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The National Action Agenda for Public Health Legal Preparedness

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Public Health Law Program
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Letter From The Editor

In this special supplement of the *Journal of Law, Medicine & Ethics,* we are proud to present the first National Summit on Public Health Legal Preparedness. The Centers for Disease Control and Prevention (CDC) and 19 multidisciplinary partners, including the American Society of Law, Medicine & Ethics, sponsored this summit held in Atlanta, Georgia, in June, 2007. The summit consisted of more than 250 participants from diverse fields, including state and federal government, policymakers, health care, law, and emergency management.

The purpose of this first national summit, much like the mission of *JLME,* was to bring these participants together to assess the current state of public health legal preparedness and to discuss viewpoints on the future of this field. Reading the articles contained in this supplement confirms that the summit was a rousing success, full of fresh, thoughtful ideas and inspiring calls to action.

We would like to thank the CDC and its partners for presenting this important summit and sheparding it to publication. We also wish to recognize the important contributions of the summit planning committee and all of the participants. Finally, we would be remiss if we did not acknowledge the fine editing team that brought this summit to the printed page, including Editor Montrece McNeill Ransom, Executive Editor Wilfredo Lopez, and Associate Editors Richard A. Goodman and Anthony D. Moulton. We thank them all for their very fine work.

Ted Hutchinson
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The findings and conclusions contained in this shared National Action Agenda for Public Health Legal Preparedness are those of the authors and do not necessarily represent the view of the U.S. Government or the organizations with which the authors and contributors are affiliated.

PREFACE

*Montrece M. Ransom, Wilfredo Lopez,
Richard A. Goodman, and Anthony D. Moulton*

In June 2007, the Centers for Disease Control and Prevention, (CDC) and eighteen multidisciplinary partners convened the first National Summit on Public Health Legal Preparedness. This Summit was without precedent in terms of the broad expertise and stature of the invited participants and its aims. The purpose of this working meeting was to provide a structured opportunity for senior officials and leaders from a wide array of sectors and disciplines to take measure of public health legal preparedness as it stands today, and to develop a shared, national action agenda supportive of law-based strategies to address potential public health emergencies such as pandemic influenza and other emerging threats. This supplemental issue to the Journal of Law, Medicine, and Ethics contains status papers developed by leading experts in the fields of public health and public health law, and presents the Summit's work product: a shared national action agenda for public health legal preparedness.

Public health legal preparedness has been defined as the attainment by a public health agency or system of specified legal benchmarks or standards that contribute to effective prevention of disease, disability, and death. The Summit and the resulting national action agenda were framed around the four core elements of legal preparedness: 1) legal authorities based in science and/or on contemporary principles of jurisprudence; 2) competency in applying law to public health goals; 3) cross-sector and cross-jurisdiction coordination of law-based interventions; and 4) information on legal preparedness best practices. The strategic goal of the Summit – to contribute to the nation's development of full legal preparedness for all types of public health emergencies – was established by the Summit's 57-member, multidisciplinary planning committee (see appendix a). Within that goal, the Summit's purpose was to bring together subject matter experts from a wide spectrum of relevant sectors and jurisdictions, and foster their best thinking in developing an agenda for action for public health legal preparedness, with an emphasis on emergencies, for implementation by policy makers, practitioners, and partners across the wide spectrum of sectors and jurisdictions.

The 242 Summit participants included senior policy makers and practitioners from federal, state, tribal, and local government public health agencies; healthcare; law; emergency management; the judiciary; law enforcement; elected state and local officials; and representatives of philanthropic and professional organizations. Participants were organized into highly interactive workgroups, each of which focused on gaps, needs, and opportunities related to one of the four core elements of public health legal preparedness. The workgroup methodology ensured that each participant had multiple opportunities to contribute actively to formulation of the Summit work product. In plenary sessions, nationally recognized leaders in public health and medicine, law, and emergency preparedness offered distinctive, but complementary, perspectives on public health emergency preparedness.

Because of the historic importance of the Summit, the organizers sought to reflect in these proceedings both the spirit and substance of the meeting. The goal of the editors has been to ensure an accurate record of the Summit, while at the same time providing a practical tool for use by public health practitioners and their partners in legal preparedness efforts. This report, therefore, presents the plenary papers establishing the framework for the Summit workgroup deliberations, four papers assessing the current status of legal preparedness across the four core areas, and four papers

that identify candidate areas for action in each of the four core areas of legal preparedness. The appendices include a roster of the Summit planning committee, a listing of Summit participants, as well as a list of the partners that convened the Summit.

The papers identifying options for action are intended to serve both as frameworks and as a springboard for further work. It is important to note that the findings and conclusions in this action agenda are those of the authors and do not necessarily represent the views of the U.S. Government or the organizations with which the authors are affiliated. Every government and private organization active in public health emergency preparedness is invited to review the action papers and identify options it may wish to pursue.

Meeting the goals of this published action agenda benefited from extraordinary efforts by the Summit planning committee, invited participants, the Summit speakers and presenters, and the editing team. In particular, we thank Dr. Richard Besser and the staff of CDC's Coordinating Office of Terrorism Preparedness and Emergency Response for their support of this endeavor. We would also like to acknowledge the important contributions from the following staff members, interns, and fellows: Melissa Thombley, J.D., Public Health Law Fellow; Andrea Hines, Program Analyst; Kevin Cartwright, Web Developer; Veronnica Hobbs, M.P.H., Public Health Prevention Service Fellow; Morjoriee White, M.P.H., Public Health Law Fellow; Erin Lichtenstein, J.D. Candidate, Public Health Law Intern; Elenora Connors, J.D./M.P.H. Candidate, Public Health Law Intern; Chinyere Ekechi, J.D., Emerging Leader; Rachel Weiss, J.D., Editor of CDC's *Public Health Law News*; Karen McKie, M.L.S., J.D., Public Health Legal Consultant; and Daniel Stier, J.D., Senior Public Health Analyst. Finally, we'd be remiss if we did not acknowledge the unfailing support and efforts of the many others who were involved in the Summit, including the participants, collaborating organizations, workgroup rapporteurs and facilitators, and primary authors of all the papers. The dedication and many contributions of all these persons and organizations ensured the success of the Summit and the development of this action agenda toward the goal of improving the nation's legal preparedness for all public health emergencies.

FOREWORD

RADM W. Craig Vanderwagen and Tanja Popovic

Public health legal preparedness is a core foundation of our ability to ensure the nation is prepared to prevent, respond to, and reduce the adverse health effects of public health emergencies and disasters. Without clear legal authorities, our preparedness and response enterprise suffers from unnecessary commotion at the very times we most need clarity.

Over the past six years, our nation has witnessed unprecedented efforts to build preparedness and response capabilities at the same time when we had been called on to collectively respond to unprecedented incidents. Public health legal preparedness has been a key element in those efforts. We continue to learn and apply lessons from real-world events with the objective of strengthening our ability to heed the call to respond when needed.

In June 2007, the Centers for Disease Control and Prevention and partners convened the first National Summit on Public Health Legal Preparedness, a milestone event in national public health preparedness. The 242 invited participants represented an exceptional group of thought leaders from every level of government, and from a broad range of sectors, including professional organizations, non-profits, and academe. The collective real-life experience, diverse backgrounds and broad spectrum of expertise that Summit participants brought to the table are a testament to the nature of our enterprise – we all must play a role in our preparedness and response efforts. Those we serve – our entire nation – will look to us for leadership and measure our success by our ability to prevent or reduce the adverse health effects of all-hazards disasters, whether naturally occurring or man-made.

This multidisciplinary approach is paramount to addressing public health issues in general, but even more in the area of public health preparedness and times of crisis, when only highly coordinated efforts can assure timely implementation of life-saving solutions. Without this multidisciplinary approach, and especially without the interconnectedness of public health and law, today's generations would not be the beneficiaries of the many major public health accomplishments of the 20th century (immunization, motor vehicle safety, etc.). The Summit presented an invaluable, first of its kind opportunity to learn from each other and build trust; the more we understand and appreciate our respective roles, responsibilities and authorities, the better prepared we will be for the challenges ahead of us so that we, as a society, continue to claim public health victories. To that end, as we strive to develop new and strengthen existing collaborations, partnerships and public health legal tools, we must, at the same time, be considerate of the possibly fragile balance of the protection of the community and the common good and the protection of individual liberties.

Our interdependence requires us to focus on maximizing opportunities for partnership and collaboration. The Summit's proceedings, contained herein in an action agenda format, provide just such opportunities. The status papers and companion action agendas focus on the core elements of public health legal preparedness: 1) legal authorities; 2) competencies; 3) coordination; and 4) information and best practices. We encourage you to read these papers closely, and to continue the dialogue about these topics among your colleagues and those you serve.

We look forward to continuing our partnership and collaboration with you to ensure a nation prepared.

Craig Vanderwagen, M.D., *is the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, Washington, D.C.* **Tanja Popovic, M.D., Ph.D., F(AAM), AM(AAFS),** *is the Chief Science Officer at the Centers for Disease Control and Prevention, Atlanta, GA.*

Setting Expectations for the Federal Role in Public Health Emergencies

Eric D. Hargan

I would like to begin by discussing the legal and administrative framework of the role of the federal government in public health. At the heart of it is, of course, the Constitution. At the Department of Health and Human Services (HHS) we depend, as does much of the federal government, on our power to regulate interstate commerce. Since the Supreme Court in 1942 removed essentially any restraint from the meaning of interstate commerce in *Wickard v. Filburn,*[1] the federal government has been regulating with wide latitude, in spite of small and, arguably, equivocal reverses in recent years. However, even though the Supreme Court no longer provides any real constitutional check on the federal government's interstate commerce power, some other restraints persist. For example, many parts of the health system have traditionally been deemed inherently state functions, such as the licensing and disciplining of doctors, nurses, and pharmacists, as well as the practice of medicine itself. The federal government has hesitated to tread across these areas, for fear of disturbing long-established patterns of regulation that work effectively at the state level.

The constitutional right of citizen groups and businesses to petition the government is another check on the federal government. For example, even during the potential outbreak of monkeypox in 2003, for which we needed to prevent the distribution and sale of prairie dogs, in crafting the ban we needed to work carefully around the prairie dog lobby's potential concerns. In fact, there is virtually no group in America that is not organized and striving to be heard by the government. This is, of course, as it should be, even if it sometimes makes life uncomfortable for those of us representing the federal government.

While the 10th Amendment is unfortunately forgotten by many, we at the Department of Health and Human Services are bound to carry out only that which is delegated to us. We do not have a plenary power to regulate. We cannot just establish power for ourselves, and we have to defer to the states when they have a system in place. For example, HHS does not generally run hospitals, administer vaccines, provide physicians or nurses, or establish quarantines. In fact, most of my presentation focuses on what powers we do not possess.

Section 247d of the U.S. Code and Section 319 of the Public Health Service Act gives the Secretary of Health and Human Services a great deal of authority in the event of a public health emergency. It says:

> If the Secretary determines, after consultation with such public health officials as may be necessary, that –
>
> (1) a disease or disorder presents a public health emergency; or
>
> (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2).

Eric D. Hargan, J.D., *is the Acting Deputy Secretary of the U.S. Department of Health and Human Services.*

Obviously, this cannot mean that the federal government can do whatever it wants simply by declaring a public health emergency. Herein we find the distinction between authorization and appropriation. Just because part of the federal government has statutory power to do something, it cannot practically do it if it lacks the funds. For example, in a public health emergency, the Secretary largely cannot use money that already has a dedicated use – and the Public Health Service Act acknowledges this. The Secretary cannot just shut down Alzheimer's research at the National Institutes of Health (NIH) in order to hire nurses to respond to an earthquake in California; NIH research has its own money set aside by Congress in the budget bill, and, with small exception, not even the President, much less the Secretary, can re-appropriate that money or sequester or otherwise switch it around once the budget bill is signed. In other words, the HHS budget, as enormous as it is, is not a big checkbook to be drawn on by the Secretary as he sees fit. As an aside, while the Secretary can draw from the Public Health Emergency Fund, it is a dry hole, since Congress has never actually put any money into it.

The public health emergency declaration does allow use of some waivers of programs and other powers, but despite what some people think, it is nowhere near as sweeping as a declaration of martial law. The health laws are just not the right place to look for that. As far as this topic goes, it is better to look at the Posse Comitatus Act,[2] the Insurrection Act[3] (which has been tediously renamed), and others, and not to our health laws, tempting as it may seem.

What does this all mean, from a practicable perspective? How are we acting under our authority? I will explain by discussing several of the most significant public health challenges we are faced with. Some of the threats we at HHS are charged by the President and Congress to prepare against are manmade, like bioterrorist attacks. Some are natural, like pandemics. I will begin with bioterrorism, an area that our friends here at the Centers for Disease Control and Prevention conduct a great deal of work on.

Bioterrorism is a terrifying concept, and the idea for using biological agents to spread disease and death is an old idea. While it is fortunately more feared than practiced, and security specialists are more concerned with nuclear and radiological devices, it should be noted that the only uses of advanced terrorism devices have been bioterror ones: the anthrax attacks of 2001.

Since September 11, 2001, we have taken a number of steps to prepare against the threat of a bioterrorist attack. Thirty days after the attacks, we put forward the Bioterrorism Act of 2002,[4] which developed critical new bioterrorism authorities for the HHS and gave the Department broad new authorities to protect the nation's food supply. The Act also allowed us certain critical waiver and response capabilities across a broad range of our programs so we could react and be more responsive in an emergency. These capabilities are focused around two main areas that use Congress-appropriated funds: assisting and encouraging states and communities in their preparedness efforts, and building up our knowledge, infrastructure, and material. Examples of related steps are that:

- We have provided more than $7 billion since 2001 for state and local preparedness.
- We have increased our spending on bioterrorism and counterterrorism activities from $273 million in 2001 to a requested $4.3 billion for next year.
- Through Project Bioshield, we are providing new tools to improve medical countermeasures protecting Americans against a chemical, biological, radiological, or nuclear attack.
- We have worked with every state to develop response plans.
- We are piloting a Cities Readiness Initiative to upgrade capabilities for the rapid distribution of antibiotics across large urban areas during emergencies.
- We have expanded and enhanced our Laboratory Response Network to aid in detection and surveillance.
- We have built stockpiles of needed drugs and supplies.

But, in my opinion, the most significant threat to public health that we face today is not a bioterrorist attack but an influenza pandemic, the current possibility being known as "bird flu." The issue of pandemic preparedness is a timely one, because we are overdue but under-prepared for a reoccurring natural disaster such as a pandemic. Pandemics are a biological fact, as history has shown us time and time again. We know that viruses and bacteria are constantly mutating, adapting – and attacking. And when pandemics strike, they not only cause a great deal of sickness and terrible loss of life, but they reshape nations.

Why are we so concerned right now? This is a good question, since H5N1 virus infection, the one that scientists are most worried about, is currently a bird disease. The problem with this strain of influenza is twofold: it is new and it is deadly. H5N1 has not developed sustained or efficient human-to-human transmission, but it has already infected 313 people and killed 191. That is a mortality rate of over 60 percent. In contrast, the 1918 pandemic had a mortality rate of at most 6

percent. And our epidemiologists tell us we are overdue for another pandemic.

When it comes to pandemics, there is no rational basis to believe that the early years of the 21st century will be different than the past. If a pandemic strikes, it will come to the United States and to communities all across the world. Of course, a pandemic might not happen for years or even decades. There is a certain cynical but natural view that this alarm about the bird flu is all hysteria. And there is a certain political calculation that would instruct us to do nothing. Tony Abbott, the health minister of Australia, said, "In the absence of a pandemic, almost any preparation will smack of alarmism. If a pandemic does break out, nothing that's been done will be enough."[5]

However, we are convinced that, whether or not we are facing an imminent pandemic, we should be better prepared for a pandemic. A century ago, America's health system was much less sophisticated in general, but its capacity for dealing with mass infectious disease was much more robust. Waves of disease were expected, and sanitaria, mass public health programs, quarantines, and adult immunization programs were more common and more widely accepted.

Another thing that the previous age of public health has us beat cold on is local preparedness. And local preparedness must be the foundation of pandemic readiness, because in case of a national pandemic, there is going to be no unaffected area from which to draw health workers and others to take care of patients in affected areas; thus, at some point in a pandemic, every local community has to make do with its own resources. In emergency preparedness, we usually think of and exercise single short disaster scenarios, like a hurricane. But as terrible as a hurricane can be, as, for example, was Hurricane Katrina, it is physically an event primarily of regional significance. It had a regional impact, it was limited in time (in spite of the continuing repercussions in the region), and volunteers and supplies from around the world poured into the area. Think instead about a pandemic: it will have a sudden, national impact. It will not last for a couple of days, but rather for months or even over a year, in multiple waves. Instead of people racing to the affected area to provide comfort and assistance, people will be staying home, many afraid to go into the affected area to lend help and support. It is a different construct for which we have to prepare.

And if none of us prepares, as a pandemic outbreak spreads, and outbreaks in communities reach their peak, the disaster will spiral downward, affecting everyone, everywhere. Due to the ubiquitous nature of a pandemic, it is dangerously unrealistic to expect the federal government to be able to swoop in and fix everything. That is why it is important that every community have its own plan and be able to rely on its own resources as it fights the outbreak or anticipates an imminent one. That is why it is vital that we understand the role of the federal government versus the role of states and communities when it comes to pandemic readiness.

We have delineated our role as the federal government to include five main objectives:

- Disease monitoring,
- Stockpiling countermeasures,
- Developing vaccines,
- Establishing communications plans, and
- Setting up local plans.

First, disease monitoring. HHS Secretary Leavitt uses a metaphor when describing this goal. Think of the world as a vast forest, thick with underbrush and dead trees. It is very vulnerable to fire. A single spark can burst into a great inferno that is extremely difficult to put out. But if you are there right after the spark ignites so you can extinguish it, you can limit the damage. We believe that could be true with a pandemic. If we are able to discover the spark quickly, there is a chance we can extinguish it and stop a pandemic. Therefore, we are building a network of nations to cooperate in disease monitoring. Likewise, we need communities in the United States with sophisticated systems to watch for the emergence of disease.

Second, we must have stockpiles of anti-viral medications and other supplies. We are building up supplies of antivirals such as Relenza and Tamiflu and subsidizing our states' antiviral purchases as well. There is a nuance when it comes to stockpiling countermeasures, however. People imagine an airlift, probably by the armed forces, of medicines from a large federal stockpile. The federal government steps in and saves the day! Unfortunately, our readiness exercises have shown us that stockpiles are not the problem. Distribution is the problem. Unless you can get medicine to those who are sick within 24 to 36 hours, the size of your stockpile will not much matter. And, as the experience of 1918 showed, soldiers who might be carrying out those airlifts get sick just like everyone else.

Parenthetically, if I seem like I am belaboring the military point, it is because it is always the first recourse of people wanting to wish away this distribution problem, and no expert in this area that I know of thinks the military can solve this problem. Many people seem to think that in any disaster, the federal government can simply step in and fix everything. That is an unrealistic worldview, however. Instead, when it comes to distributing stockpiles, it is the state

and local plans that will spell the difference between defeat and victory. Thus, we have been working to help states set up distribution plans and to investigate how to partner with additional groups like the U.S. Postal Service.

Third, we need vaccines. Fortunately, a vaccine that produces an immune response in humans was developed last year and approved by the FDA. We are testing it, and getting through the bumps in the road on that. Of course, we are working on this vaccine with no assurance that H5N1 will be the virus to develop into a pandemic, but we need to be as prepared as we can. We are also spending several billion dollars to improve vaccine and antiviral production capacity, purchase vaccines and antivirals, and conduct research on new production technologies.

Fourth, preparedness needs to include communications plans as well. We all need the capacity to inform people without inflaming them, so there is not panic. In this area, SARS was a wake-up call. Across the world, only 8,000 people got sick, with 800 of them dying, but it paralyzed the Chinese and Canadian economies for several weeks and caused several billion dollars worth of economic disruption.

The fifth – and most important objective – is that every state, every Indian tribe, every city, every school, every business, every church, and every family needs a plan that addresses the unique challenges they would face. During a pandemic, there will not be any unaffected areas from which to draw health care workers to take care of patients in affected areas, so at some point in a pandemic, every local community has to make do with its own resources. And when it comes to pandemics, any community that fails to prepare – expecting that the federal government can or will offer a lifeline – will be tragically wrong. Leadership must come from governors, mayors, county commissioners, pastors, school principals, corporate planners, the entire medical community, individuals, and families. For when a pandemic comes, we believe it will hit everywhere in a short period of time.

All governments have plans established to ensure continuity of government in case of a decapitating event, like an assassination. Many governments also have plans to ensure continuity in the event of a degrading event, like a pandemic. But how many cities, businesses, or schools have plans for fighting outbreaks with their own resources when as many as 30 to 40 percent of their workforce are absent for 6 to 8 weeks? If none of us prepare, then as the pandemic spreads and outbreaks reach their peak, the consequences would cascade. Medical centers would be overwhelmed. Schools would close. Transportation would be disrupted. Food and fuel would run out. There would be power and telecommunications outages.

Therefore, to help mobilize the American people in their planning efforts, we are making available extensive information resources including planning guides and checklists targeted toward specific groups. We have released more than a dozen so far, to help businesses, schools, health care services, to individuals and families, and many more categories. We have adopted a comprehensive approach with these guides, and they cover everything from assigning a person responsible for coordinating preparedness planning, to developing an education and training program to ensure that everyone understands the implications of pandemic influenza, to determining how vaccines and antivirals would be used.

We will continue to release guides as we develop them. These checklists and plans, along with a great deal of other useful material, such as hundreds of pages of technical guidance we have provided to state and local health officials and providers, can be found on the Web site <www.pandemicflu.gov>. Pandemicflu.gov serves as our government's one-stop access point to pandemic and avian flu information. And, since all the information is online, anyone around the world is more than welcome to use them. As countries, states, local groups, and individuals carry out preparedness activities, they may find weaknesses in our plans – and we need to discover these while we still have the time to correct them.

There is the possibility that a pandemic might not happen for years or even decades. Some people may think that our preparation is a waste and that we are being alarmist. In reply, I can only say that these people are right – until they are wrong. And the consequences of them being wrong are greater than the consequences of us being wrong. We probably cannot prevent a pandemic. But preparation can delay its onset. Preparation is likely to reduce the peak of a pandemic to a level that is much less overwhelming than it could have been, bringing it down to a number of cases that could be cared for. Preparation is likely to save lives.

Even if it is a long time before a pandemic strikes, there are real benefits to preparing now:

- We would have established new vaccine technology,
- We would have the capacity to manufacture vaccines much more quickly than we currently do,
- Annual flu would be much less of an issue, and
- We would be better prepared against any medical disaster or health crisis.

Over the past few years, we have been confronted with a variety of disasters, from hurricanes to bird flu to terrorist attacks. We have learned a great deal about what response efforts do and do not work. We are implementing all of the reports that have been issued, and are working to patch the flaws in the system.

But one fundamental flaw persists in the public imagination: people seem to think that, if only it were properly administrated, that the federal government should – or even could – push state and local authority aside in the aftermath of any disaster. This is neither federal doctrine nor realistic – there are limits to what bureaucrats, even highly-trained bureaucrats, can do. To tie this back to the point I made earlier, the federal government is constitutionally one of plenary state power, with federal authority primarily depending on one clause of the Constitution and one set of Supreme Court decisions for its wider powers. Even though there are also statutory powers, which give us broad authority, they are not paired with appropriations to implement them.

Therefore, when it comes to emergency preparedness, though unforeseen by the founding fathers, the Constitution and all sense of practicality agree: there must be a balance of federal and state roles, with the states virtually owning entire responsibilities in this area.

We may never perfectly balance the role of the federal government against the obligations of states and communities in preparing against all possible disasters. But each day that we prepare, each day that we hash out these questions while we have the luxury of time, we make ourselves more ready and more capable of an effective response.

We are not prepared yet. But we are more prepared today than we were yesterday. And, with enough people aware and engaged, we will all be more prepared tomorrow than we are today. Thank you.

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Public Health Legal Preparedness: A Framework for Action

Georges C. Benjamin and Anthony D. Moulton

A. Introduction

Public health emergencies have occurred throughout history, encompassing such events as plagues and famines arising from natural causes, disease pandemics interrelated with wars (such as the influenza pandemic of 1918-1919), and industrial accidents such as the 1986 Chernobyl disaster, among others. Law and legal tools have played an important role in addressing such emergencies. Three prime U.S. examples are Congressional authorization of quarantine as early as 1796,[1] legally mandated smallpox vaccination upheld in a landmark 1905 U.S. Supreme Court ruling,[2] and the President's 2003 executive order adding SARS to the federal government's list of "quarantinable communicable diseases."[3]

The public health emergencies of the present – both actual and potential – pose equally serious threats but do so in the context of greatly magnified expectations that stem directly from the attacks of September 11, 2001, and the immediately following anthrax attacks. These events transformed the environment in which government agencies – public health, emergency management, law enforcement, and others – work to address public health emergencies in the U.S. As a result, public health emergencies now are seen under the intense spotlight of national security concerns. The agencies charged to prepare for, and respond to, public health emergencies at all levels face extraordinary expectations for safeguarding the nation from potentially catastrophic health threats.

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Other trends have further transformed the operating environment for public health emergency preparedness, including, for example: the rapid emergence of new threats to the public's health, such as SARS and influenza A (H5N1); the expectations of elected officials and the public for effective emergency response on an accelerated timeline and on a 24/7 "always on" basis; and, certainly not least, expansion in the origins and scope of public health threats from the local and regional levels to the national and global levels.

The public health emergencies the nation faces today require urgent and highly complex responses that involve multiple governments, agencies, jurisdictions, and social sectors. They also may require the use of many public health tools rooted in legal authority, such as disease surveillance; control of movement through quarantine and isolation; government use of private property; allocation of vaccines, medicine and medical supplies; and evacuation of populations.

The nation needs modern legal tools to enable rapid, effective responses to such highly complex challenges. Many states and communities, like the federal government and partners at every level, have worked hard to strengthen legal preparedness beginning even before the attacks of September and October 2001. Most, if not all, states have updated their public health emergency laws since then. Many have conducted training in legal preparedness and have incorporated legal issues into preparedness exercises. Further, beginning in 2002, legal preparedness has been an explicit focus of CDC's program of preparedness grants to the states.[4]

In spite of this progress, continually emerging events – such as the case of a U.S. citizen who traveled internationally in 2007 while infected with a dangerous form of tuberculosis – underscore that much remains to be done. The driving impetus for the 2007

National Summit for Public Health Legal Preparedness was the planning committee's conviction that it is critical to take measure of the current status of legal preparedness, identify gaps as well as opportunities for improvement, and shape a plan of action that all concerned professionals and organizations can pursue toward the strategic goal of full legal preparedness for public health emergencies of all kinds. The committee was fully cognizant that any improvements in legal preparedness for public health emergencies will help strengthen legal preparedness for many non-emergency public health concerns as well.

B. A Conceptual Framework

The conceptual framework used to organize the deliberations of the 2007 Summit had two parts. First was the following definition of the term "public health emergency preparedness" articulated in early 2007 by an expert panel convened at the request of the U.S. Department of Health and Human Services (HHS):

> The capability of the public health and health care systems, communities, and individuals, to prevent, protect against, quickly respond to, and recover from health emergencies, especially those whose scale, timing, or unpredictability threatens to overwhelm routine capabilities.[5]

The panel further identified sixteen key components of "a well-prepared community" of which the second was what the panel called "legal climate."

The second part of the Summit's conceptual framework was first published in a 2003 article that introduced and defined the term "public health legal preparedness" (closely congruent with the HHS panel's term) as follows:

> Public health legal preparedness is the attainment by a public health system...of specified legal benchmarks or standards essential to the preparedness of that system.[6]

In the same article four core elements of public health legal preparedness were further identified as:

- *Laws and legal authorities*
  Laws and legal authorities (i.e., statutes, regulations, ordinances, court rulings, and other authoritative statements by government bodies) are foundational to public health legal preparedness.

- *Competency in using laws effectively and wisely*
  Public health professionals need to know the legal powers they have and how best to apply them. Public health emergency legal preparedness depends also on emergency responders, law enforcement officials, judges, hospital managers, and many others knowing the legal authorities held by public health officials as well as their own relevant legal powers and limitations.

- *Coordination of legally based interventions across jurisdictions and sectors*
  Coordination is important precisely because many public and private organizations typically take part in responding to public health emergencies, and do so across multiple jurisdictions. This adds further complexity to the operating environment that surrounds public health.

- *Information on public health laws and best practices*
  Information resources are the fourth core element of public health legal preparedness. These varied resources include, for example, practitioner guides to the established public health laws of a given jurisdiction, updates on relevant new laws and court rulings, and science- or experience-based best practices in using laws to support public health interventions.

C. Case Studies of the Core Elements of Public Health Emergency Legal Preparedness

This section presents examples from real-world public health practice to illustrate how policymakers and practitioners in public health and related sectors can use this conceptual framework in shaping and applying law as a public health tool. The examples – of public health emergencies and other acute public health concerns stemming from highly diverse causes – reflect recent public health history as well as the experience and perspectives of author GCB, a former state health commissioner.

When Laws and Legal Authorities Are Uncertain or Unknown

In early 2001, a Baltimore, Maryland journalist published a report on a cluster of young women who had contracted severe conjunctivitis potentially associated with the use of cosmetic lenses that had been sold without prescriptions, and hence illegally, by a number of Baltimore City beauty salons. In light of the significant health risks, the governor, attorney general, and press demanded to know how the sales had been permitted and expected immediate corrective action.

An urgent need was to determine rapidly which federal or state agencies, if any, had jurisdiction to act. Review of alternative courses of action determined that the U.S. Food and Drug Administration lacked enforcement authority and that the Maryland Board of Optometry had no legal authority to intervene. The state health department lacked powers specific to this type of public health danger but had broader protection powers that might be used.[7]

The state health department weighed such options as issuing public health advisories, seeking an attorney general's order to declare the sales illegal, issuing agency cease and desist orders, and even seeking new legislative authority. The composite course chosen was to issue cease and desist orders to known retailers, to seek injunctions against non-compliant retailers, and to issue health advisories through the media. As a result, the number of illegal sales declined although there were some ongoing reports of injuries from the inappropriate sale and use of the implicated lenses. Later, in 2003, the state legislature passed a bill specifically empowering the state health department to "prohibit the sale of cosmetic lenses without a valid prescription."[8]

While relatively limited in scope, this case illustrates by extension the critical role law plays in efforts to protect the public from untested or even fraudulent products or practices sold during public health emergencies. An egregious example is the large number of unvalidated tests and treatments for anthrax contact promoted and sold following the anthrax attacks of 2001. Within eight weeks of the first anthrax attack, the Federal Trade Commission issued warnings to marketers of "bogus" products to cease those activities subject to potential civil and criminal penalties.[9] Appropriate, tested laws should be in place well before the occurrence of an emergency so that public health and other agencies can apply them to support timely, effective response.

The Difference that Competency in Applying Public Health Law Makes

Public health officials' contrasting uses of isolation laws in two contemporary cases illustrate the importance of public health legal competency, i.e., the requirement to understand the public health legal authorities available for dealing with a specific health threat, legal constraints on their use, and the steps and procedures through which they can best be implemented.

From July 1998 until May 1999, a California county health department quarantined and detained in the county jail a multi-drug resistant tuberculosis (MDR TB) patient who had not complied with her treatment plan nor with a health department order for examination. The detention order did not give a specific reason for detention nor did it communicate the patient's rights to request release, to a hearing, or to counsel as afforded by the state's TB control laws. Further, that order held the patient in the jail until completion of the prescribed course of treatment. After some ten months' incarceration, and after consulting with the county counsel, the health department issued a revised order correcting the documentary and procedural deficiencies of the first order. The patient was provided counsel and a hearing, leading to her unconditional release.

The patient then filed two lawsuits. The state Court of Appeals upheld a trial court ruling, finding that the county health officer and health department had acted in direct violation of the state's 1997 statutory proscription on such use of jails; the appeals court issued a parallel, separate prohibition specific to the involved county. The federal lawsuit resulted in the county's making a $1.2 million settlement to the patient. Both outcomes might well have been avoided had the public health officials – whose paramount concern undoubtedly was to protect the community's health – fully understood the procedural requirements of, the legal constraints under, and the legislative intent of, the state's TB control laws.[10]

A contrasting example – one that illuminates competency in the application of public health law – involved a Montana college student who was diagnosed with MDR TB in 2006. In 2003, as part of its public health emergency preparedness efforts, the Montana legislature had clarified its statutory isolation and quarantine authorities. In the summer of 2006, the state health department began conversations with local health departments regarding their need to understand how to implement isolation and quarantine protocols effectively to meet federal grant requirements for public health emergency preparedness.

The state and cognizant local health departments were aware of the student's desire to travel internationally at the time they learned that she had MDR TB. It was determined that her local health department should issue an isolation order restricting the student's travel and that was done. Because the student would have had to depart from an airport located in a different county, that county's public health department issued a second order specifically barring flight from that airport. Further, to prevent air travel from any other city, notice of the case and of the travel restrictions was communicated to the regional CDC quarantine office and also to the airline. The student complied with the order and her treatment regimen. She was permitted to travel, within specified parameters, to a hospital where timely and appropriate

treatment was initiated; ultimately, she was allowed to return home when she no longer was contagious.[11]

Coordination in the Use of Public Health Laws

In the summer of 1997, commercial fishermen reported large fish kills on three Maryland rivers. Laboratory tests confirmed that the organism *Pfiesteria piscicida* was present in the affected waters at toxic levels and was the probable cause of the fish kills. Virginia fishermen operate from the shore across Chesapeake Bay where a similar organism was identified in Virginia waters and was associated with a high incidence of lesions in fish there as well.

A local internist stated in the media that he had treated fishermen for rashes, lethargia, and memory loss.[12] There was unjustified but nonetheless widespread public concern even with the safety of Chesapeake Bay seafood. Concern was heightened after a medical team reported findings of short-term memory loss and neurological findings in fisherman exposed to the waters where acute fish kills occurred. An urgent need thus existed for accurate, consistent information to reach the public throughout the region.

Mounting a coordinated response to the *Pfiesteria* outbreak became complicated because of the large number of government jurisdictions involved. Federal agencies had uncertain authority to intervene. Multiple state agencies in both Maryland and Virginia had potential roles. Additional complexity stemmed from the necessary and appropriate roles played by several Maryland county governments.

The Maryland Department of Health and Mental Hygiene ultimately closed affected Maryland rivers pursuant to orders issued by local health departments until the outbreaks had ceased.[13] Virginia, however, chose not to close its affected waters. The two states' divergent approaches were widely publicized, contributing to public confusion about the danger. In addition, Maryland attributed some difficulties in enforcing river closure to public confusion about the actions it had taken. River closure entailed additional challenges and problems because of the substantial economic losses suffered by fisherman prohibited from working on the affected rivers.

This case illustrates challenges posed by public health emergencies in complex jurisdictional settings. Similar complexity was seen at far more acute levels and on a global basis during the 2003 SARS outbreak which accelerated such improvements in public health law as the 2005 International Health Regulations and led, at the national level, to extensive changes in Canadian federal and provincial public health emergency laws.[14]

Why Information on Legal Preparedness Best Practices is Crucial

When a pet ferret bit a child at a sleepover in a Maryland home in 1994, the county health officer was confronted with the need to apply both public health and legal preparedness best practices.

Risk of rabies exposure and transmission of rabies to the child was the immediate concern as was the potential for the ferret to bite others. The public health best practice at the time was to monitor the child closely and to euthanize the ferret and test tissue for rabies. Implementation, however, was complicated by the refusal of the child's physician and family to give the child post-exposure rabies prophylaxis.

The parent of the child whose ferret was involved, upon receiving a legal order from the health department to deliver the ferret for testing and destruction, initially refused to do so. The county health department then petitioned the court, under applicable state and county law, to require the owners to turn the animal over. The court granted the request, finding that the health department acted within the legitimate boundaries of its police powers. The autopsy studies determined that the animal did not have rabies.

Upon the owners' appeal, the appellate court upheld the trial court ruling, finding, in part, that the state's

> ...decision to destroy biting ferrets is, as a matter of law, a lawful use of the State's police powers because it is rationally calculated to protect the public health.[15]

This case demonstrates how important it is that public health officials employ the legal best practices applicable to a given public health threat, i.e., application of the pertinent legal authorities by officials competent in their use and with coordination across the relevant jurisdictions and sectors. In many cases, best practices may encompass such additional complications as using private property for a public purpose or seizing or destroying it to protect the public.

D. The Core Elements and the 2007 National Summit

These cases demonstrate that any attempt to assess and improve legal preparedness for public health emergencies – indeed, for any public health purpose – must address all four of the core elements. Any attempt that focuses on only one element, such as laws and legal authorities, will be incomplete and address only one facet of the required solution.

These cases also show that the conceptual framework of which the core elements are part can have direct utility for those who wish to take practical action to make law a better tool for public health preparedness. This is why the four core elements formed the organizing basis for the deliberative sessions of the 2007 National Summit, for the papers prepared before the Summit assessing the current status of legal preparedness, and for the action agenda papers that were generated during the Summit. This is not to imply, however, that the four core elements constitute an immutable orthodoxy. To the contrary, the exercise of legal authorities and tools during future public health emergencies undoubtedly will broaden understanding of the contribution the core elements make to effective legal preparedness and may even lead to identification of additional elements.

The four action agenda papers that appear later in this publication present the results of the first systematic attempt to identify options for practical steps to strengthen legal preparedness for all-hazards public health emergencies. The many partner and stakeholder organizations that are active in public health emergency preparedness will tailor the individual options to their own priorities as well as to their capacity to contribute to implementation of the options. Any individual organization is likely to find that it can contribute more to strengthening one or two core elements than to others. Here, too, is an example of the helpful, practical effect of the framework: no single organization need feel the weight of having to contribute to all four of the core elements. Instead, by aligning their efforts, the concerned partners will help strengthen all the core elements.

This paper opened by defining public health legal preparedness as "attainment…of specified legal benchmarks or standards essential to the preparedness" of a public health system. Implementation of the options offered in the action agenda papers – in ways that reflect the unique needs and priorities of the concerned jurisdictions – in effect will give practical definition to those benchmarks and standards. Equally important, implementation will engage policymakers and professionals across a wide spectrum of sectors and jurisdictions in advancing the Nation's legal preparedness for public health emergencies and for public health risks of many other kinds.

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Public Health Emergency Legal Preparedness: Legal Practitioner Perspectives

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Introduction

This paper provides an overview of recent US Department of Health and Human Services (HHS) initiatives and efforts – under the leadership of the General Counsel, the Secretary, and the President – regarding legal preparedness for public health emergencies. In addressing this topic, the paper focuses on four core elements comprising public health legal preparedness:

(1) effective legal authorities to support necessary public health activities;
(2) competencies of public health professionals to know and then to apply those laws;
(3) coordination of the application of laws across jurisdictions (local, state, tribal, federal, and international) and across multiple sectors; and
(4) information and best practices in public health law.[1]

This paper's review of four core elements of public health legal preparedness also implicates common themes and issues that are at the center of constitutional law, including:

- Federalism
- Individual rights
- Separation of powers

Laws and Legal Authorities

The first element of legal emergency preparedness – "effective laws and legal authorities" – is the central, substantive aspect of public health legal preparedness. The matter of legal authority presents particularly salient and uniquely important constitutional and administrative law issues to government lawyers. By comparison, for many lawyers in private practice, seldom does a legal question center on what the legal authority is for a client's actions; rather, the lawyer's focus is to identify the extent of the government's authority to effectively impose a requirement. In contrast, for lawyers advising federal agencies and officials, the question of legal authority is the first and most important issue to consider for every legal problem. Lawyers who advise federal clients – who are fundamentally, constitutionally limited to exercise only enumerated powers – are well-situated to recognize the genius of the Framers who wrote into the Constitution that the federal government shall have only the authorities provided in the Constitution, and all other powers shall be reserved to the States. While Congress has legislated broadly in many public health areas, every federal government action involving expenditures – from purchasing vaccine stockpiles to supporting travel – must be based in some way on a constitutional and/or statutory authority.

At the federal level, with respect to public health matters, Congress has relied on key constitutional authorities, including the commerce clause[2] (both its interstate and foreign clauses) and the spending clause[3] to provide the Executive Branch with many legal authorities. For federal actions in public health, the primary statutory legal authority is the Public Health Service (PHS) Act.[4] This law can be traced to August 14, 1912, when it was enacted into law as "An Act to change the name of the Public Health and Marine-Hospital Service to the Public Health Service, to increase the pay of officers of said service, and for other purposes."[5] At that time, the Public Health Service Act comprised

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only two sections and one-half page of text. Today, its compilation is many times greater in length. (One of the predecessors of the PHS Act dates to 1796, when Congress passed the first National Quarantine Act after extensive debate regarding whether quarantine should be a federal or state function.[6])

In recent years, identification of the need for additional Federal laws – particularly to deal with the threats of bioterrorism and pandemic influenza, and to clarify roles and responsibilities in public health responses in the modern administrative state – has prompted HHS to work with Congress to enact these additional laws. The new laws encompass a broad spectrum of authorities:

- The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA),[7] establishes the Assistant Secretary for Preparedness and Response (ASPR) and enhances ASPR authorities for leading the Federal Government in emergency preparedness and response.[8] It also enhances grants to States and localities for surveillance activities and improvement of medical surge capacity. In addition, PAHPA establishes the Biomedical Advanced Research and Development Authority (BARDA)[9] which facilitates HHS collaboration with other Federal agencies, relevant industries, academia, and others regarding advanced research and development of countermeasures and pandemic or epidemic products.
- The Public Readiness and Emergency Preparedness Act (PREP Act)[10] within the Department of Defense Appropriations Act of 2006[11] provides liability immunity for administration of covered countermeasures specified in a declaration by the Secretary of HHS. It also establishes a process to provide compensation to covered persons under the declaration.
- The Public Health Security and Bioterrorism Preparedness Response Act of 2002 enhanced national preparedness and planning, established the Strategic National Stockpile and the National Disaster Medical System by statute, authorized the Secretary of HHS to award grants and cooperative agreements to improve state and local preparedness for response to public health emergencies, established enhanced requirements regarding the handling of select agents and toxins, and partially authorized BioSense – a national program intended to improve the nation's capabilities for developing near real-time health situational awareness.[12]
- The Project Bioshield Act of 2004 established authorities to encourage the research and development of specific countermeasures (such as drugs and vaccines for bioterrorism agents) that would otherwise lack a commercial market, and established a process for emergency use of investigational products for civilians.[13]

Some other changes in Federal law have been minor, but nevertheless important. For instance, in 2002, the HHS quarantine authorities were amended to provide that neither those authorities nor its implementing regulations should be read to supersede or preempt any provision in state law unless the state law conflicts with the exercise of federal authority.[14] This is a clear example of a common occurrence in public health law – the co-existence of federal and state authorities and the resulting challenges created for policymakers in deciding at what level action should be taken in the face of a public health emergency and how best to coordinate with other levels of government.

Importantly, the Supreme Court has made clear that although the federal government has the authority to preempt (or override) state laws, the federal government cannot commandeer and/or direct the use of state governmental assets in order to further a federal regulatory scheme relating to state governmental powers.[15] Thus, for example, a federal law commanding state legislatures to pass a particular law would be considered unconstitutional, although requiring such a law as a condition for receipt of relevant federal funds would generally be permissible. As a result of this constitutional design, all the governmental stakeholders in public health have a role in using their authorities in concert and no single entity is usually "in charge" of everything.

In identifying, enacting, and implementing legal authorities, another important limitation – besides the doctrine of enumerated powers – is the provision of safeguards for the individual rights that are enshrined in the Constitution. Public health actions, even (and perhaps especially) during a public health emergency, must comport with the Bill of Rights and the 14th Amendment as they have been interpreted by the courts. Although federal courts historically have been deferential to the Executive Branch in matters of public health, such deference cannot be presumed or relied upon in any particular case. Therefore, legal emergency preparedness necessarily encompasses lawyer's advice and policymakers' planning with regard to the inevitability that the independent judiciary will balance the government's legitimate need to protect the public's health against individuals' rights. One important and current example of policymak-

ers planning in this regard is evident in the published notice of proposed rulemaking for the Control of Communicable Diseases issued by HHS' CDC.[16]

Competencies

Legal authority is without effect if the lawyers who advise on and policymakers who implement the laws are neither prepared nor able to offer advice and act decisively, and appropriately, when the time comes. In this regard, HHS has invested substantially in planning and training efforts. The information resource Pandemicflu.gov provides one access portal to the array of plans, training options, and policies developed by HHS and offered to help prepare the nation for public health emergencies. These documents have been subjected to rigorous review to ensure legal sufficiency and accuracy. In addition, HHS' Office of the General Counsel serves on continuity of operations teams and participates in key exercises and simulations.

There is, however, one underestimated and vitally important aspect of legal competency that is quite difficult, if not impossible, to train for: sound legal judgment. Even the most realistic training cannot simulate the personal, mental, and emotional pressures presented by an actual crisis. Fundamentally, the matter of sound legal judgment is one of personal choices, and pubic health and emergency management hiring processes for lawyers should include consideration of expectations for a lawyer seated at the table during an emergency.

The attribute of sound legal judgment, as a component of legal competency, is tightly intertwined with the following three roles for legal counsel:

- First, during an emergency, a primary role of the public health lawyer is to advise whether an action is legally permissible. In this regard, it is crucial – especially given the potentially severe consequences posed by many public health emergency threats – that legal counsel be able to effectively and judiciously distinguish between law (those limits and procedures that are inherent in a nation of laws, including the protection of individual rights), administrative bureaucracy (procedural requirements that present no real legal risk and can be remedied or waived), and policy questions that cannot be answered through legal reasoning.
- The second important role of the public health lawyer is to think creatively and put options on the table. For example, during the Hurricane Katrina response, there was a need for medical personnel beyond what the federal and state governments were ordinarily able to provide, and resulting concerns of liability protections. The legal problem was that medical personnel willing to play a role had concerns about the availability of liability protections. The solution to the legal problem was the appointment of medical personnel as temporary, uncompensated federal employees, thereby allowing for their integration into HHS field medical operations, including the availability of tort liability coverage under the Federal Tort Claims Act.[17]
- The third important role of the public health lawyer is to be a zealous advocate for their client by thinking of the client and by informing the client of long-term institutional legal risks for the client, at the very time the client is instead focused on providing assistance to others. The public health lawyer can include advice about testing legal theories in particular fact patterns and the client's reputation in judicial forums which, under a separation of powers, will independently decide the facts and the law in a particular case. Similarly, lawyers have uniquely trained to constantly anticipate what lawyers for other parties involved in an issue or matter will claim, say, or do – and this is information a client needs and wants in making informed policy judgments.

A final point on competencies is that attorneys and their clients also need to educate and train one another regarding their respective roles. Clients need to learn, in advance of an emergency or other crisis, about the inherent ambiguities of law, and attorneys need to learn from clients what kinds of legal advice can be optimally utilized by the client.

Coordination

In the context both of federalism and ever-increasing global inter-connectivity, effective coordination is more crucial than ever. This encompasses coordination among lawyers regarding the respective roles of their clients, and coordination among various local, state, federal, and international public health officials regarding their respective roles and the exercise of legal authority.

For example, one issue involving coordination in emergency preparedness within the structure of federalism is that of professional licensing. Since the states have authority to enact their own varying requirements regarding professional licensing, an important question is under what emergency circumstances may physicians practice medicine in a state where they are not ordinarily licensed. HHS has worked with states to address this and also relies on authorities enacted by Congress to help develop solutions to this "perfect

storm" of federalism. For example, HHS – through its Health Resources Services Administration – has developed the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), a program that supports a national network of State operated systems that register and verify the credentials of health professional volunteers in advance of an emergency.[18] In addition, the PHS Act authorizes the Secretary to develop and implement a plan under which personnel, equipment, medical supplies and other resources of the PHS and other agencies within HHS can be used to control epidemics and meet other health emergencies or problems.[19]

Information and Best Practices

Finally, the most practical and most operational element of legal emergency preparedness is the sharing of information and best practices among the public health law community.

The concept of the "OODA loop" is a useful analogue for considering public health information and best practices for emergencies. The OODA loop, originated by the U.S. military strategist Colonel John Boyd, comprises four overlapping and interacting processes for making battlefield decisions: (1) Observe, (2) Orient, (3) Decide and (4) Act.[20] The practical implications of this concept are that decision makers first must develop situational awareness by observing. Second, they must orient themselves by processing situational information against the backdrop of prior experience and analyzing how the information presents issues in relation to systems' values and capabilities. Third, they must move beyond these steps to make decisions. Fourth, organizations and individuals must act to implement the decisions. The aggregate effect of this concept is that applying and completing its steps more rapidly than an adversary will help to overcome or defeat the adversary. In public health emergency preparedness, the enemy is a naturally occurring or man-made disease or health threat, as well as its resultant social consequences. The time cycle for such threats can vary tremendously from situation to situation, but it can be short – in those cases, it is crucial that legal advice be available and thoughtful and thorough. This can be achieved through the sharing of knowledge and information, and by coordinating extensively within and external to public health organizations.

As examples of the application of these principles, within HHS, legal practitioners in the Office of the General Counsel have:

- Collaboratively prepared model documents, identified and analyzed relevant legal authorities, and provided practice pointers and risk assessments as a means of giving thought to the application of these situations in advance.
- Extensively shared knowledge developed through this work throughout HHS and through informal means such as regular conference calls and meetings.
- Institutionalized the responsibility for legal emergency preparedness issues by creating a senior position to coordinate legal advice on emergency preparedness issues across HHS' Office of the General Counsel from our CDC branch to our Food and Drug Division, to coordinate our internal efforts for legal public health preparedness, and to coordinate our communications on these matters with legal partners in other agencies.
- Participated in national and multi-sector meetings, such as the National Summit on Public Health Legal Preparedness, which bring together public health officials, their counsel, the judiciary, and legislators to maximize public health legal preparedness.

Conclusion

One additional aspect of public health legal preparedness not explicit among the four core elements, but addressed within the Summit's context, is the human element. The human element encompasses the notion that in the course of preparing for and responding to public health problems, and while preserving the paramount need for legal objectivity, the lives and needs of individuals who can be so dramatically affected by public health threats always must be kept in mind as a reality rather than a hypothetical abstraction.

As an example, during the response to Hurricane Katrina, as lawyers in HHS' Office of the General Counsel were carrying out many of the functions described above, a decision was made to communicate with colleagues in the private sector to learn from them directly the nature and scope of challenges confronting them. A primary purpose for doing this was to identify firsthand potential and important legal concerns of health care provider entities and, as a result, use the information to improve the legal advice given to HHS policymakers. The American Health Lawyers Association agreed to organize a conference call that included counsel for health care providers in the areas affected by Katrina and leadership of the HHS Office of the General Counsel. These private-sector colleagues were invited to describe and share the issues with which they were dealing. Given an opportunity to speak directly to HHS' most senior lawyers, the private sector lawyers did not suggest that their clients needed waivers of regulations, nor did they assert that government action or precedent in a particular area was inhibiting

their clients' response. Rather, the lawyers reported how they were tiring from many days of 24-hour crisis management; how their clients' staffs were running out of food, water, and stamina; and that their greatest concern was about keeping the floodwaters at bay so that hospitals could continue operating to care for the sick and injured. While the exchange validated the importance of coordinating, it also poignantly underscored the human element that must never be forgotten in public health legal preparedness.

These issues of law and public health are ones that societies have been struggling with for a very long time. For example, the Greek Byzantine Emperor Justinian, facing possibly the first recorded pandemic in 532 AD, instituted a quarantine law for persons traveling to Constantinople from areas where the plague was spreading.[21] But the literature suggests that even long before that, there were public health benefits provided during the Athenian plague of 430 BC from measures including the institution of isolation in two cities in Greece, as well as the separation of animals and humans in the areas outlying Athens.[22] As an object lesson in the importance of public health is shaping history and civilizations, many historians believe that the Athenian plague led to Athens' loss to the Peloponnese/Spartans.[23] Influenced in part by such historical context, the federal government, from the top-down and bottom-up, has embarked on a course to be the first generation in human history to be prepared for a pandemic. Public health legal preparedness is a crucial part of this ambitious objective.

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Assessing Laws and Legal Authorities for Public Health Emergency Legal Preparedness

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Introduction

Public health legal preparedness begins with effective legal authorities, and law provides a key foundation for public health practice in the United States. Laws not only create public health agencies and fund them, but also authorize and impose duties upon government to protect the public's health while preserving individual liberties.[1] As a result, law is an essential tool in public health practice[2] and is one element of public health infrastructure, as it defines the systems and relationships within which public health practitioners operate.[3]

For purposes of this paper, law can be defined as a rule of conduct derived from federal or state constitutions, statutes, local laws, judicial opinions, administrative rules and regulations, international codes, or other pronouncements by entities authorized to prescribe conduct in a legally binding manner. Public health legal preparedness, a subset of public health preparedness,[4] is defined as attainment of legal benchmarks within a public health system.[5] Law is one of four core elements of public health legal preparedness (the remaining three – competencies, information, and coordination – are each the subject of individual papers that follow).

In this paper we briefly describe the evolution and status of essential legal authorities for public health preparedness. Our review focused on *three* specific preparedness initiatives – health care system surge capacity, the Pandemic and All-Hazards Preparedness Act, and implementation of the International Health Regulations. These issues do not represent the entire range of legal preparedness nor the only relevant perspectives. The limited scope of this paper prevents a comprehensive treatment of these and other issues we considered. Rather, we chose these three initiatives because they exemplify the span of public health legal preparedness from the state and local, federal, and international perspectives.

After a brief overview of these initiatives, we describe several themes that emerged during our review. First, the series of events from September 11, 2001 and the anthrax attacks later that year to Hurricane Katrina in 2005 prompted a flurry of legislative and regulatory activities that sought to provide new authorities[6] at every level, modernize public health law,[7] and reorganize Federal preparedness and response functions.[8] Collectively, these legal reforms sought to improve the legal frameworks for the attainment of public health preparedness. Reviewing this legal landscape raises

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the questions of whether new laws and legal authorities are still needed, as well as whether the public health community is making the most effective use of existing authorities.

An additional question is whether existing laws form a barrier to achieving effective preparedness and response to public health emergencies. How we improve health care system surge capacity while complying with a patchwork of existing laws is a challenge at the state and local levels. Finally, the paper serves as a foundation for the companion paper that addresses gaps and potential limitations in existing authorities that merit consideration for action.

Background

The 20th century witnessed significant public health achievements, from advancements in the control of infectious diseases and motor vehicle safety to vaccination and worker safety.[9] Additionally, the prevention and control of non-communicable chronic diseases, such as heart disease and stroke and their associated risk factors, represent one of the greatest public health achievements of the past century.[10] Law played a key supportive role in these achievements.[11] Among the essential legal authorities that enable such achievements are laws that establish public health and related agencies, confer authorities upon those agencies to act (e.g., public health surveillance and investigation, environmental regulation, and public health interventions), and provide funding to those agencies.

Most notable, for purposes of this paper, may be the evolution of laws that relate to emergency preparedness and response, and the subset of those laws that address the preparedness of the public health system to respond to emergencies and disasters.

At the state level, the primary legal authority to respond to emergencies has been the police power, or the authority of the state to enact laws and regulations that protect the health, safety, and welfare of citizens.[12] The police power is among the powers reserved to the states under the Tenth Amendment to the U.S. Constitution.[13] The type of laws and regulations enacted under this authority that have a direct impact on public health include disease reporting and medical surveillance, personal control measures (e.g., mandatory vaccination), traffic safety, and nuisance abatement.

At the federal level, the Constitution empowers the federal government to regulate matters that affect public health through the Commerce Clause,[14] which authorizes regulation of interstate and foreign commerce, and Congressional authority to tax, spend, and address national security and foreign affairs.[15] Based on these broad foundational authorities, federal law regarding the response to emergencies and disasters has evolved over time to reflect an emphasis on an all-hazards approach that enables preparedness and response to emergencies and disasters, both natural and manmade, including terrorism.

The primary framework for federal emergency response authority is the Robert T. Stafford Disaster Relief and Emergency Assistance Act,[16] which outlines the programs and processes through which the federal government provides disaster and emergency assistance to state and local governments, tribes, eligible private nonprofit organizations, and individuals affected by a major disaster or emergency as declared by the President. The primary federal public health response authority is the Public Health Service Act,[17] which authorizes the Secretary of the Department of Health and Human Services to, among other actions, declare a public health emergency in response to the introduction and spread of communicable diseases, bioterrorism, or other situation that threatens the public's health.

The evolution of these legal frameworks over the 20th century and the development of comprehensive emergency management systems such as the National Incident Management System (NIMS) and the National Response Plan (NRP) have deviated from traditional civil defense and hazard-specific legislation and systems to focus on an all-hazards approach organized under the general framework of homeland security. This general homeland security framework includes the statutes, regulations, and the Presidential directives that, among other actions, created the Department of Homeland Security and the White House Homeland Security Council and required a wide range of preparedness and response planning. Recent legislation[18] requires the development of a National Health Security Strategy to address the preparedness of the nation to respond to public health emergencies, which is a similar framework to U.S. government national security[19] and homeland security[20] strategies.

Coupled with this new all-hazards approach and focus is the evolution of safeguards to protect individual liberties against unconstitutional government action. These safeguards include due process protections against deprivation of individual liberty (e.g., interstate travel restrictions and compulsory vaccination) and procedural protections that require proper notice and hearings before government can act. Protection of individually identifiable health information to ensure privacy is another example of enhanced individual protections, although there are limitations on these protections during emergencies.[21] As careful observers have noted, development of individual safeguards over the 20th century has occurred at the same time that public health officials have been able

to move away from community-wide disease control measures such as quarantine due to medical advances (e.g., vaccines and pharmaceuticals).[22] Although not yet tested in case law, the developments in constitutional due process may be relevant to the exercise of police powers to respond to public health emergencies. The threat of an influenza pandemic from the H5N1 strain of avian influenza has renewed attention on balancing the potential need for community-wide measures and the concomitant need to protect individual liberties.

Essential Legal Authorities and Selected Issues

With this broad framework, we turn to three specific issues that highlight the development of public health legal preparedness at the state/local, federal, and international levels. We examine several specific legal authorities and raise broader questions of the effectiveness of the current legal landscape and potential gaps to address.

1) Surge Capacity

With the seminal events of 2001 to 2005, a great deal of attention has focused on "filling gaps" in the legal authority of states and the federal government to respond to emergencies affecting public health. The urgency to complete this process was heightened by the potential threat of pandemic influenza. Because of the potential for rapid spread of pandemic flu and the potential absence of effective countermeasures in the initial months, there has also been much focus on how to address the anticipated overwhelming "surge" of patients into the health care system, some possibly requiring significant respiratory support. Such a surge could occur statewide or nationwide and continue in waves over months. Traditional means of dealing with sudden but localized surges of patients from an event such as a mass transportation accident may likely be ineffective. For example, communities may not have additional health care facilities immediately available to which surplus patients could be redirected by health facilities legally incapable of accepting more patients. Even the most promising new concepts in building surge capacity, such as "ER One" (an emergency department renovation plan that allows a standard 60-70 bed emergency department to accommodate four times that number of patients with less than 30 minutes' notice and increase its normal patient volume tenfold with only a few hours' notice),[23] may not meet bed requirements in the setting of pandemic flu.

In an emergency, the primary responsibility for the preservation of life and property falls on government, particularly at the state and local levels. The California Government Code, for example, specifically enunciates the state's responsibility to mitigate the effects of natural, man-made and war-caused emergencies.[24] Thus, it would be the responsibility of the state to address, to the extent possible, the surge of patients that the health care system cannot handle. If a state response became overwhelmed, federal resources would likely augment state capabilities. These facts mean it is in the interest of government (both state and local) to maximize the number of patients that can be absorbed by the health care system.

At the same time, however, the health care industry is highly regulated, and the standards established by regulation often restrict the ability of the health care system to absorb and treat additional patients. These standards range from facility licensing and certification requirements to labor and employment laws, from professional licensing requirements to standards for reimbursement.[25] These laws were not written with an eye toward their operation in a public health emergency. The potential liabilities to the health care community for deviating from the regulatory standards, however, can be criminal, administrative and civil, and can include fines and loss of certification, among other penalties.

While it may be possible for regulatory agencies to waive the enforcement of some or all standards during an emergency, doing so has its own risks as those standards may continue to provide the guidance the health care provider needs to meet for purposes of avoiding liability. A violation of applicable standards that allegedly results in an unfavorable medical outcome can become the basis for a claim of negligence on the part of the provider. Thus, the greatest obstacle to the regulated health care system's expanded participation in emergency relief may be the state's own standards. Absent a modification, suspension or waiver of the standards, there may be little legal or economic incentive for health care providers to risk providing the additional services that the state may need.

Some states authorize the suspension of regulatory statutes and regulations where strict compliance would impair the mitigation of the effects of an emergency.[26] In California, the process of modifying, suspending or waiving specific standards requires the identification of (1) the authority to suspend regulatory requirement, (2) which standards impair the expanded utilization of the healthcare system, (3) a mechanism to inform those with the political authority to implement a suspension, (4) a mechanism to determine what circumstances will justify the suspension, (5) a system of monitoring adverse effects or events for purposes

of evaluation, and (6) a mechanism for determining when the standards should be reinstituted.[27]

Thus, among the primary themes of our review is whether the operation of existing laws impairs public health legal preparedness to respond to a disaster or emergency.

2) The Pandemic and All-Hazards Preparedness Act
The President signed the Pandemic and All-Hazards Preparedness Act (PAHPA)[28] into law in December 2006. The statute builds upon the homeland security framework described earlier and represents the most comprehensive legislative treatment of public health preparedness to date. The 137-page statute affects all aspects of federal public health preparedness and response functions, consistent with existing federal policies outlined in relevant Homeland Security Presidential Directives and the National Response Plan.

Among other things, PAHPA directed the transfer or alignment of a variety of preparedness and response programs within the U.S. Department of Health and Human Services by a new Assistant Secretary for Preparedness and Response who is appointed by the President and confirmed by the Senate. The law provides new authorities in the development and acquisition of medical countermeasures, international preparedness and response programs, renews emphasis on the alignment of preparedness and response at all levels of government, and requires evidence-based benchmarks and standards that measure levels of preparedness. The statute also requires the development of a National Health Security Strategy, to include an evaluation of the preparedness of federal, state, local, and tribal entities based on the required evidence-based benchmarks and objective performance standards. The initial strategy is due in 2009 and then every four years thereafter.

At the federal level, in addition to creating new authorities, PAHPA renews a general movement toward alignment of existing preparedness and response activities both within HHS and across the federal government. This raises the second theme whether – given the substantial body of legal authorities that now exist – relevant partners are implementing those authorities in a way that maximizes their effectiveness.

3) International Health Regulations
Public health legal preparedness also occurs on the global stage. The goal of the newly revised International Health Regulations (IHR)[29] is to protect the health of people worldwide without interfering with travel and trade. The regulations took effect in June 2007 and represent a legally binding agreement regarding "public health emergencies of international concern."[30] Such events are defined as extraordinary public health events that pose a health risk – through the international spread of disease – to the rest of the world.

Consistent with the domestic evolution of public health legal preparedness from disease or incident-specific laws, the 2005 revision of the 1969 version of the IHR broadens the scope of coverage from cases of cholera, plague and yellow fever to all events that may constitute public health emergencies of international concern and requires the reporting of other serious international health risks, irrespective of origin or source. The new IHR require notification of the World Health Organization and outline new routine public health measures for the entry of people and goods into a country.

Discussion and Summary

The three specific areas examined in this paper address public health legal preparedness at the state and local, federal, and international levels. In this broadest span and range of issues, two key themes emerge. First, are we using existing laws effectively? Have we adequately trained public health professionals and others engaged in public health preparedness in this legal landscape? Do we need additional authorities to fill gaps in public health legal preparedness?

Second, as noted by the analysis of health care system surge capacity, have we unintentionally impeded public health preparedness, and its subset of legal preparedness, with existing laws? For example, are the legal requirements related to the operation of health care systems (which have very legitimate bases in protecting patient and worker safety) an impediment to meeting surge capacity during a public health emergency? If so, how might we best balance the day-to-day operational requirements with preparedness to respond during a public health emergency for which waiver of certain requirements might best accomplish public health preparedness? Have we adequately (1) identified the laws authorizing waivers or suspensions; (2) identified the laws or regulations that may need to be waived or suspended; and (3) drafted the appropriate executive orders to accomplish waiver or suspension?

Public health legal preparedness begins with effective legal authorities. We have considered the existing legal landscape, whether relief from existing law might be needed, and whether we have made maximum use of the authorities we have. While the answers are not immediately clear and require additional analysis, one thing is certain. Given the complexity of public health preparedness, law will remain an essential tool in public health practice.

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Assessing Competencies for Public Health Emergency Legal Preparedness

James G. Hodge, Jr., Kristine M. Gebbie, Chris Hoke, Martin Fenstersheib, Sharona Hoffman, and Myles Lynk

Introduction

Among the many components of legal preparedness for public health emergencies is the assurance that the public health workforce and its private sector partners are competent to use the law to facilitate the performance of essential public health services and functions.[1] This is a significant challenge. Multiple categories of emergencies, stemming from natural disasters to emerging infectious diseases, confront public health practitioners.[2] Interpreting, assessing, and applying legal principles during emergencies are complicated by the changing legal environment and differences in governmental organization of emergency management functions.[3] While law and legal competencies are essential to routine public health practices, once government declares a state of public health emergency or disaster, the legal landscape changes.[4] Typical legal responses to protect the public's health may no longer be the norm. Public health practitioners, legal counsel, health care partners, and others need to be able to assess changing laws and policies and apply them in real-time. To do so, they must be competent in their understanding and use of the law during public health emergencies.

In the context of public health systems, competencies may be defined as a complex combination of knowledge, skills, and abilities demonstrated by members of an organization that are critical to the effective and efficient function of the organization.[5] Competency statements describe specific activities that individuals are able to do or perform depending on their respective roles, responsibilities, and qualifications.[6] Competency resources have been developed for a full range of public health services,[7] including emergency response[8] and legal preparedness.[9]

In this article we describe the modern development of competencies in public health law, ethics, and policy, providing numerous examples of types of competency tools and materials. We further discuss existing and emerging actors within the public and private sectors for whom legal competencies in public health emergency preparedness are essential. Through these examinations, we analyze the current status of legal competencies for public health emergency preparedness and identify various gaps to be addressed in improving competencies.

Modern Development of Competencies in Public Health Law

Competencies for the public health workforce have developed through extensive dialogues sponsored largely by the Centers for Disease Control and Prevention (CDC) beginning in the late 1990's.[10] Yet, competencies have conceptual origins in industry practices that assess the ability of the workforce to perform job-related activities. They have also been used extensively

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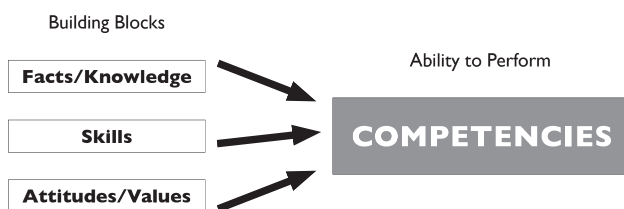
in health education, particularly related to technical and "just in time" training. Through this training, persons with specific skills are evaluated based on their ability to perform needed tasks and fill gaps. For example, the training and certification of emergency medical technicians have traditionally been competency-based, and included evaluation components.[11] Required competency sets also guide curricula in nursing,[12] dentistry,[13] preventive medicine,[14] and other disciplines.

Whether utilized in practice or academic settings, competencies are comprised of facts, knowledge, skills, attitudes, and values, as illustrated in Figure 1, below.

Figure 1
Competency Creation



Competency statements are typically based on a standard formula, including: (1) an *action verb* indicating a level of performance (e.g., describe, apply, identify, recognize); (2) a *subject* or content area (e.g., chain of command); and occasionally (3) *contextual references*. The following example of a competency in emergency preparedness for public health workers includes these elements:

A public health worker must be competent to...:

> **Describe** the public health role in emergency response in a range of emergencies that might arise (e.g., "This department provides surveillance, investigation, and public information in disease outbreaks, and collaborates with other agencies...).[15]

As requirements for employment, competency statements may describe complex performance expectations within the workplace similar to the knowledge/skills/abilities (KSAs) statements of many job classifications. They can include a series of embedded tasks that are either sequential or parallel and are demonstrated over long periods of time. Correspondingly, they require contextual measurement based on a range of contingent indicators. In contrast, educational competency statements form the building blocks of learning experiences by describing structured learning objectives. Measurement indicators, such as examinations, are usually used in the short term (e.g., specific class or a course of study) to assess achievement of specific competencies.

Competencies in a field of work or education should not be confused with specific job requirements. A single position may use only some of a worker's pre-existing competence, and may require the addition of job-specific abilities. For example, public health legal competencies may add to general competence in the practice of law for attorneys working in public health. An understanding of public health law may also be an important addition to public health competencies for many professional, technical, and support staff working in public health, and are thus referenced in other public health competency sets.

In 2001, the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities led a collaborative effort to describe necessary public health law competencies for public health professionals.[16] With support from CDC, the Center produced a set of statements on law-specific skills and legal knowledge desirable for the practice of public health. As featured in Table 1, these statements were drafted to serve as guides for public health leaders with specialized roles related to public health law, as well as for front-line professional staff who need a basic understanding of the role of law to protect the public's health. Though not tailored to emergency legal preparedness, they help provide a base for competencies in emergency response.

Since the development of the Center's competency statements in public health law, there have been initial efforts to (1) specify competencies (e.g., in the context of specific achievements) or desired level of competencies (e.g., related to what an individual has achieved) for public health legal preparedness and response and (2) expand the number of persons receiving competency-based training. CDC authors and others have suggested that legal competencies for public health preparedness should include:

- Interpreting public health laws before, during, and after public health emergencies;
- Applying emergency laws and provisions in response to a declared emergency;
- Identifying legal issues requiring potential reform or modification;
- Assessing the consequences of legal action or inaction; and
- Integrating legal decisions within the larger public health response.[17]

Table 1
Public Health Law Competencies (Select)

I. Public Health Powers—Generally	Level
Describes the basic legal framework for public health; roles of federal, state, and local governments; and the relationship between legislatures, executive agencies, and the courts.	F
Describes the meaning, source, and scope of states' powers to protect the public's health, safety, and general welfare (i.e., police powers) and to protect the individual from identifiable harm (i.e., *parens patriae* powers).	M, O
Identifies and applies basic provisions of the governmental unit's health code and regulations within the particular area of practice (e.g., communicable disease control, environmental health, public health nursing).	M, O
Describes the scope of statutory and regulatory provisions for emergency powers.	O
Distinguishes public health agency powers and responsibilities from those of other governmental agencies, executive offices, police, legislature, and courts.	O
II. Regulatory Authority/Administrative Law	**Level**
Describes basic legal processes, such as how legislatures create and amend laws, how executive officials enforce laws, and how courts make and interpret laws.	O
Determines procedures for promulgating administrative regulations.	O
Determines procedures for obtaining mandatory or prohibitory injunctions from a court.	O
Follows administrative procedure laws for conducting investigations, holding hearings, and promulgating regulations and provisions concerning open public records.	M, O
Weighs options and applies, when necessary, processes to address public health problems through criminal charges for specific behaviors and civil suits for damages.	O
III. Ascertaining Authority/Obtaining Legal Advice	**Level**
Identifies legal issues for which legal advice should be sought and knows what action to take where legal issues arise, including contacting legal advisors.	M, O
Provides factual assistance and states basic legal issues to legal advisors.	M, O
Reads and comprehends basic statutory and administrative laws.	M, O
Recognizes that legal rules do not always specify a course of conduct.	M, O
Develops enforcement strategies consistent with the law and in the interest of protecting the public's health.	M, O
IV. Laws and Public Health Services and Functions	**Level**
Describes how law and legal practices contribute to current health status of the population.	O
Determines how the law can be used as a tool in promoting and protecting the public's health.	M, O
Identifies the mechanisms through which law can deter, encourage, or compel health-related behaviors.	M, O
Identifies and exercises legal authorities, responsibilities, and restrictions to assure or provide health care services to populations.	M, O
Identifies and exercises legal authority over the quality, delivery, and evaluation of health care services within the agency's jurisdictions.	M, O
Applies ethical principles to the development, interpretation, and enforcement of laws.	F, M, O
V. Legal Actions	**Level**
Describes how and under what circumstances legal searches of private premises can be performed.	S, M, O
Knows how and under what circumstances legal seizures of private property for public health purposes can take place.	S, M, O
Describes the limits of authority for legally closing private premises.	S, M, O
Identifies legal authority for compelling medical treatment or instituting mandatory screening programs.	S, M, O
Knows legal authority for imposing quarantine, isolation, or other restrictions.	S, M, O
VI. Legal Limitations	**Level**
Recognizes prominent constitutional rights implicated through the practice of public health (e.g., freedom of speech, right to privacy, due process, equal protection).	S, M, O
Acknowledges the sources of potential civil and criminal liability of public health workers.	S, M, O

Legend: F = Front-line Professional Staff; M = Supervisory and Management Staff; O = Health Officials and Governance Boards; and S = Senior Level Professional Staff.
Center for Law and the Public's Health, *Core Legal Competencies for Public Health Professionals, Baltimore, MD 2001, available at <http://www.publichealthlaw.net/Training/Training PDFs/PHLCompetencies.pdf>.*

A growing array of new competency-related products has emerged to guide workforce development. Table 2 provides examples of these products relevant to public health legal competencies for emergency preparedness.

Targeting Sectors for Competencies in Public Health Legal Preparedness

One of the key factors in broadening the application of competencies in public health legal preparedness is identifying the individuals who should be capable of demonstrating specific or general knowledge before, during, and after emergencies. While many existing public health legal competency models target the governmental public health workforce, public health legal preparedness requires the efforts and competence of a wider array of persons in public and private sectors.[18] These individuals must work together to use the law as a tool for public health responses during emergencies.

Pivotal to these responses are legal counsel to public health agencies or departments.[19] These individuals encompass attorneys in a variety of organizational settings, including (1) general counsels and their staff employed by public health agencies; (2) attorneys general and their staff representing public health agencies; (3) tribal, county, and city attorneys representing public health agencies; and (4) academic attorneys who guide and train public health lawyers and consult others during emergency situations.[20] Collectively, these counsels must be able to:

- Analyze legal issues in emerging areas of concern in public health preparedness by interacting with public health practitioners, identifying legal issues related to appropriate public health responses, and resolving legal barriers;
- Draft legislation, regulations, model orders, motions, and other legal documents in accordance with constitutional, national, state, and local laws; ethical norms; and best practices in public health;
- Train practitioners in the effective use of public health law;
- Participate in preparedness planning and exercises;
- Assist in analyzing gaps and weaknesses; and
- Provide real-time representation during emergencies.

Public health legal counsel must accomplish these and other functions in partnership with other members of the public health workforce, a diversely trained, multi-disciplinary group that includes physicians, nurses, epidemiologists, health educators, laboratorians, community outreach workers, and others. These persons have important roles that may require legal competency during emergencies based on their training and education.[21]

In 2003, the Institute of Medicine identified law as one of the essential areas of competence for public health practice that should be included in the curriculum of schools of public health.[22] Public health practitioners are increasingly cognizant of the importance of law in day-to-day functions and emergency situations.[23] Quarantining persons with communicable diseases, closing unsafe buildings or unsanitary restaurants, initiating vaccination programs, reporting diseases, and restricting children with infectious diseases from school are longstanding responsibilities of public health practitioners that require competence in public health law.[24]

However, the modern, multi-sectoral approach to emergency preparedness and response presents new challenges. Routine responses to complex, unpredictable emergency situations are inadequate. Accessing information efficiently and accurately is critical. Decisions must be made in real-time with a firm understanding of their legal and ethical implications.[25] Gaps or impediments in the laws must be anticipated, identified, and rectified in collaboration with public health legal counsel.

Accordingly, public health legal preparedness also requires differing types of competency among (1) legislators and judges at the federal, tribal, state, and local levels; (2) general legal counsel in the attorney's general and corporation counsel's offices, departments of emergency management, public health, environment, labor, housing, and other government services; (3) private sector counsel representing hospitals, insurers, medical practitioners, and volunteers; and (4) some members of the public participating in community efforts. Functional knowledge of public health law can help these persons use the law effectively during emergencies to collaborate and coordinate responses.[26]

Identifying Gaps to Improving Competencies in Public Health Legal Preparedness

The public health workforce and many of its private sector partners recognize the value of using a competency-based approach to increasing public health legal preparedness, training, and response.[27] Extensive work to refine and broaden the scope of legal competencies has led to new products (see Table 2) and better understanding of the role of law during public health emergencies. Raising the level of competencies through training in legal preparedness is increasingly

Table 2
Select Examples of Competency (and related) Materials That Facilitate Public Health Legal Preparedness and Response

Title & Source	Application Site/ Target Audience	Subject Areas
General Resources		
Identifying Individual Competency in Emerging Areas of Practice: An Applied Approach (2002), Gebbie et al., Qual. Health Res <http://qhr.sagepub.com/cgi/content/abstract/12/7/990>	Education and Research	Competency Development
Competency-to-Curriculum Toolkit: Developing Curricula for Public Health Workers (2004), Center for Health Policy, Columbia University School of Nursing <http://www.cumc.columbia.edu/dept/nursing/chphsr/pdf/toolkit.pdf>	Education and Research	Competency Application Through Training
Public Health Competency Sets (including legal competencies)		
Core Competencies for Public Health (2005), Council on Linkages Between Academia and Public Health Practice <http://www.phf.org/Link/corecomp.pdf>	Workplace/Education – Foster workforce development by helping academic institutions and training providers to develop curricula and course content and to evaluate public health education and training programs	Analytic/Assessment Skills Policy Development/Program Planning Skills Communication Skills Cultural Competency Skills Community Dimensions of Practice Skills Basic Public Health Sciences Skills Financial Planning and Management Skills Leadership and Systems Thinking Skills
Public Health Nursing Competencies (2004), Quad Council of Public Health Nursing Organizations <http://www.astdn.org/publication_quad_council_phn_competencies.htm>	Workplace/Education – Guide for agencies that employ public health nurses and academic settings that facilitate education and training	Application of Core Competencies in Public Health Nursing
Core Competencies for Local Environmental Health Practitioners (2001), American Public Health Association <http://0-www.cdc.gov.mill1.sjlibrary.org/nceh/ehs/Corecomp/Core_Competencies_EH_Practice.pdf>	Workplace	Assessment Management Communication
Applied Epidemiology Competencies (2005), Centers for Disease Control and Prevention/Council of State and Territorial Epidemiologists <http://www.cste.org/assessment/competencies/comp.pdf>	Workplace – Frontline, Mid-level, and Senior Level Epidemiologists	Assessment and Analysis Skills Basic Public Health Sciences Skills Communication Skills Community Dimensions of Practice Skills Cultural Competency Skills Financial and Operational Planning and Management Skills Leadership and Systems Thinking Skills Policy Development Skills
Core Legal Competencies for Public Health Professionals (2001), Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities <www.publichealthlaw.net/Training/Competencies.htm>	Workplace/Education	Public health powers – generally Regulatory authority Ascertaining authority Public health services and functions Legal actions Limitations Personnel/contracts Public health powers
Core Competency Development Project (2006), Association of Schools of Public Health <http://www.asph.org/userfiles/Version2.3.pdf>	MPH Education	Communication Diversity Cultural Proficiency Leadership Professionalism and Ethics Program Planning and Assessment Systems Thinking

Bioterrorism & Emergency Readiness: Competencies For All Public Health Workers (2002), Center for Health Policy, Columbia University School of Nursing <http://www.cumc.columbia.edu/dept/nursing/chphsr/pdf/btcomps.pdf>	Workplace – Public Health Leaders/Administrators, Health Professionals, and Technical and Clerical Support	Emergency Response (all public health workers, in addition to official-specific areas)
Introduction to Public Health Law for Bioterrorism Preparedness and Response (2002), Center for Law and the Public's Health <http://www.publichealthlaw.net/Training/Sources.htm>	Workplace/ Education – Public health leaders/professionals, legal counsel, students in law and public health	Public Health Emergency Legal Responses
Public Health Emergency Law (PHEL) (2004), CDC Public Health Law Program, CDC Coordinating Office for Terrorism Preparedness and Emergency Response <http://www2a.cdc.gov/phlp/phel.asp>	Workplace/Education – Public health officials/professionals	Public Health Emergency Legal Issues and Responses
Resources for Applying Legal Competencies		
Pennsylvania Public Health Law Bench Book (2006), University of Pittsburgh Center for Public Health Preparedness <http://www.prepare.pitt.edu/pdf/benchbook.pdf>	Workplace – Judicial Bench Book	Emergency Response Jurisprudence Resources
Public Health Emergency Bench Book (2006) Washington State <http://www.courts.wa.gov/content/manuals/publicHealth/pdf/publicHealthBenchBook.pdf>		
Public Health Law Bench Book for Indiana Courts (2005), Center for Public Health Law Partnerships, University of Louisville <http://www.publichealthlaw.info/INBenchBook.pdf>		Jurisprudence Resources
Health Officer Practice Guide for Communicable Diseases in California (2007), California Department of Health Services, Division of Communicable Disease Control <http://www.dhs.ca.gov/dcdc/pdf/Practice%20Guide.pdf>	Workplace – Health officers	Legal Review of General authority of health officers; Constitutional limits; Enforcement authority; Interjurisdictional coordination; Confidentiality; Media resources; Various public health powers
Pandemic Influenza and Public Health Law: What Public Health Departments Need To Know (2007) (DVD), CA Dept of Health Services, Immunization Branch <http://cdlhn.com/default.htm>	Workplace – Health officers	Review of specific public health law powers in response to pandemic flu

seen as an essential part of comprehensive public health emergency planning.[28]

Awareness of legal issues during public health emergencies is advantageous for preparedness, but practitioners must also be able to work together to construct a favorable legal environment for emergency response.[29] This implies a higher level of competency for some persons to not just understand the law, but also to wield it effectively to further legitimate public health goals. Despite significant advances in legal competency-building, several gaps or limitations must be considered:

Development of specific legal competencies for public health emergency preparedness. Existing approaches to public health legal competencies are beneficial, but incomplete. Some existing competency products were developed when the public health community had a limited understanding of specifying and applying competencies. These products may fail to identify key sub-topics related to emergency preparedness; do not always reflect changing legal and ethical norms during emergencies; do not fully address the multitude of individuals who are key to legal preparedness; and may lack application in real-time. Competence in legal preparedness should be developed within an organizational structure that allows for regular dissemination, extensive training, and routine updating. As an initial goal, core elements of public health legal preparedness should be produced through processes similar to those used to create existing competency statements,[30] with input from the relevant actors identified above.

Clarification. Coupled with the prior gap is the need to clarify competencies for persons practicing public health and public health law. Competencies must be stratified to delineate knowledge, skills, and abilities for each of the following groups:

- Public health leaders at each level of government;
- Legal counsels representing public health departments, institutions, and organizations involved in protecting the public's health;

- Public health policymakers, including members of city and county boards of health or councils, federal or state agencies, and the judiciary;
- Public health professionals (in public health departments generally or in specific public programs such as environmental regulation or professional/institutional licensing);
- Public health technicians and support staff (in public health departments generally or in specific positions such as persons handling laboratory specimens, accessing vital records, or receiving public inquiries);
- Staff of other organizations contributing to the public's health; and
- Academics teaching public health law and ethics (or related subjects).

Uniformity. Existing competency resources in public health legal preparedness have been developed in response to specific needs within some portion of the public health and legal communities (see Table 2). Many of these excellent resources may be described as core public health law materials that are meant largely for a legal audience. Other competency tools may feature or reflect legal or ethical principles for a non-legal audience. However, because these legal and non-legal resources have been developed over many years, through multiple entities, and for differing purposes, they lack cohesion. Users may question which competency tools are the most authoritative or helpful. Inconsistencies among approaches lead to incongruous legal responses. Uniformity of competency resources across sectors of the public health workforce could improve emergency preparedness.

Assignment of levels of competency. Competencies for public health legal preparedness are not static. Rather, they must be consistently examined and used to assess whether certain individuals have obtained a specific level of competence (e.g., novice, knowledgeable, proficient). Achieving levels of competency may be based on several factors, including the individual's title or position, existing education, years of experience, and anticipated role(s) during emergencies. The competency in legal preparedness of a counsel who serves as the lead for emergency management issues may differ from that of her counterpart in a public health department whose responsibilities are unrelated to emergency management. Still, both counsels need some level of competency in public health legal preparedness because each may be called to act during emergencies.

Implementation and evaluation. Beyond production or refinement of competency resources is the need to ensure implementation of competence building at the workforce level. Legal public health preparedness is deemed optional for many members of the public health workforce. Required training exercises or curricular objectives that coordinate individuals and institutions in the public and private sectors may help disseminate legal knowledge. For example, the New York City Department of Health and Mental Hygiene requires workforce training on core public health functions (including some legal topics) to better prepare for public health emergencies. In addition, competencies among various individuals should be routinely measured and evaluated with an understanding that achieving competencies is continual. These suggestions may require increased funds, new methods to deliver competency resources, and changes to public health curricula – each of which underlies an improved national commitment to public health legal preparedness.

Conclusion

Assessing public health legal preparedness among the public and private sectors is challenging. Public health emergencies raise unique legal issues, necessitate rapid responses, and require consistent approaches. Existing efforts to improve competencies in legal preparedness have contributed to an awareness of the role of law during emergencies. Yet, there is no coherent, national strategy to improve competencies in legal emergency preparedness that invites participation among partners in public and private sectors. As a result, response to future emergencies may be hampered, as has occurred in the past, by varying legal responses among persons who lack the ability to use the law effectively in real-time to improve the public's health. A uniform set of legal competencies that are routinely implemented and evaluated would prove invaluable to emergency preparedness and response.

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Assessing Cross-sectoral and Cross-jurisdictional Coordination for Public Health Emergency Legal Preparedness

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Introduction

A community's abilities to promote health and maximize its response to public health threats require fulfillment of one of the four elements of public health legal preparedness, the capacity to effectively coordinate law-based efforts across different governmental jurisdictions, as well as across multiple sectors and disciplines.[1] Government jurisdictions can be viewed "vertically" in that response efforts may entail coordination in the application of laws across multiple levels, including local, state, tribal, and federal governments, and even with international organizations. Coordination of legal responses to public health emergencies also may involve a horizontal dimension comprising numerous and diverse sectors, such as public health, public and private health care, emergency management, education, law enforcement, the judiciary, and the military.

Although responses to many acute health threats can implicate multiple jurisdictions and sectors, the jurisdictional and sectoral dimensions of legal preparedness are complex and may vary substantially by the nature of a threat, its geographic and geopolitical extent, and the operational response demanded. For example, the investigative response to the bioterrorism attacks involving the mailing of anthrax spores in 2001 consisted of concurrent, coordinated, and legally complex efforts by officials primarily from two sectors (public health and law enforcement) at multiple jurisdictional levels (federal, state, and local) in different regions of the United States (Florida, Washington, D.C., and New York City and its environs).[2] In comparison, the response to the 2005 hurricane disasters involved the sequentially coordinated and extended efforts of multiple sectors (e.g., emergency management, public health, the military, public and private health care) predominantly in one region, and implicated a host of legal issues.[3] Also, ongoing efforts to prepare for an influenza pandemic have involved coordination among tens of thousands of persons in multiple sectors at virtually every jurisdictional level in the country.

In addition to the requirement that officials and agencies are both prudent and responsible when exercising legal powers during responses to emergencies, they also must recognize the competing legal powers of different jurisdictions and contend with a broad spectrum of obligations and conflicts inherent in the exercise of their powers. Furthermore, legal issues encompass questions about who and what agency(ies)

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have authority for response and coordination, whether the authority differs depending on the nature of the problem, and who has precedence over whom in the event of conflicts of authority and of laws.

The complexities of coordinating law-based emergency preparedness and response efforts have evolved continuously throughout U.S. history, reflecting changes in science, government structures and relationships, and the spectrum of public health threats confronting communities. As one example, in 1796, Congress passed a quarantine act that limited the scope of federal quarantine activities to any cooperation that may first have been requested by the states in enforcing their own quarantine laws.[4] By 2005, acting under additional and modernized federal laws on quarantine, the Department of Health and Human Services had undertaken efforts to revise quarantine regulations to comport with needs for coordinating responses with a host of public and private-sector interests, including, for example, the commercial airline and cruise ship industries.[5]

In addition to such evolving complexity, increasingly apparent is the effect of emergencies in actuating coordination of responses, or intensifying the nature of coordination out of necessity, when compared with intergovernmental and intersectoral efforts during "routine" operating conditions. These and other considerations underscore the manifold issues for law-based coordination (also see Table 1 for examples). The following examples have been selected for detailed comment because they illustrate varying degrees of law-based coordination involving a spectrum of jurisdictions and sectors.

Status of Selected Legal Preparedness Coordination Efforts

Coordinating with Public and Private Healthcare Providers

Recent public health emergencies have underscored the need to strengthen intersectoral coordination between public health and health care – including hospitals, health care delivery organizations, and providers – in emergency preparedness and response efforts. Hospitals and health care providers played crucial roles in responses to the bioterrorism anthrax attacks of 2001, the epidemic of Severe Acute Respiratory Syndrome (SARS) in 2003, and the hurricane disasters of 2005.[6] The hurricanes, among the worst natural disasters in U.S. history, necessitated the evacuation of patients, including the critically ill, nursing home residents, and vulnerable populations.[7] These three events dramatically illustrated the importance of coordinated preparedness and response efforts, and highlighted the coordinated application of legal authorities across the public health and healthcare sectors, as well as across jurisdictions.[8]

Enhanced coordination between these sectors, in part, requires that health lawyers and their clients be familiar with relevant laws related to emergency response in their jurisdictions, and with public health agencies' legal authorities as they may impinge upon providers' interests, legal duties, responsibilities, and protected rights during emergencies. For the health care sector, public health preparedness must include planning for a spectrum of key legal challenges.[9] Only recently have health care lawyers intensified their focus on these and related issues.[10] Moreover, for many providers, emergency management and response plans and policies have only marginally reflected consideration of these issues. This key gap presents opportunities for the public health community to engage the

Table 1

Selected Functional Domains and Related Legal Issues in Coordinated Responses to Public Health Emergencies.

Managing Emergency Supplies

- Agreements for sharing resources across jurisdictions (e.g., mutual aid agreements)
- Seizure of property and materiel, and compensation
- Destruction of property
- Effect of an emergency or public health declaration on the emergency release of medical supplies
- Equitable distribution and use of emergency medical supplies

Protecting People

- Social distancing measures (e.g., isolation, quarantine, closure of public places)
- Mandated medical screening and treatment (e.g., vaccination, post-exposure chemoprophylaxis)
- Evacuation of populations and patients
- Medical surge capacity and standards of care
- Use of unlicensed clinical space for patient care

Data Sharing

- Disease surveillance (e.g., mandatory reporting requirements)
- Privacy and confidentiality concerns

Ensuring Effective Use of Professional Resources

- Licensing and credentialing of professionals
- Review of workers' compensation laws

Addressing Potential Liability

- Status of causes of action
- Immunities and protections for response actors (e.g., volunteers, public and private sector)

health care sector in coordinated legal preparedness efforts by including health lawyers and their clients as partners in community preparedness task forces and enlisting their participation in the drafting of state and community emergency response plans, particularly to ensure that protocols are in place to involve the correct officials and agencies in decisions to evacuate or close facilities.[11]

Coordinating Tribal Public Health with Other Entities

Tribal governments face a monumental task in coming to grips with public health science, emergency preparedness, and all the relevant laws, regulations, policies, and agreements of surrounding jurisdictions. For some tribes, cultural beliefs play a major role in determining how the tribe deals with disease related to emergencies. Injustices, perceived and real, perpetuated against Native Americans within neighboring counties and in state houses of government, have compounded these difficulties.

In some parts of the country, coordination among tribes, counties, and states is a fairly new phenomenon. The Indian Health Service (IHS), a federal agency, has encouraged tribes to become actively involved in state preparedness planning and response; in general, tribes have been receptive to this idea. Some states are now providing direct funding to tribes, while others fund tribal coordinators within the state health department. At the federal level, cooperative agreements may encourage state and tribal coordination.

In 2004, the Arizona Department of Health Services entered into Inter Governmental Agreements (IGAs) with twelve of 21 tribal governments in Arizona for receipt of public health preparedness funding.[12] In 2006, tribes successfully advocated for direct funding for pandemic influenza planning. The IGAs contain deliverables that will assist tribes in strengthening their public health capacities and address key considerations such as quarantine/isolation and jurisdiction.

Recently, IHS has undertaken to assure that service units (a defined geographical area with a hospital at its core) across Indian country are prepared for pandemic emergencies. Because no funding was provided by Congress to IHS for response efforts, IHS must rely on its health care facilities at the local level which, in turn, must work closely with state public health agencies.

The roles of tribes regarding public health emergencies vary by circumstances, and possibly by states. For example, if IHS is the primary health care provider, then it will take the lead in close conjunction with tribal government. However, if a tribe has assumed management of health care through contracting with the IHS, then its tribal health department, tribal emergency management, Tribal Emergency Response Commission (TERC), or another tribal department may assume lead responsibility. Currently, there is no comprehensive public health system at the local level to use as a model when it contracts to provide health services from IHS (see <www.IHS.gov> for more information on the Indian Health Service). Consequently, coordination potential has been hampered, in part, because tribal governments have been unable to develop comprehensive public health laws and systems needed within a given, defined jurisdiction.

Coordinating with the Judiciary

In times of uncertainty, citizens rely on courts to define or clarify their rights and responsibilities. The scope and variety of legal issues cannot be predicted with confidence, but can be substantial. Planners must anticipate they will be required to litigate issues that may arise from the implementation of public health statutes, as well as defending the many collateral issues that may arise from the implementation of public health responses. Although public health law bench books are being developed,[13] they are only one important tool in strengthening the judiciary's and bar's understanding of the scientific principles and police powers underlying modern public health practice. Discussions between the judiciary and other key actors (e.g., public health officials, attorneys general, corporation counsels, state and federal legislators, the civil liberties and public health bar) are helping to minimize the legal uncertainties that could impede an effective public health response. Judicial education conferences that focus on public health law in general and emergency powers in particular are significantly augmenting public health emergency preparedness. Finally, judiciary coordination must include the cross-sectoral role of law enforcement, particularly sheriffs' offices that provide courthouse security and coordinate alternative sites for court proceedings. However, at present, such cross-sectoral coordination with the judiciary is only at its beginning.

Coordinating the Military with Other Sectors

The federal government's National Response Plan (NRP) provides a structure for coordination with and among federal agencies to support state and local government emergency responses.[14] The NRP includes 15 Emergency Support Functions (ESFs), among which is ESF #8, Public Health and Medical Services. The lead agency for ESF #8 is the Department of Health and Human Services, and the lead HHS office is the Office of the Assistant Secretary for Preparedness and

Response (ASPR).[15] ASPR coordinates interagency activities related to medical and public health issues between HHS, other federal departments, agencies, offices and state and local officials responsible for emergency preparedness and the protection of the civilian population from acts of bioterrorism and other public health emergencies. The Department of Homeland Security has responsibility for overall incident management functions.

U.S. military forces have a long history of supporting responses to public health emergencies, as evident, for example, in the massive response effort following Hurricane Katrina in 2005. When authorized by the President or the Secretary of Defense, provisions of the Stafford Act and the National Response Plan allow military forces to support federal emergency response with any available assets. Federal law[16] and policy, however, generally preclude federal military forces from conducting law enforcement-type activities – such as searches, seizures, and arrests, as well as enforcement of quarantine or mandatory evacuation – although the president may authorize exceptions in some circumstances.[17] Separately, State military forces (i.e., the National Guard under a governor's command[18]) may support emergency response, including law enforcement activities, consistent with that state's laws.

While legal authorities for involving the military may be relatively clear-cut, there has been little, if any, recent experience in actually using them in the context of potentially catastrophic emergencies such as those posed by pandemic influenza, wide-scale bioterrorism, or a "dirty bomb" attack that contaminates a wide and densely populated area. It is likely that the most recent experience of such nature and scope was nearly nine decades ago during the 1918-1919 Spanish influenza pandemic that accounted for an estimated 500,000 deaths in the United States. Therefore, against this background, jurisdictions and agencies may need to consider the development of standards that define the conditions guiding and protocols for coordination of response efforts with the federal government, consistent with the NRP, as well as with their State National Guard.

Coordinating Mutual Aid: EMAC and Key Gaps in Agreements

Cross-jurisdictional sharing of information, supplies, equipment, personnel, or other resources is most effectively accomplished by entry into mutual aid agreements. Agreements may involve U.S. states,[19] local governments, tribes or First Nations, provinces in Canada, or states in Mexico. The Emergency Management Assistance Compact (EMAC) is a mutual aid agreement among the states. It addresses key issues such as liability, reimbursement, and response, and provides rules for sharing personnel and other resources during an emergency declared by the governor of a state requesting assistance from another jurisdiction.

However, because EMAC only provides a broad legal framework, it contains legal "gaps." For example, EMAC liability protection extends only to officers or employees of responding states; consequently, during Hurricane Katrina response efforts, many states were unable or uncertain about how to avail themselves of the services of volunteers. Furthermore, because EMAC is triggered only by gubernatorial declaration of emergency, the sharing of resources during smaller-scale, undeclared emergencies may be most effectively accomplished by agreements separate from EMAC. The same holds true with regard to the sharing of epidemiological or laboratory data designed to detect threatened infectious disease outbreaks. Finally, EMAC does not contemplate resource sharing with provinces in Canada or states in Mexico; appropriate mutual aid agreements with those entities must be negotiated and executed outside the EMAC umbrella.[20]

Implementing Law-based Social Distancing Measures: Coordinating with Law Enforcement and Schools.

1) COORDINATING WITH LAW ENFORCEMENT

When a health authority issues a quarantine order, it may be necessary to enforce it by compulsory means. For example, when an ill individual is ordered to be isolated in a hospital room, or when a group of exposed travelers is confined in some other kind of facility, enforcement may necessitate the posting of guards to ensure adherence to the quarantine order. In the circumstance of only one patient, or even a few, this need may be met through coordination with and the use of private hospital guards or local peace officers. However, as the number of detained individuals grows, it is likely that the additional resources of law enforcement agencies – whether local, state or federal – will be needed to maintain the quarantine. In many jurisdictions, local or state laws contain provisions that require the police department to assist the health officer, upon request, in order to maintain the public health.[21] Moreover, such provisions potentially can be utilized to press local law enforcement into service to enforce not only a local quarantine order, but also, upon request of the local health officer, a federal quarantine order. However, such an unusual detailing of law enforcement to the service of health authorities should be coordinated and planned in advance so as to

minimize or avoid delays in implementation in times of emergency.

Universal understanding of the applicable laws is indispensable. Coordination is necessary not only between local public health and law enforcement, but also between health authorities and health care facilities, as well as between local and state health and law enforcement authorities and CDC in the case of a federal quarantine order. Such vertical cross-jurisdictional and horizontal cross-sectoral coordination constitutes best practice, while failure to undertake such coordination contributes to increasing the gap in public health emergency legal preparedness.

2) Coordinating with the educational system

A pandemic, or only a large outbreak, of a highly communicable disease might necessitate the cancellation of mass gatherings or the closure of schools. Such measures require clear planning, an understanding of the consequences of such actions, and close coordination between sectors. For example, closing elementary schools raises the question of who will take care of these young children when parents are at work. The issue of who has the power to order such closures can be complicated and involve overlapping legal authorities among potential actors, including the superintendent of a local public school district, the state education commissioner (who may or may not have jurisdiction over private schools), the local or state health officer, the mayor, or the governor upon declaring a state of emergency. These lines of authority need to be understood by all the relevant parties.

Best practice compels that, prior to the occurrence of a major public health threat, plans be in place coordinating the closure of schools as a public health social distancing measure, and for addressing the ramifications of such closures. The development of such plans additionally requires the involvement of school officials and parents, while implementation will rely on close coordination between public health, public and private school sectors, and parents and parent organizations. The school sector is an indispensable link to communicating with children and parents. Developing models of such coordination can help to fill this gap in emergency legal preparedness.

Summary and Conclusion

Responding to an emergency requires societal coalescence and cohesion to optimize effectiveness. Different jurisdictional levels of government – whether local, state, territorial, tribal, federal or international – will have to cooperate with each other in ways that are distinct from the norm in order to maximize resource utilization and minimize response time. In addition to intergovernmental cooperation, coordination between the public and private sectors also will be imperative. For example, public health authorities and hospitals will need to deal with a surge of patients, while the business sector may need to devise ways of accommodating a workforce that is sick or needing to stay home to care for children who have been displaced because of school closures. These requirements for interaction and cooperation must be coordinated in advance, and also underscore the importance for jurisdictions to review their laws, rules and regulations, and also assess whether their laws present a barrier to necessary cooperation.

In this paper we have highlighted the need for coordinated planning and action. We focused on only a few of the issues that require coordination. Coordination between public health agencies, hospital regulators and both public and private hospitals and health care providers, and their lawyers, is crucial to being prepared for public health emergencies. Many issues such as waivers of bed capacity limitations, credentialing, or legal liability for volunteers have begun to be discussed, but greater coordination is needed. This paper also recognizes the need for coordinating with tribal governments during emergency response efforts. The judiciary is a critical player in responding to public health emergencies, whether in the context of adjudicating statute-based interventions, such as quarantine orders, or in reviewing public health responses; however, efforts to coordinate with the judiciary have been initiated only recently.

While the military may have a key role in responding to emergencies, whether in rescue efforts or in providing heightened security, this role is highly circumscribed by applicable laws and binding documents such as the NRP. These parameters need to be understood and the means for coordinated action planned in order to optimize effective use of the military's resources. Although mutual aid agreements, such as between the states pursuant to EMAC, are an effective way of sharing resources in times of emergency, some legal gaps remain, including for example, liability protections for volunteers. Implementing social distancing measures such as mass quarantines or school closings will require substantial coordination between public health authorities and the law enforcement and educational sectors; models for cooperation and protocols for action need to be developed and exercised.

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Assessing Information and Best Practices for Public Health Emergency Legal Preparedness

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Introduction

Information is the fourth core element of public health legal preparedness and of legal preparedness for public health emergencies specifically. Clearly, the creation, transmittal, and application of information are vital to all public health endeavors. The critical significance of information grows exponentially as the complexity and scale of public threats increase.

Only a small body of organized information on public health law existed before the 21st century: a series of landmark books published beginning in 1926 by Tobey,[1] Grad (1965),[2] and Wing (1974);[3] model public health laws published as early as 1907;[4] systematic reviews of original research studies published in the 1990s;[5] and a small but growing number of articles published in public health journals and law reviews.

With the new century came new public health law programs and activities at the Centers for Disease Control and Prevention (CDC), in public health professional associations, and in numerous non-profit and academic organizations. Many of these have developed valuable, new information resources for practitioners and policymakers, undergirded by comprehensive new texts that position public health law in the Constitutional framework[6] and that articulate the close relationship between public health law as a discipline and as a tool for practitioners and policymakers.[7]

This paper assesses the status of information resources about public health emergency legal preparedness, identifies gaps in information on law that may detract from the ability of public health practitioners and policymakers – along with their counterparts in other agencies and private-sector organizations – to perform public health emergency roles, and suggests opportunities for improving information resources for public health legal preparedness.

Assessment

This section is organized around the first two phases of all-hazards emergency preparedness: the pre-event phase where work focuses on maximizing preparedness; and the event phase where efforts are mounted to minimize the health consequences of an actual, unfolding emergency. We address the information needs of users of information across some of the sectors and disciplines that have key roles in public health emergency preparedness and response. These include, for example: local, state, and federal public health officials; their colleagues in emergency management, law enforcement, and other agencies; elected officials; local and state boards of health; health care providers; non-profit emergency response organizations; and legal counsel to all of these. Also important are counterparts in other countries and in international agencies such as the World Health Organization and INTERPOL.

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Information during the Pre-Event Phase

Information critical to legal preparedness for the pre-event phase can be sorted into at least four categories, three of which are treated here. A fourth – basic information about the U.S. legal system (e.g., the Constitution, federalism, and the police powers) – is better gained through formal education as encompassed by the "Competencies" core element of public legal preparedness.

A. Existing Legal Powers and Current Developments in Public Health Emergency Legal Preparedness

Members of all the sectors, organizations, and disciplines key to effective public health emergency preparedness need to know their relevant legal powers and responsibilities and, importantly, those of their partner organizations. This information is foundational to their exercise of those powers. Further, because the relevant laws evolve in response to legislative changes and court rulings, among other factors, these parties also need ongoing access to information about emerging issues and current developments in public health law.

Although systematic assessments have not been conducted of the availability of this type of information, it is widely accepted that most practitioners and policymakers active in public health emergency preparedness have limited access to it. This limitation, in turn, constrains the sound, coordinated application of legal powers.

Recent innovations in public health legal preparedness are beginning to address this gap. Among these are a guide to communicable disease laws prepared for use by California public health officials, their legal counsel, and the courts;[8] the Community Public Health Emergency Legal Preparedness Initiative cosponsored by CDC and the American Bar Association;[9] and the 2005 Public Health Law Bench Book for Indiana Courts.[10] Also new are Web-based resources such as the CDC Public Health Emergency Legal Preparedness Clearinghouse (a growing library of training curricula, legal documents, and related publications) and the weekly *CDC Public Health Law News*, the only periodical that reports regularly on developments in public health law.[11]

While these new resources are valuable, they only address a small fraction of the need for information on existing laws and current developments in public health emergency legal preparedness. Most, for example, are oriented largely to public health practitioners and legal counsel. Their reach could usefully expand to serve additional sectors – including those in other countries and in relevant international bodies – and their content might be expanded accordingly.

B. Best Practices Guidelines and Benchmarks

Practitioners in many disciplines increasingly follow "best practices" guidelines promulgated, in many cases, by professional societies and government agencies. This is true, for example, of public health (e.g., the Guide to Community Preventive Services[12] and CDC's "Interim Pan Flu Guidance"[13]), emergency management (e.g., the National Incident Management System),[14] and law enforcement (e.g., the Council on Accreditation of Law Enforcement Agencies).[15] But few such guidelines exist for the multi-sector domain of legal preparedness for public health legal preparedness. A prominent exception is the "Lessons Learned from the Gulf Coast Hurricanes" report published by the American Health Lawyers Association.[16]

Best practices guidelines typically are based on information derived from practical experience and outcomes that is evaluated through a systematic methodology. At least two kinds of activities can be sources of such information relevant to legal preparedness for public health emergencies. The first is public health emergency exercises conducted by state, federal, and other agencies. Although some such exercises have generated valuable findings about laws and legal issues relevant to the responses mounted by all the involved sectors, the value of this information as an experiential basis for public health emergency legal preparedness is largely untapped. The second source should be a sustained program of applied research on the effectiveness of legal authorities, competencies, and methods of coordination, with findings synthesized, and ultimately translated into practitioner-relevant guidelines and disseminated to users throughout the critical sectors and disciplines.

Legal preparedness best practices should meet at least two standards. First, they should be demonstrated to result in improved protection of the public's health. Second, they need to meet accepted legal standards of practice. For example, they should be consistent with federal case law and with the Tenth Amendment's reservation of the police powers to the states. They also should conform, to the greatest extent possible, to existing state public health laws and systems. For example, in California, local health departments must be headed by physicians who hold relatively comprehensive and purposefully general legal powers while, in contrast, New Mexico has a more centralized public health system in which the state Department of Health is responsible for nearly all local public health functions.

Benchmarks describe a targeted level of performance and are used to steer developmental efforts. Benchmarks, in this sense, have not been widely established to guide progress toward what could be termed full, multi-sector, cross-jurisdiction legal preparedness for public health emergencies. While elements of legal preparedness benchmarks have appeared in CDC's emergency preparedness grant guidance, they address only a small part of full legal preparedness.

C. Information for Assessing Public Health Emergency Legal Preparedness

A critical type of pre-event information is diagnostic information about the adequacy of legal preparedness for public health emergencies. Ideally, such information can be gathered operationally to assess coordinated implementation of existing legal preparedness on a regular basis for a given state, tribe, locality, or territory, and should reflect all relevant sectors and disciplines. Development of a standard template for evaluation of legal preparedness during exercises and drills could assist in identifying gaps, as well as strengths, and provide a basis for needed corrective action by law-makers or practitioners.

A number of useful tools have been developed to aid such assessments. Examples include the 2001 draft Model State Emergency Health Powers Act (Draft Model Act)[17] – commissioned by CDC specifically as an assessment tool for states' voluntary use – the Turning Point Model State Public Health Act,[18] checklists prepared by the Center for Law and the Public's Health,[19] and the AHLA's "Emergency Preparedness, Response, and Recovery Checklist: Beyond the Emergency Management Plan."[20] The Social Distancing Law Project, co-sponsored by the Association of State and Territorial Health Officials (ASTHO) and CDC, is a new assessment tool currently in development.

While these and other tools have been used widely (e.g., an estimated 38 states and the District of Columbia have enacted provisions of the Draft Model Act),[21] they do not address the full need. Importantly, they do not speak directly to the legal preparedness of tribes, counties, cities, or territories. Also, each focuses largely on a single sector; none addresses comprehensive legal preparedness. Further, none addresses the international dimension of legal preparedness.

Information during the Event Phase

All jurisdictions and sectors should achieve full legal preparedness for public health emergencies before emergencies occur and attention turns to response and recovery. Two types of legal information resources, however, are essential during the event phase: ready-to-use legal tools, and a unified system to communicate legal situational awareness. While work to develop these types of information – and systems to support them – takes place during the pre-event phase, they make up part of the critical response armamentarium for the event phase.

A. Ready-to-Use Legal Instruments

Officials in all three branches of government need to have legal instruments at hand for immediate use during public health emergencies. These include, for example, draft emergency declarations, orders for issuance by health and other officials (e.g., for student dismissal, *cordon sanitaire*, and mass dispensation of prophylactic medicines), requests for court orders, activation of mutual aid agreements, and procedures for legislatures' consideration of executive requests to extend an emergency declaration. All these tools – plus copies of relevant legal memoranda, case law, statutes, rules and regulations, and other, related information – could be stored in multiple media (e.g., as paper copies, on line, and on flashdrives) for ready access during the event phase.

Many states and local jurisdictions have prepared such instruments but it is essential that all have them and keep them updated. In that vein, a state health commissioner recently called for creation of "a compilation of resources" including "a selection of model public health orders for state and local jurisdictions" and noted that "[o]n a practical level, whether it is a major disaster, or a serious pertussis outbreak in a community requiring restrictions on public gatherings or possibly closure of schools…these are the tools we need on a state and local level" for use by health officials and also as references for courts.[22] These instruments, moreover, should encompass response actions across all the concerned agencies and jurisdictions, local, state, tribal, federal, and, where relevant, international.

B. Information for Legal Situational Awareness

Maintaining situational awareness of unfolding events is vital to successful response to public health emergencies. The nation's public health, emergency response, and homeland security agencies, among others, have made this a major focus of their efforts to strengthen response capability.

Equally important is situational awareness of legal issues and developments that may surface rapidly in the event phase. An example was issuance of executive orders by the governors of Wisconsin and Illinois, and by the President, to restrict domestic and international commerce in designated pets during the 2003 monkeypox outbreak. Also in 2003, the President's Executive Order 13295 added SARS to the federal

government's list of "quarantinable communicable diseases."[23] Because a court ruling denying a medically justified quarantine order in one city could have serious implications for the success of efforts to slow the spread of a pandemic, to give one example, it is critical that officials and their legal counsel in many agencies, the courts, and affected private sector entities learn about such legal developments rapidly.

A useful beginning has been made in this respect. During the monkeypox outbreak, the Public Health Law Association and the CDC Public Health Law Program co-sponsored teleconferences in which public health officials and legal counsel from across the U.S. (joined by Canadian counterparts) exchanged information on relevant legal issues. The CDC Public Health Law Program brings such issues and developments to the attention of the 6,500 multi-sector subscribers to its weekly *CDC Public Health Law News* and can communicate electronically with the legal counsel to all state (and selected local) public health agencies. The Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and a number of professional societies and academically based programs also have the ability to communicate such situational awareness information widely.

While these steps and resources help begin to address information needs, further systems development should meet the public health law-related situational awareness needs of all the agencies and sectors that have roles in responding to all-hazards public health emergencies.

Summary

Against the background of recent expansion in information resources on public health law in general and on public health emergency legal preparedness in particular, it is clear that the nation has significant work yet to do to achieve the goal of full legal preparedness for public health emergencies. Examples of key opportunities include:

- Conduct of a systematic baseline assessment of the law-related information required by the many public- and private-sector actors who are central to effective public health emergency preparedness and response;
- Implementation of a sustained program of applied research to evaluate the effectiveness of public health emergency laws and to assess important legal and ethical issues – e.g., how best to protect civil liberties during the application of law-based emergency response and how to develop guidelines for ethical allocation of scarce vaccines and medical care.
- Mining of the legal "lessons learned" from public health emergency exercises for data to use in developing benchmarks and best practices as well as in developing laws and related information, training materials, and coordination mechanisms;
- Development of benchmarks and best practices for legal preparedness as a backbone on which the operational elements of legal preparedness can be shaped and evaluated. Benchmarks and best practices should be articulated within larger frameworks – such as the National Response Plan, the National Incident Management System, federal preparedness programs, and the comprehensive plans of states, tribes, localities, and territories – and should be made available to all concerned practitioners and policy makers.

There is a clear and compelling need for improved and more complete information about public health emergency legal preparedness in the pre-event and event phases. Three guiding principles for work toward that goal are that its scope should encompass all the relevant jurisdictions, sectors, and disciplines; that it must be aligned with the larger, accepted framework of public health emergency response; and that all the information resources created should be continually tested, evaluated and updated as needed. Adhering to these principles will raise legal preparedness for public health emergencies to a much-elevated level of readiness and effectiveness.

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Improving Laws and Legal Authorities for Public Health Emergency Legal Preparedness

Robert M. Pestronk, Brian Kamoie, David Fidler, Gene Matthews, Georges C. Benjamin, Ralph T. Bryan, Socrates H. Tuch, Richard Gottfried, Jonathan E. Fielding, Fran Schmitz, and Stephen Redd

Introduction

This paper is one of the four interrelated action agenda papers resulting from the National Summit on Public Health Legal Preparedness (Summit) convened in June 2007 by the Centers for Disease Control and Prevention and multi-disciplinary partners. Each of the action agenda papers deals with one of the four core elements of legal preparedness: laws and legal authorities; competency in using those laws; coordination of law-based public health actions; and information. Options presented in this paper are for consideration by policymakers and practitioners – in all jurisdictions and all relevant sectors and disciplines – with responsibilities for all-hazards emergency preparedness.

Law and Public Health Preparedness

One expert's framing of the mission of public health may help improve understanding of the range of hazards for which to be legally prepared.[1] These hazards include urgent realities – such as chronic disease, injury, disabilities, conventional communicable diseases, and an aging and obese population – and urgent threats, such as pandemic influenza, natural disasters, and terrorism. The impact of both types of hazards is exacerbated by such factors as conditions of extreme poverty, climate change, and ideological extremism. Both types have the potential to cause grave disruptions in the functioning of society. Reviewing, assessing the adequacy of, and, if necessary, creating laws which support all-hazards preparedness will help assure legal preparedness.[2] Legal preparedness is an essential part of public health preparedness.

Summit participants engaged in discussions on these aspects of public health legal preparedness and deliberated about what laws are essential to prevent hazards, to protect people from threats that can not be or are not prevented, to respond effectively to the impact of hazards, and to recover comprehensively from the aftermath of an emergency or disaster.

Participants stressed the importance of doing more than identifying gaps in existing law. They pointed to many examples of existing law that reveal complexities and contradictions, barriers to practical action, inflexibility in the face of rapidly changing circumstances, jurisdictional conflicts, and operational difficulties during day-to-day work and emergencies. Examples cited in the companion assessment paper

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on laws and legal authorities illustrate the breadth and depth of such challenges. They include: the need for surge capacity in operation of health care systems during emergency; timely procurement of goods and services in crisis situations; the protection of privacy of medical information; the use of the National Guard and military to assist public health officials; seizure of private property; the role of legal counsel during emergencies; and the "fit" of the federal Pandemic and All-Hazards Preparedness Act and the World Health Organization's new International Health Regulations (IHR) with U.S. constitutional law and other domestic legal and political considerations.

Use and Assess Existing Law

Although Summit participants identified some areas where new law would be useful, they did not believe that developing new law was the first priority. Instead, those who make, use, and are affected by law should become more familiar with the scope, substance, and application of existing laws. Closer scrutiny of present law and its use should reveal the need for not only better competence in its application but also more precise understandings of where new law might be required.

Summit participants also noted that public health practitioners and their counsel are not in all cases comfortable making use of existing legal authorities, even if they are familiar with those laws, or are using versions of law that are not up-to-date. Reasons suggested for this include: lack of familiarity with the law; confusion over perceived and actual conflicting authorities; distress over conflicting ethical considerations; and perceived and real political considerations. Further, Summit participants noted that attorneys, practitioners, elected and appointed officials, and the general public may need ongoing training and education to continuously improve their understanding, use, and reaction to application of the law in situations involving public health emergencies.

Continuously improving the substance and use of laws and legal authorities will require many steps at all levels of government and governance over time including better means to share legal best practices with those needing to be legally prepared; skillfully facilitated dialog among diverse groups (with particular attention to documenting the discoveries from dialog and making them widely available or, perhaps, requiring specific evidence of that dialog through reports to policymakers and funders); ongoing efforts to train practitioners and inform community members; continuous assessment of existing law; and where necessary, adoption of new law.

Threats to Legal Preparedness

Despite best intentions, significant obstacles confront efforts to have the best law in place. Personal and professional energy and attention-span are finite and regularly committed to other important tasks. In addition, limitations in resources may constrain day-to-day legal work related to preparedness and training necessary to sustain preparedness for specific hazards. The experienced workforce, needed to create and effectively employ laws and legal authorities, is in a constant state of turnover and is now beginning to leave the workforce permanently because of retirement and the perception of better career options elsewhere. Their successors will lack training and experience unless better and more effective ways are developed to preserve capacity and competency among public health practitioners and their counsel. Time really is of the essence to assess and, where indicated, improve the law.

Options for Improving Laws and Legal Authorities for Public Health Legal Preparedness

This section presents selected options that policymakers and practitioners – in all jurisdictions and in all the relevant sectors and disciplines – may consider taking toward the goal of full legal preparedness for all-hazards public health emergencies.

Near-Term Actionable Options

- Jurisdictions should consider: conducting regular, periodic assessments, including exercises, analysis, and other tests of sufficiency of laws for public health emergency response to identify potential gaps in these powers and authorities; avoiding unnecessary overlapping authorities or create necessary ones; clarifying the balance of powers and responsibilities among jurisdictional officials; and facilitating smooth operations during emergencies.
- Following final rulemaking and adoption of the new federal quarantine regulations, develop methods for optimizing understanding of approaches to coordinating implementation between different jurisdictional levels.
- Assess the adequacy of law at all jurisdictional levels to control the entry and exit of persons at ports of entry with suspected or known highly infectious diseases.
- Within specific jurisdictions, through multi-disciplinary groups (comprising public health and other government agencies concerned with wild animals, livestock and pets, veterinarians, and

others) examine the laws needed to protect people and animals from zoonotic-related threats, and prevent and detect outbreaks of transmittable zoonotic diseases.
- Assess the adequacy of, enhance, and give visibility to existing domestic cross-jurisdictional agreements and compacts (e.g., EMAC, regionalized public health services, and tribal/non-tribal agreements) and encourage the adoption of similar effective compacts.
- Assess the implications of the 2005 International Health Regulations (IHR 2005), including the degree to which federal, state, local, tribal, and territorial laws are consistent with the new surveillance and reporting requirements.
- Assess the extent to which regulatory requirements related to health care systems operations may impede availability of needed surge capacity during emergencies.
- Assess and improve, as needed, the ability of federal, state, local, tribal or territorial governments to waive, suspend, modify or flexibly apply existing laws and regulations, including certain standards applicable to healthcare systems and personnel licensing, during emergencies.
- Draft executive orders to waive, suspend, modify or flexibly apply certain, relevant standards during emergency.
- Review, assess, and as needed, draft alternative approaches for jurisdictions to protect privacy of medical information as much as possible during emergencies.
- Review, assess, and as needed, draft alternative procedures for the emergency procurement of medical supplies, protective equipment, and other materiel.
- Review, assess, and as needed, draft alternative laws and policies related to the evacuation of people, pets, livestock, and other animals during emergencies.
- Assess and clarify legal authorities for states' activation of the National Guard during public health emergencies.
- Clarify laws related to the dissemination and use of medical countermeasures during emergencies (e.g., mass distribution of prescription drugs).
- Assess the sufficiency of, and improve as necessary, local state, and tribal laws for social distancing (e.g., isolation, quarantine, closure of public facilities, curfews, and relevant procedural due process considerations).

Long-Term Actionable Options
- Review, assess, and, if indicated, improve laws for appropriate immunity for emergency responders (e.g., government officials, businesses, non-governmental organizations, and volunteers).
- Review, assess, and if indicated, improve laws regarding liability for emergency response.
- Assess jurisdictions' legal authorities to allocate and gain access to adequate resources to support response efforts that may extend over long periods of time (e.g., during responses to pandemic influenza that may span many months).
- Review, assess, and if indicated, improve laws regarding compensation to workers and organizations for injury or property damage incurred during emergency response.
- Review and assess laws regarding employer/employee relations in the context of a public health emergency (e.g., policies and contractual terms related to leave and compensation).
- Review, assess, and clarify laws regarding authorization of specific government agencies (e.g., law enforcement and public health agencies) to implement and enforce differing public health interventions (e.g., social distancing measures, mandatory vaccinations and treatment, or screening) during an emergency.
- Review, clarify, and, if needed, modify laws regarding compensation for private property (e.g., real property, pharmaceuticals, and other supplies) seized by public agencies for emergency response purposes.
- Review, assess, and if needed, improve law regarding the disposal and transport of human remains.
- Clarify the role for legal counsel, including states' attorneys general, private counsel for corporations and non-profit entities in public health emergency matters.
- During and after a public health emergency, systematically identify, document, and disseminate information on the effectiveness of laws and legal authorities.

Discussion
In the course of identifying and enumerating action options for laws and legal authorities, three salient themes emerged at the Summit that are particularly relevant for guiding the strengthening of legal preparedness for public health emergencies. These themes relate to U.S. legal preparedness in the context of global preparedness for emergencies; coordination between the public and private sectors in legal pre-

paredness; and advocacy for public health emergency preparedness.

U.S. Legal Preparedness in the Global Context
Legal preparedness efforts in the United States must take account of the global context in which serious threats to public health arise and are handled. As efforts to address the threat of SARS and pandemic influenza have demonstrated, U.S. health security can be enhanced through improvements in public health globally.

In this context, review is needed of the implications of such developments as the proposed revisions to the federal quarantine regulations. Clarification is also needed with regard to the reservation filed by the United States with respect to the IHR 2005 as well as federal action and federal-state coordination for their effective implementation. The IHR 2005's entry into force provides an exceptional opportunity to make legal preparedness an integral part of the strategy to protect U.S. health security and contribute to global health. Moreover, additional work is needed to clarify, strengthen, and expand certain legal preparedness aspects of the bilateral public health cooperative arrangements with Canada, Mexico, and other countries; to embed aspects of legal preparedness in the work of the Global Health Security Initiative; and to incorporate legal preparedness concepts within U.S. efforts to help other countries with the implementation of the IHR 2005 and otherwise prepare for public health emergencies.

Public/Private Coordination in Legal Preparedness
Many of the action options identified by the Summit participants – including considerations regarding liability, immunity, status of volunteers, and compensation – resonate with concerns expressed in the business and private non-profit sectors. These issues were cited in analyses of responses to the 2003 SARS outbreak in Ontario.[3] More recently, the Hurricane Katrina response effort underscored the need to identify and address any legal barriers to public/private cooperation and coordination.[4]

Some states have considered providing incentives for voluntary participation in emergency response from the private sector by individuals, businesses, non-profit organizations, and professional groups, and further consideration of this approach is warranted.[5]

Practitioners, Legal Preparedness, and Advocacy
Advocacy for public health legal preparedness involves effective communication of the importance of adopting and implementing a particular law or legal authority that advances the public's health. Law frames the rules under which advocates may seek to influence lawmakers. More specifically, laws govern the ways in which government employees may legitimately inform lawmakers without crossing the line into prohibited forms of advocacy. Three aspects of these relationships are particularly important for executive-branch officials concerned with public health emergency legal preparedness: legal restrictions on lobbying, ethics rules, and agency policies. While legal requirements in this area probably are well defined in most jurisdictions, periodic training can help government employees identify and comply with the fine line between lobbying and advocacy.

Conclusion

While an action agenda for laws and legal authorities should address a wide range of hazards and threats, heightened attention in the United States has been paid to threats of a biological nature since the anthrax attacks of 2001. As a result, public health practitioners in the governmental and non-governmental sectors have taken appropriate steps in their practice and have worked systematically to assess and make needed revisions to relevant legal authorities. In addition, they have projected themselves into future scenarios that require strengthened legal preparedness for the anticipated challenging environment of the 21st century.

Pandemic diseases, among which influenza is just one example, highlight the need to assess, clarify and identify gaps in laws and legal authorities. Hazards and threats will prompt use of and challenges to traditional and untested public health law. Relief from liability and immunity will be sought by manufacturers of countermeasures, members of the governmental and non-governmental workforce (including medical and non-medical care personnel and organizations), and other community members. Legal and other forms of advocacy will continue to reshape laws and legal authorities.

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Improving Competencies for Public Health Emergency Legal Preparedness

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Introduction

This paper is one of the four interrelated action agenda papers resulting from the National Summit on Public Health Legal Preparedness (Summit) convened in June 2007 by the Centers for Disease Control and Prevention, and multi-disciplinary partners. Each of the action agenda papers deals with one of the four core elements of legal preparedness: laws and legal authorities; competency in using those laws; and coordination of law-based public health actions; and information.

This action agenda offers options for consideration by those responsible for or interested in ensuring that public health professionals, their legal counsels, and relevant partners understand the legal framework in which they operate and are competent in applying legal authorities to public health emergency preparedness.

Competencies are critical to an individual's ability to make effective legal response to all-hazards public emergencies. The accompanying assessment paper outlines the state of existing competencies in public health legal preparedness by discussing the development of public health emergency competencies and public health law competencies and identifies gaps in competencies that detract from attainment of the goal of full legal preparedness for public health emergencies.[1] It concludes that "public health emergencies raise unique legal issues, necessitate rapid responses, and require consistent approaches…A uniform set of legal competencies that are routinely implemented and evaluated would prove invaluable to emergency preparedness and response." This action paper, based on extensive deliberations among the co-authors and participants at the 2007 National Summit on Public Health Legal Preparedness, frames an agenda for advancing legal competencies as a core element in effective public health emergency preparedness. The agenda identifies activities in response to identified gaps in 4 areas: (1) expanding the range of sectors that should have competency in public health legal preparedness, (2) improving competency specification, (3) disseminating competency information to key target audiences, and (4) improving measurement and evaluation of practice impacts.

Competencies as a Practice Tool

Despite the common use of "competency" to describe education and performance standards, there are misunderstandings of what it means to have a competent workforce or to provide competency-based education.

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A common misunderstanding is to focus on only one of the three building blocks for competency, either knowledge, or skills, or values. In the area of legal preparedness, for example, it is easy to focus on knowledge (specific laws and regulations, contracts, plans) or values (the law as a positive force for public good or public health as a shared value) at the expense of the composite competency, which also requires skills such as analysis, communication or definition. A complete competency statement reflective of all three building blocks requires an active verb that translates to a clearly observable (and thus measurable) action or impact. An example of the importance of the active verb is illustrated in Box 1, in which the competency associated with isolation and quarantine law varies widely based on the verb selected to fill the blank.

Box 1:

A lawyer competent in public health emergency preparedness is able to ____ isolation and quarantine law.

- Recite
- Locate
- Interpret for tuberculosis
- Apply to the case of Mary Doe
- Explain to the media
- Defend in court
- Critique

An individual is often described as moving across three levels of competence: aware, proficient, and expert. More clearly stated, an individual will initially achieve competency at a novice level, and may proceed to a higher level (proficient or expert) if the competency is practiced or applied regularly. If, however, the person moves to a different competency, even one associated with the same context or object, then he or she is again considered a novice until experiences lead to greater expertise. Using the example from Box 1, a novice at locating isolation and quarantine law may need to consult an index each time; a proficient practitioner will be able to find the correct section of the law without outside assistance. Applied to different contexts, the individual who is expert at locating isolation and quarantine law may be proficient at interpreting the law as it applies to tuberculosis, but he or she may be only a novice at explaining this law to the media.

Options for Improving Legal Competencies for Public Health Emergency Preparedness

The following actionable options are organized into *4 key areas* that respond to issues raised in the accompanying assessment paper and move beyond them to additional points developed in Summit deliberations. Together, they outline a framework for action to strengthen competency in public health emergency legal preparedness at all levels of government (local, state, tribal, and federal), all sectors involved in the application of law in emergency preparedness and response, and academic institutions that support this practice.

1) Expand sectors that require competency in public health law and public health legal preparedness

In examining the work to date on public health emergency legal competencies, it becomes clear that legal competency efforts have focused first on the public health community and public health legal counsel. Less attention has been given to professionals in other sectors that play critical roles in public health emergency legal preparedness. Given the potential complexities of interpreting and applying legal remedies or interventions under emergency conditions, the summit participants concluded that the range of persons who should have at least some minimal level of public health emergency legal competencies should be expanded from the current focus on select public health officials to at least eight sectors – as identified in Box 2.

Box 2:

Priority sectors requiring attainment of competency in public health legal preparedness

1. Governmental public health and healthcare professionals, especially field staff in such key program areas as epidemiology, communicable disease control, and environmental regulation.
2. Leaders of non-governmental public health and other health organizations (hospitals, clinics, charitable organizations).
3. Legal counsel to key emergency response organizations, including government agencies (e.g., emergency management, law enforcement, environmental protection, education, and transportation), NGOs (e.g., the Red Cross) and business groups (e.g., chambers of commerce).
4. Members of the judiciary and their staff.
5. Members of legislative bodies and their staff, especially those serving on committees dealing with public health issues.
6. Elected and appointed members of the executive branch.
7. Leaders of all sectors identified in the National Response Plan as having Emergency Support Functions.
8. Leaders of the military, including National Guard.
9. Academics providing education and training to any of the above personnel.

As a lower priority, all law schools should move toward including some content on public health emergency preparedness in curricula, so that all members of the bar have opportunity to develop competency in this important area of practice.

2) Specify the core and sector-specific sets of required competencies
The competency sets described in the status paper were developed over an extended period of time, beginning with a period in which the public health community was not as sensitive to the importance of constructing competency statements using the conceptual and language standards discussed above. Furthermore, they have been developed using a range of methods that may or may not adequately represent expectations in the field. For these reasons, the action agenda must include two phases of competency development, beginning with the competencies identified in the status paper and then improving competency specification through an ordered, inclusive and technically sound method such as that recently employed in identifying competencies for epidemiologists in public health practice.[2]

- *Identify a limited set of core competencies for which all members of the groups identified in the preceding section are responsible*. Those practicing full-time in the public health sector, whether as legal counsel or health professionals, would be expected to master the core competencies and advance quickly to additional skills (see following section). For others (e.g., leaders of non-public health emergency support functions), the competency expectations might not rise above the novice level, given their relatively rare opportunities for practice or application. For selected examples of a set of core competencies in public health legal preparedness that all public health nurses should master, see Box 3.
- *Identify additional profession-, position- or sector-specific competencies that can be expected of all members of the specified group*. For example, additional competencies beyond the core should be expected of chief public health officials (agency heads) at the local, state, tribal and federal levels, since they will be called upon to make use of legal counsel when delivering public information messages or making regulatory decisions during an emergency event.

Box 3:

Selected examples of public health law core competencies for nurses related to emergency preparedness and response

A legally competent public health nurse should be able to:

1. Describe the basic legal framework for public health emergency response; roles of federal, state, and local governments; and the relationship between legislatures, executive agencies, and the courts,
2. Explain the purpose and scientific basis of public health emergency laws related to scope of practice,
3. Apply ethical principles to the development, interpretation, and enforcement of laws,
4. Adhere to confidentiality laws in the collection, maintenance, and release of data in a public health emergency,
5. Access, effectively apply, and defend the use of legal information, tools and remedies (e.g., quarantine and isolation orders, injunctions, abatement orders) in a public health emergency, and
6. Apply essential tenets of antidiscrimination laws, such as the Americans with Disabilities Act (ADA) affecting the delivery of services in a public health emergency.

[Ctr. For Law and the Public's Health: Core Legal Competencies for Public Health Professionals]

- *Reevaluate competency statements on a periodic basis*. As practitioners apply the competencies, it is likely that gaps will be identified, or that one or more of the statements will be deemed unnecessary. Evaluation of these newly-identified competencies should be led by the public health law community in collaboration with experts in public health practice and competency-based workforce development. While 3 to 5 years is a typical competency review interval, the rapidly evolving nature of emergency preparedness and related training suggests that an initial evaluation should take place within 2 to 3 years, with reevaluations taking place concurrent with the redrafting of emergency response plans. Periodic review of the competency statements – particularly in the aftermath of legal responses to actual events, as seen most recently in the legal response to patients with multi-drug resistant tuberculosis (MDR-TB) – would provide practitioners with the evolving tools they will need to keep pace with experiential learning in emergency preparedness and response.[3]

- *Incorporate core competencies and those sector-specific competencies into the existing competency sets that currently guide public health education and practice.* For example, given that public health nurses compose the largest group of professionals practicing public health (and a public health nurse may be, in smaller jurisdictions, the only full-time professional), it would be appropriate for the core legal preparedness competencies, and those developed specifically for public health professionals, to be incorporated into the competency materials developed for public health nurses by the Association of State and Territorial Directors of Nursing.[4]

3) Disseminate competency information to facilitate use
As the competencies for public health legal preparedness are elaborated, it is essential to develop plans for disseminating them to institutions that can then translate them into practice. This translation involves both formative and continuing education:

- *Use the identified core competencies in all public health pre-practice education*, consistent with the Institute of Medicine recommendation that law is an essential component of public health education.[5]
- *Include the identified core competencies in the curricula of all health professional schools* (e.g., public health, medicine, dentistry, nursing).
- *Include the identified core competencies in the curricula of all law schools.* It is critically important that all members of the bar have an opportunity to develop core competency encompassing the legal authority for public health.
- *Support faculty instruction at the intersection of law, public health, and emergency preparedness with an expanded set of scholarly and applied materials.* Professional schools may seek to create specialized academic programs and advanced resource materials that go beyond the core competencies and into specific subsets of the competencies.
- *Provide continuing education based on the identified competencies for the current workforce.* Continuing education may be offered either by law or public health organizations, in a variety of in-person or distance-based formats. Support for continuing education would be strengthened if one or more professional societies or certifying bodies included requirements for training in public health emergency legal preparedness in their standards. While there may be some interest in a program that certifies attainment of competency, certification programs do not assure sound practice, and should only be considered in this area after public health practitioners and others gain more experience in certification at a basic level.
- *Include public health emergency legal competency training in existing law enforcement and judicial training programs.* Schools of public health or law schools with public health law expertise should be encouraged to work with these training programs in the development of appropriate materials.
- *Develop a national public health law training program (or academy) for more advanced preparation, within which preparedness for emergencies can be given thorough attention.* Offered once or twice a year, this program would meet the needs of the relatively small number of newly employed, appointed, or elected individuals requiring updated education beyond the core competencies in any one locale. Through such an academy, expert faculty could be drawn from across the country; the full range of interested professional communities could participate in sessions that demonstrate the cross-sectoral collaboration essential to effective public health emergency legal practice; and a common interpretation of key competencies could be assured.[6]
- *Create communities of practice, both horizontally across all levels (community, region, state, tribal, national) and vertically (from local health agency to state and federal counterparts), to stimulate the development of best legal practices in public health emergency preparedness for specific communities and specific types of emergency events.* As discussed in other action agendas, a professional's isolation from those doing overlapping work may limit his or her ability to perform effectively. Engagement in a community of practice will also support the novice in public health emergency legal preparedness in maintaining his or her achieved level of performance or in moving to a higher level of competency.
- *Build a specialized network of public health legal practitioners active in emergency preparedness to support public health officials' response to legal issues that emerge during declared emergencies.* This network or collaborative could improve emergency response by supporting those who are directly involved but who have limited experience in public health legal emergency preparedness, developing their competencies in legal response for future events.

4) Improve Measurement of Practice Impact
Public health assessment is moving toward measurement of the relationship between competencies and public health outcomes. As public health legal competencies, including those essential to public health emergencies, are more clearly specified, taught to existing and emerging practitioners, and applied in simulated and real emergencies, it is essential to measure the impact of increased competence on the effectiveness of response efforts and protections of the public's health.

- *Assess competence of individual public health practitioners and legal practitioners through the inclusion of legal preparedness competencies in workforce hiring, job performance appraisals, and promotion evaluations.*
- *Include in public health emergency drills and exercises at least one objective that requires application of public health emergency legal competence.* This would give participants opportunities to practice the legal components of emergency preparedness and response, which should be a central element in every emergency exercise.
- *Research specific hypotheses on the correlation between competence and performance* through evaluations (case-control or otherwise) of drills and exercises or through methodical data analyses following real emergent events. Achieving this needed knowledge requires the inclusion of additional scholars in the competency endeavor, as well as additional funding structures to develop and test this research agenda.

Conclusion

Competency in public health emergency legal preparedness is consistent with the holistic view that law is integral to all public health practice settings and situations. Effective competency-based public health legal practice will enable more effective management of emergency events. Given the centrality of public health law to an effective public health emergency response, it will be necessary to achieve better developed and more widely disseminated competence in public health emergency legal response. The public health community, specifically those working actively at the intersection of law and public health, should prioritize the action options presented here and develop specific plans for their implementation.

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Improving Cross-sectoral and Cross-jurisdictional Coordination for Public Health Emergency Legal Preparedness

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Introduction

This paper is one of the four interrelated action agenda papers resulting from the National Summit on Public Health Legal Preparedness (Summit) convened in June 2007 by the Centers for Disease Control and Prevention (CDC) and multi-disciplinary partners. Each of the action agenda papers deals with one of the four core elements of public health legal preparedness: laws and legal authorities; competency in using those laws; coordination of law-based public health actions; and information. Options presented in this paper are for consideration by policy makers and practitioners – in all jurisdictions and all relevant sectors and disciplines – with responsibilities for all-hazards emergency preparedness.

Advancing and protecting the public's health depends upon the coordination of actions by many, diverse partners. For effective public health preparedness, there must be effective coordination of legal tools and law-based strategies across local, state, tribal, and federal jurisdictions, and also across sectors such as public health, health care, emergency management, education, law enforcement, community design, and academia.

Needs for Strengthening Coordination of Law-Based Responses

Recent catastrophic events and other public health emergencies – such as the terrorism attacks of late 2001 and the hurricane disasters of 2005 – have yielded many lessons for overall emergency preparedness, including exposing issues and gaps in legal preparedness for emergencies.[1] Particularly important are issues concerning coordinating the application of legal authorities across sectors and jurisdictions including, but not limited to, public health and private health care providers, tribes and tribal authorities, the judiciary and court system, the military,[2] and federal, state, and local governments. Other gaps in legal preparedness that have been identified concern the use of mutual aid agreements for preparedness and response, and directing and enforcing social distancing measures to control transmission of influenza or other serious communicable diseases.

Summit deliberations focused particularly on challenges and options for improving coordinated applications of law-based interventions across sectors and jurisdictions during emergencies. A set of fundamen-

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tal principles emerged from the discussions at the Summit. These include the need for:

- A legal framework appropriate to support continuity, stability, and efficiency in response efforts;
- Transparent and streamlined communications in support of applications of the law to coordinated responses;
- Trust and credibility among legal support partners and emergency responders;
- Robust and dynamic partnerships among responders and organizations involved in the application of law-based interventions; and
- Legal tools to ensure consistent responses across multiple sectors and jurisdictions.

Options for Improving Coordination and Public Health Legal Preparedness

This section presents selected options that policy makers and practitioners – in all jurisdictions and in all the relevant sectors and disciplines – may consider taking toward the goal of full legal preparedness for all-hazards public health emergencies.

As a result of the extensive planning efforts preceding the Summit and workgroup deliberations, the following *six* topics were highlighted in the development of action agenda options for improving public health legal preparedness for coordination: (1) public health and healthcare providers; (2) tribes and tribal authorities; (3) the judiciary; (4) the military; (5) mutual aid; and (6) coordination in implementing social distancing measures. A series of action agenda options are listed for each of these topics. The principles and imperatives for action may also be relevant or adaptable to needs for strengthening law-based coordination involving other sectors that were not an explicit part of the Summit discussions.

1) Coordinating Public Health with Health Care Providers

The challenges of coordination in legal preparedness between public health and health care providers must include a wide range of issues, tasks, and methods. In particular, Summit participants identified options that recognized the distinctions in legal frameworks bearing on public health and health care providers and the implications of public health emergencies for these legal frameworks. As one example, health care providers, whether public or private, may be subject to regulatory issues that do not affect all public agencies, such as state licensure requirements that restrict services offered by health care providers and the number of persons that can be treated.[3] These requirements may complicate or limit response during emergencies when healthcare organizations and individual providers are expected or required to deliver services in off-site, non-medical facilities or other settings. The following options to improve legal preparedness coordination between public health and health care include the review and improvement of response plans, the review of relevant laws and legal frameworks, the development of checklists and other tools, and training.

- Assess the adequacy of health care provider and facility emergency response plans and procedures to ensure they address legal issues including: pharmaceutical dispensing in cases where prescription records cannot be located, or states which will not allow the dispensing of pharmaceuticals by an unlicensed healthcare professional; coordination with public health in decisions to close facilities or evacuate patients during emergencies; the implementation of isolation and quarantine; and emergency credentialing of volunteer health professionals.
- Review and, if indicated, improve the ability of jurisdictions (local, state, tribal) to provide liability protections to health care providers and organizations, including hospitals and health care professionals required by state law to respond, for care delivered during emergencies when they are acting in good faith as part of an emergency response.
- Analyze and clarify the implications that local, state, and federal emergency declarations and public health emergency laws have for health care systems and organizations, hospitals, and individual providers, and disseminate findings to health care provider entities and their legal counsel.
- Assess and improve, as needed, the ability of jurisdictions to waive, suspend, modify, or flexibly apply laws and legal authorities related to health care service delivery, such as health care personnel licensing and regulatory requirements during an emergency, including the waiver of jurisdictional laws related to liability protections of health care-provider volunteers.
- Develop, modify, or implement existing jurisdiction-specific (local, state, tribal) legal preparedness checklists, tools, and educational resources to ensure health care provider preparedness through collaboration between public health and healthcare providers.[4]
- Develop educational and training programs, in conjunction with local, state and national bar associations, academic institutions, and legal counsel for health care providers and public health agencies, that focus on key legal and

operational issues, the roles and responsibilities of their respective clients in a public health emergency, the interventions that may be employed, and considerations of civil liberties, property rights, and other fundamental legal issues.
- Consult with exercise designers to evaluate how best to modify exercises to: (a) ensure that legal issues are considered in the development and conduct of state and local legal preparedness exercises; (b) identify and promote awareness of key legal and operational issues and challenges faced by healthcare providers and facilities in an emergency; and (c) test healthcare provider and facility emergency response plans to ensure effectiveness and integration with other local emergency preparedness efforts.

2) Coordinating Tribal Public Health with Other Entities

Summit planners and participants identified several gaps in coordinating tribal public health with other entities at local, state, and federal levels. The coordination between tribal authorities and other jurisdictions has been constrained for many historical, financial, and political reasons, which have undermined trust and common understanding between the tribal leaders and other jurisdictions. Action recommendations include reviews and improvement of basic public health powers, and the development of mutual aid frameworks and templates.

- Identify and evaluate tribal health and emergency management authorities' legal preparedness for public health emergencies; compare these authorities to those of surrounding jurisdictions to address and optimize coordination.
- Coordinate with other jurisdictions to strengthen authorities, and, when necessary, enact new laws to facilitate exchange of public health surveillance data.
- Coordinate with other jurisdictions in reviewing and, when necessary, strengthening tribal authorities for implementation of specific law-based interventions such as isolation, quarantine, and closure of public places.
- Identify who has authority to close public and private schools and day care facilities located on tribal lands as a social distancing measure, and develop agreements or protocols for coordinating with tribal public health organizations and neighboring public health agencies. Conduct assessments of tribes' capacities and develop templates for entering into mutual aid agreements with proximate state and local jurisdictions.
- Consider improving emergency preparedness through coordinated state and tribal agreements, such as Arizona's Inter Governmental Agreements (IGAs), to address law-based emergency response measures and plans.[5]
- Explore, with the Indian Health Service, options for strengthening of emergency preparedness capacity within service units and in coordination with state public health agencies.

3) Coordinating with the Judiciary

In identifying options for strengthening coordination with and preparedness among the judiciary, Summit planners and participants recognized that public health issues are especially likely to be presented to trial-level systems and courts.[6] Accordingly, it is important that efforts be made both to ensure that such courts would be operational during a public health emergency and also that they would be prepared to address the public health issues likely to be presented during emergencies. Of paramount concern are the education of judges and practitioners, the preparation of continuing operations emergency plans, and the development of best practice standards. However, judges for such courts and court administrators may not possess the technical or personnel resources or capacity to undertake plan preparation, development, and implementation necessary for emergencies. The following options, therefore, especially address these problems.

- Review state and local emergency operation plans to determine if the judiciary is included and modify if necessary.
- Encourage state Supreme Courts and state court administrative offices to develop and update the necessary legal and administrative expertise and effective all-hazards continuity of operations plans, including how legal matters related to the emergency will be handled (for example, the impact of the emergency on child welfare and criminal justice systems, and on civil proceedings).
- Identify, approach, and involve key judges, court administrators, or judicial educators as leaders in efforts to develop public health law resources for courts in jurisdictions where those efforts have not yet begun.
- Condense, organize, and regularly update public health law resource materials to facilitate practical and efficient use by judges during public health emergencies.
- Encourage government and applicable professional organizations to develop and provide the educational and planning resources required for

state and federal trial-level court systems and courts to develop effective plans for emergency response, including:
   a. Education conferences with content directed at the unique requirements of judges who will preside over public health-related proceedings, including: (i) applicable public health law; (ii) fundamentals of public health practice; (iii) relevant scientific principles (e.g., infectious diseases principles, concepts underlying non-pharmacological interventions); and (iv) benchbooks.
   b. Education conferences with content encompassing the needs of public health law practitioners, including attorneys general, municipal solicitors, hospital legal counsel, and human resource attorneys.
   c. Development of statewide continuity-of-operations templates which could be adapted to local needs and conditions and which assist judges and court administrators in initiating local planning.
- Include plans for operating outside the courthouse during emergencies and disseminate plans to public health and other government sectors.
- Explore federal and state development of best-practice standards for judicial personnel and others in the legal system likely to interact during public health emergencies (e.g., deputy sheriffs and other corrections officials, and police); standards might address appropriate personal protective equipment, disinfecting procedures, and supplies that should be inventoried.
- Ensure that judicial continuity of operations plans consider and incorporate plans to address the surge of court cases, such as those related to guardianship as well as potential isolation and quarantine cases.
- Provide liability protections to attorneys who provide legal services to clients, whether voluntarily or by court appointment, for representation provided during emergencies when acting in good faith.

4) Coordinating with the Military

As noted in the Summit's companion status assessment on coordination, federal law and policy generally preclude federal military forces from conducting certain emergency response activities, such as quarantine, evacuation, and law enforcement. The President may authorize exceptions in some circumstances. State military forces (i.e., the National Guard under a Governor's command) may support emergency response, including law enforcement activities, consistent with that state's laws.[7] State and local jurisdictions and agencies need to understand the roles the military might play in an emergency response, and should review and consider conditions under which coordinated responses to emergencies might involve military forces.[8] The following options address this need:

- Review, clarify, and disseminate guidance within individual states regarding legal authorities that govern use of the National Guard in support of emergency response activities.
- Identify legal barriers and opportunities for use of military assets (e.g., military medical assets) in an emergency.
- Disseminate lessons learned from reviews of legal aspects of previous civil-military coordination efforts in response to public health emergencies (e.g., Hurricanes Andrew and Katrina) to public health and other relevant partners.
- Consider options for exercising and testing the feasibility of Department of Defense support of civilian emergency response efforts.
- Explore the development of agreements between public health departments, Department of Veterans Affairs medical centers, and other hospitals for coordinated medical care of patients in meeting communities' surge care requirements during emergencies.

5) Mutual Aid: EMAC and Key Gaps in Agreements

The Emergency Management Assistant Compact (EMAC) is the principal agreement for facilitating mutual aid among the states. EMAC addresses key issues (i.e., liability, compensation, and reimbursement for expenses) and provides rules for sharing personnel and other resources during an emergency declared by the governor of a state requesting assistance from another jurisdiction.[9] However, EMAC provides only a broad, general framework for mutual aid between states, and does not include cross-border mutual aid agreements with the provinces of Canada or the states of Mexico. Summit planners and participants identified several gaps of concern related to the following: planning; information and data sharing; supplemental agreements to EMAC; agreements covering mutual aid during undeclared emergencies; inclusion of tribes; constitutional analysis; and mutual aid across borders and in international contexts; and the authorities of the federal government in international agreements. The following options address these and other gaps.

- Develop, negotiate, and execute agreements formalizing inter- or multi-state cooperative

planning and information-sharing policies and procedures.

- Analyze and modify state and federal privacy laws governing private health information to facilitate entry into multi-jurisdictional agreements to share epidemiologic and laboratory data to detect and control infectious disease outbreaks.
- Analyze differences in state laws and procedures to determine legal gaps in EMAC coverage during declared emergencies, and utilize EMAC authority to enter into supplementary agreements to fill the gaps.
- Assess legal authority to enter into agreements to share information, supplies, equipment, or personnel during smaller scale public health emergencies not covered by EMAC.
- Ensure the inclusion of tribes in mutual aid agreements.
- Conduct further analysis of the "Compact Clause" of the U.S. Constitution, in consultation with State Department attorneys, to fully comprehend the limits imposed on interstate and international mutual aid agreements.
- Assess legal authorities to negotiate and execute cross-border mutual aid agreements between U.S. states, provinces of Canada, and states of Mexico.
- Assess the need to enact laws to address legal liabilities of entities that have entered into mutual aid agreements for use of their facilities during emergencies, or whose facilities might be commandeered for emergency response activities, and to provide immunity to the facility for use for those purposes.

6) Implementing Law-Based Social Distancing Measures: Multi-sector Coordination

An emergency response to a severe contagious disease threat will require timely, decisive, and highly coordinated action based on accurate information and advanced preparedness planning. A key intervention strategy for countering such threats is using social distancing measures, including isolation, quarantine, closure of schools and public places, and cancellation of public events.[10] The need for a clear definition of the authority to act is a common thread running through the use and coordination of these measures across multiple disciplines, sectors, and jurisdictions. "Best practices" compel that, prior to the occurrence of a major public health threat, decision trees be developed and law-based models of coordination be implemented in order to fill this gap in legal preparedness. Best practices also mandate the pre-event drafting of relevant legal agreements that encompass coordination of personnel and material resources among different sectors and jurisdictions. One example of this is agreements between public health and law enforcement agencies in some jurisdictions for coordinated investigative responses to bioterrorism.[11] To ensure cross-sectoral and cross jurisdictional coordination of social distancing and other law-based measures, there must be adequate training of and communication to all sectors on legal preparedness. (See Box 1 for examples.)

Box 1:

Selected sectors and populations with involvement in coordinated implementation of law based social distancing measures:

- Public health
- Emergency management
- Law enforcement and corrections
- Elected and appointed government officials
- Public and private bar
- Judiciary
- Private sector health care providers
- Educators, school officials, education administrators, education lawyers, and parent-teacher organizations
- Business leaders and managers
- City and county attorneys and local prosecutors
- Transportation agencies
- Racial and ethnic populations
- Faith-based communities and organizations
- Media (radio, television, print)

The following options for legal preparedness in support of social distancing measures emphasize coordination of law enforcement personnel, who may be called upon to assist in implementing social distancing measures and maintaining the peace, and the educational system and schools, which represent a primary locus for the potential interruption of infectious disease transmission.

- Clarify and disseminate information regarding jurisdictional (local, state, tribal) legal authorities concerning coordination among public health, law enforcement, and other public safety agencies in planning for and responding to all-hazards public health emergencies.
- Review and address the sufficiency of laws guiding coordination of public health and law enforcement in implementing social distancing measures and pharmaceutical interventions during declared and undeclared emergencies.
- Examine, clarify, and disseminate information on the status of laws (local, state, tribal) providing legal authority for and guiding coordination

between public health, school, and other officials in closing schools during public health emergencies. Identify who has authority to close public and private schools and day care facilities as a social distancing measure, and develop agreements or protocols for coordinating with public health organizations and neighboring public health agencies.
- Develop and conduct table top exercises to test legal authorities and preparedness for multi-sector coordination in school closures; conduct after-action review, including legal response to issues.[12]
- Identify the agency or agencies authorized to close or restrict use of public roadways, and to restrict use of public and private transportation conveyances (e.g., airplanes, trains, and buses, cars, limousines, and truck rental agencies), if necessary, as social distancing measures, and develop agreements and protocols for coordination with the public health agency for the use of those authorities.
- Assess legal authorities for gaining access to the broadcast media for dissemination of urgent information about social distancing measures.

Conclusion

Strengthening the public health legal preparedness core element of coordination must account for the involvement of multiple sectors and disciplines at all jurisdictional levels. This paper focuses on those areas that emerged as most important during discussions at the Summit, but recognizes that there are many other sectors for which legal preparedness is important. These other sectors (e.g., business and the insurance industry) have not been seen as traditional public health partners, and, therefore, additional outreach and coordination is needed. In addition, coordination efforts must address human services components, such as services for elderly persons, disabled and displaced populations, the provision of food, and the procurement of energy resources.

An effective approach to further improving multi-sector and jurisdictional legal preparedness comprises several key considerations. First is the need to identify and engage all relevant traditional and newer partner sectors – including, for example, law enforcement and corrections, the judiciary, the military, business leaders, school officials and parent-teacher organizations, emergency management, non-profit organizations, and faith-based organizations. Second, the laws authorizing the response roles for each of these sectors must be reviewed and clarified or revised, if needed; similarly, the potential liabilities for each sector (and corresponding immunity policies) need to be analyzed and addressed. Third is the need to educate each sector regarding its roles and underlying legal authorities and potential liabilities during a coordinated response to a public health emergency. Crucial to the education process is the after-action review of table-top exercises, which must include review of legal issues mediating effective response. Finally, appropriate coordination mechanisms (e.g., preparedness plans, memoranda of understanding, mutual aid agreements) should be developed and tailored to sectors, partners, and anticipated cross-sector involvement in emergency response.

Summit participants concluded that, although there are barriers to coordination in the application of law-based measures during emergency responses, as well as gaps in both authority and implementation, these shortcomings are being, or can be, addressed. To progress further in strengthening this element of public health legal preparedness, however, it will be paramount to add and engage multiple relevant sectors at all levels in planning, reviewing legal authorities, and exercising those authorities necessary for coordinated responses to public health emergencies. Finally, the development of familiarity and trust among sector partners must be a key part of the planning and implementation of coordinated, law-based responses to public health emergencies.

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Improving Information and Best Practices for Public Health Emergency Legal Preparedness

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Introduction

This is one of four interrelated action agenda papers resulting from the National Summit on Public Health Legal Preparedness convened in June 2007 by the Centers for Disease Control and Prevention and nineteen multi-disciplinary partner organizations. Each of the action agenda papers deals with one of the four core elements of public health legal preparedness: laws and legal authorities; competency in using those laws; coordination of law-based public health actions; and information. Options presented in this paper are for consideration by policymakers and practitioners – in all jurisdictions and all relevant sectors and disciplines – with responsibilities for all-hazards emergency preparedness.

This paper focuses on the fourth core element: information that can be used in shaping and applying law as a public health tool, specifically in the context of public health emergencies. Timely, accurate, and accessible information, including case law, legal advice and opinion, and other information describing innovations in the application of legal authorities, is critical to all jurisdictions' and sectors' attainment of effective preparedness for public health emergencies of all kinds, both domestically and internationally.

A companion paper in this publication reports on the status of information on public health emergency legal preparedness. It also points to gaps in the availability of information that may detract from the ability of public health practitioners and policymakers – along with their counterparts in other government agencies and private-sector organizations – to perform critical roles in preparing for, responding to, or assisting in recovery from public health emergencies.

Scope and Types of Information

In addition to its direct value to policymakers and practitioners, information is of vital importance to the three other core elements of public health legal preparedness as these illustrations indicate:[1]

- *Laws and Legal Authorities:* Those who shape public health emergency laws and legal authorities need information about laws' effectiveness and about their consistency with protections for civil liberties and property rights and with other, prevailing principles of jurisprudence.
- *Competency:* Attainment of competency in using law as a public health tool is clearly enhanced when training materials are developed on the basis of information about practices demonstrated to be effective in the context of exercises and actual public health emergencies and, further, if competency standards reflect accepted best practices.

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- C*oordination:* Effective coordination in the use of law-based responses to public health emergencies is strengthened when information from exercises or actual response efforts is used to develop agreements for provision of aid across state, local, tribal, and international borders.

As used here, the concept of information is broad in scope, encompassing many different categories, subjects, and sources. The following examples illustrate the scope and variety in this core element of public health emergency legal preparedness:

- Information about the relevant public health laws and legal authorities of a specific state, locality, tribe, or territory for use by its officials and legal counsel in addressing pandemic influenza, by judges asked to approve quarantine orders, by law enforcement officers who execute such orders, by hospitals that may be required to house patients, and by television and other media that inform the public about the use of law-based interventions during public health emergencies
- Checklists and templates that public health officials, tribal governments, school administrators, and hospital and business managers can use to review their legal roles and responsibilities related to public health emergencies[2]
- Information on "best practices" in applying public health emergency laws based on after-action reports from actual emergency response efforts or from exercises and other simulations of emergencies[3]
- Public health law "bench books" for judges and "pocket guides" for law enforcement officers to use as ready references to current public health laws and procedures[4]
- Data from on-going surveillance of emerging legal issues and problems (for example, confusion over which public official is authorized to order evacuation of a disaster area) that may compromise the success of an emergency response effort
- Legal advice and opinions, where not protected and privileged, given to a health officer on her authority to mass-distribute antiviral prescription drugs, to the CEO of a corporation regarding its continuation of wages to employees subjected to extended home quarantine, or to a private citizen who violates a "no fly" order
- The findings – in forms usable by policymakers and practitioners in public health – of applied research into factors that support development and implementation of effective legal preparedness tools
- Directories of the legal counsel to public health and other agencies active in public health emergency preparedness, as well as their counterparts in business and private, non-profit organizations,[5] and
- Periodic reports on current developments, emerging issues, and new training resources and other tools in public health law.

A Practical Question as a Framework

Preparedness and prevention are at the core of the public health approach to protecting the health of the public – in all jurisdictions – from potentially catastrophic public health emergencies. In that context, the approach this paper takes to identifying opportunities for improving the contribution information makes to public health emergency legal preparedness can be expressed succinctly in this question: *Who* needs what types of information on laws, legal issues, and legal tools (and when and through what channels) in order to perform their defined, critical roles in public health emergency preparedness?

Successful protection of the public's health and safety hinges on the actions of government health agencies and also on a wide array of private-sector organizations. The "who" in the question above thus refers, in part, to policymakers and practitioners who work in the three branches of government (legislative, executive, and judicial) at all levels and in any of a broad spectrum of government agencies: public health, health care, emergency management, law enforcement, and transportation, among others. "Who" also encompasses counterparts in a wide array of private organizations that are integral to successful public health emergency preparedness. These include, among others, private hospitals and other health care providers, suppliers of prescription drugs and emergency response materiel, businesses and non-profit employers (who need information, for example, on public health officials' legal powers to close publicly accessible facilities if needed as a social distancing measure and also on protection against potential litigation related to their own contributions to emergency response and recovery); and community-based organizations that serve vulnerable populations.

These actors operate in all three phases of public health emergencies: the pre-event (planning) phase, the event (response) phase, and the post-event (recovery) phase. Their needs for law-related information vary across these phases – and according to their actual roles and responsibilities – as may their preferences for the media and channels through which to communicate and receive that information. The pre-event phase is the time, for example, to develop

and disseminate baseline information about laws pertinent to public health emergencies as well as tools that policymakers and practitioners can use to assess the status of their jurisdictions' and organizations' legal preparedness. Time is of the essence during the event phase and practical legal instruments – such as pre-drafted declarations of emergency, quarantine orders, and targeted waivers of health care regulations – should be ready at hand. Continuous surveillance should be conducted of legal developments during the response and recovery phases to identify problems that can be addressed with legal tools, such as barriers that state medical registration requirements may pose to volunteer services. Another example of law-related information needed during the recovery phase is information on problems those with chronic diseases (e.g., diabetes and asthma) experience in qualifying for financial assistance for prescription drugs and medical supplies.

Options for Improving Information for Public Health Emergency Legal Preparedness

This section presents selected options that policymakers and practitioners – in all jurisdictions and in all the relevant sectors and disciplines – may consider taking toward the goal of full legal preparedness for all-hazards public health emergencies. The options are presented in *three* categories: development and dissemination of information; improvement in the means used to communicate information; and implementation of a sustained program of applied research on the impact legal preparedness has on the health and safety of those affected by public health emergencies.

1) Develop and Disseminate Jurisdiction Specific Public Health Emergency Legal Preparedness Information

- Develop and disseminate baseline information about relevant legal powers and responsibilities for members of all the government agencies and other organizations (and about those of partner organizations) critical to effective public health emergency preparedness – including, in the private sector, businesses, non-profit organizations, and their legal counsel.
- Develop and disseminate templates, checklists, and other tools for use by policymakers and practitioners in assessing the status of all four core elements of legal preparedness for public health emergencies in all jurisdictions.
- Develop and disseminate ready-to-use legal instruments (e.g., draft executive orders, court pleadings, and temporary regulatory waivers) for use during the emergency response and recovery phases.
- For attorneys' ready use during public health emergencies, develop electronic libraries containing legal memoranda, opinions, and other legal documents provided to public- and private-sector organizations active in public health emergency preparedness by their legal counsel.
- Develop and disseminate information to inform the public media about legal authorities pertinent to public health emergencies and about plans for their potential implementation.
- Conduct real-time "situational awareness" surveillance of legal developments during the response and recovery phases of public health emergencies to identify critical emerging legal issues and problems.
- Conduct periodic assessments of the law-related information needed by those active in public health emergency preparedness and develop new information resources as indicated, potentially including provision of legal consultation.

2) Improve Means to Communicate Public Health Emergency Legal Preparedness Information

- Assess the communications needs (e.g., timeliness and preferred media) of professionals and organizations critical to effective public health emergency preparedness for communicating and receiving law-related information and resources.
- Evaluate the capacity of existing communications channels (e.g., electronic clearinghouses and Web sites, periodicals, listservs, and teleconferences) to address communications requirements for law-related information and resources, and identify gaps and potential enhancements.
- Develop and implement plans to improve existing means of communications and information exchange – or to develop new ones, such as "webinars" for use during the event or response phases of public health emergencies – to better serve the law-related information needs of the members of all sectors key to effective public health emergency preparedness.

3) Conduct Applied Research and Development in Legal Preparedness

- Evaluate the impact and effectiveness of jurisdiction-specific and broader initiatives to strengthen legal preparedness for public health emergencies, including actions taken pursuant to the action agenda created at the 2007 National Summit on Public Health Legal Preparedness.

- Capture legal "lessons learned" from actual public health emergency response efforts and from exercises for use in developing new legal preparedness information resources, training materials, legal authorities, and legal coordination mechanisms.
- Capture similar "lessons learned" to use in developing best practices, standards, and benchmarks for public health emergency legal preparedness.
- Disseminate the findings of applied research on public health emergency legal preparedness and assist in translating them into improved policy and practice; target audiences should include, among others:
  - Elected officials and other public health emergency preparedness policy makers
  - Officials in public health, emergency management, law enforcement, and other relevant public agencies, including their legal counsel
  - Counterparts in private-sector organizations and their legal counsel, and
  - Educators and trainers for their use in developing learning materials in public health emergency legal preparedness.

Conclusion

Participants in the June 2007 National Summit on Public Health Legal Preparedness discussed many potential options for action to improve the information element of legal preparedness for all-hazards public health emergencies. Those presented above represent the individual actions or steps the participants considered likely to make the most significant contributions to that goal.

The Summit participants also gave attention to a qualitatively different kind of action: establishment of an institute, center or other type of institution that could serve as a nationally accessible source of authoritative information on public health emergency legal preparedness for concerned public- and private-sector organizations. One important function such an organization could perform would be to collect legal documents (e.g., opinions issued by states' attorneys general, legal analyses prepared by counsel to metropolitan health departments, rulings by appellate courts, and governors' executive orders), store them in an electronic library, and make them available online. One purpose of such a continually updated and growing archive would be to reduce the need for legal counsel to state, tribal, and local public health agencies in order to develop such documents *de novo* each time they are needed. The working archive also could house the checklists, bench books, research findings, and training materials mentioned earlier in this paper.

Summit participants discussed some of the alternative configurations such a resource could take (e.g., a new, non-profit organization, an expansion of an existing resource, or a decentralized network of colleagues); issues related to assurance of the quality of the archived information resources; and challenges the heterogeneity of the public health laws of the different states, tribes, localities, and territories could pose for practical use of the archived legal documents. With resolution of these and other issues, the conceptualized new organization could be the stimulus for valuable improvements in information as a critical core element in the nation's progress toward full legal preparedness for public health emergencies.

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