Public Health and Bioterrorism: Ready or Not?

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Not too long ago, a terrorist attack with a biological agent was considered by many as unthinkable. Today, bioterrorism is no longer a hypothetical threat and we cannot afford to be complacent. Another attack could occur again at any time, from many potential sources and using many potential biological agents. Furthermore, the magnitude of such an attack could be far greater than what we have experienced to date. Yet, an event does not need to cause mass casualties, in terms of victims or actual deaths, to still be terrorizing and drastically disrupt life as we know it-- undermining public confidence in government and other critical institutions, creating panic, possibly disorder, and inflicting enormous economic harm.

SARS is also a powerful reminder of our vulnerability to infectious disease threats. Ironically, as our nation braced for military action in Iraq, we went into a heightened state of alert for terrorism here at home; threat levels were increased and response teams were notified to be ready to take action in the event of such attack, including bioterrorism. So far, no domestic terrorist strike has occurred -- with biological weapons or any other. Yet another kind of assault -- this one from Mother Nature – has underscored the continuing challenge of microbial threats, and is spotlighting critical issues in biodefense.

It is my firm belief that the best defense against any outbreak is robust public health—both science and practice. And while it will never be possible to fully prepare for every potential, imaginable threat, it is possible for our nation to shore up its general biodefense/public health preparedness to a level which can minimize, if not prevent, the potentially catastrophic consequences of the many and varied microbial threats we may have to face.

In my remarks today, I want to offer my sense of what are some of the essential elements of an effective public health strategy to counter bioterrorism, and then focus on some of the critical challenges before us.

In the organization where I currently work—and in some of the more arms control crowds where I now sometimes find myself—I have had to spend a lot of time explaining why the demands of bioterrorism preparedness are unlike those posed by threats from conventional terrorism, military strikes, or chemical, radiologic or nuclear attack. As I am sure most of you appreciate, by its very nature, the bioweapons threat requires a different paradigm. Meaningful progress against this threat depends on understanding it in the context of

biological organisms and disease.

Although our nation has experienced its first lethal bioterrorism attack, we cannot assume that the public and key policy makers truly understand the threat that looms. The anthrax attacks were somewhat misleading as to the kinds of events we must prepare for. These episodes were as close to a traditional HAZMAT event as a biological attack could be in terms of an identified source, and the fact that teams could arrive at the site, define a perimeter, and identify those who required care. But it must be emphasized that there are many potential biological scenarios that would unfold in very different ways.

Most likely there would be no announcement—no envelope saying this is anthrax, take penicillin-- and without a fortuitous discovery early on, there would be no discrete signal that an attack had occurred. Rather, a biological terrorism event would probably unfold as a disease epidemic, spread out in time and place from the initial site of release before authorities even recognize that such an attack has occurred. In fact, it may prove difficult to ever identify the perpetrators, the site of release, or even determine whether the disease outbreak was intentional or naturally occurring.

And while most bioterrorism, especially in the near term, will no doubt reflect an infectious disease model. Biological attacks do not necessarily have to involve infectious agents. Expanding insights into various regulatory and other systems within the human body may offer new opportunities for the determined terrorist to develop tools that will disrupt critical functions for life or behavior…we know that the Russians, in their former bioweapons program, were already experimenting with so called neuromodulators.

In any case, the "first responders" to a bioterroism event will almost certainly be public health officials and health care providers…and how swiftly we recognize and respond to a potential attack will dramatically influence our ability to reduce casualties and control disease.

In this time of heightened anxiety and concern, our nation has a real opportunity – and obligation – to make sure that we have in place the programs and policies necessary to better protect ourselves against this threat. While there are many challenges, we do know a great deal about what needs to be done and how to do it. A national response to bioterrorism must incorporate the certain important elements:

> **Prevention**. Every effort must be made to reduce the likelihood that dangerous pathogens will be acquired or used by those that want to do harm. This must include improving intelligence, limiting inappropriate access to certain biological agents and efforts to establish standards that will help prevent the development and spread of biological agents as weapons.
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> **Strengthening public health** . Rapid detection and response will depend on a well-trained cadre of trained public health professionals to enhance disease surveillance and outbreak investigation, educated and alert health care providers, upgraded laboratories to support diagnosis and improved communications across

all levels of government, across agencies and across the public and private sector.

Enhancing medical response. This requires training health professionals to diagnose, report and treat these diseases, developing strategies to improve the ability of the health care system to rapidly increase emergency capacity, and providing necessary drugs, vaccines or other medical equipment/material where needed through mechanisms such as the National Pharmaceutical Stockpile.

Research. A comprehensive research agenda will serve as the foundation of future preparedness. Perhaps most urgently, we need improved detectors/diagnostics, along with better vaccines and new medications.

Some of these activities are already underway, but need to be strengthened and extended. Other programs and policies still need to be developed and implemented. Clearly these activities are all essential for homeland security. Yet it is important to note that while certain aspects of these activities are required to respond to the threat of bioterrorism specifically, many of these programs are just as important for the day-to-day, routine activities of public health and medical care.

As you know, in the aftermath of 9/11 and the anthrax letters, considerable new attention and financial support is being directed towards combating the threat of bioterrorism, and other possible catastrophic attacks. This offers the chance to address many troubling and persistent gaps in public health preparedness. There will be no quick fixes or simple solutions. Approaches must be comprehensive and investments must be both well directed and sustained if we are to achieve meaningful and enduring solutions to the problems before us.

In that context, I want to raise with you a set of key challenges where I think we need further leadership, vision and support :

First I want to underscore the critical role of public health. There is an evolving understanding that public health is an essential pillar in our national security framework. This is increasingly obvious—whether anthrax or SARS—but yet we are not fully acting on that knowledge. Public health expertise should be an important and prominent component of our national security efforts, including within the new Department of Homeland Security, and on the White House national security team. Similarly, at the state and local level, public health leaders and public health expertise must be integrated into decision-making at all levels of government when it comes to public safety and security issues.. In some places this is working well (Georgia), but in many places these new working relationships still haven't jelled. And even in the best conditions, us public health types have to keep our elbows sharpened sometimes to assure a place at the table.

We all understand that in doing this work, resources are key. Unfortunately this is a bad time no matter where you work. Recent federal bioterrorism funding for public health programs has been impressive—and I think has made--and will continue to make--a considerable difference. Yet while we've taken some steps forward, there are some real

concerns.

For one thing, we must ensure that these new and very significant resources are distributed in a manner that reflects a carefully considered strategic framework for action, and that the money goes where it needs to and that there is accountability for how the resources are actually spent.

Sustainability is an enormous concern. We cannot have a quick infusion of resources with no follow-through. There is no one-shot activity that can rebuild our faltering public health system, provide the needed surge capacity that our health care system will need to cope with a public health emergency or the demands of mass casualty care, or provide the biomedical breakthroughs that will represent new tools for preparedness in the future. Thus far, my impression is that the Department of Health and Human Services has been quite mindful of these concerns in how they have tried to structure their programs and program oversight. But I was deeply troubled to hear that there has been serious talk among certain Members of Congress who wield considerable influence, suggesting that the funding for these programs should be short term. This kind of thinking could lead to disaster

In addition, preparing against the threat of bioterrorism requires a multifaceted approach. Critical components may rest on many broader program and systems. The budget process must reflect this concern, and requires comprehensive attention so that unintentional dislocations in capacity or function do not occur. We certainly do not want to inadvertently undermine the very programs and infrastructures that form the foundation of efforts to prevent or respond to a bioterrorist attack.

For example, there is trepidation that while large sums of money are being put into the public health components of bioterrorism preparedness at CDC, cutbacks in crucial, but non-bioterrorism programs at the federal level --such as cuts in CDC's emerging infections program and other aspects of their public health funding support-- may have real consequences. These activities are all inter-connected. An effective program of public health preparedness for bioterrorism can only be built on a strong, effective and broad based infrastructure for public health.

And, of course, as many of you are painfully aware, states and localities are operating under extreme fiscal pressures these days. Cuts to public health programs in state and local budgets across the country, mean that overall dollars to build and sustain the necessary elements for infectious disease preparedness and response may not be there.

What is more, specialized efforts such as the smallpox immunization campaign, while well-intentioned, has drawn vital resources—both human and financial—away from the task of building the systems needed for our overall preparedness and response. This unfortunately has proven to be a very large, unfunded mandate. In my view, when it was determined that an extensive vaccination effort was required to support our national defense, a new allocation of resources should have been made commensurate to the national importance of the task. You certainly don't want to "rob Peter to pay Paul" when overall gains in security is, in fact, what suffers.

In a related arena, meaningful response capability for bioterrorism must rest on a robust and flexible health care system. Already we know that most hospitals are operating in a precarious financial environment, with limited ability to "surge" in response to increased demands for care. While new dollars have been targeted to support planning for how institutions and regions might respond in the event of a mass casualty attack, these dollars have been quite limited. A couple hundred million dollars have been appropriated thus far, which no matter how efficiently used, will simply not reach very far or deep. What is more, while financially strapped hospitals are trying to figure out what they need to do to prepare, let alone implement those plans. Other components of the budget, such as shifts in Medicare reimbursement to hospitals and the continuing costs of indigent care—quite far afield from bioterrorism budgets--may have more profound effects on the stability of these institutions.

We must be realistic about the potential costs that would be incurred by these institutions, as well as the enormous up-front investments needed if they are to truly to prepare. Effective public health preparedness demands new partnerships and improved coordination between government and the non-governmental health care providers. It is evident that we must find better ways to strategically support our health care institutions, both because of the implications of a bioterrorist attack and the existing demands on the system, as evidenced in recent years when routine flu seasons overwhelmed hospital capacity in many cities, and the fact that certain urban hospitals already frequently redirect emergency vehicles because they are operating beyond capacity.

There is an urgent need to develop programs that target dollars for health care disaster planning and relief, including training, templates for preparedness, and efforts to develop strategies in collaboration with other critical partners for providing ancillary hospital and health care support in the event of a crisis. In so doing, we need to support local and state planning efforts to assess community assets and capabilities, and we need to take a look at what federal support can realistically be brought to bear locally in a crisis.

Beyond these critical domestic needs, successful strategies must also include a renewed and ongoing commitment to improving global public health. Historically, we have not contributed much to global health needs. We are beginning to wake-up to the importance of these investments. It is heartening that in the last few years we have developed new international initiatives to address HIV/AIDS, TB and malaria, and we have paid our dues (and arrears) to the WHO. But we still need to do much, much more. My guess is that—at least temporarily—SARS will stimulate new attention and resources to global health needs. But again, we must attempt to ensure that new efforts will go into developing or strengthening fundamental systems for disease detection, investigation and response.

My guess is that SARS will also have a stimulatory impact on another important area for public health preparedness…and that is the further clarification and coordination of legal authorities. In planning for an effective response, an array of legal concerns still need to be addressed. There is still confusion about basic issues such as the declaration of an emergency. What are the existing authorities? Are they public health, or do they rest in

other relevant domains? What are the criteria for such a declaration? What are the authorities that still need to be established? Of course these questions and their answers differ from state to state. There is also a growing debate about the role of federal authorities and how much can and should these decisions, in the context of communicable diseases that don't abide by state boundaries, be made at the federal level.

Other outstanding legal questions concern the ability to isolate, quarantine, or detain groups or individuals; the ability to mandate treatment or mandate work; restrictions on travel and trade; the authority to seize community or private property such as hospitals, utilities, medicines, or vehicles; and the ability to compel production of certain goods. Also, questions involving emergency use of pharmaceuticals or diagnostics that are not yet approved or labeled for certain uses need to be answered now. Related to this are the, as yet, unresolved issues of liability and indemnification which have been especially troubling in the context of vaccine development and delivery, for both routine and possible biodefense needs. Certainly the issues of liability and compensation resulted in a major impediment to the success of the smallpox vaccination campaign.

These questions involve many different levels of government and sectors of society, many different laws and authorities, and involve many complex intertwined ethical, political and economic issues. In a systematic and coherent way, we must address these pressing issues and concerns -- not just what laws are in place or could be put in place, but also what policies and procedures would be necessary to actually implement them. SARS is offering some useful real-time experience with some of these issues, but we have a great deal more to think about and learn…hopefully before the next major crisis emerges.

Sadly, the many fears, anxieties and uncertainties that have surrounded both SARS and the anthrax incidents reinforce another major gap identified in current preparedness and planning efforts. This involves how to engage the public, and importantly, how to most effectively work with the public in the event of a crisis. Both the anthrax attacks and SARS—in somewhat different ways-- give new insights into how complex these issues may be. Certainly, the specter of a silent, invisible killer, such as an infectious agent, evokes a different level of fear and panic than other disaster scenarios.

In any disaster, how the needs of the public are handled from the very beginning is critical to the overall response. For a biological event, this may be even more crucial. In fact, effective implementation of disease control measures may well depend on the constructive recruitment of the public to behave in certain ways, such as avoiding congregate settings or following isolation orders. Managing the worried well may interfere with the ability to manage those truly sick or exposed. In the final analysis, clear communication and appropriate engagement of the public will be the key to preventing mass chaos and enabling disease control as well as critical infrastructure operations to move forward.

Correspondingly, the needs and concerns of response personnel, including health care workers, must also be addressed. Again, prior experience with serious infectious disease outbreaks tells us that when this does not occur, essential frontline responders and key workers are just as likely as the public to panic, if not flee. The mass exodus of health care

workers following onset of the Ebola epidemic in Kikwit, Zaire in the mid 1990s serves witness to this point. The response to SARS has been more promising.

Especially in this era of 24 hour news, the media is key to efforts to communicate important information to protect health and control disease, as well as to reduce the potential for panic in a crisis. In recent times, it has been enlightening to see both the press and the public receive crash courses infectious disease—first anthrax and now SARS. They have been fast learners, and for the most part, the media has done a credible and responsible job in communicating important information. In both instances, the very officials dealing with the crises also were learning as they went. But no matter what, successful leadership requires that there must be a clear plan for providing the news media with timely and accurate information. Furthermore, the credible and consistent voices of well-informed health officials are critical to this effort.

It is also evident that the ability of the media to mobilize effectively in a crisis is greatly enhanced by a process of ongoing and continuing mutual communication and education in calmer times. We must strive for the development of a set of working relationships grounded in mutual trust -- trust that they will be provided with factual information in a timely and appropriate manner, and in turn, that they will use that information in a responsible, professional way.

Beyond just working with the media, prior planning and preparation can greatly mitigate the death and suffering that would result from a serious bioweapons attack. As a nation, we still need comprehensive, integrated planning for how we will address this threat. We still need to define the relative roles and responsibilities of the different agencies involved, and identify the mechanisms by which the varying levels of government will interact and work together, and with the private sector.

Certainly, the response to anthrax demonstrated many gaps in the effective coordination of government led response activities and the need to enhance our ability in a crisis to gather information and communicate it efficiently to all relevant parties. For example, among the public health agencies at the local, state, and federal levels, concerted efforts were made to work together as a team. Yet these efforts were clearly hampered by inadequate systems for information sharing, jurisdictional issues, and the fact that people and facilities were rapidly overwhelmed by the competing demands of response to the crisis. Similarly, communication and coordination between the public health and law enforcement communities followed along the same path, although these were further exacerbated by the differences in mission, goals and professional cultures between these two different, but important elements of an effective response.

Planning can make a difference, but we cannot begin to prepare in the midst of a crisis. Moreover, planning efforts must be backed by the necessary resources and authority to translate planning into action. And we must practice what we plan.

Shifting gears a bit, I want to say something about research. Today's investment in research and development will be the foundation of tomorrow's preparedness. A

comprehensive research agenda should be developed and pursued that extends across many important research domains. Our ability to detect and respond to a bioterrorist attack depends considerably on the state of relevant medical science and technology. Without rapid techniques for accurate identification of pathogens and assessment of their antibiotic sensitivities, planning for the medical and public health response will be significantly compromised. Without efficacious prophylactic and treatment agents, even the best planned responses are likely to fail. The more we understand about the basic mechanisms of pathogenesis and the nature of the human immune response, the more likely we will be to discover and develop future generations of treatments, protections and cures. NIH has developed an ambitious research agenda to address many of these goal and has been given the largest budget increase in its history to do so, at about $1.7 billion.

But other types of research are clearly needed to support our overall preparedness for a bioterrorist attack, and many of these "non NIH type" research efforts are more fragmented and less well-funded. For example, concerns such as defining the requirements for appropriate personal protective gear, strategies for securing ventilation systems or making air-handling safer, and decontamination procedures under different circumstances. Also, we need more applied public health research that actually examine the effectiveness of various interventions, ranging from evaluating strategies for syndromic surveillance to modeling the use of quarantine in controlling communicable disease. Also, research into the behavioral issues and psychosocial consequences of a catastrophic event of this kind is currently very limited but should be made a high priority.

Finally, I want to say something about prevention. Prevention is a fundamental principle of public health and should be a central focus of how we think about terrorism.

This is a broad area and there will be no quick fixes. At the most fundamental level, it includes understanding the motivations of terrorism and addressing the roots of terrorism--the causes and conditions that create an environment that fosters terrorism and allows it to take hold. Obviously this is a complex and challenging topic, and more than we can address today. Nonetheless, I wanted to at least mention it because it is so crucial for the longer term. And in this context, we cannot forget the potential special role of health, including the fact that international, collaborative health programs can serve as a pathway to new hope and opportunity in regions impoverished of hope, and a bridge to new trust and partnership among communities or nations formerly at odds.

Looking more specifically at the bioterrorist threat, are there strategies to limit or prevent potential bioweapons from getting into the hands of those who might misuse them, and how do we reduce the likelihood that they would be misused?

To block the proliferation and use of biological weapons, we must significantly bolster our intelligence about the threat-- where it may come from and what it may be.

As it turns out, the bio threat is especially tough. It is hard to track the movement of biological materials by satellite, like you can with certain munitions. Biological weapons can be produced in legitimate looking labs or pharmaceutical sites, and, at least in recent

times, there have been few people with backgrounds in the life sciences to gather and sort through human intelligence on the biolological threat.

There is a desperate need for greater biomedical and scientific expertise to be applied to intelligence data collection and analysis. In addition, members of the scientific community may yield new understandings through routine international scientific activities and collaborations, as well as insights into what information is available in the open scientific literature, including what could be potentially misused or misapplied by those who might want to do harm. Similarly, public health professionals may have important insights into infectious disease outbreaks or events of potential significance. As such, these scientists may be crucial to building new expertise in this complex area within the intelligence community.

Building these new working partnerships is not necessarily easy or comfortable. For those of us working at the precarious interface of public health, law enforcement and intelligence, there are many tensions that need to be addressed concerning our various–and often differing-- roles, responsibilities, and missions. These are real concerns, but I think that we can and must work together as true partners if we are going to meaningfully address the complex challenges of the bioterrorism.

The scientific and medical community will also need to be engaged on the issue of improving biosecurity with respect to reducing access to dangerous pathogens. Important steps have been taken in recent years, but the anthrax situation demonstrated that there was not an adequate handle on whether dangerous pathogens were adequately secured, who was using them, and why. Shortly following the anthrax experience, several legislative measures (such as the patriot act) were taken to further address such concerns. Some of these new laws made sense and will be helpful; other aspects will create disincentives and barriers to research, and may not even improve security. The scientific community really needs to step up to the plate to help policy makers address these concerns, and develop strategies to reduce risks in ways that will be meaningful but not overly cumbersome to legitimate research.

In addition, we must recognize that while advances in science and technology hold enormous promise for improving health, they also present many opportunities for misapplication or inadvertent harm. For example, we need to ensure that the tools of modern genomic biology are not used to create new and more dangerous organisms. This is a complex challenge, for no one would want to impede the progress of legitimate and important science. However, we also have a responsibility to face up to a very real set of concerns.

Several recent studies have heightened attention to these issues. For those of you familiar with it, the Australian mousepox study is one case often cited of an inadvertent finding that has laid out a potential road map for others to make an already dangerous pathogen more lethal. The recently reported creation of poliovirus *de novo* underscores that the capabilities for the intentional creation of new biological agents for potential use as weapons will be increasingly available.

With leadership from the scientific community, we must begin to examine the context and conduct of modern science, and what opportunities may exist to constructively reduce this emerging threat.

On a policy level, such prevention efforts require a global approach, including the development and implementation of international standards, norms or guidelines for biosecurity and the practice of biomedical research. In addition we must continue to pursue ways to meaningfully strengthen and enforce the Biological Weapons Convention.

Conclusion

I think we can all agree that there are many complex challenges before us. We may never be truly prepared for some of the most catastrophic scenarios, but there is a great deal that can and should be done. And as we move forward to address this disturbing new threat, it is heartening to recognize that many of these investments --strengthening the public health system, expanding medical capacity, and enhancing our medical research knowledge base -- will also greatly enhance our nation's ability to prevent or respond to the threat of naturally occurring disease, whether flu or food poisoning or the yet unknown or unrecognized.