimized?

Responsiveness

Though it is often accepted that public health actions should ultimately be determined by experts, involving the public can help build trust and increase acceptance of the proposed policy (CDC, 2007). Public engagement may occur along a spectrum: at one end of the spectrum, the public is merely informed of the policy. The most extreme version of this is to be informed after the policy is in place. A less extreme version is to be informed that the policy is being developed. At the other end of the spectrum, the public has the power to give or withhold permission for the policy to be developed or implemented. At this extreme, the public is a "partner" in the development of the policy. In the middle of this spectrum, the public has the opportunity to express views about the policy. Public health professionals may consider these views, but they do not have an obligation to do so.

Questions regarding the involvement of the public and health professionals include:

- What outlets are available to the public and to health professionals for inclusion in policy formation? Are these outlets accessible to representatives from all groups of stakeholders?
- What outlets are available to the public and to health professionals for expression of concern about or dissent for the policy? For example, will a website or call center be established to receive this input? Dissent alone does not sufficiently justify blocking a public health program, but if the majority of complaints are coming from a particular subgroup, corrective actions may be required to assuage these grievances (Kass, 2001).
- What steps will be taken to respond to the concerns of the public and of health professionals?

Proportionality

Policies and procedures should be based on sound scientific evidence or on the best evidence available (CDC, 2007). An ineffective intervention will not achieve the desired outcome, no matter how perfectly implemented. In addition, the policy's measures should reflect the severity of the situation while remaining as minimally invasive as possible. According to Kass (2001), "The greater the burdens posed by the program, the stronger the evidence must be to demonstrate that the program will achieve its goals" (p. 1779).

When determining if a policy's measures are proportional to its need, the following questions should be carefully considered:

- Do the benefits of the policy outweigh the burdens of implementing it? For example, is sacrificing individual liberty or scarce financial or human resources appropriate given the anticipated outcome?
- Could a less restrictive measure achieve the desired results?
- Is any group taking on more burden than is necessary to achieve the desired outcome (i.e., is any group subjected to improper discrimination)? In other words, is the policy substantively fair?

Reciprocity

In the event of a pandemic influenza crisis, certain communities and individuals may face increased risk of illness and/or restrictions on their autonomy. In such an event, decisionmakers must have a developed procedure to minimize the resulting encumbrance. "If leaders expect people exposed to or suffering from communicable diseases to act in a manner that does not put others at risk, it is important that they create a social environment that does not leave people without supports," writes the University of Toronto bioethics group (2005, p. 13).

Questions to be considered include:

- What steps are being taken to support those individuals who take on a necessary but disproportionate burden of the disease, such as health care professionals or individuals subjected to isolation or quarantine? For example, are healthcare workers being offered lifelong care for any disabilities that result from acquiring the illness, or are quarantined individuals being protected from financial burden resulting from work absenteeism?
- Are those citizens without immunization being informed of other preventive measures available to them?
- Are those citizens who are denied access to limited medical supplies informed of other options available to them?

Uniformity of Implementation

Consistency in the implementation and application of the policy helps to ensure that similar cases will be treated equally (CDC, 2007). This will aid in eliminating unnecessary discrimination and may assist in conveying the policy's fairness to the public and to the affected parties.

On the topic of uniformity, the following questions should be considered:

- What steps are being taken to ensure that the policy is being implemented consistently throughout the state?
- How will this consistency of implementation be enforced, and by whom?
- What procedures will be in place for evaluating policy implementation and for proposing revisions to it? For example, how will ISDH revise procedures if significant new epidemiological data arises?
- What exceptions may be made to the policy, and who has the authority to make these exceptions? Under what guidelines will this authority evaluate the appropriateness of any exceptions?

Implementation/Operationalizing the Points to Consider

The points in this document should be acknowledged explicitly whenever a policy is being developed. We intend for the reader to answer individual questions identified within each point and, in so doing, provide a justification for the extent to which the point is or is not being accommodated in policy.

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ALTERED STANDARDS OF CARE AND PANDEMIC INFLUENZA PREPAREDNESS:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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In 2007, the Indiana State Department of Health contracted with the Indiana University Center for Bioethics (IUCB) in order to explore the ethical dilemmas that would arise in an influenza pandemic. The necessity of implementing altered standards of care comprised one such topic to be explored, and this was accomplished primarily through literature review. In August 2007, IUCB presented a set of five recommendations to the State to address altered standards of care. In the months since the original research was conducted, the body of literature related to such topics has continued to grow, with many perspectives presented in greater depth. Because the area of pandemic planning and response remains a developing field, it was necessary for IUCB to revise previous documents and recommendations in order to reflect the most current thinking on the topic.

As with the previous documents, a significant amount of the research for the current documents was based on a review of the literature and relevant policies. In addition, expert panels were convened to determine the feasibility of implementing the previous recommendations, as well as to help develop case studies that could be used as part of an instructional tool that would stimulate discussion and critical thinking. These case studies represent real-world scenarios that may occur in an influenza pandemic, and it should be noted that they may be applicable to several areas of pandemic influenza planning that are presented in the four technical advisory documents developed by IUCB.

Case Studies

#1. *Three weeks into the first pandemic wave, the intensivist who has been directing care at a hospital has become ill and a replacement is found. The new physician, an internist who had been staffing at an alternate care site, expresses deep anxiety about the rigid triage criteria in use, and he states he will not abide by them because of fear of being sued for malpractice. What can be done?*

#2. *After the pandemic begins, a hospital reports that 30% of its workforce has become ill, and another 25% has refused to report to work. Several people have offered to volunteer at the hospital to supplement its workforce. How can the hospital identify appropriate volunteers?*

Introduction

With nearly 40 years passed since the last influenza pandemic, experts are warning that the next pandemic is overdue and that the H5N1 strain of avian influenza has pandemic potential (Ontario Health Plan for an Influenza Pandemic [OHPIP], 2006). According to the World Health Organization (2006), H5N1 "has met all prerequisites for the start of a pandemic save one: an ability to spread efficiently and sustainably among humans" (para. 18). As a result of this threat, international organizations, governments, health departments, institutions, and healthcare professionals throughout the world are currently preparing for a modern influenza pandemic. Such preparations require a shift in priorities and expectations in medical care delivery and setting. This includes the allocation of "scarce equipment, supplies, and personnel in a way that saves the largest number of lives in con-

trast to the traditional focus on saving individuals" (Agency for Healthcare Research and Quality [AHRQ], 2005, p. 8).

A scarcity of resources within the context of a severe influenza pandemic emergency will inevitably require an alteration in healthcare practice. Indeed, not only will practice need to be modified but so too might the very norms and assumptions underlying provision of healthcare. As such, any recommendations for altering the standards of care will require careful consideration and justification. This document addresses the ethical implications of implementing altered standards of care, including alternative sites for providing healthcare services and altered standards for utilization of healthcare personnel.

The Issues

A review of the relevant literature (AHRQ, 2005; AHRQ, 2007; Berlinger & Moses, 2007; Bogdan et al., 2004; Cantrill, Eisert, Pons, & Vinci, 2004; Center for Law and the Public's Health at Georgetown and Johns Hopkins universities, 2001; De Ville, 2007; Gomersall, Loo, Joynt, & Taylor, 2007; Gostin et al., 2002; Illinois Department of Health, 2006; Levin, Gebbie, & Qureshi, 2007; Martin, 2007; Minnesota Department of Health, 2006; New York State Workgroup on Ventilator Allocation in an Influenza Pandemic, 2007; Occupational Safety and Health Administration [OSHA], 2007; OHPIP, 2006; Public Health Agency of Canada, 2006; Qureshi et al., 2005; Rubinson et al., 2005; United States Department of Health and Human Services [HHS], 2007a; United States Department of Health and Human Services, 2007b; World Health Organization, 2006) found five areas of agreement regarding the implementation of altered standards of care.

These topics are presented in Table 1 below.

Table 1: Areas of Agreement Regarding Altered Standards of Care

Issue	Explanation
Timing of protocol development	Planning must be done prior to a pandemic in order to ensure the most ethically and operationally sound policies. "Actions that are carefully planned, justified, and executed are easier to defend retrospectively than those made out of panic or confusion" (De Ville, 2007, p. 317).
Communication with the public and healthcare providers	It is essential to make the public and healthcare providers aware of the need for altered standards of care, as well as the details about the specific alterations. Messages must be consistent, simple, and clear and take into consideration the various segments of the population (e.g., non-English speakers). This will help to gain compliance and reduce civil unrest.
Management of psychological crises	The public in general and healthcare staff in particular may experience emotional and psychological distress due to the unique demands that may arise in the event of a public health crisis. Psychological First Aid should be provided in order to help al-

	leviate this situation.
Legal protection for providers and facilities	Healthcare providers and facilities may face litigation in response to decisions that are necessitated by the altered standards of care. Because healthcare facilities, professionals, staff, and volunteers may be reluctant to provide care due to fear of legal repercussions, alterations to relevant healthcare laws and regulations are necessary in the event of an emergency in order to ensure the participation of as many providers as possible. Planners must identify in advance any applicable laws and regulations that may be altered or suspended during an emergency. These may include the Emergency Medical Treatment and Active Labor Act, the Health Insurance Portability and Accountability Act, the Federal Volunteer Protection Act, and the Good Samaritan Law (AHRQ, 2007). For further discussion on the legal aspects of influenza pandemic planning, please refer to the document produced by individuals from the Indiana University School of Law-Indianapolis, which was developed under the same grant as this document.
Security	The combination of the health crisis and the shift in healthcare delivery methods may result in civil unrest and increased violence, particularly in healthcare facilities. Increased and adequate security at each healthcare delivery site will be necessary in order to protect the safety of patients and providers alike.

We note that though these issues represent areas of agreement, other ethical issues may not enjoy the same level of accord, perhaps because the deviation from standard healthcare norms affects several areas of healthcare delivery. Three additional issues arise: (a) the need for alternate care sites; (b) adequate staffing; and (c) standards of documentation.

Alternate Care Sites. Pandemic influenza will require planners to consider alternate care sites for healthcare delivery, quarantine and isolation, and mortuary services if hospitals and morgues become overwhelmed (AHRQ, 2005; AHRQ, 2007; Bogdan et al., 2004; Cantrill, Eisert, Pons, & Vinci, 2004; Center for Law and the Public's Health at Georgetown and Johns Hopkins universities, 2001; Gostin et al., 2002; HHS, 2007a; HHS, 2007b; Illinois Department of Health, 2006; Levin et al., 2007; OSHA, 2007; OHPIP, 2006; Public Health Agency of Canada, 2006; Rubinson et al., 2005). In addition to the question of which facilities to utilize, planners also will be expected to consider how they will obtain access to and control of these facilities (coercion vs. partnership) and whether the owners and administrators of these facilities will be compensated or insured for their assistance.

Adequate Staffing. A pandemic inevitably will lead to staffing losses resulting from illness, fear, and conflicting obligations (e.g., family needs). Due to the combination of such absenteeism and a surge in patients, a shortage of workers is expected (AHRQ, 2005; AHRQ, 2007; Bogdan et al., 2004; Cantrill et al., 2004; Center for Law and the Public's Health at Georgetown and Johns Hopkins universities, 2001; De Ville, 2007; Gostin et al., 2002; HHS, 2007a;

HHS, 2007b; New York State Workgroup on Ventilator Allocation in an Influenza Pandemic, 2007; OHPIP, 2006; Rubinson et al., 2005). Institutions should consider how to anticipate and address these shortages because the alteration of staff members' regular responsibilities may result in increased stress for the affected staff or a decreased quality of the usual care.

Standards of Documentation. In the event of an influenza pandemic, healthcare facilities' current documentation standards for charting, medical records, diagnostic procedures, and consent "will be impossible to maintain" (AHRQ, 2005, p. 10). The consequences of these challenges include backlogs of patients to be seen and deaths to be processed (AHRQ, 2005; AHRQ, 2007; Gostin et al., 2002), which may lead to delayed care and delayed burial, potentially disrupting the customs of certain religious groups (AHRQ, 2007). The modification of documentation standards, however, may result in inadequate or inappropriate care and difficulties obtaining reimbursement (AHRQ, 2005).

The Approaches

Using Alternate Care Sites. Bogdan et al. (2004) write that call centers can be important resources involved in processes including "syndromic surveillance, emergency medicine and triage, and home health care support" (p. 34). The Occupational Safety and Health Administration (2007) and the Illinois Department of Health (2006) reiterate the importance of the use of telephones in providing health advice to the public and in applying triage techniques. The one-on-one communication that callers receive may be an important source of reassurance and instruction, and utilizing such an approach may be useful in alleviating hospital overflow.

Should hospitals require an expansion of their facilities, several possible locations have been suggested to handle triage, non-critical care, isolation and quarantine, and mortuary services, among other functions. For medical care provision, such facilities include outpatient clinics, adult detention facilities, aircraft hangars, churches, military facilities, schools, hotels, convalescent care facilities, and sports facilities (AHRQ, 2007; Cantrill et al., 2004; OHPIP, 2006; OSHA, 2007), provided they are readily accessible to the public (e.g., near public transportation). For alternate sites for mortuary services, the Illinois Department of Health (2006) recommends areas such as "hangers [sic], large garages, [and] National Guard armories" (p. 81). The department also advises against the use of schools and recommends that sites be away from public view. Gostin et al. (2002) recommend that if private property (e.g., a sports facility) is confiscated by the government for public services such as acute care, the owner(s) should be compensated. The Public Health Agency of Canada (2006) similarly states that the Canadian government may seize property as a last resort, but this must occur with "due compensation" (p. H-13). The Illinois Department of Health (2006) has a similar stance supporting the provision of compensation. Gostin et al. (2002) state, however, that if property is taken and destroyed because it poses a serious health threat, then the owner(s) need not be compensated. Another approach to obtaining alternate care sites is through partnership and agreement with, instead of the outright seizure from, the owners

of facilities that potentially may be used (OHPIP, 2006). Such collaboration should be initiated prior to an acute emergency. The OHPIP (2006) and Public Health Agency of Canada (2006) documents also address the inclusion of insurance coverage for the utilized sites. Such coverage includes issues such as "fire, damage, theft, and site liability" (OHPIP, 2006, p. 11A-6).

Levin et al. (2007) deviate from the typical discussion of expanding critical care facilities and instead state that "there is no level of care that can be provided in these settings that cannot be given in the home" (p. 575). The authors state that in-home care provided by home-care personnel, family, and friends is preferable to care provided at alternate sites, since alternate care sites are likely to be congested and not conducive to adequate sanitation and hygiene procedures. Such conditions may worsen the already declining standards of care provided during the pandemic. Because of this, the authors recommend the inclusion of home healthcare entities in the planning process.

Ensuring Adequate Staffing. Should the number of employees required to sustain normal operations and standards be insufficient, healthcare facilities may supplement staff from various sources. The first option is to supplement the workforce from the regular hospital staff. This would require an alteration in responsibilities. For example, Rubinson et al. (2005) state that if hospitals have a shortage of intensivists, those in nonintensivist positions may instead work with critically ill patients under the supervision of an intensivist. The New York State Workgroup (2007) also includes a discussion of the modification of individual responsibilities, stating that "less experienced staff may need to manage patients" (p. 12), so added duties should be simplified to the furthest extent possible. The Minnesota Department of Health (2006) states that registered nurses may delegate duties such as medication administration to other employees, provided that these employees are "supervised by an RN or monitored by an LPN" (p. 4). Gomersall et al. (2007) recommend using operating theatre staff because such individuals "are familiar with caring for unconscious ventilated patients and are likely to be relatively available when elective surgery is discontinued during the peak of a pandemic" (p. 744).

According to AHRQ (2005) and OSHA (2007), other potential staff should be identified prior to a pandemic and should begin training in their new responsibilities and in infection control. These staff may include "retired or currently unemployed but qualified volunteer providers" (AHRQ, 2005, p. 27), reserve military and nursing providers, medical, nursing, and respiratory therapy students, emergency medical technicians, health care aides (Public Health Agency of Canada, 2006), veterinarians, dentists, and pharmacists. In addition, nonmedical responders may be trained to "support health and medical care operations" (AHRQ, 2005, p. 27; Rubinson et al., 2005). Healthcare professionals who are not currently licensed in the state are another potential source, even though their involvement in providing care may result in what would ordinarily be considered substandard care. Licensing requirements may be suspended via gubernatorial orders (Cantrill et al., 2004).

In order to ensure the ability to call upon these individuals in times of staffing needs and to verify their credentials and capabilities, AHRQ (2005), Cantrill et al. (2004), Rubinson et al. (2005), and the Public Health Agency of Canada (2006) recommend the development of a registry or database of potential replacement staff. Such a database may expedite the process of increasing staffing, as well as make certain that the called-upon individuals are qualified to perform their newly assigned duties. However, "developing and maintaining databases of staff is a time consuming and expensive task. Databases are only useful if kept up to date with licensing, skill set and contact information" (Public Health Agency of Canada, 2006, p. H-12). In addition to database development, AHRQ (2007) recommends the development of identification procedures, such as site-generated photo IDs, for staff members in response to the unfamiliarity of the staff with each other. This will help to assure patients and employees alike that all workers have been credentialed and/or verified.

Whether retrieved from existing staff or from a group of volunteers, AHRQ (2005) states that healthcare workers involved in providing care during an influenza pandemic should be instructed and prepared to the greatest extent possible. "Planners should not assume that individual providers will know how to deliver appropriate care in a mass casualty event, but rather should develop or identify training programs to ensure a knowledgeable and systematic, coordinated response effort" (AHRQ, 2005, p. 28). Martin (2007) echoes this statement and urges planners not to assume that providers understand the specifics of pandemic influenza. Additionally, Martin recommends that providers be administered a test to determine the effectiveness of instructional activities and to ensure that providers are adequately prepared. Rubinson et al. (2005) state that staff should receive training in the use of personal protective equipment, which will help workers feel more adequately prepared for dealing with infected patients. Educating healthcare workers with information about the etiology of the illness and its proper control measures is expected to increase willingness to provide care (Tzeng, 2004) and also will aid in maintaining workers' safety and health.

Finally, some literature suggests the necessity of meeting various needs of the staff—regular and volunteer—during the crisis in order to ease the burden of the heavy and stressful workload. These needs may involve housing (AHRQ, 2007; Center for Law and the Public's Health at Georgetown and Johns Hopkins universities, 2001), transportation, child care, pet care (Cantrill et al., 2004; Qureshi et al., 2005), and workers compensation (Rhyne, 2007). Additional compensation for those working in times of a pandemic also has been recommended (Berlinger & Moses, 2007; OHPIP, 2006).

Documentation Alterations. AHRQ (2005) and Martin (2007) suggest that it is necessary to alter current documentation procedures in such a way that adequate information is gathered regarding patient medical needs and means of reimbursement "without posing an undue administrative burden" (AHRQ, 2005, p. 13). Martin (2007) emphasizes the need to identify information that may be considered extraneous in the case of a pandemic event prior to the pandemic

occurring. Though changes in documentation procedures may result in decreased patient privacy and confidentiality, the rights of patients should be preserved to the greatest extent possible (AHRQ, 2005). Nonetheless, some argue that citizens must be required to sacrifice some of their liberties in order to maintain the health and safety of the masses (Gostin et al., 2002).

Documentation not only affects patient care and reimbursement, it also affects mortuary procedures. A backlog of mortality processing may result in delays in burial. Gostin et al. (2002) write that "the authorities are required to exercise their powers with respect for cultural and religious beliefs and practices such as observing, wherever possible, religious laws regarding burial" (p. 626). Similarly, AHRQ (2007) writes that procedures for complying with individuals' funeral and burial practices should be outlined in advance, while remaining flexible to meet the demands of the situation. Religious and cultural communities should be informed of any such procedures, which should "ensure that the minimum level of disruption to usual cultural practices and the maximum level of dignity are afforded the deceased and their families" (AHRQ, 2007, p. 73). A major barrier to complying with such procedures, however, is that the remains may pose a threat to the living in the event of an influenza pandemic (AHRQ, 2007). In such an event, careful consideration must be made to manage conflicting priorities.

Recommendations

The discussion provided in this document lends itself to five recommendations that the Indiana University Center for Bioethics believes would lead to the development of ethically sound statewide policies regarding altered standards of care. Each recommendation is followed by its justification and has been evaluated by an expert panel convened by IUCB.

<u>Recommendation 1</u>: 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. Triggers for this declaration should be identified prior to their occurrence. This protocol should specify those healthcare professionals affected by the protocol and should include legal protections for healthcare providers and institutions.

It is necessary for any decisions about altering the standards of providing healthcare to patients in Indiana to be statewide and uniform. As a part of this protocol, it is critical for the State to identify relevant laws and regulations that may need to be altered or suspended during an emergency in order to provide legal protections to healthcare institutions, providers, staff, and volunteers. Doing so may increase healthcare workers' and healthcare institutions' compliance with the recommended alterations by removing the fear of litigation that may result from following altered standards of care. It also may help to ensure that these altered standards are implemented consistently statewide.

Expert panel members expressed concern about the extent to which the State would be able to provide protection. Members emphasized the need to clarify

how such protections would be implemented, as fear of litigation would be a major concern for healthcare providers and undoubtedly would influence their adherence to altered standards protocol. For further discussion on this topic, please refer to the document regarding legal issues during an influenza pandemic that was produced by individuals from the Indiana University School of Law-Indianapolis.

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 site acquisitions by consensus and partnership.

The key to a smooth transition from the current system to any system that amends the standards of care is the emphasis on early planning. The use of partnership instead of coercion may result in less resistance and greater compliance to the use of alternate care facilities. In addition, it is recommended that such facilities be insured and the owners compensated to the most reasonable extent possible for their cooperation so that they do not suffer large financial or property losses. Finally, such facilities should be located in readily accessible sites to ensure ease of access for citizens.

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 their skills and qualifications and register them into this database prior to a pandemic.

Through the creation of a database, volunteers such as retired or inactive nurses and physicians, as well as professionals from other related fields (e.g., dentists), could be called upon in times of emergency. A common database can be accessed efficiently to manage workforce flow.

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 influenza and their anticipated responsibilities.

By being prepared, these potential staff members are more likely to report to work and to provide care of the greatest quality possible. In addition, these workers should be provided compensation and have their basic needs met (e.g., housing, child care) while working under the stressful conditions.

Recommendation 5: The State should provide guidance on developing minimal standards for modified documentation procedures that can be implemented efficiently at the time of a pandemic for all healthcare institutions, mortuaries, and other relevant organizations.

This will help to reduce the backlog of patients and fatalities; provide patients with the most appropriate care available given their individual needs; reduce the privacy and confidentiality each patient must sacrifice; and ensure reimbursement for the healthcare facilities. If at all possible, mortuary procedures should

allow families to carry out their desired funeral and burial practices, provided the deceased does not pose a significant threat to the health of the community. The possibility of mortuary delays and non-adherence to religious burial practices should be discussed with citizens and faith-based communities in advance.

Expert panel members emphasized the need not only to develop altered documentation standards for intake procedures, but also for daily review of patients' health status.

Application to the Points to Consider

In our previous work we developed an ethical framework entitled *Points to Consider*. This framework was designed to provide guidance for those working through specific ethical issues and as a tool for assessing the ethical basis for proposed policy. The *Points to Consider* contains seven "points" that IUCB believed would need to be addressed in any policy development if such a policy were to be considered ethically sound and acceptable to Hoosiers.

Expert panel members were provided with the *Points to Consider* document as part of their deliberations but were not required to use it as their only guide.

We believe that the recommendations presented in this TAD are consistent with the ethical framework presented in the *Points to Consider* document.

The aforementioned recommendations, in addition to the areas of agreement regarding altered standards of care mentioned earlier, adhere to several of the points stated in the *Points to Consider* document. These relevant points are presented in Table 2 below.

Table 2: Points to Consider Reflected in the Altered Standards of Care Document

Ethical Point to Consider	Applicability to Recommendations
Transparency	Providing the public and healthcare providers with information regarding alterations in healthcare procedures will help to achieve compliance with these procedures. Discussions with citizens and faith-based communities regarding potential barriers to adherence to funeral and burial procedures will prepare these communities for potential delays and alterations that may occur while attempting to follow cultural practices. By making these communities aware of these implications prior to the event, they may be more likely to comply with the necessary course of action.
Responsiveness	Through partnerships with the owners/administrators of potential alternate care sites, planners may develop procedures that will ensure that the public's health needs are met while assuring owners that their facilities will be properly insured and protected.

Proportionality	Alternate care sites are to be used only when hospitals lack sufficient capacity; alternate staffing procedures are to be used only during a staffing shortage; and documentation procedures are to switch to truncated procedures only when current standards are impossible to maintain given a large patient influx. Patients must sacrifice privacy and confidentiality only when absolutely necessary to maintain a functioning care facility.
Reciprocity	Providing legal protection and mental health services to healthcare workers will help to ease the disproportionate amount of burden they will bear. Preparing these workers prior to a pandemic will reduce the stress they will face. Providing additional security also will help to ease the burden on healthcare professionals, since they will be more able to perform their duties in the absence of fear. Furthermore, meeting the basic needs of these workers, such as providing housing for non-local volunteers, will help to reduce stress and retain these staff members. Apart from staffing reciprocity, the owners/administrators of alternate care site facilities are to be provided insurance and/or be reimbursed for their contributions.

Case Study Responses

#1. Upon the governor's declaration of a statewide pandemic influenza emergency, legal protections will be put into place to protect healthcare workers who follow altered standards protocol from litigation. The new physician should be informed of these legal protections and the necessity to follow altered standards protocol to ensure fair and consistent implementation.

#2. The hospitals will have available to them a database of potential alternate healthcare workers whose skills and qualifications have been assessed prior to the occurrence of the pandemic. These may include retired nurses and physicians, as well as medical and nursing students.

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Technical Advisory Document (TAD-0D-08)

TRIAGE AND PANDEMIC INFLUENZA:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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In 2007, the Indiana State Department of Health (ISDH) contracted with the Indiana University Center for Bioethics (IUCB) to explore ethical dilemmas that may arise in an influenza pandemic. The necessity of implementing triage in response to limited medical supplies and equipment comprised one such topic to be explored, which was accomplished primarily through literature review. In August 2007, IUCB presented a set of three recommendations to the State to address triage protocol. In the months since the original research was conducted, the body of literature related to this topic has continued to grow, with many perspectives presented in greater depth. Because the area of pandemic planning and response remains a developing field, it was useful for IUCB to revise previous documents and recommendations in order to reflect the most current thinking on the topic.

As with the previous documents, a significant amount of the research for the current document was based on a review of literature and policies. In addition, expert panels were convened to determine the feasibility of implementing the previous recommendations, as well as to refine these recommendations. Additionally, case studies were developed to be used as part of an instructional tool, as well as to stimulate critical thinking and discussion. These case studies represent real-world scenarios that may occur in an influenza pandemic, and it should be noted that they may be applicable to several areas of pandemic influenza planning that are presented in the four technical advisory documents developed by IUCB.

Case Studies

#1. *A 67-year-old housekeeper and a 24-year-old medical student present to the emergency room with pandemic influenza. An unemployed 39-year-old also presents after having been in a motor vehicle accident. All patients require a ventilator to survive, but the hospital has only one available. Who should get the ventilator?*

#2. *After two weeks of implementing triage criteria that were developed for pandemic use, several physicians begin to question the methodology they have been instructed to use. They express their concerns to their supervisor and state that they would like to implement alternative triage methodologies. What steps should be taken?*

Introduction

As of June 2, 2008, the World Health Organization (WHO, 2008) reports that 383 human cases of avian influenza H5N1 have been confirmed and that 241 of these cases have been fatal. With experts warning that an influenza pandemic is overdue and that H5N1 has pandemic potential (Ontario Health Plan for an Influenza Pandemic [OHPIP], 2006), governments, health departments, healthcare professionals, and many others have been working to develop response plans for such a crisis. Those plans must include ethical strategies for allocating resources that become insufficient to support the demand, because “shortages of specialized staff, medical equipment, and supplies could limit the number of patients who can receive the appropriate supportive critical care interventions” (Rubinson et

al., 2005, p. 6). Such resource allocation strategies may be referred to as "triage" of scarce resources because they necessarily involve prioritizing which patients will receive care when not all can. Consistent, ethically defensible methods for allocating scarce resources require careful planning and deliberation. This document presents several ethical issues that must be considered and addressed in the development of a triage protocol for Indiana, followed by a set of recommendations. When considering the recommendations, it should be noted that triage prioritization differs from immunization prioritization in the event of an influenza pandemic. The arguments presented in this document refer only to triage.

The Issues

A review of the small but growing literature on allocation of scarce resources during a pandemic event (Agency for Healthcare Research and Quality [AHRQ], 2007; Berlinger & Moses, 2007; Burkle, 2006; Centers for Disease Control and Prevention [CDC], 2007; Challen, Bright, Bentley, & Walter, 2007; Christian et al., 2006; Clarian Ethics Policy Review Committee Working Group on Ethics in Pandemic Flu [Clarian], 2006; Hick & O'Laughlin, 2006; Hick, Rubinson, O'Laughlin, & Farmer, 2007; Indiana Pandemic Influenza Community Advisory Groups, 2006; Letts, 2006; Levin, Gebbie, & Qureshi, 2007; McGorty et al., 2007; Melnychuk & Kenny, 2006; New York State Workgroup on Ventilator Allocation in an Influenza Pandemic, 2007; OHPIP, 2006; Rubinson et al., 2005; Utah Hospitals and Health Systems Administration [Utah HHSA], 2007) suggests several areas of agreement, summarized in Table 1 below.

Table 1: Areas of Agreement Regarding Triage

Issue	Explanation
Timing of protocol development	It is necessary to establish triage guidelines prior to the occurrence of an influenza pandemic in order to make the most ethically sound, well-considered choices possible.
Triage classification personnel	Identification of who will be responsible for making triage decisions is necessary before an influenza pandemic strikes. Teams of triage officers, such as supervising clinicians, are recommended. Individual physicians should not make such decisions unless absolutely necessary, in order to avoid conflicting obligations regarding patients and the public and to ensure equitable application of triage guidelines.
Location of implementation	Policies must be implemented statewide and/or regionally in order to ensure fairness and equal opportunity for care for all the State's citizens.
Transparency and public awareness	Preparing the community for the challenges in an influenza pandemic event will help to reduce civil unrest and may assist with gaining compliance.
Managing psychological crises	Clinicians, first responders, the afflicted and their families, and the "worried well" may all require Psychological First Aid to treat emotional distress, and

	provisions should be made to make this available to them.
Proportionality in implementation	Inclusion and exclusion factors should only be considered when all other options have been exhausted. For example, if canceling or postponing elective surgeries will result in a sufficient supply of ventilators, then other criteria need not be considered.
Inclusion of patients in acute care	Non-influenza patients in acute care facilities also must be included in triage in order to maximize the number of lives saved. This also will help to ensure that care and resources are distributed fairly and similarly among all acute care patients.
Use of palliative care	Those denied access to ventilators and other medical resources should be provided palliative care and pain management.
Flexibility of guidelines	Because current triage protocols have yet to be tried in a real-world situation, their effectiveness and potential drawbacks are not entirely known. In addition, technological advances may require revision of procedures in order to accommodate new innovations. Triage guidelines must be adaptable.
Plan for legal protection	Healthcare providers may face litigation for following triage criteria. Providing legal protection for those who make allocation decisions using established guidelines will increase healthcare worker compliance and ensure consistent implementation.

In addition to these issues, the use of smart systems for assigning prognosis based on acute physiology is a vital component of any system of triage. Such predictive systems have been developed in critical care populations to predict the likelihood of a patient's survival to discharge, including APACHE III, SAPS, LOD, MODS, and MPM II (Hick & O'Laughlin, 2006). Variations of the Sequential Organ Failure Assessment model—sometimes referred to as the Sepsis-related Organ Failure Assessment model or SOFA—arose most frequently in the literature review as the fairest and most effective prognostic scoring method (Christian et al., 2006; Hick & O'Laughlin, 2006; New York State Workgroup, 2007; OHPIP, 2006; Utah HHSA, 2007). SOFA assesses six organ systems, "each graded from 0 to 4 points according to the degree of dysfunction" (Arts, de Keizer, Vroom, & de Jonge, 2005, p. 1988). The resulting scores can be compared to predetermined treatment categories to establish a patient's treatment plan. For example, individuals with a SOFA score greater than 11 have more than a 90% mortality rate (OHPIP, 2006) and would be unlikely to benefit from intensive care treatment. Despite being frequently recommended, SOFA has been faulted for not being validated in pediatric populations (Hick et al., 2007). In addition, because it was "derived and validated on cohorts" (p. 5), it may not accurately predict outcomes for individuals. Furthermore, some may reject its use because it depends partly on laboratory testing, which may be "resource intensive and will unnecessarily delay triage decisions" (Talmor, Jones, Rubinson, Howell, & Shapiro, 2007, p. 1255). Nonetheless, SOFA, or variations upon it, is so far the most recommended algorithm for use.

Because triage criteria have been recommended for use in all acute care patients, as mentioned in the table above, other conditions in addition to pandemic influenza may need to be assessed. The Utah HHSA (2007) document addresses these, such as the consideration of trauma score and burn severity in triage decision-making.

Though we found general agreement regarding the majority of ethical considerations that should affect triage planning, other key issues surrounding triage allocation decisions remain unresolved. These involve disagreement over which non-physiological considerations should be incorporated into inclusion and exclusion criteria. These considerations include: role in society (e.g., should healthcare workers receive preferential treatment within an allocation framework?), age (e.g., should younger patients receive preferential treatment compared to older patients?), and "social worth" (e.g., should any other individual characteristics influence preferential treatment?).

Table 2: Summary of Groups' Non-physiological Considerations for Triage Criteria

Source	Social Factors	Age
AHRQ (2007)	--	--
CDC (2007)	●	●
Challen et al. (2007)	●	●
Clarian (2006)	●	●
New York State Workgroup (2007)	--	--
OHPIP (2006)	--	●
Utah HHSA (2007)	●	●

● = *should be considered*
-- = *not considered*

The Approaches

Those Supporting Inclusion of Social Role and Age in Triage Criteria. According to the CDC (2007), in the event of an influenza pandemic, preserving society's function should be given priority over maximizing the number of lives saved. Likewise, McGorty et al. (2007) state that "assuring the functioning of society" (p. 41) should be one factor taken into account when making disease control and medical decisions, but socioeconomic factors should not be included in such decision-making. This may seem contradictory, particularly because an individual's socioeconomic status may be linked directly to his or her social function. Nonetheless, such an argument suggests a need for the determination of an individual's "value to societal function" and his or her contributions to society. The CDC (2007) acknowledges the difficulties inherent in this process and advocates discussion among diverse stakeholders in order to resolve this issue, as well as transparency with the public in order to increase acceptance and compliance. The Clarian (2006) working group addresses the issue of social role by placing healthcare workers, public health officials, first emergency responders,

government officials, and workers involved with critical infrastructure in positions of priority over others in treatment allocation decisions. Challen et al. (2007) also support these considerations and write that "social factors" (p. 2) should be considered in patient categorization. Their scoring system includes a point system that takes into account "social isolation … [and a] performance status of limited activity or worse" (p. 2). Similarly, the Utah HHSA (2007) draft document states that an additional consideration should include whether the "patient is homeless and/or has someone to care for [him or her] at home" (p. 3). Although determining social function is a complex undertaking, at the minimum the government workforce can be prioritized legally in the event of an emergency (AHRQ, 2007). The literature suggests clearly that, in cases where priority is given to individuals for the sake of preserving societal function, "justification for such decisions should be drawn up in advance and publicized" (Gomersall et al., 2006, p. 1011).

In addition to social role, the question of whether to include age in triage criteria has been addressed in several documents (AHRQ, 2007; Challen et al., 2007; Christian et al., 2006; Clarian, 2006; New York State Workgroup, 2007; OHPIP, 2006; Utah HHSA, 2007). The Clarian (2006) document suggests that, if all other factors are equal, a younger individual should be given priority over an older individual because the younger has more potential life to lose or gain. The OHPIP (2006) method of addressing age, in contrast to Clarian's, is not dependent upon comparisons with other patients. Instead, it uses age as an exclusion criterion only if the age of the individual is greater than 85 years. Likewise, the Utah HHSA (2007) document does not use age to compare patients. Instead, depending on the level of triage (level 1 is used in the early stages of the pandemic, level 2 is used in a worsening pandemic, and level 3 is used in the worst-case scenario of the pandemic), an age of 95 and over, 90 and over, or 85 and over, respectively, may be used as an exclusion criterion. Challen et al. (2007) suggest that a scoring system be used that accommodates age, giving the patient an extra "point" if he or she is at least 65 years old. Other literature also suggests considering age in exclusion criteria, but methods of how to do so are not overtly stated. Christian et al. (2006) write that although they did not include an age criterion in their draft, they "received both strong and consistent feedback from both expert and stakeholder consultations" (p. 1379) that an age criterion should be included.

Those Rejecting Inclusion of Social Role and Age in Triage Criteria. Letts (2006) states that "the potential ramifications of giving preferential treatment to individuals on any social grounds are disturbing" (p. 133). The New York State Workgroup (2007) offers the most extensive discussion on the inclusion of priority groups and social worth in triage classification procedures, and its views are similar to those of AHRQ (2007). Ultimately, the groups reject prioritization using any criteria other than medical or physiological factors. The New York State Workgroup acknowledges that healthcare workers who become ill and require acute care will be unlikely to recover and return to their duties before the pandemic runs its course, making their preferential

treatment unproductive. In addition, the group argues that the inclusion of all healthcare workers as priority groups—such as morgue workers, ambulance staff, firefighters, etc.—would result in healthcare workers being provided ventilators and other medical treatment to the exclusion of all other groups in some locales and "ordinary" citizens consistently would be denied ventilator access and life-saving care. This sentiment is echoed by Letts (2006) in that if social function is taken into account, "the socially disadvantaged in the community might be subject to exclusion and injustice" (p. 133). Furthermore, New York workgroup members "objected strongly to the appearance of favoritism, in which those who devised the rationing system appeared to reserve special access for themselves" (2007, p. 28). They suggest that the public will hold decision-makers accountable for any protocol regarded as biased and inequitable, and any procedure that may be viewed as discriminatory will evoke a harsh response from the public at large.

The New York State Workgroup (2007) also rejects the use of age as an exclusion criterion in their ventilator allocation protocol. The group's argument is based upon the idea that aged individuals intrinsically are more likely to suffer physiological derangement than their younger counterparts. This increased risk will be taken into account inherently by the SOFA prognostic scoring system used by the New York group to determine the individual's triage status. Thus, age indirectly affects the likelihood of survival without being made an explicit factor. AHRQ (2007) presents a similar argument, stating that "age may be considered only as it relates to underlying organ function and diagnosis" (p. 71).

Included in the New York State Workgroup's (2007) planning document is an acknowledgement of the difficulty of the removal of life support. Because such procedures can be traumatic for both the patient and the attending physician, the New York group recommends limiting circumstances that would require such actions. For this reason, the group rejects the idea of a universal "trial period" for ventilator use for incoming patients, as it ultimately could result in large numbers of extubated patients. It also has reservations about removing a ventilator from a patient who is stable or improving in favor of a new patient with a better prognosis. Instead, the workgroup suggests evaluation based on the SOFA score. Patients on ventilators would be assessed at 48 and 120 hours. "Those who meet the criteria for benefit or improvement would continue until the next assessment, while those who no longer met these criteria would lose access to mechanical ventilation" (New York State Workgroup, 2007, p. 32). The Utah HHSA (2007) also recommends routine assessment of ventilated patients, but in contrast to the New York Workgroup's (2007) plan, such assessments would occur daily. Hick et al. (2007) also stress the importance of frequent reevaluation of patients' health status in order to ensure that ventilators are allocated to those who would benefit the most. Any patients who are removed from life support should be given palliative care with the option of sedation. Justification for extubation and sedation should be

documented (New York State Workgroup, 2007).

It should be noted that the New York group's suggested protocol aims to prevent the need for the inclusion of a "tiebreaker" in the event that two patients with identical SOFA scores present for medical attention. It does so by recommending the adjustment of each day's threshold SOFA score so that a few extra ventilators are always available in intensive care units. For example, at times when relatively few patients are in need of intubation, the SOFA threshold may be set high so that the most severely ill patients—individuals with high SOFA scores—still may have access to a ventilator. When many patients are in need of ventilators, however, the SOFA threshold must be set lower, and those individuals with high SOFA scores no longer may be allowed access. Though this protocol theoretically will eliminate the need for a tiebreaker, in reality it remains a possibility that individual hospitals may face rare instances in which a tie does occur. How to address such an occurrence is not discussed in the New York document.

Terminal extubation of patients in chronic care facilities is addressed in the New York protocol. The group recommends that triage criteria not be expanded to include individuals in chronic care facilities, since such actions would "make victims of the disabled" (New York State Workgroup, 2007, p. 29). Should an individual from such a facility require admittance into an acute care facility, however, he or she would be subject to the same triage criteria as other acute care patients.

Berlinger and Moses (2007) recommend the development of a method to review triage protocol "after it goes into effect to fix problems and prevent abuses" (p. 5). The New York State Workgroup (2007) includes such an appeals process in its triage protocol. Appeals may be used, for example, when a clinician disagrees with a patient's triage classification. The group presents two possible methods for undertaking such an appeals process. The first is for a committee to review the appeal as it occurs. This could benefit individual cases, but it also may delay some from receiving care. In addition, it could spark "explosive debate during a time of scarce manpower and other resources" (p. 36). An alternative approach would be to have a daily retrospective review of all triage decisions in order to identify flaws in the protocol and to provide accountability. In this situation, however, individual patient interventions would not be possible (New York State Workgroup, 2007).

Recommendations

The discussion provided in this document lends itself to three recommendations that IUCB believes would lead to the development of ethically sound statewide policies regarding triage implementation. Each recommendation is followed by its justification and has been evaluated by an expert panel convened by IUCB.

<u>Recommendation 1</u>: The Indiana State Department of Health should adopt a protocol similar to that of the New York State Workgroup's (2007), 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 physiological prognosis. This triage protocol should be applied to all acute care patients.

This protocol is preferred for the following reasons: (a) it allows for public accountability by using quantitative and objective data, which are much more easily justified to the general public than are subjective "social worth" evaluations; (b) it facilitates uniformity of implementation, because the analysis of objective data creates less variation in triage decisions than subjective considerations would create; and (c) it is the only system of all those considered that logistically could be implemented on a statewide level. The New York proposal relies on a prognostic scoring system based only on readily available physiological criteria. Scores can be calculated easily for all individuals presenting for consideration, and allocation decisions can be made centrally, based on the resources available at the time (e.g., ventilators or ICU beds) and the number of individuals above and below a threshold score for that time. Threshold scores can be adjusted based on availability of resources.

The adoption of a system similar to the proposal developed by the New York State Workgroup would, of necessity, require centralized allocation decision-making. This would include collecting real-time information about patients at risk, their SOFA scores, and resources available, and setting thresholds for triage up to several times per day. Such a centralized decision-making process would take individuals on the ground out of the decisions and allow them merely to implement decisions made at the State level.

Expert panel members emphasized that although the SOFA scoring method may be utilized for adults, there exists a need to develop a triage method for the pediatric population. Any such method similarly should be based on physiological prognosis.

Additionally, panel members expressed great concern regarding the omission of age as an inclusion/exclusion criterion. Members argued that consideration of age is traditionally accepted in triage decision-making and should not be disregarded. Panel members also acknowledged that healthcare worker resistance likely would occur in response to not considering age in triage decision-making. This concern emphasizes the importance of communicating the rationale behind the omission of age and social worth as triage criteria prior to an influenza pandemic.

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.

We acknowledge the ethically sensitive nature of any tiebreaking criterion. Although this protocol is expected to be used only in rare circumstances, it is necessary for institutions to have in place a common policy for addressing these issues.

In the event that a tiebreaker must be used, we previously recommended the concept of "first come, first served" be applied, with "time arrived" being defined as the time the individual's SOFA score is entered into the system. This will reduce the need to extubate those patients who already have begun intensive care treatment, thus reducing further psychological trauma for those patients, their families, and their physicians. "First come, first served" also is an objective deciding factor, as opposed to the evaluation of social role.

Expert panel members recommended the development of "multilevel" triage criteria to confront the possibility that a tie still may occur between patients after the application of the first tiebreaker. Suggestions for possible additional tiebreakers centered primarily on the use of alternative prognostic scoring methods, such as APACHE, but it must be acknowledged that this method includes age in its scoring methodology and therefore may conflict with our recommendation not to include age as an exclusion criterion.

<u>Recommendation 3</u>: The State should advise all acute care facilities to adopt a common procedure to conduct a daily retrospective review of all triage decisions in order to identify areas of the protocol in need of improvement, which may become clear as the pandemic progresses, as well as to provide accountability. This information should be reviewed at both the State and institutional levels, and modes of communication to and from these facilities and the State should be identified clearly in order to communicate any areas in need of improvement.

Since an appeals process would be likely to interfere substantially with the system of resource allocation, we instead would recommend daily review of decisions by the central triage officials, with prospective, system-wide resolution of discrepancies that become apparent.

Expert panel members believed that this review should occur at the institutional level as well as the State level. It was agreed that data from each healthcare site and facility should be stored in a centralized database with the State. This would allow review to occur at the State level and would likely help to identify necessary areas of improvement more readily than if the review were performed only at the institutional level. Alterations of protocol could then be made as needed.

Application to the Points to Consider

In our previous work, we developed an ethical framework entitled *Points to Consider*. This framework was designed to provide guidance for those working through specific ethical issues and as a tool for assessing the ethical basis for proposed policy. The *Points to Consider* contains seven points that IUCB believed would need to be addressed in any policy development if such a policy were to be considered ethically sound and acceptable to Hoosiers.

Expert panel members were provided with the *Points to Consider* document as part of their deliberations but were not required to use it as their only guide.

We believe that the recommendations presented in this TAD are consistent

with the ethical framework presented in the *Points to Consider* document.

Table 3 below summarizes the applicable points and how they are addressed.

Table 3: Points to Consider Reflected in the Proposed Triage Protocol

Ethical Point to Consider	Applicability to Protocol
Transparency	The protocol proposes that the State educate the public about the developing triage guidelines. Ethical justification for triage criteria is enumerated.
Public Accountability	Objective decision-making procedures eliminate subjectivity and bias from the triage protocol. As a result, allocation decisions will be able to withstand public scrutiny.
Responsiveness	The inclusion of an appeals process allows healthcare workers and the general public to voice concern and dissent. Evaluation of these appeals will result in more effective and acceptable triage protocol.
Proportionality	Less drastic methods of preserving scarce resources, such as canceling elective surgeries, are recommended prior to the implementation of rationing procedures. As need becomes greater and resources become more scarce, the policy's inclusion and exclusion criteria become more restrictive, reflecting the severity of the situation.
Reciprocity	The protocol provides various means of support to affected individuals. For example, those individuals denied access to scarce resources (e.g., ventilators) are provided other means of medical attention, such as palliative care, and those with emotional and psychological burdens resulting from the crisis (e.g., healthcare workers) are provided Psychological First Aid.
Uniformity of Implementation	The analysis of objective physiological data creates less variation in triage decisions than subjective considerations would create.

Case Study Responses

#1. Triage criteria must be applied to all acute care patients, including those not presenting with pandemic influenza. The decision of who receives the ventilator should depend solely on the patients' physiological prognoses, which are calculated using the SOFA prognostic scoring method. Neither the ages nor the social roles of the patients should be considered in the decision-making process. Should any of the patients have identical prognoses, the

tiebreaker of "first come, first served" should be applied based on when each patient's case was entered into the system.

#2. Review of triage decisions should be made daily at the institutional and State levels, and any areas identified to be in need of improvement during this review must be communicated quickly and efficiently between the State and the institutions. The physicians' concerns should be evaluated to determine whether a change should be made. The physicians, however, should not depart from the protocol until such a departure is deemed necessary by protocol reviewers.

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Technical Advisory Document (TAD-03-08)

VACCINES, ANTIVIRALS, AND PANDEMIC INFLUENZA PREPAREDNESS:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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This Technical Advisory Document was prepared by the Indiana University Center for Bioethics under contract with the Indiana State Department of Health as a part of the project "Translating Ethics Advice into Practice: Public and Professional Outreach about Pandemic Influenza Planning in Indiana". The views expressed in this document are those of the authors and may not necessarily reflect the opinions of the Center for Bioethics, Indiana University, Clarian Health Partners, Inc., or the Indiana State Department of Health.

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In 2007, the Indiana State Department of Health contracted with the Indiana University Center for Bioethics (IUCB) to research and provide insight on ethical dilemmas that may arise in the event of an influenza pandemic. One topic that was addressed was vaccine and antiviral allocation, which would be a necessary task due to a finite amount of these supplies. The original research was conducted primarily through literature and policy review, and two recommendations were formed based on these findings. The resulting technical advisory document was presented to the State in August 2007. Since that time, new literature has been produced on the topic of vaccine and antiviral allocation. Because the area of pandemic planning and response remains a developing field, it was necessary for IUCB to revise previous documents and recommendations in order to reflect the most current thinking on the topic.

As with the previous documents, a significant amount of the research for the current documents was based on a review of the most recent literature and policies. In addition, expert panels were convened to determine the feasibility of implementing the previous recommendations as well as to refine these recommendations. Case studies were developed to be used as part of an instructional tool, as well as to stimulate critical thought and discussion. They represent real-world scenarios that may occur in an influenza pandemic, and it should be noted that the presented case studies may be applicable to several areas of pandemic influenza planning that are presented in the four technical advisory documents developed by IUCB.

Case Studies

#1. *A clinic has one remaining bottle of oseltamivir. A married 34-year-old woman presents to the clinic with her 5-year-old son. The woman has been experiencing fever, cough, muscle aches, and sore throat for 24 hours. Her physiological assessment reveals that she is eligible to receive treatment, a 5-day course of oseltamivir. The boy shows no symptoms of infection, and his physiological assessment reveals that he is not eligible to receive the medication. The woman says her husband also is not showing signs of infection. She requests that she not receive the medication so that her treatment can be given to her son for use as prophylaxis. Who should receive the oseltamivir?*

#2. *A vaccine for the pandemic influenza has been developed but is still in extremely limited supply. A 47-year-old pulmonologist qualifies to receive this vaccine. He requests that his family also be vaccinated. His wife is a healthy 44-year-old who works from home. His two children are 16 and 17 with no known immune system impairment. The pulmonologist states that he will not report to work without his family being vaccinated. What should be done?*

Introduction

The pandemic potential of the H5N1 strain of avian influenza has created the necessity of comprehensive planning for resources and procedures. Although H5N1 has not yet acquired efficient transmission between humans, evidence suggests that soon this may be possible, causing widespread transmission (World Health Organization [WHO], 2006).

Experts have projected that this strain of avian influenza has the potential to be comparable to the 1918 pandemic, causing approximately 180 to 360 million deaths globally, with 1.7 million deaths possible in the United States alone. As a result, the Centers for Disease Control and Prevention (CDC), the U. S. Department of Health and Human Services (HHS), and other governmental agencies have established pandemic preparedness as a top priority. Included in those plans must be strategies for allocating vaccine and antiviral resources, which will become insufficient to support the demand. A consistent, equitable, and well-developed method for the prioritization of target groups for vaccination and antiviral therapy requires detailed consideration. Presented in this document are several issues to be deliberated and addressed in the development of such allocation priorities. This discussion is followed by recommendations for the Indiana State Department of Health.

The Issues

A review of the developing literature on vaccine and antiviral agent prioritization (Barnett et al., 2005; California Department of Health Services [CDHS], 2006a; California Department of Health Services [CDHS], 2006b; California Department of Health Services [CDHS], 2006c; California Department of Health Services [CDHS], 2006d; Centers for Disease Control and Prevention [CDC], Ethics Subcommittee of the Advisory Committee to the Director, 2007; Florida Department of Health [Florida DOH], 2004; Gostin, 2006a; Gostin, 2006b; Gostin & Berkman, 2007; HHS, 2005a; HHS, 2006; HHS, 2007; Minnesota Department of Health, 2006; New York City Department of Health and Mental Hygiene, 2006; New York State Department of Health, 2006; Olson, Simonsen, Edelson, & Morse, 2005; Public Engagement Pilot Project on Pandemic Influenza [PEPPPI], 2005; Virginia Department of Health, 2006) identifies four areas of agreement.

These are presented in Table 1 below.

Table 1:

Areas of Agreement Regarding Vaccination and Antiviral Agent Prioritization

Issue	Explanation
Planning	Establishing target group prioritization guidelines prior to the occurrence of a pandemic is necessary in order to prepare for the inevitable shortages of vaccines and antiviral agents.
Implementation	Policies must be implemented consistently to ensure fairness and equal opportunity for care.
Transparency and public awareness	Preparing and informing the community regarding how target groups are intended to be prioritized during a pandemic will help to reduce civil unrest and may assist with gaining compliance.
Flexibility of guidelines	The epidemiology of an actual influenza pandemic may vary from what is projected. Plans must be modifiable to ensure the most appropriate response and usage of vaccines and antiviral agents. Changes in the production vo-

	lume of vaccine manufacture also may affect prioritization. Technological advances in vaccine production and other innovations may require a revision of procedures. Prioritization guidelines must be able to accommodate changes that result from these factors.

Providing vaccines and antiviral medications will be a principal strategy in the response to an H5N1 pandemic, and a majority of the proposed expenditures in the federal influenza plan are devoted to these countermeasures (Gostin, 2006a). Within the $6.7 billion federal plan, $4.7 billion has been allotted for vaccine stockpiling and technology development, and $1.4 billion has been allotted for antiviral agents (Gostin, 2006a; Gostin & Berkman, 2007). Allocation of these federal stockpiles has been predetermined based on state population (HHS, 2006). However, in the event of a pandemic, there almost certainly will be an insufficient supply of vaccines and antiviral medications, and particular target groups will need to be prioritized (Gostin & Berkman, 2007).

The Approaches

Vaccines. Debates over which populations deserve priority in receiving vaccinations are directly related to the primary objective of vaccination. Emanuel and Wertheimer (2006) put forth the argument that prioritization should be based on the "life cycle principle," which favors early adolescents to middle-aged individuals rather than the very young or the very old "on the basis of the amount the person invested in his or her life balanced by the amount left to live" (p. 855). In response, Wynia (2006) states that any plan that prioritizes adults over young children is likely to be rejected, since parents would likely refuse their own immunization in order for their children to receive it. Additionally, prioritizing these age groups would still require further subgrouping due to the relatively large proportion of the population that fits into these categories. As such, other criteria would need to be considered.

More commonly, debates regarding the objective of vaccination in pandemic influenza have centered on whether the primary aim should be to minimize societal disruption or to minimize morbidity and mortality. Societal disruption can be described as a significant disturbance to the functioning of society (e.g., the cessation of essential services or the occurrence of severe economic distress). Proponents of placing top priority on maintaining societal function (CDC, 2007; McGorty et al., 2007; PEPPPI, 2005) would favor vaccinations for those "essential to the provision of health care, public safety and the functioning of key aspects of society" (CDC, 2007, p. 2), and as such, a "social worth criterion and its use is justified in these limited circumstances" (CDC, 2007, p. 7). The CDC (2007) document does not state explicitly who would be considered essential and recommends that policymakers engage in a dialogue with all stakeholders to make this determination. The PEPPPI (2005) project elaborates slightly on which individuals would be

considered essential, such as those involved in "maintaining homeland security, utilities, food distribution, and communications" (p. 19). Only intended for policy guidance, neither of these documents contains specific prioritization lists.

Documents and policies that favor minimization of morbidity and mortality as the primary objective of immunization and minimizing social disruption as the secondary objective do have similarities to those that favor the reverse. For example, healthcare workers are placed at or near the top of the prioritization list in nearly all documents and policies (CDC, 2007; CDHS, 2006d; Engel, 2007; Florida DOH, 2004; HHS, 2007; Illinois DOH, 2006; Minnesota DOH, 2006; PEPPPI, 2005; Straetemans et al., 2007) regardless of which objective is favored. Medical personnel not only treat the afflicted but also come into contact with large numbers of individuals who are not infected. Their vaccination, then, would allow medical care to continue and would slow the transmission of the virus throughout the population by preventing transmission from the provider to uninfected patients.

Despite the consensus on prioritizing healthcare workers, agreement regarding other groups' prioritization is somewhat lacking. Even among themselves, those who favor the primary objective of maximizing lives saved (CDHS, 2006a; Florida DOH, 2004; Illinois DOH, 2006; Minnesota DOH, 2006) have different methodologies and prioritization lists of varying degrees of detail. For example, although some plans have placed utility workers high on the priority list (Florida DOH, 2004), others have not due to these employees' relatively low risk of exposure or transmission (CDHS, 2006d). Debates such as this are the source of deviation between various proposed policies.

The original U.S. Department of Health and Human Services pandemic preparedness plan (2005a) included an appendix that described the recommendations put forth by the National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP). These recommendations contained 21 priority groups categorized into four tiers, two of which were further divided into subtiers (HHS, 2005a). For each tier and subtier, the NVAC/ACIP group provided rationale for prioritization ranking. These included statements regarding each priority group's susceptibility to complications from influenza or to that subgroup's function in pandemic response efforts. Several states (Illinois Department of Health, 2006; Minnesota Department of Health, 2006; New York State Department of Health, 2006; Virginia Department of Health, 2006) have adopted these previous HHS recommendations directly in their plans, although many specifically state that such prioritizations are considered part of a draft only. The state of Florida differs from HHS and the aforementioned states in that it has developed its own recommendations for priority group rankings (Florida DOH, 2004). The Florida plan identifies nine at-risk groups and, similar to the HHS guidelines, provides a rationale for each group's ranking.

Though the earlier HHS document and the states that adopted its preliminary prioritization list provide reasonable explanations for the rankings of the various priority groups, these explanations are provided by committee participants and

may be considered subjective and not entirely transparent. The state of California, by contrast, appears to have the most original, most developed, and most transparent methodology for determining subgroup prioritization of any of the states researched. The California guidelines consider the minimization of health consequences as the primary objective in the response to a pandemic, under the assumption that "focusing intervention efforts on reducing the direct health consequences [such as death] reduces indirect consequences (e.g., economic loss and social disruption)" (CDHS, 2006b, p. 15). The minimization of societal disruption and economic loss also are identified as critical factors, however, and as a result, strategies presented are required to achieve all three of these goals.

CDHS has developed a mathematical methodology to determine its prioritization listings—the Decision Analysis Scoring Tool (DAST). The department identifies DAST as a resource to analyze "multiple goals, criteria, and alternatives to develop an optimal prioritization scheme" (CDHS, 2006b, p. 14). This tool takes into account seven criteria: risk of complication, risk of transmission, risk of infection, vaccine effectiveness, whether the individual provides direct response service, whether the individual provides support response service, and whether the individual provides essential community service (CDHS, 2006d). DAST was distributed to individuals from several different groups so they could rank 69 populations on a scale of 0 to 10 on each of the predetermined criteria. For all identified populations, CDHS has calculated the average scores for each criteria category, and the sums of these averages are the basis for the priority rankings. This mathematical method allows for clear identification of priority groups. Should new epidemiological data become available that identify some groups at greater risk for infection or transmission than previously assumed, DAST scores and rankings then may be adjusted accordingly. Such elements of the California guidelines enable them to be comprehensive, yet remain flexible to allow potential modifications that are necessary in the event of a pandemic. Currently, essential medical and emergency response personnel retain the highest rankings in the priority list, and healthy adults who otherwise do not hold essential positions are ranked at the bottom (CDHS, 2006b).

One limit to the prioritization list generated by CDHS (2006d) using DAST methodology was that only 10 individuals were involved in the initial ranking of the subpopulations. Though this may put into question groups' exact placement on the list, it does not alter the effectiveness of the DAST methodology. Gathering feedback from stakeholders from all facets of society would help to ensure that the resulting prioritization list would be acceptable to all who will be affected.

In the time since the original version of this document was provided to the Indiana State Department of Health, HHS has made available a revised version of its vaccination allocation plan (HHS, 2007). This document was "drafted by a Federal interagency working group whose members represent all sectors of the government" (HHS, 2007, p. 2) and included the input of stakeholders such as community organizations and businesses. In contrast to other planning documents, this draft explicitly identifies

10, rather than two or three, objectives for vaccine allocation. These are to: protect persons critical to the pandemic response and who provide care for persons with pandemic illness; protect persons who provide essential community services; protect persons at high risk of infection because of their occupation; protect children; protect homeland and national security; indirectly protect persons who cannot be vaccinated; protect persons at high risk of severe illness and death; protect those who have essential economic functions; protect persons guarding our borders; and target vaccine to persons among whom it is most likely to be effective (HHS, 2007).

To create the prioritization list, the working group members undertook a method similar to the DAST methodology utilized in the California plan, which allows for the prioritization decisions to be more transparent and objective than in the original HHS (2005a) document. Members ranked the importance of the 10 objectives of vaccination. Then individuals from the HHS working group, the CDC, and academia were involved in rating populations in relation to their fulfillment of the objectives. Weighted scores were calculated from each group, and the resulting prioritization lists were divided into four categories: homeland and national security, healthcare and community support services, critical infrastructure, and the general population (HHS, 2007). Each category has individuals who are identified as highest priority (tier 1), as well as second and third highest priorities. Some categories additionally have fourth and fifth priority tiers, and some also have a tier of "not targeted." This tiered system throughout categories ensures that vaccinations are distributed throughout the categories of populations and will not favor only one group.

In addition to the mathematical methodology HHS has undertaken in its new prioritization list, pandemic severity also is taken into account. The tier to which a group is assigned is dependent upon the severity of the pandemic, whether it be less severe, moderate, or severe. For example, in a less severe pandemic, electricity, natural gas, communications, and water sector personnel are not targeted for vaccination. In a moderate or severe pandemic, however, these groups fall into the second tier of vaccination priority (HHS, 2007). Public health personnel and inpatient healthcare providers fall into tier 1 no matter the pandemic severity, as do pregnant women, infants, and toddlers.

The new HHS (2007) plan and the California (CDHS, 2006d) vaccination prioritization scheme have their own strengths and weaknesses. The California plan defines 69 distinct subgroups, whereas the HHS plan defines only 39. Given the expected scarcity of the vaccine, defining groups as narrowly as possible, as in the California plan, would likely be beneficial. One weakness of the California plan is that it neglects to alter prioritization schemes based on pandemic severity. This is accomplished in the new HHS plan. Additionally, the HHS (2007) document classifies subgroups into four categories, which ensures that vaccine will be spread throughout the population and not only to the few groups at the top of the prioritization list.

Both the HHS (2007) and California (CDHS, 2006d) plans identify mathematically how a subpopulation fulfills

several criteria. Though the DAST methodology utilizes seven criteria and the HHS methodology uses 10, there is a great deal of overlap between the two. Only one objective from the HHS plan is novel to this document: to protect children. The following table illustrates the overlap between the two documents. The HHS criteria frequently can be classified within the California criteria.

Table 2: Comparisons between the California and HHS vaccine prioritization criteria

California (CDHS, 2006d) criteria	HHS (2007) criteria
Risk of complication	-Protect persons at high risk of severe illness and death
Risk of transmission	-Protect persons who cannot be vaccinated
Risk of infection	- Protect persons who are at high risk of infection because of their occupation
Vaccine effectiveness	-Target vaccine to persons among whom it is most likely to be effective
Provides direct response service	-Protect persons critical to the pandemic response and who provide care
Provides support response service	-Protect persons critical to the pandemic response and who provide care
Provides essential community service	-Protect homeland and national security -Protect persons guarding our borders -Protect those who have essential economic functions
	-Protect children

From this, it is possible to create a combined criteria list. This list likely would include the seven original DAST criteria (CDHS, 2006d) and would add the criterion of protecting children (HHS, 2007), provided that the definition of "child" is clarified (i.e., an age range is identified). Other HHS criteria can be considered to help determine the extent to which a subpopulation fulfills the DAST criteria. For example, when determining if someone provides an essential community service, that person's role in protecting homeland security, protecting our borders, or providing essential economic functions are some of the factors that can be taken into account. These functions, however, are not exhaustive and should not be considered the only essential community services.

Antivirals. Though vaccinations will most certainly play an important role in achieving pandemic planning objectives, it is generally accepted that a vaccine will unlikely be available in the first three to six months of a pandemic (HHS, 2005a). Because of this, use of antivirals will likely be necessary in order to reduce the impact of an influenza pandemic. All policies and plans are based on the assumption that antivirals such as oseltamivir will be effective in limiting the effects of the pandemic virus strain.

It must first be noted that no methodology similar to California's (2006d) or

HHS's (2007) vaccination plans has been developed for antiviral distribution. This lack of a mathematical decision-making model may compromise the transparency and objectivity of any plan that is put forth. Nevertheless, national, state, and local plans have developed allocation prioritization lists (CDHS, 2006a; HHS, 2005b; Indiana State Department of Health Pandemic Influenza Community Advisory Groups [ISDH CAG], 2006; New York City Department of Health and Mental Hygiene [NYC DOHMH], 2006). Additionally, several states have adopted the HHS antiviral guidelines in their entirety (Arizona Department of Health Services, 2006; Florida Department of Health, 2006; Virginia Department of Health, 2006).

Though many studies have attempted to predict the effects of different antiviral allocation strategies (Gani et al., 2005; Lipsitch, Cohen, Murray, & Levin, 2007; Longini, Halloran, Nizam, & Yang, 2004; McCaw & McVernon, 2007; Swaminathan et al., 2007), conclusions are based on a variety of assumptions about the epidemiology of the illness and therefore cannot be used as the sole justification of antiviral allocation. Because of this, differences between prioritization lists primarily are the result of differences in views on the purpose of antiviral use, whether for prophylaxis, post-exposure prophylaxis, or treatment. Prophylaxis is the provision of antiviral treatment in order to prevent illness in individuals who may not necessarily have been exposed to the virus. It may be used early in the pandemic in order to prevent the spread of the illness throughout an affected community (HHS, 2005b). Post-exposure prophylaxis is the provision of the antiviral to individuals who are known to have been in close contact with an infected individual, such as a family member. Treatment is the use of antivirals in individuals who have a documented infection or exhibit signs of infection. It is most effective if dispensed in the first 48 hours of symptoms (HHS, 2005b).

In its report on antiviral allocation, HHS (2005a) states that both treatment and post-exposure prophylaxis require a single course of medications, for a total usage of 10 capsules. In contrast, prophylaxis is expected to require at least 40 capsules, or four courses of medication (HHS, 2005a). Such use for prophylaxis may therefore quickly deplete the antiviral stockpile. For this reason, the United States Homeland Security Council (2006) states that if antiviral supplies are very limited, antiviral medications would be "reserved for symptomatic individuals who are at high risk of serious complications or death" (p. 106). If supplies are more abundant, "it may be feasible to expand priority groups and implement strategies to limit disease transmission" (Homeland Security Council, 2006, p. 106), such as in initial containment efforts.

Not surprisingly, all researched plans place the highest prioritization on groups requiring treatment (HHS, 2005a; CDHS, 2006a; ISDH CAG, 2006; NYC DOHMH, 2006). The HHS (2005a) plan identifies 11 priority groups, the first five of which are prioritized for treatment. Three of the remaining six groups are prioritized for prophylaxis, and one is prioritized for post-exposure prophylaxis. The rationale for each group's prioritization is provided. For example, at the top of the list to receive antiviral medications are patients who have been

admitted to the hospital with influenza. The rationale provided is that this is "consistent with medical practice and ethics to treat those with serious illness and who are most likely to die" (HHS, 2005a, p. D-21). The New York City plan (NYC DOHMH, 2006) identifies the same 11 priority groups as the HHS (2005a) document. The main difference between the two lists is that the first seven groups in the New York City plan are prioritized for treatment. The final four are then prioritized for prophylaxis. In other words, all treatment groups are placed ahead of the prophylaxis and post-exposure prophylaxis groups. The rationale similarly is given for each group. Furthermore, despite identifying prioritization groups for prophylaxis, the New York City plan states that "all stockpiled antiviral drugs will likely be reserved for treatment purposes only" (NYC DOHMH, 2006, p. 189). The ISDH CAG (2006) recommendations also emphasize the use of antivirals for treatment purposes, but priority groups are not ranked. Prophylaxis is recommended only if supplies of antivirals are increased within the state (ISDH CAG, 2006). The ISDH CAG identifies age, medical necessity, medical effectiveness, and social utility as considerations in an individual's antiviral allocation categorization.

The California plan (CDHS, 2006a) does not have the level of depth as the other plans and does not identify subpopulations in detail. However, the California plan does identify allocation strategies in the different WHO pandemic phases. In phases 3, 4, and early 5, "lab confirmed cases, close contacts, high risk individuals, and exposed healthcare workers" (CDHS, 2006a, p. 129) are prioritized for treatment. In late phase 5 and phase 6, cases are to be treated with prioritization given to healthcare professionals and public safety workers.

Recommendations

The discussion provided in this document lends itself to three recommendations that IUCB believes would lead to the development of ethically sound statewide policies regarding vaccine and antiviral allocation. Each recommendation is followed by its justification and has been evaluated by an expert panel convened by the IUCB.

<u>Recommendation 1:</u> The Indiana State Department of Health should adopt a rank-order prioritization scheme similar to those developed by the United States Department of Health and Human Services and the California Department of Health Services in order to develop a vaccine prioritization list.

The use of such mathematical prioritization methods, which are based on a variety of criteria rather than simple subjective rankings, allows for greater transparency and accountability to the public, as well as the consistent implementation of the developed protocol. Additionally, such methodology allows for flexibility and adjustment should new epidemiologic data arise. It also may be distributed and calculated in Indiana to adapt the prioritizations to the State's unique needs.

A possible method of combining the criteria of the California and HHS strategies was presented within this document. It is advised that the State define its subpopulations clearly, similar to the methodology of the California document. However, it also is recommended that

the State classify these subpopulations under the four categories described in the HHS document so as to ensure that vaccine is distributed throughout the population and not only to a few high-ranking groups. The State also should vary prioritization based on pandemic severity.

Recommendation 2: The Indiana State Department of Health should adopt an antiviral allocation strategy that places greater emphasis on treatment than on prophylaxis. Non-pharmaceutical prophylaxis, such as the use of personal protective equipment, should be emphasized.

Given the limited amount of antiviral medications that will be available, use of prophylaxis in those who may not be infected would quickly diminish the supply of antivirals at the expense of those who are infected and in definite need of medical attention. Such a strategy of prophylactic use would likely receive limited public support and may increase unrest. On the other hand, use of antivirals primarily for treatment would ensure that the maximum number of individuals would receive the medication. The emphasis on non-pharmaceutical prophylaxis would reduce the demand for antiviral prophylaxis and would limit the potential risks involved in extended antiviral use.

Some expert panel members expressed a desire to have a triage scoring tool similar to the Sequential Organ Failure Assessment (SOFA) methodology, which would be used to determine which patients presenting for treatment would receive antiviral medications. Time since the onset of symptoms would likely be one point of assessment, since those presenting 48 hours or more after symptom onset would be less likely to benefit. It also was suggested that a supervisor, not the treating physician, decide who does or does not receive antiviral medication so as to reduce the treating physician's conflicting obligations.

Recommendation 3: The Indiana State Department of Health should develop an educational toolkit regarding the criteria by which the prioritization plan is developed. This toolkit should be disseminated to county health departments, emergency management agencies, hospitals, physicians' offices, and other stakeholders in vaccine and antiviral allocation.

In times of scarcity, a common approach to allocation is essential. Each group of stakeholders should be confident that it fully understands the objectives of ISDH with respect to prioritizing vaccine and antiviral availability. Therefore, each stakeholder should be briefed as to how ranking and prioritization will occur.

Application to the Points to Consider

In our previous work for the Indiana State Department of Health regarding pandemic influenza planning, we developed an ethical framework entitled *Points to Consider*. This framework was designed to provide guidance for those working through specific ethical issues and as a tool for assessing the ethical basis for proposed policy. The *Points to Consider* contains seven "points" that IUCB believed would need to be addressed in any policy development if such a policy were to be considered ethically sound and acceptable to Hoosiers.

Expert panel members were provided with the *Points to Consider* document as part of their deliberations but were not required to use it as their only guide.

We believe that the recommendations presented in this TAD are consistent with the ethical framework presented in the *Points to Consider* document.

Table 3 below summarizes the applicable points and how they are addressed.

Table 3: Points to Consider in the Proposed Prioritization Strategy

Ethical Point to Consider	Applicability to Protocol
Transparency	The inclusion of open communication facilitates public awareness of the prioritization policies and their implications.
Public Accountability	The inclusion of the public in the various levels of the policymaking process, as well as the inclusion of means of communication to the public, allows policymakers to address the public promptly regarding any complications of the guidelines.
Responsiveness	Public and professional input in the decision-making process, along with the presence of communication mechanisms, allows for the iterative evaluation and improvement of the prioritization guidelines.
Reciprocity	Healthcare workers engaged in direct patient care and emergency response personnel will be at highest risk of infection and are prioritized for protective equipment and vaccines to minimize their increased risk of infection and allow them to fulfill their duties.
Uniformity of Implementation	Development of vaccine prioritization groups at the State level via the use of DAST and HHS methodology allows for clear and consistent identification of priority groups.

Case Study Responses

#1. The woman should be informed that the medication is to be used for treatment only and that an assessment of her son's health revealed that he did not qualify for this. Additionally, prophylaxis generally requires four courses of medication, so the one bottle she would provide him likely would be insufficient. If the woman continues to refuse the medication, it should be saved for the next qualifying patient. If she accepts the medication, the first dose should be given at the clinic so as to ensure she is the one taking the medicine and that she is not providing it to her son. She should be informed of the potential complications involved in giving the child medication that is intended for an adult. Additionally, she should be informed of non-pharmaceutical methods of preventing transmission of the virus to her son and husband, such as frequent hand washing, isolating herself in the household, and allowing her husband to care for their son to the extent possible.

#2. Though the pulmonologist qualifies as a top priority for vaccination due to his occupation and direct exposure to pa-

tients, his wife and adolescent children likely do not qualify in times of extreme scarcity due to their relatively low prioritization rankings and limited risk factors. The pulmonologist and his family should be educated on non-pharmaceutical ways

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to protect themselves from exposure and illness, such as proper hand washing and social distancing. The doctor should then be encouraged to report to work given his specialized skill set and the needs of the community.

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Technical Advisory Document (TAD-0F-08)

HEALTHCARE WORKFORCE MANAGEMENT AND PANDEMIC INFLUENZA PREPAREDNESS:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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In 2007, the Indiana State Department of Health contracted with the Indiana University Center for Bioethics (IUCB) in order to explore the ethical dilemmas that would arise in an influenza pandemic. The difficulties that would accompany management of the workforce in such a health crisis comprised one such topic to be explored, which was accomplished primarily through literature review. In August 2007, IUCB presented a set of four recommendations to the State to address workforce management issues that may occur during an influenza pandemic. In the months since the original research was conducted, the body of literature related to such topics has continued to grow, with many perspectives presented in greater depth. Because the area of pandemic planning and response remains a developing field, it was useful for IUCB to revise and amend previous documents and recommendations in order to take the most current thinking on the topic into account.

As with the previous documents, a significant amount of the research for the current documents was based on a review of the most recent literature and policies. In addition, expert panels were convened to refine previous recommendations and to determine their feasibility, as well as to develop case studies that could be used as part of an instructional tool for critical thought and discussion. These case studies represent real-world scenarios that may occur in an influenza pandemic, and it should be noted that they may be applicable to several areas of pandemic influenza planning that are presented in the four technical advisory documents developed by IUCB.

Case Studies

#1. *A 42-year-old single father works as a custodian at a local hospital. He has two children, ages 7 and 9, both of whom have developed respiratory symptoms within the past 24 hours. Due to a shortage of janitorial staff, the man is called into work. He refuses to report to the hospital in order to remain at home with his sick children. He has no family members in the immediate area who would be able to care for his children in his absence. Given that custodians are not subject to professional codes of ethics or obligations, how should the hospital respond to the employee's refusal to report to work?*

#2. *A hospital has begun stockpiling personal protective equipment for its employees. When the influenza pandemic begins, the hospital only has enough supplies to cover half its workforce. Neighboring healthcare facilities also have limited supplies and are unable to provide assistance. What steps must the hospital take to address this situation?*

Introduction

Serious outbreaks of avian influenza A (H5N1) have occurred among birds in Asia, Europe, and the Middle East. Although highly contagious among bird populations, the H5N1 virus is rare in human populations due to a significant species barrier (World Health Organization [WHO], 2006). However, as of June 2, 2008, the number of human infections has continued to increase with 383 reported cases, 241 of which were fatal (WHO, 2008). While no efficient

human-to-human transmission has occurred to date (WHO, 2006), the underlying knowledge of the virus—its highly virulent nature, constant evolution and mutation, and the potential for transmission from migratory birds to mammals and humans—has raised global concern of a pandemic potential.

The World Organization has recognized the potential of an influenza pandemic and have called for member nations to start planning for the next pandemic (WHO, 2005), which WHO refers to as "inevitable, and possibly imminent" (Barnett et al., 2005, p. 1235). Some professionals have suggested preparing for a pandemic similar to the 1918 "Spanish flu" that is estimated to have caused 50 to 100 million deaths. A similar pandemic could cause about 180 to 360 million deaths globally, including 1.7 million deaths in the United States, with transmission of the disease lasting at least two years (Barnett et al., 2005).

If such a pandemic occurs, it will require drastic, though temporary, changes in many areas of society, including hospitals, schools, workplaces, and other public service organizations. In planning a response for such a pandemic, many decisions will have to be made both to contain and control its spread, and policies to guide decision-making will require consideration of ethical issues related to workforce management, allocation of scarce resources, and minimization of societal disruption.

This paper discusses the ethical concerns related to workforce management. By "workforce" we mean all persons employed in the various occupational fields. As such, this paper identifies workforce-related ethical issues and suggests relevant questions that policymakers should take into account when planning for an influenza pandemic response. Finally, it provides revised recommendations to the Indiana State Department of Health that may be used in the planning process.

It is necessary to note that although an influenza pandemic would affect the workforce indiscriminately throughout society, we will focus primarily on the healthcare sector and healthcare workers in clinical environments such as hospitals, outpatient clinics, and other organizations employing workers who care for patients. We also will consider other workers, such as food service and janitorial workers, in these institutions. This focus is intentional given the direct impact on the delivery of health care to patients should these essential healthcare workers be unavailable to carry out their responsibilities. Nevertheless, it is paramount to note that other non-clinical workers are vital to uninterrupted healthcare delivery (e.g., suppliers of drugs and medical devices).

The Issues

A review of current literature on workforce management (Agency for Healthcare Research and Quality [AHRQ], 2005; AHRQ, 2007; Barnett et al., 2005; Berlinger & Moses, 2007; Cole, 2007; Ehrenstein, Hanses, & Salzberger, 2006; Engel, 2007; Gomersall et al., 2006; Gomersall, Loo, Joynt, & Taylor, 2007; Gostin, 2006; Gruber, Gomersall, & Joynt, 2006; Hsin & Macer, 2004; Illinois Department of Public Health, 2006; Iserson et al., in press; Jan, 2007; Letts, 2006; Levin, Gebbie, & Qureshi, 2007; Lo & Katz,

2005; Martin, 2007; McGorty et al., 2007; Morin, Higginson, & Goldrich, 2006; Occupational Safety and Health Administration [OSHA], 2007; Payne, 2007; Public Health Agency of Canada, 2006; Qureshi et al., 2005; Reid, 2005; Rhyne, 2007; Tzeng, 2004; University of Maryland Center for Health and Homeland Security, 2005; WHO, 2005) suggests some areas of agreement.

These are summarized in Table 1 below.

Table 1: Areas of Agreement Regarding Workforce Management

Issue	Explanation
Planning	Planning for a response strategy to a pandemic prior to its occurrence is crucial.
Involvement in policymaking	It is necessary to include both the public and healthcare workers in the planning process in order to gain support for and compliance to the plan. Public and worker involvement also will help to cultivate ethically sound decision making.
Prioritization	Healthcare workers should be given priority to scarce protective resources, such as protective equipment and vaccines.

We note that the agreement reached on these three issues is not surprising, since they can be considered uncontroversial. Other ethical issues may not enjoy the same level of agreement, including the following four additional issues: the duty to care in healthcare provision; sanctions for absenteeism; control measures; and obligations of other important individuals in the workforce.

Duty to Care. Healthcare workers and healthcare professionals are faced with the risk of being infected while providing care to both infected and exposed patients. The level of risk is relative to the specific agent involved in the pandemic, which in most instances will be unknown, at least when the first cases are identified. Since most healthcare professionals are bound by a code of ethics that obligates them to provide care to patients, the scenario above gives rise to several ethical concerns: what degree of risk is acceptable in occupational exposure? Should the obligation to provide care diminish with rising levels of risk? Is there a level of risk at which the duty to care no longer remains (Reid, 2005)? How should healthcare workers balance competing obligations when they come into conflict, such as when obligations to family clash with obligations to patients (Hsin & Macer, 2004)? Is the obligation to treat absolute (Morin et al., 2006)? Each of these questions speaks to the central ethical concern facing healthcare workers in a pandemic: the nature and extent of their obligation to care for patients, even when this creates a risk of harm to the healthcare workers themselves.

Sanctions for Absenteeism. The public will demand that healthcare professionals be held accountable for providing care throughout a pandemic.

However, enforcing accountability raises several ethical questions. For example, should care providers be sanctioned for choosing not to treat infected patients in a severe pandemic, and should healthcare workers be reprimanded for choosing not to report to work (Hsin & Macer, 2004)? Are there cases when absenteeism is acceptable, such as when a worker tends to an ill family member? What if a worker fraudulently claims to be tending to a family member when no such family member exists? Some of the possible sanctions for noncompliance with one's employment contract or professional duties to care include professional licensure revocation (Center for Law and the Public's Health at Georgetown and Johns Hopkins universities, 2001) and imprisonment (AHRQ, 2007; University of Maryland Center for Health and Homeland Security, 2005). Other forms of sanctions may include warnings; letters of reprimand; financial penalties; license suspension (for examples, see Indiana Code 25-1-9-9); or termination of employment. Noncompliance with professional ethical obligations to care for patients always raises profound ethical issues in the normal course of affairs. When extraordinary events arise, they may demand extraordinary responses, and institutions must exercise caution in the actions they take.

Control Measures. The State will be required to institute public health control measures immediately in order to contain the spread of the disease. Some of the control measures may include quarantining workers in places believed to be exposed, such as hospitals, clinics, airports, and bus terminals. These issues arose in the 2003 SARS epidemic in Asia and Canada, where quarantine was invoked in various workplaces (Hsin & Macer, 2004), and in the more recent case of an airline passenger who was initially diagnosed with extremely resistant tuberculosis and was placed in isolation upon his return to the United States (Centers for Disease Control and Prevention [CDC], 2007a; Centers for Disease Control and Prevention, 2007b). The principal ethical questions are: (a) whether quarantine should be ordered without warning or preparation, and (b) whether families of care providers should be quarantined after the provider has a documented exposure (Hsin & Macer, 2004).

On the other hand, negative outcomes from quarantine, such as fear, depression, anxiety, anger, frustration, community isolation, and stigma for workers providing care to infected individuals, produce another set of ethical concerns: whether families of care providers should be prioritized for scarce protective resources; whether healthcare workers should be quarantined; and whether control measures should aim primarily at controlling the spread of a disease or at reducing societal disruption (Hsin & Macer, 2004; Reid, 2005).

Other Vital Workers. For healthcare institutions to be able to provide care to infected and exposed individuals during an influenza pandemic, other vital staff members need to be at work. These include translators, cooks, hospital janitorial staff, and suppliers of critical resources, who are hourly employees critical to the daily operation of healthcare organizations. In the absence of the use of accrued paid sick leave or invocation of Family and Medical Leave Act (FMLA) rights, a choice not to

report to work, for whatever reason, would result in these workers not being paid. Thus, the main ethical concerns that revolve around reporting to work are: Should such groups of hospital workers, who do not have the same kinds of professional obligations as doctors and nurses, be expected to work? What should the consequences be when such workers do not report to work? Will the consequences differ depending on the underlying reason for absence (e.g., not reporting to work due to fear versus staying home to care for a sick family member)?

The Approaches

A number of approaches have been offered to address the ethical issues that arise for workers during an influenza pandemic. We outline these below.

Emphasizing Duty to Care. As previously noted, healthcare professionals have a duty to assure adequate availability of care in emergencies, but some studies have suggested that as few as 48% of at-risk employees may be willing to report to work (Qureshi et al., 2005). Others, however, have found that healthcare professionals recognize their professional obligation to treat patients in an influenza pandemic (Ehrenstein et al., 2006; Iserson et al., in press). In their review of healthcare professionals' responses to recent disasters, Iserson et al. (in press) note that emergency department physicians tend to have "rescue personalities" (p. 5) and therefore are likely to remain at their posts. Iserson et al. (in press) also observe that religious values may motivate individuals to perform their work. Additionally, these professionals may present to work in order to take on their own "fair share" of the responsibilities and not leave excess burdens on the shoulders of their fellow colleagues (Iserson et al., in press). Fear of ostracism from their colleagues due to "abandoning their posts" is another potential motivator to avoid absenteeism (Iserson et al., in press). The presence of senior-level physicians who remain calm in the situation and model appropriate behavior can further improve employee response (Iserson et al., in press).

The debates that arose about healthcare workers' obligations to assume risk during the early years of the HIV/AIDS era provide a useful comparison to the issues in pandemic influenza planning. In the context of treating HIV/AIDS, some commentators have argued that the obligation to provide care to infected patients should be inversely related to risk (Morin et al., 2006). The main ethical concern was whether there exists a point where risk outweighs the obligation to provide care. However, the experience in the context of SARS suggests that risk and obligation do not stand in an inverse relationship (Reid, 2005); rather, the authors suggest that the greater the risk, the more obligation health professionals have to respond. Rhyne (2007) evaluated the American Medical Association and the American College of Physicians statements and policies regarding duty to care and concluded that "medical professional associations and societies support the safety of physicians, but also assert an ethical obligation and responsibility to work during a public health crisis despite personal risks" (p. 52). Letts (2006) argues that healthcare professionals should be encouraged to take on a higher level of risk out of professional

obligation. Iserson et al. (in press) state that observing healthcare workers abandoning their duties would create a sense of panic and social instability in the public. This is based on the argument that no one else in our society is "more appropriately trained and more deeply obligated to serve in [the] case of a medical emergency" (Reid, 2005, p. 352) than healthcare professionals. Given their unique and specialized ability to provide care (McGorty et al., 2007), if they do not tend to the sick, who will (Reid, 2005)? Indeed, some even contend that vital workers must not only fulfill their current responsibilities, but are ethically obligated also to "assume new responsibilities for which they are trained, as long as their actions will not lead to greater harm than failure to act" (McGorty et al., 2007, p. 40). Nonetheless, despite many healthcare professionals appearing ready to take risk in care provision, other healthcare workers, such as health administrators, have been reported not to have the same commitment (Ehrenstein et al., 2006).

It should be noted that a difference exists between *ability* to work and *willingness* to work (Qureshi et al., 2005). Ability may be affected by logistical problems, such as barriers to transportation and child and pet care, and by health status, specifically whether an individual is personally affected by influenza. Identification of these specific barriers can lead to appropriate intervention strategies, such as establishing protocols to provide workers with child care (Qureshi et al., 2005).

Level of willingness to work is reflective of the worker's level of fear for his or her family, own health (Qureshi et al., 2005), and professional liability. It has been proposed that educating healthcare workers with information about the etiology of the illness and its proper control measures would increase willingness to provide care (Tzeng, 2004). It also has been suggested that some staff may be more willing to provide care if housing is provided so as to "avoid taking the flu home" (Martin, 2007, p. 599). In addition, the critical issue of ensuring protection from litigation for following protocols for the crisis situation may encourage professionals to report to work by helping to protect their professional status (McGorty et al., 2007).

Much of current thinking focuses not only on the individual healthcare workers' duty to care, but also on the duty of employers to ensure these workers are as prepared and protected as possible (Berlinger & Moses, 2007; Cole, 2007; Gomersall et al., 2007; Gruber et al., 2006; Illinois Department of Public Health, 2006; Iserson et al., in press; Jan, 2007; Levin et al., 2007; Martin, 2007; McGorty et al., 2007; OSHA, 2007; Payne, 2007; Public Health Agency of Canada, 2006; Qureshi et al., 2005; Rhyne, 2007), which will aid in sustaining adequate levels of workforce attendance. Extra pay (Berlinger & Moses, 2007), effective risk communication and readily available information for workers (Iserson et al., in press), provision of counseling services (Cole, 2007; Gruber et al., 2006; Martin, 2007), adequate personal protective equipment (Martin, 2007), and the availability of workers compensation (Rhyne, 2007) are all possible incentives and facilitators for employees to report to work. Developing explicit protocols and practicing response exercises and drills

also may increase worker attendance by increasing preparedness and confidence (OSHA, 2007).

Sanctions for Absenteeism. Although some argue that the choice of whether or not to report to work during an influenza pandemic should be an individual decision, others contend that the decision should not be left to individuals (Morin et al., 2006). Nonetheless, there has been growing consensus that healthcare workers' choice to report to work should be voluntary (Ehrenstein et al., 2006; Hsin & Macer, 2004; Letts, 2006).

Since absenteeism is a real possibility, planning for countermeasures in case of understaffing is recommended. Some have proposed the identification of volunteers, such as retired physicians and veterinarians, prior to a pandemic (AHRQ, 2005; Cantrill, Eisert, Pons, & Vinci., 2004; Rubinson et al., 2005). These individuals could then be registered in a database for their quick retrieval and verification (Cantrill et al., 2004; Rubinson et al., 2005). Gomersall et al. (2006) suggest drafting of staff to work in intensive care units if sufficient volunteers are unavailable. However, he cautions that this should be done before a pandemic in a manner that is "fair, transparent, participatory, [and] understood" (Gomersall et al., 2006, p. 1009).

As with the duty to care, approaches to sanctions for absenteeism and refusal to care vary greatly. Regarding penalties for those choosing not to report to work, the survey by Ehrenstein et al. (2006) found that most healthcare professionals did not support sanctions for absenteeism. At the opposite end of the spectrum, Maryland law requires healthcare professionals to report to work in times of medical emergencies (University of Maryland Center for Health and Homeland Security, 2005). One's failure to do so may result in arrest (AHRQ, 2007). Permanent dismissal from work remains another option, as was carried out in Canada during the SARS epidemic (Rhyne, 2007). Reasons for absenteeism were not considered when determining sanctions (Rhyne, 2007). Also suggested as a form of penalty, the Center for Law and the Public's Health at Georgetown and Johns Hopkins universities (2001) discusses the possibility of making a practitioner's license dependent upon that individual assisting "in the performance of vaccination, treatment, examination, or testing of any individual" (p. 33) during a public emergency. The Public Engagement Pilot Project on Pandemic Influenza [PEPPPI] (2005) suggests obtaining "commitments from vaccinated individuals stating that they will conduct the work for which they received the immunization" (p. 21). Sanctions then may be reserved for those who break these commitments.

Letts (2006) proposes a middle-ground approach, where health professionals are neither coerced into providing care "through problematic notions of enforceable duties" (p. 133) nor are allowed to "withdraw care unchecked" (p. 133).

There are substantial difficulties in assessing whether the reasons for absenteeism are legitimate among healthcare professionals. What is a legitimate reason for not reporting to work? Family obligations? Overwhelming fear of infection? How

can the system verify the reasons provided? Will "verification officials" check on healthcare professionals and verify the excuses they provide for absenteeism? Admittedly, these are complex decisions that require care and consideration.

Control Measures. As control measures, isolation and quarantine of exposed individuals "are extreme measures that require rigorous safeguards" (Gostin, 2006, p. 1703), especially in pandemics, which are known to be socially divisive, so that they are exercised fairly and not as subterfuges for discrimination (Gostin, 2006). Researchers have proposed that individuals likely will quarantine or isolate themselves voluntarily (Engel, 2007), in which case government and employers would not need to exercise any such strategies. Forced isolation and quarantine, however, may be ineffective because most healthcare workers not only dislike mandatory control measures, but they also are more likely to fulfill their obligations during a pandemic in the absence of strict prophylactic quarantine (Tzeng, 2004). Additionally, "in our global society with rapid international travel, traditional public health measures such as quarantine and isolation may not contain many identified illnesses" (Iserson et al., in press, p. 2). Still, some maintain that quarantining healthcare workers during a pandemic will be necessary (Gruber et al., 2006). As Lo and Katz (2005) have argued, the need to protect the general public from serious illness is more important than respecting the individual's autonomy. Nonetheless, this "loss of individual liberty must be balanced by the demonstrable need for restrictive measures to protect society" (Gomersall et al., 2006, p. 1010).

This need to protect society came to the forefront in 2007 with the case of Andrew Speaker, an individual initially diagnosed with extremely resistant tuberculosis (Conant & Wingert, 2007; WHO, 2007). Few would disagree that Speaker's isolation was necessary to protect the public against the risk of possible transmission. Indeed, had the Centers for Disease Control and Prevention put the patient in isolation immediately, he would not have exposed fellow airline passengers and others to this potentially lethal illness. His forced isolation upon return to the United States prevented further possible transmission to other members of society.

Actions Regarding Other Vital Workforce. Few have commented directly on the issue of whether all or only "vital" healthcare workers should be subject to workforce management strategies, but the topic is increasingly being addressed. Berlinger and Moses (2007) state, "It is never ethically appropriate to add to the burden of the most vulnerable members of any society. If low-status workers do not receive a fair share of their society's benefits, it is not fair to tell them they have a professional or civic duty to do dangerous work" (p. 11).

Not surprisingly, then, strategies for encouraging other vital employees to report to work are somewhat similar to those directed toward healthcare professionals, including providing family support (Iserson et al., in press), providing education about the pandemic, and conducting simulation exercises (OSHA, 2007). Furthermore, emphasizing each worker's importance for pandemic response will help to

encourage the individual to report to work. Iserson et al. (in press) report that during the SARS epidemic in Toronto, many non-clinical employees failed to present to work because "they believed they were not valued or given important information" (p. 6). It is essential, then, to create an environment that offers up-to-date information and boosts morale.

The AHRQ (2005) recommends offering protection to all staff and their families (e.g., providing prophylaxis) in order to ensure the staff report to work. In contrast, Berlinger and Moses (2007) state that while providing incentives such as extra pay, child care, housing, or other similar benefits is recommended, offering vaccines to workers' families is not appropriate unless those family members belong to priority groups themselves. Because vaccine will likely be limited in supply, nonpharmaceutical methods to prevent exposure at home, such as frequent and proper hand washing and self-quarantine, should be emphasized. Providing housing to non-clinical employees, as with professional clinical staff, in order to reduce family members' potential exposure to the virus is one possibility. Cole (2007) and McGorty et al. (2007) state that all employees should be encouraged to develop a family pandemic plan in order to address any issues before a pandemic occurs, which would include stocking necessary supplies and coordinating care for family members.

In addition to financial and service benefits, experts have suggested that staff be given "opportunities for rest and recuperation" (WHO, 2005, p. 40) between waves and at the end of the pandemic in order to decrease worker burnout.

Recommendations

The discussion provided in this document lends itself to four recommendations that IUCB believes would lead to the development of ethically sound statewide policies regarding workforce management. Each recommendation is followed by its justification, as well as comments on its potential implementation. These comments were provided by expert panels convened by the IU Center for Bioethics.

<u>Recommendation 1</u>: The State Department of Health should work with healthcare organizations to identify and designate healthcare workers, both clinical and non-clinical, deemed to be critically necessary during a pandemic.

This recommendation is central to all workforce policy recommendations, and as such needs to be made centrally by the State. A common list that can be adapted by institutions for their own use will ensure that all workers know their status and what will be expected of them.

Mathematical approaches to prioritizing subgroups, such as California's Decision Analysis Scoring Tool (DAST), are transparent and reproducible and have been developed for vaccine distribution strategies. Such an approach could be expanded to apply to the identification of critical staff members. The strategy would include clearly identifying all healthcare workforce subpopulations and scoring each on various criteria that would be considered "necessary functions." Staff members ranking the

highest on all criteria deemed "necessary" would be considered critical workforce members. Please see our technical advisory document regarding vaccine and antiviral distribution for further discussion on DAST.

<u>Recommendation 2</u>: The State should set and communicate the expectation that healthcare facilities should have adequate supplies of appropriate medical equipment (as defined by the State), prophylaxis, and related materials and that these institutions should ensure that these supplies are readily available to all critical personnel expected to interact with patients. Healthcare organizations and facilities should be expected to inform the relevant county and State health officials of the extent to which they are able to meet these expectations. The routes of this communication between the State, counties, healthcare organizations and facilities, and other relevant entities must be identified clearly.

Since healthcare facility employees will be interacting with patients and thereby will be placing their own lives at risk, this recommendation recognizes that healthcare institutions have a commensurate obligation to provide as safe a work environment as possible for those workers who will be placing themselves at increased risk. Since healthcare coordination in a pandemic is a statewide responsibility, it is incumbent on the State to ensure that institutions carry out these functions. Identified critical personnel should be given priority access to scarce protective resources, such as equipment and vaccines. They must have adequate protection in order to protect the health and safety of the general public. However, the limitations and eligibility criteria need to be outlined clearly in advance. Finally, due to workers' tendency to resist isolation and quarantine control measures, these measures should be undertaken only if alternative approaches (e.g., voluntary isolation and quarantine) fail.

Expert panel members emphasized the need for modes of communication to be clearly defined. This will help to ensure that messages reach their intended targets as quickly and efficiently as possible.

<u>Recommendation 3</u>: The State of Indiana and healthcare organizations should plan an influenza response on the premise of high expectations for workplace continuity for clinical healthcare staff. Efforts should be made to provide detailed education to all healthcare workers, clinical and non-clinical, 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 non-clinical worker's vital role in the pandemic response.

Because verifying reasons for absenteeism would be practically impossible, we favor a "high expectations, no punishment" approach. By adopting a policy of high expectations, most healthcare workers will be encouraged to participate voluntarily in the response to a pandemic, thereby winning their commitment and compliance. In

addition, efforts should be made to involve all stakeholders to the extent possible at various levels of the planning process before, during, and after a pandemic. It is critically important that workers be sufficiently informed about the nature of pandemic influenza, its causes, modes of transmission, and risk. Members of a fully informed workforce are less likely to make inappropriate judgments about their personal safety. Furthermore, ensuring that each employee knows his or her importance to the pandemic response will help to boost morale and sense of obligation.

It is necessary to identify who will be educating the workforce, when the workforce will be educated, and where this education will occur. Possible actions suggested by expert panel members included making licensure dependent upon completion of pandemic influenza training or including pandemic influenza in new hire education.

Recommendation 4: The State should provide guidance to healthcare organizations and facilities in the development of fair and responsive policies for reimbursement of employees, for developing incentives for presenting to work, and for determining sanctions for noncompliance with expected responsibilities. Examples of topics these policies should address include whether some or all workers may be permitted to be absent; whether workers may use accrued leave/vacation time; and whether sanctions will be applied to workers who elect to be absent without acceptable reasons.

Most healthcare workers have demonstrated readiness to fulfill their obligations in pandemic situations if they are in agreement with the policies adopted. Listing "reasonable" and "unreasonable" justifications for missing work, as well as the practical impossibility of verifying reasons provided, causes us to favor a system that sets expectations for participation in the care of sick people high, and sanctions and other punishments low. Allowance of some absences but not others may prove to be problematic because of the difficulties involved in verifying the legitimacy of absentees' excuses. For example, it is recognized that in exceptional cases (e.g., a critical care nurse who is responsible for her own child at home), absence from work may be justifiable.

Expert panel members emphasized the need to develop incentives for employees to report to work. It was their concern that communication of high expectations would not provide sufficient motivation to take on personal risk for much of the workforce. Panel members advised that a group of specialists be convened in order to analyze the feasibility and utility of various incentives. Additionally, panel members were concerned that the sharing of employees between institutions and with alternate care sites would create reimbursement confusion. Convening a group of specialists to address this issue is recommended, and communication of findings on how to implement reimbursement strategies will be vital for the State and healthcare organizations and facilities.

By encouraging a uniform set of reimbursement and sanction policies

throughout healthcare institutions in Indiana, the State would help to ensure the fair and consistent treatment of members of the state's healthcare workforce. This will help to maintain worker morale and encourage employees to tend to their respective responsibilities. Ultimately, however, the decision of whether or not to adopt the State's recommendations will likely rest with the individual institutions.

Application to the Points to Consider

In our previous work for the Indiana State Department of Health regarding pandemic influenza planning, we developed an ethical framework entitled *Points to Consider*. This framework was designed to provide guidance for those working through specific ethical issues and as a tool for assessing the ethical basis for proposed policy. The *Points to Consider* document contains seven "points" that IUCB believed would need to be addressed in any policy development if such a policy were to be considered ethically sound and acceptable to Hoosiers.

Expert panel members were provided with the *Points to Consider* document as part of their deliberations but were not required to use it as their only guide.

We believe that the recommendations presented in this TAD are consistent with the ethical framework presented in the *Points to Consider* document.

Table 2 below summarizes the applicable points and how they are addressed.

Table 2: Points to Consider Reflected in the Proposed Protocol

Ethical Point to Consider	Applicability to Protocol
Consistency of the Mission of ISDH and Other Healthcare Professionals	The recommendation to involve healthcare professionals in the planning process will help to ensure that the protocol is supported by the various missions of the affected organizations.
Transparency	The inclusion of stakeholders in the decision making process, as well as the presence of communication mechanisms, ensures that those affected will be informed of the developing protocol.
Public Accountability	The inclusion of healthcare workers in the various levels of the policy-making process, as well as the presence of communication mechanisms, allows policymakers to address the workers promptly regarding any complications of the protocol.
Responsiveness	Healthcare professionals' input in the decision-making process, in addition to the presence of communication mechanisms that allow for the expression of dissatisfaction by the healthcare professionals, allows for the iterative evaluation and improvement of the policy.
Proportionality	As personal risk increases, healthcare workers are able to weigh their own priorities to determine whether they will report to work. They are to decide if the benefits of reporting to work outweigh the burdens of doing so.

Reciprocity	Healthcare workers, who bear a large portion of the burden of caring for the afflicted, are prioritized for protective equipment and vaccinations in order to minimize their increased risk of infection.
Uniformity of Implementation	Development of workforce management protocol at the State level, the inclusion of healthcare professionals in the development process, and open communication will help to ensure that members of the healthcare field statewide will be aware of and approve of the recommended protocol, resulting in policy compliance.

Case Study Responses

#1. Custodial staff members are needed to maintain as clean and hygienic an environment as possible to reduce further influenza transmission. Prior to a pandemic, non-clinical employees, including janitorial staff, should be informed of the vital role they will play in a pandemic response. They also should be educated on the nature of a pandemic and how to protect themselves, and they should be encouraged to develop a personal family plan for how to respond to the situation. The hospital should anticipate providing personal protective equipment. Nonetheless, if all recommendations are followed and the employee still is unable or unwilling to report to work, no sanctions or punishment are recommended. The hospital should be prepared to implement a backup strategy.

#2. The hospital has an obligation to protect its employees. Given its ability to provide adequate personal protective equipment (PPE) to only half its workforce, the hospital must identify "critically necessary" employees who will be expected to work and who will receive the PPE. All others must not be expected to report to work given the excessive risk they will face. Additionally, the hospital must inform the State, through pre-established modes of communication, of its limited supplies.

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Annotated Bibliography (AB-0G-08)

ALTERED STANDARDS OF CARE AND PANDEMIC INFLUENZA PREPAREDNESS:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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This annotated bibliography was prepared by the Indiana University Center for Bioethics under contract with the Indiana State Department of Health as a part of the project "Translating Ethics Advice into Practice: Public and Professional Outreach about Pandemic Influenza Planning in Indiana". The views expressed in this document are those of the author and may not necessarily reflect the opinions of the Center for Bioethics, Indiana University, or the Indiana State Department of Health.

With nearly 40 years passed since the last influenza pandemic, experts are warning that the next pandemic is overdue and that the H5N1 strain of avian influenza has pandemic potential. According to the World Health Organization, H5N1 "has met all prerequisites for the start of a pandemic save one: an ability to spread efficiently and sustainably among humans." As a result of this threat, international organizations, governments, health departments, institutions, and healthcare professionals throughout the world are currently preparing for a modern influenza pandemic. Such preparations require a shift in priorities and expectations in medical care delivery and setting. This includes the allocation of "scarce equipment, supplies, and personnel in a way that saves the largest number of lives in contrast to the traditional focus on saving individuals."

Several references for this document were found via the Indiana University Center for Bioethics website's pandemic resources page (*http://bioethics.iupui.edu/pandemic.asp*). Others were found through searches on the PubMed database (*http://www.ncbi.nlm.nih.gov/sites/entrez/*), the Web of Science database (*http://scientific.thomson.com/products/wos*), the World Health Organization's website (*http://www.who.int/en/*), the United States Department of Health and Human Services website (*http://www.hhs.gov/pandemicflu/plan*), the Ovid Web Gateway (*http://gateway.ovid.com*), and the Yahoo! search engine (*http://www.yahoo.com*) using the terms "pandemic influenza," "pandemic triage," "avian influenza," "triage," "pandemic altered standards," "pandemic alternate care sites," "pandemic ventilator allocation," and "pandemic law."

This document is not exhaustive of all possible resources regarding the topic of pandemic altered standards of care, but it is our hope that these resources may be of some use to those who are interested in pursuing the topic further. This document is current as of June 2, 2008

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Agency for Healthcare Research and Quality. (2005, April). ***Altered standards of care in mass casualty events - AHRQ Publication No. 05-0043*** **[Electronic version]. Retrieved April 27, 2007, from http://www.ahrq.gov/research/altstand/altstand.pdf**

The purpose of this document is to provide planners with a framework from which they can develop a protocol to change the provision of medical care in the event of a mass casualty event (MCE). It examines how current care standards may need to change and which tools are available to make these changes, and it provides recommendations to emergency planners on the most reasonable and ethical methods to address an MCE. The authors make recommendations regarding alternate care sites, adequate staffing, and documentation standards.

Agency for Healthcare Research and Quality. (2007, February). ***Providing mass medical care with scarce resources: A community planning guide - AHRQ Publication No. 07-0001*** **[Electronic version]. Retrieved March 28, 2007, from http://www.ahrq.gov/research/mce/**

The purpose of this document is to guide planners in their development of strategies to address mass casualty events. It provides examples of resources currently available to states and communities that may assist in their planning. Included is a list of relevant laws that may need to be suspended or altered during an event such as an influenza pandemic. Also included are discussions on alternate care sites, staffing considerations, and documentation standards.

Berlinger, N., & Moses, J. (2007). Five people you meet in a pandemic—and what they need from you today. ***Hastings Center Report.*** **Retrieved February 29, 2008, from http://www.thehastingscenter.org/pdf/Pandemic-Backgrounder-The-Hastings-Center.pdf**

In their article, Berlinger and Moses attempt to provide guidance to pandemic influenza planners on the use of ethical considerations in policy development. The authors briefly discuss three "ethical duties" of decision-makers. They then identify and describe five categories of first responders that will need to be considered and addressed in the decision-making process. Included in the discussion is the use of incentives to ensure vital employees report to work in order to help provide for adequate staffing.

Bogdan, G. M., Scherger, D. L., Brady, S., Keller, D., Seroka, A. M., Wruk, K. M., et al. (2004, December). ***Health emergency assistance line and triage hub (HEALTH) model - AHRQ Publication No. 05-0040*** **[Electronic version]. Retrieved April 27, 2007, from http://www.ahrq.gov/research/health/health.pdf**

Bogdan et al. developed a model protocol to address communication difficulties that occur during public health emergencies. In this document, the authors identify best practices in the medical call center industry and combine these practices into their model, which aims to use various communication methods to

provide the public with necessary information to respond to the emergency properly. The use of efficient call centers equipped with the latest technology is recommended in order to reduce the surge in demand for information from other sources that must tend to other aspects of the public health emergency (e.g., hospitals).

Cantrill, S. V., Eisert, S. L., Pons, P., & Vinci, C. E. (2004, August). ***Rocky Mountain regional care model for bioterrorist events: Locate alternate care sites during an emergency - AHRQ Publication No. 04-0075*** **[Electronic version]. Retrieved May 14, 2007, from http://www.ahrq.gov/research/altsites**
This document was developed in order to address medical surge capacity needs in the event of a bioterrorism event, but its methods also are applicable to a naturally occurring bioevent. The authors created a surge capacity model in order to anticipate medical surge capacity needs. Included in the protocol is a recommendation pertaining to maintaining adequate staffing, stating that volunteers, such as retired physicians, should be registered into a database so they may be called upon to assist in medical care provision should regular workforce numbers drop too low to maintain a minimally functioning healthcare site.

Center for Law and the Public's Health at Georgetown and Johns Hopkins universities. (2001, December). ***Model state emergency health powers act*** **[Electronic version]. Retrieved May 11, 2007, from http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf**
The purpose of this document is to provide a model for state legislation that addresses the need for State and local governments to act quickly and effectively in handling public health emergencies. It grants governors and public health authorities emergency powers to address events such as a bioterrorist attack or a pandemic event. The authors state that planners must identify sites for isolation and quarantine, medical supply and food distribution, and healthcare worker housing.

De Ville, K. (2007). Legal preparation and pandemic influenza. ***Journal of Public Health Management Practice, 13*****(3), 314-317.**
De Ville discusses legal issues that may arise in the event of a pandemic and stresses the importance of states and localities identifying and addressing such issues prior to a pandemic. He analyzes and expands on publications that discuss the topic, including those by the Centers for Disease Control and Prevention and other authors. De Ville discusses such topics as isolation and quarantine, immunization, property confiscation, and healthcare volunteer and worker temporary licensure.

Gomersall, C. D., Loo, S., Joynt, G. M., & Taylor, B. L. (2007). Pandemic preparedness. ***Current Opinion in Critical Care, 13*****(6), 742-747.**
Gomersall et al. discuss the broad topic of pandemic preparedness in terms of occupational safety, availability of staff, expansion of services, stockpiling and use of drugs and disposable supplies, and triage. The authors discuss the necessity

of ensuring staff safety, protecting staff from litigation, and providing staff additional training in the new tasks they are expected to perform.

Gostin, L. O., Sapsin, J. W., Teret, S. P., Burris, S., Mair, J. S., Hodge, J. G., et al. (2002). Model state emergency health powers act: Planning for and response to bioterrorism and naturally occurring infectious disease. ***Journal of the American Medical Association, 288*****(5), 622-628.**

Gostin et al. review the Model State Emergency Health Powers Act, which was published in 2001 by the Center for Law and the Public's Health at Georgetown and Johns Hopkins universities as a model for state legislation that addresses the need for State and local governments to act quickly and effectively in handling public health emergencies. The authors describe the act's inclusion in legislation in 34 states, as well as the adoption of some form of the act in 16 states. Also included is a discussion on property seizure and compensation, which is related to the establishment of alternate care sites. Documentation alterations and the need for cultural sensitivity also are discussed.

Illinois Department of Health. (2006, October). ***Pandemic influenza preparedness and response plan*****. Retrieved January 25, 2008, from http://www.idph.state.il.us/pandemic_flu/Illinois%20Pandemic%20Flu%20Plan%20101006%20Final.pdf**

This plan was developed by the Illinois Department of Health to provide a framework for decision-making entities, public and private, in the state of Illinois regarding pandemic influenza preparedness. The document discusses several areas of preparedness and response planning, including surveillance, antiviral and vaccine allocation, and methods to increase surge capacity. Included in this discussion are recommendations regarding alternate care site acquisition and strategies to reduce the numbers of individuals presenting to healthcare facilities, such as through the use of telephone triage.

Levin, P. J., Gebbie, E. N., & Qureshi, K. (2007). Can the health-care system meet the challenge of pandemic flu? Planning, ethical, and workforce considerations. ***Public Health Reports, 122*****(5), 573-578.**

Levin et al. discuss the impact an influenza pandemic may have on healthcare services, the necessity of effective and consistent communication, and the need to plan for ethical dilemmas (e.g., triage implementation) and workforce management issues. Regarding altered standards of care, the authors argue against the use of alternate care sites, recommending instead that the ill be treated in the home setting.

Martin, S. D. (2007). Code flu: Common sense steps to the development of an agency pandemic flu plan for home care. ***Home Healthcare Nurse, 25*****(9), 595-601.**

The author discusses the importance for healthcare providers to develop a "code flu," which would be implemented in the event of an influenza pandemic. Included in such a plan would be the development of a communication strategy and identification of decision-makers. In addition, it is recommended that

employees develop individual plans for managing the emergency. Other parts of the strategy include assigning a nurse to handle calls regarding influenza and establishing a list of volunteers to help manage influenza patients.

Minnesota Department of Health. (2006). ***Technical section G: Antivirals and Vaccines - Minnesota Department of Health Pandemic Influenza Plan (Draft)*****. Retrieved January 24, 2008, from http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/7antivirals.pdf**

This document is a supplement to the Minnesota Department of Health's pandemic influenza planning document. Its primary purpose is to describe the state's antiviral and vaccine distribution strategy. It also includes a description of state legislation that allows a nurse to delegate responsibilities to other nursing personnel, which could acted upon in the event of a pandemic.

New York State Workgroup on Ventilator Allocation in an Influenza Pandemic. (2007, March 15). ***Allocation of ventilators in an influenza pandemic: Planning document.*** **Retrieved March 17, 2007, from http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventilator_guidance.pdf**

The New York State Workgroup has developed a comprehensive plan to address the issue of triage management, specifically ventilator allocation. This protocol attempts to provide the most ethically sound method of triage possible and uses only physiological data assessed as a SOFA score in determining ventilator access, thereby eliminating subjective "quality of life" and "social role" decision-making criteria, as well as rejecting the use of age as an exclusionary criterion. In addition to the primary discussion on ventilator triage, the workgroup discusses the potential need to alter individual healthcare workers' responsibilities in times of staffing shortages and states that this alteration of duties should be as simplified as possible.

Occupational Safety and Health Administration. (2007). ***Pandemic influenza preparedness and response for healthcare workers and healthcare employers*****. Retrieved January 25, 2008, from http://www.osha.gov/Publications/OSHA_pandemic_health.pdf**

This OSHA publication is intended to be a guidance document that discusses clinical background information on influenza, infection control, pandemic influenza preparedness, and OSHA standards that will apply to workforce management issues in an influenza pandemic. Included in this discussion is the use of alternate care sites and policies to ensure adequate staffing, such as using effective risk communication and undertaking strategies to support employee safety.

Ontario Health Plan for an Influenza Pandemic. **(2006, September). [Electronic version]. Retrieved March 28, 2007, from**

http://www.health.gov.on.ca/english/providers/program/emu/pan_flu/ohpip2/plan_full.pdf
This document is intended to be the guiding plan for health and response efforts for the Canadian province of Ontario in the event of an influenza pandemic. It includes information on necessary public health measures that must be taken, as well as a detailed plan on how to maximize communication efforts. It provides an in-depth discussion on the identification and use of alternate care sites, stating that partnership in obtaining such sites is preferable over coercion and that alternate sites should be provided insurance. It also discusses the need to compensate healthcare workers for the disproportionate burden they may endure.

Public Health Agency of Canada. (2006). *Canadian pandemic influenza plan for the private sector*. Retrieved January 25, 2008, from http://www.phac-aspc.gc.ca/cpip-pclcpi/pdf-e/CPIP-2006_e.pdf
This document contains detailed strategies and recommendations for the private health sector of Canada. It addresses topics such as vaccine and antiviral prioritization, infection control, resource and workforce management, and management of mass casualties during a pandemic. Discussion on use of alternate care sites and staffing methods is included.

Qureshi, K., Gershon, R. R. M., Sherman, M. F., Straub, T., Gebbie, E., McCollum, M., et al. (2005). Health care workers' ability and willingness to report to duty during catastrophic disasters. *Journal of Urban Health: Bulletin of the New York Academy of Medicine, 82*(3), 378-388.
Qureshi et al. conducted a survey of 6,428 healthcare workers from the New York City area to determine how these workers would respond to various emergencies that would require mass care. The researchers discovered that workers would report to work in lower numbers during a biological event such as SARS or smallpox than in environmental disasters or mass casualty incidents. Through this survey, Qureshi et al. were able to identify several potential barriers to healthcare worker attendance. By doing so, they were able to suggest potential methods for overcoming these barriers in order to help ensure adequate staffing in an influenza pandemic.

Rubinson, L., Nuzzo, J. B., Talmor, D. S., O'Toole, T., Kramer, B. R., Inglesby, T. V., et al. (2005). Augmentation of hospital critical care capacity after bioterrorist attacks or epidemics: Recommendations of the working group on emergency mass critical care [Electronic version]. *Critical Care Medicine, 33*(10). Retrieved from Ovid Web Gateway on March 27, 2007.
The authors of this document address possible mass critical care alterations that should be made in the event of a bioterrorist attack but also write that such alterations also may apply to naturally occurring biological events such as a pandemic. In the document, Rubinson et al. discuss triage implementation, alternate care sites, the need for altered workforce responsibilities, and possible legislative actions to protect healthcare workers and facilities from litigation. They provide examples of how to redistribute healthcare worker responsibilities.

They propose the need for identification and registration of volunteers, such as retired physicians and veterinarians, whose names can be stored in a database for rapid accessibility.

Tzeng, H. M. (2004). Nurses' professional care obligation and their attitudes towards SARS infection control measures in Taiwan during and after the 2003 epidemic. ***Nursing Ethics, 11*****(3), 277-289.**
Tzeng conducted a study to determine statistically significant predictors of nurses' willingness to provide care during the SARS epidemic. The researcher found that nurses were more likely to provide care if they were in agreement with infection control measures and they were not subjected to quarantine. This information may be applicable to the development of pandemic influenza response protocols regarding how to maintain adequate staffing during an influenza pandemic.

United States Department of Health and Human Services. (2007a). ***Pandemic influenza plan, part 2: Public health guidance for state and local partners*****. Retrieved May 15, 2007, from http://www.hhs.gov/pandemicflu/plan/pdf/part2.pdf**
This document aims to assist states and localities in pandemic preparedness planning and assist in the collaboration between states and localities and private healthcare institutions. It outlines state and local responsibilities, describes the ideal planning process, identifies legal preparedness as a priority, and discusses community planning. It also includes checklists that may help to guide emergency preparedness planners. Furthermore, the authors identify the need to consider the use of alternate care sites and alternative staffing procedures.

United States Department of Health and Human Services. (2007b). ***Pandemic influenza plan: Supplement 3*****. Retrieved May 15, 2007, from http://www.hhs.gov/pandemicflu/plan/sup3.html**
This HHS document is a guide for influenza pandemic response plans. Its primary focus is the development of plans during the interpandemic period. Such plans address communication methods, vaccine and antiviral allocation, and surge capacity, among many other issues. Pertaining to altered standards of care, the document includes lists of steps planners should take in order to identify and utilize alternate care sites, as well as steps to take in order to address emergency staffing needs.

World Health Organization. (2006). ***Avian influenza ("bird flu") - Fact sheet*****. Retrieved June 5, 2007, from http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html**
This WHO document provides an overview of avian influenza, including discussion on its presence in birds and its history of human infection. It also provides a discussion on human epidemiology and symptoms. Finally, it identifies the nations currently affected by H5N1 infections. This document describes the potential of H5N1 to become the next influenza pandemic.

Annotated Bibliography (AB-0H-08)

TRIAGE AND PANDEMIC INFLUENZA:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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This annotated bibliography was prepared by the Indiana University Center for Bioethics under contract with the Indiana State Department of Health as a part of the project "Translating Ethics Advice into Practice: Public and Professional Outreach about Pandemic Influenza Planning in Indiana". The views expressed in this document are those of the author and may not necessarily reflect the opinions of the Center for Bioethics, Indiana University, or the Indiana State Department of Health.

The World Health Organization reports that 383 human cases of avian influenza H5N1 have been confirmed, and 241 of these cases have been fatal. With experts warning that an influenza pandemic is overdue and that H5N1 has pandemic potential, governments, health departments, healthcare professionals, and many others have been working to develop response plans for such a crisis. Those plans must include ethical strategies for allocating resources that become insufficient to support the demand, because "shortages of specialized staff, medical equipment, and supplies could limit the number of patients who can receive the appropriate supportive critical care interventions." Such resource allocation strategies may be referred to as "triage" of scarce resources because they necessarily involve a prioritization of which patients will receive care when not all can. Consistent, ethically defensible methods for allocating scarce resources require careful planning and deliberation. Several references for this document were found via the Indiana University Center for Bioethics website's pandemic resources page (*http://bioethics.iupui.edu/pandemic.asp*). Others were found through searches on the PubMed database (*http://www.ncbi.nlm.nih.gov/sites/entrez/*), the Web of Science database (*http://scientific.thomson.com/products/wos*), the Yahoo! search engine (*http://www.yahoo.com*), and the World Health Organization's website (*http://www.who.int/en/*) using the terms "pandemic influenza," "pandemic triage," "avian influenza," "triage," "pandemic ventilator allocation," and "SOFA." Finally, the Clarian document and the Indiana Pandemic Influenza Community Advisory Groups document were obtained from each group directly.

This document is not exhaustive of all possible resources regarding the topic of pandemic influenza triage, but it is our hope that these resources may be of some use to those who are interested in pursuing the topic further. This document is current as of June 2, 2008

References

Agency for Healthcare Research and Quality. (2007, February). *Providing mass medical care with scarce resources: A community planning guide - Publication No. 07-0001.* [Electronic version]. Retrieved March 28, 2007, from http://www.ahrq.gov/research/mce/

The purpose of this document is to guide planners in their development of strategies to address mass casualty events. It provides examples of resources currently available to states and communities that may assist in their planning. The authors discuss ethical considerations of triage, rejecting the use of gender, race, financial status, and social role. Age also is only to be considered as it relates to physiological diagnosis.

Arts, D. G. T., de Keizer, N. F., Vroom, M. B., & de Jonge, E. (2005). Reliability and accuracy of sequential organ failure assessment (SOFA) scoring. *Critical Care Medicine, 33*(9), 1988-1993.

The authors of this document performed a study in order to evaluate the accuracy of SOFA scoring. Their findings supported the scoring method's reliability. The statistics and conclusions provided in this document support the New York State Workgroup's recommendation to use SOFA scores as the primary inclusion and exclusion criterion.

Berlinger, N., & Moses, J. (2007). Five people you meet in a pandemic—and what they need from you today. *Hastings Center Report.* Retrieved February 29, 2008, from http://www.thehastingscenter.org/pdf/Pandemic-Backgrounder-The-Hastings-Center.pdf

In their article, Berlinger and Moses attempt to provide guidance to pandemic influenza planners in the use of ethical considerations in policy development. The authors briefly discuss three "ethical duties" of decision-makers. They then go on to identify and describe five categories of first responders that will need to be considered and addressed in the decision-making process. One of these five categories is the "triage officer," and the authors put forth questions decision-makers should address when developing a triage protocol.

Burkle, F. M. (2006). Population-based triage management in response to surge-capacity requirements during a large-scale bioevent disaster. *Academic Emergency Medicine, 13*(11), 1118-1129.

Burkle discusses the strategy of implementing population-based triage in the event of a biological crisis. Using the SEIRV methodology, he describes two phases of population-based triage. Phase 1 involves generic strategies that are applied to the entire population, such as social distancing. Phase 2 involves person-specific strategies, such as denial of rigorous medical care due to an unlikelihood of survival. In this document, Burkle includes a discussion on the use of call centers as primary triage points. He also discusses the need for psychological care for all those who are affected by the event, including healthcare providers and the afflicted.

Centers for Disease Control and Prevention, Ethics Subcommittee of the Advisory Committee to the Director. (2007, February 15). ***Ethical guidelines in pandemic influenza*****. Retrieved March 15, 2007, from http://www.cdc.gov/od/science/phec/panFlu_Ethic_Guidelines.pdf**

This document provides guidance in ethical decision-making related to vaccine and antiviral medication distribution (pharmaceutical interventions) and to social distancing and limiting individual freedom (non-pharmaceutical interventions). It discusses general ethical considerations, such as public involvement and transparency, as well as recommendations for the allocation of scarce resources during a pandemic. It also allows for the use of age and social role as inclusion and exclusion criteria.

Challen, K., Bright, J., Bentley, A., & Walter, D. (2007). Physiological-social score (PMEWS) vs. CURB-65 to triage pandemic influenza: A comparative validation study using community-acquired pneumonia as a proxy [Electronic version]. ***BMC Health Services Research, 7*****(33). Retrieved March 28, 2007, from the Biomed Central database, http://www.biomedcentral.com**

The authors of this document developed the Pandemic Medical Early Warning Score (PMEWS) as a method of triaging patients. PMEWS was found to be readily applicable for the triage of large numbers of patients, but it was not found to be an accurate predictor of inpatient mortality. The authors of this study included social role and age in their triage scoring method.

Christian, M. D., Hawryluck, L., Wax, R. S., Cook, T., Lazar, N. M., Herridge, M. S., et al. (2006). Development of a triage protocol for critical care during an influenza pandemic. ***Canadian Medical Association Journal, 175*****(11), 1377-1381.**

This document presents a triage protocol that was developed by the authors through stakeholder and expert involvement, evaluation of best methods, and the use of general ethical principles. Their protocol includes the use of the sequential organ failure assessment (SOFA) method and applies it to all incoming patients, not only influenza patients. It does not include age as an exclusion criterion, but the authors write that they had consistent feedback that indicated age should be considered in triage.

Clarian Ethics Policy Review Committee Working Group on Ethics in Pandemic Flu. (2006). ***Pandemic influenza triage principles*****. Unpublished policy draft.**

This policy draft addressing triage was developed by an interdisciplinary team, with contributions from Clarian Health Partners experts and individuals from Indiana University-Purdue University Indianapolis. The group's goals were to develop methods that would maximize healthful life and contribute to ethically sound triage decisions in times of extreme scarcity. The group's recommendations included the use of allocation based on priority groups and medical factors, as well as including a "first come, first served" prioritization. This document allows for the use of age and social role as exclusionary criteria.

Gomersall, C. D., Tai, D. Y. H., Loo, S., Derrick, J. L., Goh, M. S., Buckley, T. A., et al. (2006). Expanding ICU facilities in an epidemic: recommendations based on experience from the SARS epidemic in Hong Kong and Singapore. *Intensive Care Medicine, 32,* 1004-1013.

The authors of this document present the recommendations of expert groups who expanded intensive care services in response to outbreaks of severe acute respiratory syndrome in Hong Kong and Singapore. These recommendations address estimating bed requirements, infection control, staffing, counseling and stress reduction, communication, and other ethical issues. In regards to triage, the authors recommend that any groups selected for prioritization be identified clearly in advance and that the decision to prioritize a group should be transparent and justifiable.

Hick, J. L., & O'Laughlin, D. T. (2006). Concept of operations for triage of mechanical ventilation in an epidemic. *Academic Emergency Medicine, 13*(2), 223-229.

Hick and O'Laughlin's report provides a three-tiered approach to the triage of mechanical ventilation in the event of a pandemic situation that causes a scarcity of resources. With each successive tier, inclusion criteria become more stringent. The authors write that a patient may be removed from ventilation if a new patient arrives with a better prognosis. Age is suggested as a possible exclusionary criterion only in the third and most stringent tier.

Hick, J. L., Rubinson, L., O'Laughlin, D. T., & Farmer, J. C. (2007). Clinical review: Allocating ventilators during large-scale disasters—problems, planning, and process [Electronic version]. *Critical Care, 11*(3). Retrieved January 25, 2008, from http://ccforum.com/content/11/3/217

Hick et al. discuss the potential need for the use of a triage protocol during an influenza pandemic. The authors describe several aspects of triage planning, including ethical and operational goals, allocation decision-making, and triage algorithms and support tools. They encourage critical care physicians to take part in the triage planning process, as well as to validate and/or develop triage algorithms.

Indiana Pandemic Influenza Community Advisory Groups. (2006, November 15). *Report to the state health commissioner on the findings and recommendations of the pandemic influenza community advisory groups*.

This report outlines the pandemic influenza response recommendations provided to the State of Indiana by four separate community advisory groups: the Community Advisory Group on the Role of Antiviral Medications in Pandemic Influenza; the Community Advisory Group on Community Containment Measures: Isolation, Quarantine and Social Distancing; the Community Advisory Group on Altered Standards of Care; and the Community Advisory Group on Mental Health Issues. It provides each group's justifications for its recommendations. Included in discussion of the Community Advisory Group on

Mental Health Issues is the group's support for the use of the Psychological First Aid Model used by the Center for Excellence in Disaster Management and Humanitarian Assistance in order to assist individuals suffering from psychological and emotional distress during the crisis.

Letts, J. (2006). Ethical challenges in planning for an influenza pandemic. ***NSW Health, 17*****(9-10), 131-134.**

Letts provides a concise ethical framework on which pandemic planning should be based, including the concepts of transparency, consistency, flexibility, responsiveness, and proportionality. The author then briefly discusses the topics of isolation, quarantine, and social distancing measures; prioritization of antiviral medications; access to intensive care; healthcare professional duty to care; and altered standards of care. In regards to triage, Letts describes aspects of the triage decision-making process that must be made in advance, including to whom triage should be applied, denial or removal of ICU support, and the use of social worth criteria.

Levin, P. J., Gebbie, E. N., & Qureshi, K. (2007). Can the health-care system meet the challenge of pandemic flu? Planning, ethical, and workforce considerations. ***Public Health Reports, 122*****(5), 573-578.**

Levin et al. discuss the impact an influenza pandemic may have on healthcare services, the necessity of effective and consistent communication, and the need to plan for ethical dilemmas (e.g., triage implementation) and workforce management issues. The authors note the importance of preparing the public for the possibility of needing to use triage criteria. They also stress the need to plan for the crisis and develop protocol now in order to have it available to healthcare providers when the need arises.

McGorty, E. K., Devlin, L., Tong, R., Harrison, N., Holmes, M., & Silberman, P. (2007). Ethical guidelines for an influenza pandemic. ***North Carolina Medical Journal, 68*****(1), 38-42.**

McGorty et al. discuss the ethical guidelines and recommendations for an influenza pandemic that were developed by a task force convened by the North Carolina Institute of Medicine to assist the North Carolina Department of Health and Human Services, Division of Public Health. The task force addressed healthcare workforce management, limitations on civil liberties, and altered standards of care, including triage. The authors state that the task force recommended that "disease control and medical decisions be based on clinical factors, the epidemiology of the spread of the disease, and assuring the functioning of society."

Melnychuk, R. M., & Kenny, N. P. (2006). Pandemic triage: The ethical challenge. ***Canadian Medical Association Journal, 175*****(11), 1393-1394.**

Melnychuk and Kenny provide a commentary on the triage recommendations put forth by Christian et al. (2006) and the Pandemic Working Group at the University of Toronto's Joint Centre for Bioethics (2005). The authors argue that

such publications that attempt to address ethical approaches to triage must elaborate on the underlying ethical principles that lead to their conclusions. The authors regard the concepts of equity of outcomes and fairness as vital in triage implementation, such as the provision of palliative care and pain management to those individuals who are denied other intensive care treatment.

New York State Workgroup on Ventilator Allocation in an Influenza Pandemic. (2007, March 15). ***Allocation of ventilators in an influenza pandemic: planning document.*** **Retrieved March 17, 2007, from http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventilator_guidance.pdf**

The New York State Workgroup has developed a comprehensive plan to address the issue of triage management, specifically ventilator allocation. This protocol attempts to provide the most ethically sound method of triage possible and uses only physiological data assessed as a SOFA score in determining ventilator access, thereby eliminating subjective "quality of life" and "social role" decision-making criteria, as well as rejecting the use of age as an exclusionary criterion. This document is proposed to be the guiding document for the Indiana State Department of Health's pandemic influenza triage plan.

Ontario Health Plan for an Influenza Pandemic. **(2006, September). [Electronic version]. Retrieved March 28, 2007, from http://www.health.gov.on.ca/english/providers/program/emu/pan_flu/ohpip2/plan_full.pdf**

This document is intended to be the guiding plan for health and response efforts for the Canadian province of Ontario in the event of an influenza pandemic. It includes information on necessary public health measures that must be taken, as well as a detailed plan on how to maximize communication efforts. OHPIP also provides a thorough protocol for the implementation of triage. The physiological assessment is based on the SOFA scoring method, which also is proposed to be the assessment method of healthcare facilities in the State of Indiana.

Rubinson, L., Nuzzo, J. B., Talmor, D. S., O'Toole, T., Kramer, B. R., Inglesby, T. V., et al. (2005). Augmentation of hospital critical care capacity after bioterrorist attacks or epidemics: Recommendations of the working group on emergency mass critical care [Electronic Version]. ***Critical Care Medicine, 33*****(10). Retrieved from Ovid Web Gateway on March 27, 2007.**

The authors of this document address possible mass critical care alterations that should be made in the event of a bioterrorist attack but also write that such alterations may apply to naturally occurring biological events, such as a pandemic. In the document, Rubinson et al. discuss triage implementation, the need for altered workforce responsibilities, and possible legislative actions to protect healthcare workers and facilities from litigation. In this protocol, triage decisions are based on the objective of maximizing the number of lives saved.

Talmor, D., Jones, A. E., Rubinson, L., Howell, M. D., & Shapiro, N. I. (2007). Simple triage scoring system predicting death and the need for critical care resources for use during epidemics. *Critical Care Medicine, 35*(5), 1251-1256.
Talmor et al. performed a retrospective cohort study to determine independent predictors of death in patients presenting to emergency departments with infection. The researchers then validated their findings internally in the medical center where the predictors were determined and externally in another facility. They found that respiratory rate, shock index, oxygen saturation levels, mental status, and age all were predictors of mortality in the patients studied. Talmor et al. concluded that the triage assessment tool they developed may serve as an initial guide for the triage process.

Utah Hospitals and Health Systems Administration. (2007, December 7). *Utah pandemic influenza hospital and ICU triage guidelines (Draft)*. Retrieved February 28, 2008, from http://www.pandemicflu.utah.gov/plan/med_triage120707.pdf
The Utah Hospitals and Health Systems Administration Triage Guidelines Workgroup developed guidelines intended to direct healthcare providers in the allocation of scarce medical resources when demand greatly exceeds supply. The workgroup developed an algorithm that describes inclusion and exclusion criteria in detail, utilizing scoring tools such as a modified version of SOFA, the Revised Trauma Score, the Glasgow Coma Score, assessment of burn victim burn size, and others. The workgroup also included consideration of age and certain social criteria (e.g., homelessness) in the protocol.

World Health Organization. (2008, May 28). Cumulative number of confirmed human cases of avian influenza A/(H5N1) reported to WHO. Retrieved June 2, 2008, from http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_05_28/en/index.html
This website is maintained by the World Health Organization and reports the most current numbers relating to cases of H5N1 around the world. It currently lists 15 countries as having reported cases, 12 of which also have reported deaths.

Annotated Bibliography (AB-0I-08)

VACCINES, ANTIVIRALS, AND PANDEMIC INFLUENZA PREPAREDNESS:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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This annotated bibliography was prepared by the Indiana University Center for Bioethics under contract with the Indiana State Department of Health as a part of the project "Translating Ethics Advice into Practice: Public and Professional Outreach about Pandemic Influenza Planning in Indiana". The views expressed in this document are those of the author and may not necessarily reflect the opinions of the Center for Bioethics, Indiana University, or the Indiana State Department of Health.

The pandemic potential of the H5N1 strain of avian influenza has created the necessity for comprehensive planning of resources and procedures. Although H5N1 has not yet acquired efficient transmission between humans, evidence suggests that soon this may be possible, causing widespread transmission. Experts have projected that this strain of avian influenza has the potential to be comparable to the 1918 pandemic, causing approximately 180 to 360 million deaths globally, with 1.7 million deaths possible in the United States alone. As a result, the Centers for Disease Control and Prevention (CDC), the U. S. Department of Health and Human Services (HHS), and other governmental agencies have established pandemic preparedness as a top priority. Included in those plans must be strategies for allocating vaccine and antiviral resources, which will become insufficient to support the demand. A consistent, equitable, and well-developed method for the prioritization of target groups for vaccination and antiviral therapy requires detailed consideration.

Several references for this document were found via the Indiana University Center for Bioethics website's pandemic resources page (*http://bioethics.iupui.edu/pandemic.asp*). Others were found through searches on the PubMed database (*http://www.ncbi.nlm.nih.gov/sites/entrez/*), the World Health Organization's website (*http://www.who.int/en/*), the United States Department of Health and Human Services website (*http://www.hhs.gov/pandemicflu/plan*), the Centers for Disease Control and Prevention website (*http://www.cdc.gov*), and the Yahoo! search engine using the terms "pandemic influenza," "pandemic triage," "avian influenza," "pandemic vaccine allocation," "pandemic law," and "state influenza plans."

This document is not exhaustive of all possible resources regarding the topic of pandemic influenza vaccine and antiviral medication allocation, but it is our hope that these resources may be of some use to those who are interested in pursuing the topic further. This document is current as of June 2, 2008.

References

Arizona Department of Health Services. (2006). ***Arizona influenza pandemic response plan, supplement 7: Antiviral drug distribution and use*****. Retrieved February 7, 2008, from http://www.azdhs.gov/pandemicflu/pdf/supp_7_antiviral_distribution_and_use.pdf**

This supplement to the state of Arizona's pandemic influenza response plan includes a discussion on the potential uses of antiviral medications in an influenza pandemic, such as for prophylaxis or treatment. It also describes the strategies that the state plans for antiviral allocation throughout the various phases of the pandemic. The state's antiviral prioritization list was adopted from the plan of the U.S. Department of Health and Human Services in its entirety.

Barnett, D. J., Balicer, R. D., Lucey, D. R., Everly, G. S., Jr., Omer, S. B., Steinhoff, M. C., et al. (2005, December). A systematic analytic approach to pandemic influenza preparedness planning [Electronic version]. ***PLoS Medicine, 2*****(12), 1235-1241. Retrieved May 15, 2007, from http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0020359**

This document provides an overview of the pathology and pandemic potential of H5N1. In addition, it discusses human, agent, environmental, and sociocultural factors that may influence the spread of the disease. The authors identify a need for phase-specific planning for the time prior to the pandemic, during the pandemic, and after the pandemic.

California Department of Health Services. (2006a, September 8). ***Pandemic influenza preparedness and response plan*****. Retrieved May 16, 2007, from http://www.dhs.ca.gov/ps/dcdc/izgroup/pdf/pandemic.pdf**

CDHS has prepared a pandemic influenza response plan that outlines how it will coordinate the pandemic preparedness, response, and recovery efforts with various federal, county, local, and private partners. The authors discuss relevant legal references, in addition to surveillance and epidemiology, healthcare planning and infection control, risk communication, community disease control and prevention, and vaccine and antiviral allocation, among other topics. In reference to vaccine and antiviral allocation, CDHS has identified the minimization of morbidity and mortality as the primary priority to be addressed, with the minimization of societal and economic disruption following as priorities.

California Department of Health Services. (2006b, January 18). ***Pandemic influenza preparedness and response plan, Appendix 6: Pandemic influenza vaccine program*****. Retrieved May 16, 2007, from: http://www.idready.org/pandemic_influenza/CDHS_plan_appendix6A.pdf**

This CDHS document provides an in-depth discussion on the department's decision-making process regarding how to prioritize groups for vaccine allocation. Ultimately CDHS opted to use the Decision Analysis Scoring Tool (DAST),

which analyzes multiple goals and criteria in the prioritization process. The tool was used based on the primary priority of minimizing morbidity and mortality under the assumption that societal and economic consequences will then be lessened indirectly. This is the prioritization method that is recommended for the Indiana State Department of Health.

California Department of Health Services. (2006c). ***Vaccine prioritization plan supplemental document B: Target population group profiles*****. Retrieved May 16, 2007, from: http://www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_B.pdf**

This document describes the 69 target population groups that CDHS ranked in terms of vaccine prioritization. This includes subgroups of five general categories: individuals with specific health-related characteristics; individuals with professions in certain health industries; individuals with roles in public administration, safety, and justice; individuals with professions in non-health commercial industries; and other healthy populations. These target groups and their subgroups are prioritized in other CDHS documents (see, for example, CDHS, 2006d).

California Department of Health Services. (2006d). ***Vaccine prioritization plan supplemental document E: Analysis of DAST survey results*****. Retrieved June 13, 2007, from http://idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_E.pdf**

This supplemental document provides the Decision Analysis Scoring Tool survey results for the CDHS plan. It presents the vaccine prioritization rankings for each of the 69 previously identified target groups. At the top of the list are healthcare professionals who have a high risk of both contracting and transmitting the virus. At the bottom of the prioritization list are healthy children and adults. These rankings are based on the minimization of morbidity and mortality being the top priority of vaccine allocation.

Centers for Disease Control and Prevention, Ethics Subcommittee of the Advisory Committee to the Director. (2007, February 15). ***Ethical guidelines in pandemic influenza*****. Retrieved March 15, 2007, from http://www.cdc.gov/od/science/phec/panFlu_Ethic_Guidelines.pdf**

This document provides guidance in ethical decision-making related to vaccine and antiviral medication distribution (pharmaceutical interventions) and to social distancing and limiting individual freedom (non-pharmaceutical interventions). It discusses general ethical considerations, such as public involvement and transparency, as well as recommendations for the allocation of scarce resources during a pandemic. It identifies the need to maintain a functioning society as the primary priority to be addressed regarding vaccine and antiviral allocation.

Emanuel, E. J., & Wertheimer, A. (2006). Who should get influenza vaccine when not all can? ***Science, 312*****(5775), 854-855.**

Emanuel and Wertheimer discuss the inevitable need to ration vaccine in the event of an influenza pandemic. The authors disagree with the strategies of using vaccine to maximize lives saved and decrease societal and economic impacts. Instead, the authors argue that immunization strategies should follow the "life-cycle principle," which aims to maximize individual's life spans and their abilities to reach life goals. Such a strategy favors those from adolescence to middle age.

Engel, J. P. (2007). Pandemic influenza: The critical issues and North Carolina's preparedness plan. ***North Carolina Medical Journal, 68*****(1), 32-37.**

Engel provides an overview of the possibility of the occurrence of an influenza pandemic, discussing the zoonotic origins of such a pandemic, as well as the likelihood of H5N1 to fulfill all the prerequisites to becoming a pandemic virus. The author then summarizes the tasks the state of North Carolina has already undertaken in pandemic preparedness planning and various interventions that likely will be used. A brief overview of the state's plan for vaccine allocation is given, which identifies four subtiers of the population who would get the vaccine first, including healthcare workers, persons with comorbidities, pregnant women, and key government leaders.

Florida Department of Health. (2004, March). ***Action plan for pandemic influenza.*** **Retrieved May 17, 2007, from: http://www.doh.state.fl.us/disease%5Fctrl/epi/htopics/flu/Pandemicdraft8.pdf**

The Florida DOH has prepared this document to assist in pandemic emergency planning and response at all levels of government. Among other issues, it discusses surveillance, communication, and antiviral allocation. Its prioritization for immunizations and antiviral medication is based on the main priority being the minimization of morbidity and mortality, with the minimization of societal and infrastructure disruption ranked as the second priority. The Florida guide lines rank healthcare workers, those responsible for law enforcement, and those with specialized skills essential for utility services all as having priority over those at high risk for illness and mortality.

Florida Department of Health. (2006, October). ***State of Florida emergency operations plan, pandemic influenza annex, appendix 11: Vaccine and antiviral medication distribution and use*****. Retrieved February 8, 2008, from http://www.doh.state.fl.us/rw_Bulletins/flpanfluv104final.pdf**

The Florida DOH includes a discussion on the use of vaccines and antiviral medications in this appendix to its pandemic influenza plan. In the document is an overview of strategies to obtain, store, protect, and distribute the vaccines and antivirals. Additionally, the document includes prioritization lists for vaccines and antivirals. The antiviral prioritization list was adopted from the U. S. Department of Health and Human Services plan in its entirety.

Gani, R., Hughes, H., Fleming, D., Griffin, T., Medlock, J., & Leach, S. (2005) Potential impact of antiviral drug use during influenza pandemic. *Emerging Infectious Diseases, 11*(9), 1355-1362.

Gani et al. conducted a study using statistical methods to assess various antiviral allocation strategies. These included treating all patients, treating only the working population, and treating the elderly and children. The authors conclude that the most effective strategy would be to treat those at highest risk for hospitalization, but they also emphasize the need to take into account new epidemiological data regarding the pandemic in order to ensure that the most effective strategy can be developed and undertaken.

Gostin, L. O. (2006a). Medical countermeasures for pandemic influenza: Ethics and the law. *Journal of the American Medical Association, 295*(5), 554-556.

Gostin discusses the inevitable shortage of vaccines and antiviral medications that will occur during an influenza pandemic. He discusses various issues that can be taken into consideration in order to determine prioritization for medical countermeasure allocation. These include virus transmission, scientific and social functioning, medical need and vulnerability, and equitable access and social justice. Gostin identifies the maximization of lives saved and the preservation of societal functioning as priorities.

Gostin, L. O. (2006b). Public health strategies for pandemic influenza: Ethics and the law. *Journal of the American Medical Association, 285*(14), 1700-1704.

Gostin suggests a multidimensional approach to addressing the problems that may arise with a pandemic influenza event. This approach includes surveillance, community hygiene, hospital infection control, social distancing, travel and border controls, and isolation and quarantine. Regarding vaccines and antiviral agents, Gostin identifies the public benefits from the use of such medical countermeasures, as well as the private interests and rights that would be affected by them.

Gostin, L. O., & Berkman, B. E. (2007). Pandemic influenza: Ethics, law, and the public's health. *Administrative Law Review, 59*(1), 121-176.

Gostin and Berkman discuss in detail the allocation of scarce vaccines and antiviral medications, as well as potential ethical and human rights concerns that may occur during an influenza pandemic. In addition, the authors identify and address various legal considerations that are applicable to each of these areas of discussion. They argue for thoughtful reflection on not only scientific responses but also on ethical responses. In terms of vaccine and antiviral allocation, the authors identify eight rationing criteria they believe should be considered.

Homeland Security Council. (2006, May). *Implementation plan for the national strategy for pandemic influenza*. Retrieved February 8, 2008, from http://www.whitehouse.gov/homeland/nspi_implementation.pdf

This document discusses federal planning strategies for pandemic influenza, as well as international and border control efforts to limit and slow spread of infection. Additionally, the document includes chapters addressing the protection of human health, the protection of animal health, and ensuring public safety. It also

provides guidance to state, local, and nongovernmental agencies in their planning activities. In regards to prioritization for antiviral medications, the document states that it is unlikely for antivirals to be used for any purposes other than for treatment due to limited supply.

Illinois Department of Health. (2006, October). ***Pandemic influenza preparedness and response plan*****. Retrieved January 25, 2008, from http://www.idph.state.il.us/pandemic_flu/Illinois%20Pandemic%20Flu%20Plan%20101006%20Final.pdf**

This plan was developed to provide a framework for decision-making entities, public and private, in the state of Illinois regarding pandemic influenza preparedness. The document discusses several areas of preparedness and response planning, including surveillance, antiviral and vaccine allocation, and methods to increase surge capacity. In reference to vaccine and antiviral prioritization, the state adopts the lists presented by the U. S. Department of Health and Human Services in 2006 in their entirety.

Indiana State Department of Health Pandemic Influenza Community Advisory Groups. (2006, November). ***Report to the State Health Commissioner on the findings and recommendations of the pandemic influenza community advisory groups.***

This report was developed at the request of the Indiana State Commissioner of Health to address four issues that would arise in an influenza pandemic. These are: (a) the role of antiviral medication, (b) community containment, (c) altered standards of care, and (d) mental health issues. The community advisory group (CAG) specific to antiviral medication allocation decisions identifies, in no particular order, seven subpopulations that would be prioritized for antiviral medication. All are prioritized for treatment, not prophylaxis. The CAG also identifies four more subpopulations that may be prioritized if the antiviral stockpile were to increase.

Lipsitch, M., Cohen, T., Murray, M., & Levin, B. R. (2007). Antiviral resistance and the control of pandemic influenza. ***PLoS Medicine, 4*****(1), 111-121.**

Lipsitch et al. use mathematical modeling to estimate the impact of various antiviral allocation strategies on the population. Included are projections regarding the number of individuals susceptible to the virus if only treatment were provided, if only prophylaxis were provided, if both were provided, and if neither were provided. The authors also project the number susceptible to an antiviral-resistant strain of virus for each scenario. They conclude that widespread use of antivirals could lead to a large number of resistant cases. The authors state, however, that they "do not believe that concerns about resistance should preclude the widespread deployment of antivirals as part of the response to a pandemic" (p. 119).

Longini, I. M., Halloran, M. E., Nizam, A., & Yang, Y. (2004). Containing pandemic influenza with antiviral agents. ***American Journal of Epidemiology, 159*****(7), 623-533.**

Longini et al. use mathematical modeling to conduct epidemic simulations in order to estimate the potential effects of targeted antiviral prophylaxis. The researchers determine that "targeted prophylaxis for up to 8 weeks has nearly as high an overall effectiveness as vaccinating 80 percent of the entire population" (p. 627). The analysis does not take into account cost or cost effectiveness.

McCaw, J. M., & McVernon, J. (2007). Prophylaxis or treatment? Optimal use of an antiviral stockpile during an influenza pandemic. *Mathematical Biosciences, 209*(2), 336-360.

McCaw and McVernon develop a mathematical model in order to estimate the effects of different antiviral allocation strategies. The authors state that the model takes into account subclinical infections and antiviral resistance. They conclude that targeted post-exposure prophylaxis, rather than treatment, would reduce attack rate, delay pandemic onset, and minimize consequences of the pandemic.

Minnesota Department of Health. (2006). *Technical section G: Antivirals and vaccines. Minnesota Department of Health Pandemic Influenza Plan (Draft)*. Retrieved January 24, 2008, from http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/7antivirals.pdf

This document is a supplement to the Minnesota Department of Health's pandemic influenza planning document. Its primary purpose is to describe the state's antiviral and vaccine distribution strategy. Included in its content are the state's recognized responsibilities in the various pandemic phases. The state appears to have adopted all U. S. Department of Health and Human Services recommendations for prioritization lists.

New York City Department of Health and Mental Hygiene. (2006, July). *Pandemic influenza preparedness and response plan*. Retrieved February 6, 2008, from http://www.nyc.gov/html/doh/downloads/pdf/cd/cd-panflu-plan.pdf

The purpose of this document is to provide details on New York City's pandemic influenza response plan. It includes information on command procedures, surveillance strategies, and antiviral and vaccine allocation strategies. The stated antiviral strategy is similar to that of the U. S. Department of Health and Human Services in the identification of priority groups, but in contrast to the HHS document all groups receiving treatment are given priority over those receiving prophylaxis.

New York State Department of Health. (2006, February 7). *Pandemic influenza plan*. Retrieved May 17, 2007, from http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/docs/pandemic_influenza_plan.pdf

The purpose of this document is to provide guidance, consistent with national advisories, to public health officials and healthcare providers in their development of pandemic influenza preparedness and response plans. Included in the document are discussions on surveillance, infection control, vaccine and antiviral allocation, communication, and workforce management, among other issues. Relating to

vaccines and antivirals, NYSDOH bases its prioritizations on the minimization of morbidity and mortality and the minimization of social disruption, but it does not explicitly rank one priority over the other. It does, however, recommend that groups considered to be at medical risk be given higher priority over those with infrastructure roles.

Olson, D. R., Simonsen, L., Edelson, P. J., & Morse, S.S. (2005). Epidemiological evidence of an early wave of the 1918 influenza pandemic in New York City. *Proceedings of the National Academy of Sciences of the United States of America, 102*(31), 11059-11063.

Olson et al. describe the occurrence of an influenza epidemic in New York City in early 1918. They argue that its epidemiology suggests it was an early wave of the Spanish flu preceding the rise of the epidemic in Europe that occurred that summer. This analysis of a historical case of pandemic influenza provides statistics and epidemiological data that may be relevant to a future H5N1 pandemic.

Public Engagement Pilot Project on Pandemic Influenza. (2005, December). *Citizen voices on pandemic flu choices*. Retrieved March 13, 2007, from http://pandemicflu.gov/plan/federal/pepppimaintext.pdf

This publication documents public sessions that were held in Washington, D. C., Georgia, Oregon, Nebraska, and Massachusetts in order to assess stakeholders' and the general public's opinions on pandemic flu vaccination prioritization. The authors state that those involved believed that prioritization first should be based on assuring the functioning of society. Minimizing deaths and hospitalizations was identified as the second priority.

Straetemans, M., Buchholz, U., Reiter, S., Haas, W., & Krause, G. (2007). Prioritization strategies for pandemic influenza vaccine in 27 countries of the European Union and the Global Health Security Action Group: A review [Electronic version]. *BMC Public Health*, *7*(236). Retrieved January 25, 2008, from http://www.biomedcentral.com/1471-2458/7/236

Straetemans et al. conducted a survey of 31 countries to determine international vaccine prioritization strategies. The authors find that the majority of the countries identified at least one priority group. Healthcare workers are identified as a priority group in all the 26 countries with established prioritization lists.

Swaminathan, A., Martin, R., Gamon, S., Aboltins, C., Athan, E., Braitberg, G., et al. (2007). Personal protective equipment and antiviral drug use during hospitalization for suspected avian or pandemic influenza. *Emerging Infectious Diseases, 13*(10), 1541-1547.

The authors conduct a simulation exercise at nine hospital sites in Australia to determine how many healthcare workers would become exposed to influenza infected patients requiring critical care. The result of this exercise shows that 41% of workers exposed to the patient would likely require antiviral prophylaxis if such a strategy were implemented. The authors conclude that there would be insufficient personal protective equipment for healthcare workers, as well as insuf-

ficient antiviral medication available to provide prophylaxis to all exposed employees.

United States Department of Health and Human Services. (2005a, November). ***HHS pandemic influenza plan*****. Retrieved May 15, 2007, from http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf**
The purpose of this HHS document is to serve as a framework for all HHS pandemic response plans. It outlines federal plans and provides guidance to state and local planners. The top priority in vaccine and antiviral allocation in this document is the minimization of morbidity and mortality. The vaccine allocation strategy presented in this document has since been revised.

United States Department of Health and Human Services. (2005b). ***HHS pandemic influenza plan, supplement 7: Antiviral drug distribution and use*****. Retrieved February 11, 2008, from http://www.hhs.gov/pandemicflu/plan/sup7.html**
This supplement to the HHS pandemic influenza plan identifies federal, state, and local responsibilities in planning for and responding to an influenza pandemic. It also describes the purpose of using antiviral medications in response to such a pandemic—such as for treatment, prophylaxis, or post-exposure prophylaxis—as well as which medications would likely be used. Procedures for the distribution of these medications also are discussed.

United States Department of Health and Human Services. (2006, October). ***Antivirals – state allocation*****. Retrieved May 16, 2007 from: http://pandemicflu.gov/plan/states/antivirals.html**
This website shows the allocation of federally and state-purchased antiviral medications by state, which is based on population. Indiana is allotted approximately 1.5 million courses.

United States Department of Health and Human Services. (2007, October). ***Draft guidance on allocating and targeting pandemic influenza vaccine.*** **Retrieved February 4, 2008, from http://www.pandemicflu.gov/vaccine/prioritization.pdf**
This draft put forth by HHS is the most recent document made publicly available by the agency regarding pandemic influenza vaccine prioritization recommendations. The prioritization strategy involves mathematical assessments of several subpopulations in regards to the applicability of 10 vaccine allocation objectives adopted by the participants in the draft development. The resulting prioritization list was then divided into four categories of populations, into which the subpopulations were classified.

Virginia Department of Health. (2006, March). ***Emergency operations plan, attachment pandemic influenza, supplement 7: Antiviral drug distribution and use (Draft)*****. Retrieved February 7, 2008, from http://www.vdh.virginia.gov/PandemicFlu/pdf/DRAFT_Virginia_Pandemic_Influenza_Plan.pdf**

This draft pandemic influenza document provides background information on pandemic influenza, discusses relevant Virginia laws that may be acted upon in a pandemic, and describes federal and state responsibilities in regards to planning and response. Also included are 11 supplemental documents that describe such topics as pandemic surveillance, infection control, and vaccine and antiviral distribution and use. In this plan, the state of Virginia has adopted the vaccine and antiviral allocation prioritization lists developed in 2005 by the U. S. Department of Health and Human Services.

World Health Organization. (2006). ***Avian influenza ("bird flu")—Fact sheet.*** **Retrieved June 5, 2007, from http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html**

This WHO document provides an overview of avian influenza, including discussion on its presence in birds and its history of human infection. It also provides a discussion on human epidemiology and symptoms. Finally, it identifies the nations currently affected by H5N1 infections. This document describes the potential of H5N1 to become the next influenza pandemic.

Wynia, M. K. (2006). Ethics and public health emergencies: Rationing vaccines. ***American Journal of Bioethics, 6*****(6), 4-7.**

Wynia discusses a wide range of ethical issues that must be addressed in pandemic influenza vaccine allocation planning, such as deciding which ethical principles should direct planning efforts, finding a way to minimize the need to ration, ensuring that the pandemic is addressed globally, and deciding who will be making the rationing decisions. The author predominantly favors the rationing scheme put forth by Emanuel and Wertheimer (2006). He acknowledges, however, that such a strategy would likely meet resistance, particularly from parents of young children.

Annotated Bibliography (AB-0J-08)

HEALTHCARE WORKFORCE MANAGEMENT AND PANDEMIC INFLUENZA PREPAREDNESS:
ETHICAL ISSUES AND RECOMMENDATIONS TO THE INDIANA STATE DEPARTMENT OF HEALTH

June 2008

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This annotated bibliography was prepared by the Indiana University Center for Bioethics under contract with the Indiana State Department of Health as a part of the project "Translating Ethics Advice into Practice: Public and Professional Outreach about Pandemic Influenza Planning in Indiana". The views expressed in this document are those of the author and may not necessarily reflect the opinions of the Center for Bioethics, Indiana University, or the Indiana State Department of Health.

The World Health Organization has recognized the potential of an influenza pandemic and have called for member nations to start planning for the next pandemic, which WHO refers to as "inevitable, and possibly imminent." Some professionals have suggested preparing for a pandemic similar to the 1918 "Spanish flu" that is estimated to have caused 50 to 100 million deaths. It is projected that a similar pandemic would cause about 180 to 360 million deaths globally, including 1.7 million deaths in the United States, with transmission of the disease lasting at least two years. If such a pandemic occurs, it will require drastic, though temporary, changes in many areas of society, including hospitals, schools, workplaces, and other public service organizations. In planning a response for such a pandemic, many decisions will have to be made both to contain and control its spread, and policies to guide decision-making will require consideration of ethical issues related to workforce management.

Several references for this document were found via the Indiana University Center for Bioethics website's pandemic resources page (*http://bioethics.iupui.edu/Pandemic.asp*). Others were found through searches on the PubMed database (*http://www.ncbi.nlm.nih.gov/sites/entrez/*), the Web of Science database (*http://scientific.thomson.com/products/wos*), the World Health Organization's website (*http://www.who.int/en/*), the Centers for Disease Control and Prevention website (*http://www.cdc.gov*), and the Yahoo! search engine (*http://www.yahoo.com*) using the terms "pandemic influenza," "avian influenza," "pandemic altered standards," "pandemic triage," "pandemic absenteeism," "pandemic alternate care sites," "pandemic altered care," "pandemic workforce management," "medical professional obligations," "pandemic law," "Indiana medical standards," and "tuberculosis patient."

This document is not exhaustive of all possible resources regarding the topic of workforce management during an influenza pandemic, but it is our hope that these resources may be of some use to those who are interested in pursuing the topic further. This document is current as of June 2, 2008.

References

Agency for Healthcare Research and Quality. (2005, April). ***Altered standards of care in mass casualty events - AHRQ Publication No. 05-0043*** **[Electronic version]. Retrieved April 27, 2007, from http://www.ahrq.gov/research/altstand/altstand.pdf**

The purpose of this document is to provide planners with a framework from which they can develop a protocol to change the provision of medical care in the occurrence of a mass casualty event (MCE). It examines how current care standards may need to change and which tools are available to make these changes, and it provides recommendations to emergency planners on the most reasonable and ethical methods to address an MCE. The authors recommend the use of a database with registered volunteers, who may include dentists and retired physicians and who can be called upon in times of staffing shortages. It is also recommended that healthcare workers and their families be given prophylaxis in order to ensure that all employees will report to work.

Agency for Healthcare Research and Quality. (2007, February). ***Providing mass medical care with scarce resources: A community planning guide - AHRQ Publication No. 07-0001*** **[Electronic version]. Retrieved March 28, 2007, from http://www.ahrq.gov/research/mce/**

The purpose of this document is to guide planners in their development of strategies to address mass casualty events. It provides examples of resources currently available to states and communities that may assist in their planning. It describes potential sanctions for healthcare workers who are absent during mass casualty events. It also discusses the legality of prioritizing the government workforce for various health interventions, such as immunization and antiviral allocation.

Barnett, D. J., Balicer, R. D., Lucey, D. R., Everly, G. S., Jr., Omer, S. B., Steinhoff, M. C., et al. (2005, December). A systematic analytic approach to pandemic influenza preparedness planning [Electronic version]. ***PLoS Medicine, 2*****(12), 1235-1241. Retrieved May 8, 2007, from http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pmed.0020359**

This document provides an overview of the pathology of H5N1 and its pandemic potential. In addition, it discusses human, agent, environmental, and sociocultural factors that may influence the spread of the disease. The authors identify a need for phase-specific planning, relating to the time prior to the pandemic, during the pandemic, and after the pandemic.

Berlinger, N., & Moses, J. (2007). Five people you meet in a pandemic—and what they need from you today. ***Hastings Center Report.*** **Retrieved February 29, 2008, from http://www.thehastingscenter.org/pdf/Pandemic-Backgrounder-The-Hastings-Center.pdf**

In their article, Berlinger and Moses attempt to provide guidance to pandemic influenza planners in the use of ethical considerations in policy development. The authors briefly discuss three "ethical duties" of decision-makers. They then go on to identify and describe five categories of first responders that will need to be considered and addressed in the decision-making process. Included in the discussion is the use of incentives to ensure vital employees report to work in order to help provide for adequate staffing.

Cantrill, S. V., Eisert, S. L., Pons, P., & Vinci, C. E. (2004, August). ***Rocky Mountain regional care model for bioterrorist events: Locate alternate care sites during an emergency - AHRQ Publication No. 04-0075*** **[Electronic version]. Retrieved May 14, 2007, from http://www.ahrq.gov/research/altsites**

This document was developed in order to address medical surge capacity needs in the occurrence of a bioterrorism event, but its methods also are applicable to a naturally occurring bioevent. The authors created a surge capacity model in order to anticipate medical surge capacity needs. Included in the protocol is a recommendation that volunteers, such as retired physicians, be registered into a database so that they may be called upon to assist in medical care provision should regular workforce numbers drop too low to maintain a minimally functioning healthcare site.

Center for Law and the Public's Health at Georgetown and Johns Hopkins universities. (2001, December 21). ***Model state emergency health powers act.*** **Retrieved May 10, 2007, from http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf**

This document is a model for state legislation that addresses the need for State and local governments to act quickly and effectively in handling public health emergencies. It grants governors and public health authorities emergency powers to address events such as a bioterrorist attack or a pandemic event. In this document, the authors include a discussion on forms of sanctions that possibly may be applied to healthcare workers who do not perform their duties in a time of emergency. One suggested sanction is the revocation of an individual's professional license.

Centers for Disease Control and Prevention. (2007a, May 29). ***Corrected: Investigation of U.S. traveler with extensively drug resistant tuberculosis (XDR TB)*****. Retrieved June 14, 2007, from http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00262**

This press release discusses the CDC's investigation into the recent actions of a man with a drug-resistant form of tuberculosis who flew on several long flights, affecting United States- and European-based airlines. The CDC identifies the flights that were affected by this passenger's travels. This article is applicable to this workforce document in that it demonstrates the public's support for patient isolation in the case of deadly, contagious illness.

Centers for Disease Control and Prevention. (2007b, June 6). *Recent case of extensively drug resistant TB: CDC's public health response*. Retrieved June 14, 2007, from http://www.cdc.gov/washington/testimony/6-06-07_XDR_TB_testimony.html

This document is the statement released by the director of the CDC to the United States Senate that outlines the events that led to a man with a drug-resistant form of tuberculosis flying on two trans-Atlantic flights, as well as several other shorter flights, possibly exposing numerous fellow passengers to his disease. This article is applicable to this workforce draft in that it demonstrates the public's support for isolation in the case of deadly, contagious illness.

Cole, R. L. (2007, August). Not just for the birds: Assessing your medical practice for pandemic readiness. *MGMA Connexion*, 7(7), 36-41.

Cole discusses strategies that private medical practices can use in order to help prepare for an influenza pandemic. He includes a brief discussion on the development of a planning committee. The remainder of the article addresses essential components of a pandemic response plan, such as the establishment of an influenza reporting system, the education of staff, and the development of strategies to manage employee absenteeism.

Conant, E., & Wingert, P. (2007, June 11). A long, strange TB trip: An Atlanta lawyer with a potentially deadly contagious disease talks about a journey that has triggered fear and outrage [Electronic version]. *Newsweek*. Retrieved June 14, 2007, from http://www.msnbc.msn.com/id/19000895/site/newsweek/?from=rss

This Newsweek article includes an interview with Andrew Speaker, the man with a drug-resistant form of tuberculosis who flew on several airline flights, potentially exposing numerous passengers to the deadly and difficult-to-treat disease. The article also discusses the outrage expressed by his fellow passengers and the general public that Mr. Speaker was allowed to leave the country and was allowed back in over the Canadian border. This supports the idea that the public would prefer control measures, such as isolation, over individual freedom in the case of deadly, contagious illnesses.

Ehrenstein, B. P., Hanses, F., & Salzberger, B. (2006). Influenza pandemic and professional duty: family or patients first? A survey of hospital employees [Electronic version]. *BMC Public Health*, 6, 311. Retrieved May 8, 2007, from the Biomed Central database.

Ehrenstein et al. performed a study in which they surveyed hospital employees regarding their beliefs about workforce obligations during a pandemic influenza, as well as ethical considerations about obligation to work or choice to work. The general findings were that physicians and nurses were more likely than hospital administrators to report to work during a pandemic. In addition, it was found that most disagreed with the possible strategy of permanently dismissing employees who do not report to work during an influenza pandemic.

Engel, J. P. (2007). Pandemic influenza: The critical issues and North Carolina's preparedness plan. *North Carolina Medical Journal*, 68(1), 32-37.
Engel provides an overview of the possibility of the occurrence of an influenza pandemic, discussing the zoonotic origins of such a pandemic, as well as the likelihood of H5N1 to fulfill all the prerequisites to becoming a pandemic virus. The author then summarizes the tasks the state of North Carolina has already undertaken in pandemic preparedness planning and various interventions that likely will be used. Also included is a discussion on the use of isolation and quarantine.

Gomersall, C. D., Loo, S., Joynt, G. M., & Taylor, B. L. (2007). Pandemic preparedness. *Current Opinion in Critical Care*, 13(6), 742-747.
Gomersall et al. discuss the broad topic of pandemic preparedness in terms of occupational safety, availability of staff, expansion of services, stockpiling and use of drugs and disposable supplies, and triage. The authors discuss the necessity of ensuring staff safety, protecting staff from litigation, and providing staff additional training in the new tasks they are expected to perform.

Gomersall, C. D., Tai, D. Y., Loo, S., Derrick, J. L., Goh, M. S., Buckley, T. A., et al. (2006). Expanding ICU facilities in an epidemic: Recommendations based on experience from the SARS epidemic in Hong Kong and Singapore. *Intensive Care Medicine*, 32(7), 1004-1013.
The authors of this document present the recommendations of expert groups who expanded intensive care services in response to outbreaks of severe acute respiratory syndrome in Hong Kong and Singapore. These recommendations address estimating bed requirements, infection control, staffing, counseling and stress reduction, communication, and other ethical issues. Should a shortage of staffing occur, it is recommended that employees be drafted to work. The authors also support the use of control measures, such as isolation and quarantine, for employees if necessary to protect the general public's health.

Gostin, L. O. (2006). Public health strategies for pandemic influenza: Ethics and the law. *Journal of the American Medical Association*, 285(14), 1700-1704.
Gostin discusses a multidimensional approach to addressing the problems that would arise with a pandemic influenza event. This approach includes surveillance, community hygiene, hospital infection control, social distancing, travel and border controls, and isolation and quarantine. In the document, Gostin states that isolation and quarantine are to be used carefully and with rigorous safeguards so that individuals are not subjected to discrimination. This supports the belief that isolation and quarantine measures, including those for the workforce, should be implemented if the public's health would benefit substantially.

Gruber, P. C., Gomersall, C. D., & Joynt, G. M. (2006). Avian influenza (H5N1): Implications for intensive care. *Intensive Care Medicine*, 32(6), 823-829.

Gruber et al. provide a discussion on the epidemiology, prevention, and treatment of a pandemic influenza. The authors then discuss the implications such a pandemic would likely have for intensive care providers and the need for these providers to develop response plans in advance. An additional point of discussion is the need to maintain staff morale during the stressful situation.

Hsin, D. H., & Macer, D. R. (2004). Heroes of SARS: Professional roles and ethics of health care workers. *Journal of Infectious Diseases*, 49(3), 210-215.
The authors of this article examined the relationship of professional moral duties with the SARS epidemic in 2003. Hsin and Macer argue that healthcare workers should have the right to make their own choice about whether to report to work in times of a public health crisis such as SARS. They state that there should be reasonable expectations from healthcare workers in such crises, but that they should not "be expected to be martyrs for society" (p. 210). In other words, they support the high expectations, limited sanctions approach recommended in this document.

Illinois Department of Public Health. (2006, October). *Pandemic influenza preparedness and response plan*. Retrieved January 25, 2008, from http://www.idph.state.il.us/pandemic_flu/Illinois%20Pandemic%20Flu%20Plan%20101006%20Final.pdf
This plan was developed by the Illinois Department of Public Health to provide a framework for decision-making entities, public and private, in the state of Illinois regarding pandemic influenza preparedness. The document discusses several areas of preparedness and response planning, including surveillance, antiviral and vaccine allocation, and methods to increase surge capacity. Included in this discussion are recommendations for ensuring adequate staffing and protecting and educating employees.

Indiana Code 25-1-9-9. (n.d.) *Health professions standards of practice*. Retrieved June 14, 2007, from http://www.in.gov/legislative/ic/code/title25/ar1/ch9.html
This is an Indiana law pertaining to the standards of practice set for various professions, including those of physicians. In this document, potential forms of sanctions are discussed for physicians who violate their professional codes of conduct. Should a law be passed requiring physicians to report to work during a pandemic, such sanctions may be expanded in order to apply to a violation of such a new law.

Iserson, K. V., Heine, C. E., Larkin, G. L., Moskop, J. C., Baruch, J., & Aswegan, A. L. (In press). Fight or flight: The ethics of emergency physician disaster response [Electronic version]. *Annals of Emergency Medicine*. Retrieved January 8, 2007, from the PubMed database.
Iserson et al. discuss professional codes regarding care for patients in the case of a healthcare crisis, reasons healthcare workers may or may not report to work, and the importance of risk communication during an influenza pandemic to ensure

adequate staffing. The authors conclude that whether an individual presents to work will be dependent upon his/her own risk assessment and value systems.

Jan, K. (2007). Avian flu pandemic preparedness. *Home Healthcare Nurse, 25*(10), 637-642.

Jan provides an overview of pandemic influenza, as well as global and national strategies to prevent and respond to such a pandemic. She discusses the relevance of the topic to home health providers, including the need to provide for mental and physical health issues in the event of such a crisis. The importance of education and preparation for the pandemic also is emphasized.

Letts, J. (2006). Ethical challenges in planning for an influenza pandemic. *NSW Health, 17*(9-10), 131-134.

Letts provides a concise ethical framework on which pandemic planning should be based, including the concepts of transparency, consistency, flexibility, responsiveness, and proportionality. The author then briefly discusses the topics of isolation, quarantine, and social distancing measures; prioritization of antiviral medications; access to intensive care; healthcare professional duty to care; and altered standards of care. In regards to professional duty to care, Letts supports an approach that emphasizes high expectations and no sanctions for healthcare providers.

Levin, P. J., Gebbie, E. N., & Qureshi, K. (2007). Can the health-care system meet the challenge of pandemic flu? Planning, ethical, and workforce considerations. *Public Health Reports, 122*(5), 573-578.

Levin et al. discuss the impact an influenza pandemic may have on healthcare services, the necessity of effective and consistent communication, and the need to plan for ethical dilemmas and workforce management issues. The authors stress the need to plan for the crisis and develop protocol now in order to have it available to healthcare providers when the need arises.

Lo, B., & Katz, M. H. (2005). Clinical decision making during public health emergencies: Ethical considerations. *Annals of Internal Medicine, 143*(7), 493-498.

Lo and Katz provide recommendations for clinical decision-making during a public health emergency, such as the decision whether or not to provide a patient with prophylactic medication that is in short supply simply because the patient requests it. They discuss the alterations to clinical medicine that must take place during a public health emergency, with individual liberty potentially becoming a lesser priority than the overall health of the public. Related to this, the authors discuss the relevance of and need for control measures such as isolation and quarantine.

Martin, S. D. (2007). Code flu: Common sense steps to the development of an agency pandemic flu plan for home care. *Home Healthcare Nurse, 25*(9), 595-601.

The author discusses the importance for healthcare providers to develop a "code flu," which would be implemented in the event of an influenza pandemic. Included in such a plan would be the development of a communication strategy and identification of decision-makers. In addition, it is recommended that employees develop individual plans for managing the emergency. Other parts of the strategy include assigning a nurse to handle calls regarding influenza and establishing a list of volunteers to help manage influenza patients.

McGorty, E. K., Devlin, L., Tong, R., Harrison, N., Holmes, M., & Silberman, P. (2007). Ethical guidelines for an influenza pandemic. ***North Carolina Medical Journal, 68*****(1), 38-42.**

McGorty et al. discuss the ethical guidelines and recommendations for an influenza pandemic that were developed by a task force convened by the North Carolina Institute of Medicine to assist the North Carolina Department of Health and Human Services, Division of Public Health. The task force addressed healthcare workforce management, limitations on civil liberties, and altered standards of care. Regarding workforce management, the authors stress that healthcare providers are the most qualified to provide care during a pandemic and thus are expected to do so.

Morin, K., Higginson, D., & Goldrich, M. (2006). Physician obligation in disaster preparedness and response. ***Cambridge Quarterly of Healthcare Ethics, 15*****(4), 417-421; discussion 422-431.**

Morin et al. provide an overview of the historical development of medical ethics. They discuss opposing views on whether physicians have an obligation to care for patients if providing care results in great personal risk, such as in a bioterrorist attack, as well as the extent of such an obligation. The authors conclude that those in the medical profession are obligated to provide care even if it means risking their own safety. They also state, however, that the medical workforce "is not an unlimited resource" (p. 421) and should not be sacrificed to care for the unsalvageable now if it compromises their ability to provide care for the public in the future.

Occupational Safety and Health Administration. (2007). ***Pandemic influenza preparedness and response for healthcare workers and healthcare employers.*** **Retrieved January 25, 2008, from http://www.osha.gov/Publications/OSHA_pandemic_health.pdf**

This OSHA publication is intended to be a guidance document that discusses clinical background information on influenza, infection control, pandemic influenza preparedness, and OSHA standards that will apply to workforce management issues in an influenza pandemic. Included in this discussion is the use of alternate care sites and policies to ensure adequate staffing, such as using effective risk communication and undertaking strategies to support employee safety.

Payne, K. (2007). Ethical issues related to pandemic flu planning and response. *AACN Advanced Critical Care, 18*(4), 356-360.

Payne discusses the potential impact of an influenza pandemic on the population and on healthcare facilities. She also discusses the American Nurses Association's code of ethics and its applicability to a pandemic. In addition, Payne elaborates on the importance of education, proper personal protective equipment, proper personal hygiene, and nurses' involvement in the pandemic planning process.

Public Engagement Pilot Project on Pandemic Influenza. (2005). *Citizen voices on pandemic flu choices*. Retrieved March 13, 2007, from http://www.keystone.org/spp/documents/FINALREPORT_PEPPPI_DEC_2005.pdf

This publication documents public sessions that were held in Washington, D.C., Georgia, Oregon, Nebraska, and Massachusetts in order to assess stakeholders' and the general public's opinions on pandemic flu vaccination prioritization. The authors state that those involved believed that prioritization first should be based on assuring the functioning of society. Minimizing deaths and hospitalizations was identified as the second priority. Relevant to workforce management, the authors write that a possible method of assuring that healthcare employees report to work would be to require that they sign a commitment to do so upon receiving immunization.

Public Health Agency of Canada. (2006). *Canadian pandemic influenza plan for the private sector*. Retrieved January 25, 2008, from http://www.phac-aspc.gc.ca/cpip-pclcpi/pdf-e/CPIP-2006_e.pdf

This document contains detailed strategies and recommendations for the private health sector of Canada. It addresses topics such as vaccine and antiviral prioritization, infection control, resource and workforce management, and management of mass casualties during a pandemic. Discussion on use of alternate staffing methods is included.

Qureshi, K., Gershon, R. R. M., Sherman, M. F., Straub, T., Gebbie, E., McCollum, M., et al. (2005). Health care workers' ability and willingness to report to duty during catastrophic disasters. *Journal of Urban Health: Bulletin of the New York Academy of Medicine, 82*(3), 378-388.

Qureshi et al. conducted a survey of 6,428 healthcare workers from the New York City area to determine how these workers would respond to various emergencies that would require mass care. The researchers discovered that workers would report to work in lower numbers during a biological event such as SARS or smallpox than in environmental disasters or mass casualty incidents. Through this survey, Qureshi et al. were able to identify several potential barriers to healthcare worker attendance. By doing so, they were able to suggest potential methods for overcoming these barriers in order to help ensure adequate staffing in an influenza pandemic.

Reid, L. (2005). Diminishing returns? Risk and the duty to care in the SARS epidemic. *Bioethics, 19*(4), 348-361.

Reid outlines various points of view regarding whether there is a direct or inverse relationship between risk and duty to care, putting these issues in the context of both the early years of AIDS and the SARS epidemic. The author includes discussions on the American Nursing Association's stance, as well as that of the American Medical Association. She also reviews other relevant literature published on the topic of medical professionals' duty to care. Reid concludes that the SARS epidemic showed that physicians are willing to accept increased risk, and the duty to care is directly proportional to risk. This conclusion may hold true for an influenza pandemic.

Rhyne, J. A. (2007). Likely ethical, legal, and professional challenges physicians will face during an influenza pandemic. *North Carolina Medical Journal, 68*(1), 51-53.

Rhyne briefly analyzes the code of ethics for the North Carolina Medical Board, the American Medical Association, and the American College of Physicians to determine the stance each association takes on how to address an influenza pandemic. The author concludes that "medical professional associations and societies support the safety of physicians, but also assert an ethical obligation and responsibility to work during a public health crisis despite personal risks" (p. 52). She then puts forth recommendations to reduce physicians' reluctance to provide care during an influenza pandemic.

Rubinson, L., Nuzzo, J. B., Talmor, D. S., O'Toole, T., Kramer, B. R., Inglesby, T. V., et al. (2005). Augmentation of hospital critical care capacity after bioterrorist attacks or epidemics: Recommendations of the working group on emergency mass critical care [Electronic version]. *Critical Care Medicine, 33*(10). Retrieved from Ovid Web Gateway on March 27, 2007.

The authors of this document address possible mass critical care alterations that should be made in the event of a bioterrorist attack but also write that such alterations may apply to naturally occurring biological events, such as a pandemic. In the document, Rubinson et al. discuss triage implementation, the need for altered workforce responsibilities, and possible legislative actions to protect healthcare workers and facilities from litigation. They propose the need for identification and registration of volunteers, such as retired physicians and veterinarians, whose names can be stored in a database for rapid accessibility.

Tzeng, H. M. (2004). Nurses' professional care obligation and their attitudes towards SARS infection control measures in Taiwan during and after the 2003 epidemic. *Nursing Ethics, 11*(3), 277-289.

Tzeng conducted a study to determine statistically significant predictors of nurses' willingness to provide care during the SARS epidemic. The researcher found that nurses were more likely to provide care if they were in agreement with infection control measures and if they were not subjected to quarantine. This information

may be applicable to the development of pandemic influenza response protocols regarding workforce management.

University of Maryland Center for Health and Homeland Security. (2005, September 9). ***Maryland public health emergency preparedness legal handbook*** **[Electronic version]. Retrieved June 6, 2007, from http://www.umaryland.edu/healthsecurity/docs/Handbook%209-9-05.pdf**
This handbook provides an overview of Maryland laws that are applicable to public health emergencies. Its purpose is to shorten research time for state, county, and local lawyers should they be confronted with legal challenges related to such emergencies. This handbook includes Maryland law 14-3A-03(c), which states that the governor may order any healthcare provider to participate in disease surveillance, treatment, and control. Failure to comply would have legal implications.

World Health Organization. (2005). ***WHO global influenza preparedness plan: The role of WHO and recommendations for national measures before and during pandemics.*** **Retrieved May 8, 2007, from http://www.who.int/csr/resources/publications/influenza/GIP_2005_5Eweb.pdf.**
This document was created to assist nations in their development of pandemic influenza response plans. It identifies six pandemic phases, ranging from interpandemic and pandemic alert periods to the pandemic period itself. WHO recommends steps national, public health, and medical policymakers should take during each phase. In the described plan, it also is recommended that those in the healthcare workforce be allowed time to rest and recuperate between waves and after the pandemic in order to decrease worker burnout, which may result from high demands at work.

World Health Organization. (2006). ***Avian influenza ("bird flu") - Fact sheet.*** **Retrieved June 5, 2007, from http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html**
This WHO document provides an overview of avian influenza, including discussion on its presence in birds and its history of human infection. It also provides a discussion on human epidemiology and symptoms. Finally, it identifies the nations currently affected by H5N1 infections. This document describes the potential of H5N1 to become the next influenza pandemic.

World Health Organization. (2007, May 30). ***Extensively drug-resistant tuberculosis (XDR-TB) in United States of America air passenger*****. Retrieved June 14, 2007, from http://www.who.int/csr/don/2007_05_30a/en/index.html**
This article provides a brief overview on the situation in which a man diagnosed with a drug-resistant form of tuberculosis took multiple long airplane flights, potentially infecting his fellow passengers.

World Health Organization. (2008, May 28). ***Cumulative number of confirmed human cases of avian influenza A/(H5N1) reported to WHO*****. Retrieved June 2, 2008, from http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_05_28/en/index.html**

This website is maintained by the World Health Organization and reports the most current numbers relating to cases of H5N1 around the world. It currently lists 15 countries as having reported cases, 12 of which also have reported deaths.