Despite the fact that influenza vaccine is an important health resource, the structure and organization of the US vaccine manufacturing system has produced influenza vaccine shortages or distribution delays in five out of the last six influenza seasons. These shortages have produced the need for local public health officials to develop protocols for rationing and redistributing influenza vaccine at the local community level. In so doing, local health officials are confronted with significant practical and legal constraints associated with allocating a resource that is largely not under direct government control. In the face of an impending influenza vaccine shortage, local public health departments endeavor to do three things: (1) assess the local supply of vaccine, (2) assess the local demand from high-risk community members, and (3) ensure that to the greatest extent, the limited local supply of vaccine is used exclusively by those at highest risk within the local jurisdiction. There are a number of legal tools and strategies that local health officials have at their disposal to carry out these functions. This article will attempt to outline some of the significant legal impediments and practical constraints that local public health officials face in managing influenza vaccine supply-demand issues and will offer some suggestions for strengthening their ability to effectively manage these increasingly common situations.

KEY WORDS: influenza vaccine, laws, local health official, rationing

Influenza vaccine shortages or distribution delays have occurred in five out of the last six influenza seasons in the United States. Given that the manufacturing and distribution of influenza vaccine in the United States is largely in the hands of the private sector, during periods of shortage, local public health departments are forced to develop more sophisticated approaches in the management of community-wide influenza vaccination campaigns. In order to minimize illness and death from influenza in recent years, public health officials have invariably had to consider the prospect of rationing and redistributing a scarce health resource. In so doing, local health officials are confronted with significant practical and legal constraints associated with allocating a resource that is largely not under direct government control.

During influenza season, local health officials have one primary goal: to minimize local influenza-induced morbidity and mortality in their jurisdictions. Epidemiological evidence suggests that there may be several different strategies that local public health agencies might employ to blunt the impact of the annual influenza epidemic. In seasons where there is a relative abundance of influenza vaccine, achieving high levels of influenza vaccine coverage in all segments of the population may be desirable, particularly given the recent evidence that immunizing preschool children may be worthy of consideration as an effective strategy to slow down the spread of the virus in the community. However, in seasons where there are shortages or production delays, ensuring high levels of influenza vaccine coverage among high-risk persons in the community, particularly those residing in specific settings such as nursing homes, senior residential facilities, and other institutional settings, has been the strategy recommended by federal health officials and pursued by state and local health agencies.

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three things: (1) assess the local supply of vaccine, (2) assess the local demand from high-risk community members, and (3) ensure that to the greatest extent, the limited local supply of vaccine is used exclusively by those at highest risk within the local jurisdiction. There are a number of legal tools and strategies that local health officials have at their disposal to carry out these functions. The article is in no way intended to be a comprehensive summary of all of the relevant public health statutes or other sources of legal authority in all of the 50 states but rather is designed to outline some of the significant legal impediments and practical challenges that many local public health officials must contend with in their efforts to manage influenza vaccine supply-demand issues at the local level. In order to illustrate these legal impediments, the article will make reference to selected state statutes and discuss their potential application to local health officials’ efforts intended to manage influenza vaccine supplies at the local level. A thorough review and analysis of communicable disease law in the 50 states and 2 territories can be found in Gostin et al.3

● General Legal Authority for Local Health Officer Actions

The power to protect the public from communicable disease is vested in the states under their broad “police power.” The police power has been defined as “the inherent authority of the state (and, through delegation, local government) to enact laws and promulgate regulations to protect, preserve and promote the health, safety, morals, and general welfare of the people.”4 Although the jurisdictional architecture of state-local relationship varies widely from state to state, local health officials, in essence, operate as agents or delegates of the state health department and derive their authority from state health statutes most commonly organized in the form of a state “health code.” Among the actions that state/local health officials have historically exercised under their public health police powers are restriction on movement of people (isolation and quarantine), mass vaccination (including compulsory vaccination programs), and inspection and seizure of private property. These powers, however, are limited by the due process and liberty guarantees that are enshrined in the US Constitution. In deciding whether local health officials have acted constitutionally, courts will balance the state’s interest in protecting the public from disease, and the reasonableness of the measures taken, against the liberty or property interests at stake for the individuals restricted by the public health action. Thus, the exercise of public health police power must be judicious and local health officials must be cognizant of the need to balance the need to protect their constituents from ill health, injury, or death against the constitutionally protected liberty and property rights of those who may be impacted by public health actions.

● Legal and Practical Constraints on Local Health Officer Authority

Although it is generally recognized that local health officials in most states have broad general powers to prevent the spread of communicable disease,∗ the specific steps necessary to carry out that authority are often not clearly spelled out in most state health codes or administrative regulations. Broad nonspecific grants of authority suffer from two significant limitations. First, this authority tends to be somewhat unenforceable from a practical point of view. Local health officials are heavily dependent on local law enforcement officials to enforce public health orders. Generally speaking, local law enforcement officials need a relatively high degree of specificity in laws in order to clearly identify infractions of the law. This practical limitation is best overcome by having clear and specific statutory support for the actions that local health officials are taking. Law enforcement officials need to know what actions or behaviors actually constitute a violation of a public health order and what level of force to apply. A second limitation of broad grants of statutory authority is that modern courts may look askance at seemingly unlimited grants of authority and will likely look carefully at the actions of the local health official and apply a test for constitutionality based on the nature of the individual rights at stake. Over a century ago, the US Supreme Court established that state public health actions must bear a “real or substantial relation”5 to a public health objective; however, as noted by Professor Larry Gostin, subsequent case law has failed to establish a clear legal standard for assessing the legality of specific public health measures implemented pursuant to broad public health police powers.3 Consequently, such legal determinations will likely be highly circumstance-specific and may provide only limited legal guidance for future local health official actions. Thus, despite the appearance of wide latitude for local health officials to

*For instance, in Connecticut’s health code, the local health official “shall have and exercise all the power for preserving the public health and preventing the spread of diseases . . . ” (Connecticut General Statutes 19a-206(d)). In Vermont, the health code directs the local health officer to “mitigate any significant public health risk” (18 V.S.A. 602a). In Utah, the state health code requires the local health officer to “direct the investigation and control of diseases and conditions affecting public health” (Utah R380-40-6). In Wisconsin, “local health officers may do what is reasonable and necessary for the prevention and suppression of disease . . . ” (Wisconsin 252.03).
prevent disease, these decades-old statutes may actually present significant potential legal liabilities. In essence, these broad statements of authority are probably not enough justification for many of the specific strategies that local health officials might employ to ration or redistribute influenza vaccine.

In addition to the insufficiency of broad statutory justification, there are significant interpretation issues associated with translating state health codes into discrete actions for local health officials. Although each of the state health codes is unique and must be read in conjunction with the body of state-specific case law, state regulations and any municipal ordinances that serve to contextualize these codes in their respective states, in general a majority of these interpretation issues may be categorized in the following three ways: (1) disease-specific powers versus general powers, (2) the power to prevent versus the power to respond, and (3) routine business powers versus emergency powers.

Disease-specific powers versus general powers

All state health departments establish a list of reportable diseases that physicians and laboratories must report to local health departments or directly to the state. The powers of the local health official to control communicable disease often relate directly to that list of specific enumerated diseases. For some diseases, such as tuberculosis, state codes often provide very specific and detailed powers for local health officials. In Washington State, with regard to the control of tuberculosis, health officers are

- directed to use every available means to ascertain the existence of, and immediately to investigate, all reported or suspected cases of tuberculosis in the infectious stages within his or her jurisdiction and to ascertain the sources of such infections. In carrying out such investigations, each health officer is hereby invested with full powers of inspection, examination, treatment, and quarantine or isolation...

Similar tuberculosis-specific statutes exist in many other states. These disease-specific statutes have the effect of implying that these specific and more intrusive local health officer powers are not necessarily available for other diseases. A local health officer in the routine course of business would feel justified in demanding medical or administrative records relevant to the treatment of a tuberculosis-infected patient from a nursing home or health maintenance organization. However, that same health officer would likely not feel as justified in demanding medical or administrative records relevant to influenza immunization from these private medical providers. This is true despite the fact that influenza is a reportable disease in many health jurisdictions. Courts would be more likely to uphold a local health officer’s actions where clearly documented authority exists. The existence of clear and explicit authority in one disease would likely be interpreted by a court to suggest that the legislature had not intended to grant local health officials the same authority in all diseases.

The power to prevent versus the power to respond

Several state health codes are structured in such a way as to require that an actual case of disease be reported in their jurisdiction before local officials can act. These codes were generally written at a time when outbreaks of communicable disease were inevitable (eg, smallpox, plague, and tuberculosis), and the primary role of the local health official was to manage epidemics once initiated rather than endeavor to prevent them altogether. These codes describe an essentially reactive role for local health departments with response to communicable disease triggered by a passive report from a clinician. In these states, it is arguable that local health officials have very limited power, if any, to act in ways designed to prevent disease before an actual case is known to be present. This limitation has significant implications for the management and oversight of community-wide influenza vaccine campaigns given the significant preparatory efforts that must take place before there is any evidence of actual influenza cases within the local jurisdiction.

In California, the state health code reads:

Each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the department, or any other contagious, infectious or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, shall take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases.

As written, California law requires local health officer actions to prevent the spread of disease be contingent on the existence of a case of the disease in question within the local jurisdiction. Thus arguably under California law, under routine circumstances, a local health officer is not empowered to take steps to prevent an outbreak of influenza until such a time as a case of influenza exists in his or her jurisdiction. Somewhat similarly, in Wisconsin the state health code reads, in part, “(e)very local health officer, upon the appearance of any communicable disease in his or her territory, shall immediately investigate all the circumstances. . . .” This statute could also be interpreted to suggest that authority for local health department action is triggered only “upon the appearance of any communicable disease in his or her territory” and not before. In contrast, in New
York State, local health officers are required to “guard against the introduction of such diseases as are designated in the sanitary code. ...”9 New York State’s sanitary code includes influenza. Thus, unlike California and Wisconsin, in New York State during an influenza vaccine shortage, prior to the occurrence of any known cases of influenza, a local health officer’s actions to ascertain in detail the supply of vaccine within his or her jurisdiction is clearly justified under his or her mandate to “guard against the introduction” of influenza into his or her jurisdiction. These seemingly technical legal differences can present important barriers to local health efforts to organize and oversee a community-wide influenza vaccine campaign during times of vaccine scarcity. Health providers, large corporations, or others in possession of influenza vaccine that may be less inclined to cooperate with a local health jurisdiction may find legal support for their recalcitrance in the wording of state health codes. Local health officials who operate under such potential statutory limitations might be more inclined to pursue the declaration of a local state of emergency in order to expand their scope of authority during a vaccine shortage.

Routine business powers versus emergency powers

As discussed above, local health officials’ power under routine circumstances while broad in scope is not well defined in many states and may actually be quite limited when the actions contemplated are purely preventive in nature and/or are not targeted at a disease for which there is an explicit and detailed statutory scheme. For this reason, state or local health officials may be inclined to pursue the declaration of a state of emergency when circumstances suggest that the actions that are contemplated may not be easily justifiable under routine conditions. In the fall of 2004, several states issued “emergency orders” in response to the concern that influenza vaccine would need to be rationed. In addition to compelling licensed healthcare providers to limit their influenza vaccine supply to high-risk persons, these orders also demanded the cooperation of possessors of influenza vaccine with state and local health officials in order to effectively manage the scarce supplies of influenza vaccine. For instance, state health officials in Michigan, Delaware, and Oklahoma ordered “that health care providers and others that possess influenza vaccine cooperate with” state public health officials “to assess vaccine supply and coordinate vaccination of persons in high-risk categories.”10–12 Similar orders were issued by several other states. The presumption behind these orders is that such coop-

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See archived orders from various states.13 Also see National Association of County and City Health Officials.14

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Managing Local Influenza Vaccine Shortages: Legal Strategies, Tools, and Barriers

In wake of the 2004 nationwide influenza vaccine shortage, several states introduced legislation designed to address specific issues created by the shortage, such as price gouging and hoarding.15 However, only a few states developed specific influenza vaccine rationing laws that provide a clear directive to local health officials.16 Many state health codes remain broadly worded and fail to provide local health officials with clear legal guidance for managing local influenza vaccine shortages. As a consequence, many local health agencies feel constrained in their ability to adequately manage the vaccine distribution process in their jurisdictions and continue to be unable to judge with any certainty the degree of misuse of influenza vaccine within their jurisdictions. This uncertainty does not bode well for coordinated pandemic influenza management or other communicable disease epidemics such as smallpox where control of and rationing of a limited vaccine supply is critical to disease control.

In order to optimally manage local vaccine allocation protocols in the event of vaccine scarcity, local public health agencies must have appropriate and well-exercised legal strategies available to them. Without monopoly control over the vaccine supply, local health officials must be empowered to direct these local rationing and redistribution efforts efficiently and accurately. This means having clear authority to control resources largely in the hands of private entities. This action by government invokes clear constitutional issues. The Constitution defines a series of enumerated individual rights (most notably, the due process and equal protection rights found in the Fifth and Fourteenth Amendments, and the Fourth Amendment’s freedom from unreasonable searches) all of which act to limit the state’s police power. In designing and conducting community-wide influenza campaigns during periods of vaccine shortage, local health officials must have legal strategies and approaches that recognize
and address each of these constitutionally protected rights.

Assessing the local vaccine supply

In order to assess the local supply of influenza vaccine available to the local jurisdiction, local health departments must inventory the stocks of influenza vaccine in both public and private hands. In most local communities, influenza vaccine programs are conducted by a wide variety of entities and institutions, including local public health departments, community clinics, private physicians, nursing homes and senior residential facilities, senior centers, county and municipal jails, private employers, government employers, universities and community colleges, local hospitals, large managed care organizations, military facilities, private retail chains, visiting nursing agencies, and others. Inventorying local supplies of influenza vaccine held by such a broad array of institutional and individual entities poses both logistical and legal challenges. Health departments may simply ask the various known local providers of influenza vaccine how many doses of vaccine they have ordered and received and assume that an accurate and timely response will be forthcoming. However, influenza vaccine providers may have many reasons why they do not desire to divulge such information, including proprietary trade secret concerns and other issues related to business competition, perceived potential liability for having ordered inadequate supplies, concerns about the appearance of hoarding, and a desire to control information release for optimal public relations purposes. Consequently, local health departments may face some resistance to these inquiries. In addition, in some cases, access to business records such as invoices, shipping information, customer lists, and other correspondence may be necessary to validate inventory information that is provided verbally. These somewhat more intrusive requests will often raise providers’ legitimate concerns over how the confidentiality of this information will be maintained and the degree of administrative burden associated with such requests.

Some local health officials have the power to issue administrative subpoenas. In New York State, local boards of health may “(a) issue subpoenas which shall be regulated by the civil practice law and rules; (b) compel the attendance of witnesses; (c) administer oaths to witnesses and compel them to testify.” Although this important legal tool has the potential to encourage providers of influenza vaccine to be candid in their statements regarding vaccine inventory, most local health agencies do not have this power. Local health officers might instead simply issue an order to a healthcare provider to produce invoices, shipping records, and other relevant business records; however, legal challenges to this kind of order might be upheld on purely administrative grounds that such an order amounts to a subpoena and the local health agency has no such explicit powers. Fourth Amendment protections against unreasonable searches would also have to be resolved. Increasing access to administrative subpoenas and similar types of legal tools, with the appropriate judicial oversight, is a strategy that state and local health agencies should strongly consider in anticipation of pandemic influenza, bioterrorism events, or other situations where rationing of a scarce health commodity might suddenly become necessary.

In some rare instances, it may be necessary to seize vaccine supplies from an entity that either refuses to comply with state or local health orders or appears to be acting otherwise irresponsibly with a scarce resource. Here, clear Fourth Amendment protections against unreasonable searches and seizures would apply and local health departments would need substantial justification for such an action. Many state health statutes grant local health officials the power to conduct inspections, and seize and destroy property when indicated. However, most of these statutes apply to the abatement of nuisances or other sources of contamination. A seizure of valuable personal property for purposes of re-allocation would not generally be pursuant to an inspection but rather would follow a traditional search and would almost certainly, except in exigent circumstances, have to be carried out with a warrant, particularly if consent to search has been denied by the party in possession of the vaccine. Some local health agencies have the authority to issue warrants; however, most local agencies do not and must rely on the traditional judicial system to obtain warrants.

Assessing the local demand from community members who fall into one of the high-risk groups

In order to make a determination of whether there is enough influenza vaccine for the high-risk population within a local jurisdiction, an assessment must be made of residents of the jurisdiction who may be patients in hospitals, long-term care facilities, or other institutions. There will also be people living in the community who may be enrolled in managed care organizations or large group practices. Local health officials may need to request relevant medical records, pharmaceutical records, health plan encounter data, quality assurance data, or other records that accurately indicate the number of high-risk persons that are resident in the local jurisdiction. In addition to the Fourth Amendment issues raised here, federal and state privacy and confidentiality statutes pose barriers to obtaining this kind of information. The federal Health Insurance
Portability and Accountability Act of 1996 (HIPAA) contains a broad exemption for disclosures of protected health information to a “public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions.” Despite a broad exemption for public health disease control activities under HIPAA, state medical records privacy laws may in some cases be even more stringent than HIPAA and fail to provide appropriate exemptions for local public health agencies. For instance, California law medical records privacy laws provide no explicit exemption for local public health agencies. Local health officials may need to work to develop appropriate exemptions within state law for such activities.19

**Ensuring that the limited local supply of vaccine is used exclusively by those at high risk within the local jurisdiction**

A natural concern of providers during a vaccine shortage is that the government will seize or commandeer this property for an alternative use. Most providers are better suited to making determinations about which of their patients is at highest risk for influenza complications. However, some providers may choose, for a variety of reasons, not to perform this type of triage. In addition, extensive research on health disparities reveals that providers may consciously or unconsciously discriminate against patients from certain minority groups and fail to offer proven therapies despite clear indications.20 For these reasons, local health officials may want, to some practical extent, oversee or audit the process by which selection of high-risk influenza vaccine recipients is made. This may require the local health agency to commandeer influenza vaccine from providers and possibly conscript providers in the administration of this vaccine to a specified population in a specified setting. For instance, a private agency that conducts public vaccine clinics may be conscripted to perform vaccinations in a long-term care institution. Their supply of influenza vaccine may be commandeered for this or another purpose. Most state health codes do not contain explicit authority for local health officials to commandeer private property or conscript private citizens. Such actions should almost invariably be taken under a declared state of emergency. However, there may be a variety of political and practical reasons why politicians might not want to declare a state of emergency and so local health officials may need to develop enforceable plans to take control over and redirect the administration of influenza vaccines in situations where an emergency declaration has not been issued.

**Conclusion**

Despite the fact that influenza vaccine is an important health resource, the structure and organization of the US vaccine manufacturing system has produced influenza vaccine shortages or distribution delays in five out of the last six influenza seasons. These shortages have produced the need for local public health officials to develop protocols for rationing and redistributing influenza vaccine at the local community level. In so doing, local health officials are confronted with significant practical and legal constraints associated with allocating a resource that is largely not under direct government control.

In the face of an impending flu vaccine shortage, local public health departments endeavor to do three things: (1) assess the local supply of vaccine, (2) assess the local demand from high-risk community members, and (3) ensure that to the greatest extent, the limited local supply of vaccine is used exclusively by those at highest risk within the local jurisdiction. There are a number of legal tools and strategies that local health officials have at their disposal to carry out these functions.

Although local health officials in most states have broad general powers to prevent the spread of communicable disease, the specific steps necessary to carry out that authority are often absent from state health codes. Broad nonspecific grants of authority are generally unenforceable and are regarded unfavorably by courts. Broad statements of authority are generally not enough justification for many of the specific strategies that local health officials must consider employing to ration influenza vaccine. Local health agencies should review their state health code and consider advocating for more explicit legal authority to conduct and oversee local influenza vaccination campaigns, including the authority to inspect business records and inventories, and seize vaccine when indicated. Local health agencies should also pursue efficient and timely judicial protocols for commandeering and possibly conscripting healthcare providers to vaccinate high-risk populations as necessary. Local health agencies should consider pursuing through legislation the development of quasi-judicial administrative processes that would permit the issuance of subpoenas and warrants. The current legal uncertainty does not bode well for coordinated pandemic influenza management or other communicable disease epidemics such as smallpox where control of and rationing of a limited vaccine supply is critical to disease control.
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