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Influenza Vaccine: Who Buys It and Who Sells It

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CONTENTS

LIST OF FIGURES

This issue brief is one of five produced for the Assistant Secretary for Planning and Evaluation (ASPE) by RTI International. The contents of these briefs is based on research involving a review of literature including peer-reviewed journals, media reports, and other nonreferenced sources (including those identified using the World Wide Web search engine Google) as well as confidential interviews with 30 key informants representing influenza vaccine manufacturers, wholesalers, community immunizers, state and local public health officials, and other experts. The other briefs in the series are

- *Influenza Vaccine Economics*
- *Influenza Vaccine Manufacturing*
- *Influenza Vaccine Demand: The Chicken and the Egg*
- *Influenza Vaccine Overview: Summary and Assessment*.

This issue brief was written by Christine Layton, PhD, MPH and Nathan West, MPA.

INFLUENZA VACCINE: WHO BUYS IT AND WHO SELLS IT

ISSUE BRIEF

1. Introduction

The process by which influenza vaccine is purchased and distributed is highly complex and unlike that of other vaccines, which lack seasonality. Influenza vaccine purchase and distribution involves numerous entities and different channels, many of which are little understood outside the vaccine industry. This issue brief summarizes the process and provides a more in-depth understanding of the challenges and potential solutions for facilitating an influenza vaccine purchase and distribution system whose goal is to protect the public's health.

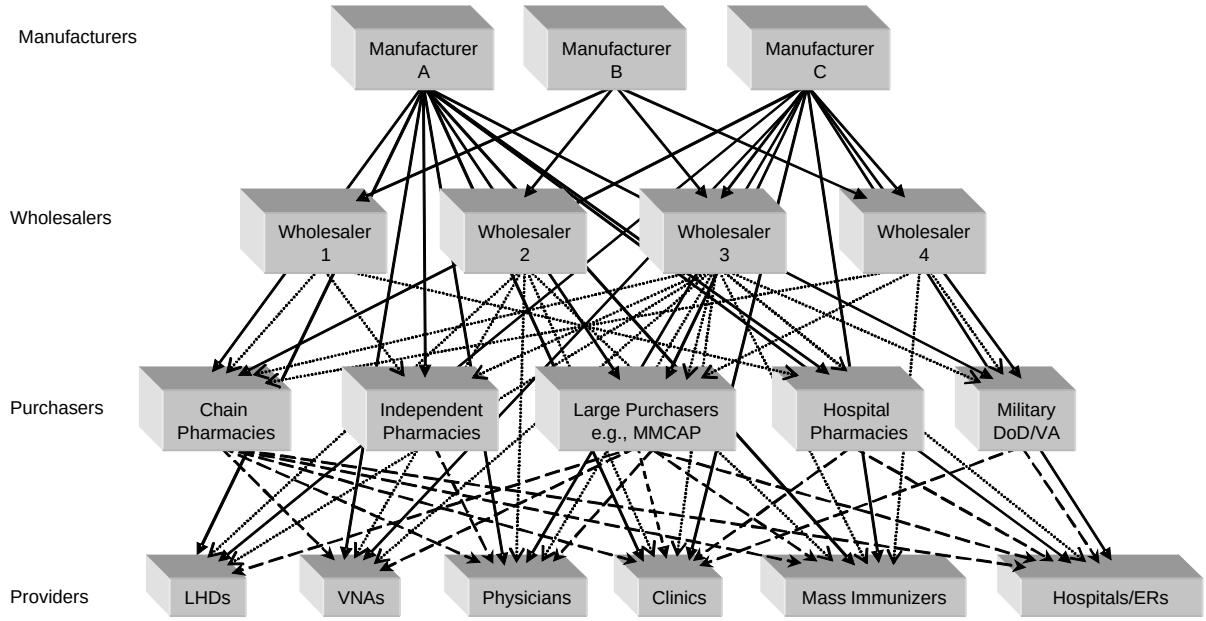
Key issues of influenza vaccine purchase and distribution include

- multiple means of purchase. Influenza vaccine is purchased by numerous entities including providers and distributors—including the federal and state governments.
- multiple means of distribution. Wholesalers include medical-surgical distributors, pharmaceutical distributors, and redistributors.
- vulnerabilities inherent in the current supply chain. Many wholesalers are so concerned about the problems created by an unreliable influenza vaccine supply that they question their continued role in influenza vaccine distribution.
- the link between sellers, buyers, demand, and supply. Influenza vaccine purchase, distribution, demand, and supply are all interrelated and associated with financial risks that are unique to influenza vaccine.

2. Who Buys Influenza Vaccine?

Influenza vaccine is purchased by various entities that can be categorized in a number of ways. Figure 1 depicts the complexity and varying levels of interconnectedness among vaccine manufacturers, sellers (wholesalers), buyers, and immunization providers. Some of these entities overlap in that they may serve a dual role. For instance, immunization providers may buy vaccines directly from manufacturers, so they are both purchasers and immunization providers. For the purposes of this issue brief, purchasers fall into three broad categories: (1) wholesalers, (2) immunization providers, and (3) companies/agencies, including state and federal governments, that purchase large quantities and may redistribute vaccine to providers.

Figure 1. Schematic of Influenza Vaccine Distribution Pathways



DoD = U.S. Department of Defense; ERs = emergency rooms; LHDs = local health departments; MMCAP = Minnesota Multi-State Contracting Alliance for Pharmacy; VA = U.S. Department of Veterans Affairs; VNAs = Visiting Nurse Associations

2.1 Wholesalers

According to the Health Industry Distributors Association (2005), the 2005–2006 influenza season has 26 wholesalers selling influenza vaccine. Although a few wholesalers specialize, most offer a broad array of products. Wholesalers include medical-surgical (med-surg) and pharmaceutical distributors, as well as redistributors. Med-surg distributors are organizations that provide everything from "bandages to wheelchairs" to health care providers. They generally have sales representatives that develop relationships with physician offices, clinics, and larger health care facilities and sell all the supplies a health care provider needs. Overall, med-surg distributors generally do not offer pharmaceuticals, but some elect to offer influenza vaccine as a convenience to their customers.

Pharmaceutical distributors generally sell influenza vaccine to pharmacies. These pharmacies include chain pharmacies (including those located in large retail stores), independent pharmacies, and those located in hospitals and clinics. Because physicians and other health care providers cannot directly dispense drugs, pharmaceutical distributors do not generally provide them with influenza vaccine.[1]

[1] Vaccines are in a regulatory grey zone. Although vaccines are regulated as drugs, they cannot be administered without a syringe or other device (such as the one used with vaccines administered intranasally). Devices are

In addition to wholesalers, redistributors buy influenza vaccine from med-surg or pharmaceutical distributors and then sell it to others in the supply chain (including other wholesalers or redistributors). The number of redistributors is unknown. By definition, any entity (organization or individual) that purchases vaccine from one source and sells it to another is a redistributor. As such, the definition of what constitutes a redistributor is not straightforward. Often, redistributors are portrayed in a negative light. For example, past claims of "price gouging" in times of vaccine shortage usually have been attributed to redistributors. Meanwhile, some redistributors are merely reallocating vaccine from areas where supply is abundant to areas in need.

2.2 Immunization Providers

Immunization providers include a broad array of entities that directly or indirectly assure the administration of influenza vaccine to individuals. In general, providers may buy influenza vaccine directly from vaccine manufacturers or distributors (or both). Providers include traditional (physicians' offices and clinics) and nontraditional (community) immunizers. Here, we focus on four types of providers that buy influenza vaccine directly from the manufacturer: (1) private health care providers, (2) community immunizers (3) large purchasers, and (4) health departments.

2.2.1 Private Health Care Providers

Private health care providers include physicians in private practice as well as those in small clinics. Depending on which vaccine they buy, private providers may buy vaccine directly from a manufacturer or a wholesaler. One manufacturer of inactivated vaccine sells nearly all of its vaccine directly to immunization providers. Other manufacturers sell their influenza vaccines to wholesalers who, in turn, sell vaccine to providers and purchasers.

2.2.2 Community Immunizers

Community immunizers include all of those within the community that administer immunizations outside the traditional doctor's office or other clinical setting. Community immunizers include so-called "mass immunizers," local Visiting Nurse Associations (VNAs), and local health departments (LHDs).[2] In general, community immunizers can be characterized as organizations that have contracts with other organizations, most notably retailers and large

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regulated separately from drugs. This regulatory issue explains why device (med-surg) distributors may sell vaccine despite the fact that it is a drug.

[2] Although "local health departments" is a commonly understood term, it is important to recognize that as the public health infrastructure varies around the United States, other agencies provide essential public health services. In some areas, hospitals, VNAs, and other entities may perform the roles traditionally associated with LHDs.

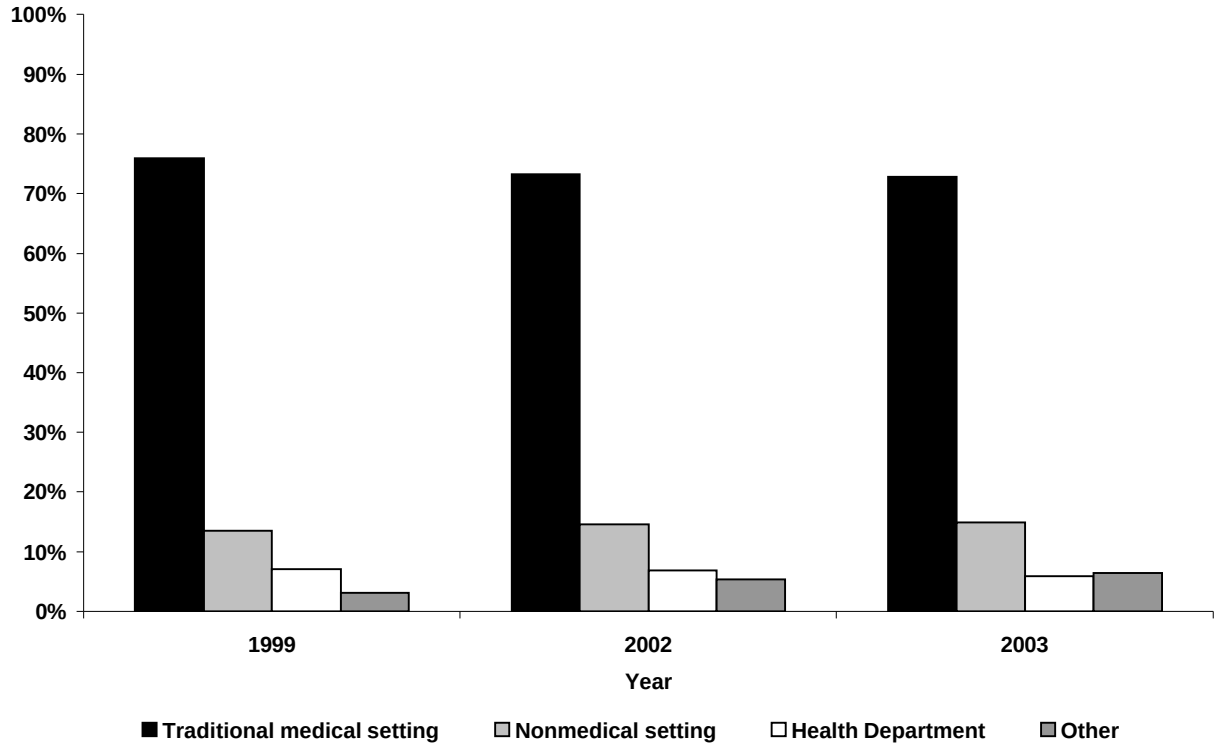
employers, to provide on-site immunization services. Community immunizers may be for-profit or not-for-profit organizations. In general, mass immunizers are for-profit organizations, whereas VNAs are not-for-profit. Some community immunizers' clinics provide only influenza vaccines; however, many also offer pneumococcal vaccine. Moreover, some mass immunizers provide other wellness services such as hypertension or diabetes screenings.

The Centers for Medicare & Medicaid Services (CMS) relies heavily on community immunizers to reach the elderly Medicare population. Many community immunizers receive reimbursement through CMS for immunizing Medicare beneficiaries so long as they accept Medicare assignment (Centers for Medicare & Medicaid Services [CMS], 2005). There is no reliable estimate regarding how many community immunizers are providing services in the United States. Mass immunizers include large, for-profit firms as well as some not-for-profit organizations such as the VNAs, which are focused primarily on providing in-home nursing care and are among the best established community immunizers (CMS, 2002).

Delivering immunization services in nontraditional settings (e.g., retail stores and workplaces) is becoming more common. Figure 2 shows that although vaccines are predominately administered in traditional medical settings (e.g., private doctor's offices, hospitals, and clinics) the proportion of those 65 years of age and older receiving influenza vaccine in nontraditional settings is rising. In 2003, almost three-quarters of influenza vaccines were administered in traditional medical settings. A smaller proportion of vaccines, about 22 percent, were administered in nonmedical settings. Only seven percent of vaccines were administered in a health department. Although these proportions remained steady between 1999 and 2002, the proportion of vaccines administered in nonmedical settings increased for 2003. While a formal analysis has not explained the shift toward nontraditional providers, our research suggests this is likely due to a number of factors including private physicians' growing reluctance to offer influenza vaccine due to economic and administrative burdens. Moreover, as mass immunizers increase their efforts to offer their services in the community, the public is likely to take advantage of the convenience.

Large purchasers are entities that purchase in sufficient volume to potentially obtain a discount. Health departments, including both state and local health departments, may sponsor their own immunization clinics (thus serving as community immunizers) as well as redistribute vaccine to local providers.

Figure 2. Site of Vaccination of Persons 65 Years of Age and Older



Source: Compiled from Behavioral Risk Factor Surveillance System survey data (Centers for Disease Control and Prevention [CDC], 1999, 2002, 2003).

2.3 State and Federal Governments

Numerous federal and state agencies and programs purchase vaccines directly. The Vaccines for Children Program (VFC), a federal entitlement program administered by the Centers for Disease Control and Prevention (CDC), buys Advisory Committee on Immunization Practice (ACIP)[3]-recommended childhood vaccines for eligible children. The current ACIP recommendation is for children 6 to 23 months of age to receive the influenza vaccine. Only about seven percent of influenza vaccine is purchased through VFC. The U.S. Department of Verterans Affairs (VA) and U.S. Department of Defense (DoD) are additional direct purchasers of influenza vaccine. The DoD purchases influenza vaccine to vaccinate military personnel and some civilian employees and contractors. As a primary health care provider, DoD also administers vaccines as necessary to its retirees and current personnel and their families. The VA administers vaccines to U.S. veterans who seek care in its facilities. Federal Occupational Health (FOH) is a service unit within the U.S. Department of Health and Human Services' (HHS)

[3] ACIP is a 15-member panel of experts on immunization from the fields of medicine, immunology, and public health. ACIP advises CDC and the U.S. Department of Health and Human Services and develops written recommendations for routine vaccine administration.

Program Support Center. FOH offers influenza vaccine to federal employees, and vaccines are generally administered in FOH Health Centers throughout the country (FOH, n.d.). FOH purchases influenza vaccine through the HHS Supply Service Center, which serves health care facilities of the various departments of the federal government as a source of pharmaceutical, medical, and dental supplies (D'Angelo, n.d.; Program Support Center, 2003).

Another large government purchaser of influenza vaccine is a purchasing alliance known as the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP). This is a voluntary group-purchasing organization operated by the State of Minnesota that serves government-operated health care facilities in 42 states and the City of Chicago. The purchasing group contracts with over 150 pharmaceutical manufacturers and also with wholesalers (to support the pharmaceutical contracts) for goods and services such as hospital supplies, drug testing, returned goods processing, influenza vaccine, and vials and containers. MMCAP's niche is to provide, through volume contracting and careful contract management, the best value in pharmaceuticals and related products to its members—eligible governmental health care facilities (Minnesota Multi-State Contracting Alliance for Pharmacy [MMCAP], 2005).

3. Where Does Influenza Vaccine Go?

3.1 Manufacturers

Due to a number of factors described more thoroughly in the companion brief *Influenza Vaccine Overview: Summary and Assessment*, a limited number of manufacturers produced vaccine for the 2004–2005 influenza season. Three manufacturers were licensed in the United States: Sanofi Pasteur,[4] Chiron, and MedImmune (Knight, 2005). Although Chiron has been a major producer of the influenza vaccine in recent years, only Sanofi Pasteur was able to sell inactivated influenza vaccine during the 2004–2005 influenza season because Chiron's vaccine plant in Liverpool, England, was shut down late in the production process by U.K. regulators due to contamination issues. This event complicated the purchasing and distribution process of influenza vaccine for myriad reasons.

Each vaccine manufacturer has its own method for distributing vaccines to purchasers and health care providers. Among inactivated vaccine manufacturers, Sanofi Pasteur sells the large majority of its influenza vaccine directly to purchasers and health care providers. The one wholesaler with whom they work is contractually obligated to carry no other manufacturers'

[4] In 2004, Sanofi merged with Aventis Pasteur to create the Sanofi Aventis Group. The vaccine division of the Sanofi Aventis Group changed its name to Sanofi Pasteur.

product. On the other hand, Chiron relies exclusively on wholesalers to sell its vaccines to health care providers. GlaxoSmithKline (GSK), who was recently approved by the FDA to sell influenza vaccine during the 2005–2006 influenza season, will rely on its preexisting distribution chain, which includes wholesalers. MedImmune's vaccine must remain frozen until administration.[5] Because of the complexities associated with assuring the "cold chain" from manufacturer to health care provider, MedImmune distributes most of its vaccine directly.

3.2 Wholesalers

In addition to all of the other vagaries of the influenza vaccine purchase and distribution process is the fact that the supply chain linking the point of vaccine manufacture to the person who actually administers vaccine varies by manufacturer. As a result, the route taken by a given brand of influenza vaccine to the person vaccinated differs depending on which company made the vaccine. Manufacturers consider a number of factors when deciding whether to sell their product directly to health care providers or via wholesalers.

> *There's an issue of customer satisfaction. We need to assure that the end user has the products when they need them … There's a cost-effectiveness piece … [influenza vaccine] is a low cost product. We have to keep a keen eye on the costs associated with distribution*.

For some products there is a further consideration: "There's an overall quality issue with a cold chain. That takes a little bit more control in the distribution in the storage and packing end." In addition, "[the distribution pathway is] decided by history—you have channels already set up." The historical reasoning behind using wholesalers can also be related to corporate mergers. When one vaccine manufacturer acquired a company that included a wholesale distributor, this wholesaler became the distributor for its product.

Distributing vaccines directly has advantages and disadvantages compared to using wholesalers. One manufacturer explained that it wants to assure that, in times of vaccine shortage, it is able to assure that its vaccine is distributed to those who are most likely to follow ACIP recommendations.

> *We like to make sure that when we utilize distributors, first of all that they're solid partners—that they have a good track record, are very ethical organizations, and we know that they're going to be following the ACIP recommendations, but … a track record*

5 A second-generation live attenuated influenza vaccine (LAIV) product that will not require freezing is anticipated for the 2007–2008 season. How this product will be distributed is not clear.

of experience and the ability to partner effectively with the distributor are the principal criteria. We work with a few distributors. And contrary to popular belief, we have contracts with 12 or 14 community immunization providers. When we see that we're pretty much the largest game or the only game in town, our principal philosophy is to ensure that we're getting the vaccine into the hands of the people that get it to the priority groups.[6]

This response illustrates a key point regarding the process by which influenza vaccines are distributed: once the vaccine is in the supply chain, it is extremely difficult to know where it is going. This is relevant because in times of vaccine shortage or delay—whether nationally or in specific regions—the ability to redistribute vaccine relies on knowing where vaccine is located.

During the 2004–2005 influenza season, when Chiron's production was shut down and none of its product was able to be distributed, the United States was faced with a huge challenge to identify available undistributed vaccine from other manufacturers and assure that it was diverted to those in greatest need. This task was accomplished by unprecedented cooperation from Sanofi Pasteur, whose product was the only one approved for use in all age groups.[7] Sanofi Pasteur held the vaccine that had not yet been released for shipment prior to October 5, 2005, (when it was known that Chiron's vaccine would be unavailable that season) and worked with CDC and other partners to assure that the limited amount of vaccine would target those with at highest risk for influenza complications.

Our research suggests that one factor (among others) that contributed to the successful response to the crisis in 2004–2005 was that Sanofi Pasteur knew its customer base. Because the majority of those who purchased Sanofi Pasteur influenza vaccine were providers or purchasers who could identify those who had ordered the vaccine, Sanofi Pasteur and CDC and its partners had an easier challenge than if the manufacturer had worked exclusively with wholesalers, who may or may not have been able to identify the end users.

One of the problems … when we have a shortage is figuring out who's going to use how much vaccine and how to distribute it. … if you had some sort of a government program, you [could] begin to track where most doses are used.

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[6] Priority groups include persons 65 years of age or older, persons of any age with chronic diseases, pregnant women, children 6 to 23 months of age, health care personnel, and household contacts of previously listed groups. Target (or targeted) groups include priority groups plus healthy adults 50 to 64 years of age.

[7] MedImmune also cooperated to identify available vaccine, but as its product was approved for use only among those 5 to 49 years of age without certain health conditions; in many instances, it could not be substituted for Chiron's product.

Some vaccine wholesalers also distribute medical and surgical supplies; (i.e., med-surg companies), whereas others distribute pharmaceutical products, or both. This overlap makes it more difficult to identify the exact number of vaccine distributors in the United States because these organizations are not mutually exclusive. The national organizations that represent these wholesalers acknowledge that there is some overlap between their members. Some wholesalers specialize in serving specific types of customers. For example, some wholesalers specialize in serving hospitals, whereas others specialize in serving private physicians. Among those who specialize in serving physicians, some may target particular medical specialties (e.g., oncology practices). As such, it is possible for some wholesalers to make an "educated guess" as to whether or not a customer may be immunizing those at high risk for influenza-related complications (e.g., one may assume that a pulmonologist's patients are all at high risk for influenza-associated complications.) However, as many wholesalers resell to other wholesalers, the ability to locate influenza vaccine once it is within the wholesale supply chain is limited.

Purchasers and providers generally make decisions on how to buy their influenza vaccine based not on who is the manufacturer, but on who is their sales representative for supplies in general. As one key informant explained,

> *It's not like they understand who bought what from whom. They know their reps [sales people]. They trust their reps. Their reps are people they've built relationships with. It's not like they sit there and say, 'This person's with this company.' They build personal relationships with these people.*

4. Challenges and Solutions

4.1 Challenges

The primary challenge to the supply chain is how to balance the potential financial liability of unused (and thus unpaid for) vaccine with the desire to provide influenza vaccine to those who need it. Influenza vaccine is unlike other vaccines (or health care products) in that (1) it has an extremely short sales period (traditionally October through December for the current influenza season) and (2) it cannot be returned once purchased. Another great challenge to the supply chain is the uncertainty of demand from one influenza season to another. Although demand has grown in response to public policies, it still fluctuates from year to year, depending on many factors that are difficult to predict and almost impossible to control. Vaccine manufacturers cannot predict when outbreaks will occur in an influenza season, or how severe these outbreaks will be. These challenges put the entire system at financial risk since vaccine production is very expensive and seasonal demand is unpredictable.

From the wholesalers' perspective, they carry the largest risk in the vaccine supply system. This is particularly true for distributors who prepurchase vaccines from manufacturers before the actual demand of the vaccine is known. This problem has led some wholesalers to discuss no longer selling influenza vaccine at all.

The greatest challenge to the influenza distribution process is the ability to track influenza vaccine through the supply chain. At the present time, the only means to track influenza vaccine once it has left the manufacturer is by using information regarding who has prebooked vaccine (i.e., client lists). Prebooking is used by purchasers and providers to, in essence, "reserve" influenza vaccine months before the influenza season. Prebooking, which is unique to the influenza vaccine market, generally occurs the spring before a given influenza season. Because influenza vaccine is sellable for such a short period, manufacturers rely on prebooking to calculate how much vaccine to make in a given year. In turn, wholesalers also rely on their own prebooking numbers to predict how much to order from manufacturers.

Policies concerning prebooking have varied from season to season. For example, CDC and ACIP adopted a two-tiered vaccine prebooking plan for the 2005–2006 influenza season (CDC, 2005). This prebooking plan is intended to prevent the vaccine supply problems encountered during the past influenza season. CDC is encouraging health care professionals and vaccine manufacturers and distributors to submit prebooking orders for inactivated influenza vaccine in two parts: (1) doses needed based on anticipated demand by persons in priority groups and (2) doses needed based on anticipated total demand. The new policy encourages distribution of vaccine in partial shipments, starting with doses allocated for priority patients. However, one should keep in mind that wholesalers are not in a position to know who will be adhering to ACIP recommendations, "[wholesalers] can't police that in terms of who's high risk. We as a distributor can't make that decision."

The information collected in the prebooking process is essentially client lists. Because client lists are proprietary, manufacturers are under no obligation to share this information. As such, in times of shortage manufacturers may elect to sell their influenza vaccine to whomever they choose. This past season showed a good example of manufacturers coming forth with their client lists, but this is a voluntary process that is vulnerable to the whims of the vaccine manufacturers.

4.2 Solutions

4.2.1 Improve Vaccine Supply

Distributors with whom we spoke expressed the belief that a first step to improve supply is to have more manufacturers willing to produce an influenza vaccine. As one wholesaler explained, “There needs to be more manufacturers involved in the process, because it gives people more of a sense of security that there will be vaccine actually available, more standardization in the sense that there’s a supply that will go around.”

Additional manufacturers would give providers more choice and would likely increase confidence among the public that vaccine is available when needed. Having more than two manufacturers will give providers and ultimately the public more of a sense of security that vaccines will be available as the need arises. Although additional vaccine supply could theoretically be achieved by existing manufacturers increasing their current capacity, such an approach would not resolve the threat to vaccine supply from production problems. When a problem with production occurs, it generally affects all of a manufacturers’ supply.

4.2.2 Improve Uniformity of Distribution and Vaccine Tracking

An additional solution to the challenges faced by the influenza vaccine supply chain is improving its uniformity and standardization. Presently, different influenza vaccines are distributed to purchasers and providers in a variety of means. Although this approach has been acceptable, it does not offer a means to track influenza vaccine in the supply chain. When influenza vaccine is limited or delayed due to vaccine shortage or production problems, those at highest risk of influenza-related complications need to have priority in receiving the vaccine. However, the current approach has an extremely limited capacity to identify or otherwise track the location of influenza vaccine in the supply chain and where it is directed. Reallocation of influenza vaccine is extremely difficult—if not impossible—if its location and intended recipient cannot be identified easily.

The overarching challenge of influenza vaccine distribution is the means to track the vaccine once it is in the supply chain. In times of vaccine shortage or maldistribution, it is necessary to know where vaccine is in the supply chain in order to redirect it to priority groups. Key informants agreed that—under ordinary circumstances—vaccine distribution should remain in the private sector. However, nearly all key informants believed that the federal government ought to play a sizable role in time of vaccine shortage. The 2004–2005 influenza shortage was an example of a situation in which CDC, Sanofi Pasteur (the sole inactivated vaccine manufacturer), and other partners worked together to assure that available influenza vaccine was

redirected to priority groups. Despite the ultimate success of their efforts, the approach was not necessarily reproducible—nor does it appear that those involved desire to adopt that approach again.

One readily available way to track influenza vaccine once it is in the supply chain is for manufacturers and wholesalers to share their prebooking information with public health officials, so the information is readily available in case of vaccine shortage or maldistribution. While this is being done on a voluntary basis during the 2005–2006 influenza season, it would be helpful for public health officials to be able to rely on these data being available, rather than hope that manufacturers and distributors will provide this information on a voluntary basis. Although this approach is not without its limitations, it does let public health officials use information already collected to redirect vaccine in times of vaccine shortage or maldistribution.

4.2.3 Improve Infrastructure

Former director of CDC's National Immunization Program, Walter Orenstein, and colleagues argue that the present vaccine delivery system has been more successful in protecting children than adults. They attribute this disparity in part to the fact that adult vaccines, such as influenza or pneumococcal vaccine, while effective, are not as effective as other vaccines used in children, and the vaccine delivery system fails to reach adult target populations (Orenstein, Douglas, Rodewald, & Hinman, 2005). For example, in 2002 although more than 90 percent of children 19 to 35 months of age received recommended childhood vaccines (which did not include influenza vaccine), only 66 percent of people 65 years of age or older received an influenza vaccine (CDC, 2003).[8]

The 109th Congress has proposed legislation (S. 1527 and H.R. 3502) that would establish a new adult vaccination program using VFC as the model. The bill, known as the Vaccine Access and Supply Act, would authorize Section 317A funding to purchase vaccines recommended for (1) uninsured adults, (2) adults who are receiving care in certain public clinics and have no insurance coverage for vaccination, (3) adults who are incarcerated and have no insurance coverage for vaccination, and (4) adults vaccinated by public health departments. The adult vaccine program would be administered by states, similar to the VFC program (Vaccine Access and Supply Act, 2005).

[8] One distinction of note between influenza vaccine and pneumococcal vaccine is that influenza vaccine must be administered annually, whereas pneumococcal vaccine is necessary only every 10 years.

4.2.4 Improve Support for Public Health in General

Wholesalers with whom we spoke thought that that the vaccine supply could be improved through an enhanced public health education effort. From one wholesaler's perspective, the public needs to understand that the benefits of influenza immunization go far beyond protecting themselves to benefiting the community at large. Universal immunization benefits the public by reducing the transfer of influenza from one individual to another. Those who receive influenza vaccine, in most cases, would dramatically decrease their odds of developing influenza and potentially infecting other individuals they encounter in their lives. One manufacturer argues that "a universal recommendation that all Americans receive annual influenza vaccine will drive demand … which in turn provides the impetus on the part of vaccine manufacturers to increase their production" (Brown, 2004).

One debate currently ongoing among health care professionals, experts, and researchers is whether or not to mandate influenza vaccinations for health care workers. Despite recommendations, only 38 percent of health care workers report having received an influenza immunization (Harper, Fukuda, Uyeki, Cox, & Bridges, 2004). Health care workers may transmit influenza to those for whom they care, whether or not they have symptoms. Studies have shown that immunization of health care workers can result in reduced mortality in their patients (Carman et al., 2000) as well as reduced influenza infection and absenteeism among the health care workers themselves (Wilde et al., 1999). Challenges and unanswered questions remain as to how a mandate would be implemented and enforced, but there is consensus that such a mandate would drastically increase demand and inherently improve supply.

5. Summary

Wholesalers want policymakers to recognize three very important and distinct issues regarding the purchase and distribution of influenza vaccines:

- the complexity of influenza vaccine demand, supply, and distribution;
- the high level of financial risk for vaccine wholesalers; and
- the need to better educate the public regarding the benefits of vaccination for themselves and for the greater public good.

First, policymakers need to understand that production and distribution of influenza vaccine is unique and cannot be compared to any other type of vaccine or pharmaceutical. The complexity of the system is borne out of the immense unpredictability of demand for the vaccine; the relatively long time required for production coupled with the short season of use; and the public reaction to supply delays, shortages, or surpluses. Wholesalers understand this

complexity and recognize that solutions that will improve vaccination supply and distribution cannot be achieved solely by one entity of the system—whether manufacturers, providers, or wholesalers. Wholesalers with whom we spoke discussed the notion that influenza vaccine manufacturers need greater incentives to develop new technologies to produce the vaccine more quickly and efficiently. Furthermore, wholesalers reported the notion that the influenza vaccine distribution system could benefit from a public that is better educated regarding the importance of universal vaccination.

Second, wholesalers feel that they carry the greatest financial risk among the various entities involved in the vaccine production and supply chain. Wholesalers recognize that manufacturers carry a great financial risk producing influenza vaccines in such an unpredictable market, and this risk is transferred to the wholesalers once vaccine supplies are prebooked and sold. Additional protections are needed to reduce the risk that manufacturers, and particularly wholesalers, face in a marketplace where profit margins are lower than for other products (making influenza vaccine a less financially attractive product to produce or distribute).

Third, wholesalers see a need for the public to be better informed regarding the importance of vaccination. A more informed public would conceivably increase demand, which may in turn solve many of the vaccine supply and distribution issues. Current prebooking requirements are based on the supposition that the actual or potential supply of vaccine is limited. Greater demand and therefore greater supply will alleviate prebooking requirements and minimize shortages that make it necessary for CDC to develop a distribution strategy unique to the influenza vaccine.

6. Conclusion

The process by which influenza vaccine is purchased and distributed is highly complex with many idiosyncrasies that are unique to influenza vaccine. Such complexity creates challenges to the existing supply chain—especially in times of vaccine supply delay, shortage, or maldistribution. As the supply chains vary from one vaccine manufacturer to the next, new manufacturers entering the U.S. market may increase the number of different supply chains for influenza vaccine. However, although additional manufacturers may be beneficial in terms of increasing overall supply, additional supply chains may add more complexity to an already complicated supply chain.

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