

Minutes from the April 28, 2011

CDC Advisory Committee to the Director

***Release Date
July / 2011***



Advisory Committee to the Director: Record of the April 28, 2011 Meeting

Table of Contents

Advisory Committee to the Director Record of the April 28, 2011 Meeting.....3
Call to Order, Welcome, and Introductions.....3
Ethics Subcommittee Report: Ethical Considerations for Non-Communicable Disease Interventions
.....3
Ethics Subcommittee Report: Ethical Considerations for Decision-Making Regarding Allocation of
Mechanical Ventilators During a Severe Influenza Pandemic or Other Public Health Emergency7
National Biosurveillance Advisory Subcommittee Final Report: “Improving the Nation’s Ability to
Detect and Respond to 21st Century Health Threats: Second Report of the National
Biosurveillance Advisory Subcommittee”8
State, Tribal, Local, and Territorial (STLT) Workgroup: Directional Recommendations for Enhancing
CDC Support to STLT Community9
Global Workgroup (GWG) Update.....14
Public Comments14
Closing Remarks.....14
Certification16
Attachment #1: Attendance17
Attachment #2: Acronyms Used in This Document.....24



**Advisory Committee to the Director
Record of the April 28, 2011 Meeting**

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director on April 28, 2011. The agenda included reports from the Ethics Subcommittee; the National Biosurveillance Advisory Subcommittee (NBAS); State, Tribal, Local, and Territorial (STLT) Workgroup; and the Global Workgroup (GWG).

Call to Order, Welcome, and Introductions

Dr. Eduardo Sanchez, ACD Chair, called the meeting of the Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC), to order at 1:06 pm. A quorum of 18 ACD members was present on the call. Dr. Sanchez recognized that a number of other staff members from CDC and CDC Foundation were present on the call.

Dr. Sanchez welcomed four new members to the ACD: Sylvia Drew Ivie, JD, and Dr. Benjamin Chu, who spoke at the October 2010 ACD meeting; and Dr. George Isham and Dr. Anthony Iton. Dr. Sanchez emphasized that the ACD ordinarily meets in person and has time to work through issues, and that telephone meetings are the exception rather than the custom.

The following conflicts of interest were indicated by ACD members:

- Dr. Alan Greenberg disclosed that his department receives indirect funding from CDC on three projects: DC Department of Health, Elizabeth Glazer Pediatric AIDS Foundation, and Association of Public Health Laboratories.
- Dr. Sara Rosenbaum disclosed that her department in health policy receives at least one CDC grant that focuses on sexually transmitted diseases, health policy, and Patient Protection and Affordable Care Act (PPACA).

**Ethics Subcommittee Report:
Ethical Considerations for Non-Communicable Disease Interventions**

Dr. Sanchez introduced Ruth Gaare Bernheim, Chair of the Ethics Subcommittee. He explained that during the ACD's meeting in October 2010, there was discussion of ethical considerations for non-communicable disease (NCD) interventions. The Ethics Subcommittee was asked to create a framework around these issues.

Ms. Bernheim thanked the ACD for the opportunity to present and acknowledged the input of the two ACD representatives on the Ethics Subcommittee, Cass Wheeler, and Sara Rosenbaum. She explained that the central question regarding the ethics of non-communicable disease interventions is, *"How can we address ethical tensions that arise when public health intends to implement restrictive or regressive policies and approaches that focus on chronic diseases and injuries rather than infectious diseases?"*

The ethics of NCD interventions raises specific questions:



Advisory Committee to the Director: Record of the April 28, 2011 Meeting

- ❑ When is it appropriate or acceptable for public health to limit individual choice, either directly, such as by requiring use of helmets or prohibiting use of food vouchers for soft drinks, or indirectly, such as increasing taxes on cigarettes?
- ❑ What are the ethical considerations that need to be thought through in these situations?
- ❑ How do we best facilitate the adoption of public health interventions for NCDs?

The Ethics Subcommittee discussed a strategy for addressing the central question. They further discussed how to expedite the translation of scientific knowledge into implementation of interventions that protect the public, prevent disease and injury, and promote health. The gap between knowledge and implementation is an important area of focus for policy makers and public health officials. In this gap, it is critical to have information about values and norms, as well as the competing claims of various stakeholders.

While population health impact, based on science and data, is the preeminent value animating public health, moving from science to implementation involves collective action and acceptance by the public. Given the religious and moral pluralism in society, it is inevitable that ethical tensions arise in public health that cannot be resolved without some controversy and without policy justifications in the “gap” between science and implementation. Therefore, implementation of effective programs and policies requires understanding the competing moral claims of various stakeholders, and developing counter claims and policy rationales that resonate ethically with the public at any given time.

The story of tobacco control illustrates this point. Public health justifications countered early claims of paternalism that were mounted against tobacco restrictions by focusing on third party harms, youth onset, and the addictive quality of tobacco. These counter ethical arguments garnered support for grassroots initiatives at the local and state levels. The various initiatives (e.g., smoking bans in restaurants, point-of-sale restrictions, and anti-tobacco curricula in schools) were ethically acceptable in particular communities at different times across the country. Understanding context matters in the gap. Local and state successes in the gap helped foster larger shifts in social norms and generated the political will necessary for stronger and more restrictive tobacco control measures. State and local health departments have expressed strong interest in more ethics training and guidance. With regard to NCD issues, the goal is to use a combination of interventions that are least restrictive and most empowering of individuals. They may begin with interventions that focus on information and non-coercive nudges so that over time, social norms are changed without the need for sanctions and enforcement.

Ethical analysis in public health provides information about stakeholder values, norms, and ethical tensions. This analysis is parallel to legal consultation in that it provides a systematic way to understand, balance, and address competing claims, and provides a method for developing policy justification or rationales. For example, perhaps a proposed tax, such as a much higher tax on tobacco products, is likely to disproportionately affect vulnerable and poor populations. Upon analysis, the tax may be justifiable: 1) If the revenues generated from that tax are used only for programs for the poor; 2) If there is evidence that those programs are likely to be successful in lowering tobacco use among



that group; and 3) If it is shown that they are necessary to address disparities in tobacco use and get to the next stage of this Winnable Battle.

The Ethics Subcommittee considered various levels of public health interventions and examined how the mandate for government action and the tensions created by competing stakeholder claims vary for different intervention content areas. One example is a classic case that state and local health departments face regularly: interventions for preventing the transmission of infectious diseases, such as tuberculosis (TB). These interventions typically involve restricting individual liberty by placing restrictions on movement in the name of protecting the public good. These types of interventions are generally well-accepted by the public and are believed to be justifiable when there is a risk of direct harm to others. Factors that influence acceptability are severity, probability, and the imminence of risk or harms. These types of interventions show that alignment of the public with government authority is strongest when members of the public fear imminent harm and / or risk of infectious disease for themselves or their families.

Another example involves the use of sanctions and enforcement for injury prevention, such as legislation requiring airbags in cars, use of seatbelts, and motorcycle helmets. These types of interventions often focus on product regulation and making it safer to use vehicles. Product regulation and the safe use of products is widely accepted by the public as within government's appropriate domain; however, these regulations were initially perceived by some as coercive government intervention that limited individual liberty. Framing these interventions as ways to avoid or reduce social costs to others and as the best way to make products and the environment safer for individuals has led to greater acceptance of these types of interventions.

An additional example focuses on interventions for chronic disease prevention that involve use of incentives and nudges. In the prevention of cardiovascular disease and lung cancer, the use of coercive interventions that override individual liberty, such as limiting tobacco use, was initially not widely accepted to be within the government's purview. This case is instructive because despite having overwhelming scientific evidence concerning tobacco's danger to health, it required decades of activities in the gap addressing stakeholder claims and values to begin making a case for stronger tobacco regulation.

It is useful to compare the public values pertaining to the proposed soda tax and cigarette tax. Both of these interventions are seen by some as regressive in that the burden falls most heavily on those with less disposable income. The health effects of both products are proportional to use. Health effects of moderate consumption of sugared beverages are less clear, however, as soda is not an inherently dangerous product that directly leads to increased disease risk. Further, the relationship between cigarette use and indirect harms to others is clear, whereas the impact of soda use on others is unclear. From a public health ethics perspective, neither of these taxes addresses the root cause of the role of manufacturers in producing and marketing unhealthy products.

It is clear that the context of the public's view of the use of governmental public health authority to override individual liberty changes along the spectrum from government protection to prevention and promotion. It is also clear that in chronic disease prevention, some public resistance focuses on the appropriateness of government's role. Some perceive these types of government interventions as unnecessary because there is no imminent risk of grave harm. These interventions are also sometimes perceived as



unjustified intrusions into individual liberty and a “slippery slope” to the “nanny paternalistic state.”

Approaches to chronic disease are especially challenging because they often involve behavior change in the population, which can also lead to claims about a “nanny government.” Unlike infectious disease control, where there is more support for government authority, judicious use of government authority is key in NCD issues. For example, policies that shift default conditions in the environment to make it easier for individuals to choose healthier food options are powerful tools, partially because this use of authority is ethically supported in that the policies support individual choices and enhance personal freedoms. Thus, in chronic disease, it is important to counter claims of paternalism and “nanny government” by demonstrating support for individual responsibility and enhanced consumer choice. It is also important to remember that changing social norms and behavior is a gradual process. There are advantages to working with coalitions and in collaboration with stakeholder groups, including affected industries. Legal intervention or policy may be helpful, and should be within already-accepted government mandates whenever possible. Even the declarative effect of some laws can assist with the gradual change of social norms, as with seat belt laws.

The Ethics Subcommittee felt that ethical frameworks and precedent cases could be helpful in developing interventions in a gradual sequence, taking into account evolving social values, unintended consequences, and the policy rationales in the public arena. Health equity is also an important ethical concern. The tools of tobacco control, for instance, have been relatively ineffective in reaching lower socioeconomic groups. For example, some tobacco control interventions have a disproportionate effect on the poor who can least afford to pay higher tobacco taxes.

To achieve implementation and best outcomes, CDC must not only gather surveillance data and provide scientific evidence about health impact and effectiveness of interventions, but also should gather information about this area of the gap between knowledge and implementation. To do that, public health officials need information about ways to address ethical tensions in the gap creatively, with counterarguments based in science or with imaginative policy justifications based on ethical considerations or principles, to facilitate implementation. Science and data are the foundation of public health and are critically necessary, but may not be sufficient to win the battles involving competing moral claims in the gap.

Discussion Points

- Dr. Sanchez thanked Ms. Bernheim and acknowledged Dr. Drue Barrett, the Designated Federal Officer (DFO) for the Ethics Subcommittee. He commented that the presentation provides a beginning of a framework for thinking about the translation of scientific knowledge into policy and practice. He felt that CDC leadership should have time to review the presentation in order to assess how the Ethics Subcommittee might best provide further input. There is a desire among those who engage in public health work for this information to address the ethical tensions in that gap. The Ethics Subcommittee is developing case studies, and the examples provided in the presentation peaked his interest. The development of the cases may be useful in helping people think through the challenges they encounter in their work.
- Dileep G. Bal, MD, MS, MPH, District Health Officer, Island of Kauai, Hawaii, thought the presentation was fascinating and comprehensive. However, he expressed his



hope that the presentation did not imply that any interventions should slow down pending what could be an extended and drawn-out review of these ethical considerations. Further, he hoped that the presentation would not have the reverse effect of its intent. In recent years, the translation of scientific evidence to policy has been hampered by various elements, including social context. If ethical consideration issues are introduced as a major level of litmus test, it may do a disservice to the process. He was thinking specifically of obesity in this instance. While he observed that the presentation was thoughtful and balanced, Dr. Bal was concerned that it may give naysayers in industry evidence to call for more science and to ask for a slowdown in interventions.

- Ms. Bernheim replied that their goal is the opposite of slowing things down. The intent is to address barriers in the gap area that slow the process from science to implementation. In particular, competing moral claims in the gap should be addressed. Addressing the barriers will speed movement from science to implementation. Barriers can include scientific information that is not well-understood, as well as stakeholder moral claims that are introduced by those who want to slow movement to policy.
- Carmen Villar, MSW, Chief of Staff, CDC, DFO for the ACD, clarified that the presentation did not need to be accepted formally by the Committee. The presentation will be shared with senior CDC staff for further discussion.

Ethics Subcommittee Report:

Ethical Considerations for Decision-Making Regarding Allocation of Mechanical Ventilators During a Severe Influenza Pandemic or Other Public Health Emergency

Ms. Bernheim reminded the group that the Ventilator Document provides an overview of ethical points to consider for the allocation of ventilators during a severe influenza pandemic when the number of people requiring ventilation outnumbers the available supply of ventilators. The document is intended to supplement a previous document written by the Ethics Subcommittee, "Ethical Guidelines in Pandemic Influenza," which was released in 2007. This document focused on the allocation of vaccines and antivirals and the use of interventions to create social distancing.

Since the ACD last reviewed this document in April 2010, comments were solicited from a variety of public health, healthcare, and emergency management professionals, including hospital directors, administrators, physicians, and risk managers; hospital associations; professional medical associations; state health department officials; regional emergency coordinators; non-profit organizations; and private physicians and community / patient advocates. The comments pointed to the importance of having ethics input on ventilator allocation decisions and raised a number of issues relating to implementation details; the needs of infants and children; the triage process and details about the triage team; uniformity of decision making versus local flexibility; and the importance of public engagement.

The primary revisions to the document involved adding language to reiterate the intent of the document to serve as a conceptual framework for assisting the planning process and to emphasize that planning still needs to occur at the state, local, and institutional level to develop specific operational details and implementation steps. The Ethics Subcommittee also added a section on special considerations relating to children.

The Ethics Subcommittee hopes to finalize this document so that it can be of assistance to the public health officials who act “on the front lines.” These issues have been raised in the Ethics Subcommittee’s series of Webinars, Ms. Bernheim noted.

Discussion Points

- Dr. Sanchez thanked the Ethics Subcommittee for its work in creating the ventilator allocation document, and for gathering input from a wide range of public health practitioners and emergency responders. People in the field are clearly thinking about these issues, and are in need for a framework of ethical considerations as they plan.
- Ms. Bernheim acknowledged the service of Cass Wheeler, who will rotate off the ACD at the end of June 2011. He has been an important member of the Ethics Subcommittee, and they have appreciated his insights. With his departure, there is an opening for a second ACD representative on the Ethics Subcommittee. Any interested ACD members should contact Ms. Villar, Dr. Barrett, or Dr. Sanchez. Ms. Bernheim offered to speak with anyone who had questions about the Subcommittee.

Motion

It was moved and seconded to accept the Ethics Subcommittee report on ventilator allocation. The ACD accepted the document unanimously, with Dr. George Isham and Dr. Anthony Iton abstaining.

National Biosurveillance Advisory Subcommittee Final Report: “Improving the Nation’s Ability to Detect and Respond to 21st Century Health Threats: Second Report of the National Biosurveillance Advisory Subcommittee”

Dr. Sanchez reminded the group that the National Biosurveillance Advisory Subcommittee (NBAS) was established by the ACD in May 2008 as a result of a mandate in Homeland Security Presidential Directive-21. The Biosurveillance Coordination Activity in CDC’s Public Health Surveillance Program Office provides support to the NBAS. The Subcommittee is charged with providing biosurveillance recommendations to the federal government. The first report of NBAS was completed in April 2009 and was approved at the ACD Meeting in October 2009. Dr. Sanchez acknowledged the tremendous amount of work conducted by NBAS members. The second iteration of NBAS began its work last summer.

NBAS Co-Chair, Dr. Jeffrey P. Engel, provided an overview of the NBAS final report. Six workgroups were responsible for preparation of the report, and recommendations contained therein represent the input of the entire subcommittee. The process was highly collaborative, and the six workgroups included the following:

- Governance (Inter-Agency Collaboration and Engagement)
- Healthcare and Public Health Information Exchange
- Innovative Information Sources
- Global and Regional Biosurveillance Collaboration



- Biosurveillance Workforce, New Professions and Cross-Training
- Integrated Multi-Sector Information

Dr. Tom Frieden, CDC Director, attended the NBAS meeting in August 2010. He suggested that NBAS focus on thoughts to action and concrete recommendations. The Subcommittee appreciated Dr. Frieden's attendance and comments, and the workgroups subsequently conducted 46 meetings and 74 briefings. The group maintains a GoogleDocs collaborative website containing over 230 documents. The workgroup reports were completed on January 31, 2011. On February 1, 2011, the NBAS co-chairs and workgroup champions met to review the reports and identify common themes, determining the direction of the NBAS report recommendations.

NBAS Co-Chair, Dr. W. Ian Lipkin, emphasized that the NBAS members worked together closely and the Subcommittee was unanimous in its recommendations. The first NBAS report was the basis of their work, and many of the recommendations in the first report continue into the second. He presented the following four consolidated themes that emerged from NBAS's most recent discussions:

- Governance
- Information Exchange
- Workforce Needs
- Research and Development

Dr. Pamela S. Diaz (Director, Biosurveillance Coordination, Public Health Surveillance Program Office, Office of Surveillance, Epidemiology, and Laboratory Services (OSELs), Designated Federal Officer, NBAS) commented that the report represents a successful next step in providing recommendations to the federal government. Members of the National Security Staff of the White House have engaged the Subcommittee over the course of its deliberations, and there appear to be first steps underway toward organizing the biosurveillance enterprise of the federal government. A sub-inter-agency policy committee has been formed. She pointed out that the second NBAS report includes the individual workgroup reports, which were attached as appendices to the report.

Motion

It was moved and seconded to accept the second report from NBAS. The motion was unanimously accepted, with no abstentions.

**State, Tribal, Local, and Territorial (STLT) Workgroup:
Directional Recommendations for Enhancing CDC Support to STLT Community**

Dr. Sanchez introduced the State, Tribal, Local, and Territorial (STLT) Workgroup, which is chaired by Dr. David Fleming, and which includes several ACD members. He emphasized that a Workgroup is different from a Subcommittee, and noted that the next ACD meeting would include guidance on these differences. The STLT Workgroup was created to provide input to the ACD on STLT public health policies and priorities; provide



Advisory Committee to the Director: Record of the April 28, 2011 Meeting

input as requested to the ACD regarding other CDC programs; and provide public health practice input to the ACD from the STLT community to assist in translating public health science and innovation into practice.

Public health is facing unprecedented challenges, from economic challenges to NCDs. Public health entities and jurisdictions bear the brunt of the current economic environment and inevitable budget cuts. CDC will need to be an effective partner in helping to address STLT public health issues. To answer this need, in October 2010, the ACD issued a specific charge to the STLT Workgroup to produce recommendations for the ACD to consider how CDC should provide assistance and frame new and existing grants to maximize resources to develop the needed capacity throughout the STLT community. This assignment is large and open-ended.

This presentation is the start of a conversation. The Workgroup generated 18 recommendations across four focus categories: Flexibility, Outcome-Focused and Accountable, Substantial Engagement, and Technical Assistance. The STLT Workgroup is requesting that ACD review the directional recommendations, provide input, and determine next steps.

STLT Workgroup Chair, Dr. David Fleming, pointed out that the charge to the STLT Workgroup recognizes that much, if not most, of CDC's effect in the United States is as a result of the monies that flow from CDC to governmental public health partners at the state, tribal, local, and territorial levels. The STLT Workgroup was asked to make recommendations regarding how to improve that process. These recommendations are a high-level, conceptual first pass. The STLT Workgroup seeks approval to further vet these recommendations within CDC in order to proceed and generate more specificity. This task is especially relevant now, given funding pressures and the likelihood of budget reductions at all levels of government, which will require that they conduct business more efficiently. The STLT Workgroup created a sub-group to consider these issues. Dr. Fleming acknowledged the hard work of this group. A breadth of expertise from all aspects of governmental public health was represented on the workgroup. Rather than focusing on the mechanics of how monies are distributed, the workgroup instead examined larger policy issues.

CDC's operating environment is undergoing important changes. Continued cuts in domestic spending are expected, and changes to, or repeal of, PPACA are possible. Cuts to CDC's budget are probable. Mechanisms for how the cooperative agreement process works are not just determined by CDC, but in conjunction with the Department of Health and Human Services (HHS) and Congress. Important transformations in public health practice are also occurring at the STLT level. Most state and local health departments have endured years of budget cuts. Consequently, some core public health programs and efforts are increasingly at risk not only due to budget shortfalls, but also due to the slowing of hiring and contracting processes. Public health infrastructure has never been well-funded, and it is especially fragile in this environment as increasing requirements are being placed on the infrastructure to do its job more efficiently and effectively. Tremendous loss in capacity has occurred at the state and local level, with about 20% of the state health department workforce and about 15% of the local health department workforce being cut in the last few years.

The workgroup established a vision for how the cooperative agreement process could be improved. The current process does not fail in these areas, but the group felt that



progress could be made in these areas. There is a need to prioritize and target resources to the most pressing health needs of the country. There is inefficiency in the current categorical, or siloed approach to funding. In an era of increased demands for accountability and performance, clearer goals and objectives with measurable outcomes should be developed. With increasing sophistication in the public health workforce, active partnerships should be cultivated between CDC and STLT groups. The evidence and science bases are critical to the work they do, but many of their problems are not fully amenable to attack by proven science. Therefore, there is a need to remain innovative. Although funding is likely not to be stable, the cooperative agreement process should assume that funding will be long-term and reliable. With reductions in infrastructure, funds should be better used for critical infrastructure needs.

Dr. Fleming described the Workgroup's recommendations to CDC in each of the categories:

Flexibility

- CDC should work with HHS to determine strategies for greater flexibility to award funds for jointly developed deliverables that cut across current categorical programs.
- CDC should evaluate feasibility and, where possible, grant awards that are bundled or integrated, rather than limited or categorical in nature.
- CDC should enable funding and coordination of linked or common activities that cross multiple grants within a single jurisdiction.
- CDC should develop and implement a process to better define and fund program-related and agency-wide infrastructure costs that are necessary for effective execution of grants.
- CDC should think about new cross-jurisdictional approaches, incentivizing collaborations across states, tribes, territories, and counties with unified funding.
- CDC should develop a new mechanism for quickly resolving questions about expenditures and grant funds. This recommendation does not suggest a "court process," but a streamlined way to resolve disagreements.
- CDC should support a more interactive process at the start of a cooperative agreement, which would allow for openness and innovative approaches.

Outcome-Focused and Accountable

- CDC should create incentives that enable the use of grant funds to attack not only end-stage disease issues, but also the causal social determinants that underpin specific program goals.
- CDC should develop consistent, cross-CDC guidance to balance and define the use of metrics for both process and outcome accountability in Cooperative Agreements.
- In adopting a categorical approach, it is possible to "lose sight" of what the overall public health enterprise seeks to accomplish. CDC should encourage a strategic focus on balancing those categorical outcomes with public health system enterprise objectives. For example, surveillance systems should be designed into a "horizontal" approach at the state and local level, rather than being only for one disease.

Advisory Committee to the Director: Record of the April 28, 2011 Meeting

- ❑ CDC should recognize the need for innovation and develop specific approaches that enable a balance of innovation and the evidence base.
- ❑ In this era of increased accountability and attention to performance, CDC should support the Public Health Accreditation Board (PHAB) process as a beneficial measure of infrastructure and capacities.

Substantial Engagement

- ❑ CDC should seek meaningful input in a consistent and predictable way from the STLT community in areas such as making the business case, setting priorities, determining goals and objectives, and selecting intervention and evaluation methods.
- ❑ CDC should establish enterprise-wide, consistent principles related to the Cooperative Agreement approach. CDC has a wide reach, but there is inefficiency in the different rules and processes that govern cooperative agreements across different centers, institutes, and offices (CIOs). At the execution level, these differences are complicated.
- ❑ CDC should consider the nature of the expertise provided by Project Officers. These Officers guide the grants' execution and should have expertise in grant management issues and in technical issues.
- ❑ CDC should hire, train, and recruit Project Officers with a knowledge of current and emerging best practices as well as an extensive understanding of the diversity and reality of practice in the field.

Technical Assistance

- ❑ CDC should consistently offer grantees access to program expertise using not just internal, but external stakeholder organizations and contractors. More peer-to-peer assistance across Cooperative Agreements would be a promising approach.
- ❑ CDC should prioritize working with grantees toward a process of continuous quality improvement (CQI) of program effectiveness.

Regarding the next steps envisioned by the STLT Workgroup, the broad recommendations presented by the workgroup should be translated into more specific recommendations which can be operationalized. There should be work within the Workgroup and with Office for State, Tribal, Local and Territorial Support (OSTLTS) to develop an on-going process to operationalize the recommendations. The Workgroup felt that additional issues remain that are not addressed in this set of recommendations. The group would like to address these issues in the future. Examples include: 1) Formula versus competitive funding for cooperative agreements. Competitive funding may allow dollars to go to those who are best able to deliver programs. Formula funding assures that the areas that are most in need receive resources; and 2) In terms of eligibility for cooperative agreements, particularly at the local level, should metropolitan areas or small health departments be direct recipients of grants, or should funds flow through state health departments? More work is also needed to develop a suite of process and outcome metrics that is more consistent across cooperative agreements and will allow for a demonstration of performance.

The workgroup recommended that OSTLS take the recommendations, with any modifications or changes suggested by ACD, and vet them to obtain CDC's perspective of their merit and to generate specific ways to execute them. The STLT Workgroup will then



incorporate those results into a more specific and final set of recommendations for the full ACD during the October 2011 meeting.

Discussion Points

- Dr. Sanchez noted that the ACD is not “shy to talk.” Their compressed time schedule and telephone meeting may have caused them to self-censor, but he assured the new ACD members that lively discussion would take place at their in-person meeting. He thanked Dr. Fleming for the presentation and appreciated that CDC is working on these issues.
- Regarding the “Outcome-Focused and Accountable” recommendations, Sara Rosenbaum, BA, JD, George Washington University, asked for an example of a specific issue that CDC works on in collaboration with stakeholders and how these recommendations might play out in practice.
- Dr. Fleming replied that the workgroup hopes to take the next step to work with individual CDC programs to vet the recommendations and to increase their specificity. CDC is moving in this direction in its chronic disease granting programs. Historically, this program has included a large number of categorical grants around specific disease issues. While they have been effective, the programs may not have been as efficient as they could be because of a lack of consistency across approaches, especially in terms of how outcomes are defined, how specific rules of the agreements work, the number of different program officers, and other issues. Improved communication will help alleviate transaction costs at the local and state levels as those officers translate multiple, independent funding streams into a coordinated community approach. Synthesizing and combining programs with common processes and practices will increase efficiency. Many factors underpin an effective chronic disease program, including expertise in advocacy, communications, and other areas. No individual grant provides that necessary infrastructure support. Designated funding is needed for this kind of support across grants.
- Regarding the recommendations under “Technical Assistance,” George Isham, MS, MD, Chief Health Officer and Plan Medical Director, HealthPartners, commented that CQI is one type of management technique that focuses on process improvement. In this context, he asked whether the workgroup considered CQI in a narrower, technical sense or in a broad sense that encompasses a broader suite of process management tools.
- Dr. Fleming clarified that the group’s intent was to think broadly about the various available methodologies for improving program effectiveness.
- Dr. Bal acknowledged the excellent work done by the workgroup chair and OSTLTS staff. He noted that Dr. Anthony Iton has a model for addressing social justice issues early in the process of structural change. He felt that it would be useful to add Dr. Iton, or someone with similar expertise, to the workgroup.
- Anthony Iton, MD, JD, MPH, Senior Vice President for Healthy Communities, the California Endowment, expressed that he would enjoy participating in the workgroup and noted his appreciation for their work thus far. He felt that great progress had been made in thinking about the relationship between CDC and the STLT community. This area is critical for advancing chronic disease and health equity practices.
- As there were no additional comments, Dr. Sanchez thanked Dr. Fleming and those who had worked hard to generate the recommendations. The recommendations are



Advisory Committee to the Director: Record of the April 28, 2011 Meeting

in line with the mission of CDC and the public health enterprise. There was support for the STLT Workgroup moving forward as planned.

- Dr. Fleming said that he would return to the Workgroup with the understanding that ACD's support was at a sufficiently high level for the Workgroup to proceed and move through the vetting process.

Global Workgroup (GWG) Update

Global Work Group Chair, Dr. Alan Greenberg, offered updates on the Global Workgroup (GWG). He thanked his fellow ACD members on the workgroup and invited any of the new ACD members to join them. GWG is a new workgroup of the ACD, which was charged to gather information for the ACD and make recommendations to the ACD regarding the newly-formed Center for Global Health (CGH) at CDC. The first GWG meeting was convened prior to the ACD meeting in October 2010. This workgroup includes ACD members, external experts, international representatives, and senior leadership at the CGH. Dr. Greenberg presented a summary of their discussions at the ACD meeting on October 28, 2010. He created a brief summary report, and the full content of the meeting was reported via detailed minutes of the meeting, both of which have been reviewed by the GWG and are provided to the ACD.

The second meeting of the GWG was held in Atlanta on April 27, 2011. The workgroup felt that it would be of benefit to convene another in-person meeting in advance of this ACD meeting. Given the reformatting of the ACD meeting, they did not have complete attendance, but did have good representation. The CGH provided further updates on its important work, and numerous other CDC centers summarized their global health activities. This meeting gave the GWG and the CGH the opportunity to better understand the wide spectrum of global activities at CDC. The GWG will develop a brief summary of the second meeting, and the CGH will provide the full meeting minutes to the ACD in advance of the next ACD meeting.

Discussion Points

- Larry Slutsker, MD, MPH, Associate Director for Science, CGH, spoke on behalf of the center. He thanked Dr. Greenberg for his work, noting that the GWG was a strong partner with the center.
- Dr. Fleming added that the new Center holds tremendous promise.
- Dr. Sanchez said that the GWG would be included on the agenda of the fall 2011 ACD meeting.

Public Comments

No public comments were offered during this ACD meeting.

Closing Remarks

Ms. Villar thanked Dr. Sanchez for chairing the meeting, and she thanked the ACD members for their time and flexibility. During the next meeting, language will be provided regarding workgroup specifics. She thanked Gayle Hickman for her hard work.



Advisory Committee to the Director: Record of the April 28, 2011 Meeting

Dr. Sanchez thanked all of those who support the subcommittees and workgroups. He summarized the results of the meeting, reminding everyone that they addressed important issues concerning ethical considerations for non-communicable disease interventions; they voted to accept the ventilator allocation document from the Ethics Subcommittee; they voted to accept the second NBAS report; the STLT Workgroup presented a set of recommendations; and they will hear more from the GWG during the Fall 2011 meeting.

Dr. Sanchez thanked the ACD members who would rotate off of the committee on June 30, 2011, including Nick Baird, Nisha Botchwey, Ken Mandl, John Seffrin, and Cass Wheeler. He thanked them all for the work they had done in support of CDC and in support of the health of the nation.

Dr. Bal asked about the next steps for the report from the Ethics Subcommittee regarding ethical considerations in non-communicable disease interventions. He suggested that the presentation serve as an opening foray into the issues, but that they discuss it further due to the possibility that it could be used by industry for purposes other than they intended. Dr. Sanchez agreed and asked them to keep that precautionary point in mind.

Motion

It was moved and seconded to adjourn the meeting. The motion was approved unanimously, and Dr. Sanchez adjourned the meeting at 2:47 p.m.



Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the April 28, 2011 meeting of the Advisory Committee to the Director, CDC are accurate and complete.

Date

Eduardo J. Sanchez, MD, MPH, FAAFP
Chair, Advisory Committee to the
Director, CDC



Attachment #1: Attendance

ACD Members Present:

James Nicholson (Nick), Baird, Jr., MD

Chief Executive Officer, Alliance to Make US Healthiest and
President, Stillwater Solutions, LLC

Dileep G. Bal, MD, MS, MPH

Kauai District Health Officer
Island of Kauai, Hawaii

Nisha D. Botchwey, MCRP, PhD, MPH

Associate Professor of Urban and Environmental Planning and Public Health Sciences,
School of Architecture
University of Virginia

Benjamin K. Chu, MD, MPH, MACP

President, Southern California Region
Kaiser Foundation Health Plan, Inc. and Hospitals

Sanford R. Climan, MBA, MS

President, Entertainment Media Ventures

Suzanne Frances Delbanco, PhD

Executive Director
Catalyst for Payment Reform

Sylvia Drew Ivie, JD

Senior Deputy for Human Services and Development
Office of Supervisor Mark Ridley Thomas
Second District, Los Angeles County Board of Supervisors

Thomas A. Farley, MD, MPH

Commissioner
New York City Department of Health and Mental Hygiene

David W. Fleming, MD

Director and Health Officer for Public Health
Seattle and King County
Chair, STLT Workgroup

Alan E. Greenberg, MD, MPH

Professor and Chair
Department of Epidemiology and Biostatistics
George Washington University School of Public Health and Health Sciences
Chair, Global Workgroup

George Isham, MD, MS

Medical Director and Chief Health Officer
HealthPartners, Incorporated



Anthony B. Iton, MD, JD, MPH
Senior Vice President, Healthy Communities
The California Endowment

Mary Kelly
Executive Vice President
Merchandising and Category Management
Shoppers Drug Mart

Jonathan T. Lord, MD
Chairman of the Board
DexCom, Inc.

Kenneth D. Mandl, MD, MPH
Associate Professor, Harvard Medical School and
Director, Intelligent Health Laboratory, Children's Hospital Informatics Program
Children's Hospital, Boston

Sara Rosenbaum, JD
Harold and Jane Hirsh Professor of Health Law and Policy and Chair
George Washington University Medical Center School of Public Health and Health
Sciences

Eduardo J. Sanchez, MD, MPH, FAAFP
Vice President and Chief Medical Officer
Blue Cross and Blue Shield of Texas

M. Cass Wheeler
Strategic Consultant/Coach/Speaker
Former Chief Executive Officer
American Heart Association, Inc.

ACD Members Absent:

Kelly J. Henning, MD
Director, International Health Programs
Bloomberg Foundation

John R. Seffrin, PhD
Chief Executive Officer
American Cancer Society



Subcommittee Chairs Attending:

Ruth Gaare Bernheim, JD, MPH

Chair, Department of Public Health Sciences, School of Medicine
Associate Director, Institute for Practical Ethics and Public Life
University of Virginia
Chair, Ethics Subcommittee

Jeffrey P. Engel, MD

State Health Director for North Carolina
Division of Public Health
Co-Chair, National Biosurveillance Advisory Subcommittee (NBAS)

W. Ian Lipkin, MD

John Snow Professor of Epidemiology
Director, Center for Infection and Immunity
Mailman School of Public Health
Columbia University
Co-Chair, National Biosurveillance Advisory Committee (NBAS)

CDC Staff Attending:

Ileana Arias, PhD

Principal Deputy Director, CDC
Principal Deputy Administrator
Agency for Toxic Substances and Disease Registry

Drue Barrett, PhD

Lead, Public Health Ethics Unit
Office of the Science Integrity
Office of the Associate Director for Science
Office of the Director
Designated Federal Officer, Ethics Subcommittee

Mark Biagioni, MPA

Public Health Analyst
Office of the Principal Deputy Director

Mark Byers

Management and Program Analyst
Biosurveillance Coordination Activity
Public Health Surveillance Program Office
Office of Surveillance, Epidemiology, and Laboratory Services

Janet Collins, PhD

Associate Director for Program
Office of the Director



Advisory Committee to the Director: Record of the April 28, 2011 Meeting

Linda Degutis, DrPh, MSN

Director
National Center for Injury Prevention and Control
Office of Noncommunicable Diseases, Injury and Environmental Health

Pamela Diaz, MD

Director, Biosurveillance Coordination
Public Health Surveillance Program Office
Office of Surveillance, Epidemiology, and Laboratory Services
Designated Federal Officer, National Biosurveillance Advisory Committee

Kevin Fenton, MD, PhD, FFPH

Director
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Office of Infectious Diseases

Kathryn Foti, MPH

Special Assistant to the CDC Director

Donna Garland, BA

Associate Director for Communication
Office of the Director
Designated Federal Officer, Communications Workgroup

Rana Hajjeh, MD

Division Director
Division of Bacterial Diseases
National Center for Immunization and Respiratory Diseases
Office of Infectious Diseases

Sonja S. Hutchins, MD, MPH, DrPH (SSH1)

Senior Medical Epidemiologist
Office of Minority Health and Health Equity (Proposed)

Gayle J. Hickman

Logistics Specialist
Advance Team
Office of the Chief of Staff
Office of the Director

Robin Ikeda, MD, MPH, CAPT, USPHS

Director for Noncommunicable Diseases, Injury and Environmental Health

Rear Admiral Ali S. Khan, MD, MPH

Assistant Surgeon General
Director, Office of Public Health Preparedness and Response

Rima Khabbaz, MD

Director for Infectious Diseases



Gladys. G. Lewellen, MBA, MPA

Federal Advisory Committee Management Policy and Oversight Team Lead
CDC Committee Management Officer
Management Analysis and Services Office

Leandris Liburd, PhD, MPH

Director, Office of Minority Health and Health Equity (Proposed)
Designated Federal Officer, Health Disparities Subcommittee

Judy Lipshutz, MPH

Public Health Analyst
Office for State, Tribal, Local and Territorial Support
Office of the Director

Amy Loy

Public Health Advisor
Knowledge Management Branch
Division of Public Health Capacity Development
Office for State, Tribal, Local and Territorial Support

Kathy Meyer, MBA

Federal Advisory Committee Management Branch
Management Analysis and Services Office

Judy Monroe, MD

Director, Office for State, Tribal, Local and Territorial Support
Designated Federal Officer, State, Tribal, Local and Territorial Workgroup

Ron Otten, PhD

Director
Office of Scientific Integrity
Office of the Associate Director for Science

Nancy Peterson

HR Specialist
Office of the Chief of Staff

Harald Pietz

Senior Advisor
Technical Assistance Branch
Division of Public Health Capacity Development
Office for State, Tribal, Local and Territorial Support

Robert Pinner, MD

Associate Director, Informatics
National Center for Emerging and Zoonotic Infectious Diseases
Office of Infectious Diseases



Tanja Popovic, MD, PhD, F(AAM), AM(AAFS)

Deputy Associate Director for Science
Office of the Associate Director for Science

Christopher J. Portier, PhD

Director
National Center for Environmental Health/Agency for Toxic Substances and Disease
Registry
Office of Noncommunicable Diseases, Injury and Environmental Health

Andrew S. Rein, MS

Associate Director for Policy
Office of the Associate Director for Policy
Office of the Director

Laurence Slutsker, MD, MPH

Associate Director for Science
Center for Global Health

Dixie Snider, MD, MPH

Special Consultant
Innovation and Special Project Activity
Office of the Associate Director for Science

Esther Sumartojo, PhD, MSc

Associate Director for Science and Public Health
National Center on Birth Defects and Developmental Disabilities
Office of Noncommunicable Diseases, Injury and Environmental Health

Stephen B. Thacker, MD, MSc, ASG/RADM (Ret.), USPHS

Director, Office of Surveillance, Epidemiology, and Laboratory Services

Timothy W. Van Wave, DrPH

Branch Chief (Acting) and Health Scientist
Research and Outcomes Branch
Office for State, Tribal, Local and Territorial Support

Carmen Villar, MSW

Chief of Staff
Designated Federal Officer, ACD

Curtis Weaver, BS, MFA

Public Health Advisor
Biosurveillance Coordination Unit
Public Health Surveillance Program Office
Office of Surveillance, Epidemiology, and Laboratory Services



General Public

Kendra Cox

Cambridge Communications, Atlanta, GA
CDC Contractor Writer/Editor

Lynn R. Goldman, MD, MS, MPH

George Washington University School of Public Health

David Kittross

Senior Editor, CD Publications

Lynne D. Richardson, MD, FACEP

Mount Sinai School of Medicine

Charles Stokes

President and CEO
CDC Foundation

Chloe Knight Tonney

Vice President for Advancement
CDC Foundation

Carrie S. Zoubul, JD, MA

New York State Department of Health



Attachment #2: Acronyms Used in This Document

Acronym	Expansion
ACD	Advisory Committee to the Director
CDC	Centers for Disease Control and Prevention
CGH	Center for Global Health (CDC)
CIOs	Centers, Institutes, and Offices
CQI	Continuous Quality Improvement
DARPA	Defense Advanced Research Projects Agency
DFO	Designated Federal Official
DHS	Department of Homeland Security
DoD	Department of Defense
GWG	Global Work Group
HHS	(Department of) Health and Human Services
NBAS	National Biosurveillance Advisory Subcommittee
NCD	Non-Communicable Disease
NIH	National Institutes of Health
OSELS	Office of Surveillance, Epidemiology, and Laboratory Services
OSTLTS	Office for State, Tribal, Local and Territorial Support
PHAB	Public Health Accreditation Board
PPACA	Patient Protection and Affordable Care Act
STLT	State, Tribal, Local, and Territorial (Workgroup)
TB	Tuberculosis
USDA	United States Department of Agriculture



Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency

*Prepared by the Ventilator Document Workgroup,
Ethics Subcommittee of the Advisory Committee to the Director,
Centers for Disease Control and Prevention*

July 1, 2011

Disclaimer: This document represents the recommendations of the Advisory Committee to the Director, Centers for Disease Control and Prevention and does not necessarily represent Centers for Disease Control and Prevention views or policy. The document was approved by the Ethics Subcommittee on February 18, 2011¹ and by the Advisory Committee to the Director on April 28, 2011.

¹ Members of the Ethics Subcommittee at the time that the document was approved include Ronald Bayer, PhD, Columbia University; Ruth Gaare Bernheim, JD, MPH, University of Virginia; LaVera Marguerite Crawley, MD, MPH, Stanford University; Norman Daniels, PhD, Harvard University; Kenneth Goodman, PhD, University of Miami; Nancy Kass, ScD, Johns Hopkins University; Bernard Lo, MD, University of California, San Francisco; Sara Rosenbaum, JD, George Washington University Medical Center and Advisory Committee to the Director Representative; Jennifer Prah Ruger, PhD, MSc, Yale University; Pamela Sankar, PhD, University of Pennsylvania; Marion Cassady Wheeler, Strategic Consultant and Advisory Committee to the Director Representative; and Leslie Wolf, Georgia State University

Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency

Table of Contents

Table of Contents 2
PREAMBLE 3
INTRODUCTION 4
KEY ASSUMPTIONS..... 4
ROUTINE VERSUS EMERGENCY PRACTICE 6
PRIORITIES FOR VENTILATOR ALLOCATION 8
WHAT PRINCIPLES SHOULD GUIDE VENTILATOR ALLOCATION?..... 10
 Basic Biomedical Ethical Principles 10
 Respect for Persons and their Autonomy..... 10
 Beneficence 10
 Justice..... 10
 Specific Ethical Considerations 12
 Maximizing Net Benefits 12
 Social Worth 14
 The Life Cycle Principle..... 15
 Fair Chances versus Maximization of Best Outcomes 15
 Incorporating Multiple Principles 16
WHO SHOULD MAKE VENTILATOR ALLOCATION DECISIONS? 16
OTHER CONSIDERATIONS..... 17
 Uniform Decision Criteria versus Local Flexibility 17
 Community Engagement 18
 Obligations to Healthcare Professionals 19
 Provision of Palliative Care 20
 Withdrawal of Patients from Ventilators 20
 Special Considerations Relating to Children 21
CONCLUSIONS..... 22
REFERENCES 23
VENTILATOR DOCUMENT WORKGROUP MEMBERS 27

PREAMBLE

This document provides ethical considerations that the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) proposes to aid in the decision making specific to allocation of mechanical ventilators during a severe influenza pandemic. This document supplements a previous document written by the Ethics Subcommittee, *Ethical Guidelines in Pandemic Influenza*, and released by CDC in 2007 (1). The 2007 document was developed in response to a request from HHS/CDC that the Ethics Subcommittee address ethical considerations in vaccine and antiviral drug distribution prioritization and in the development of interventions that create social distancing (in discourse on pandemic influenza, often referred to as non-pharmaceutical or community mitigation interventions). After release of the initial ethics document, numerous public health stakeholders requested that HHS/CDC specifically address ethical issues for allocation of mechanical ventilators. This current document is not intended to comprehensively revisit all of the topics and issues promulgated in the 2007 document; instead, it is intended to supplement the initial document. Circumstances and major issues specific to allocation of mechanical ventilators as well as issues which require alternative ethical considerations from that proposed in the original document form the basis for this supplemental document.

The intent of this document is to provide decision makers at all levels—federal, tribal, territorial, state, and local—with an overview of the complex ethical landscape associated with decision making about allocation of scarce life-sustaining healthcare resources. This document is not meant to serve as detailed guidance about allocation decisions. Rather it is intended to serve as a conceptual framework to assist the planning process. Planning will need to occur at the state, local, and institutional level to develop specific operational details and implementation steps. Thus, this document will not address how to approach specific allocation decisions, but will instead highlight ethical standards and principles relevant to allocation of ventilators during a severe pandemic or other public health emergency and discusses some of the advantages and disadvantages inherent in different approaches to allocation. Some of the approaches are sufficiently and obviously problematic that we suggest that they not be used to guide decisions. Other approaches have positive and negative aspects that must be considered. In the interest of encouraging broader public deliberation about ethically contested matters, we refrain from making specific recommendations and instead highlight these issues and controversies.

Although this document does not provide simple, direct recommendations, our intent is for the document to promote and enhance use of a fair and equitable process for making policy choices. We believe it is important that state and local health departments and federal agencies work with hospitals and each other to implement fair, consistent, and coordinated triage processes for ventilator distribution using the ethical considerations discussed in this document as a framework for decision making. Development of triage plans will require input from a variety of stakeholders, including public health, medical and other health care professionals, ethics and legal experts, and representatives of patients and the public who will be impacted by the plans. An important first step is to engage the stakeholders in a discussion about how to weigh the various ethical principles, values, and approaches reviewed in this document. In addition to preparing for how to fairly distribute limited resources, health officials should be taking appropriate steps to maximize health systems' capabilities to safely deliver appropriate

mechanical ventilation, in order to reduce the need to make these difficult allocation decisions in the future, keeping in mind that allocation of limited resources for ventilators to be used in an emergency will involve tradeoffs with other public health and health care priorities.

INTRODUCTION

Difficult decisions are made on a regular basis in both the practice of public health and clinical medicine; however, the process for decision making, including the framework and reasoning that support ethical choices, may not always be clearly articulated. This document addresses conditions during an influenza pandemic that causes severe illness in sufficient numbers of people to overwhelm routine clinical services. The term pandemic refers largely to a geographic development: an epidemic that has spread beyond its original region to several countries or continents and that effects a large portion of the population because few people have pre-existing immunity to the causative pathogen. Pandemics are always potentially serious public health events. However, in order to call for the kind of emergency policies discussed in this document, they have to cause severe illness in large numbers and thereby create demands significantly exceeding the system's capacity for treating patients despite attempts to increase surge capacity. Depending on the capacity and flexibility of the healthcare system, a pandemic's impact may vary from one region or country to another and the point at which a pandemic will become severe and overwhelm resources may vary by disease and by different communities or regions experiencing the same disease.

The timeliness of this discussion of ethical issues in pandemic influenza was highlighted by the emergence of 2009 pandemic influenza A (H1N1). This virus was officially declared by the World Health Organization as the cause of a pandemic in June 2009. The profound level of respiratory failure experienced by those who developed 2009 H1N1 associated critical illness, especially in older children and young adults, raised much concern that shortages of mechanical ventilators or alternative therapies for very severe critical illness could occur during the fall and winter 2009-2010. While hospitals were challenged by the resource intensity of care these patients required, fortunately the overall proportion of people who developed severe illness was no greater than in recent years with seasonal influenza epidemics, and in the United States there were sufficient mechanical ventilators to meet the response need.² Although the 2009 H1N1 influenza pandemic did not produce a situation that would have required the use of this document, its emergence should serve as a reminder of the importance of being prepared for a situation if the demands for treating patients significantly exceed our health system's capacity.

KEY ASSUMPTIONS

This document is based on a number of assumptions regarding severity of illness and the availability of resources. It is intended only for circumstances when people with severe acute respiratory failure far outnumber available and adequate mechanical ventilator supply. For most U.S. communities, such extreme imbalances are only anticipated in special circumstances (e.g.,

² Information on cases of pandemic (H1N1) 2009 influenza is posted at <http://www.cdc.gov/h1n1flu/>.

an influenza pandemic that is both widespread and severe). Federal, tribal, territorial, state, local, and private entities have undertaken extensive preparedness activities and supported rapid advancement of vaccine and antiviral treatments to reduce the potential burden of a severe influenza pandemic on communities. Advances have also been made in increasing the supply of ventilators. Currently the National Ventilator Inventory undertaken by the Office of the Assistant Secretary for Preparedness and Response together with the American Association for Respiratory Care has revealed that there are approximately 62,000 full-feature mechanical ventilators in the United States (2). Almost half (46%) of these full-feature devices were capable for use with pediatric and neonatal patients. In addition, there are approximately an additional 100,000 devices across a range of categories of respiratory equipment (not including anesthesia machines) at U.S. acute care hospitals which might be used for surge capacity. Almost half of the 100,000 additional devices have enough features to be useful for anticipated surge capacity events. Furthermore, some states and other groups have purchased additional ventilators, not included in the above counts of devices, for surge demand. There has also been significant federal investment to procure and stockpile additional ventilator assets. Despite these crucial activities, it is possible that in the event of a particularly virulent pandemic influenza virus, many hospitals and other healthcare facilities will not have adequate numbers of ventilators to support a major disaster response.

During a severe influenza pandemic, many patients with respiratory failure who are able to receive mechanical ventilation (and all associated supportive critical care components) may survive, while patients with respiratory failure who do not receive mechanical ventilation are likely to die. Thus, a major underlying assumption for this document is that advanced critical care will save lives during a severe influenza pandemic. This assumption is based on everyday experience with acute respiratory distress syndrome (ARDS), recent experience with 2009 pandemic influenza A (H1N1), and past experience with avian H5N1 influenza virus and severe acute respiratory syndrome (SARS). For 2009 pandemic influenza A (H1N1), 60-95% of critically ill patients required mechanical ventilation, and the mortality in these patients was lower than 40% and less than 20% in some countries. The level of respiratory failure in many of these patients was very severe, yet numerous patients who clearly would have died without mechanical ventilation and resource-intensive critical care survived (3-6). Although the majority of patients infected with H5N1 influenza who received mechanical ventilation have not survived (7), many persons infected with SARS who received mechanical ventilation during the 2003 outbreak did survive (8). Moreover, 40-70% of patients with acute respiratory failure (including acute lung injuries and ARDS which is predominant in current H1N1 and H5N1 cases) survive in intensive care units in U.S. hospitals under non-pandemic circumstances (9).

Another of the assumptions of this document is that cases of pandemic influenza infection will occur in waves and most likely a well-matched vaccine will not be available until the second wave. This was the experience with 2009 pandemic influenza A (H1N1). A pandemic wave is defined as a series of community outbreaks that occur nearly simultaneously across the country. Pandemic waves typically occur in the spring, fall, or winter and more than one wave is likely; however waves may occur during any season. In 1918-1919, for example, there were three pandemic waves, and in 1957 and 1968 there were two waves. Periods between waves (typically measured in months) are characterized by very little disease and can be a time of recovery and preparedness for a subsequent wave. For example, following the initial wave of 2009 pandemic

influenza A (H1N1) in North America, public health authorities prepared guidance for patients, clinicians, and other groups, and monitored first-wave influenza activity in the Southern Hemisphere.³

During a severe influenza pandemic it is anticipated that resources will be overwhelmed in the first or second wave of illness because the entire community will be at risk for illness. Equipment for emergency respiratory care, including ventilators, may be in full use and no longer available to additional patients by the first or second wave of a severe influenza pandemic, depending on the geographical spread and timing of the waves, the symptoms of the disease, the availability of pandemic vaccine, and the local effectiveness of community mitigation strategies. This document assumes that ventilators may be in short supply in some communities as early as prior to or during the peak of the first wave of a severe influenza pandemic.

The need to make difficult decisions during a severe influenza pandemic or other public health emergency will most likely occur in an environment of overall limited public health resources. Considerable costs are associated with stockpiling, maintaining reserve ventilators, and funding the training of personnel needed to operate and maintain ventilators skillfully and safely. The decision by states, regions, healthcare systems, or hospitals to augment mechanical ventilation capacity (and all associated critical care elements) for emergency use during a severe influenza pandemic should be made within the larger context of everyday public health and clinical obligations, as well as broader community-based emergency preparedness and response resource needs. This document assumes that individual communities will need to balance pandemic-preparedness requirements with other healthcare and public health needs.

ROUTINE VERSUS EMERGENCY PRACTICE

The central ethical requirement of routine clinical practice is competence. Healthcare professionals should be competent to perform the functions of their professional practice and make continuing efforts to maintain their level of competence. In general, the professional should not perform functions that lie outside the boundaries of his or her specialty. Healthcare professionals also have a fiduciary duty to patients. This requires undivided loyalty to the health interests of the patient. Any actual, potential or apparent competing loyalty must be disclosed to the patient.

Public health emergencies have an impact on each of these ethical standards. During severe pandemics it may be necessary to call upon health professionals and even non-health professionals to temporarily and occasionally perform tasks that lie outside the bounds of their certification (or even competence). A public health emergency also has an impact on healthcare professionals' fiduciary duty to patients. The central purpose of public health practice is to maintain the health of populations. Because of the need to establish priorities to maximize the health of the public during a public health emergency, practicing physicians may on occasion be constrained in acting in the best interests of particular patients. In addition, they may have to

³ See <http://www.cdc.gov/h1n1flu/> for examples of guidance documents.

report to authorities individuals who would be considered candidates for quarantine or isolation. These constraints are not alien to usual medical practice. Healthcare providers are accustomed to rules establishing priorities and the need to address how to best use limited resources (e.g., rules pertaining to admitting patients to intensive care units). Healthcare providers are also familiar with the obligation in many jurisdictions to notify authorities in certain circumstances (e.g., in suspected cases of child or elder abuse or when patients are a danger to themselves or others and need to be involuntarily committed).

A public health emergency creates a need to transition from individual patient-focused clinical care to a population-oriented public health approach intended to provide the best possible outcomes for a large cohort of critical care patients. The trigger for the transition from usual critical care procedures to emergency mass critical care should occur when there is a substantial extreme mismatch between patient need and available resources, that is, when the numbers of critically ill patients surpass the capability of traditional critical care capacity.

Triage is the process of sorting, classifying, and assigning priority to patients, especially when available medical resources are insufficient to provide care to all who need it. Triage is commonly used in situations such as natural disasters, deadly epidemics, and battlefield situations, where shortages are extreme and people die who might be saved if they had immediate access to medical care available in ordinary clinical circumstances. The decision to initiate triage plans is usually made by specific authority within local or state emergency management systems only after all reasonable efforts to augment resources have been exhausted⁴.

Considerable progress has been made by federal agencies, state and local health departments, professional societies, and other institutions on the development of pandemic preparedness plans and guidance about crisis standards of care, including plans for allocation of scarce resources. The Task Force for Mass Critical Care has published guidance regarding use of triage during mass critical care emergency events when surge capacity has become overwhelmed in a nation, state or region and resources are inadequate to meet patient care needs (10). They recommend that triage plans be invoked after all attempts at resource procurement have failed and when all area hospitals are facing a similar short-fall. The Task Force suggested that triage plans should be based upon a graded response that matches the need resulting from the public health emergency and that all impacted hospitals have a uniform response for providing mass critical care. This would be considered the most extreme of situations and the guiding principle is that the provision of usual critical care, when able to meet demand, is always the preferred approach. The Task Force recommended that triage plans remain in effect only until the imbalance between need and resources is remedied and all hospitals are able to provide safe critical care. Return to previous standards of care is warranted when critical resources or infrastructure are augmented or when the need abates.

The Task Force for Mass Critical Care suggested that the following conditions be present to initiate the triage process (10):

- Surge capacity fully employed within healthcare facility

⁴ This should also include exploring resources which may be available from Department of Veterans Affairs and Department of Defense treatment facilities,

- Attempts at conservation, reutilization, adaption, and substitution are performed maximally
- Identification of critically limited resources (e.g., ventilators, antibiotics)
- Identification of limited infrastructure (e.g., isolation, staff, electrical power)
- Request for resources and infrastructure made to local, regional, and state health officials
- Current attempt at regional, state, and federal level for resource or infrastructure allocation

In September 2009 the Institute of Medicine (IOM) released *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations* (11). This report provides guidance for state and local public health officials, healthcare facilities, and professionals on the development and implementation of policies for crisis standards of care in disasters, both naturally occurring and manmade, in which resources are scarce. The report identifies key elements that should be included in crisis standards of care protocols and potential triggers for adopting these standards. The IOM recommends developing consistent crisis standards of care protocols that are built on strong ethical and legal underpinnings with input from community and provider stakeholders, and strong coordination among federal, tribal, state and local health officials. The IOM report addresses a number of issues also considered in this guidance, including the importance of establishing fair and equitable processes that are transparent, consistent in application across populations and among individuals, and proportional to the emergency and degree of scarce resources.

As many healthcare providers may be unaccustomed to approaching healthcare decision making from a population perspective, it is crucial that individual providers be informed about and provided training on the implementation of crisis standards of care and triage protocols prior to the need to institute these procedures; this will facilitate the smooth transition to crisis care. It is also crucial for the guidance and training to provide clear information about when and how the transition back to usual standards of care will occur.

PRIORITIES FOR VENTILATOR ALLOCATION

Historically, during routine clinical practice the organizing principle for ventilator distribution, as well as for the distribution of most therapeutic procedures and interventions has been the minimization of adverse outcomes, including hospitalization and death. Typically all patients who have a medical need for and can benefit from mechanical ventilation and who consent to treatment (or have the concurrence of a surrogate) are provided this type of care. However, during a severe pandemic when there is a shortage of health care resources, it may be necessary to re-evaluate the ethical considerations that govern the usual provision of care (12). In this and in the next two sections, we explore how the usual ethical considerations that govern allocation to ventilators may need to be modified during a severe influenza pandemic or other public health emergency when there might not be enough ventilators for all who need one.

During a public health emergency, there will be competing priorities for ventilator use from patients whose need for a ventilator is unrelated to influenza. In addition, decisions will need to be made regarding whether patients should be removed from ventilators if this is needed to free up ventilators for others who may have a much better chance of recovery, and whether there should be suspension of non-emergency surgical procedures that might create a need for ventilator therapy.

The principle of *sickest first* is routinely employed to triage patients presenting for care in the emergency department, where staff time is scarce but medical resources are not. Other patients will still receive care, but they must wait. During a severe influenza pandemic that creates a critical shortage of ventilators, however, this strategy may lead to resources being used by patients who ultimately are too sick to survive.

First-come, first-served is used to allocate intensive care unit (ICU) beds during routine clinical circumstances. Once a patient is in the ICU, they are generally not transferred out of the ICU if they still need intensive care unless the patient or surrogate agrees to forego life-sustaining interventions. That is, fiduciary duties to existing patients take priority over potential benefits to other patients. During ordinary clinical care, the healthcare system generally can accommodate patients with a very poor prognosis who require an ICU bed for many days and who ultimately may not survive. Other patients are still able to receive intensive care if needed. However, the situation would be different if ventilators are in extremely short supply during a severe influenza pandemic; other patients, who may have a much better prognosis if they receive intensive care, will not have access to it. After a public health emergency is declared, rules that favor the overall benefit to the population and society may have to be considered.

In order to use scarce resources most efficiently, in some clinical situations where there is a severe shortage of life-saving medical resources, priority is given to those who are *most likely to recover* after receiving them. When treating soldiers with life threatening injuries, medics give priority to those who are most likely to survive with a relatively small amount of scarce resources. Such triage is carried out without regard to rank. Similarly during cholera epidemics in refugee camps, limited supplies of intravenous fluid are given not to those with the most severe dehydration, but instead to those with moderate dehydration who will likely recover with small amounts of fluid (13). During a declared public health emergency, prudent stewardship of scarce resources is an important ethical consideration.

In the Ethics Subcommittee's previous document, *Ethical Guidelines in Pandemic Influenza*, which addressed distribution of vaccines and antiviral medications, the *principle of preserving the functioning of society* was given greater priority than preventing serious complications (1). This is because vaccines and antiviral medications are predominantly used to prevent or lessen illness and thus can be useful in maintaining or restoring health for groups identified as essential for preserving the functioning of society. However, decisions about priorities for ventilator distribution pose a different situation. Ventilators are an essential life-saving intervention. Moreover, the vast majority of patients who required mechanical ventilation due to illness caused by 2009 pandemic influenza A (H1N1) had ARDS. While published data regarding systematic post ICU follow-up of these patients has been limited, patients with ARDS due to bacterial pneumonia and sepsis take a median of one week to recover from requiring mechanical

ventilation and then frequently have prolonged recoveries with long-term reduction of quality of life. Therefore, those who are ill enough to require ventilator therapy are unlikely to recover sufficient function to be able to contribute to the preservation of the functioning of society—at least not during the ‘wave’ of the pandemic during which they fell ill. Thus, prioritizing based on preserving the functioning of society is not as relevant to decision making about distribution of ventilators as with vaccines and antiviral medications.

WHAT PRINCIPLES SHOULD GUIDE VENTILATOR ALLOCATION?

Basic Biomedical Ethical Principles

A consideration of the basic biomedical ethical principles should be the cornerstone for decision making about ventilator allocation. These basic principles include respect for persons and their autonomy, beneficence (which includes nonmaleficence), and justice.

Respect for Persons and their Autonomy

The principle of respect for persons and their autonomy requires physicians to obtain informed consent from patients and to respect their informed refusal. During ordinary clinical practice, it is highly unusual to discontinue or withhold mechanical ventilation without the consent or concurrence of the patient or surrogate. During a severe influenza pandemic, public health mandates may override patient autonomy. If a public health emergency is declared and emergency guidelines are triggered, treating physicians may be constrained by these guidelines. In addition, if there are severe shortages of ventilators, ICU beds, and staff, not all patients with respiratory failure will be able to receive these resources. Regardless, patients still must be treated with dignity and compassion. This will include the provision of palliative care, discussed in more detail later.

Beneficence

The principle of beneficence requires physicians to act in the best interests of their patients and to subordinate their personal and institutional interests to those of the patient. During a severe pandemic, however, physician decisions will be guided by benefits to the population as a whole, not only to the individual patient. However, within the constraints of public health mandates, treating physicians will still have obligations to provide benefits to individual patients. These obligations include the provision of palliative care and non-abandonment. Beneficence is closely related to nonmaleficence, which requires physicians to not harm patients and to try to prevent harm.

Justice

The principle of justice during a severe pandemic has several dimensions. First, physicians and public health officials should “steward resources during a period of true scarcity (14).” Second, the distribution of benefits and burdens should be equitable; allocation decisions should be applied consistently across people and across time. Responses to a pandemic should not exacerbate existing disparities in health outcomes, as unfortunately has occurred in some past public health emergencies (14). Fair process or procedural justice is especially important during a public health emergency to sustain public trust (15).

Fairness requires the absence of unjustified favoritism and discrimination. Citizens may be more likely to subordinate their own personal self-interest to the common good if they believe the same rules apply to all. Conversely, if people believe that others are receiving special consideration, they may be less likely to accept mandatory public health measures. Even the perception of favoritism may undermine willingness to sacrifice for the sake of the greater good of the community.

As described in the Ethics Subcommittee's prior pandemic influenza ethics document (1), procedural justice requires the following:

- Consistency in applying standards across people and time (treating like cases alike)
- Decision makers who are impartial and neutral
- Ensuring that those affected by the decisions have a voice in decision making and agree in advance to the proposed process. This would require meaningful public engagement, as has been carried out with other aspects of pandemic planning (16-20). These public engagement exercises have moved beyond public education and soliciting input at public hearings to include balanced learning from credible sources on all sides of an issue, neutral facilitation, and opportunities for frank dialogue and genuine deliberation, and linkage to the government decision-making process. This process allowed both organized stakeholders and ordinary citizens to provide meaningful input into policy choices that involved tradeoffs among conflicting values.

Procedural justice is closely related to other procedural guidelines, such as transparency and accountability, which help to establish the legitimacy of public health policies. Transparency refers to making policies and their rationale available to the public. Accountability refers to explaining and justifying policies and taking responsibility for the consequences of actions and decisions. Prior to an influenza pandemic, the public need to have input on ventilator allocation decisions and to know how ventilators will be allocated in order to trust that allocation is fair. As such, it is the responsibility of public health leaders to provide timely information regarding the pandemic, even when there is uncertainty due to the lack of data. Transparency will be enhanced if triage priorities and policies are explicit and if the public has ready access to the triage guidelines, the data and reasoning underlying them, and the process by which they were derived. Public input into the formulation of triage guidelines is more feasible before a pandemic occurs rather than during a pandemic.

In order to promote transparency and accountability, there should be interim and retrospective review processes to ensure that triage guidelines are applied accurately, consistently, and fairly. These reviews would also serve as a quality-improvement process. However, because of the need for triage decisions to be made in a timely manner, it may be impractical for the review process to function as an appeal process for real-time decisions (14). The reviews of triage decisions should be conducted by a different group of people than those involved in the initial triage decisions.

In addition, policies for allocation of resources during a pandemic should involve the following:

- Proactive planning. Public health officials should maximize preparedness in order to minimize the need to make allocation decisions later after a pandemic occurs.

- Adequately reasoned decisions based on accurate information. This would require guidelines to be based on the best available evidence. Because adequate evidence to guide policy may not exist before a pandemic strikes, it is essential to carry out research during a pandemic to provide evidence to inform public health policies. Such research, of course, needs to be carried out in ways that minimize risks to participants, respect them as persons, and select participants equitably. Research should never conflict with the public health emergency response.
- Processes to revise, improve, or correct approaches as new information becomes available. For instance, this might involve retrospective review of allocation decisions in individual cases to adjust triage standards for future allocations.

Specific Ethical Considerations

In addition to the basic biomedical ethical principles discussed above, there are a number of more specific ethical considerations that will be useful in guiding decision making about allocation of ventilators. These considerations focus on differing approaches to maximizing and distributing benefits.

Maximizing Net Benefits

Historically, allocation decisions in public health have been driven by the utilitarian goal of maximizing net benefits (21). Although this broad principle can be specified in numerous ways (i.e., maximizing the number of lives saved, maximizing years of life saved, maximizing adjusted years of life saved), several recent guidelines for allocating life support during a public health emergency have specified it narrowly as “maximize the number of people who survive to hospital discharge (10, 14, 22).”

Maximize the number of lives saved - The utilitarian rule of maximizing the number of lives saved is widely accepted during a public health emergency (23). Some non-consequentialist views also favor maximizing the number of lives saved, not because this approach produces the most good; but, because each life has an equal claim on being saved. Prioritizing individuals according to their chances for short-term survival also avoids ethically irrelevant considerations, such as race or socioeconomic status. Finally, it is appealing because it balances utilitarian claims for efficiency with egalitarian claims that because all lives have equal value the goal should be to save the most lives.

Various groups have been developing models for allocating ventilators. Several groups have proposed modifying a relatively simple mortality prediction model—the Sequential Organ Failure Assessment (SOFA) score—to determine an individual’s priority for access to a ventilator (22, 24-26). No model can predict with perfect accuracy which patients will benefit from mechanical ventilation during a severe influenza pandemic and which will not. When selecting a predictive score model, physicians and policy makers need to take into account several considerations, including whether the scoring system is validated in the populations for which it is being considered (e.g. pediatrics, non-influenza patients who will be triaged together with patients with influenza-related critical illness), whether it is a disease-specific or general score, if the score can be used at multiple time points in disease course in addition to feasibility, ease of use, accuracy, validity, objectivity, and transparency. The predictive score model

employed should be based on the best available science; hence research needs to be carried out to validate and potentially modify whatever predictive score model is employed.

Any predictive score model yields probabilities of outcomes, which may not accurately predict the outcome for any one individual. This concern has limited the use of probabilistic scoring systems to make treatment decisions during routine clinical practice. However, the rationale for their use is stronger during a severe influenza pandemic, when the goal is to maximize population-level outcomes. Such an objective approach during a severe pandemic may also be viewed by the public as fairer than decisions based on more subjective criteria. However, if valid scoring systems are not available (as for example in the case of infants and children, explicit criteria based on expert opinion may be the most feasible option. No matter which scoring system is utilized within a triage schema, the performance of the score must be reviewed to assess its accuracy and to minimize misclassification of people's predicted outcomes. Ideally this reevaluation should be ongoing during the event, and data collection systems must be planned for and implemented during an event.

Maximizing years of life saved - A broader conceptualization of maximizing net benefits is to consider the *years of life* saved in addition to the *number of lives* saved. Assuming equal chances of short term survival, giving priority to a 60-year old woman who is otherwise healthy over a 60 year-old woman with a limited life expectancy from severe co-morbidities will result in more "life years" gained. The justification for incorporating this utilitarian claim is simply that, all other things being equal, it is better to save more years of life than fewer.

The principle of maximizing years of life saved has been used in organ transplantation to exclude as recipients persons with such severe co-morbidities that they have a very poor prognosis for survival even if they receive a transplant. Furthermore, this principle has also been invoked in some published guidelines regarding triage of ventilators during a severe influenza pandemic to exclude certain poor-prognosis subgroups of patients from access to ventilator support. For example, one group advocates denying ventilator support to persons who are functionally dependent from a neurologic impairment (27). Another group recommends excluding those older than 85 years of age and those with New York Heart Association Class III or IV heart failure (10, 22). These recommendations have been criticized because the criteria for exclusion (age, long-term prognosis, and functional status) are selectively applied to some patients, rather than to all patients who require life-sustaining interventions. Such selective application violates the principle of justice because patients who are similar in ethically relevant ways are treated differently. Categorical exclusion may also have the unintended negative effect of implying that some groups are "not worth saving," leading to perceptions of unfairness.

Maximizing adjusted years of life saved - A still more nuanced utilitarian approach would be to maximize years of life after adjusting for the quality of those years. However, predicting quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs) for an individual patient requires considerable clinical information about an individual and would not be feasible when making decisions regarding intubation and mechanical ventilations in an emergency department or ambulance during a public health crisis (28, 29). Another limitation of basing decisions on QALYs or DALYs is their potential to create invidious distinctions between people based on arbitrary judgments regarding quality of life.

Although the utilitarian goal of maximizing net benefits is an important public health principle, we conclude that ethically, allocating scarce resources during a severe pandemic by only considering chances of survival to hospital discharge is insufficient because it omits other important ethical considerations.

Social Worth

Additional principles that have been used to allocate scarce resources are concerned with the distribution of benefits among patients, rather than the aggregate level of benefit. This has included criteria based on social worth and instrumental value.

Broad social value - Broad social value refers to one's overall worth to society. It involves summary judgments about whether an individual's past and future contributions to society's goals merit prioritization for scarce resources (23). When dialysis was first introduced, social value was a key consideration in allocating scarce dialysis machines. Patients who were professionals, heads of families, and caregivers received priority over others who were perceived as less worthy (30). The public firestorm in response to revelations that social worth was a key factor in the Seattle Dialysis Committee's deliberations partly led Congress to authorize universal coverage for hemodialysis (31).

In our morally pluralistic society, there has been widespread rejection of the idea that one individual is intrinsically more worthy of saving than another. Many writers advocate the egalitarian view that all individuals have an equal moral claim to treatment regardless of whether they can contribute measurably to broad social goals (32). As one philosopher put it, one's "dignity as a person...cannot be reduced to his past or future contribution to society (33)."

Instrumental value: The multiplier effect - Instrumental value refers to an individual's ability to carry out a specific function that is viewed as essential to prevent social disintegration or a great number of deaths during a time of crisis. It has also been described as "narrow social utility" and the "multiplier effect (21, 23)." Federal guidance on prioritization of pandemic vaccines adopted this principle by recommending that priority be given to individuals essential to the pandemic response (including public health and healthcare personnel) and to those who maintain essential community services (34, 35). The ethical justification is that prioritizing certain key individuals will achieve a "multiplier effect" through which more many lives are ultimately saved through their work.

Instrumental value must be distinguished from judgments about broad social worth. Individuals who have instrumental value for one type of public health disaster may not have instrumental value during another type of crisis. For example, vaccine manufacturer workers would not be prioritized during the public health response to a terrorist attack with chemical or nuclear weapons. Individuals are prioritized not because they are judged to hold more "intrinsic worth," but because of their ability to perform a specific task that is essential to society. In this sense, instrumental value is a derivative allocation principle; it is desirable because it ensures an adequate workforce to achieve public health goals. Even critics of allocation based on broad social value accept the use of instrumental value in certain circumstances (32).

However as indicated previously, using instrumental value may be ethically problematic for decision making about allocation of ventilators. In general, to justify a restrictive public health measure, there must be good evidence that the measure is *necessary* and will be *effective* (36). Most important, will individuals with respiratory failure who receive priority for mechanical ventilation recover in time to re-enter the work force and achieve their instrumental purposes during the pandemic wave? Because of the uncertainty about which key personnel will be in short supply and whether they will recover in time to achieve their instrumental value, this criterion would likely be highly controversial.

The Life Cycle Principle

The life cycle principle grants each individual equal opportunity to live through the various phases of life (37). Similar ideas have been based on the “fair innings” argument and “intergenerational equity (38).” In practical terms, the life cycle principle gives relative priority to younger individuals over older individuals. The ethical justification of the life cycle principle is that it is a desirable as a matter of justice to give individuals equal opportunity to pass through the stages of life—childhood, young adulthood, middle age, and old age (37). The justification for this principle does not rely on considerations of one’s intrinsic worth or social utility. Rather, younger individuals receive priority because they have had the least opportunity to live through life’s stages.

Empirical data suggest that when individuals are asked to consider situations of absolute scarcity of life sustaining resources, most believe younger patients should be prioritized over older (39). One advocate for a life cycle approach declares: “it is always a misfortune to die... it is both a misfortune and a tragedy [for life] to be cut off prematurely (40).” Prioritization based on the life cycle approach is not a simple linear function of a persons’ age (that is, the claim of priority does not decrease bit by bit as one ages year by year). Instead, this approach appeals to significant age differences rather than small differences of a few years.

Some critics contend that the life cycle principle unjustly discriminates against older individuals. However, others respond that this principle is inherently egalitarian because it seeks to give *all individuals* equal opportunity to live a normal life span. It applies the notion of equality to individuals’ *whole lifetime experiences* rather than just to their current situation (38). In their view, unlike prioritization based on gender or race, everyone faces the prospect of aging and everyone hopes to move through all stages of life (37). However, when public input was sought in Seattle-King County on values and priorities for delivery of medical services during a severe influenza pandemic, most participants agreed that the number of years a person would live if they survive should only be a factor in the absence of other priority criteria (19).

Fair Chances versus Maximization of Best Outcomes

Traditionally, public health emergency response has focused on maximizing population health, for example, through saving the most lives. However, some have challenged this assumption and have suggested that fairness considerations be more explicitly included in policy decisions, even if doing so does not maximize population health (41-43). Conflict between providing “fair chances” and maximizing “best outcomes” arises when there are relatively small differences in expected benefits that may be gained by people in different prioritization groups. In the case of

access to ventilators, if ventilators are provided only to people with the highest probability of surviving and denied to those with a somewhat less, but still significant chance of survival, then we may save more lives but we do so by asking some individuals to give up all chance of survival. Some argue that this approach is not fair to those who give up their chance of survival, even though more total lives are saved. Some propose an alternative approach (e.g., a “weighted lottery”) to provide more people with a fair chance at survival, even if it would not maximize the number of lives saved (41, 42). Objections to the fair chances approach include: lack of clarity and transparency about what criteria are being used to make choices and practical limitations in applying a complex, weighted lottery in an emergency setting. A deliberative public engagement process may be required to establish appropriate weights (44).

Incorporating Multiple Principles

Because several different considerations for allocating ventilators during a severe influenza pandemic may be justified, some writers have proposed that several principles be combined into a composite priority score (12). Although a multi-principle allocation system may be more complex to implement in a timely and practical manner than a single principle allocation system, it may better reflect the diverse moral considerations relevant to these difficult decisions. In addition, this approach avoids the need to categorically deny treatment to certain groups, a problem that one legal scholar calls a “political and legal minefield (45).” This multi-principle approach can take into account the degree of scarcity—patients with lower priorities can receive ventilators until no more remain. However, a multi-principle allocation approach that relies on a composite priority score raises difficult questions regarding what principles should be represented in the composite score and how to weight the various components that contribute to the score. People may legitimately disagree about the weights. It will be important to have a broad public deliberation about the various tradeoffs among the principles in order for such an index to be accepted as legitimate. The values and priorities of community members who will be impacted by decisions about allocation of scarce life-saving resources must be considered in the development of triage plans.

WHO SHOULD MAKE VENTILATOR ALLOCATION DECISIONS?

A lesson learned in routine medical practice is applicable for public health emergencies. Healthcare professionals will, in general, attempt to interpret priority rules in a way that favors the access of their own patients to scarce life-saving therapies such as organ transplants and placement in the ICU (with ventilator therapy). It is very helpful, in the interest of fair distribution of such therapies to have in advance well-formulated prioritization guidelines that are interpreted (in particular cases) by professionals who have no fiduciary commitment to the individual patient.

Separating the roles of clinical care and triage allows physicians who are caring for patients with respiratory failure to continue to maintain loyalty to their patients and to act in their best interests (46). This separation of roles will mean that treating physicians will not need to make a decision to withhold mechanical ventilation from patients who still desire it. Instead, a triage expert could make decisions impartially based on the overall outcomes for the population according to pre-determined guidelines, while the treating physician is free to act in the best interests of the

individual patient, within the constraints of the public health emergency. Constant communication with the treating provider and establishment of prioritization of patients to receive a critical resource is necessary in the event a ventilator or other scarce resource becomes available (10).

The role of the triage expert will need to be specified in some detail in advance of a pandemic. Details that will need to be specified include identification of qualifications for the triage expert and establishment of training requirements, establishment of procedures for providing support to the triage expert (both decisional support and emotional support), agreement of whether an appeals process will be permitted, and establishment of a mechanism to review triage decisions for quality improvement purposes. Devereaux and colleagues have pointed to the need for triage experts to have “exceptional clinical expertise, outstanding leadership ability, and effective communication skills (10).” The triage expert should be a senior-level provider within the institution with the experience, respect, and authority to carry out the function. When possible, it is desirable to establish a triage team composed of at least three members rather than relying upon a single triage expert. The team approach allows for consultation, multiple professional perspectives, and a broader base of support from clinical/community stakeholders. The suggested professional makeup of a triage team would include at least a critical care nurse, a respiratory care professional, and a physician. It is also desirable to have an ethicist on the triage team if available. Additionally, if the hospital has an ethics team, this team can serve as a valuable resource to the triage team. All team members must be fully licensed or certified and credentialed to engage in their profession. All triage experts, whether individuals or members of a team, should be chosen by the institution based on a past record of trustworthiness, integrity, compassion, competency in making consistent and difficult choices, and competency in clinical skills (especially in critical care medicine).

OTHER CONSIDERATIONS

Uniform Decision Criteria versus Local Flexibility

Effective emergency response requires coordination of various partners, including government authorities at the local, state, territorial, tribal, and federal levels, not-for-profit organizations, and public and private sectors. The need for coordination is strongest in an acute catastrophic emergency that overwhelms basic social systems for health and safety. Coordination of efforts is enhanced when there are uniform, consistent criteria for access to life-saving interventions in functional medical referral areas. Such consistency across hospitals promotes fairness. Uniform criteria would help ensure that cases that are similar in ethically and clinically relevant ways are treated similarly. In contrast, reliance upon a variety of criteria established at the local level has the potential to undermine the principle of fairness if individuals living in contiguous areas receive different treatment based on non-medical criteria. Making decisions about ventilator distribution and triage using a standard framework for incident management creates a clear hierarchy of accountability and responsibility, facilitates consistent communication, and helps minimize differential treatment of patients. Strongly encouraging all institutions within a functional medical referral area to adopt uniform triage plans for access to ventilators, and making this expectation clear in advance of an event, creates a common framework for providers and enhances public trust by minimizing the potential for conflicting decisions from different

partners or jurisdictions. Also, uniform treatment criteria may help address the moral hazard that an institution may "free ride" upon others, rather than sharing the burden of making appropriate plans in advance.

Healthcare professionals and community representatives should be actively engaged in the development of uniform criteria for access to ventilators and the rationale supporting the criteria should be clearly articulated in advance of an influenza pandemic. During an event of long duration, it is important to demonstrate an ongoing commitment to transparency by continuing to seek community input on the adequacy of the criteria and whether the criteria are being applied consistently. Additionally, steps should be taken to ensure that all patients reaching the highest priority group have equitable access to the pool of ventilators. This assures that allocation does not exacerbate pre-existing inequalities in access to health care or disproportionately impact vulnerable populations. For example, public health officials should work with institutions to address issues of fairness recognizing that institutions with trauma centers and larger intensive care services will bear a disproportionate burden.

It is important to recognize the need for flexibility and ongoing evaluation of whether a coordinated decision making process and uniform criteria are indicated, because there may be instances where specific local needs should be taken into consideration. Institutions should be allowed to opt out of coordinated ventilator distribution plans when there is no evidence to support a belief that coordination of decision making will contribute substantially to fairness of access to care. However, institutions should make their reasons for implementing different criteria transparent. In general, state and local health departments and federal agencies are strongly encouraged to work with hospitals and with each other to implement uniform triage processes for ventilator distribution. The presumption should be to follow uniform guidelines in the interest of fairness, consistency, and coordination of efforts. State and local laws may provide authority for public health officials to control, restrict, and/or regulate the use of resources, such as ventilators, for the general welfare and may vary from jurisdiction to jurisdiction. Officials should understand the scope of their authority during emergencies.

Community Engagement

Active involvement of the community in the planning and triage process is critical. Public health officials, as health professionals with ethical responsibilities to their communities, should collaborate with health care institutions and perhaps other government bodies, such as city or county councils, to ensure that a diverse and broad representation of community members are included in the planning and implementation of the triage process. Diverse and broad representation of citizens in multiple phases of the planning process will impact the quality and depth of decisions made. Concurrent with the planning phase, information about the planning process should be communicated widely in the community so that the public anticipates the outcome of the process. The principles and considerations that are utilized in determining triage protocols should be transparent and clearly communicated. The community should also participate in planning how the information about an impending pandemic will be communicated. Considerations for engaging the community include the following:

- Consistent messages
- Particular attention to historically marginalized and potentially vulnerable groups

- Engagement of spokespeople who might best be heard by communities or who can emphasize centrally communicated messages
- Use of a variety of modes of communication that will best reach the whole community

Since activities designed to engage communities exist to varying degrees in federal, state, and local health agencies and their partners, these existing efforts should be expanded. It may be appropriate to re-direct previously implemented or ongoing community engagement initiatives to focus on issues raised by a severe influenza pandemic.

We acknowledge that the public engagement process can be difficult to implement. It requires resources and can be time consuming; it may be difficult to identify the appropriate spokespersons who accurately reflect the sentiments of the community; and the discussions may raise political challenges due to sensitive nature of the issues which involve life and death decisions. However, despite these challenges, it is crucial that decision making about allocation of scarce life-saving resources reflect the value choices of the community thus necessitating the active involvement of the community in the planning and triage process. There are a number of excellent examples of public engagement for pandemic planning that can serve as useful models (16-20).

Obligations to Healthcare Professionals

Clinicians and hospitals have a responsibility to prepare for emergencies, clarify expectations about the roles of physicians and staff during an emergency, and plan and provide for necessary support so clinicians may continue to provide care. Hospitals and area health jurisdictions should ensure clinicians have timely and accurate information, and ensure that any reluctance to provide care is not based on a misunderstanding, such as misunderstandings about liability during an emergency. The right to practice medicine is conveyed at the state level and standards of practice are enforced at the state level. To the extent that medical care during an emergency may be deficient compared with standard of care, health jurisdictions and boards of medicine should address concerns of physicians about immunity from liability and regulatory oversight when practicing under regionally or nationally required uniform criteria and processes. Hospitals should clarify their role in supporting legal protections for tort liability in the jurisdiction, and provide information about immunity from tort for actions undertaken during a public health emergency.

During a severe influenza pandemic and declared public health emergency there may be a severe shortage of healthcare professionals skilled in providing intensive care. In the planning phase increasing the number of individuals trained or cross-trained to manage ventilator-dependent patients should be a goal. These staff should also be trained to utilize supplemental ventilators whose settings and controls differ from those typically at use in the institution. Staff will need to be informed of existing triage plans and trained regarding their specific roles in implementing the triage protocol.

State medical boards, nursing boards and other licensing and certifying agencies should be partners in planning efforts to “adjust scopes of practice” and “alter licensure and credentialing practices” during declared emergencies (11). The IOM report also urged state and local governments to explicitly tie liability protections to crisis standards of care, so that concerns

about legal liability do not deter health care workers from providing needed care to individual patients and to society during a declared public health emergency.

We have suggested in this document that prioritizing based on preserving the functioning of society is not relevant to decision making about distribution of ventilators. However, some may argue that the ethical principle of reciprocity may provide ethical justification for giving priority to those who put themselves at risk during a severe pandemic (i.e., health care providers and emergency responders), especially prior to the availability of a vaccine. The application of this principle for allocation of ventilators will depend on the extent of the shortage and the extent to which an individual healthcare provider faces additional risk when providing care to others. In situations where health care providers or other essential workers may benefit from a ventilator, the fact that they may have become ill as a consequence of their work may be a factor to be considered.

Provision of Palliative Care

During a severe influenza pandemic, patients with respiratory failure who do not receive mechanical ventilation should receive respectful and compassionate palliative care to relieve the symptoms of respiratory failure (47). Doses of sedatives and analgesics that will cause unconsciousness are appropriate if lower doses fail to relieve symptoms (48). Although such palliative sedation has strong ethical and legal justification, health-care workers are often confused about the distinction between palliative sedation, which is intended to relieve suffering, and active euthanasia, which is intended to kill the patient. During a public health emergency, such misunderstandings may be particularly prominent (49). Thus, emergency-preparedness plans should include provisions for training physicians and nurses about palliative sedation, for providing emotional and spiritual support to patients, families, and health-care workers, and for addressing shortages of trained nurses to administer sedation and analgesia and shortages of medications caused by disruptions to hospital supply chains (46, 50). Plans also need to be put in place to address the possibility of a shortage of both ventilators and palliative medications. These plans should be based on sound scientific and ethical reasoning, be open to public input and scrutiny, and include steps for ensuring that disadvantaged and vulnerable populations have fair access to scarce resources.

Withdrawal of Patients from Ventilators

In the United States, there is ethical consensus that mechanical ventilation may be withheld or withdrawn as requested by an informed patient or a qualified surrogate, and courts have consistently ruled that there is no distinction between discontinuing such medical interventions and not initiating them (51-57). During usual clinical practice, about 75% of deaths in critical care units occur after a conscious decision to withdraw or withhold life support. Mechanical ventilation may be withdrawn at the request of a competent, informed patient. For patients who lack decision-making capacity, mechanical ventilation may be withdrawn or withheld by a duly appointed surrogate, usually a family member, in accordance with the patient's previously expressed wishes or best interests. More controversially, critical care physicians may withdraw life support from patients who lack decision-making capacity, have no surrogate, and have given no advance directives (58, 59).

In ordinary clinical practice, it is rare for patients not to receive beneficial critical care because of resource scarcity (60). However, when the need for ventilators temporarily exceeds the supply of ventilators or critical care unit beds, typically arrangements are made to postpone elective surgery, try to wean recovering patients from ventilators, utilize emergency department beds or post-operative recovery suites to treat patients on ventilators, or transfer patients to another healthcare institution. Because there are few precedents and policies in ordinary clinical care for denying the use of mechanical ventilation to patients who would benefit from it and who would agree to it, it is essential that careful policies be developed in advance for use of mechanical ventilation during a severe influenza pandemic in which the need for mechanical ventilation far exceeds capacity (12).

To achieve the public health goal of minimizing the number of preventable deaths during a severe pandemic emergency, states and hospitals need to address the issue of removing from ventilators patients with respiratory failure whose prognosis has significantly worsened in order to provide access to patients with a better prognosis. During a declared public health emergency, decisions about allocation of scarce resources must be made in accordance with transparent, accountable, and fair public health directives. Policies for withdrawal of patients from ventilators need to be the least restrictive possible - i.e., withdrawal of ventilation without requiring assent of patient or surrogate continues only as long as the shortage of ICU resources continues. The policy should be transparent, formed with input from the public, and include explicit criteria for identifying patients from whom ventilation will be withdrawn. There should also be procedural safeguards for prioritizing patients to receive ventilator support (e.g., triage expert, post-event review of decisions for quality improvement; policy developed with public input). Patients who are removed from mechanical ventilation and their families or surrogates, like patients with respiratory failure who are not placed on mechanical ventilation, should be notified this will occur, given a chance to say good-byes and complete religious rituals, and provided compassionate palliative care.

Special Considerations Relating to Children

Children make up a significant percentage of the population for whom there are special considerations in an influenza pandemic. Dependent on the strain of influenza, children may have greater susceptibility to disease and a disproportionate need for ventilation. However, not all ventilator equipment is customized to children or infants, and emergency services and hospitals may not have adequate age- appropriate equipment or supplies, or staff trained to provide ventilation to children. When making emergency preparations and in constituting triage teams, the special needs of children should be taken into account. State and local disaster planning should include assessment of the capacity of pediatric facilities as well as the capacity of all hospitals to treat children. The implications for keeping children and parents or other family members together during treatment should be considered. A number of important efforts have been made to address treatment of children during a disaster, including work by the National Commission on Children and Disasters which provides recommendations regarding addressing considerations for pediatric populations in disaster planning (61). CDC has also collaborated with various stakeholders and is preparing recommendations regarding pediatric emergency mass critical care (62, 63).

CONCLUSIONS

The intent of this document is to provide decision makers at all levels—federal, tribal, territorial, state, and local—with ethical points to consider when life-sustaining healthcare resources are limited due to a severe influenza pandemic. It is intended only for circumstances when people with severe acute respiratory failure far outnumber adequate mechanical ventilator availability and when a public health emergency has been declared. Fortunately, the 2009 H1N1 pandemic did not produce a situation requiring the use of this document. However, it is imperative that health officials be prepared for the future possibility of the emergence of a severe pandemic.

If a scarcity of ventilators occurs during a severe influenza pandemic, ventilators will need to be allocated according to different guidelines than during usual clinical care. In the allocation of vaccines and antiviral medications during a pandemic, the principle of preserving the functioning of society has a high priority. Such a priority does not apply to allocation of ventilators. Individuals who require a ventilator are unlikely to recover sufficient function to contribute to the preservation of the functioning of society—at least not during the ‘wave’ of the pandemic during which they fell ill. In this document, we present a number of general ethical principles that should serve as a conceptual framework for guiding ventilator allocation decisions—respect for persons and their autonomy, beneficence, and justice—and review several strategies for establishing priorities for who should receive a ventilator when there are not enough for everyone. We suggest that a multi-principle allocation system may best reflect the diverse moral considerations relevant to these difficult decisions. Most importantly, triage models for allocation of scarce life-saving resources should be evaluated based on the extent to which they result in fair processes and should take into account the values and priorities of the community members who will be impacted.

While ethics guidance can articulate considerations that need to be taken into account, policy decisions need to be set and implemented by the responsible public health officials. In the interest of fairness, consistency, and coordination of efforts, we suggest that state and local health departments and federal agencies work with hospitals and each other to implement uniform triage processes for ventilator distribution using the ethical considerations described in this document as a framework for decision making. Development of these plans will require input from a variety of stakeholders, including public health, medical, ethics and legal experts and representatives from those who will be impacted by the plans. While preparing for how to fairly distribute limited resources, health officials may want to consider taking appropriate steps to increase supplies, and to conserve and make adaptations in current usage in order to reduce the need to make these difficult allocation decisions in the future.

REFERENCES

1. Kinlaw K., Levine R. Ethical Guidelines in Pandemic Influenza, 2007. Available at http://www.cdc.gov/od/science/phethics/panFlu_Ethic_Guidelines.pdf.
2. Rubinson L, Vaughn F, Nelson S, et al. Mechanical ventilators in US acute care hospitals. *Disaster Med Public Health Preparedness* 2010;4:199-206.
3. Kumar A, Zarychanski R, Pinto R, et al. Critically ill patients with 2009 influenza A(H1N1) infection in Canada. *JAMA* 2009;302:1872-1879.
4. Dominguez-Cherit G, Lapinsky SE, Macias AE, et al. Critically ill patients with 2009 influenza A(H1N1) in Mexico. *JAMA* 2009;302:1880-1887.
5. The Australia and New Zealand Extracorporeal membrane Oxygenation (ANZ ECMO) Influenza Investigators. Extracorporeal membrane oxygenation for 2009 influenza A(H1N1) acute respiratory distress syndrome. *JAMA* 2009;302:1888-1895.
6. The ANZIC Influenza Investigators. Critical care services and 2009 H1N1 influenza in Australia and New Zealand. *N Engl J Med* 2009;36:1925-1934.
7. Arabi Y, Gomersall CD, Ahmed QA, Boynton BR, Memish ZA. The critically ill avian influenza A (H5N1) patient. *Crit Care Med* 2007;35:1397-1403.
8. Manocha S, Walley KR, Russell, JA. Severe acute respiratory distress syndrome (SARS): A critical care perspective. *Crit Care Med* 2003;31:2684-2692.
9. Erickson SE, Martin GS, Davis JL, Matthay MA, Eisner MD. Recent trends in acute lung injury mortality: 1996-2005. *Crit Care Med* 2009;37:1574-1579.
10. Devereaux AV, Dichter JR, Christian MD, et al. Definitive care for the critically ill during a disaster: A framework for allocation of scarce resources in mass critical care. *CHEST* 2008;133:151-66(S).
11. Institute of Medicine. Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report. Washington DC: National Academy Press; 2009.
12. White DB, Katz MH, Luce JM, Lo B. Who should receive life support during a public health emergency? Using ethical principles to improve allocation decisions. *Ann Intern Med* 2009;150:132-138.
13. Burkle FM, Jr. Mass casualty management of a large-scale bioterrorist event: An epidemiological approach that shapes triage decisions. *Emerg Med Clin North Am* 2002;20:409-436.
14. Powell T, Christ KC, Birkhead GS. Allocation of ventilators in a public health disaster. *Disaster Med Public Health Prep* 2008;2:20-26.
15. Gostin LO. *Public Health Law: Power, Duty, Restraint*. 2nd ed. Berkeley: University of California Press; 2008, pp 421-458.
16. The Keystone Center. Citizen Voices on Pandemic Flu Choices. A Report of the Public Engagement Pilot Project on Pandemic Influenza; 2005. Available at: http://keystone.org/files/file/about/publications/FINALREPORT_PEPPI_DEC_2005.pdf.
17. The Keystone Center. The Public Engagement Project on Community Control Measures for Pandemic Influenza: Findings and Recommendations from Citizen and Stakeholder Deliberation Days; May, 2007. Available at: http://keystone.org/files/file/about/publications/FinalReport1_CommunityControl5_2007.pdf.

18. Ohio State University, Center for Public Health Practice. Ohio Pandemic influenza public engagement demonstration project: Mass fatality management, Final Report, August 2009, Available at:
http://www.ohiopa.org/admin/uploads/documents/OH_Rural_Final_Report_2009.pdf
19. Public Health-Seattle & King County. Public engagement project on medical service prioritization during an influenza pandemic: Health care decisions in disasters, September, 2009. Available at:
http://s3.amazonaws.com/propublica/assets/docs/seattle_public_engagement_project_final_sept2009.pdf.
20. Vawter DE, Garrett JE, Gervais KG, et al. For the good of us all: Ethically rationing health resources in Minnesota in a severe influenza pandemic. Minneapolis, MN: Minnesota Center for Health Care Ethics and University of Minnesota Center for Bioethics, 2010, in press.
21. Pesik N, Keim ME, Iserson KV. Terrorism and the ethics of emergency medical care. *Ann Emerg Med* 2001;37:642-646.
22. Christian MD, Hawryluck L, Wax RS, et al. Development of a triage protocol for critical care during an influenza pandemic. *CMAJ* 2006;175:1377-1381
23. Childress JF (Ed). *Triage in Response to a Bioterrorist Attack*. Cambridge, MA: The MIT Press; 2003.
24. NYS Workgroup on Ventilator Allocation in an Influenza Pandemic, NYS DOH/ NYS Task Force on Life & the Law. NYS document Allocation of Ventilators in an Influenza Pandemic: Planning Document; 2007. Available at
http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventilator_guidance.pdf.
25. Utah Hospitals and Health Systems Association Triage Guidelines Workgroup. Utah pandemic influenza hospital and ICU triage guidelines, August, 2009. Available at
http://pandemicflu.utah.gov/plan/med_triage081109.pdf.
26. Minnesota Department of Health. Mechanical ventilation strategies for scarce resource situations, 2010. Available at:
<http://www.health.state.mn.us/oep/healthcare/scarcevent.html>.
27. Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med* 2006;13:223-229.
28. Daniels N. Fair process in patient selection for antiretroviral treatment in WHO's goal of 3 by 5. *Lancet* 2005;366:169-171.
29. Shortt SE. Waiting for medical care: Is it who you know that counts? *CMAJ* 1999;161:823-824.
30. Sanders D, Dukeminier J. Medical advance and legal lag: Hemodialysis and kidney transplantation. *UCLA Law Review* 1968;15:366-380.
31. Rescher N. The allocation of exotic medical lifesaving therapy. *Ethics* 1969;79:173-186.
32. Ramsey PG. *Patient as Person*. New Haven, CT: Yale University Press; 1970.
33. Childress JF. Who shall live when not all can live? *Soundings* 1970;53:339-55.
34. Department of Health and Human Services. *HHS Pandemic Influenza Plan*; 2005. Available at <http://www.hhs.gov/pandemicflu/plan/appendixd.html>.
35. Department of Health and Human Service. *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*; 2008. Available at
<http://www.flu.gov/individualfamily/vaccination/allocationguidance.pdf>.

36. Gostin LO, Sapsin JW, Teret SP, et al. The model state emergency health powers act: Planning for and response to bioterrorism and naturally occurring infectious diseases. *JAMA* 2002;288:622-628
37. Emanuel EJ, Wertheimer A. Public health. Who should get influenza vaccine when not all can? *Science* 2006;312:854-855.
38. Williams A. Intergenerational equity: An exploration of the 'fair innings' argument. *Health Econ* 1997;6:117-132.
39. Neuberger J, Adams D, MacMaster P, Maidment A, Speed M. Assessing priorities for allocation of donor liver grafts: Survey of public and clinicians. *BMJ* 1998;317:172-175.
40. Harris J. *The Value of Life*. London: Routledge & Kegan Paul; 1985.
41. Brock DW. Ethical issues in recipient selection for organ transplantation, In Mathieu D (Ed). *Organ Substitution Technology: Ethical, Legal, and Public Policy Issues*. London: Westview Press; 1988.
42. Kamm FM. *Morality/Mortality. Volume One. Death and Whom to Save From It*. Oxford: Oxford University Press; 1993.
43. Daniels N. Rationing fairly: Programmatic considerations. *Bioethics* 1993;7:224-233.
44. Daniels N, Sabin J. Limits to health care: Fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philos Public Affair* 1997;26:303-350.
45. Tanner L. Who should MDs let die in a pandemic? Report offers answers. *Washington Post* 2008; May 5, 2008.
46. Lo B, White DB. Intensive care unit triage during an influenza pandemic: The need for specific clinical guidelines. In Lemon SM, Hamburg MA, Sparling F, Choffnes ER, Mack A (Eds). *Ethical and Legal Considerations in Mitigating Pandemic Disease*. Washington, D.C.: National Academies Press; 2007, pp. 192-197.
47. Rubenfeld GD (Ed). *Managing Death in the ICU: The Transition from Cure to Comfort*. New York: Oxford University Press; 2000.
48. Lo B, Rubenfeld G. Palliative sedation in dying patients: "We turn to it when everything else hasn't worked." *JAMA* 2005;294:1810-1816.
49. Okie S. Dr. Pou and the hurricane: Implications for patient care during disasters. *N Engl J Med* 2008;358:1-5.
50. Quill TE, Lo B, Brock DW, Meisel A. Last-resort options for palliative sedation. *Ann Intern Med* 2009;151, 421-424.
51. Lo B. *Resolving Ethical Dilemmas: A Guide for Clinicians*. 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2009.
52. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. New York: Oxford University Press; 2008.
53. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: *Deciding to Forego Life-Sustaining Treatment*. Washington, DC: US Government Printing Office; 1983.
54. Luce JM, Alpers A. Legal aspects of withholding and withdrawing life support from critically ill patients in the United States and providing palliative care to them. *Am J Respir Crit Care Med* 2000;162:2029-2032.
55. Meisel A. *The Right to Die*. 2nd ed. New York: John Wiley & Sons; 1995.
56. American Thoracic Society Bioethics Task Force. Withholding and withdrawing life-sustaining therapy. *Am Rev Respir Dis* 1991;144:726-731.

57. Truog RD, Campbell ML, Curtis JR, et al. Recommendations for end-of-life care in the intensive care unit: a consensus statement by the American College of Critical Care Medicine. *Crit Care Med* 2008;36:953-963.
58. White DB, Curtis JR, Wolf LE, et al. Life support for patients without a surrogate decision maker: Who decides? *Ann Intern Med* 2007;147:34-40.
59. White DB, Curtis JR, Lo B, Luce JM. Decisions to limit life-sustaining treatment for critically ill patients who lack both decision-making capacity and surrogate decision-makers. *Crit Care Med* 2006;34:2053-2059.
60. Ward NS, Teno JM, Curtis JR, Rubenfeld GD, Levy MM. Perceptions of cost constraints, resource limitations, and rationing in United States intensive care units: Results of a national survey. *Crit Care Med* 2008;36:471-476.
61. National Commission on Children and Disaster. 2010 Report to the President and Congress. AHRQ Publication No. 10-M037. Rockville, MD: Agency for Healthcare Research and Quality, October 2010. Available at <http://www.ahrq.gov/prep/nccdreport/nccdreport.pdf>.
62. Pediatric Emergency Mass Critical Care Task Force. Deliberations and recommendations of the task force on pediatric emergency mass critical care, 2011, in preparation.
63. Centers for Disease Control and Prevention. Coordinating pediatric medical care during an influenza pandemic: Hospital workbook. Prepared by Oak Ridge Institute for Science and Education, January 2010. Available at http://emergency.cdc.gov/healthcare/pdf/hospital_workbook.pdf.

VENTILATOR DOCUMENT WORKGROUP MEMBERS

- Drue Barrett, PhD, Office of the Associate Director for Science, Centers for Disease Control and Prevention; Designated Federal Official, Ethics Subcommittee, Advisory Committee to the Director
- Asha Devereaux, MD, Internist, Pulmonologist, and Critical Care Practitioner, Coronado, California
- Barbara Ellis, PhD, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention
- Debralee Esbitt, BSN, MS, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention
- Lindsay Feldman, MPH, Office of the Associate Director for Science, Centers for Disease Control and Prevention
- Neelam Ghiya, MPH, Office of the Associate Director for Science, Centers for Disease Control and Prevention
- Robert Hood, PhD, Florida Department of Health; Chair, Ethics Subcommittee, Advisory Committee to the Director
- Kathy Kinlaw, MDiv, Emory University; Consultant to the Ethics Subcommittee, Advisory Committee to the Director
- Mary Leinhos, PhD, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention
- Robert Levine, MD, Yale University; Consultant to the Ethics Subcommittee, Advisory Committee to the Director
- Alexandra Levitt, PhD, Office of Infectious Disease, Centers for Disease Control and Prevention
- Deborah Levy, PhD, MPH, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention
- Bernard Lo, MD, University of California, San Francisco; Member, Ethics Subcommittee, Advisory Committee to the Director
- Eileen Malatino, RN, MS, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention
- Mary Neumann, PhD, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention
- Leonard Ortmann, PhD, CDC-Tuskegee Public Health Ethics Fellow
- Nicki Pesik, MD, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention
- Lewis Rubinson, MD, PhD, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- Scott Santibanez, MD, Office of Infectious Diseases, Centers for Disease Control and Prevention
- Alcia Williams, MD, MPH, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention

Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: Second Report of the National Biosurveillance Advisory Subcommittee

Report to the Advisory Committee to the Director, CDC

April 2011

March 21, 2011

Eduardo Sanchez, M.D., M.P.H., F.A.A.F.P.
Chairman
Advisory Committee to the Director, CDC
1600 Clifton Road NE
Atlanta, GA 30030

Dear Chairman Sanchez,

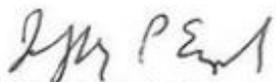
On behalf of the National Biosurveillance Advisory Subcommittee (NBAS) and in keeping with our mandate to ensure that the federal government is enhancing state and local government public health surveillance capability, we are pleased to submit the "Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats; Second Report of the National Biosurveillance Advisory Subcommittee." The report provides recommendations for action that describe how the United States could deploy people and technologies at all levels of government to improve the collection, flow and interpretation of data in a timely way as a means of preventing and mitigating threats to the health of communities.

In this report, the NBAS identifies specific recommendations that are designed to enable rigorous and effective biosurveillance through focus on governance, standardization of data collection, and investments in informatics, workforce education, and research and development (R&D) across geographic and thematic borders. Effective biosurveillance is essential to the management of catastrophic health events; it is also essential to routine public health practice and disaster response.

This work is the culmination of detailed fact-finding, consultation, and deliberation by the Committee. The NBAS is grateful to the many individuals who shared their knowledge and perspective with us in the development of this report.

We appreciate the opportunity to address this important area and hope that our deliberations and recommendations will be helpful to you and our government's leadership.

Sincerely,


Jeffrey P. Engel, MD,
Co-Chair, National Biosurveillance
Advisory Subcommittee

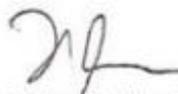

W. Ian Lipkin, MD
Co-Chair, National Biosurveillance
Advisory Subcommittee

Table of Contents

Executive Summary.....	ii
NBAS Membership List.....	iii
Acronym Glossary	vi
NBAS Recommendations	1
Appendix I: NBAS Work Group Reports	A1-1
Appendix II: Acknowledgements	A2-1

Executive Summary

Governance

Achievement of comprehensive, effective domestic and international biosurveillance is compromised by jurisdictional complexity and inefficiencies. Federal biosurveillance policy oversight should be established in the Executive Office of the President (EOP) with the National Security Staff (NSS) as the lead entity identified to coordinate investments, interagency collaboration, and program implementation including those activities in support of the President's Global Health Initiative. An outside representative advisory group should be established to facilitate key stakeholders' interface with White House policy and technology coordinating groups.

Information Exchange

Methods and metrics used in acquiring biosurveillance data are highly variable. This impedes data sharing and analysis, and recognition and response to health threats. Efficient, comprehensive aggregation and analysis of actionable biosurveillance data should be promoted through support for implementation of IHR 2005; integration of human, animal, food, vector, and environmental surveillance systems into a national biosurveillance strategy; and expansion of biosurveillance to include environmental aspects that are the greatest threat to human health, including water, food, animals, and vectors.

Workforce

The current biosurveillance workforce is inadequate to address existing challenges to biosecurity let alone those that are anticipated to arise with increasing data, globalization, and synthetic biology. The federal government should promote and ensure a sustainable interdisciplinary workforce with investments in expertise, especially in public health informatics; social and behavioral epidemiology; environmental, human and animal health; vector biology; and disaster response.

Research and Development

The federal government should continue to invest in a new generation of research to develop and build on innovative technologies in molecular and cellular sciences, engineering, chemistry, physics, information technology, mathematics, and communications that will enhance the efficiency and sensitivity of regional, national and global biosurveillance. Understanding the baseline and variance of human and animal health using these emerging technologies with clear processes to select the best approaches and scale them will allow for the creation of the functional equivalent of a national and international immune system that can protect the public in real time.

NBAS Membership List

Co-Chairs

Jeffrey P. Engel, MD
State Health Director
Division of Public Health,
Raleigh, NC

W. Ian Lipkin, MD
John Snow Professor of Epidemiology
Professor of Neurology and Pathology
Director, Center for Infection and Immunity
Mailman School of Public Health and
College of Physicians and Surgeons
Columbia University
New York, NY

Designated Federal Official

Pamela S. Diaz, MD
Director, Biosurveillance Coordination
Public Health Surveillance Program Office,
OSELS
Centers for Disease Control and Prevention
Atlanta, GA

Steering Committee Members

Don Burke, MD
Dean, Graduate School of Public Health
University of Pittsburgh
Pittsburgh, PA

Steven H. Hinrichs, MD
Chair, Department of Pathology and Microbiology
College of Medicine
University of Nebraska Medical Center
Omaha, NE

Robert P. Kadlec, MD
Vice President PRTM Management Consultants LLC
Washington, DC

James (Jamie) Allen Heywood
Chairman and Co-Founder
PatientsLikeMe, Inc.
Cambridge, MA

James M. Hughes, MD
Professor of Medicine and Public Health
Emory University
Atlanta, GA

Lonnie King, DVM
Dean, College of Veterinary Medicine
Ohio State University
Columbus, OH

Members

Tomas Aragon, MD, DrPH
Principal Investigator and Executive Director
Center for Infectious Disease & Emergency
Readiness
UC Berkeley School of Public Health
Berkeley, CA

Alvin C. Bronstein MD, FACEP
Associate Professor
Department of Clinical Pharmacology and
Emergency Medicine
University of Colorado Denver, School of Medicine
Medical Director Rocky Mountain Poison Center
Denver, CO

Rita R. Colwell, PhD
Senior Advisor and Chairman Emeritus
Cannon U. S. Life Services, Inc.
Distinguished Professor, University of Maryland
College Park, MD

Julia E. Gunn, RN, MPH
Director, Communicable Disease Control Division
Infectious Disease Bureau
Boston Public Health Commission
Boston, MA

Tom Inglesby, MD
Chief Executive Officer and Director
The Center for Biosecurity of UPMC
Baltimore, MA

Ann Marie Kimball, MD, MPH, BS
Director, APEC EInet
Professor of Epidemiology
University of Washington
Seattle, WA

James W. LeDuc, PhD
Professor, Microbiology and Immunology
Robert E. Shope M.D. and John S. Dunn
Distinguished Chair in Global Health
Director, Galveston National Laboratory
University of Texas Medical Branch
Galveston, TX

Kenneth D. Mandl, MD, MPH

Lawrence (Larry) Brilliant, MD, MPH
President
Skoll Global Threats Fund
Palo Alto

Heather Case, DVM, MPH, Dipl. ACVPM
Director, Scientific Activities Division
Coordinator, Emergency Preparedness and
Response
American Veterinary Medical Association
Schaumburg, IL

David R. Franz, DVM, PhD
VP and Chief Biological Scientist
Midwest Research Institute
Frederick, MD

James (Jim) L. Hadler, MD, MPH (Retired)
Former State Epidemiologist and Former Director,
Infectious Diseases Section
Connecticut Department of Public Health
New Haven, CT

Paul E. Jarris, MD, MBA
Executive Director
Association of State and Territorial Health Officials
Arlington, VA

Marcelle C. Layton, MD
Assistant Commissioner
Bureau of Communicable Disease
New York City Department of Health and Mental
Hygiene
New York, NY

Cecil O. Lynch, MD, MS
Assistant Professor
Department of Pathology
University of California at Davis
Granite Bay, CA

Linda A. McCauley, PhD, RN, FAAN

Associate Professor, Harvard Medical School and
Director, Intelligent Health Laboratory,
Children's Hospital Informatics Program
Children's Hospital Boston
Boston, Massachusetts

Kathleen Miner, PhD, MPH, CHES
Associate Dean, Applied Public Health
Emory University School of Public Health
Atlanta, GA

Richard Platt, MD, MSc
Professor and Chair, Dept of Population Medicine,
Harvard Medical School and Harvard Pilgrim
Health Care Institute; Executive Director, Harvard
Pilgrim Health Care Institute
Boston, MA

Thomas R. Slezak, MS
Associate Program Leader, Informatics
Lawrence Livermore National Lab
Livermore, CA

Mary Elizabeth Wilson, MD
Associate Professor of Global Health and
Population
Harvard School of Public Health
Washington, DC

Dean of Nursing
Nell Hodgson Woodruff School of Nursing
Emory University
Atlanta, GA

Stephen M. Ostroff, MD
Director, Bureau of Epidemiology
Pennsylvania Department of Health
Harrisburg, PA

Arthur L. Reingold, MD
Professor and Division Head
Division of Epidemiology
University of California, Berkeley
School of Public Health
Berkeley, CA

Perry F. Smith, MD
Director, Division of Epidemiology (Retired)
New York State Department of Health
Albany, NY

Acronym Glossary

Acronym	Expansion
ACD	Advisory Committee of the Director
APEC EINet	Asia Pacific Economic Cooperation Emerging Infections Network
APHA	American Public Health Association
APHL	Association of Public Health Laboratories
ASM	American Society for Microbiology
ASTHO	Association of State and Territorial Health Officials
ASTM	American Society for Testing and Materials
AVIA	American Veterinary Medical Association
AVMA	American Veterinary Medical Association
BIWAC	Biosurveillance Indications and Warning Analytic Community
BSE	Bovine Spongiform Encephalopathy
CCD	Continuity of Care Document
CCR	Continuity of Care Record
COMTRADE	International Commodities Trade Dataset
CSTE	Council of State and Territorial Epidemiologists
CTSI	Clinical and Translational Science Institute
DARPA	Defense Advanced Research Projects Agency
DHB	Defense Health Board
DMAT	Disaster Medical Assistant Teams
DOD	Department of Defense
DSA	Data Sharing Agreements
EHR	Electronic Health Records
EOP	Executive Office of the President
EPA	Environmental Protection Agency
ePCR	electronic Patient Care Record
EPT	Emerging Pandemic Threats
ER	Emergency Room
FAO	Food and Agriculture Organization
FAOSTATS	Food and Agriculture Organization, Statistics Division
FDA	Food and Drug Administration
GDD	Global Disease Detection (CDC)
GHI	Global Health Initiative
GOARN	Global Outbreak and Alert and Response Network
HHS	Department of Health and Human Services
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act

Acronym	Expansion
HITECH	Health Information Technology for Economic and Clinical Health Act
HL7	Health Level Seven
HSPD-21	Homeland Security Presidential Directive – 21 (Public Health and Medical Preparedness)
IATA	International Air Transport Association
ICSR	Individual Case Safety Report
IHR	International Health Regulations
IOM	Institute of Medicine
ISDS	International Society for Disease Surveillance
LAG	Lead Advisory Group
MMWR	Morbidity and Mortality Weekly Report
NACCHO	National Association of County and City Health Officials
NBAS	National Biosurveillance Advisory Subcommittee
NBSB	National Biodefense Science Board
NEMESIS	National EMS Information System
NGA	National Governors Association
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NSC	National Security Council
NSS	National Security Staff
OIE	World Organization for Animal Health
OMB	Office of Management and Budget
OSELS	Office of Surveillance, Epidemiology, and Laboratory Services
OSTP	Office of Science and Technology Policy
PH	Public Health
PHI	Public Health Informatics
PHII	Public Health Informatics Institute
PHIN	Public Health Information Network
PTSD	Post Traumatic Stress Disorder
R&D	Research and Development
SARS	Severe Acute Respiratory Syndrome
TB	Tuberculosis
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USG	United States Government
USGS	United States Geological Survey
VA	United States Department of Veterans Affairs
WHO	World Health Organization

NBAS Recommendations

Background

In 2007, Homeland Security Presidential Directive 21 “Public Health and Medical Preparedness” (HSPD-21) was issued in recognition of the emergence of health-related security threats to the nation. Among the mandates in HSPD-21 was the establishment of a federal advisory committee that includes “representatives from state and local government public health authorities and appropriate private sector health care entities, in order to ensure that the federal government is meeting the goal of enabling State and local government public health surveillance capabilities.” The federal Department of Health and Human Services (HHS) was charged with this mandate and delegated its implementation to the Centers for Disease Control and Prevention (CDC). On May 1, 2008, the CDC established the National Biosurveillance Advisory Subcommittee (NBAS) comprising prominent experts from the public health, health-care delivery, academic, homeland security, defense and private sectors to provide counsel to the federal government through the Advisory Committee of the Director (ACD) regarding the broad range of issues impacting the development and implementation of a nationwide biosurveillance strategy for human health. The first report, “Improving the Nation’s Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee” was released on October 16, 2009. Five major recommendations were made to ensure and continue building an adequate biosurveillance capacity for the nation. These included:

- The Executive Branch must define the strategic goals and priorities of federal investments in biosurveillance activities and technologies, and implement a plan to achieve, fund and periodically assess progress toward these goals. To accomplish this, the White House should establish an Interagency Biosurveillance Coordination Committee.
- The U.S. National Biosurveillance Enterprise must include global health threats in its purview and scope.
- The federal government must make a sustained commitment toward ensuring adequate funding to hire and retain highly competent personnel to run biosurveillance programs at all levels of government.
- Government investments in electronic health records and electronic laboratory data should be leveraged to improve how they serve biosurveillance and public health missions.
- The federal government must make strategic investments in new technologies (e.g., genomics, supply chain management, visualizations, display dashboards) to strengthen U.S. biosurveillance capabilities.

Of particular importance, it was noted that much of the domestic biosurveillance workforce capacity to detect, investigate, monitor and respond to public health events is located in state and local health

departments, that this capacity has been built with federal public health funding and is in jeopardy with decreasing federal investment in preparedness. Since the first report, these recommendations have not been fully implemented. However, the NBAS-2 recognizes their importance and continued relevance to maintaining and building on current capacity, particularly in the current economic situation with decreasing state and local investment in biosurveillance. This second report reflects the research and deliberations of a newly constituted NBAS established in the spring of 2010 (NBAS-2). Recommendations of the NBAS-2 build on those of the NBAS-1 and differ chiefly in emphasis on prioritization of areas for investment that reflect lessons learned from the H1N1 influenza pandemic, the rise of synthetic biology, and challenges of an austere economic environment.

Biosurveillance refers to the collection, management and integration of health-related data for the purpose of improving detection, characterization, prevention and management of health hazards. This report summarizes current NBAS concerns and challenges regarding governance; collection, exchange, and analysis of health information; and workforce needs. It also provides specific recommendations designed to enable rigorous, comprehensive, and efficient biosurveillance through modifications in governance, standardization of data collection, and investments in informatics, workforce education, and research and development (R&D) across geographic and thematic borders.

Governance

Comprehensive, efficient biosurveillance requires coordination among the public (local, state, and federal) and private sectors. Many institutions critical to biosurveillance operate under their own standards and practices. Moreover, despite increasing availability of electronic health records (for both humans and animals), standardized methods for collecting, analyzing, and sharing public health-related information across the private sector and local, state and federal agencies are lacking, hampering effective integration across jurisdictions. The inadequate information flow across agencies results in federal health-related policies that lack valuable insight and potential guidance from the private sector and state and local agencies. It also diminishes the probability of the functional effectiveness of early detection and response to health threats.

The NBAS reiterates an earlier recommendation that the federal government vest a lead entity in the White House the authority and responsibility for coordinating integration, collaboration, and cooperation among federal agencies conducting biosurveillance activities and to promote public, private, and state and local government agencies involved in biosurveillance. At present, the NBAS is the only federal advisory board capable of providing expert advice to that lead entity on human health-related biosurveillance only. However, the scope of its expertise should be expanded to include food safety, animal and environmental health if it is to serve as the nation's leading biosurveillance advisory committee.

This lead entity should identify strengths and gaps in biosurveillance; mandate development of standardized methods for evaluating and measuring outcomes; support international development of sustainable biosurveillance capacity; integrate plant, animal, relevant environmental and human health information; and supervise the creation of a public database cataloging biosurveillance efforts. It should also enhance communication, and reduce potential for inter-agency duplication of effort and conflict. Biosurveillance efforts must be global in scope and enable early detection and response to health threats.

Challenges

- Requirements for global, borderless biosurveillance: Biosurveillance efforts must be domestic and international in scope, because health threats that emerge anywhere may cross borders quickly and threaten people worldwide.
- Complicated Jurisdictional Oversight: Ideally, a governance structure at the Executive Office of the President is needed to oversee biosurveillance programs across the federal agencies to align efforts, prevent duplication, eliminate inefficiencies, resolve conflicts and promote effective communication and information sharing.
- Obligations under the International Health Regulations (IHR): The 2005 revision to the IHR notes specific activities designed to ensure that every country has the capacity to conduct disease surveillance, and to identify, report, and respond to health events. The IHR represents the most effective mechanism to channel investments to build worldwide biosurveillance capacity.
- Maximizing Private/Public Partnerships: White House policy oversight should promote coordinated national biosurveillance activities that ensure input from the federal, state, and local public and private sectors. U.S. contributions to global disease detection are also dependent on improved/coordinated interactions with public-private partnerships, including but not limited to international, federal, and local agencies; professional societies; businesses; academic institutions; healthcare entities; and non-governmental organizations.
- Issues concerning access: Actors in the public and private sectors may be reluctant to exchange information without explicit assurance that it will not be released to others without permission.
- Inequalities pertaining to data ownership vs. use: There are significant disparities between the federal and the local levels in terms of ownership and need for/use of data; coordination of public health data needs to include all levels.
- Siloed Data: Fractured information flow, due to incompatible surveillance systems, limits the public health system's ability to monitor and improve the delivery of interventions. Public health surveillance programs that develop in silos without attention to inter-operability tend to collect data that are difficult to integrate.

Recommendations

- Establish a robust mechanism for federal policy oversight and coordination, through the Executive Office of the President with the National Security Staff as the lead entity for USG domestic and international (global) biosurveillance programs and activities.

- Ensure input from federal, state, local and private biosurveillance entities.
 - Align and prioritize Department, Agency and private sector strategies to capitalize on potential synergies and opportunities for improvement.
 - Identify opportunities for improvement based on reviews of recent national and international events such as the H1N1 influenza pandemic, the H5N1 epizootic, Hurricane Katrina and the Deep Water Horizon Disaster.
- Create collaborative mechanisms whereby stakeholder public health and non-governmental organizations, designated representatives of existing federal biosurveillance-related advisory groups, as well as other representative private sector entities, can interface with the White House policy and technology coordinating groups.
 - Establish a lead advisory group (LAG) composed of representatives from state and local public health and relevant NGOs (ASTHO, NACCHO, CSTE, APHL, NGA) and federal biosurveillance advisory groups (e.g. NBAS, NBSB and designated private entities - a partial list includes agriculture, plant and crop sector, pharmaceutical industry, retail pharmacies, and healthcare organizations and institutions).
 - The LAG should participate in periodic performance assessments of ongoing domestic and international biosurveillance activities that reflect actual events, exercises and simulations.
 - The federal government should identify a single lead entity with responsibility, authority, and accountability to coordinate investments, ensure interagency collaboration and cooperation, and demand efficiency in program implementation of biosurveillance activities supporting the President's Global Health Initiative (GHI).
 - Develop and maintain a process to inventory and document current and planned investments across the full spectrum of activities relevant to biosurveillance that includes all US government agencies and programs (such as DOD overseas labs, HHS, Global Disease Detection [GDD] Centers [CDC], and the Clinical Trials Network [NIH]).
 - Consolidate US government investments among agencies and leverage partner agencies and organizations, NGOs, foundations, the business sector, and civil society in host nations, to ensure efficiency, avoid conflict, and maximize return on investment.
 - Establish metrics for monitoring implementation and outcomes.
 - Ensure that programs and activities are recognized by host nations and regional partners as aligned with country infectious disease priorities.
 - Advocate for an international legal framework that coordinates and prioritizes animal health programs.

Information Exchange

Efficient, comprehensive aggregation and analysis of actionable biosurveillance data is compromised by the lack of common descriptors and methods for collection of information as well as inadequate data sharing and use agreements. Standards, metrics, validation protocols, diagnostic platforms, terminology, operational systems, and cultures vary by region, making it difficult for different agencies to seamlessly share information. Additional impediments include intellectual property and indemnity concerns, as well as jurisdictional issues that preclude sharing samples and data. Moreover, the nation's current biosurveillance initiative lacks an integrated surveillance system that monitors the interaction between agricultural, environmental, animal, and human health-related issues. This information gap further hinders surveillance, analysis, and timeliness.

It is imperative that the federal government develop operating principles for data collection, integration, and sharing that allow for flexibility, expansion and innovation. These principles must promote IHR implementation and competencies domestically across states and abroad in partnership with the WHO and regional agencies, ensuring that data is shared among relevant stakeholders, and encouraging cooperation at local, regional, and federal levels. Most importantly, it must create an inclusive biosurveillance system capable of monitoring and integrating environmental, agricultural, animal, and health-related data.

These goals can be accomplished through the adoption of standard protocols, validation and use of broadly applicable metrics based on quantitative research, development of technologies that facilitate real-time data collection, reporting, and analysis, creation of nominal and computation models of disease and wellness, and use of digital clinical records. The federal government should also experiment with leveraging public media and other non-traditional data sets (social networks, user-sourced information, podcasts, and search engine queries) to collect and disseminate information, gain novel insights into population health trends, detect anomalies in health behavior and healthcare consumption, and organize stakeholders who support and promote biosurveillance efforts.

Challenges

- One Health: Domestic animal, wildlife and plant disease surveillance systems and food and vector disease monitoring systems should be integrated into the national biosurveillance strategy for human health.
- Normalized data and Interoperability: The biosurveillance enterprise requires data sharing, systems integration, efficient and timely exchanges of information, standardized diagnostic platforms, interoperable information technologies, and broad data access.
- Common Standards: Metrics must be established to assess the utility of tools, training programs and strategies employed to support national and global biosurveillance efforts.

- Data Use Agreements: Data sharing agreements are an essential building block for developing national and international capabilities, addressing concerns of trust, responsibility, and liability.
- Jurisdiction: Electronic health data are increasingly available. Biosurveillance is dependent upon transmission of these data across jurisdictional lines.
- Language: Variability in terminology is a barrier to biosurveillance. Standardization of methods for recording and reporting information is critical to realizing the promise of data sharing, informing biosurveillance and facilitating situational awareness and event detection.
- Data Sharing: Proprietary diagnostic and disease data from animal and wildlife populations should be shared with public health officials; issues of incentives, confidentiality, and potential political and economic consequences must both be understood and overcome.

Recommendations

- Establish a legal framework for data sharing between state and federal agencies to facilitate information exchange at the state and federal levels.
- Support implementation of IHR 2005:
 - o US efforts to support IHR implementation should be conducted in close cooperation with the WHO and its regional affiliates.
 - o Communication and coordination with WHO should be enhanced by secondment of an individual from CDC to the IHR implementation unit at WHO.
 - o The US should promote IHR implementation using various bilateral, multilateral, and regional diplomatic and security initiatives and encourage other countries to prioritize IHR implementation.
 - o Programs should contain objective outcome measures by which progress in building global biosurveillance capacity can be assessed and the benefits of these investments should be documented.
 - o The US should objectively target resources toward countries and regions that need additional support to develop capacity to conduct surveillance and response activities as required by the IHRs.
- Integrate domestic animal, wildlife, plant, food, vector, disease and environmental surveillance systems into a national biosurveillance strategy for human health.
 - o The USDA, CDC, EPA, USGS, and FDA should work in concert with state agriculture and public health agencies; animal health diagnostic, private food and animal health laboratories; poison centers and their National Poison Data System (NPDS) to collect and analyze surveillance data. These data should be shared with the OIE, FAO, and WHO when appropriate.
- Expand biosurveillance to include environmental sites of greatest threat to human health.

- Biosurveillance should incorporate more microbial and chemical testing, and emphasize recreational and drinking water sites and systems.
- Biosurveillance should consider low level exposures that, over time, may result in human hazards and chronic illness and conditions.
- State and local environmental protection organizations and private corporations should be recruited to ensure access to local expertise.

Workforce

The success of a coordinated biosurveillance system relies on the development of a sustainable interdisciplinary workforce with expertise in disciplines classically associated with public health such as epidemiology, microbiology and other laboratory-based sciences, biostatistics and management but also in others including but not limited to medical and bioinformatics, mathematics, information technology and computer engineering. The NBAS specifically noted a dearth of expertise in social, behavioral, and mental health epidemiology, vector biology, environmental studies, and public health informatics. Social and behavioral epidemiology have the potential to minimize morbidity and mortality and economic costs and improve community resiliency associated with a wide range of acute and chronic disorders. A new medical, public health and bioinformatics workforce will be needed to manage and analyze the exponential increase in volumes of data collected through enhanced biosurveillance efforts. The federal government, in collaboration with domestic and international public and private institutions, should invest in masters, doctoral, and continuing education programs that support the development of personnel infrastructure to address these needs. It should also promote collaboration among basic science, clinical, and public health professionals and ensure strategic placement of individuals with complementary expertise so as to maximize benefits and minimize redundancy and inefficiencies. The NBAS believes that vicissitudes in funding, particularly at the state and local levels, have been an impediment to the recruitment of creative, dedicated individuals to public health. Thus, a commitment to ongoing support will be key to sustainable biosurveillance.

Challenges

- Interdisciplinary capacity: Individuals with a wide variety of skills are needed to support biosurveillance, particularly in informatics, vector biology, behavioral epidemiology and environmental health.
- Training programs: Training programs are currently insufficient to develop the personnel infrastructure for the biosurveillance mission.
- Sustainability: Recruiting and retaining biosurveillance professionals requires a sustained funding commitment.

Recommendations

- Enhance the public health informatics, social and behavioral epidemiology, vector biology and environmental health professions.
 - Support the development and continuity of masters, doctoral and fellowship programs.

- Develop the science of public health informatics through extramural grant research programs.
 - Provide a tuition support program for state and local PH professionals and define and support sustainable biosurveillance career paths.
- Integrate the human and animal health professions
 - Encourage cross training and collaboration of clinicians and basic scientists in human and animal health.

Research and Development

The federal government should invest in research to develop and build on innovative technologies in molecular and cellular sciences, informatics, engineering, chemistry, physics, mathematics and communications that will enhance the efficiency and sensitivity of regional, national and global biosurveillance. The first NBAS report described a DARPA model for identifying initiatives with potential to support this objective. Key impediments to implementing new technologies are the lack of baseline data on biomarkers for individual and population health and disease, samples for assay optimization and validation, and the timeline and expense of pursuing regulatory compliance. Broadly applicable metrics based on quantitative research must be developed, validated, and adopted across agencies using standardized practices. Clinicians, public health professionals, and investigators must collaborate to develop and implement diagnostic and discovery platforms for use in clinical and environmental surveillance. The federal government should encourage data sharing and analysis across jurisdictions, invest in models that track population health across geographic and thematic borders, and leverage data obtained through crowd-sourcing and social networks.

Challenges

- Incentivizing Innovation: Many innovative efforts in data/information mining originate in the private sector. Incentives and funding will be critical to focusing these efforts on biosurveillance.
- Leverage Social Media: Data streams associated with social media or crowd-sourced knowledge have potential to provide new and early insights into population health.
- Aggregation and Analysis of Various Data Sources: The need for data integration, communication networking, and situation awareness has become more acute with globalization and the increasing availability and complexity of health-related information. Methods must be established to rapidly, reliably, and securely collect, synthesize, and share biosurveillance information amongst stakeholders.
- Streamlined Process for Developing/Validating Tools: Currently there is limited process clarity for validating and introducing improved tools or biosurveillance assays. This stifles innovation,

reduces quality and increases costs. There is a need to formalize processes for developing, validating, and deploying tools needed for biosurveillance.

- **Diagnostics:** Technical innovations based on molecular techniques are increasing the specificity, speed, reliability, and availability of diagnostic testing. There is need for fast, reliable, specific, point-of-care diagnostics and standardized electronic reporting of results for early detection of emerging diseases in both animals and humans.
- **Modeling:** The potential use of models to anticipate the potential spread of disease and identify probable outcomes given options for interventions is under-utilized and under-funded.
- **Defining Health:** Disease is deviation from equilibrium “healthy” status. An ideal biosurveillance system needs to baseline health so it can detect deviations from health prior to the onset of clinical disease.

Recommendations

- Develop, evaluate and implement new platforms and algorithms for real time data collection and analysis through investments in research and development.
- Develop, evaluate and implement new methods for detection of pathogens, and biomarkers for health, disease, chemical and radiation exposure, and personalized medicine that can be deployed in a variety of settings including low income countries.
- Improve and formalize pathways for assay optimization, validation and implementation by facilitating access to specimens and data, and standardizing and streamlining the process of assay validation and selection across agencies.
- Invest in nominal and computational models richly descriptive of individual health and the behaviors of healthy populations. The tools to conduct point of care assessments of biomarkers or behaviors indicative of disease, once discovered, should be rapidly deployed and stockpiled.

Appendix I:

National Biosurveillance Advisory Subcommittee

Work Group Reports

Governance:

Biosurveillance in the context of human health is the science and practice of managing health-related data and information for early warning of threats and hazards, early detection of events, and rapid characterization of the event so that effective actions can be taken to mitigate adverse health effects.

TF Scope: Governance (Inter-agency Collaboration and Engagement). There is a need for the creation of a National Biosurveillance Governance Structure that would oversee and coordinate the biosurveillance programs across the federal agencies, and would develop transparent processes for collaboration and coordination that extend across Federal, State, local and private sector biosurveillance activities. Though not formally defined, this National Biosurveillance Enterprise of federal, state, local and private entities requires a mechanism for formal oversight and collaboration. Without such collaboration and oversight, there will be the persistent risk of duplication of efforts, inefficiencies, and problems with communicating surveillance information in standardized formats to facilitate integration and provide situational awareness from a national level. These collaborative and coordinating processes should include a forum to discuss how federal, state, and local public health capabilities and needs can contribute to a global (domestic and international) biosurveillance system by creating common terms of reference and standards, and ensuring that desired activities receive the resources to achieve a sustainable biosurveillance system.

TF Approach

Issue #1: The Federal Government at the White House level has yet to implement a comprehensive mechanism to oversee and coordinate domestic and international US Government (USG) sponsored or funded biosurveillance activities across the federal, state, local and private sector domains.

Discussion

We reiterate the recommendation from the 2009 NBAS report and recommend the establishment of a robust mechanism of White House policy oversight and coordination of USG domestic and USG-funded international (global) biosurveillance activities. We note that since the earlier NBAS report, there are now offices within the National Security Council (NSC) and the Office of Science and Technology Policy (OSTP) that actively provide oversight of some federal biosurveillance activities. This existing oversight should be expanded to create seamless oversight of policy efforts of the National Security Council (NSC) and National Security Staff (NSS). There are already efforts by the NSC to coordinate federal level international biosurveillance activities. There is a need to create a similar domestic policy oversight mechanism within the NSS Resilience Directorate. There also exists an oversight and coordinating group within the OSTP that monitors research and development (R&D) of technology to support biosurveillance programs and activities, but effective overarching policy and R&D oversight is not yet fully defined or functional. In addition, the Office of Management and Budget (OMB) has an essential role to play in this collective oversight. The combined, coordinated efforts by the NSC, NSS, OSTP and OMB could create the kind of comprehensive oversight needed. To date however, their formal connections and relationships have not matured sufficiently to create this desired end-state.

We are optimistic that these White House level offices and efforts will, over time, mature into effective oversight. Until then, however, many Departments and Agencies of the federal government involved in biosurveillance have a variety of committees and advisory groups that provide oversight or guidance. While many Departments and Agencies currently operate under their own strategic plans and processes, a common set of strategic goals or implementation plan aligning or prioritizing their individual efforts does not exist. Without a coherent strategy and implementation plan based on commonly accepted standards and ongoing assessment, there is a risk of redundant or ineffective outcomes or potential gaps and vulnerabilities. In light of current and expected fiscal constraints, such outcomes are particularly worrisome and could jeopardize the achievement and sustainability of a national biosurveillance enterprise. In forging any implementation plan, we would expect that the extensive involvement by the OMB is essential.

The concept of biosurveillance has evolved since the adoption of the Homeland Security Presidential Directive (HSPD) 21 in October 2006. Electronic health data is becoming increasingly available to support biosurveillance efforts, especially with the recent Stage 1 and proposed Stage 2 Meaningful Use criteria from the Health Information Technology Policy Committee under HHS. However, transmission of this data to local and state public health agencies needs to be implemented in a standardized way that will facilitate effective integration across jurisdictional lines. This will require effective governance to ensure the development of data collection, analysis, and integration standards as well as common evaluation plans with input from local, state and federal public health agencies and the health care IT community. Input from state and local public health officials is essential because the authority for and experience with public health surveillance reporting has historically rested with the states. Governance of biosurveillance activities requires state and local public health input, support, and active participation for effective implementation and evaluation.

Recent events such as the 2009-10 H1N1 Influenza Pandemic and the Deep Water Horizon disaster provided new insights and lessons in biosurveillance. We judge that any White House led effort to revise the practice of biosurveillance should include a review of how current systems function in both detecting events of significant public health concern and monitoring the human health impact (i.e., situational awareness), and of revisions of current biosurveillance priorities and funding to help address identified gaps.

Recommendations:

- We recommend that the White House at the level of the Executive Office of the President (NSS, NSC, OSTP and OMB) create a comprehensive oversight mechanism of federal biosurveillance programs and activities.
- The objective of these White House efforts should include coordinated national biosurveillance activities that ensure input from federal, state, local and private biosurveillance entities (See Issue #2).
- This coordination should include aligning existing Department and Agency strategies, plans and programs and prioritizing resources and efforts to capitalize on potential synergies and opportunities for improvement. Identifying opportunities for improvement must involve reviews of recent national events, such as the H1N1 pandemic and the Deep Water Horizon disaster, and ongoing future evaluations of biosurveillance efforts.

Issue #2: Current federal policy and programmatic deliberations and promulgations often suffer from a lack of input from state and local public health authorities and the private sector.

Discussion

Under the current White House oversight of domestic and international biosurveillance, it is very difficult for state and local governmental and private sector entities to provide the kind of insight and input that could assist in creating a seamless, sustainable national biosurveillance system. We recommend creating a collaborative mechanism by which acknowledged federal, state, and local public health and non-governmental organizations (e.g. ASTHO, NACHO, CSTE, APHL, NGA), designated representatives of existing federal biosurveillance-related advisory groups, as well as other private sector entities, could interface with White House policy and technology coordinating groups.

We judge that representatives from these identified groups could provide valuable input, such as:

- Providing descriptions, educating and informing the NSS of current state and local biosurveillance activities
- Identifying opportunities and vulnerabilities
- Recommending improvements
- Providing guidance on prioritizing strategic objectives and actions
- Reviewing and providing feedback on proposed strategy, policy, plans and resource allocations

We recognize that creation of such a group, the Lead Advisory Group (LAG) would have to conform to existing Federal laws and policies. A semi-annual meeting of the LAG with the NSS in a public forum that permits widespread participation an exchange of new ideas, technologies and polices would support this objective.

Recommendations:

- We recommend establishing a LAG, composed of representatives from established state and local public health agencies and relevant NGOs (ASTHO, NACCHO, CSTE, APHL, NGA), chairpersons of the existing federal biosurveillance advisory groups (e.g., NBAS, NBSB, DHB) and designated private entities (TBD).
- This LAG would participate in routine meetings convened by the White House NSC and NSS policy and OSTP technology oversight committees.
- This LAG would also participate in periodic performance assessments of ongoing domestic and international biosurveillance activities that reflect actual events, exercises and simulations.

Issue #3: What is the best future role for NBAS?

Discussion

There are a number of advisory groups that provide directional advice to various agencies and entities about biosurveillance activities affecting human health, including animal, food, agriculture, and environmental factors. For example, the Defense Health Board has a standing subcommittee devoted to disease surveillance activities pertaining to deploying/deployed U.S. forces. The efforts of these groups are often not coordinated.

NBAS is the only group created by Presidential Directive HSPD-21. Under its current charter and configuration, NBAS is dedicated to address only human health biosurveillance issues. We have recommended the creation of a LAG to advise the relevant White House NSC and NSS policy and OSTP technology committees on the diverse disciplines (environmental, agricultural, animal, and human) that comprise a holistic national biosurveillance system. One alternative to creating a new advisory body is to reconfigure NBAS to serve that function.

This approach is consistent with the recommendations contained in the 2009 NBAS report. If it were infeasible to create a LAG to support the policy and programmatic deliberations at the White House level, we would recommend elevating the role and expanding the representation of NBAS. NBAS is the only existing Federal Advisory Board whose specific mandate is to provide expert guidance on biosurveillance pertaining to human health. This is a unique and vital function that resides nowhere else. While the composition of NBAS is not currently optimized to reflect the spectrum of disciplines needed to represent the current breadth of biosurveillance activities, it could be reconfigured to include expertise in the relevant areas of zoonotic diseases, food safety and environmental issues.

Irrespective of its ultimate disposition and mission, we judge that NBAS can best meet its commitments by reporting directly to Director of CDC and ultimately to the White House.

Recommendations:

- NBAS should remain as an advisory group focused on human health surveillance and be changed to report directly to the Director of CDC.
- The NBAS Chairpersons and other designated NBAS members should be statutory members of the LAG.
- If it is not feasible to create a LAG, the NBAS should be reconfigured to perform the function of LAG.

Healthcare and Public Health Information Exchange

Overview and Background of Recommendations

The Healthcare and Public Health Information Exchange Work Group (HPHIE) has identified three broad areas for improvements including: 1. Addressing the Social Context for Health Information Exchange (HIE), 2., Strengthening the Front Lines through HIE, and 3. Achieving the Potential of HIE.

Each of these topics incorporates complex and challenging issues. The workgroup had two objectives:

- Identify high-level recommendations that would significantly improve national capabilities for public health surveillance and response.
- Focus on issues related to acute or large-scale events as well as routine or ongoing health care activities with the perspective that optimal data sharing is necessary to achieve effective biosurveillance.

To accomplish these goals, a general understanding of the obstacles that have prevented greater progress in spite of longstanding agreement that our current capability is not optimal is necessary.

Issue #1: Addressing the Social Context of HIE

If there is general consensus regarding the value of information exchange between Healthcare and Public Health entities, why has it not been achieved? Jurisdictional concerns and questions over who owns samples and data have hindered the implementation of effective HIE.

Disclosure of sensitive information by entities like “Wikileaks” has raised the question of whether the public and responsible officials will accept and participate in the exchange of information when it may be released without permission. To address this point it is necessary to address who owns the data. Currently, public health events are considered local in nature and prevention and intervention take place at the local level. The workgroup endorses this concept; however, it is essential to broaden the perspective and incorporate the federal government to address gaps in functionality. Local jurisdictions miss out on functionality provided by state or federal governments, especially if they do not view

collaboration with state and federal agencies as mutually beneficial. These issues are highlighted by friction caused by jurisdictional boundaries. For example, a local epidemiologist may invite the federal government to assist in an investigation only to feel displaced when a team of federal experts arrives, questions the local population, and sends specimens to the CDC. Local officials may also want to understand the scope and source of outbreak before releasing information to other state or federal agencies, thus increasing the potential for further outbreaks. These sensitivities must be addressed in order to achieve effective HIE across jurisdictions. The workgroup believes that if the full benefit of participating in a national system is presented and appropriate safeguards are established, the goal of a national HIE can be achieved.

Issue #2: Strengthening Biosurveillance through HIE

Local health departments and hospitals are on the front lines of health care delivery and public health surveillance and response. In many jurisdictions, first responders (ambulance services, fire departments, paramedics) report to local public health departments. Electronic information exchange has increased the numbers of cases of reportable conditions and events; however, the ability of local jurisdictions to analyze and monitor the data is limited. HIE has the potential to improve detection of and response to public health emergencies. Adoption of electronic health records by local entities varies greatly across the country (see appendix XC.) Electronic health records offer the potential for data mining. The ability of health departments to efficiently manage the influx of information and avoid warehousing data will require standardization of data collection, analysis, and sharing.

Effective response to public health emergencies requires post-event surveillance. Destruction of underlying infrastructure may result in the need for alternative care sites such as Disaster Medical Assistant Teams (DMAT) facilities and on-site clinics at shelters. Post-event surveillance has identified infectious disease outbreaks, increases in carbon monoxide poisoning, and asthma exacerbation post-fires.

Opportunities to improve data collection, monitoring, evaluation and uses during public health emergencies include:

- Developing technologies that facilitate real-time data collection and reporting
- Establishing common metrics
- Simplifying data collection and reporting requirements
- Establishing systems for use routinely and during public health emergencies

Efforts in emergency management informatics include data standardization and messaging, which allow information from the field to inform biosurveillance and provide a more complete understanding of situation awareness and event detection. Ongoing work by DHS and the DOD should be coordinated with the CDC and other public health partners to create a comprehensive biosurveillance system. Coordination of efforts will be essential to maximize the resources at all levels of public health.

Recommendations:

- Coordinate biosurveillance efforts across federal domains.
- Coordination of public health information needs to include federal, state, tribal, regional and local public health departments.
- Support the development of public health infrastructure including analysis, visualization, and decision support.
- Develop a process to define the added value of data from electronic health records and the required tools needed for utility.

Issue #3: Achieving the Potential of HIE

The HPHIE Workgroup identified two broad topics under which specific activities would take place that would accelerate progress:

- Optimizing the data sets and messaging process for HIE
- Improving functional performance through implementation of data sharing agreements

Protecting the health of the American public requires individualized healthcare by the clinical workforce, personal attention to healthy living strategies, and population surveillance by public health authorities. These strategies will enable the detection and amelioration or elimination of threats to the population as a whole.

Although these entities must take some responsibility for a particular segment of healthcare and prevention work, they cannot function independently as there are undeniable requirements for data sharing between these entities. However, the amount of information needed to make health-related decisions across agencies differs widely due to the ways in which health-related data is identified and shared among agencies. These differences in granularity of the information that needs to be shared between entities yields a matrix that will help us to define a process of "working interoperability" between and across agencies.

The International Society for Disease Surveillance has identified a minimum data set for use in sharing across agencies for effective biosurveillance that includes an electronic healthcare record system and a syndrome surveillance application. The minimum data set is meant to form the baseline requirements for any vendor to meet meaningful use requirements from a public health perspective and to provide working interoperability between vendor applications and any designed surveillance system used to inform aggregate analysis of public health threats. However, it is inadequate for planning and implementing direct interventions based on specific health threats.

This implies that a different set of meaningful use criteria is needed to achieve working interoperability between electronic healthcare applications and local health departments for determining, for instance, an active case of hepatitis C or whether a case of tuberculosis has been treated according to WHO or CDC standards. Different levels of identifier information both from the perspective of patients and health care providers and organizations are needed to achieve public health interoperability. Interoperability must be bidirectional in order to cycle public health knowledge back into clinical settings.

A local public health data exchange requires that the context of the information received be clearly defined and that there be greater privacy protections for these data. This implies a difference in the data use agreements for information shared at this level of granularity than for data shared for syndrome surveillance purposes. This presents not only an information exchange issue, but also a governance issue, with implications for technology implementations.

Given the differences in the granularity of data and the context which must be applied to that data, it is appropriate to think about the different information structures needed to share this data. At the most granular level of information exchange needed for working interoperability between two clinicians caring for an individual patient, a rich context of information must be applied using an appropriate information structure. For electronic healthcare vendors to meet this level of interoperability, the Office of the National Coordinator has prescribed the continuity of care document (CCD) or the ASTM continuity of care record (CCR) as appropriate information structures to transmit data between providers.

The data structure needed to care for individual patients fits much more closely with the requirements of local public health needs than with the current recommendations for meaningful use for public health using the HL7 2.5.1 or 2.3.1 message structures. The FDA has recognized the additional level of granularity required between providers as it looks to solve the problem of adverse event reporting using electronic healthcare records. It is working on the individual case safety report (ICSR), an HL7 Version 3 message enumerating observational elements that are common across the structured document products used in the CCD. These structures provide greater semantic richness of individual datum and also proscribe a rich contextual framework for understanding the data. Providing this richer structure could significantly lessen the burden on public health professionals by promoting better data acquisition.

Recommendations:

- Establish a tiered representation of public health meaningful use data, aligned with its purpose of use and needs of working interoperability at different levels within the public health sector.

Data sharing agreements (DSAs) are an essential building block for developing national capabilities. The Workgroup believes they are one of the most important approaches for addressing key obstacles to achieving uniform HIE. The section on Social Context for HIE has described scenarios related to the

specific need for DSAs. To establish the level of trust needed to allow the sharing of information, the provider must know that the transfer will not generate negative outcomes and that all authorities have approved the transfer. Establishing trust requires knowledge of who owns, has access to, and is authorized to determine the distribution of shared data.

A DSA is a legal document or contract in which two or more parties define the conditions and limitations under which data can be shared or exchanged. For purposes of the current recommendation, the goal is to exchange data electronically. The working group has discussed several examples in the private sector related to sharing sensitive information with commercial value and has assembled a non-exhaustive list of existing or time-limited agreements between health care entities (see appendix XZ). DSAs have been put in place during national emergencies; however, it is essential that such agreements be established in the course of routine business. DSAs accelerate information exchange, but such agreements are not in place (with rare exception) between key federal agencies, including the CDC and state and local entities.

The workgroup notes the development of some DSAs between federal agencies; however until the local source of data (state, county, city) is brought into the agreement, these do not achieve long-term HIE goals. The workgroup has considered a number of key issues related to DSA implementation. While a detailed document is beyond the current scope of this report, some general principles have been identified:

- The DSA we are recommending should be considered a “Foundational DSA.” It does not limit further development, but rather sets the basis for further expansion depending on need. This foundational approach should incorporate uniform features and should be of value at local, regional, and national levels.
- It should contain generic terms and conditions that could be modified as needed, based on relevant local law and the nature of the data being shared, such as the jurisdiction in which enforceable elements would be determined (State of New Jersey, Federal District Court).

Recommendations:

- OSELS should act as the lead CDC group to implement this proposal.
- Priority should be given to establishing a “Foundational DSA” for state and local public health entities. External PH partners will include ASTHO, CSTE and NACCHO.
- Establish agreements among and between key federal agencies including DHS and DOD. Local partners will want and need to know how broadly the data will be shared because this may determine which agency should generate a follow up contact (i.e. USDA, DHS, FDA).

References.

<http://ncb-prepared.org>.

MMWR on EMS electronic Patient Care Record (ePCR) data utility:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5921a1.htm?s_cid=mm5921a1_e%0d%0a

NHTSA Pan Flu recommendations for EMS Call Centers (See Guiding Principle #4 and Appendix C):

<http://www.nhtsa.gov/people/injury/ems/PandemicInfluenza/PDFs/Task%206.1.4.2Lo.pdf>

National EMS Information System (NEMESIS)

www.nemesis.org/theProject/whatIsNEMESIShttp://books.nap.edu/openbook.php?record_id=12992&page=63

Work Group Appendix.

XC.

The Health Information Technology for Economic and Clinical Health Act (HITECH) stimulated the adoption of technology to improve patient and population health. The act provides for payments to clinicians and hospitals when they use electronic health records for electronic laboratory reporting, immunizations, and syndromic surveillance. However, there was no funding to support the efforts of public health departments to receive electronic health data. In addition, many local health departments are safety net providers for vulnerable populations. Services provided include primary care, immunizations, and specialty clinical care for conditions such as tuberculosis and sexually transmitted infections. These departments would also be senders of health information. In 2009-2010, 13% of local health departments that provide primary care used a full electronic record.

In 2010, ASTHO conducted a meaningful use readiness assessment of state health departments. As of December 2010, information on readiness was available for 36 states. Only one state was not planning on being prepared to receive reportable laboratory results and immunization information. Of 35 states, 12 (34%) were not planning to be ready to receive HL7 2.5.1, and 11 (30%) were not planning to receive HL7 2.3.1.

#	Question	Currently prepared	Planning to be prepared	Not planning to be prepared	Responses	Mean
1	Reportable Lab Results (for reportable disease information from hospitals)	18	17	1	36	1.53
2	Immunization Information Systems	18	17	1	36	1.53

3	Syndromic Surveillance System	15	8	12	35	1.91
---	-------------------------------	----	---	----	----	------

For syndromic surveillance the messaging capacity is as follows:

#	Question	Currently prepared	Planning to be prepared	Not planning to be prepared	Responses	Mean
1	HL7 2.3.1	16	10	11	37	1.86
2	HL7 2.5.1	10	15	12	37	2.05

Appendix XV.

Governance	Information level and structure	Data Sharing Agreement	Identifier levels (most identified level)
Labs/EHR Vendors and their healthcare customers /ISDS/HHS/CDC/DOD/VA	Syndromic data across Federal agencies, various HL7 V2 messages, proprietary formats; data is coarse and high level	Multiple from interagency, hospital, ISDS secondary use to mandated federal in certain reporting cases	De-identified, no linkage needed
CDC/States	CDC Reporting from states, HL7 V2.51 in most cases; various levels of granularity based on Case Definition and program requirements	CDC through CSTE	De-identified, linkage to state identifiers
States/ local health	State Reporting from local health, multiple proprietary formats, some HL7 V2 feeds; intermediate granularity primarily to satisfy case identification requirements (TB an exception in many states)	State law mandate typically	Identified across multiple areas
Local health	Local Health Reporting from clinical providers, mostly paper, proposed HL7 2.5.1; Granular data focused on small subset	State law but also local jurisdictional law	Identified in all cases
Patient/Clinician/FDA	Clinical care data sharing, adverse event reporting Mostly paper or fax mime type based, required to move to CCD and ICSR; Granular data across broad data set	HIPAA, HITECH, FDA, State law requirements	Identified in all cases

Governance reflects the parties involved that request or provide data and have a negotiated agreement on the data shared

Innovative Information Sources:

Topic: Innovations in Biosurveillance

In order to support the NBAS advisory mandate, a working group was established to determine how to leverage innovations to enhance overall capacity to evaluate human health threats. The Innovation Working Group has identified several areas in which near-term investment could strategically advantage long-term public health outcomes:

- Enable multiplex assay development and validation
- Establish and implement methods for characterizing host susceptibility to health threats
- Leverage “crowdsourcing” and social networks to enhance surveillance and public health communication

Issue #1: Assays

The FDA has oversight over approval of diagnostic platforms and assays. FDA approval can take several years, and is done on an *ad hoc* basis, with few published guidelines and benchmarks. In the case of emerging infectious diseases, the process for biomarker discovery, validation, and assay approval and deployment can easily be overcome by events.

Assay validation is not limited to FDA oversight of human clinical diagnostics. Assays for biosurveillance are also overseen by the CDC (e.g., assays used in the nationwide BioWatch Laboratory Response Network), the USDA (agricultural/veterinary assays for plants and animals), the EPA (water safety), and the DOD (assays used by the military for force protection). Each of these agencies has its own validation practices, with little or no coordination between agencies or acceptance of each other’s assays as equivalent. Furthermore, despite advances in technologies toward multiplex assays over the past decade, no agency has yet determined how to validate highly multiplexed assays. The validation of synthesized microarrays or genomic sequencing to diagnose pathogens in human, animals, and plants is also lagging far behind the demonstrated research ability for these techniques to provide great advances in health care and biosurveillance in general.

Methods:

Following the initial working group discussion, follow-up interviews were conducted with leading edge stakeholders in assay development, particularly those recognized as “rapidly” innovative. Their best practices were taken into consideration to bolster the committee’s recommendations.

Discussion:

The majority of assays for infectious agents are singleplex. Thus, surveillance and differential diagnosis is tedious, and resource-, sample- and time-intensive. Furthermore, singleplex assays may fail completely in the event a new agent emerges. There is no centralized sample or database with which to optimize and validate assays and platforms. Many biomarker assays are initially developed in rodents, but rodents are not good surrogates for human health and disease.

Further, no standard validation procedures exist across agencies to allow mutual acceptance of actionable information from assays used by other agencies. Additionally, validation procedures for highly multiplexed assays, microarrays, or genomic sequencing for clinical diagnostic use are completely lacking.

Recommendations:

- Develop multiplex assays for pathogen detection.
- Integrate data on cellular pathways and biomarkers that can provide insights into host exposure and response.
- Extend research in animal models to nonhuman primates.
- Improve pathways for assay optimization, validation and implementation.

Specific recommendations include:

- Determine “best-in-class” or “gold standard” assays for evaluation of new competitors. These standards should be updated as improvements are developed.
- Development of assay standards for direct versus indirect pathogen detection via host biomarkers and for triage, environmental survey, and human clinical diagnostic assays, as each of these missions has separate cost and sensitivity thresholds.
- Standardization of assay validation and approval process across agencies, including validation procedures for high information content assays (e.g., multiplex PCR, microarrays, next-gen sequencing).
- Improve storage, accessibility, and management of biobanked samples.
- Develop rapid manufacturing capability for reagents of interest.
- Create generic disease discovery assay platforms.

Issue #2: Baseline Human Health

Disease can be defined as a deviation from equilibrium “healthy” status. To better define what should be perceived as “disease,” and develop models that can differentiate between well and sick populations we first need to standardize what it means to be healthy.

We conducted a review of existing systems for modeling disease, as well as efforts to generate models of “wellness.” Discussions were held with federal stakeholders who innovate in disease monitoring, with reflections on efforts during the H1N1 pandemic.

Discussion:

Biosurveillance is typically conducted through baseline and resampling of human health. Individuals and populations are serially resampled to detect deviations from a standard equilibrium. Measures of health may include but are not limited to death or absentee rates, frequency of ER visits, language usage in search engines, changes in consumer behavior, such as cold medicine purchases, and genomic or proteomic analyses.

Recommendations:

- Further investment should be made in efforts that seek to create nominal and computational models that are richly descriptive of individual health and the behaviors of healthy populations. A variety of emerging modeling techniques can continue to be supported.
- The means to conduct point of care assessments of biomarkers or behaviors indicative of disease, once discovered, must be rapidly deployed and stockpiled in advance of potential pandemics. Emphasis should be placed on improving the accuracy, use, and transparency of methods that do not require direct interaction with patients.

Specific recommendations include:

- Develop passive models that mine “public” or transparent records for disease signatures.
- Validate and verify models of baseline health as well as emerging diseases.

Issue #3: Social Media and Biosurveillance

The biosurveillance enterprise includes a wide range of stakeholders in addition to public health professionals and clinicians. Many of these individuals participate and contribute to social media or crowd-sourced knowledge via Facebook, Twitter, Wikipedia, or similar applications. New and early insights into population health could be realized if these data streams were organized for systematic analysis.

A search was conducted to determine whether a generalized public health online community existed. While disease specific clinical networks do exist, these are generally hierarchical in nature. Additionally, one-off projects based on open platforms such as Google Maps provide an initial view into how information can be managed in such an environment.

Discussion:

Specialized social communities exist in computer programming, are deployed in the intelligence community, and have recently been created to allow sales and marketing specialists to share “leads” between companies. A similar social network would allow for similar value creation in the biosurveillance space. Public social network platforms could be used to create networks of stakeholders who support biosurveillance. Such a network could also exist as a source for passive information collection of public health trends. Questions of credentialing, privacy, and security readily arise in such an environment, and the system would need to balance the quality of information with existing regulatory frameworks such as HIPAA. Tools should be broadly socialized to ensure sustainability.

Recommendations:

- A working group consisting of stakeholders from various agencies and actors in public health should be convened to develop pilot projects in “social media” style platforms.
- Address regulatory, privacy, security and credentialing concerns, data elements of common interest, and tools with immediate utility.

Global and Regional Biosurveillance Collaboration

Introduction

Biosurveillance efforts must be global in scope because health threats that emerge in any part of the world may cross borders and threaten people worldwide. Examples include outbreaks of new, resurgent, drug-resistant, or highly dangerous diseases; pandemics of respiratory diseases like influenza or SARS; and deliberate or accidental release of microbes, chemicals, or radiation into air, water, or food. Mitigation of these dangers requires coordinated and collaborative U.S. action that makes optimal use of current tools and opportunities to enhance global disease detection and response.

Scope

The Work Group was charged with exploring ways to more efficiently manage, coordinate, and leverage U.S. government (USG) global health biosurveillance and development policies and activities. The goal is to maximize the effectiveness and impact of the United States' efforts to contribute to and participate in disease detection and response to improve global public health, safety and security.

Approach

The Work Group compiled this report based on the outcomes of two face-to-face meetings, review of dozens of documents stored in Google Docs with open access for all NBAS members, over twenty briefings from multiple agencies, several conference calls, discussions with key stakeholders, and feedback from members on several drafts of the report.

The members of the NBAS Global Workgroup agreed that:

The US has compelling interests in global human and animal health for humanitarian, development, economic, and security reasons.

- Support for the ability of every country to fully implement the International Health Regulations (IHR 2005) is currently the best opportunity for the United States to build global disease detection and response capacity. Assisting individual countries to improve their human and animal biosurveillance capacities benefits their population and other countries around the world, including the U.S.
- Given the adoption of the IHR in 2005 by the World Health Assembly, implementation of these regulations around the world represents a strategic opportunity for the US to advance global health and its own national interests.
- US contributions to and participation in global disease detection and response through an all-hazards approach that increases global capacity and coordinated international action are dependent upon
 - Coordinated, leveraged, and more effectively managed USG bilateral and multilateral global health investments and policies across and within agencies

- Enhanced engagement with WHO, OIE, FAO and other international multi-lateral organizations
- Improved and coordinated interactions with public-private partnerships, professional societies, the business sector, academic institutions, NGOs, and civil society organizations engaged in global public health activities

As part of its deliberations, the NBAS Global Workgroup considered the following issues:

1. Surveillance is the ongoing, systematic collection, analysis and interpretation of data to facilitate timely response. Biosurveillance requires managing health-related data and information for early warning of threats and hazards (both the routine and the unusual), early detection of events, and rapid assessment to facilitate rapid, effective responses to mitigate health effects.
2. Emerging diseases and all other hazards can occur in any location. No country is immune or insulated from these risks, although the types, scope, and vulnerabilities vary from place to place. Therefore, each jurisdiction should have the ability to identify, monitor, and respond to human-, animal-, environmental-, and food-associated public health threats.
3. USG biosurveillance investments are unevenly distributed and are at times driven by strategic and diplomatic priorities rather than public health needs, capacities, and threats and are often short-term and not sustained.
4. In an era of restrained resources, US global investments in biosurveillance must be efficiently managed both centrally and at the country level, avoiding duplication and inefficiencies that result in sub-optimal impact.
5. Non-governmental investments by the philanthropic sector have grown dramatically and are substantially contributing to global biosurveillance. Improved coordination between USG investments, other countries' investments, and these philanthropic efforts would lead to better outcomes and benefits.
6. Capacity within international organizations (e.g., WHO, OIE, FAO) has grown substantially. Providing opportunities to work with and through these organizations to leverage existing U.S. investments would increase their impact.
7. National surveillance capacity, especially within emerging economies, has also increased. These emerging economies can also significantly contribute to improving global biosurveillance.
8. Globally, human public health is intrinsically linked to animal health and agriculture. Biosurveillance investments in these sectors are as strategically important as investments in human health biosurveillance.
9. There is a need for metrics, evaluation, tools and training to monitor and support global biosurveillance efforts.

The NBAS Global Workgroup also identified and considered changes that have taken place over the past 15 years that have modified the environment in which biosurveillance is conducted. The Workgroup identified the following as opportunities upon which to build:

- **U. S. initiatives and investments in global health**, which can be coordinated and synergized for maximum public health impact. Current U.S. initiatives that enhance global biosurveillance include the *National Strategy to Counter Biological Threats*, which promotes global disease detection (http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Counteracting_BioThreats.pdf); the President's *Global Health Initiative*, which strengthens data collection and diagnostic services in developing countries (<http://www.pepfar.gov/documents/organization/136504.pdf>); and the USAID Emerging Pandemic Threats (EPT) Initiative which supports global surveillance and response capacity for zoonotic diseases — a major source of emerging threats to human health. US investments in global health include establishment of Global Disease Detection Centers (<http://www.cdc.gov/globalhealth/GDD/gddcenters.htm>), new Field Epidemiology and Laboratory Training Programs (<http://www.cdc.gov/globalhealth/fetp/>), and the Global Emerging Infections Surveillance and Response System (<http://www.afhsc.mil/geis>), among many others.
- **2005 International Health Regulations (IHR)**; (<http://www.who.int/ihr/en/>). The IHR provide a legal and political framework for international engagement that ties reporting to response and promotes capacity-building in developing countries. Under the IHR, each WHO member nation must maintain or develop core competencies in disease surveillance, reporting, and response capacity (IHR, Annex 1A), with industrialized nations providing support to developing nations in building and strengthening these competencies (Article 5, IHR). International outbreak assistance is available, if requested, from the Global Outbreak and Alert and Response Network (GOARN; <http://www.who.int/csr/outbreaknetwork/en/>), which serves as WHO's IHR response arm.
- **Multi-sectoral partnerships**, which can expand and enhance global disease surveillance and response. Biosurveillance partnerships go beyond the traditional healthcare and public health sectors to include animal and environmental health experts (e.g. the One Health Initiative; <http://www.onehealthinitiative.com/>), trade groups (e.g., Asian-Pacific Economic Cooperation (APEC) EINet; <http://depts.washington.edu/einet/about.html>), and diplomatic fora (e.g., the Global Health Security Initiative [<http://www.ghsi.ca/english/index.asp>]), foundations and non-governmental organizations (e.g., the Gates Foundation), multinational corporations, and university research networks.
- **Innovations in telecommunications and molecular diagnostics**, which underpin new methods for data-gathering and laboratory-based biosurveillance. The internet and telecommunications tools have made collection and analysis of large amounts of information operationally feasible— as demonstrated by the Biosurveillance Indications and Warning Analytic Community (BIWAC)— and have helped create global and regional networks that share data on microbial threats. At the same time, technical innovations based on molecular techniques are increasing the specificity, speed, reliability, and availability of diagnostic testing.

Recommendations:

United States Government Leadership

The USG must play a leadership role in coordinating national investments in biosurveillance to ensure optimum return on investment, especially during this era of fiscal austerity, affecting the United States as well as our partners.

1. The USG should identify a single, senior-level lead entity (such as NSS in the EOP) with responsibility, authority, and accountability to coordinate investments, require and ensure interagency collaboration and cooperation, and demand efficiency in implementation of biosurveillance activities in support of the President's Global Health Initiative (GHI).
 - An inventory of current and planned investments across the full spectrum of activities relevant to biosurveillance should be created, along with a process to keep the database up-to-date (i.e., on a quarterly basis). The inventory should contain input from all USG agencies and programs. In addition to surveillance activities, the database should incorporate information on training programs, capacity-building efforts, disease- and pathogen-specific vertical programs, and other relevant activities that could contribute to identification of hazards and improved accuracy, timeliness, and efficiency of USG biosurveillance efforts. The inventory should be easily accessible to all governmental agencies and be publicly available to extra-governmental organizations (e.g., NGOs, private foundations, host nations, and other stakeholders). The inventory should serve as tool to enhance coordination, communication, and efficiency.
 - Investments should be assessed horizontally (across agencies) and on a location-by-location basis to avoid duplication, assure maximal impact, enhance efficiency, and identify priority gaps. When feasible, existing projects with overlapping goals and strategies should be combined, and new projects should be carefully assessed and approved to maximize potential synergies with existing activities and to avoid duplication.
 - USG investments should be consolidated among agencies and leveraged whenever possible with those of partner agencies and organizations, NGOs, foundations, the business sector, host nation civil society, and other stakeholders to ensure efficiency, avoid conflict, and maximize return on investment.
 - Evaluation and outcome measurement must be a key component of each activity and include key metrics indicative of success in achieving specific targets. All investments in biosurveillance must be results-oriented and their impact clearly demonstrated.
 - Sustainability of every global biosurveillance investment must be a key consideration at the onset of any program and be an ongoing consideration during periodic evaluation. Programs and activities must be recognized by host nations and regional partners and aligned with host country infectious disease priorities. Each activity should include a

clear exit or transition strategy defined prior to implementation to ensure that the impacts of investments are sustained by the host jurisdiction and region.

Implementation of IHR 2005

The 2005 revision to the IHR contains a specific set of activities designed to assure that each jurisdiction has the capacity to conduct disease surveillance, to promptly identify and report health events that may pose a threat for international spread, and to respond to these threats through timely investigation and implementation of control measures. As a globally agreed upon framework for disease monitoring and control, the IHRs represent the single most effective mechanism to channel investments to build worldwide biosurveillance capacity.

2. Any location can be the source of an emerging global public health threat. Therefore, all jurisdictions need to have systems in place to properly identify, diagnose, investigate, and respond to such threats. IHR implementation at home and abroad is a public health and security priority for the US. The USG should support full and robust implementation of IHR 2005 in every jurisdiction and target and leverage resources to achieve this goal.
 - US efforts to support IHR implementation should be conducted in close cooperation with the WHO and its regional affiliates. WHO is the lead agency for IHR implementation and has created an infrastructure for monitoring and assessing IHR capacity at the country and regional levels. US support for IHR implementation could best be accomplished by working in partnership with WHO to assist specific locations or regions in developing biosurveillance capacity.
 - Communication and coordination with WHO should be enhanced by secondment of an individual from CDC to the IHR implementation unit at WHO.
 - Implementation of the IHR has important security implications for the US, and coordination between DOD and DOS initiatives focused on international threat reduction and disease monitoring programs should be carefully coordinated with other USG partner agencies, WHO, and international partner states and organizations to ensure coordination and cooperation while avoiding duplication of efforts.
 - The USG should promote IHR implementation using various bilateral, multilateral, and regional diplomatic and security initiatives, encourage other countries to prioritize IHR implementation, and support international efforts to increase transparency and sharing of information and etiologic agents that pose potential regional or global threats.
 - Support for IHR implementation is consistent with the priorities of the President's GHI. Programs to build IHR capacity should be developed and implemented within the overall GHI framework.
 - Any programs developed through the GHI process should contain objective outcome measures by which progress in building global biosurveillance capacity can be assessed

and the benefits of these investments documented. The US should support development and use of an objective IHR implementation scorecard to measure progress in achieving IHR surveillance goals.

- The US should objectively target resources toward locations and regions that need additional support to develop institutional capacity to conduct surveillance and response activities as required by the IHRs.
- An equivalent framework to the IHR is needed for animal health. The USG should advocate the creation of a similar international legal framework to organize, coordinate, and prioritize animal health biosurveillance emphasizing an all-hazards approach.

Research and Innovation

A robust research agenda to support effective, efficient, and innovative biosurveillance is needed. This research agenda should encompass human, animal, and plant pathogens and diseases; draw on a broad spectrum of approaches and tools including basic biological sciences, ecological approaches, systems research, and social network analysis; build capacity that engages public and private institutions, the business and philanthropic communities, and global partners; and seek to better understand cross-species movement of microbes and the appearance of novel microbes, whether developed through human intent or emerging naturally.

3. The USG should lead the development of a comprehensive research agenda supporting the strengthening of global biosurveillance capacity. Areas of focus should include development and evaluation (sensitivity, specificity, speed, cost, reliability, among others) of new technologies offering the potential for the efficient, effective collection and dissemination of critical information to key individuals:
 - Fast, reliable, specific, point-of-care diagnostics for the early detection of emerging diseases and interruption of their spread (and avoidance of unnecessary interventions).
 - Models used to project “what might happen if” scenarios to anticipate the potential spread of disease and population effects and to monitor how epidemics unfold. These can serve to identify the most likely outcomes given several policy options for interventions.
 - Technologies that can be used for communication, including the use of social networks to report, track, and intervene during outbreaks, and geo-referencing systems that can be used in tracking disease.
 - Capabilities to rapidly recognize emergence of antimicrobial resistance, genetic changes, or recombination events that may lead to more virulent pathogens. Development and validation of metrics for measurement and communication of risk in a way that allows an appropriate level of response. Metrics should be broadly applicable

and understandable across many disciplines and based on quantitative or semiquantitative measurements.

- Assessment of the efficacy and effectiveness of research training programs to facilitate adjustments based on findings. Metrics should include sustainability of learned behavior or activity and allow evaluation of effectiveness of different approaches. Feedback on performance should be provided to program leaders so that adjustments can be made when indicated.
- Development of potential climate change scenarios and projections that identify vulnerable places, settings, and populations that may be displaced or otherwise impacted. The scenarios should take into account animal and plant pathogens that have implications for food security.
- Consideration of trade and travel as key factors favoring disease emergence and global spread. To date, the key metrics of interest for these global phenomena have not been identified and systematically evaluated, although global databases are available (e.g., COMTRADE, FAOSTATS, IATA). A research program that tests and incorporates such metrics (i.e., point-to-point connection, load factors for passengers/freight, volume of agricultural commodities, etc.) and rigorously defines their actions on the course of epidemics and pandemics should be implemented. Such systems should be utilized when outbreaks occur to minimize cross-border spread.

Acknowledgements

NBAS Consultants: Ray Arthur, John Ridderhof, Alexandra Levitt

Federal Liaisons: Clifford Brown, Teresa Quitugua, Raul Sotomayor

PHPS/OSELS/CDC Staff: Pamela Diaz, Curtis Weaver, Mark Byers, Danielle Stewart

Emory University Staff: Ashley Freeman

Biosurveillance Workforce & New Professions

Approach

The Task Force began its work in September, 2010 with a series of conference call discussions during which it reviewed the work and recommendations in 2009 of its previous iteration (the NBAS Biosurveillance Workforce of the Future Task Force), defined areas in which it felt additional information was needed, and decided to arrange presentations by key informants involved in workforce development, use of electronic health records for public health surveillance and training of public health informaticians. Following the conference calls and presentations, a face-to-face meeting on January 14, 2011 in Atlanta was held to bring together Task Force members' views of what was most important in this area and to define and develop consensus recommendations on the two or three most important issues relating to its charge.

Endorsement of Previous Recommendations: The Task Force recognized that the previous recommendations were still salient and of critical importance. One of five NBAS final recommendations in 2009 was that "The federal government must make a sustained commitment toward ensuring adequate funding to hire and retain highly competent personnel to run biosurveillance programs at all levels of government."⁽¹⁾ At that time it was noted that federal public health preparedness funding allocated to state and local health departments and schools of public health beginning in 2002 had been critical to building domestic biosurveillance epidemiologic and laboratory capacity for both emergency and non-emergency public health conditions, that the corps of personnel created with it had become the domestic biosurveillance workforce, and that it was critical to maintain rather than allow further erosion of this workforce without at least a thorough assessment of what was needed. Since this recommendation was made, the situation has not improved. No formal assessment has been done; a survey of state health departments by the Council of State and Territorial Epidemiologists in 2009 found that epidemiology capacity for bioterrorism/emergency response peaked in 2006 and has deteriorated since (2,3), most states are reducing their public health workforce in response to the budget crisis that began in September 2008 and in the process have lost but not replaced many experienced leaders, and there are competing public health priorities (e.g., chronic disease, obesity, health disparities) attracting newer leaders. However, the Task Force felt that there were other critically important biosurveillance workforce issues that needed to be and could be addressed independently of the uncertain economic situation and ability to maintain the current workforce. These are the issues the Task Force has chosen to highlight and make new recommendations to address, while acknowledging that the previous workforce-related recommendation still needs critical attention.

New Workforce Requirements in Public Health Informatics: Public Health Informatics, defined as the systematic application of information and computer science and technology to public health practice, research, and learning, has become a central function of public health systems and yet this infrastructure is woefully inadequate, fragmented, and underfunded. This fractured information flow limits the public health system's ability to monitor and improve the delivery of interventions for

acute or chronic conditions. It causes public health programs to develop in silos and lack coherence with data elements with little or no uniformity. (4) Another important feature of public health's informatics infrastructure is its expected role in collaboration with the larger clinical and response community during a biosurveillance event. The public health system is often the lynch pin of laboratory and other population-based information. (5) In addition to the disarray of informatics systems architecture, the public health workforce does not have sufficient competency-based trainings to work with the pieces of the architecture that may actually be in place within their public health system. For public health systems to achieve their core functions and undertake their charge for biosurveillance, we need a well-trained workforce in the basics of public informatics. In recognition of the desperate need for additional public health informatics capacity both ASTHO and NACCHO have passed policy statements encouraging access training for public health professionals. (6, 7)

During the last decade, public health informatics has become more defined as science and a discipline; some are beginning to call it a profession. This field now has its own competencies and a number of universities are offering degrees and certificates. (8) What this means is that the potential for offering training and/or finding future public health professionals is promising.

Recommendation #1. Strengthen public health informatics as a key element of the future national biosurveillance workforce.

Enhance the public health informatics profession by: 1) developing suitable federal and state job classifications series (e.g. tier I, II, III); 2) increasing the number of formal masters level degree programs in public health informatics; 3) increasing the number of doctoral level degree programs in public health informatics; and, 4) developing the science of public health informatics through extramural grant research programs to study topic such as computational modeling, simulation, decision support, and applications for public health practice.

- Expand the training of the public health workforce by: 1) expanding the public health informatics fellowships programs (e.g. CDC, PHII) in a way that ensures that qualified applicants can be placed to fill the need; 2) developing a public health informatics tuition support program for state and local public health professionals to cover the cost of training in an approved PHI program.; 3) supporting public health informatics professionals to join and or participate in the PHIN, AMIA, and other relevant emerging technology conferences.
- Integrate the public health informatics professionals with other human and animal health professionals by: 1) including social science, mental health, environmental health, and veterinary health professionals in the development public health information systems; 2) encouraging public health informatics professionals within universities to engage with their NIH funded colleagues, notably CTSIs; 3) ensuring that the focus of the

public health informative data collection leads to early warning, detection, monitoring, investigation, and inference for the population-based concerns within the community.

New Workforce Requirements in Social, Behavioral and Mental Health: An expected component to any type of disaster or terrorist event is the adverse social or behavioral consequences accompanying the event. In a natural event when human life is threatened and social structures disrupted or destroyed, fear and terror are expected consequences. In the case of terrorist events, the goal of the perpetrators is often not just to inflict death and destruction but also to induce terror throughout the nation. Fear produces stress resulting in mental health casualties. Increased incidence of psychiatric disorders (e.g., generalized anxiety, panic, posttraumatic stress disorder [PTSD], depression), psychological distress (e.g., insomnia, irritability, feelings of vulnerability, work absenteeism, withdrawal, social isolation), and health risk behaviors (e.g., smoking, imbibing alcohol, drug use) can be expected. Numerous studies have documented a heightened prevalence of psychiatric disorders, domestic violence, and substance use in the aftermath of most major disasters (12). Communities impacted by Katrina saw rates of mild to moderate mental illness almost double (10). Rates of mental disorders have also increased in response workers as seen in reports of the impact of the response to the events of September 11, 2001 (8). Social and mental health outcomes were a major area of concern in the consequences of the 2010 Gulf Oil Spill as was also seen during and after similar man-made oil spills throughout the world (11). Analysis of the health consequences of the World Trade Center disaster point out the need for identification of psychological response and at-risk populations that can be targeted for preventive interventions (8). To adequately and rapidly characterize the full scope of the event, integration of surveillance of the mental health or behavioral health consequence is needed. This need was also pointed out in the recommendations of a 2003 IOM report that urged the determination of background rates of behavioral and psychological factors important in predicting psychological consequences. The report pointed out the need for agencies to develop a common protocol and work cooperatively to develop, implement, and sustain comprehensive public health surveillance across phases of a terrorist event.

Effective surveillance and early response to the psychological health impacts of man-made or natural disaster events is compounded by a lack of mental health resources and manpower. Reports focused on the health effects of the 2010 Gulf Oil Spill suggest that mental health was one of the most urgent public health concerns and that while the vast majority of surveillance data collected by the state health offices was for acute physical illnesses public health officers from all five states impacted by the event identified the need for increased and better targeted mental health surveillance as an immediate challenge (11). Historically the social/behavioral workforce has not played an integrated role in biosurveillance events. States' mental health disaster plans have evolved through the years, but they suffer from lack of integrated planning with other health sectors responsible for surveillance and response. In 2003 the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services reported that resources- both human and financial-

are key components to successful mental health disaster planning and implementation. Few states, have even a single person whose full-time responsibility is disaster and emergency mental health. (9). Surveillance systems for mental illness and substance abuse must be strengthened with both intellectual and human capital investment. Syndromic surveillance for mental health indicators requires refinement, given the varied somatic manifestations of stress and the potential reluctance of historically marginalized populations to seek mental health or substance-abuse services. Local engagement is key: community agencies can alert public health officials to emerging issues. (12)

Recommendation #2. Enhance the national capacity to assess and manage the psychological dimensions of man-made or natural disasters

- Ensure that social, behavioral and mental health epidemiologists be considered as full members of biosurveillance investigation and monitoring teams, and that when biosurveillance is conducted, it should also focus on indicators of community resiliency.
- Provide training informatics to socio-behavioral and mental health epidemiologists, and recruit social, behavioral and mental health experts into informatics training programs.

References

1. National Biosurveillance Advisory Subcommittee. Improving the nation’s ability to detect and respond to the 21st century urgent health threats: first report of the National Biosurveillance Advisory Subcommittee. Report to the Advisory Committee to the Director, CDC, April 2009; pages 1-10. Available at: <http://www.cdc.gov/osels/pdf/NBAS%20Report%20-%20Oct%202009.pdf> Accessed January 21, 2011.
2. CDC. Assessment of epidemiology capacity in state health departments - United States 2009. *MMWR* 2009; 58(49):1373-1377.
3. CSTE. 2009 National assessment of epidemiologic capacity: findings and recommendations. CSTE 2009. Available at <http://www.cste.org/dnn/>.
4. Jennifer Ellsworth Fritz, Priya Rajamani, Martin LaVenture (No Date). Developing a Public Health Informatics Profile: A Toolkit for State and Local Health Departments to Assess their Informatics Capacity. The Minnesota Department of Health.
5. Rebecca A Hills, William B. Lober, Ian. S. Painter. (2008). Biosurveillance, Case Reporting, and Decision Support: Public Health Interactions with a Health Information Exchange. BioSecure D. Zeng et al (Eds.) Springer-Verlag: Berlin Heidelberg pps 10-21.
6. NACCHO. (2007). Statement of Policy: Public Health Informatics Workforce (No. 07-06) <http://www.naccho.org/advocacy/positions/upload/MicrosoftWord-0706PUBLICHEALTHINFORMATICSWORKFORCE.pdf> (retrieved 1/16/2011).

7. ASTHO. (2008). Public Health Informatics Policy Statement.
<http://www.astho.org/Display/AssetDisplay.aspx?id=165> (retrieved 1/16/3011).
8. CDC. (2009). Competencies for Public Health Informaticians. HHS and the University of Washington Center for Public Informatics. Cone, J. Lessons from the World Trade Center. Presentation to the IOM Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill. September 23, 2010, Tampa, FL.
9. IOM 2003. *Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy*. Washington, DC: The National Academies Press.
10. IOM. 2009. *Assessing Medical Preparedness to Respond to a Terrorist Nuclear Event: Workshop Report*, DC: The National Academies Press.
11. IOM. 2010. *Assessing the Effects of the Gulf of Mexico Oil Spill on Human Health*. Washington, DC: The National Academies Press.
12. U.S. Department of Health and Human Services. *Mental Health All-Hazards Disaster Planning Guidance*. DHHS Pub. No. SMA 3829. Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, 2003. Yun, K.Y., Lurie, N., Hyde, P.S. 2010. Moving mental health into the disaster-preparedness spotlight. **New England Journal of Medicine**. 363(13):1193–1195.

Integrated Multi-Sector Information

Task Force Approach

The Task Force on Integrated Multi-Sector Information met on multiple occasions. The Task Force (TF) initially discussed the scope and reach of its work and agreed on a group of subject matter experts to present to the TF and engage in further discussions. The TF reviewed the Concept Plan for Implementation of the National Biosurveillance Strategy for Human Health and the final National Biosurveillance Strategy. The group also reviewed the findings from an earlier NBAS subgroup on “Animals, Food, and Vectors.” In addition, the TF reviewed reports from the CDC’s Office of Critical Information Integration and Exchange. At a final meeting, the TF synthesized its findings, established priorities, and created five working papers about the Human-Animal Interface; Local State-Global Connectivity; Environmental and Data Base overview; Use of Technology, and Overarching Issues. Finally, these reports were merged into the TF Report and issues and recommendations were finalized from this process.

Introduction

Integrated biosurveillance information was identified as a priority in developing a cohesive strategy for effective national biosurveillance. The objective was to generate actionable health intelligence by increasing access to information resources and synthesizing multiple streams of information into one coherent picture. Key advances in technology, science, and communications need to be leveraged and adapted to achieve effective biosurveillance integration.

There is a critical need to improve and integrate biosurveillance across human and animal health, agricultural, and environmental disciplines to create a One Health model. These domains are inextricably connected. Thus, our ability to identify and respond to hazards impacting human health and to develop an effective national biosurveillance system is dependent on a holistic, integrated strategy that crosses domains, sectors, professions, and data resources. The One Health model emphasizes the need to shift surveillance “upstream” closer to the genesis of the threat to improve prevention, early detection and response.

Specifically, more effective environmental biosurveillance is necessary. Our water sources pose a threat to human health due to microbial and chemical contamination. Disease vectors must be added to an integrated biosurveillance program to improve awareness and track microbial migration prior to human exposure. There is obvious shared responsibility that crosses and includes wildlife, domestic animals, and their products, food, water, environment, and vector monitoring. Data and information sharing must be attained from government agencies, international organizations, poison control centers, food systems, recreational and potable water, and diagnostic labs that are government, university, and private.

Current biosurveillance systems that involve animal, human, and environmental domains, however, are fragmented, with little or no integration. A biosurveillance system that is multi-sectored will need to overcome challenges of information and operational systems that are not standardized or connected;

cultural and incentive differences in sharing data; ensuring integration across agricultural and public health agencies and organizations; and, incorporation of massive amounts of microbial data sets from private and corporate diagnostic labs whose testing results are considered proprietary.

Issue #1

The human-animal interface has progressively increased, creating a greater chance of human exposure to multiple hazards from direct contact with animals or through food and water.

The TF had discussions with USDA and CDC experts in food borne and vector borne illnesses; TF members included representatives from the AVMA and experts in One Health and emerging zoonoses.

Discussions

With the realization that 60% of human pathogens are multi-host microbes, it is abundantly clear that animal populations (domestic, exotic, and wildlife) and their products need to be included in a national biosurveillance plan. The interface between animals and people is both intensifying and accelerating. Today seven billion people share the earth with 25-30 billion food animals, approximately 500 million pets, and countless wildlife and exotic species. Pathogens are transmitted directly from animals or indirectly through food, water, environment, and through vectors such as mosquitoes, fleas, and ticks. These need to be included in a comprehensive biosurveillance strategy.

Accurate and rapid surveillance systems are necessary to detect food-, water-, and vector-borne pathogens. Antimicrobial resistant organisms need to be included in the biosurveillance plan because they are an emerging group of pathogens that may originate in animal species. The global food system needs to be monitored to prevent the transmission of pathogens and to serve as an early warning system. Eighty percent of select agents are zoonotic and may be discovered in animals, animal health diagnostic laboratories or private veterinary clinics before becoming a human threat. Increasing interconnectivity through travel, trade, and new diasporas create unprecedented hazards to human health and represent areas that need to be monitored to achieve early detection and response.

Recommendations:

- Develop a plan to include animal disease surveillance systems (food-animal, exotic, wildlife, and companion) along with food and vector disease monitoring systems, and integrate these into a national biosurveillance strategy for human health.
- The USDA, CDC, and FDA should take responsibility and involve state agriculture and public health agencies, animal health diagnostic laboratories, and private food and animal health laboratories. These agencies should also collaborate with and share surveillance data with the OIE, FAO, and WHO.

Issue #2

There is a critical need to maximize connectivity and utilization. Expansive biosurveillance data sets across sectors including human and animal health, agriculture and environment at the private, local, state, national, and global levels need to be integrated to achieve rapid detection of hazards and timely response capabilities.

This issue was a common thread that emerged from all our internal and external discussions and subject matter experts we interviewed. It has been highlighted on numerous occasions when assessing past disease outbreaks and epidemics such as influenzas, West Nile virus, SARS, BSE, and food- and water-borne outbreaks, including Salmonella and E. coli.

Discussion

Private and public agencies participate in biosurveillance activities across human and animal health, agricultural, and environmental sectors. Within private and public human and animal sectors, a great deal of data is already being collected. Sharing information across sectors, however, does not always occur. Expansive biosurveillance information is scattered across the public, private, federal, state, local, academia, non-profit, and global organizations.

Collection of biosurveillance data within the private sector varies regarding what type of data is collected and at what level. Many private companies within the food and agriculture industry collect such data routinely, but the data from these sources are poorly utilized and coordinated.

In addition to the food and agriculture industry, those participating in biosurveillance activities within the private sector include laboratories, medical facilities (including human and animal hospitals and clinics), poison centers, research facilities, and universities. In many cases, similar facilities collect potential biosurveillance information in the public sector (publicly funded universities versus private universities, for example).

Global, national, state, county, and municipal governments vary widely. States' statutes and constitutions define the nature, distribution and power of local and county government. Within the US alone there are currently 3,143 counties, many of which are further subdivided into independent and self-governing municipalities. Each government can—and in many cases does—have its own biosurveillance and data collection agencies. Policy, legal, technical, fiscal control, and authorization barriers have prevented integration of key data and information, and a substantial gap will remain if these data points are not linked.

Recommendations:

- Data and information involving animal, agriculture, food, and environmental sources that might present a human health hazard must be shared, coordinated, analyzed, and synthesized across organizations, jurisdictions, agencies, and the private sector to achieve an efficient and fully integrated biosurveillance strategy.

- A National Biosurveillance staff should coordinate and facilitate this recommendation. However, the implementation and data collection still resides within respective organizations and jurisdictions. The financial and legal components needed to achieve this recommendation should be incorporated into a national strategy.

Issue #3

Many human health hazards are inherently components of larger ecological systems. These systems arise through the convergence of people, animals, and our environment. A singular focus on human health surveillance will often miss the origin, transmission processes, and maintenance sites of potential hazards. Furthermore, the detection and response to threats may be delayed resulting in more widespread and sustained outbreaks and much more costly response and control mechanisms. An effective biosurveillance strategy must be more holistic and integrated, and we should shift our monitoring and diagnostics closer to the source of the hazard or threat. Currently, many environmental surveillance systems have been limited to clean-up sites, waste handling, chemical release, and hazardous material accidents. There are also standards to promote safe water. Although these systems are very helpful, a more proactive and comprehensive risk-based, real-time environmental biosurveillance system has not been realized. Such a system needs to be incorporated into a national strategy.

Discussion

As our population continues to grow and becomes increasingly interconnected, our environment has been altered, contaminated, and stressed in unprecedented ways. This is especially apparent globally and has been accentuated by the creation of large urban and peri-urban settings and industrialization. Billions of domestic and wild animals share our environment and add to its potential hazards. The convergence of animal and environmental health with human health is creating new exposures to human health hazards and sources of microbial, chemical, and toxic contamination. Biological, chemical, and potential radiological hazards found at known sites are closely monitored, but many exposures are increasingly found at unknown locations and are broadly distributed through water and land sources. The environment represents new sources of human health hazards, and the response to and amelioration of such hazards is an increasing complex and vexing issue.

The issue is further complicated by the fact that many exposures to chemicals and toxins take place at low levels over time and may lead to cumulative effects and chronic disease conditions. Most existing surveillance systems specially focus on acute hazardous events, but biosurveillance should also consider long-term, low level exposures that represent serious health threats. This is especially problematic when we consider shrinking water resources globally.

The TF met with subject-matter experts and reviewed existing environmental databases. We discussed critical issues with the EPA and CDC experts on water-borne illnesses, poison control centers, and with agriculture and animal health experts.

Recommendations:

- Expand biosurveillance to include environmental sites of greatest threat to human health. This expansion should incorporate more microbial and chemical testing and involve more recreational and drinking water sites and systems not currently assessed. In addition, a National Biosurveillance strategy should consider low level, non-acute exposure that, over time, may result in human health hazards and chronic illnesses and conditions.
- A National Biosurveillance staff should coordinate and facilitate this work, but implementation must continue to be coordinated and facilitated by state and local environmental protection organizations and agencies including private corporations.

Issue #4

A key area of emphasis and concern with NBAS is ultimately implementation. NBAS will necessitate data sharing, systems integration, efficient and timely exchanges of information, standardized diagnostic platforms, interoperable information technologies, broad data access, and high utility of system reports and results to ensure cost-effectiveness of operations. Thus, there need to be operating principles to guide system design and execution of recommendations. This issue was discussed within the TF, and the TF reviewed lessons learned from development of other surveillance systems and personal experiences.

Discussion

Effective execution will be determined by the skill and commitment of the NBAS leadership. For NBAS to be successful, a coherent biosurveillance system must be embedded into the organization's personnel, strategies and operational plans and actions. NBAS needs to focus, at least initially, on existing systems and data sources. Resources need to be used only for the highest priority recommendations and those that are feasible, leveraged, serve the greatest need, address the greatest threats and risks and are the most cost-effective. Animal and environmental domains should not be neglected, and any operational strategy needs to assure that the surveillance systems from these domains remain a high priority in NBAS. The TF further discussed and highlighted three critical cross-cutting issues for consideration as NBAS becomes operational:

1) Designing new electronic health information systems to support NBAS needs. Health information technology is in rapid flux nationally, driven generally by the requirements of the health reform act and by health information technology investments. Of particular relevance to NBAS activities is the planned development of "meaningful use" requirements during the next several years. These requirements are intended to ensure that electronic health records will be deployed in hospitals and providers' offices to support a wide array of functions. The meaningful use criteria for public health have yet to be articulated. It will be important to ensure that the needs of all NBAS sectors are well represented in

these deliberations. This is especially true for the animal and environmental health perspectives, which might not otherwise be articulated clearly.

2) Ensuring public health access to electronic health data. It will be necessary to ensure that the electronic health information that will be increasingly available is accessible to public health practitioners to support NBAS goals. Examples of issues that need to be addressed include:

- **Privacy protection.** While the Health Insurance Portability and Accountability Act (HIPAA) includes a provision for public health use of protected health information, the way in which holders of this information (“covered entities”) interpret their compliance needs, for example for disclosure, can complicate ready access to this information, especially when a public health agency requires information from multiple providers. Harmonization of the requirements, for instance through development of model policies and procedures, would reduce the transaction costs for effective use of electronic health information.
- **Distinguishing between public health practice and research.** There remains considerable lack of clarity about the boundary between public health practice and research, with similar activities being classified differently in different locations or at different times. A clearly articulated standard will reduce this uncertainty.
- **Need for standardization.** The availability of electronic health information does not assure its usability for public health purposes. There is a need to develop and then update computable definitions for public health conditions of interest. The public health community will need to adopt a standards mechanism that develops and tests definitions for conditions of interest that can be applied rigorously to electronic health data. It will also be necessary to create a mechanism to keep these definitions current, as new diagnoses, tests, and treatments are adopted in clinical practice and translated from animal and environmental health systems.
- **Consolidation of requests for information.** It will be necessary to develop efficient mechanisms for public health agencies to share information from health care delivery systems and other sources including animal health systems. While data holders may be persuaded to make information available for public health purposes, they will want to be assured that the information requests adhere to fair information practices, e.g., minimum necessary data is requested; and to be able to provide information to serve multiple public health functions simultaneously. Thus, when separate public health users need certain data, it will be advantageous for them to develop a mechanism to pool their requests, so the data holders do not need to evaluate and respond to multiple requestors, some of whom will ask for similar or identical data.

3) Establishing priorities. The many valid responses to NBAS needs will almost certainly exceed available personnel and financial resources. It will thus be important to develop a framework for prioritizing the use of resources that will exist through assessment of likely health benefits that can be achieved. This

analysis should take into account the probability of specific events, their potential health impact, and the potential for mitigation. This analysis should be sufficiently quantitative to guide resource allocation.

Recommendations:

- The implementation of NBAS strategies and actions will be more difficult to achieve than creating the recommendations from this report. NBAS leadership needs to create a set of operational principles to guide and inform decisions and resource allocation, setting priorities, gaining access and sharing data, considering meaningful use requirements, adopting standardization for IT and diagnostics, and ensuring both the incorporation and integration of key animal, animal product and environmental surveillance data.

Appendix II: Acknowledgements

The Subcommittee was aided in its deliberations by the testimony and advice of many knowledgeable and experienced individuals, and the efforts of a dedicated Subcommittee and staff. Consultants, Federal Liaisons, and CDC Senior Scientists to the Subcommittee and working groups contributed ideas and report materials.

The Subcommittee thanks the **NBAS Consultants to the Working Groups:**

Governance (Interagency Collaboration and Engagement)

Pamela Diaz, Centers for Disease Control and Prevention (CDC) – Public Health Surveillance Program Office (PHSPO)

Healthcare & Public Health Information Exchange

Laura Conn, Centers for Disease Control and Prevention (CDC) – Public Health Informatics and Technology Program Office (PHITPO); **Taha Kass-Hout**, Centers for Disease Control and Prevention (CDC) – Public Health Surveillance Program Office (PHSPO)

Innovative Information Sources

Taha Kass-Hout, Centers for Disease Control and Prevention (CDC) – Public Health Surveillance Program Office (PHSPO)

Global and Regional Biosurveillance Coordination

Ray Arthur, Centers for Disease Control and Prevention (CDC) – Division of Global Disease Detection and Emergency Response (DGDDER); **John Ridderhof**, Centers for Disease Control and Prevention (CDC) – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID); **Alexandra Levitt**, Centers for Disease Control and Prevention (CDC) – Office of Infectious Diseases (OID)

Biosurveillance Workforce, New Professions & Cross-training

Denise Koo, Centers for Disease Control and Prevention (CDC) – The Scientific Education and Professional Development Program Office (SEPDPO); **Pat Dreho**, Centers for Disease Control and Prevention (CDC) – The Scientific Education and Professional Development Program Office (SEPDPO); **Mehran Massoudi**, Centers for Disease Control and Prevention (CDC) – The Scientific Education and Professional Development Program Office (SEPDPO)

Integrated Multi-Sector Information

Carol Rubin, Centers for Disease Control and Prevention (CDC) – Division of High-Consequence Pathogens and Pathology (DHCPP); **Colleen Martin**, Centers for Disease Control and Prevention (CDC) – Division of Environmental Hazards and Health Effects (DEHHE); **Amy Funk-Wolkin**, Centers for Disease Control and Prevention (CDC) – Division of Environmental Hazards and Health Effects (DEHHE); **Art Liang**, Centers for Disease Control and Prevention (CDC) – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The Subcommittee thanks the **Federal Liaisons in the following NBAS Working Groups:**

Governance (Interagency Collaboration and Engagement)

Teresa Quitugua, United States Department of Homeland Security

Healthcare & Public Health Information Exchange

Laura Conn, Centers for Disease Control and Prevention (CDC) – Public Health Informatics and Technology Program Office (PHITPO); **Taha Kass-Hout**, Centers for Disease Control and Prevention (CDC) – Public Health Surveillance Program Office (PHSPO)

Innovative Information Sources

David Lipman, United States Department of Health and Human Services – National Institute of Health; **Michael Kurilla**, United States Department of Health and Human Services – DMID, NIAID, NIH, Office of BioDefense Research Affairs; **Randy Kincaid**, United States Department of Defense, Defense Threat Reduction Agency

Global and Regional Biosurveillance Coordination

Raul Sotomayor, United States Department of Health and Human Services; **Capt. Clifford Brown**, United States Department of Homeland Security; **Ray Arthur**, Centers for Disease Control and Prevention (CDC) – Division of Global Disease Detection and Emergency Response (DGDDER)); **John Ridderhof**, Centers for Disease Control and Prevention (CDC) – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Biosurveillance Workforce, New Professions & Cross-training

Denise Koo, Centers for Disease Control and Prevention (CDC) – The Scientific Education and Professional Development Program Office (SEPDPO); **Mehran Massoudi**, Centers for Disease Control and Prevention (CDC) – The Scientific Education and Professional Development Program Office (SEPDPO)

Integrated Multi-Sector Information

Teresa Quitugua, United States Department of Homeland Security; **Jessica Pulz**, United States Department of Agriculture, Office of Homeland Security and Emergency Coordination; **Carol Rubin**, Centers for Disease Control and Prevention (CDC) – Division of High-Consequence Pathogens and Pathology (DHCPP)

The NBAS would like to thank **Dr. Thomas R. Frieden**, CDC Director for his recognition of the importance of biosurveillance and the ongoing support of the NBAS.

The Subcommittee wishes to thank **Curtis Weaver**, CDC; **Mark Byers**, CDC; **Christine Bradshaw**, CDC; **Prachi Mehta**, CDC; **Michael Latham**, CDC; **Julie Lipstein**, L3 STRATIS; **Randy Mitchell**, L3 STRATIS; **Daniel Morris**, L3 STRATIS; **Christina Zackery**, L3 STRATIS; **Richard White**, L3 STRATIS; **Stacey Smith**, McKing Consulting Corporation; **Shu McGarvey**, Northrup Grumman; **Danielle Stewart**, Lockheed Martin; **Lindsay Oweida**, Deloitte Consulting LLP; **Matthew Boulton**, University of Michigan Medical School; **Dr. Ruth Maeschiro**, AAMC; **James Tyson**, CDC; **Anthony Williams**, ChemSpider; **Kevin Russell**, GEIS; **Virginia Lee**, CDC; **David Ross**, Task Force for Global Health; **Eric Myers**, DOD; **May Chu**, CDC; **Jay Morris**, FDA; **Cynthia Lucero**, VA; **Christina Egan**, Wadsworth Center; **Larry Granger**, USDA; **Michael Beach**, CDC; Division of Public Health Surveillance and Program Office (PHSPO); **Sylvain Aldighieri** Division of Public Health Surveillance and Program Office (PHSPO), PAHO; **Roberta Andraghetti**, PAHO; **Kerri Ann Jones**, OES/IHB; **Louise Gresham**, NTI; **Matthew Hepburn**, NSS; **Richard Hatchett**, NSS; **Franca Jones**, NSS; **Toni Boni**, USAID; **Ann Moen**, CDC; **Don Shriber**, CDC; **Alan Rudolph**, DTRA; **Rebecca Daley**, DOS; **Ana West**, DOS; **Scott Dowell**, Program and GDD Operations Center, CDC; **Partick Kelley**, IOM; **Ben Petro**, EOP; **Jose Fernandez**, HHS; **Phillip Lambach**, WHO; **Murray Trostle**, EPT; **Ron Yoho**, DTRA; **Dan Lowe**, BEP; **Tricia Schmitt**, OMB; **Kevin DeCock**, CDC for their hard work in supporting the meetings of the NBAS and repeated attention to the ongoing needs and support of the Subcommittee.