Ethical Considerations in Preparedness Planning for Pandemic Influenza

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Emergency Management Summit
Washington DC February 2008
6.1 Time series of respiratory ambulatory visits to primary care providers, age and gender aggregated, 1992-2002

Note: "Respiratory ambulatory visits" include all ambulatory visits to a physician for COPD, asthma, pneumonia or respiratory infectious diseases.
Outline

- Rationale for ethics & pandemic planning
- Development of an ethical framework
- Framework as a guide for decision making
- Key recommendations from *Stand on Guard for Thee*
- Additional considerations
- Discussion
Will it be a ‘health tsunami’ or ‘health Y2K’?
Evolution of Ideas

- Sunnybrook Pandemic Planning Committee requests ethics assistance
- Working Group formed through Joint Centre for Bioethics U of T
- *Ethics in a Pandemic Influenza Crisis: Framework for Decision Making*
- Adopted into Ontario Plan and Toronto Academic Health Sciences Network Plan
- *Stand on Guard for Thee*
- *WHO Global Consultation*
What is bioethics?

- Bioethics involves critical reflection on moral/ethical problems faced in health care settings toward:
  - deciding *what* we should do
  - explaining *why* we should do it and
  - describing *how* we should do it

  (Dr Barb Secker)
Bush cites U.S. plans against bird flu risk

By Brian Knowlton International Herald Tribune
WEDNESDAY, OCTOBER 5, 2005

WASHINGTON President George W. Bush said Tuesday that he was working to prepare the United States for a possible deadly outbreak of avian flu.

If an epidemic appears, he said, he has weighed whether to quarantine parts of the country and whether to rescue those who are," he said of avian flu. "We're trying to put plans in place." A bipartisan group of senators have been pressing Bush to prepare for a bird-flu emergency. His sense of urgency appeared to have been heightened, as well, by the widespread criticism of the response to the two hurricanes that battered the Gulf Coast.

Humans have little defense against it. It kills about half of those infected.

But Bush, in devoting a long and detailed reply to the subject of bird flu, appeared intent on promoting readiness and raising the public's awareness, as well as demonstrating his own. He referred to the "H5N1..."
Pandemic's hard choice
who to help?: Ethicist issues warning

Tom Blackwell; with files from Janice Tibbetts
National Post; with files from CanWest News Service

Monday, October 17, 2005
“Collective forethought & a broad consensus would go far in helping to tackle the unique moral & ethical dilemmas that will arise when a catastrophic event occurs.”

Iserson & Pesik 2003
Rationale Ethical Guidelines

- Government and health care leaders will need to make decisions based on values
- Values based leadership may be the glue that holds society together in an intense crisis
- History will judge today’s leaders on how well they prepared for and acted during the crisis and whether they treated people in an ethical manner
Ethics & SARS – What did we learn?

Singer et al 2005 BMJ

Ethics and SARS: lessons from Toronto

Ten key ethical values
Ethics and SARS: lessons from Toronto

Peter A Sarge, Soo Hooi E Blinnur, Mark Boninna, Ahmad S Durr, Bernard M Oloko, Susan, J. Mac, Buse, E. Fe, Upmier, Linda Wright, Randal, L. Stan.

The SARS epidemic in Toronto is one of the first international incidents to spread outside of China. The unique nature of SARS places greater emphasis on the need to understand the nature of the ethical issues that are involved.

The ethical issues that are involved in the provision of health care services in the context of SARS include:

1. Confidentiality
2. Autonomy
3. Justice
4. Respect for persons
5. Non-maleficence
6. Harm
7. Beneficence
8. Truth

These ethical issues are complex and require careful consideration. The provision of health care services in the context of SARS requires a balancing of these ethical issues in order to provide effective care.

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Collateral Damage
Bernstein & Hawryluck 2003 Critical Care

- Trust, truth-telling & relationships with colleagues
- Public infection & infection control ICU
- Professional integrity & relationships with patients/families
- Resource allocation
Ethics & Disaster & Bioterrorism

What can we learn?

Triage Iserson & Pesik 2003

- Civilian Triage
  - Most ill or vulnerable prioritized

- Battlefield Triage
  - Save those soldiers who can serve & protect

- Triage following Disasters (natural, man-made & industrial)
  - Balance between civilian & battlefield triage

- Triage following biochemical terrorism
  - Optimal use of resources to benefit most people- Senior clinicians decision-makers
Lessons from Katrina

Darr, K. *Katrina: Lessons from the Aftermath.*

*Hospital Topics* 2006, 84(2) p30-33

During a crisis situation like Katrina or impending avian flu pandemic “*rules of thumb and situational ethics are not likely to produce societally desirable results*.”
Katrina & the varying perceptions for priority setting in evacuation

- **Hospital** → most critically ill patients first
- **Firefighters** → least ill patients first & most ill later
- **Helicopter Pilots** → pregnant women & babies
How should influenza vaccine be distributed?
From: Emanuel & Wertheimer Public Health. Who should get influenza vaccine when not all can? Science 2006 312 (5775) : 854-5

Examples of differing perspectives:

- National Vaccine Advisory Committee & Advisory Committee on Immunization Practices (NVAC & ACIP)
- Life-cycle Principle LCP
- Investment refinement of LCP
<table>
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<tr>
<th>Tier*</th>
<th>NVAC and ACIP recommendations (subtier)†</th>
<th>Life-cycle principle (LCP)</th>
<th>Investment refinement of LCP including public order</th>
</tr>
</thead>
</table>
| 1     | Vaccine production and distribution workers  
Frontline health-care workers  
People 6 months to 64 years old with ≥2 high-risk conditions or history of hospitalization for pneumonia or influenza  
Pregnant women  
Household contacts of severely immunocompromised People  
Household contacts of children ≤6 months of age  
Public health and emergency response workers  
Key government leaders | Vaccine production and distribution workers  
Frontline health-care workers | Vaccine production and distribution workers  
Frontline health-care workers |
| 2     | Healthy people ≥65 years old  
People 6 months to 64 years old with 1 or more high-risk conditions  
Healthy children 6 months to 23 months old  
Other public health workers, emergency responders, public safety workers (police and fire), utility workers, transportation workers, telecommunications and IT workers | Healthy 6-month-olds  
Healthy 1-year-olds  
Healthy 2-year-olds  
Healthy 3-year-olds etc. | People 13 to 40 years old with <2 high-risk conditions, with priority to key government leaders; public health, military, police, and fire workers; utility and transportation workers; telecommunications and IT workers; funeral directors  
People 7 to 12 years old and 41 to 50 years old with <2 high-risk conditions with priority as above  
People 6 months to 6 years old and 51 to 64 years old with <2 high-risk conditions, with priority as above†  
People ≥65 years old with <2 high-risk conditions |
| 3     | Other health decision-makers in government  
Funeral directors | People with life-limiting morbidities or disabilities, prioritized according to expected life years | People 6 months to 64 years old with ≥2 high-risk conditions |
| 4     | Healthy people 2 to 64 years old | | People ≥65 years old with ≥2 high-risk conditions |

* Tiers determine priority ranking for the distribution of vaccine if limited in supply. †Subtiers in purple text establish who gets priority within the tier (starting from the top of the tier) if limited vaccine cannot cover everyone in the tier; prioritization may occur within subtiers as well. ‡Children 6 months to <13 years would not receive vaccine if they can be effectively confined to home or otherwise isolated.
Why an Ethical Framework?

Decision-makers need a moral compass during public health crisis. Proportion of crisis unknown-framework needed that will guide.

*Difficult decisions will have to be made. How, why, when & by whom?*
Ethical Framework as a Guide in Decision-making

Decision–making for and during a pandemic influenza outbreak ought to be:

- 1) *guided* by ethical decision-making *processes* &.
- 2) *informed* by ethical *values*. 
STAND ON GUARD FOR THEE

Ethical considerations in preparedness planning for pandemic influenza

November 2005

A report of the University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group
Guiding Values

- Individual Liberty
- Protection of the public from harm
- Proportionality
- Privacy
- Equity

- Duty to Provide Care
- Reciprocity
- Trust
- Solidarity
- Stewardship
Ethical Processes: A4R (Norman Daniels)

- Ethical Decision-Making Processes are:
  - Open and Transparent
  - Reasonable
  - Inclusive
  - Responsive
  - Accountable
Decision Review Process: Essential Features (Jennifer Gibson)

- Anticipating the need for decision review process prior to crisis
- Assessing pre-existing mechanisms - ensure they are sufficient & adhere to ethical principles
“In the midst of a crisis where guidance is incomplete, consequences uncertain, & information constantly changing, where hour by hour decisions involve life & death, fairness is more important rather than less.” Bell et. Al. 2004
Key Ethical Issues

1. Duty to Care
2. Restrictive Measures
3. Priority Setting
4. Global Governance
Ethical Issue 1: Duty to Care

Recommendations

1. Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu. Existing mechanisms should be identified, or means should be developed, to inform college members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.

2. Governments and the health care sector should ensure that:
   a. care providers’ safety is protected at all times, and providers are able to discharge duties and receive sufficient support throughout a period of extraordinary demands; and
   b. disability insurance and death benefits are available to staff and their families adversely affected while performing their duties.

3. Governments and the health care sector should develop human resource strategies for communicable disease outbreaks that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles in the management of an outbreak, and that are equitable with respect to the distribution of risk among individuals and occupational categories.
Ethical Issue 2: Restrictive Measures

Recommendations

1. Governments and the health care sector should ensure that pandemic influenza response plans include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be founded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm, and should build in safeguards such as the right of appeal.

2. Governments and the health care sector should ensure that the public is aware of:
   i. the rationale for restrictive measures;
   ii. the benefits of compliance; and
   iii. the consequences of non-compliance.

3. Governments and the health care sector should include measures in their pandemic influenza preparedness plans to protect against stigmatization and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.

4. Governments and the health care sector should institute measures and processes to guarantee provisions and support services to individuals and/or communities affected by restrictive measures, such as quarantine orders, implemented during a pandemic influenza emergency. Plans should state in advance what backup support will be available to help those who are quarantined (e.g., who will do their shopping, pay the bills, and provide financial support in lieu of lost income). Governments should have public discussions of appropriate levels of compensation in advance, including who is responsible for compensation.
Ethical Issue 3: Priority Setting

Recommendations

1. Governments and the health care sector should publicize a clear rationale for giving priority access to health care services, including antivirals and vaccines, to particular groups, such as front line health workers and those in emergency services. The decision makers should initiate and facilitate constructive public discussion about these choices.

2. Governments and the health care sector should engage stakeholders (including staff, the public, and other partners) in determining what criteria should be used to make resource allocation decisions (e.g., access to ventilators during the crisis, and access to health services for other illnesses), should ensure that clear rationales for allocation decisions are publicly accessible and should provide a justification for any deviation from the pre-determined criteria.

3. Governments and the health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions, and to resolve disputes.
Ethical Issue 4: Global Governance

Recommendations

1. The World Health Organization should remain aware of the impact of travel recommendations on affected countries, and should make every effort to be as transparent and equitable as possible when issuing such recommendations.

2. Federal countries should utilize whatever mechanisms are available within their system of government to ensure that relationships within the country are adequate to ensure compliance with the new International Health Regulations.

3. The developed world should continue to invest in the surveillance capacity of developing countries, and should also make investments to further improve the overall public health infrastructure of developing countries.
In addition...

- Mechanism to expedite research ethics review during a public health crisis
- Ethical treatment of animals – culling of birds
- Compensation for farmers
- Huge disparities between rich & poor people/nations hit by health crisis
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Joint Centre for Bioethics University of Toronto
http://www.utoronto.ca/jcb/home/main.htm
Additional Resources