

Influenza Vaccine Scarcity 2004–05: Implications for Biosecurity and Public Health Preparedness

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In the event of a bioterrorist event or a pandemic flu outbreak, it might be necessary to ration vaccine or other treatments. In this article, researchers examine how medical and public health decision makers negotiated the unanticipated 2004–05 influenza vaccine shortage, using the regional hospital system headquartered in Pittsburgh, Pennsylvania, as the focal study site. This account of that case study describes the circumstances that contributed to the national and local vaccine shortage; the improvisation by health policymakers, hospital administrators, physicians, and nurses to prevent influenza cases despite the shortfall; and some of the legal, fiscal, logistical, social, and political pressures that local health professionals faced in deciding who should receive the limited supply of influenza vaccine. This instance of an acute vaccine shortage provided an opportunity to examine the practical and ethical dilemmas of managing medical resources during a public health emergency.

SCARCITY OF LIFE-SAVING RESOURCES is one of the most complex challenges that decision makers may face when managing the impact of a biological attack, in terms of medical outcomes, social stability, and confidence in government.^{1–5} Rationing also qualifies as one of the most troubling public health dilemmas anticipated during a pandemic of influenza: When everyone is vulnerable to a novel, potentially lethal virus, who should be vaccinated first and why?⁶ Apart from dramatic “tragic choices,” governments, healthcare administrators, practitioners, and patients around the globe contend routinely with questions about prioritized access to healthcare.^{7–10}

To understand more fully what *sudden and urgent* rationing might imply, researchers examined how medical and public health decision makers negotiated the unanticipated 2004–05 influenza vaccine shortage. Investigators took a regional hospital system headquartered in Pittsburgh, Pennsylvania, as the focal study site. This account of that case study describes the circumstances that contributed to the national and local vaccine shortage; the improvisation by health policymakers, hospital adminis-

trators, physicians, and nurses to prevent influenza cases despite the shortfall; and some of the legal, fiscal, logistical, social, and political pressures that local health professionals faced in deciding who should receive the limited supply of influenza vaccine.

This instance of an acute vaccine shortage—followed by an unintended excess several months later—provides an opportunity to examine the practical and ethical dilemmas of managing medical resources during a public health emergency. Case study observations are coupled with their implications for a hypothetical crisis as well as investigators’ suggestions for improving the ability of healthcare systems and public health agencies to handle scarcity conditions.

BACKGROUND

National Flu Vaccine Shortage

On October 5, 2004, the British Medicines and Healthcare Products Regulatory Agency suspended the license

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of Chiron, a leading vaccine manufacturer, to produce flu vaccine at its Liverpool, England, facility “due to sterility failures in filled vials” of the vaccine.¹¹ The plant had been expected to supply some 46–48 million doses of flu vaccine for the U.S. market for the 2004–05 season—roughly half of the nation’s supply.¹² Only three vaccine producers were active in the market for the 2004–05 season: Chiron Corporation and Aventis Pasteur (now Sanofi Pasteur) produce inactivated vaccine, and MedImmune makes a live attenuated vaccine, marketed as “FluMist®.”¹¹

The suspension prompted the Centers for Disease Control and Prevention (CDC), in coordination with its Advisory Committee on Immunization Practices (ACIP), to issue interim guidance (subsequently revised) on priorities for distributing available supplies (see Table 1). CDC and other elements of the Department of Health and Human Services (HHS) also worked to secure additional vaccine. Government interventions included “freezing” and nationally redistributing vaccine orders not yet delivered from Aventis Pasteur, obtaining additional FluMist® vaccine from MedImmune, and ramping up production of vaccine from both remaining U.S. sources, which, by the end of the 2004 flu season, had together produced 58 million doses.¹¹ With an additional 3 million vaccine doses from other sources, the U.S. supply for the 2004–05 flu season totaled 61 million doses, compared with about 83 million doses in the previous year.

Regional and Local Implications

Local institutions in Pennsylvania fell on a continuum from “have” to “have not,” depending on the manufacturer with whom they had placed the original order for inactivated vaccine. According to a statewide survey, more than half of the vaccine supply for hospitals was to have come from Chiron, as was one-third of the state health department’s order. The Visiting Nurse Foundation, which runs public vaccination clinics at supermarkets and similar venues in the Pittsburgh region, had ordered solely from Chiron. In contrast, the Allegheny County Health Department (ACHD), with responsibility for the Pittsburgh metropolitan area, had ordered and received all of its doses from Aventis. The Pittsburgh Veterans Administration successfully procured sufficient doses as did some area health systems and private practitioners.

During the earliest days of the flu vaccine shortage, there was initial confusion and a lack of clarity over who would have the authority to release additional vaccine to providers and, given the limited supply, which population groups should be given priority. The CDC embargo of Aventis vaccine had interrupted the flow of vaccine doses to some Pennsylvania localities, and redistribution

would take time to implement. CDC issued general guidelines for critical population groups but declined to provide more definitive subgroups, deferring specific allocation decisions to local authorities. Local providers thus faced gaps in the local supply of inactivated vaccine as well as the absence of *a priori* prioritization standards relevant to initial and evolving local conditions. Practitioners and local and state health authorities throughout the U.S. faced a similar predicament.^{13–15}

Systemwide Shortage for the University of Pittsburgh Medical Center

The University of Pittsburgh Medical Center (UPMC), the largest integrated healthcare and finance delivery system in Pennsylvania, was virtually empty-handed when the Chiron suspension was announced. In spring 2004, UPMC had placed an order for 145,000 doses solely with Chiron, based on the company’s promise and history of vaccine delivery all at once and early in the season; this arrangement would permit efficient distribution and administration later that fall. Chiron vaccine also cost slightly less than that of Aventis Pasteur.

The unanticipated gap between UPMC’s vaccine supply and demand had dramatic implications, given the scale and reach of the healthcare system: a 29-county area served by more than 40,000 employees; 19 tertiary, specialty, and community hospitals; more than 350 outpatient sites and doctors’ offices; and a rehabilitation network of more than 50 hospital and outpatient facilities. UPMC is also the largest provider of independent living, assisted living, and skilled nursing options in the region, with 14 freestanding retirement and long-term care facilities. With more than 4,000 licensed beds, UPMC cares for more than 165,000 in-patient admissions and 3 million outpatient visits per year.¹⁶

On behalf of the Chief Executive Officer, the Chief Medical Officer (CMO) assumed oversight of issues in connection with the almost complete cutoff of flu vaccine to the health system: How much vaccine do we have in hand? How much do we need? How do we get more? Who needs vaccine the most? How do we distribute supplies fairly? How do we keep everyone up to date on critical developments? In pursuit of these queries and solutions, the CMO convened the Influenza Taskforce, the core membership of which predated the crisis. The task force was a deliberative body that represented the various UPMC member institutions, health professions, and patient populations. Among its members were infectious disease clinicians, key institutional administrators, and hand-picked subject matter experts. The electronic information management and automated records system that is a key attribute of UPMC was at their disposal.

TABLE 1. ELIGIBILITY CRITERIA: FLU VACCINE PRIORITY GROUPS

<i>Centers for Disease Control & Prevention</i>	<i>Allegheny County Health Department</i>	<i>University of Pittsburgh Medical Center</i>
<p>5 October 2004</p> <ul style="list-style-type: none"> • All children aged 6–23 months • Adults aged ≥ 65 years • People aged 2–64 years with underlying chronic medical conditions • All women who will be pregnant during the influenza season • Residents in nursing homes and long-term care facilities • Children aged 2–18 years on chronic aspirin therapy • Healthcare workers involved in direct patient care • Out-of-home caregivers and household contacts of children aged < 6 months <p>22 December 2004—Groups added to above:</p> <ul style="list-style-type: none"> • Out-of-home caregivers and household contacts of people in high-risk groups (e.g., people aged ≥ 65 years; people with chronic conditions such as diabetes, heart or lung disease, or weakened immune systems because of illness or medication; and children aged < 2 years) • All adults aged 50–64 years 	<p>18 October 2004</p> <ul style="list-style-type: none"> • Children 6–23 months • Adults aged ≥ 65 years • People aged 2–64 years with underlying chronic respiratory diseases, including asthma • Residents in nursing homes and long-term facilities <p>Note: Visiting Nurse Foundation adopted same criteria for its community-based distribution.</p>	<p>20 October 2004</p> <ul style="list-style-type: none"> • Children 6 months to 18 years with chronic illness • Parent with infant < 6 months • Healthy child 6–23 months • People ≥ 65 years with 2 or more high-risk conditions • People 45–64 with 2 high-risk conditions • People aged ≥ 65 with 1 high-risk condition <p>Note: UPMC made FluMist[®] available to all health workers, everyone aged 4–49 who met certain criteria, and adults aged 50–64 years with signed waiver.</p> <p>Additional subcategories added as inactivated vaccine became available in December–January:</p> <p>1 November 2004</p> <ul style="list-style-type: none"> • Women who will be pregnant during the flu season • Chronically ill adults aged 19–44 • Healthcare workers with direct patient contact and ineligible to receive FluMist[®] <p>3 December 2004</p> <ul style="list-style-type: none"> • Patients who are healthy and receive FluMist[®] • People aged ≥ 65 and healthy <p>7 December 2004</p> <ul style="list-style-type: none"> • All other people aged ≥ 65 <p>6 January 2005</p> <ul style="list-style-type: none"> • All other people aged 50–64 • Out-of-home caregivers and household contacts of people in high-risk groups

Note: Medical and public health authorities prioritized patient groups for the allocation of scarce flu vaccine, revising protocols as more doses became available. Local health officials and hospital administrators refined the CDC's broad categories, employing more restrictive eligibility criteria to reconcile a demand greater than supply.

At the outset of the shortage, the UPMC central pharmacy implemented a number of contingency actions, including back-ordering through Aventis and trying to locate vaccine on the “spot” market. The pharmacy identified about 5,000 pediatric doses separately ordered by a few UPMC close affiliates (one pediatric hospital and two pediatric practices). Distribution of this minute amount was postponed until the task force developed in-house eligibility criteria and an overall plan.

The pharmacy immediately procured a large supply of FluMist[®] attenuated vaccine and antivirals such as Tamiflu[®], and it subsequently was able to secure an additional 10,000 doses of vaccine from external sources. UPMC eventually received and distributed two allocations of CDC-reapportioned vaccine from the state health department: 29,350 doses on December 13 and 21,770 doses on December 27. Every time that more vaccine became available, UPMC loosened its eligibility criteria (see Table 1). In the end, UPMC was able to obtain about 40% of its original order, not counting FluMist[®].

Unexpected Surplus of Flu Vaccine

By January 2005, less than 90 days after the flu vaccine crisis erupted, the vaccine shortage had turned into a surplus both nationally and locally. Five million doses of attenuated flu vaccine were available from vaccine manufacturers through CDC without any immediate takers.^{17,18} In Pennsylvania, state health officials were able to obtain surplus vaccine from other states through CDC to satisfy all pre-identified statewide priority needs. Experiencing a surplus for the first time, Pennsylvania officials conducted an outreach campaign to private practitioners and distributed 15,000 doses. At UPMC, approximately 5,500 inactivated vaccine doses went unused; all critical populations had been covered and the remainder was made available to any members of the public who wanted it. At the Visiting Nurse Foundation, enough unused vaccine was left that it “could not be given away” in the Pittsburgh area and ultimately was donated to Paraguay. Thousands of units of FluMist[®] went unused by local providers and their patients.

Lack of synchrony between vaccine supply and public demand contributed to the vaccine excess. By the time CDC via the state health department redistributed vaccine to UPMC in mid- to late December, public demand had sharply dropped off. Holidays and social obligations competed for public attention. Severe winter weather kept people away from public clinics. The flu season was proving unremarkable in terms of numbers of cases and severity of disease. By the end of the year, people may have thought that the “worst” of the season was over and that there was no compelling reason to be vaccinated if they had not already done so. Moreover, some people

held back from being vaccinated, assuming that others needed it more. National vaccination rates among groups most at risk from flu were comparable to the prior year: 43% in 2004–05 compared with 47.8% in 2003–04. CDC experts attributed this in part to “nonpriority adults” foregoing vaccination out of concern for others.¹⁹

METHODS

The study joins a body of qualitative sociological research documenting allocation decisions *in situ*, as health professionals wrestle with the practical and ethical challenges of providing quality care in the context of constrained material resources.^{20–22} Over a 16-week period from January to May 2005, the authors conducted semi-structured interviews, 1 hour in length, with 37 medical and public health professionals in the greater Pittsburgh area who played a decision-making role in vaccine allocation, whether from an administrative or direct care perspective. Investigators used preprepared questions to inquire about a person’s initial and evolving awareness about the vaccine shortage and its institutional implications, and about the design, implementation, communication, and social acceptance of local vaccine rationing policy. Lines of inquiry about an individual’s expertise and leadership role also were pursued.

Subjects included state and local health officials ($n = 4$), UPMC administrators and providers ($n = 29$), non-UPMC health administrators ($n = 2$), and leaders of non-governmental health organizations that were involved in managing the flu shortage ($n = 2$). All UPMC subjects served in a leadership capacity, and purposive sampling was conducted to capture a range of institutional perspectives *within* the health system: settings from a large, urban research hospital to a small, rural community hospital to extended care facilities; the fields of medicine, nursing, infection control, employee health, pharmacy, and communications; health system executive management; influenza task force; and providers to special populations including children, seniors, and people with immune suppression.

The authors prepared reports for each research subject that synthesized handwritten and audiotaped notes as well as investigator reactions. The majority of interviews were in person ($n = 29$) and the remainder by phone ($n = 8$). At least two members of the research team were present for each interview, and, in most cases, all three investigators participated. Over the course of data collection, the team met periodically to discuss findings, trends, and possible implications. Interview data were supplemented by review of relevant documents including government and news reports as well as UPMC corporate communications and vaccine distribution protocols.

OBSERVATIONS AND IMPLICATIONS

Framework for Rationing Vaccine

Medical leaders relied on the scientific literature, the professional judgment of relevant experts, and patient records to build an empirical base for rationing decisions. UPMC task force members discovered that having substantial scientific knowledge did not automatically make allocation choices less difficult. Deliberation about the evidence by a comprehensive set of experts was still necessary. To develop its own priority criteria, the UPMC task force examined the available clinical and epidemiological evidence, applied professional judgment when scientific data were absent, and proactively sought advice from clinicians throughout the system, including those who served at-risk populations such as children and frail seniors, pregnant women, and people who are immunocompromised. In addition, electronic databases helped establish how many patients within the system and each affiliate institution fell into risk group categories. Once a supply of vaccine was in hand, these same records proved useful in pinpointing specific patients for vaccination.

One of several dilemmas that arose for the task force was determining whether vaccine should be distributed to save the “most number of lives” or the “most years of life.” One subject put the choice in these terms: Should providers give priority to individuals who are more likely to die if infected (for example, an 89-year-old with two risk factors) or to individuals who are less likely to die if infected but who stand to lose more if they did (for example, a 51-year-old with two children)? Influenza mortality data for the frail elderly made a compelling argument for the former choice; less scientific evidence exists about the number of life-years saved by flu vaccination.

A related dilemma was whether to target vaccine to those most likely to get very sick or those most likely to spread the disease. When infected, older children are less likely to suffer serious illness, but they are efficient flu spreaders. Vaccinating children can help preempt the spread of disease to others. Again, more data on the secondary benefits of vaccinating children was desired in relation to known morbidity and mortality data—but such data did not exist. Based on the hard evidence in hand, the task force rationed to the principle of *preventing fatalities*.

Even when based on medical criteria alone, the “best” choices were not immediately obvious or conclusive to the task force. Biological nuances of the vaccine process and patient physiology required their careful consideration. The case of HIV-positive patients is illustrative. This community was considered a priority group by the CDC and UPMC. The UPMC medical community, however, was initially split as to the value of assigning vaccine to patients in this category. Task force deliberations

raised the question of whether individuals with HIV could mount a sufficient immune response to benefit from the vaccine. A similar predicament arose for transplant patients. Would vaccinating the immunosuppressed patients “waste” doses? In the end, HIV/AIDS providers argued that patients with their HIV under control were no more vulnerable to flu than the general population and could forego vaccination. The patient advisory board for the HIV/AIDS clinic affirmed the policy.

Implications: Resources will still need to be allocated in a crisis in spite of scientific knowledge gaps, making professional judgment an important element in rationing decisions. Plans for prioritizing vaccines, antibiotics, and the like can benefit from the deliberation of a broad range of medical experts. It would be prudent for local health-care institutions to pre-identify subject matter experts who would be vital resources to support decision making during a public health emergency and, if possible, to give them visibility as an institutional group that fulfills an emergency planning or evaluation function (e.g., pandemic flu preparedness, bioterrorism coordination). In addition, the ability of a healthcare system to identify vulnerable patient groups, ascertain which medicines are available, and derive useful epidemiological statistics from its database—all the better if automated and networked—can facilitate response to a public health crisis and improve decisions about prioritized access.

Medical decisions about vaccine rationing operated in a context of complex social, political, fiscal, and organizational concerns. At the onset of the shortage, UPMC decision makers faced the awkward question of who was more “deserving” of vaccine medically, socially, or otherwise: children or the elderly? Seniors expressed a strong desire to be vaccinated and were persons of concern for both health professionals and the public. Despite the relatively low risk of healthy older children dying from the flu, children were widely and culturally recognized as deserving of special protection.

Further complicating the apparent choice between children and seniors was the provenance of doses within the health system. A pediatric hospital and two pediatric physician practices *within* the UPMC corporate body had ordered and received doses from Aventis by early October. Their good fortune resulted from Aventis being the only manufacturer of pediatric doses of flu vaccine. Concerns over the social acceptability of taking vaccine “away from” children gave pause to medical administrators wanting to provide the vaccine to vulnerable adults who, clinically speaking, faced a greater risk of death. Organizational dynamics between UPMC and the pediatric hospital exacerbated this socially charged predicament. A recent merger agreement accorded the pediatric hospital a measure of autonomy; in this instance, the

hospital could opt to apply the CDC guidelines (not UPMC's) and keep what vaccine it needed. Moreover, the new partnership had been strained by disagreements over proposed capital investments.²³ Ultimately, the pediatric hospital vaccinated priority pediatric patients and then shared the remaining stocks with the health system.

Implications: Clinical knowledge and perspectives are a critical basis for making informed allocation decisions, but they are not sufficient in and of themselves because of the social values at stake in efforts to protect human lives. A range of literature suggests that science-based categories and physician decisions presumed to be objective cannot be fully disentangled from the larger social and economic systems in which they develop.^{21,24–26} The complexity and interrelationships of issues such as legal liability, social mores, clinical ethics, and institutional roles and responsibilities make preplanning and advance policy consideration with regard to rationing in a crisis essential. Attempting to resolve these issues during a public health emergency would be difficult and likely lead to missteps.

The health system's process for planning and implementing prioritized distribution was scientifically rigorous, socially fair, and transparent. The UPMC decision-making process incorporated relevant empirical evidence, represented broad interests, and was transparent—procedural features known to contribute to broader acceptability of healthcare allocation decisions. Material outcomes, according to a number of studies, are not the only measure by which individuals judge the integrity of rationing decisions. How a decision is made, as well as who it affects, have a profound influence on people's opinions about the soundness of medical resource allocation policy.^{3,27–31}

The composition of the influenza task force reflected a range of professional, institutional, and patient interests. The Chief Medical Officer facilitated task force deliberations, conferred institutional authority on them, and established a principle of inclusion, broadening task force membership when additional input was needed. Different areas of medical expertise were represented at the table, including infection control, infectious diseases, nursing, family medicine, pediatrics, internal medicine, geriatrics, and emergency medicine. In addition, clinicians who served at-risk populations (e.g., frail children and seniors, pregnant women, people with immunosuppression) could advocate for their patients' inclusion in priority groups. Many interviewees commented that UPMC's large size was advantageous, as in-house expertise was readily available to provide critical information or expert judgment.

Daily e-mails as well as regular conference calls and in-person meetings helped knit the task force together, facilitating deliberations about new conditions and information. These same channels also facilitated communications among the CMO, the influenza task force, and the

administrative and medical leadership of individual hospitals. Print and electronic newsletters apprised the larger hospital and physician workforce of policy developments. The health system's CEO, corporate officers, and board of trustees were kept abreast of the situation. The bidirectional and broad flow of information, many subjects surmised, between a centralized decision-making body and the diverse hospitals affected by that body's guidance contributed to people's assent to the prioritization framework. Some task force members remarked, however, that the sheer volume of missives, along with their evolving content, demanded substantial attention, diverting them from other professional responsibilities.

UPMC vaccine rationing policy coupled centralized decision making with discretion afforded individual hospitals and physicians. Each hospital in the UPMC system received a portion of vaccine doses relative to its size and patient needs and was authorized to develop its internal distribution policy: how to divide among different physician groups (both inpatient and outpatient), whether to convene public clinics, and so on. The influenza task force left the final decision of whether a patient received vaccine to individual providers but directed physicians to document the recipient of each dose and the justification for its administration. One practitioner noted that he deviated from the guidelines in certain cases, given the extenuating circumstances of some patients and a long-term history of providing medical care to them. For instance, the physician vaccinated some children in households that included high-risk individuals.

Implications: Procedural rigor and transparency may mitigate real and perceived inequities associated with rationing plans. In addition, a balance between centralized guidance and localized discretion may facilitate the swift implementation of such plans. As a feature of public health preparedness, public health and medical institutions should devise an open, even-handed, and empirically driven process for resource allocation decisions. An organizational framework of shared decision making and accountability, as well as input from diverse institutional stakeholders who represent the interests of medically and socially vulnerable populations, may contribute to the legitimacy of rationing policies.

Improvised Solutions to Fit Local Conditions

UPMC fulfilled a de facto public health role, devising its own vaccine rationing scheme. While the ACHD had public health authority to restrict vaccine distribution to particular patient populations, UPMC found itself in a *de facto* public health role without the authority and liability protections afforded a government entity. The medical system had to weigh the risk-benefit implications of defining age-specific subcategories of priority vaccine

recipients within and beyond the CDC guidelines. That these considerations had to reflect certain societal implications (e.g., how children should be addressed) was a further complication. Some subjects expressed frustration with what they saw as a lack of responsiveness by CDC in not providing more detailed guidance.

The mortality basis for UPMC's age-specific distribution was not sanctioned by any government authority, although founded on epidemiologic data. The decision to go "off-label" with recipient informed consent to distribute FluMist® more widely did not have official approval, although earlier drug trials had established safety for extended age groups. These and other actions reflect the "emerging law" environment in which UPMC had to operate. Given legal uncertainties, the task force carefully reviewed each policy decision, consulted with officials and outside experts where necessary, and proceeded on the basis of "good faith." In the context of a state law requiring hospitals to offer flu vaccine to all patients, UPMC extensively documented task force deliberations and the basis for distribution policies. A potential lawsuit on behalf of someone who died as a result of not receiving vaccine weighed heavily on some subjects' minds.

At the federal level, CDC redistributed vaccine to states based on projected need. Pennsylvania's health department solicited need estimates from each county health department, medical system, and long-term care facility and from other providers. In contrast, local systems of vaccine control and distribution did not exist. Each local provider—whether health department, hospital, or nonprofit—was either a "have" or "have not" based on their respective source of vaccine (Aventis or Chiron) and was compelled to locate its own source of additional vaccine. Thus, the regional population faced initial uncertainty about which institution had vaccine and where to obtain it, as well as varying eligibility criteria based on a provider's vaccine source.

Implications: Knowledge uncertainties and logistical delays experienced during the flu vaccine shortage suggest that the burden of responsibility and decision making will fall substantially to local health agencies, hospitals, and their care partners during public health emergencies. As the 2001 anthrax attacks and the 2003 SARS outbreaks both illustrated, national or even regional authorities may not be in the best position to understand local circumstances and needs, which typically demand tailored actions and day-to-day management and contingency planning. Local medical and public health institutions could benefit from joint planning that clarifies authorities and roles for coordinated pharmaceutical control, inventory, and distribution.

Informal arrangements and relationships facilitated providers' access to scarce vaccine and to knowledge relevant to decisions about prioritization. While HHS

and CDC were developing a national contingency plan to redistribute scarce vaccine, actors at the local level creatively addressed gaps on their own initiative. Interpersonal and professional networks and appeals on behalf of the larger community helped pool a range of resources, including vaccine, trained personnel, physical space, and scientific expertise. These connections also helped vaccine reach high-priority populations.

The county health department drew on substantial external resources to convene its mass vaccination clinics. For example, links between the health department and the local schools of nursing and public health at the University of Pittsburgh enabled volunteers to staff community clinics. When public demand overwhelmed the first clinic held at a tiny health department building, the director contacted the family who owns the local football franchise to secure the sports stadium for use the next day and subsequently scheduled clinics. The sense of a shared patient constituency also accelerated the movement of vaccine to critical population groups. The leadership of the county health department, the HIV/AIDS program at UPMC, and the HIV/AIDS clinic at nearby Allegheny General Hospital (which had received its Aventis vaccine order) conferred about their respective supplies and patient needs.

Similarly, prior associations among many members of the UPMC influenza task force greatly facilitated frank and collegial deliberations about the health system's prioritization plans. Core task force participants were known to one another, having worked together on other projects, such as bioterrorism preparedness initiatives, preparation for SARS, and preplanning for an intensive 2004 employee flu vaccine campaign that the shortage had undermined. One task force member's current professional ties to CDC and ACIP served as a conduit of additional knowledge and expertise to inform the local group's deliberations. The state health department's awareness of statewide vaccine inventories and unmet needs was aided in large part by trade and professional groups (e.g., hospital association, nursing home association, medical society) surveying their own memberships.

Implications: Preestablished personal and professional ties, coupled with appeals for the greater good, help health professionals improvise solutions to medical resource shortages.^{20,22} People's ability to call on prior relationships provides a high degree of flexibility and innovation with which to handle local contingencies. If, however, a group exists at the fringes of personal and professional networks, then they may have less opportunity to advocate for their needs or present aid to others in need.

Interviewees recognized, for instance, that some health facilities in rural Pennsylvania who placed orders with Chiron may have been left on their own to handle the shortage. One advantage of allocating medical resources

through a government body (as in the case of CDC reapportionment of Aventis vaccine) is that it can help minimize exploitative behavior (such as price gouging by unscrupulous distributors) and provide for individuals and institutions that do not have the informal safety net afforded by dense social networks.

Health leaders relied heavily on infection control measures, treating vaccine as only one possible intervention among others to contain influenza. While they were trying to locate and purchase additional stocks of inactivated vaccine, health institutions also turned to established infection control strategies to prevent disease—a tactic replicated nationally.^{14,32} UPMC administrators circulated messages touting the value of good personal hygiene (e.g., thorough hand washing, covering sneezes with one’s shirtsleeve) via electronic communications, newsletters, flyers, and signs. Supervisors urged employees and volunteers to exercise good judgment in deciding whether to report to work when feeling ill. Some long-term care facilities restricted visitation (e.g., cancelled holiday performances by children’s choirs) to prevent the introduction of flu to residents.

Healthcare workers in each facility, often infection control officers, were specifically tasked with educating employees, patients, and visitors on measures to prevent the spread of influenza. Aside from promoting infection control, administrators examined the use of other countermeasures—drugs, vaccine, and diagnostic tests—to avert new influenza cases. Supervisors secured antiviral medications for both treatment and prophylaxis and developed plans for their use. Some facilities used diagnostic tests to monitor closely for the emergence of flu. Once influenza infection was detected, a patient was treated promptly and, in some cases, isolated for a period of time to prevent the virus from spreading to others.

Implications: Comprehensive contingency planning around infection control and other nonmedical disease containment measures can aid in the response to vaccine shortages or bioterrorist attacks; all measures that could diminish the burden of disease warrant consideration. A national survey conducted in late October to early November found that the majority of respondents judged nonmedical protective behaviors, such as hand washing and avoiding close contact with others, as effective prevention against influenza infection, even more so than vaccination.³³ These findings suggest that health guidance on personal protective actions may enjoy a high degree of social acceptability and ought to be a provision of public health preparedness planning.

Mass Responses to the Vaccine Shortage

Prior experience and expectation as well as media reports shaped people’s sense of vulnerability or invul-

nerability during the vaccine shortage “crisis.” Several research subjects reported that the patients who expressed the most anxiety at the news of the vaccine shortage were senior citizens or family members who were concerned that an aging parent or elderly and infirm relative might go unvaccinated. Subjects provided anecdotal accounts of patients asking providers if they could give up their own vaccine for a needy relative. Many elderly members of the public placed frantic calls to their providers asking where and when vaccine might be available. The health system created an automated hotline to handle the large number of inquiries at the outset of the shortage when information was still evolving.

Representations of a flu vaccine “crisis,” some provider subjects reflected, may have unnecessarily raised a sense of personal vulnerability. Moreover, images of “long lines” may have fueled an impulse to obtain a vaccine *immediately*, before the supply ran out. Some interviewees reported that patients who had not sought out vaccine in the past did so this year. On the other hand, the county health department relied on local media outlets to publicize the time, place, and eligibility criteria for community flu clinics. Local news stations were able to announce the last minute switch in location, from health department to sports arena, promptly and broadly. National news placed local scarcity in a larger context, including events that spurred the shortage and government plans to offset the problem.

The county health department came under fire for long lines the first day of its public flu clinics, populated primarily by seniors who weathered the cold outside. Immense public demand coupled with limited space and personnel, as well as a population that moved slowly (that is, seniors with walkers or wheelchairs), contributed to the clinic bottleneck. The move to the sports field—with ample space, sufficient parking, a heated waiting area, and donated snacks—solved these difficulties. Ironically, media reports of the short wait at the sports field prompted additional demand the next day, raising wait times again. Clinic managers commented on “early birds” willing to stand in line long before the clinic opened, attributing this practice to a person’s need to feel in control of the resource allocation process.

Implications: Reasonable behaviors by patients and the larger community contrasted with media representations of a “scarcity mentality” and a panicked public. Seniors knowledgeable of their risks to flu (either through their personal experience or public reports to that effect) were understandably anxious at news of the shortage. A call to locate vaccine or standing in line early was, from their perspective, a rational behavior, not “panic.” Similarly, long lines at the county health department were more likely the result of a centralized, mass vaccination model hampered by limited personnel and physical space than of mobs of people driven by a scarcity mentality.³⁴

Local medical systems and health departments can benefit from mass vaccination planning that takes into account the logistics of handling a large public response in a short period of time, in different weather conditions, and with diverse populations, and that coordinates with the news media to present critical, accurate information about vaccination.

Live attenuated influenza vaccine administered intranasally was a very unpopular alternative to the “flu shot,” despite clinical evidence that it is equally protective. UPMC initially excluded healthcare workers from their list of priority recipients for inactivated vaccine but secured large quantities of intranasally administered live attenuated influenza vaccine (LAIV) to offer employees as an alternative. Few healthcare workers, however, availed themselves of the LAIV option, despite the fact that both LAIV and inactivated vaccine are effective at reducing the risk of infection with influenza.³⁵ In outbreaks of contagious disease, an unvaccinated and vulnerable healthcare workforce is problematic not only for patient health, but also for the sustainability of care.^{35,36} The health system attempted to increase acceptance through education, live demonstrations in which superiors including task force members received vaccine, and in some instances, communicating to direct care providers that by foregoing vaccination they might put their patients at risk. These tactics had limited success. As the flu season progressed, UPMC offered LAIV to qualifying members of the public at no cost. These community clinics similarly experienced poor turnout.

Health professionals declined the LAIV for a variety of reasons, according to research subjects. Some perceived the LAIV as a second-line treatment—that is, less than the inactivated flu shot “gold standard.” Moreover, the unfamiliar intranasal route of administration contributed to people’s aversion, as did the “live” vaccine status of FluMist®. In a few instances, healthcare workers were advised against the live vaccine by their personal physicians, some of whom warned against the possibility of Guillain-Barré syndrome. The requirement that healthcare workers over the age of 49 sign a consent form acknowledging off-label administration of the vaccine made LAIV a less desirable option; FluMist® is currently licensed only for healthy people aged 5 to 49 years old. Healthcare workers who worked with high-risk patients expressed concern over evolving LAIV recommendations by CDC and hospital administrators. Why, they asked, were health professionals who worked with immunosuppressed patients advised *against* vaccination with FluMist® in the 2003–04 season lest they unintentionally spread the vaccine strain of the virus, yet guided toward this option in 2004–05?

Implications: Resistance to unfamiliar medicines, perceptions about the inferiority of an alternative drug, and skepticism about evolving recommendations may have significant repercussions for public health preparedness. Similar issues arose after the anthrax attacks of 2001 when CDC switched from recommending costly ciprofloxacin to inexpensive doxycycline as an equally efficacious prophylactic antibiotic for inhalational anthrax. Many observers viewed the change in guidelines as an illustration of healthcare inequity, not officials’ best judgment, because postal workers received doxycycline while Capitol Hill employees received the “gold standard,” ciprofloxacin.^{37,38} Reliance on “alternative” drugs as a backup to treatments already recognized by the public should be reconsidered in light of this increasingly familiar experience, and steps should be taken proactively to educate potential recipients in advance of its being offered.

STUDY LIMITATIONS

This study has a number of limitations despite conscious design to capture broad experiences of acute scarcity conditions in a single health system and region. Very few health professionals from non-UPMC hospitals not experiencing an acute shortage were interviewed. Similarly, a comprehensive survey of all UPMC affiliates and their chains of authority was not possible. In addition, first-person accounts were not obtained from patients or nonsupervisory employees (e.g., floor nurses, receptionists). More diverse opinions regarding the shortage and its management are very likely. Interviews also took place as the health event was unfolding, providing some subjects more opportunity for retrospection than others.

Observations from this case study—a particular pathogen in a particular health system—may not be readily generalized to other contexts. While local health leaders had to tailor prioritization criteria according to their supplies, generic at-risk criteria for influenza did exist. The “flu” is a familiar illness, to which only a portion of the U.S. population feel especially vulnerable. Public health emergencies (e.g., pandemic influenza) that involve an agent that is novel, that is potentially lethal to broad categories of people, and/or that does not have a comparable scientific base may demand even greater transparency in decision making and efforts to incorporate a range of medical perspectives. UPMC is a well-integrated medical community that relies heavily on advanced information systems that permit effective management and coordination among constituent facilities. It strives toward delivery of systemwide service lines such as behavioral health, pediatrics, women’s care, and cancer treatment.

CONCLUSION

Thoughtfully reasoned rationing criteria are no substitute for a stable influenza vaccine supply at the outset of the season. Practical and ethical challenges posed by the 2004–05 influenza vaccine shortage existed at the local level of healthcare delivery (“What is the most rational and fair use of scarce medical resources?”) and at the societal level (“What constitutes an adequate vaccine production and distribution system to meet public health needs, and who is responsible for it?”). The latter issue has been subject to long and continuing debate.^{39,40} The case study presented here, however, reconfirms key management principles of public health preparedness, many of which were also revealed during the anthrax attacks, the SARS outbreak, and other past events.

Local management, planning, and decision making truly matter. In a national or regional health crisis (including an acute vaccine shortage), federal authorities will continue to defer to local prerogatives when it comes to public health. Local health officials, as well as hospitals, private practitioners, and other providers, need to be prepared—and authorized—to accept this collective responsibility. For the UPMC influenza task force, effective decision making stemmed from open and deliberative analysis supported by “the right set” of experts who were part of a close-knit network of professionals in the community. This preexisting reservoir of expertise and interrelationships is an essential, although often less tangible ingredient of public health preparedness. Cooperation and vertical integration among federal, state, and local public health authorities and medical systems also proved valuable during the flu vaccine shortage; however, these links remain weak and seldom used.

Local medical and public health leaders also must be prepared to wrestle with complex policy decisions that have scientific, social, ethical, and legal dimensions. The fair and rational distribution of a scarce medical resource requires a dynamic balancing of patient risk, treatment availability, distribution logistics, and community sensibilities. Such decision making, as the flu vaccine shortage aptly demonstrated, must often be made with incomplete knowledge and under rapidly changing conditions. Issues of mass vaccination as well as prioritized access to care in a public health emergency can benefit from pre-crisis analysis, deliberation, and planning.

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