Flu Vaccine Delivery Best Practice Analysis for Austin/Travis County Health and Human Services Department

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TABLE OF CONTENTS Page

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ABSTRACT

Influenza A virus and B virus infect human respiratory systems and may cause death if individuals contract a secondary pneumonia infection. Local health departments (LHDs) across the United States deliver flu vaccines to their community through several traditional and nontraditional delivery methods. The purpose of this project was to investigate flu vaccine delivery methods used by Austin/Travis County Health and Human Services (ATCHHSD) and other LHDs in the US and Texas during the 2011-2012 flu season. Presented here are the research findings of vaccine delivery practices among the 25 LHDs that completed the online questionnaire through Qualtrics, an online survey provider. Many similarities existed between the flu vaccine delivery systems of the 25 LHDs and ACTHHSD; both delivered vaccines through regular LHD clinics, massive flu clinics by appointment, drive-through clinics, strike teams, outreach to at-risk populations and external partnerships. They also primarily partnered with independent school districts and non-profits to deliver vaccines. They promoted their vaccine delivery through radio, television, Facebook and Twitter. The 25 LHDs and ATCHHSD cited well-trained staff as the largest factor for their self-reported rating on efficiency and effectiveness.

Many differences between the LHDs and ATCHHSD were found; the majority of the 25 LHDs did not conduct massive flu clinics, however ATCHHSD did. Those that did conduct mass clinics began conducting them in October, rather than September, like ATCHHSD. The 25 LHDs on average vaccinated more people per employee (17) than ATCHHSD (8). On average, a vaccination at a regular clinic from the 25 LHDs cost $36 per flu vaccine, while at ATCHHSD cost it $10. Twenty percent and 25% of LHDs accepted Medicare and Medicaid respectively, while 36% accepted private insurance. ATCHHSD accepted Medicare, Medicaid but no private insurance. Lastly, the throughput time of the 25 LHDs (14 minutes) was on average, lower than ATCHHSD's (20 minutes).

INTRODUCTION

History of Vaccines

The history of vaccines dates back to Louis Pasteur's microbiology discoveries, as he led the way for scientists who followed him to develop the first successful vaccines (36). Pasteur was the first to disprove spontaneous generation with thorough formal scientific experimentation, and he proposed the germ theory of fermentation. This theory proposed that all microorganisms came from other microorganisms, and microorganisms are responsible for causing most infectious diseases (36).

Prior to the nineteenth century discovery of a smallpox vaccine, the disease smallpox killed millions of people worldwide. To protect against smallpox, people in the 1700s experimented with variolation; dried smallpox scabs were blown into the nose of an individual who then contracted a mild form of the disease. Upon recovery, the individual was immune to smallpox. In contrast, in Europe, inoculation occurred through removing pus or scabs from smallpox-infected individuals and inserting them into superficial scratches in the skin of healthy individuals (7). This produced a localized infection that conferred immunity. Although two to three percent of variolated persons died from the disease, became the source of another epidemic, or suffered from diseases transmitted by the procedure itself, variolation rapidly gained popularity among both aristocratic and common people in Europe (50). Variolation improved chances of surviving smallpox significantly; 30% of individuals died when they contracted the disease naturally (50, 55).

Edward Jenner, an English country physician, was the first in the microbiological field to introduce the practice of using weakened microorganisms to elicit immunity (36). Edward Jenner observed that workers working with cattle, who were exposed to cattle rarely contracted

smallpox. In May 1796, Edward Jenner found a young dairymaid, Sarah Nelms, who had fresh cowpox lesions on her hands and arms. On May 14, 1796, using matter from Nelms' lesions, he inoculated an 8-year-old boy, James Phipps, inserting pus from a cowpox pustule into an incision on the arm (50, 19). The young boy did not contract smallpox, and remained healthy. After repeating the experiment on other children, including his own son, Jenner concluded that vaccination provided immunity to smallpox without the risks of variolation. Jenner's findings were published in 1798. These results supported his hypothesis that exposure to microorganisms could confer immunity.

Louis Pasteur applied Edward Jenner's discovery of vaccination to develop a vaccine against rabies, the first artificially weakened or attenuated vaccine (36). Pasteur used spinal cords of rabid rabbits, which were easier to handle and cheaper than dogs' spinal cords (38). Pasteur developed his rabies vaccine from partially inactivated desiccated spinal chords instead of brain tissue because the spinal cords had a higher rabies virus concentration (44). In 1885, Pasteur successfully immunized his first patient, Joseph Meister, a nine year-old boy who had been severely bitten by a rabid dog. He received thirteen inoculations of infected rabbit spinal cord over 11 days (38). Meister never developed rabies, which led Pasteur to vaccinate hundreds of other individuals bitten by rabid animals.

In 1952, Jonas Salk developed the first inactivated polio vaccine, which consisted of killed viruses. He cultured samples of each of the three types of poliovirus in monkey kidney tissue and then "cooked" them in a solution of formaldehyde to kill the viruses without destroying their immunogenicity (6, 43). In 1954, Salk tested his vaccine on over 1.8 million children across the United States. The Salk vaccine had been 60–70% effective against PV1 (poliovirus type 1) and over 90% effective against PV2 and PV3 (43). During the same time Salk

was developing his polio vaccine, Albert Sabin was experimenting with his own live-attenuated polio vaccine. He eventually found three mutant strains of the virus that differed from the three virulent polio viruses by 57, 2, and 10 nucleotides, respectively (43). In 1958, the National Institutes of Health chose Sabin's vaccine for worldwide distribution after it was tested on monkeys and later on 10 million children in the Soviet Union (43). The vaccine successfully stimulated antibody production without causing paralysis. Sabin's live-virus, oral polio vaccine (administered in drops or on a sugar cube) soon replaced Salk's killed-virus, injectable vaccine in many parts of the world. The Sabin vaccine caused an active infection of the bowel that resulted in the excretion of live-attenuated virus. Thus, those who came in contact with fecal matter from vaccinated individuals could acquire immunity even if they had not been vaccinated (12). Both the dead and live attenuated poliovirus vaccines are still used today, and polio is endemic in only three countries: Nigeria, Pakistan and Afghanistan (20).

The successful introduction and widespread use of vaccines has resulted in dramatic reductions in the incidence of many infectious diseases. In the United States (US), immunization coverage levels among children are at all-time highs, and reported vaccine-preventable disease levels are at or near all-time lows, with the exception of pertussis (29). There have been no cases of paralysis due to indigenously acquired wild poliovirus since 1979, and indigenous transmission of rubella has been interrupted. With additional vaccine research and development, the transmission of several other communicable diseases could decrease in the future.

Immunity

Vaccines work by exposing the human immune system to a pathogen and priming it so that in future cases of exposure, an adaptive immune response is triggered, and the person avoids disease. Innate and adaptive immunity work together to destroy foreign pathogens. Upon

exposure to a pathogen, the innate system is immediately triggered. This system consists of physical and chemical barriers, the inflammatory response, the complement system, and phagocytic immune cells. The innate immune system recognizes microbial-associated molecular patterns (MAMP) on the surface of pathogens and recruits macrophages, complement proteins and other immune cells, which help destroy the pathogen. Cytokines, small cell-signaling peptides secreted by nucleated cells, recruit more macrophages to the area, activating the immune response and amplifying the complement system, a cascade of binding and/or proteolytic proteins (36).

In cases when the innate immune response is unable to contain the infection, the highly specific adaptive immune response is activated to destroy pathogens and to prepare for future exposure to the same microorganism (40). Later exposure to the same foreign organism induces an anamnestic response, characterized by a more rapid and strong response to eliminate the pathogen. The adaptive immune system requires cooperation between T and B lymphocytes and antigen-presenting cells (40). It may take up to two weeks to mount a fully effective response.

Vaccine Types and Immunization

There are several types of vaccines that are able to trigger the adaptive immune response. The four most common are inactivated, live attenuated, subunit and toxoid vaccines. All are designed to elicit an immune response in the host to prevent the possibility of future diseases. Inactivated vaccines contain killed microorganisms, and they elicit an immune response without risk of illness (9). Scientists produce inactivated vaccines by killing the disease-causing microbe with chemicals, heat, or radiation. Such vaccines are more stable and safer than live vaccines because the inactivated microbes cannot mutate back and cause disease. Other advantages of inactivated vaccines is that they usually do not require refrigeration, and they can

be easily stored and transported in a freeze-dried form, which makes them accessible to people in developing countries (49). In many cases, the administration of additional doses, or booster shots, to induce and maintain an effective immune response, is required (20). Multiple injections could be a drawback in areas where people do not have regular access to health care and cannot get booster shots on time. (49). Currently available whole-cell inactivated vaccines are limited to inactivated whole viral vaccines (polio, hepatitis A, and rabies).

Live attenuated vaccines contain a version of the living microbe that has been weakened so it cannot cause disease. Because a live, attenuated vaccine closely mirrors a natural infection, these vaccines are good "teachers" of the immune system. That is, they elicit strong cellular and humoral immune responses, and often confer lifelong immunity with only one or two doses. Despite these advantages, the living microorganisms in live attenuated vaccines can mutate back and revert to a virulent form, causing disease.

Subunit vaccines, like Hepatitis B, consist of purified components of an infectious agent, not entire microorganisms. These vaccines include only the antigens that best stimulate the immune system. In some cases, subunit vaccines use epitopes, specific parts of the antigen that bind to the receptors of B or T cells, triggering an immune response (NIAD). Because these vaccines contain only the essential antigens and not all the other molecules that make up the microbe, the chances of adverse reactions to the vaccine are lower. However, they usually elicit a weaker immune response, so multiple doses are required (boosters) to increase immunity.

A fourth type of vaccines, toxoid vaccines, consist of inactivated toxins that under normal circumstances cause disease. Toxins are often inactivated by heat treatment or formalin, a solution of formaldehyde and sterilized water (NIAD). Vaccines against tetanus and diphtheria are examples of toxoid vaccines. There are three principal advantages of toxoid

vaccines. First, they are safe because they cannot cause the disease they are designed to prevent and there is no possibility of reversion to virulence. Second, because the vaccine antigens are not actively multiplying, they cannot spread to unimmunized individuals. Third, they are usually stable and long lasting, as they are less susceptible to changes in temperature, humidity and light (10). Toxoid vaccines have two disadvantages. They usually need an adjuvant, an organic or inorganic chemical that enhances immune response to an antigen, and they often require multiple doses for the reasons discussed above. Second, local reactions at the vaccine site are more common. The reaction results from excess antibody at the site complexing with toxoid molecules and activating complement by the classical pathway, causing an acute local inflammatory reaction (10).

As made clear by Jenner's work demonstrating that cowpox exposure conferred smallpox immunity, cross-protection against microorganisms can occur. Immunization against one microbe can protect against a second if two proteins critical to the pathogenesis of the two different microorganisms share key antigenic determinants (36). Today's HPV vaccines protect against strains of human papillomavirus (HPV) that are responsible for 70% of cervical cancers. Boily and co-investigators (11) showed that it is not necessary to include the other 30% of HPV strains that cause cervical cancer because of cross-protection.

The Centers for Disease Control and Prevention (CDC) recommends routine vaccination to prevent seventeen vaccine-preventable diseases that occur in infants, children, adolescents, or adults. The Advisory Committee on Immunization Practices (ACIP) revises these recommendations every three to five years (See Appendices A and B for the 2013 immunization schedules) (20). ACIP's report provides information for clinicians and other health-care providers about concerns that commonly arise when vaccinating persons of various

ages. The recommendations given are based not only on available scientific evidence, but also on expertise that comes directly from a diverse group of health-care providers and public health officials (20). The CDC does not recommend vaccination before two months of age because maternal antibodies cross the placenta and provide protection during those early months of life (36).

Contrary to common popular belief, most vaccines are safe and have few side effects (9). The risk of acquiring most infectious diseases and having permanent sequelae from an infectious disease is far greater than the side effects from vaccines. Common reactions to vaccines include fever, soreness at injection site, and general malaise. While many have tried to link administration of the measles, mumps, rubella (MMR) vaccine with autism, there is no connection (2, 5).

Influenza Viruses

Influenza viruses are members of the *Orthomyxoviridae* family, and their morphology is unique to this family of viruses. Morphologically, they may appear as spherical or tubular forms and have a diameter ranging from 80 to 120 nm with a pleomorphic shape (See Figure 1). A lipid envelope protects the protein capsid, which encases the genome of the virus.

Influenza viruses are classified into three types, A, B, and C, and are based on their nucleoprotein and matrix proteins. Only influenza A and B are pathogenic for humans (25). These viruses are subtyped based on two cell surface glycoproteins, hemagglutinin (HA) and neuraminidase (NA). The viral envelope, which surrounds the virion and is internally linked by the matrix protein, contains HA and NA (46). The HA serves several functions; it is the viral attachment protein which binds to sialic acid on epithelial cell receptors, and it promotes fusion of the envelope to the cell membrane. The NA glycoprotein cleaves the bond between sialic acid

and the cell receptor, preventing viral clumping and facilitating the release of virus from infected cells (46). To date, 16 HA subtypes and 9 NA subtypes have been identified. However since the twentieth century, only three HA subtypes (H1, H2, H3) and two NA subtypes (N1 and N2) have circulated in humans (Brammer). The genomes of influenza viruses consist of eight different segmented, linear negative-sense RNA strands and are associated with RNA polymerase and the nucleoprotein (58).

Viral Multiplication Cycle

The multiplication cycle of influenza viruses involves several steps that include transport of genomic material to different cellular components (Figure 2). When the HA envelope protein binds to a cell receptor that contains sialic acid as a terminating sequence, the virus fuses with the cell's endosomal membrane and enters the cell, where it releases its genome and several enzymes and structural proteins into the cell cytoplasm (37). The viral ribonucleoproteins (vRNPs) are released and then transported into the nucleus. In the nucleus, the vRNPs serve as templates for the production of two forms of positive-sense RNA: viral messenger RNA (mRNA) and complementary RNA (cRNA). The synthesis of mRNA is catalyzed by the viral RNA-dependent RNA polymerase, which is part of the incoming vRNP complex. Viral mRNAs are capped, polyadenylated and exported from the nucleus for translation by cytoplasmic ribosomes. The viral cRNA is neither capped nor polyadenylated, but, instead, is a perfect copy of the template. These cRNAs then form the template for synthesis of further negative-sense genomic vRNA segments for amplification of mRNA synthesis and packaging into progeny virions. The progeny virions buds selectively from the apical surface of the cell and is released approximately eight hours after infection (46).

Antigenic Variation

Mutations in HA and NA can lead to antigenic shift or drift, producing different strains of influenza virus that circulate within a population. Mutations in HA and NA are responsible for minor antigenic changes, known as antigenic drift (46). Antigenic drift occurs when the genes for HA and NA undergo stepwise mutation due to the low fidelity of the RNA-dependent RNA polymerase (59). Eventually, these mutated proteins become so different from prevailing antibodies present in the human population that they are unable to neutralize the virus, causing illness. These changes are responsible for seasonal influenza outbreaks.

Antigenic shift occurs when two different strains of influenza virus co-infect the same cell and combine form a new subtype with surface antigens from two or more original influenza strains (36). This antigenic shift results in extreme pathogenicity that can ultimately lead to a pandemic like H1N1 in 2009 the necessary antibodies to launch an immune response are not present within the population (1). Three influenza pandemics occurred in the twentieth century, with two falling after the 1950s (33). The "Spanish flu" (H1N1) of 1918 was the deadliest, killing over 500,000 people in the US and 20 to 50 million worldwide (47).

Influenza Surveillance

On a national level, the Epidemiology and Prevention Branch at CDC collects and compiles virological, outpatient illness, mortality, and hospitalization surveillances (20). State health departments report the estimated level of geographic spread of influenza activity in their states each week. This information serves as syndromic surveillance and is used to provide a national picture of influenza activity.

Under Texas law, health care providers, hospitals, laboratories, schools, and others are required to report cases of nearly 80 different diseases, including influenza, to local and state

health officials (54). The Austin Epidemiology and Health Statistics Unit receives influenza case reports and investigates the prevalence of disease within the city and reports it to the Texas Department of State Health Services, which releases a weekly *Texas Influenza Surveillance Report* to the public (8).

Surveillance teams also are using social media to monitor the spread of influenza. In November 2013, CDC launched the "Predict the Influenza Flu Challenge," which awarded $75,000 to a person who most successfully predicted the timing, peak and intensity of the 2013-2014 flu season using social media data (17). Broniatowski and co-researchers (16) developed an algorithm that detected relevant "flu tweets" and predicted changes in influenza prevalence with 85% accuracy and were strongly correlated to the CDC's surveillance data. In the past, flu surveillance has been restricted to public health officials, but now the general public can utilize resources to detect influenza patterns and predict the spread of disease (32). Social media can quickly detect flu patterns, while traditional surveillance relies on hospitals and healthcare providers to send in information on influenza numbers, which may take several days.

Flu season generally begins in September and ends in June, with peak incidence rates in January and February (20). The "peak month of flu activity" is the month with the highest percentage of respiratory specimens testing positive for influenza virus infection (19). From 1982 to 2013, flu activity most often peaked in February. This year, as of January 4, 2014, 35 US states had reported widespread prevalence of influenza, 12 had reported regional prevalence, and 3 reported local prevalence (19). Texas consistently reports widespread prevalence each year, including this year. Influenza epidemics nearly always occur during the winter in temperate climates, although the significance of this is not fully understood. Cold, damp conditions may favor virus survival outside the host airway, and there may be behavioral influences like people

spending more time indoors with others (59). An exception to this general pattern occurred in 2009 when the H1N1 influenza virus emerged. The US experienced its first wave of H1N1 in early spring and infection peaked in October of 2009 and declined quickly in January (19).

Epidemiology

Influenza is spread through airborne transmission from person to person and is extremely contagious. Individuals can spread influenza up to six feet away from each other (19). Less often, a person may get the flu by touching inanimate objects contaminated with influenza viruses and then touching their eyes, nose or mouth. Individuals with the flu can infect others one day before symptoms begin and up to five to seven days after becoming ill (19). Symptoms begin one to four days after the virus enters a person's body.

It is clear that certain groups of people are more susceptible to serious influenza infection and should be vaccinated yearly. High risk groups, identified by the CDC, include pregnant women, children under the age of five, adults over the age of 65 and individuals with certain medical conditions like asthma, diabetes, and chronic lung disease be vaccinated (20). Individuals who are regularly in contact with those who are sick and healthcare workers should also be vaccinated every year (20). An exception to the age of high-risk groups appeared during the H1N1 epidemic in 2009. 80% of H1N1 deaths were individuals younger than 65 years of age (26). While these high-risk groups are especially encouraged to get vaccinated every year, the CDC recommends yearly flu vaccination for anyone who is at least six months of age (20).

Economic Costs of Influenza

Public health initiatives to prevent influenza infection through vaccination primarily exist because of the significant morbidity and mortality of the disease. In addition to the health risks of contracting influenza, the economic and health costs expended to treat influenza also are high. A

2007 CDC study estimated the annual economic burden of influenza epidemics, an estimate necessary to effectively guide policy making. Using available epidemiological data, the study found that annual influenza epidemics resulted in an average of 610,660 life-years lost, 3.1 million hospitalized days, and 31.4 million outpatient visits. Direct medical costs averaged $10.4 billion annually. Projected lost earnings due to illness and loss of life amounted to $16.3 billion annually (15). The total economic burden of annual influenza epidemics using projected statistical life values amounted to $87.1 billion (15). These results highlight the enormous annual burden on influenza not only for hospitalization in treatment, but also lost productivity from missed workdays and lives lost.

Clinical Symptoms of Influenza

Although different strains are present each flu season, infected hosts typically display the same symptoms. Acute influenza disease is characterized by abrupt onset of symptoms that include fever, chills, sore throat, cough, headache, malaise, myalgia, anorexia and other non-specific symptoms (59). Seasonal influenza is usually diagnosed 60-70% of the time when the symptoms coincide with known influenza activity (59). Children younger than the age of five, adults 65 years and older, pregnant women and immunocomprised individuals are at high risk for developing flu complications like pneumonia, bronchitis, sinus infections, ear infections, and neurological pathologies found mainly in children (20). Although rare, the most common neurological complications are seizures and encephalopathy (31). Deaths associated with flu are not usually attributed to influenza infection, but rather most are caused by viral or bacterial pneumonia, secondary to influenza infection (59).

Rapid Diagnosis of Influenza

Rapid influenza diagnostic tests (RIDT) are the recommended detection test for influenza because they take only fifteen minutes to determine the diagnosis and can be easily done in a healthcare setting (57). Patients with flu symptoms should receive the test within three to four days from the onset of symptoms. Specimen of choice are nasopharyngeal specimens, as they are typically more effective than throat swab specimens. RIDTs detect specific influenza viral antigens in respiratory specimens of infected people (57). A color change or other optical signal indicates the presence of viral antigens. The most common antigen target in commercially available pan-influenza6, influenza A, influenza B, or combination influenza A and B tests is nucleoprotein (NP) antigen (57). A dye-labeled antibody specific for the target antigen is located on the lower half of a nitrocellulose strip (See Figure 3). Antibody, also specific for the target antigen, is bound to the strip on a thin (test) line and antigen is bound to the control line (57). Respiratory specimen and buffer, which have been placed on the strip or the well, are mixed with the labeled antibody and are drawn up the strip across the lines of bound antibody. If labeled antibody is trapped on the test line this means antigen is present, signaling a positive test. Labeled antibody is trapped on the control line in both positive and negative tests.

Some RIDTs cannot differentiate between influenza A or B subtypes. Most commercially available RIDTs cannot specifically differentiate between pandemic influenza A (H1N1) virus and seasonal influenza A viruses (57), which makes monitoring the prevalence of strains of influenza in a healthcare setting unfeasible. The sensitivity of RIDTs is alarmingly 50-70%, which has stirred some debate among clinicians using these tests to diagnose flu (57).

The definitive method of diagnosis of influenza is culture by throat swabs. This test is usually performed in state health department laboratories. Reports of the prevailing types and subtypes are then sent to the CDC, which monitors circulating strains (21).

Antiviral Treatment

If rapid influenza diagnostic tests show positive for influenza, patients are prescribed antiviral drugs. Four licensed prescription influenza antiviral agents are available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir.

Amantadine and rimantadine are related antiviral drugs in a class of medications known as adamantanes. The mechanism of Amantadine's antiviral activity involves interference with a viral protein-selective ion channel, M2, which is required for the viral particle to become "uncoated" once it is taken inside a cell by endocytosis (45). These medications are active against influenza A viruses but not influenza B viruses. In recent years, widespread adamantane resistance among influenza A (H3N2) virus strains has made this class of medications less useful clinically. In addition, circulating 2009 H1N1 virus strains are resistant to adamantanes. Therefore, amantadine and rimantadine are not recommended for antiviral treatment or chemoprophylaxis of currently circulating influenza A virus strains.

Zanamivir and oseltamivir are related antiviral medications in a class of medications known as neuraminidase inhibitors, which targets the NA protein in the viral envelope (46). These two medications are active against both influenza A and B viruses. Zanamavir is not approved for use in children under the age of five, the dosage depends on age and is administered through oral inhalation. Oseltamavir is approved for all ages, dosage depends on patient’s weight, and is available in capsule and liquid suspension form. The recommended duration for antiviral treatment is five days.

Influenza Vaccines

Due to the extensive progress in vaccine development in the past century, several types of flu vaccines are available to the public. Trivalent inactivated influenza vaccines protect against

two influenza A strains and one influenza B strain, while quadrivalent vaccines protect against two influenza A strains and two influenza B strains (9). Trivalent influenza vaccines include standard dose vaccines that are manufactured using virus grown in eggs or virus grown in cell culture. There is also standard dose egg-free trivalent shot and standard dose intradermal shot High-dose trivalent shot for individuals over the age of 65 are also available. Quadrivalent influenza vaccines come in standard dose intramuscular form and standard dose nasal spray (21).

Inactivated trivalent standard dose egg-based vaccines are the only vaccine on the market that are safe to use for ages six months and older and their safety have been well established. One disadvantage to these vaccines is that their manufacturing requires amply supply of embryonic eggs, and it requires four months to create a vaccine for a new strain of influenza virus (21). A second disadvantage of these vaccines is that there are unable to be used in individuals with allergies to eggs.

Standard dose inactivated cell-based trivalent vaccines are recommended for ages 18 years and older. Viruses are grown in frozen animal cells and creating the vaccine requires require half the time as egg-based vaccines. People with egg allergies can receive this vaccine and be protected against influenza. Because this is a newer way of manufacturing vaccines, there are insufficient data to determine the long-term safety of these vaccines. Other disadvantages to cell-based trivalent vaccines are their high cost of production and their lower volumetric virus yield compared to egg-based vaccines (21).

A second standard dose inactivated trivalent egg-free vaccine called Flublok is also an FDA-approved" alternative to egg-based" vaccine approved for ages 18-49 years old. Flublok, manufactured by Protein Sciences Corporation (Meriden, CT), uses an insect virus expression system to produce hemagglutinin; it does not manufacture the whole virus like the techniques

mentioned previously. Two advantages of Flublok are that it can be manufactured quickly, and can administered to people with drug allergies. One disadvantage of Flublok is its short 16-week shelf life. In contrast, other inactivated trivalent vaccines expire nine months after production. Because Flublok was just approved for use in 2013, long-term side effects have not been studied, and thus the age to receive the vaccine is restricted.

A high-dose inactivated trivalent influenza shot approved for people age 65 and older also exists. The components are the same as the regular inactivated vaccine, but the vaccine possesses four times the amount of antigen as the standard dose. This vaccine is administered to older individuals whose immune system needs a stronger stimulation in order to elicit a protective immune response (20). Studies have shown that there are no physiological disadvantages to elderly individuals receiving the high dose vaccine over the standard dose, but the latter is twice the price as the former. For uninsured individuals, this may be too costly of an option (4).

Lastly, an inactivated trivalent intradermal flu shot is approved for people age 18 to 64 who are needle-phobic. This shot uses a needle that is 90% smaller than regular flu shots and that only penetrates the skin. An advantage to this vaccine is that this vaccine requires 40% less antigen than intramuscular vaccines, and is thus cheaper to produce. A disadvantage to this vaccine is that the FDA has restricted its use to people between the ages of 18 to 64 because of the smaller amount of antigen present in the vaccine (21).

The standard dose inactivated quadrivalent influenza is approved for ages 6 months and older. An advantage to this vaccine is that it covers one additional strain of influenza B virus. However, quadrivalent vaccines are also more expensive than inactivated trivalent vaccines and me unaffordable for many people. Additionally, a recent *New England Journal of Medicine* study by Alhan and co-investigators (3) showed quadrivalent vaccines have similar estimates of

efficacy as trivalent influenza vaccines, so buying a more expensive vaccine might not be worth it.

The second kind of quadrivalent vaccine is a standard dose live attenuated vaccine available in nasal-spray flu form and recommended for healthy individuals ages 2 to 49 (21). As discussed previously, inactivated vaccines primarily stimulate humoral immune responses. This provides limited protective immunity in the upper respiratory tract, where the infectious process begins. Because the live attenuated vaccine more closely mimics natural infection, it provides broader and more durable immunity (9).

In the past, vaccine development strategies have mainly focused on stimulating humoral immunity and rarely have addressed cellular immunity. Osterholm and coworkers (41) recently carried out an analysis of the need for new types of influenza vaccines. They examined hemagluttinin antibody levels in elderly individuals and found that 30% of them had high levels of the virus circulating in their blood but showed no symptoms of disease. These individuals were found to have more immune T cells that specifically recognized influenza viral antigens and mounted a cellular immune response than those who displayed symptoms of H1N1 (41). The researchers concluded that cellular immunity played a significant role in protecting these people against disease. Further research should be focused on the development of new vaccines that stimulate both humoral and cellular immunity to possibly develop a universal flu vaccine (9).

Viral Strain Selection for Vaccine

Global surveillance of influenza outbreaks by the World Health Organization (56) determines which strains will be included in the vaccines for seasonal influenza (25). To facilitate global influenza surveillance and monitoring efforts, WHO has coordinated a Global Influenza Surveillance Network (GISN), comprised mainly of five Collaborating Centers and

more than 130 National Influenza Centers (NIC) around the world (57). This involves over 100 national influenza centers in over 100 countries receiving and testing thousands of influenza virus samples from patients with suspected flu illness (21).

Once the most common virulent strains are identified and the appropriate antigens are selected, the process of producing, packaging, and distributing influenza vaccines takes six to eight months (9). The CDC conducts non-randomized (i.e., observational) studies to assess how well influenza vaccines work, and they have working with researchers at universities and hospitals to estimate vaccine efficacy. These studies usually confirm disease through real-time PCR . The CDC's studies are conducted in five sites across the United States to gather more representative data (20). To assess how well the vaccine works across different age groups, CDC's studies of vaccine efficacy have included all people aged 6 months and older, the recommended age range for annual influenza vaccination. According to Osterholm and co-investigators (41), it is difficult to determine vaccine efficacy. On the basis of reviews, the currently licensed influenza vaccines can provide moderate protection against virologically confirmed influenza, but such protection is greatly reduced or absent in some seasons (9). The CDC reported that influenza vaccine effectiveness for the 2012-2013 flu season was 56% for all age groups (20).

Public Health Vaccination Efforts

Public efforts to vaccinate against influenza occur on both the national and local level in the US. CDC utilized digital and social media platforms, including a live Twitter chat, to support National Influenza Vaccination Week in December 2013 and answered questions regarding the vaccine (18). Social media also has assisted public health officials to remind community members to get vaccinated. The CDC also provides free influenza campaign materials for public

health departments or healthcare facilities to use as advertisement for seasonal influenza vaccination.

Several private entities with more robust budgets also have begun encouraging community members to get vaccinated. In 2010, Blue Cross Blue Shield of Louisiana (BCBSLA) launched a state-wide campaign called "Take your Best Shot Against the Flu" to increase awareness and eliminate fears of vaccination. BCBSLA worked with the American Red Cross to organize mobile flu clinics and began advertising for vaccinations through mail, personal phone reminders, and television. To address the fear of vaccination, the organization encouraged individuals to post their best facial expressions after getting vaccinated on their website (4). Although government-run agencies can encourage vaccination, private organizations and non-governmental agencies that have more funds to advertise can be helpful in mobilizing communities to get vaccinated.

In Austin, Texas, ATCHHSD uses a variety of methods to remind people to get vaccinated. The local health department has both Twitter and Facebook pages, informing followers of the availability of vaccines. In addition, the city's immunization begins mass vaccination clinics in September, a couple of months before the peak season of flu, to encourage early vaccination and to lower the chances of getting infected with influenza (Isabel Hargrove, personal communication). When budgets allow for advertisement, the local health department reminds community members of vaccination through radio and newspaper advertisements.

Vaccine Access

Access to vaccines also has increased due to national and local public health efforts to target underserved and at-risk populations. The federally funded program Vaccines for Children (VFC) offers vaccines to children under the age of nineteen who are Medicaid-eligible,

uninsured, underinsured or are American Indian or Alaskan natives (22). The CDC buys vaccines at a discount rate and distributes them to state and local health departments and healthcare providers who agree to VFC guidelines for vaccine storage and administration. VFC providers cannot charge for the vaccine but may charge patients an administration fee (22). Physicians are incentivized to participate in VFC because they receive free vaccines.

The Children's Health Insurance Program (CHIP), known as Title XXI, enables states to expand health insurance coverage for uninsured children. Title XXI children enrolled in a Medicaid-expansion CHIP program are entitled to VFC program benefits. CHIP is designed for families who earn too much money to qualify for Medicaid but cannot afford to buy private health coverage (22). While VFC provides vaccinations for children, Medicaid covers some influenza vaccinations for adults depending on the type of vaccine. Elderly individuals, who are Medicare beneficiaries, receive the influenza vaccine at no cost.

As public health practice agencies have turned towards more innovative methods of detecting influenza and vaccinating against the virus, more individuals are being vaccinated than in the past. According to the CDC, flu vaccination coverage among children increased by 5.1 percentage points for the 2012–13 season compared to the 2011–12 season and 12.9 percentage points from the 2009-10 season (21). Flu vaccination coverage among adults increased by 2.7 percentage points for the 2012-13 season compared to the 2011-12 season and 1.1 percentage points from the 2009-10 season (21).

Community Vaccination Models

Because influenza is easily transmitted, most communities adopt conventional methods of vaccinating people against the disease. Conventional methods of vaccination include providing vaccines at doctor’s visits or clinic visits by appointment or walk-in. These vaccination

methods are “traditional” because they employ the traditional health care center with a provider, staff and location where other health services are provided (42). Most often, people in the US visit their primary healthcare providers to receive their seasonal flu vaccine. In many cases, these providers accept Medicare and/or Medicaid, so that elderly and poorer individuals may still be eligible to receive vaccines. Many child health care providers participate in VFC.

Clinic appointments provide several benefits for both patient and provider; patients can usually obtain other health services at clinics, increasing convenience. Providers also have one-on-one time with patients making visits more personal (42). Vaccinating in these traditional settings is useful to both parties because multiple vaccines may be provided to patients, so additional visits are not required. However, vaccination in traditional settings is more expensive, considering overhead costs, labor costs and time (42). A Harvard Medical School study reported that flu vaccination for adults in scheduled doctor’s office visits cost approximately $28.67 per person.

Due to high demands for influenza vaccine, national and local organizations are implementing more nontraditional approaches to vaccinating community members. Such approaches to vaccination are becoming popular due to budgetary constraints. Massive “flu” clinics, which are usually located in a large accessible space like a school gym or parking lot, are able to vaccinate large numbers of community members in one day. Drive-through clinics are similar to massive flu clinics, except that people are vaccinated in their vehicles, which can decrease the spread of infections (39). School-based vaccinations are also beneficial because they save parents a trip to their primary care provider and reduce the worry of unvaccinated children interacting with their children (35). Finally, local health departments can utilize other organizations, like pharmacies, to deliver their vaccines through external partnerships.

Pharmacist-administered vaccinations are becoming increasingly popular because pharmacists can perform their daily tasks of filling prescriptions, while administering vaccines (42). These nontraditional methods will be reviewed below.

Several recent studies have shown promising results for the future of nontraditional approaches to vaccination. A cost-benefit model presented by Duncan and researchers (30) showed that employers who provided vaccination programs in nontraditional settings for their employees saved an estimated six dollars per vaccine. Cho and co-investigators (23) recently reported on a pilot testing of a vaccination budgeting tool with five sites in North and South Carolina. They designed an accounting tool that helps clinics calculate costs for staff, vaccines, and supplies based on previous years' influenza vaccination data. The authors conclude that mass vaccination clinics can vaccinate the US population at $3 per person to administer the vaccine, not including vaccine costs or donated supplies.

A second nontraditional approach to flu vaccination is the use of drive-through clinics where volunteers or employees vaccinate individuals in their vehicles. Drive-through medicine has become increasingly popular in the medical field because it minimizes contact between individual patients and can be more efficient (39). A simulation study done by Gilbert and researchers at Stanford University School of Medicine compared the effectiveness and efficiency of traditional walk-in emergency or clinic visits to drive-through clinics during the H1N1 pandemic in 2009 (39). Thirty-eight actors were chosen to play patients, who had vital signs measured by nurses in their car and then were evaluated by physicians at different outdoor stations. The study showed that on average, each visit lasted only 26 minutes, and Gilbert and co-authors concluded that the drive-through model was a feasible alternative to clinic visits

because it provides a social distancing strategy, using the patient's vehicle as an isolation compartment to mitigate person-to-person spread of infectious diseases (39).

A third nontraditional model considered is school-based vaccination. A 2012 study published by Fontanesi and Researchers in the *Journal of the American Pharmacists Association* assessed the fiscal and logistical viability of school-based, pharmacist-administered influenza vaccination program by measuring unit costs, productivity, and effectiveness (35). These researchers calculated that the average cost of pharmacist-administered vaccination was $24.60 compared to $39.79 at walk-in injection-only clinics. Researchers concluded that pharmacists were more consistent in following guidelines and adhering to protocols than other vaccinating health professionals, which decreased cost (35).

School-based vaccination models have proven beneficial to counties for disaster response. In 2011, Palm Beach County implemented the Emergency Incident Command System (ICS) for school-located mass influenza vaccination clinics following the destruction caused by Hurricane Wilma (34). An added benefit in this instance was that local public health department officials and staff could prepare for future disasters using ICS.

In planning a community vaccination strategy, local health departments often form external partnerships with organizations to deliver their vaccines. Hohman and co-investigators (42) conducted detailed phone interviews with health department officials who conducted massive flu clinics and pharmacists who administered vaccines. These researchers than constructed a decision tree to compare the costs and benefits of vaccination delivered in these settings. They concluded that the mean cost of vaccination was lower in mass vaccination ($17.04) and pharmacy ($11.57) settings than in scheduled doctor's office visits ($28.67) (42). Nontraditional settings have significantly lower overhead costs and shorter visits than doctor's

settings. In particular, pharmacies have no additional costs other than vaccines because pharmacists vaccinate customers while managing their major task of filling prescriptions (42). In both pharmacy and mass vaccination clinic settings, vaccination was projected to be cost saving for healthy adults over the age of 50, and for high-risk adults of all ages.

ATCHHSD Immunization Unit

Organizationally, the ATCHHSD Immunization Unit has five main divisions, each with its own supervisor. Ms. Rita Ortega supervises the federally funded VFC program, the statewide immunization registry (54), and VFC provider education. Ms. Isabel Hargrove is responsible for collection of payments for vaccination, Medicare and Medicaid billing, the clinic appointment line, and the University of Texas at Austin, Public Health internship program. Ms. Colleen Christian provides health education to the community, while Ms. Debbie Tucker is responsible for vaccination outreach, the Hepatitis B Perinatal services to pregnant women, flu vaccination, and daycare/school compliance audits. Ms. Kathy Cavin supervises the Unit's two clinics, Shots for Tots and Big Shots. Mr. Kurt Becker is the Immunization Unit manager who oversees all of these divisions.

The Immunization Unit employs both traditional and nontraditional methods to vaccinate the community. The city of Austin provided the Immunization Unit with 7,500 units of flu vaccine during the 2011-12 flu season, which they, in turn, distributed in three ways: through their established clinics, through their four massive flu clinics in September and October, through strike teams targeting high risk groups and through outreach vaccination at the county STD clinic. Forty-seven percent of the vaccines were distributed through fourteen external partners.

ATCHHSD routinely administers flu vaccines at no cost, but a suggested ten-dollar donation is requested if clients are able to pay. ATCHHSD clinics accept Medicare at established clinics and massive flu clinics, while Medicaid and CHIP are only accepted at established clinics. ATCHHSD also partners with private providers who participate in the VFC program and provide immunizations to individuals under the age of eighteen with Medicaid or with no insurance. In order to record immunizations, the Immunization Unit uses ImmTrac, a statewide opt-in registry, which contains the immunization records of every individual under 18 who are registered (54). Immunization records are only given to parents of minors or to the individuals themselves to comply with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

The purpose of this project was to investigate flu vaccine delivery methods used by ATCHHSD and other local health departments (LHDs) in Texas and the US. Based on the research findings, recommendations will be made to improve how ATCHHSD delivers its influenza vaccines.

METHODS

Study Population

The study population consisted of fifty LHDs in Texas and the US in counties whose population and demographics were similar to those of Travis County. The percentage of whites, blacks, and hispanics and the county's median household income were obtained from 2010 US Census data. Contact information from LHDs was collected online, and information included telephone number and email address. These data are summarized in Appendix C.

Design and Development

Once the study population was chosen, a questionnaire was designed to capture data about each local health department's vaccination methods. Due to low responses in past years

when faxed surveys were administered, an online questionnaire was chosen instead. Qualtrics, a professional questionnaire creator is provided free access to University of Texas at Austin students. The questions for the questionnaire were developed and shared with four team members of the Immunization Unit. Their recommendations were included before the questionnaire was distributed. See Appendix D for questionnaire.

Administration and Follow-up

Administration of the project began after the questionnaire was approved. The questionnaire was distributed to LHD immunization program managers or outreach nurses familiar with their LHDs' immunization practices. The questionnaire was distributed through email to five LHDs from Texas and 45 LHDs from 17 different US states. Participants were offered the results of the project upon completion. The follow-up period from distribution to collection of all data was one month. Participants were emailed reminders to complete the survey after one week of sending the initial email. After one month, all surveys were closed and results were analyzed.

Data Analysis

Data analysis included compiling results from each question of the survey using Microsoft Excel and comparing it to ATCHHSD's data on flu vaccination. Responses that required free text and were not quantifiable were categorized into broad themes. Based upon the data analysis, recommendations were made to the Immunization for future flu vaccine delivery practices.

RESULTS

Fifty of the local health departments that were contacted agreed to participate and to complete the questionnaire online. These LHDs were given 1.5 months to submit their responses.

Although all of them agreed to participate, 25 of them actually completed the questionnaire (Appendix E). Thus, the response rate was 50%.

Location of LHDs

Figure 4 shows a map of the US with the approximate location of the city/county local health departments, which agreed to participate in the study but did not (in red), and those who completed the questionnaire (in blue). These health departments were located in 17 states across the nation. As can be seen on the map, no health departments from the northwest part of the country were represented in the study because their county size and demographics did not closely resemble Travis County. There were also counties not shown on this map that were contacted, but a response from the was never received.

Number of Clinics by Vaccine Delivery Method Type for 25 LHDs and ATCHHSD

Figure 5 compares the number of clinics broken down by delivery method type for the 25 LHDs (blue) and ATTCHHSD (red stars). Types of delivery methods clinics included regular or permanent clinics, massive clinics by appointment and walk-in, strike teams, outreach clinics for at-risk populations, vaccines distribution through external partners, and others. The "other" category included programs vaccinating first responders and their families, programs vaccinating county employees, walk-in flu clinics for employees only, and home-bound vaccination. All 25 LHDs had permanent clinics, and 17 of them had outreach clinics for at-risk populations. Eleven LHDs distributed their vaccines through partners, while 5 had strike teams. Surprisingly, fewer than 8 LHDs offered mass flu clinics by appointment, by walk-in or by drive through. It should be noted that, although the graph shows that ATCCHDS does not conduct walk-in massive flu clinics, individuals are not denied vaccination if they do not have an appointment at massive flu clinics.

Months of Flu Vaccine Delivery

One of the main purposes of this study was to gather data to help ATCHHSD's Immunization Unit rethink what month to begin massive flu clinics based on what other LHDs are doing across the country. Table 1 presents the free responses provided by 15 local health departments to the question "What months do you deliver influenza vaccines?" Response choices included: August- June; September and on; October and on; November through January; or year-round. Data were broken down by types of clinics, including permanent clinics, massive clinics with strike teams, outreach clinics for at-risk populations, vaccines distribution through external partners, and others. As can be seen in the total column, 25 of 31 (75%) of the flu vaccines delivered were administered in September and October. Note that only one clinic delivered influenza vaccines year round. This was true across all vaccine types. Focusing only on massive clinics, 66% of LHDs began vaccinating individuals in October. ATCHHSD begins conducting massive flu clinics in September.

Hours per Day Vaccines Are Delivered by Delivery Method

Another parameter investigated was how long their vaccine delivery services were offered each day. LHDs were asked to indicate how long each day they provided immunization services, and results are broken down by delivery method. Figure 6 shows the comparison of the average values for the 25 LHDs (blue) and ATCHHSD (red). Regular LHD clinics provided 6.5 hours of service, compared to 8 offered by ATCHHSD. On average, the 25 LHDs and ATCHHSD conducted massive clinics by appointment, by walk in and via drive through, between 5 and 6 hours per day. LHDs delivered vaccines at outreach clinics using strike teams and outreach clinics for at risk populations on average 1.5 hours per day longer than ATCHHSD.

Number of Vaccines Administered per Employee by Vaccine Delivery Method

Figure 7 shows the comparison of the average number of vaccines administered per employee for the 25 LHDs (blue) and ATCHHSD (red). Using responses in the questionnaire, the efficiency of vaccine administration was calculated and broken down by vaccine delivery method. The number of vaccines administered per employee was taken as a measure of efficiency. In every category, except drive-through clinics, the 25 LHDs, on average, appeared to be more efficient than Austin/Travis County. The graph shows that the most efficient method of vaccination was through strike teams. Employees on strike teams from 25 LHDS, on average, vaccinated 63 people per employee, while ATCHHSD vaccinated 23 per employee. The 25 LHDS also reported 33 people were vaccinated per employee with vaccination through external partners and 22 at outreach clinics. 25 LHDs indicated employees vaccinating on average 13 people per employee at all massive flu clinics, opposed to ATCHHSD, which vaccinated 7 people per employee. This large difference may be attributed to the large number of employees ATCHHSD uses at massive flu clinics using the Incident Command System to train for future disasters.

Throughput Time for Vaccination by Vaccine Delivery Method Type

Figure 8 shows average throughput times for vaccination by delivery methods for the 25 LHDs (blue) and ATCHHSD (red). Throughput time referred to the time it took a person to be vaccinated from the time he or she arrived to the time he or she was vaccinated. By every delivery method, the 25 LHDs had a lower throughput time than ATCHHSD. ATCHHSD had throughput times of 13 minutes on average for the other vaccine delivery methods, while the 25 LHDs had an average throughput time of 10 minutes. These results overall support the idea that nontraditional methods of vaccination are faster than traditional approaches.

Average Price Charged Per Vaccine by LHDs that Charged a Fee and Average Vaccine Administration Fee

Figure 9 shows the average price charged per flu vaccine, broken down by delivery methods for LHDs that did charge a fee (15). Recall that ATCHHSD does not charge for the vaccines they administer, and so no red bars appear on this graph. They do have a policy of accepting donations, however, from non-Medicare patients. Overall, 60% of LHDs charged for the flu vaccines. Vaccines distributed through partners were the most expensive, costing $27.50 per dose. In contrast, none of the LHDS charged for vaccines if they were provided at drive-through clinics or facilitated by strike teams. Massive flu clinics by appointment and walk-in clinics charged an average of $16 per vaccine.

Figure 10 presents the vaccine administration fee charged by 13 LHDs across the nation compare to ATCHHSD. Thirteen (or 52%) of the 25 total LHDs charged an administration fee. As shown in the graph, outreach clinics for at-risk populations on average charged the highest administration fee ($17.50), which is surprising, because these are the groups of most concern. The average amount LHDs charged at regular clinics was $15. Two vaccine delivery methods did not charge an administration fee: drive-through clinics and strike teams. In 2013, the ATCHHSD fee policy changed, so that a $25 administration fee is now charged at regular clinics rather than the $10 administration fee, which was charged prior to that year. Donations also are accepted towards the administrative fee from non-Medicare recipients.

Insurance Types Accepted

Table 2 shows the comparison of ATCHHSD to the 25 LHDs concerning insurance types accepted. The 25 LHDs were also asked to indicate if they accepted Medicare, Medicaid and/or private insurance. Only 20% of them accepted Medicare and 25% of them accepted Medicaid.

Alarmingly, over one third accepted private insurance. LHDs are primarily designed to serve those who do not have health insurance. Gaining payment from insurance companies is more profitable for LHDs but the profit obtained comes at the cost of uninsured individuals who may choose not to be vaccinated if they don't have insurance. ATCHHSD accepts Medicare and Medicaid, but at massive clinics, vaccines are provided regardless of an individual's insurance status. ATCHHSD doesn't bill private insurance companies for their services.

External Partnerships

Figure 11 shows the responses to the question, "What types of organizations do you partner with to deliver flu vaccines?" Results for the 25 LHDs are shown in blue and those for ATCHHSD, are indicated by red stars. Study participants were allowed to select all that applied. Overall, 11 LHDs responded using non-profits as external partners, while nine used independent school districts to deliver their vaccines. Four or fewer LHDs cited using hospitals, private practices, pharmacies, and pharmaceutical companies to deliver vaccines. Only one LHD partnered with pharmaceutical companies. ATCHHSD partnered with independent school districts, non-profits, pharmacies and other organizations not included in the survey options.

The external partners included in the "other" category were enumerated in a free response section of the questionnaire (data not shown). The 25 LHDs listed Senior Services, the Respiratory Health Association, county employees, churches, daycares, Women Infants and Children (WIC), and Senior Housing as "other" external partners. "Other" external partners identified by ATCCHSD included community centers, homeless shelters, the Fire Department, the UT School of Nursing, and the Consulate of Mexico.

Advertisement Methods

Figure 12 summarizes the responses to the question: "What advertisement methods did you employ to vaccinate your community against flu?" LHDs are shown in blue and ATCHHSD are shown with red stars. LHDs used 8 different methods for advertisement. Most LHDs used newspaper (17) to advertise followed by Facebook (14). In contrast ATCHHSD only used 5 of these methods, and did not advertise through newspaper. Eleven LHDs used radio and 12 used television. The rising trend of social media has caused many LHDs to pursue this economical avenue of advertisement to promote their vaccination efforts.

Self-Reported Rating for Effectiveness and Efficiency

Figure 13 shows the average rating LHDs gave themselves for their effectiveness and efficiency in delivering flu vaccines. LHDs were asked to rate themselves on a scale of 1-10. The 25 LHDs reported on average a rating of 7, while ATCHHSD reported a rating of 9. Participants in the survey were asked to give reasons for their rating in free response question. Reasons for positive ratings of LHDs fell under the following categories: well trained staff, flexible and efficient planning, having many external partnerships, delivering vaccines efficiently, providing many vaccination options throughout the year. Reasons for poor ratings included budget restrictions for vaccine purchase and promotion and heavy reliance on partners to deliver the LHD's vaccines. ATCHHSD cited well-trained staff but a high amount of human resources used for massive flu clinics due to training for emergency preparedness using ICS.

Novel Approaches and Changes to Vaccine Delivery Methods if No Budgetary Restrictions

In a free response question, LHDs were asked if they had any novel approaches to vaccinating the community. Only a few of the LHDs identified novel approaches for the delivery of flu vaccines. One cited having a mobile van to immunize staff at daycare centers. Another LHD provides individuals with one flu shot in exchange for 3 canned goods, which are

then donated to a homeless shelter. Two novel approaches used by ATCHHSD uses ICS during massive flu clinics to prepare staff for emergency situations and begins planning early for flu vaccine delivery.

In a final free response question, LHDs were asked: "If you hypothetically had not budgetary restrictions, what changes would you make to you flu vaccine delivery system?" The 25 LHDs responded that they would increase promotion, improve outreach to vulnerable populations, hire more staff, purchase more vaccines, develop more partnerships and use mobile units to deliver vaccines. ATCHHSD responded that they would carry out campaigns with external partners to encourage early vaccination and purchase mobile technologies encounters, obtain consent, conduct surveys and collect credit card donations. In addition, they would campaign with partners to encourage early vaccination.

DISCUSSION AND FUTURE STUDIES

Based on the questionnaire results, many similarities existed between the flu vaccine delivery systems of the 25 LHDs and ACTHHSD. Both delivered vaccines through regular LHD clinics, massive flu clinics by appointment, drive-through clinics, strike teams, outreach to at-risk populations and external partnerships. They also mainly partnered with independent school districts and non-profits to deliver vaccines. They promoted their vaccine delivery through radio, television, Facebook in Twitter. ATCHHSD and the 25 LHDs cited well-trained staff as the largest factor for their self-reported rating on efficiency and effectiveness.

There were also many differences between flu vaccine delivery systems used by LHDs and ATCHHSD. For example, only 24% of LHDs conducted massive flu clinics, whereas annual flu vaccinations provided by ATCHHSD were always offered via massive flu clinics. On average, 66% of the LHDs that did offer massive flu vaccinations began vaccinating in October;

Austin Travis County begins their massive clinic in September. For all vaccine delivery methods, the 25 LHDs (on average) vaccinated 21 people per employee compared with Austin Travis County,which vaccinated 10 people per employee. This smaller number may be explained by the fact that Austin Travis County supports their flu vaccination efforts with a large number of employees, especially at massive flu vaccinations. The throughput time of the 25 LHDs (9.5 minutes) was on average lower than ATCHHSD's time of 14.5 minutes. On average, vaccine and administration fees charged by the 25 LHDs were $36 per vaccination, compared to ATCHHSD,which charged $10 in 2011. Approximately one fourth of LHDs accepted Medicare and Medicaid, while surprisingly, over 1/3 of these health departments also accepted private insurance. In 2011, ATCHHSD accepted Medicare, Medicaid but no private insurance and this continues to be their policy. Finally, the 25 LHDs rated themselves a 7/10 (on average) for efficiency and effectiveness, while ATCHHSD rated itself a 9/10.

Based on these results, three short-term recommendations for Austin Travis County can be made. Most LHDs begin conducting massive flu clinics in October. ATCHHSD should consider beginning their massive flu clinics in October as well, rather than September. Weather in Austin in September is more like summer, and delaying the vaccination by a month may attract more individuals to participate in the vaccination campaign. At the very least, it might be worth conducting a trial and assessing the benefits and costs of starting in October versus September. A search of the literature and the results of this study have demonstrated that drive-through clinics are economically feasible, and are an efficient means of delivering influenza vaccines to the public. ATCHHSD should continue drive through clinics, even though one is not planned for the upcoming flu season. In addition, when feasible, ATCHHSD should consider employing the strike team delivery model to increase their efficiency at delivery vaccinations.

This has the potential to shorten the throughput time, which will both increase productivity and same money.

Three longer-term recommendations can be made as well based on results from this questionnaire. First, due to budget restrictions, ATCHHSD should consider forming more external partnerships to distribute vaccines in order to partially alleviate the financial burden on the agency. In addition, ATCHHSD should consider increasing the use of electronic health record technologies in order to save money and time in the future. If ATCHHSD vaccine providers are equipped with tablets and scanners at massive flu clinics, clinic personnel can quickly collect information about the clients who are vaccinated and bill the appropriate payer. Finally, ATCHHSD should monitor the efficiency of vaccine delivery methods. ATCHHSD uses the ICS model for massive flu clinics, a model that has been adopted for biopreparedness and is not maximized for efficiency. Monitoring the productivity of staff members may lead to modifications in clinic planning and increases in efficiency for vaccine delivery.

Although this study provided insightful results, the short time frame allowed for data collection made it difficult to get all of the LHDs to complete the questionnaire. The study was also limited by a small sample size (25) as the final response rate was only 50%. Additionally, The term "throughput time" was not defined in the survey, so it is possible that many LHD officials misunderstood what the question was asking.

More research is needed to fully understand the effectiveness of each flu vaccine delivery method. Future public health interns might interview more LHDs and asking more in-depth questions. They might also help design and carry out a pilot program to advertise flu vaccinations using "free" social media in order to help spread the word to tech savvy Austinites about the importance of flu vaccination. An intern also might investigate external providers in

Central Texas who might be willing to partner with ATCHHSD to deliver flu vaccines**.** Finally, an intern could help get the word out about the flu vaccination services offered by ATCHHSD. Forming more partnerships with external providers will also help ships to minimize labor costs. It is also important to gain an accurate estimation of the efficiency of each delivery system by following up with LHDs over time.

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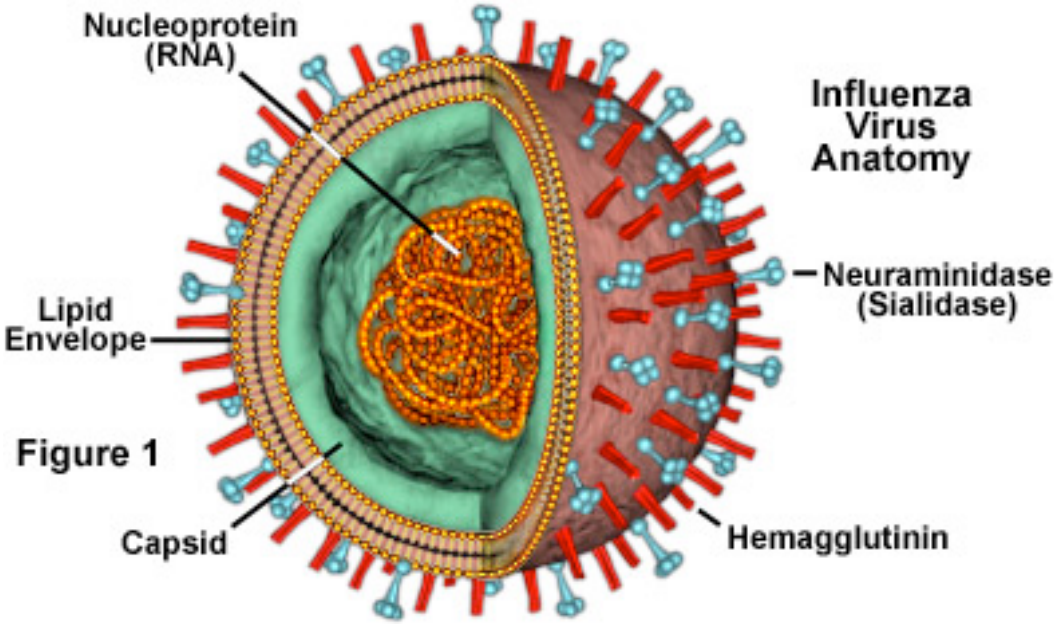
FIGURES

Figure 1. Morphology of an influenza virus.



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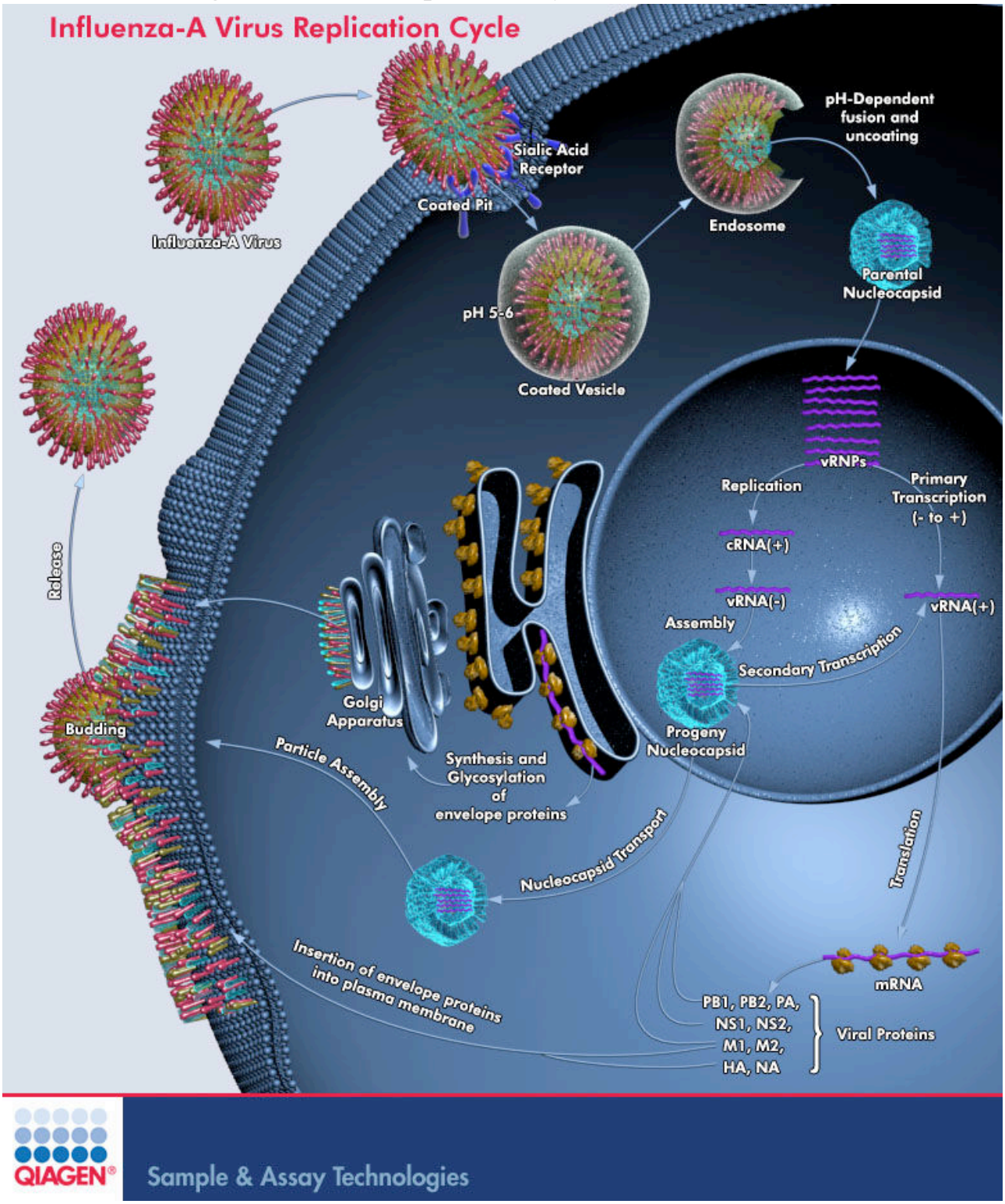
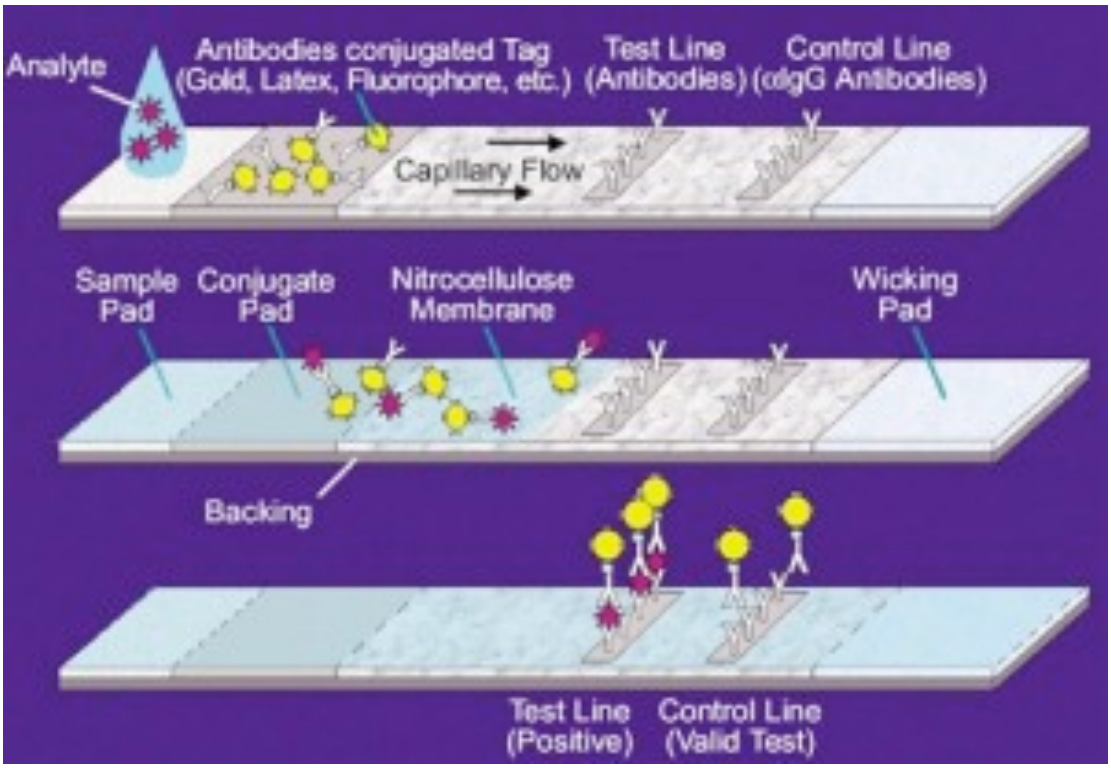
http://micro.magnet.fsu.edu/cells/viruses/influenzavirus.html

Figure 2. The multiplication cycle of the influenza virus



Taken from: **QIAGEN Sample &Assay Technology.** [Online]. http://www.qiagen.com/products/genes%20and%20pathways/pathway%20details.aspx?pwid=247

Figure 3. Rapid Influenza Diagnostic Test



Taken from: **Virology Blog.** 2009. Novel rapid test for influenza H5N1 virus. [Online]. http://www.virology.ws/2009/04/16/novel-rapid-test-for-influenza-h5n1-virus/

Figure 4. Map of the US showing LHDs that agreed to participate but did not complete questionnaire (red) and those that did participate and completed the questionnaire (blue).

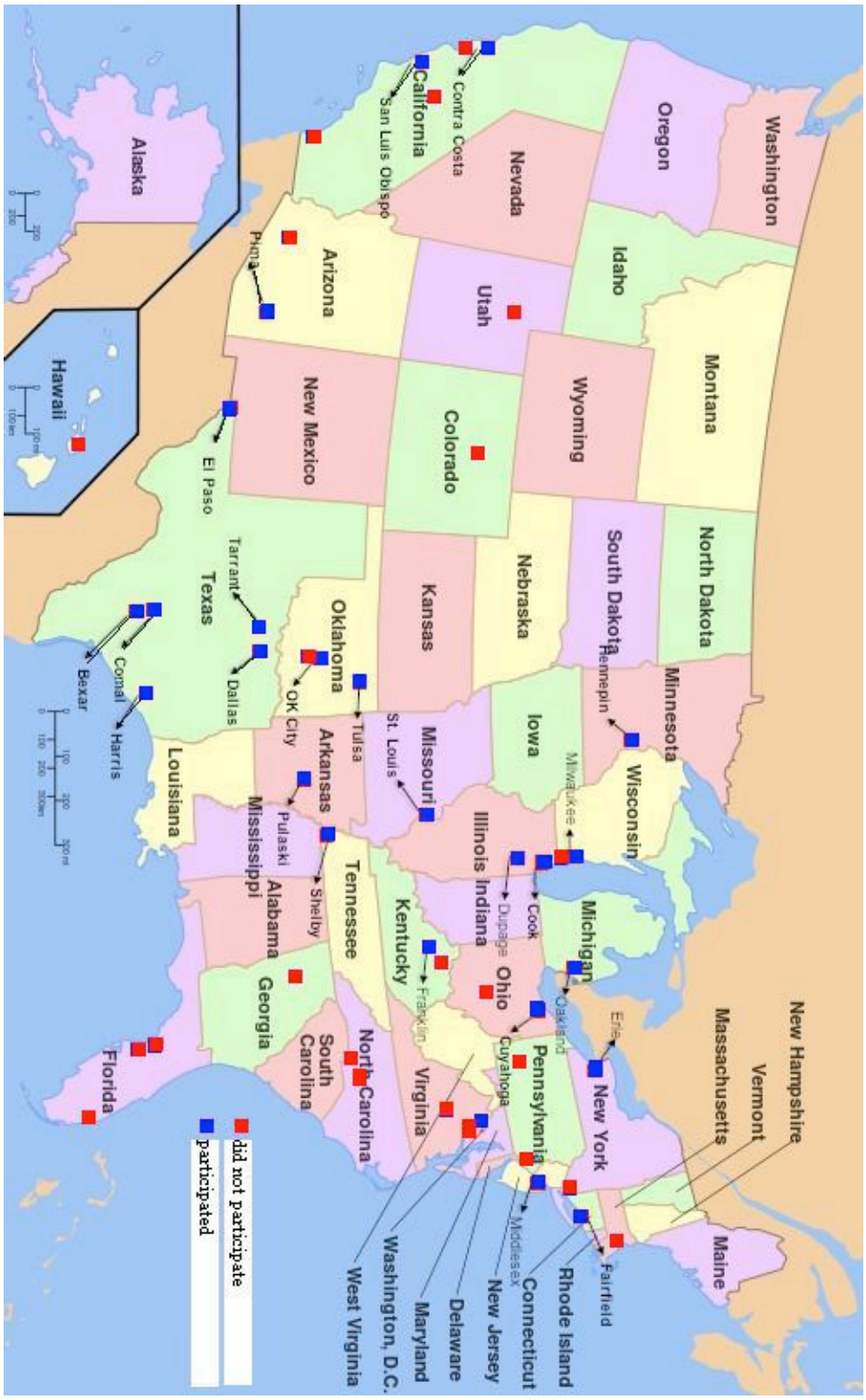


Figure 5: Number of Clinics by Vaccine Delivery Method for 25 LHDs and ATCHHSD

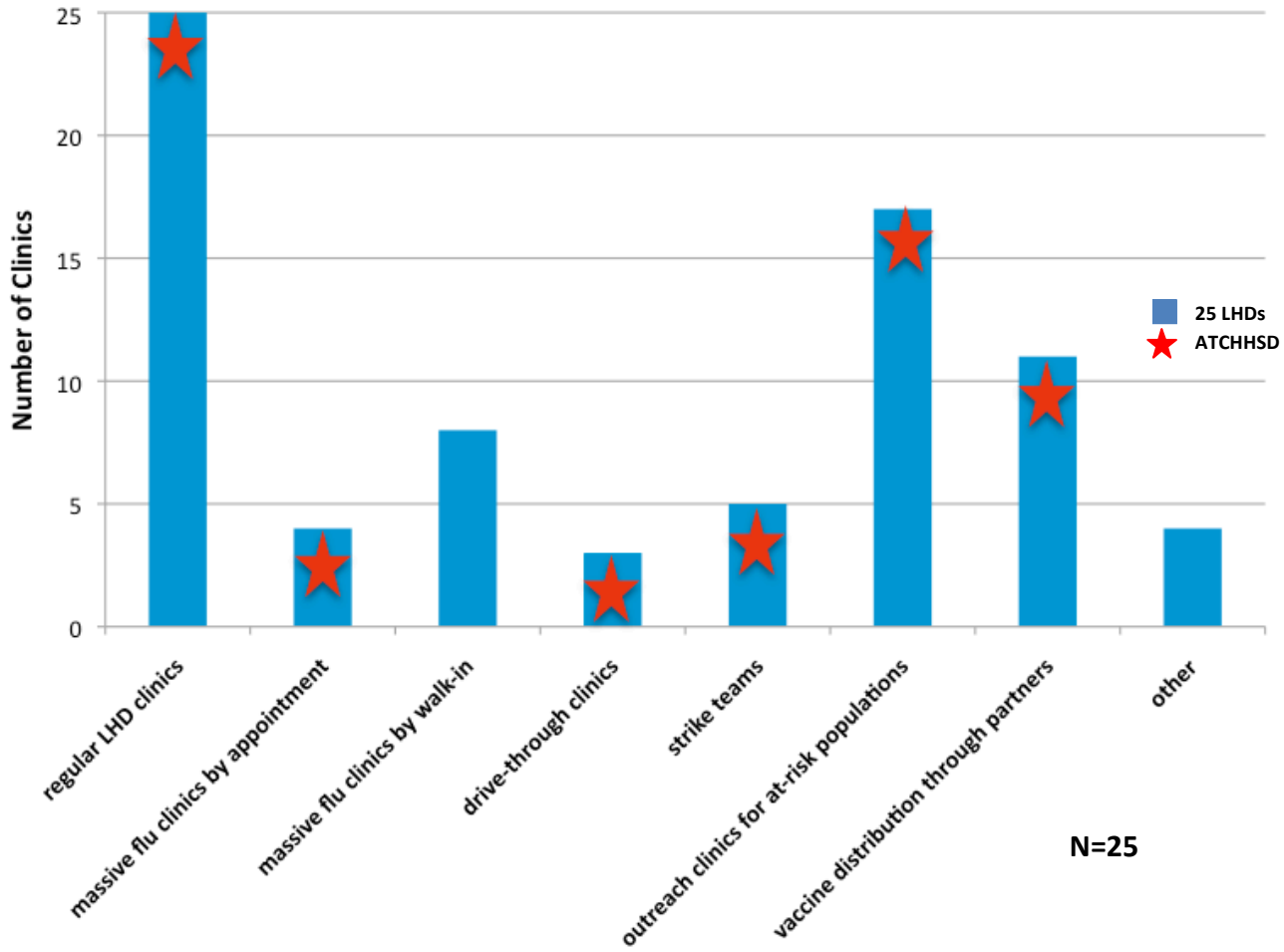


Figure 6. Time of Vaccine Delivery (hours per day) by Delivery Method

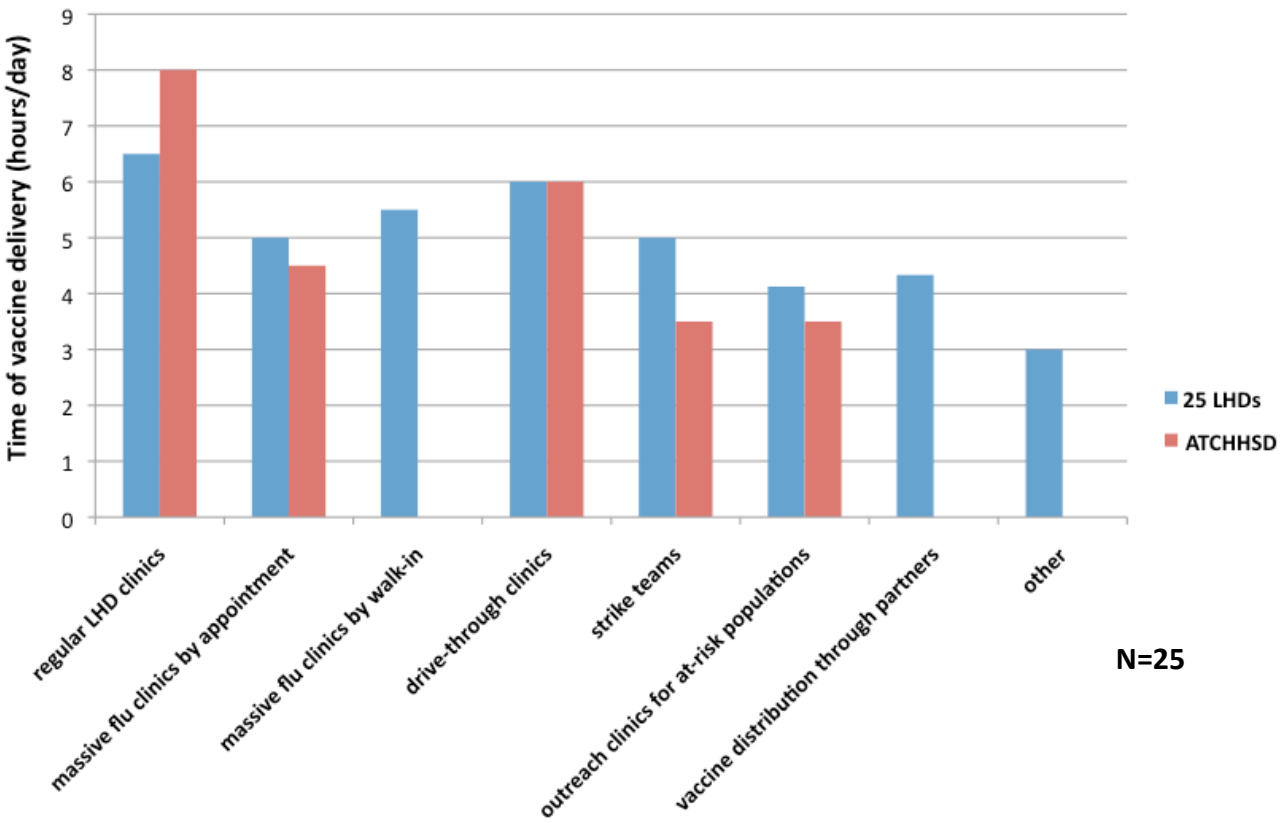


Figure 7. Number of Vaccines Administered per Employee by Vaccine Delivery Method

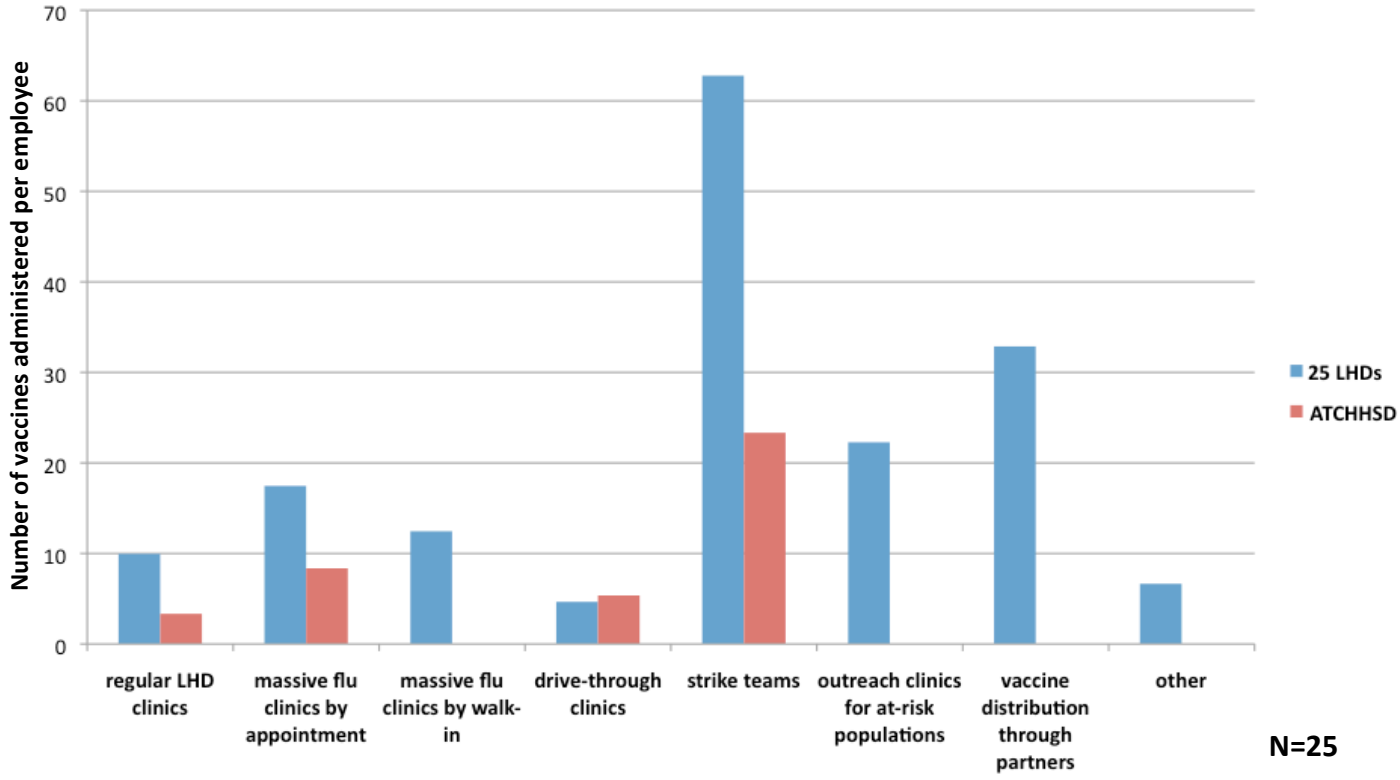


Figure 8. Throughput Time for Vaccine Delivery by Delivery Method Type

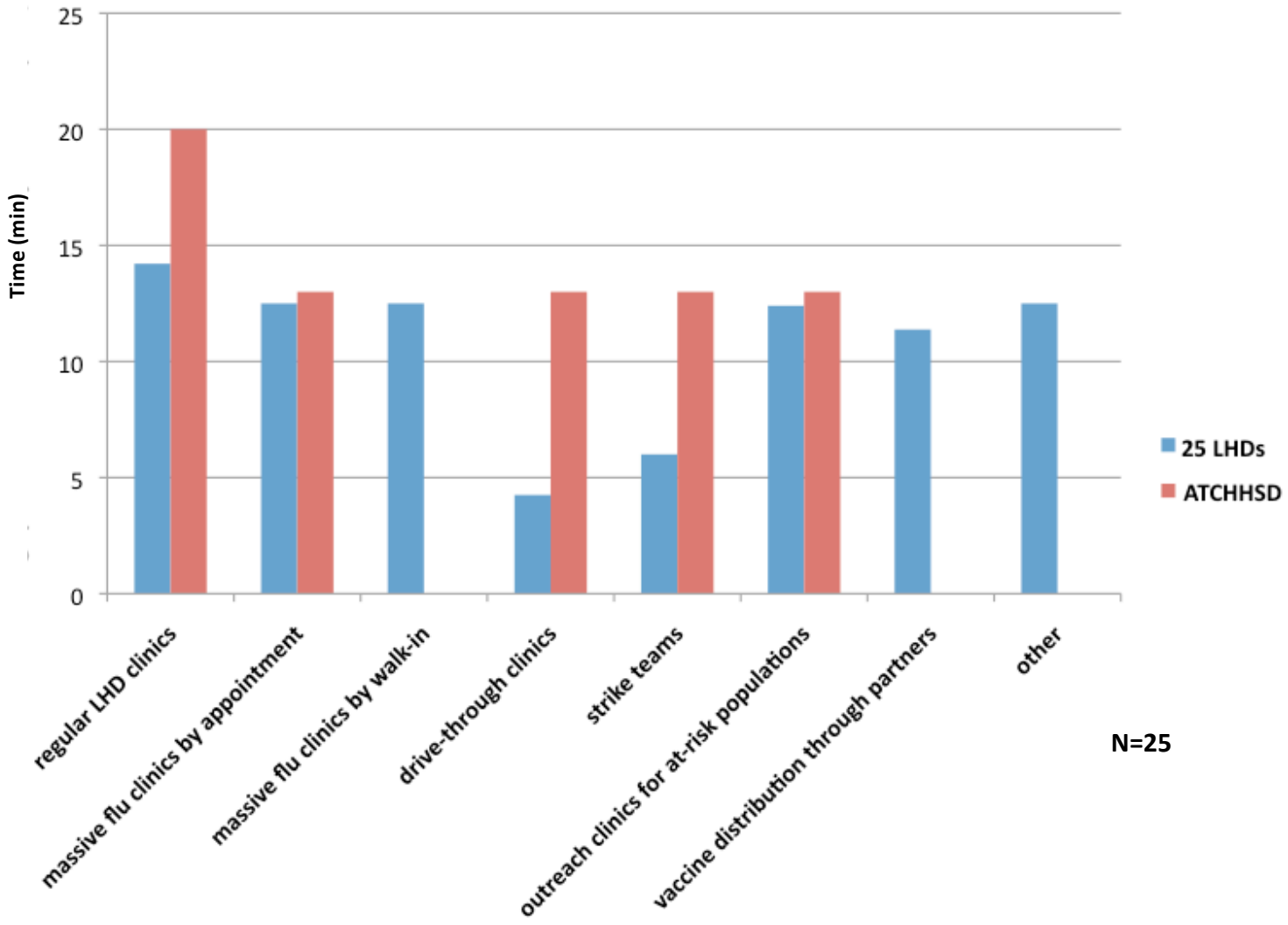


Figure 9. Average Price Charged per Vaccine by Delivery Method for LHDs that Charged a Fee

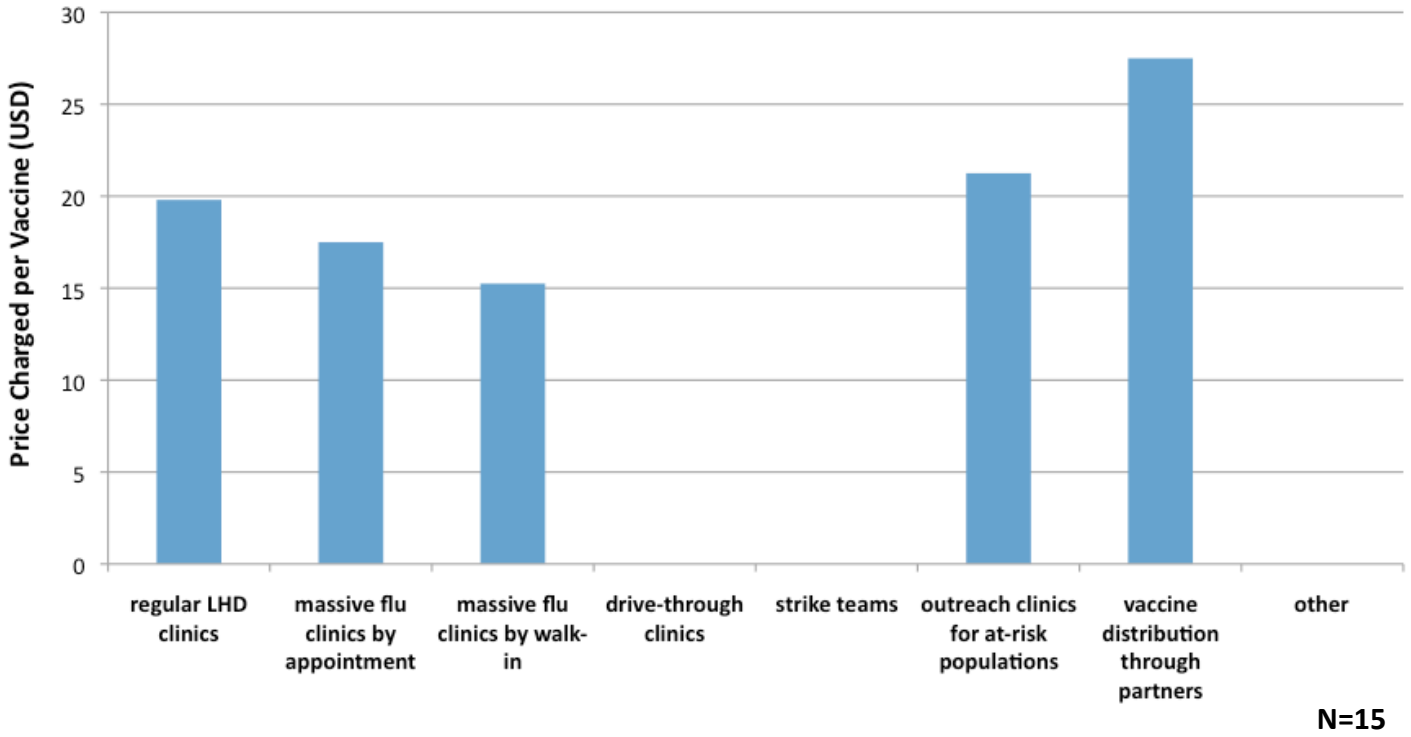


Figure 10. Vaccine Administration Fee by Delivery Method Type for 25 LHDs and ATCHHSD

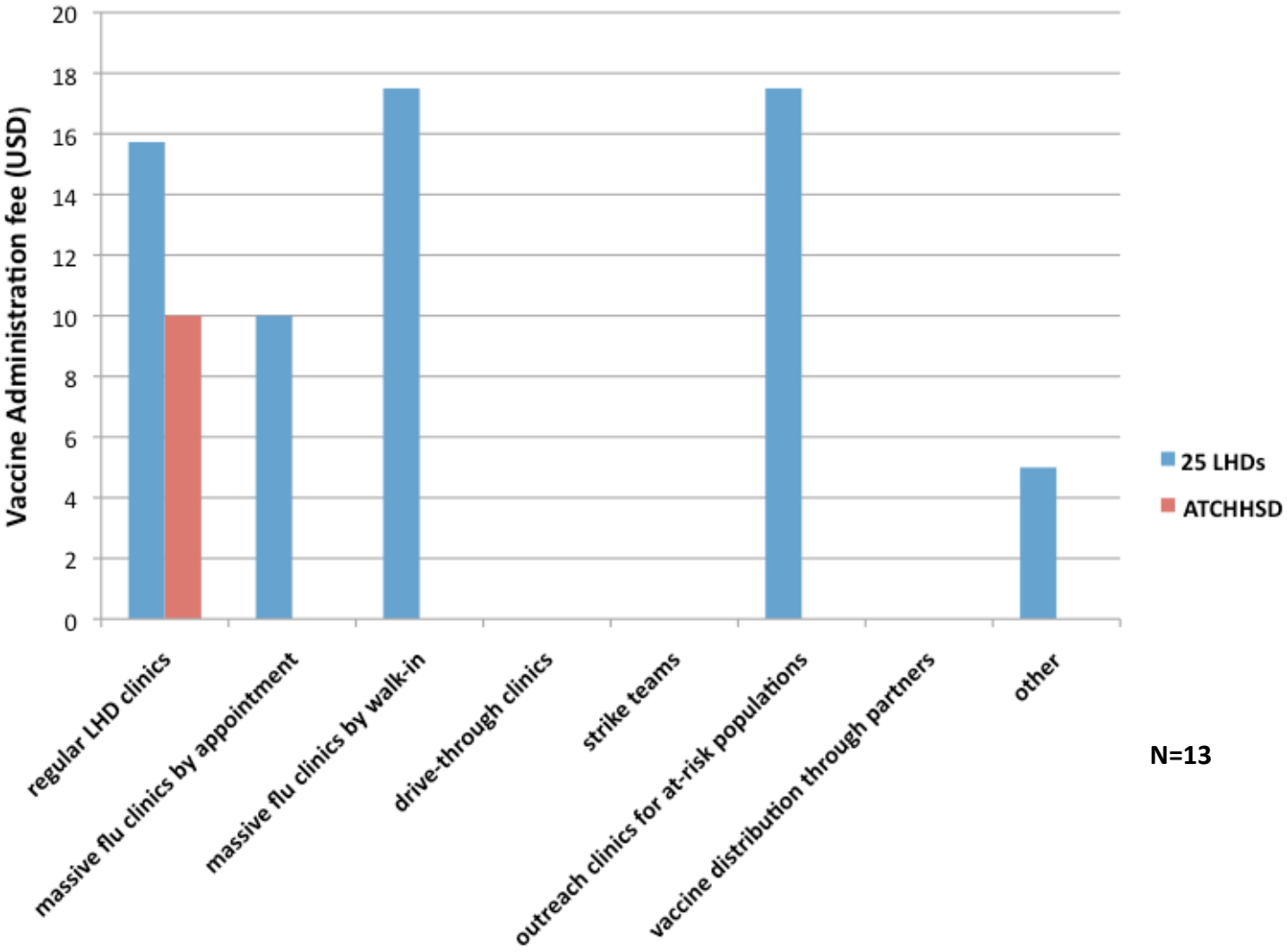


Figure 11. External Partnerships of 25 LHDs (blue) and ATCHHSD (red stars)

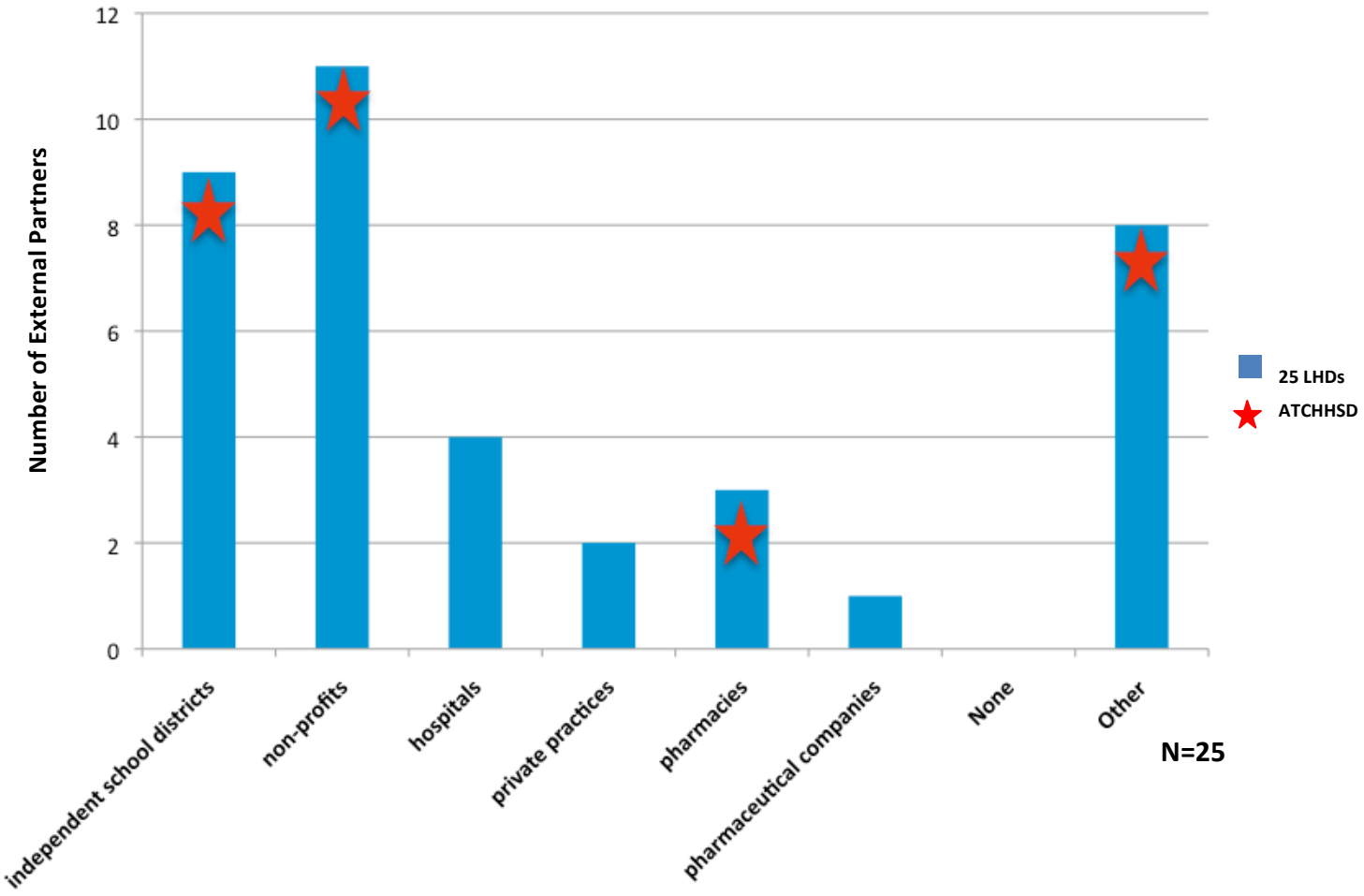


Figure 12. Frequency of Advertisement Methods used by 25 LHDs and ATCHHSD

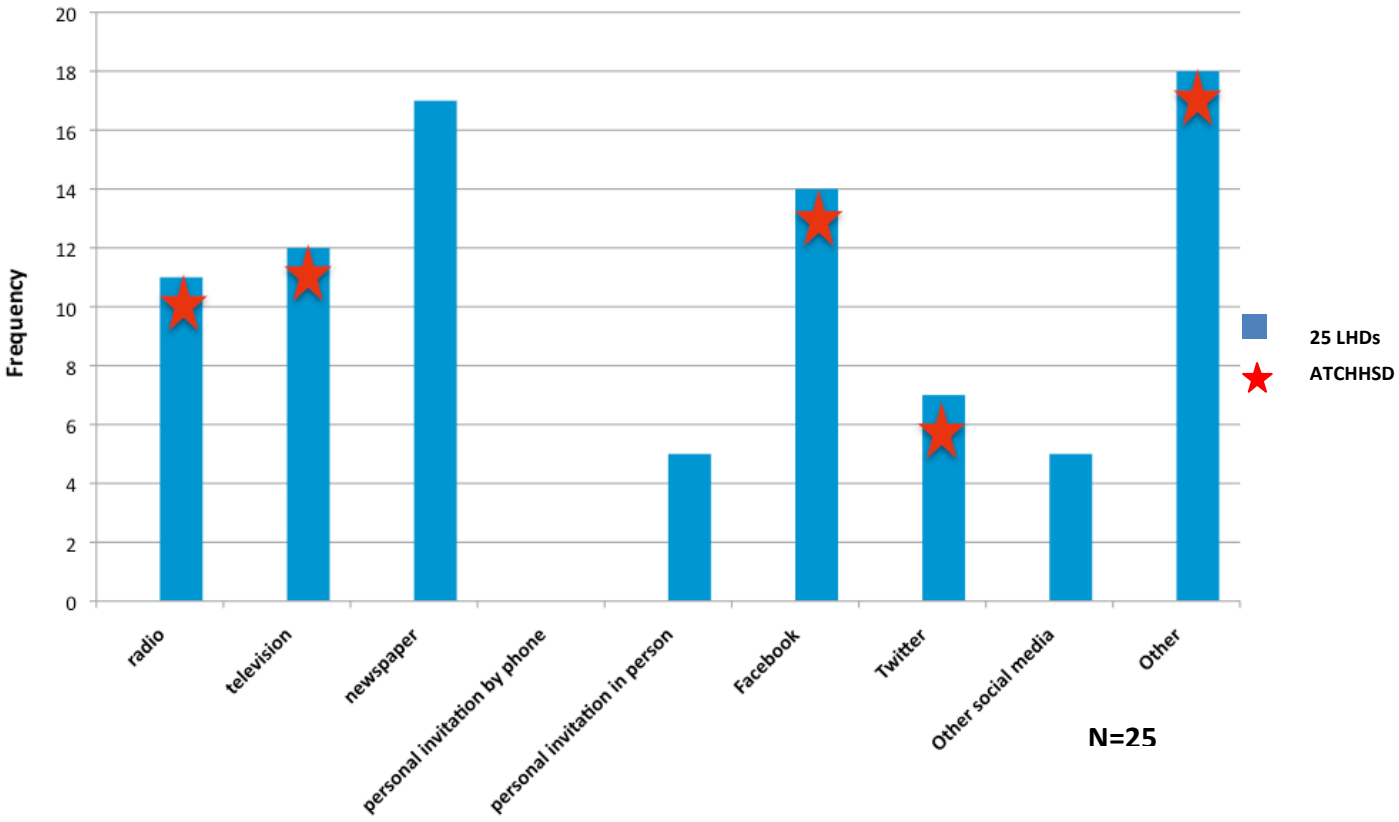
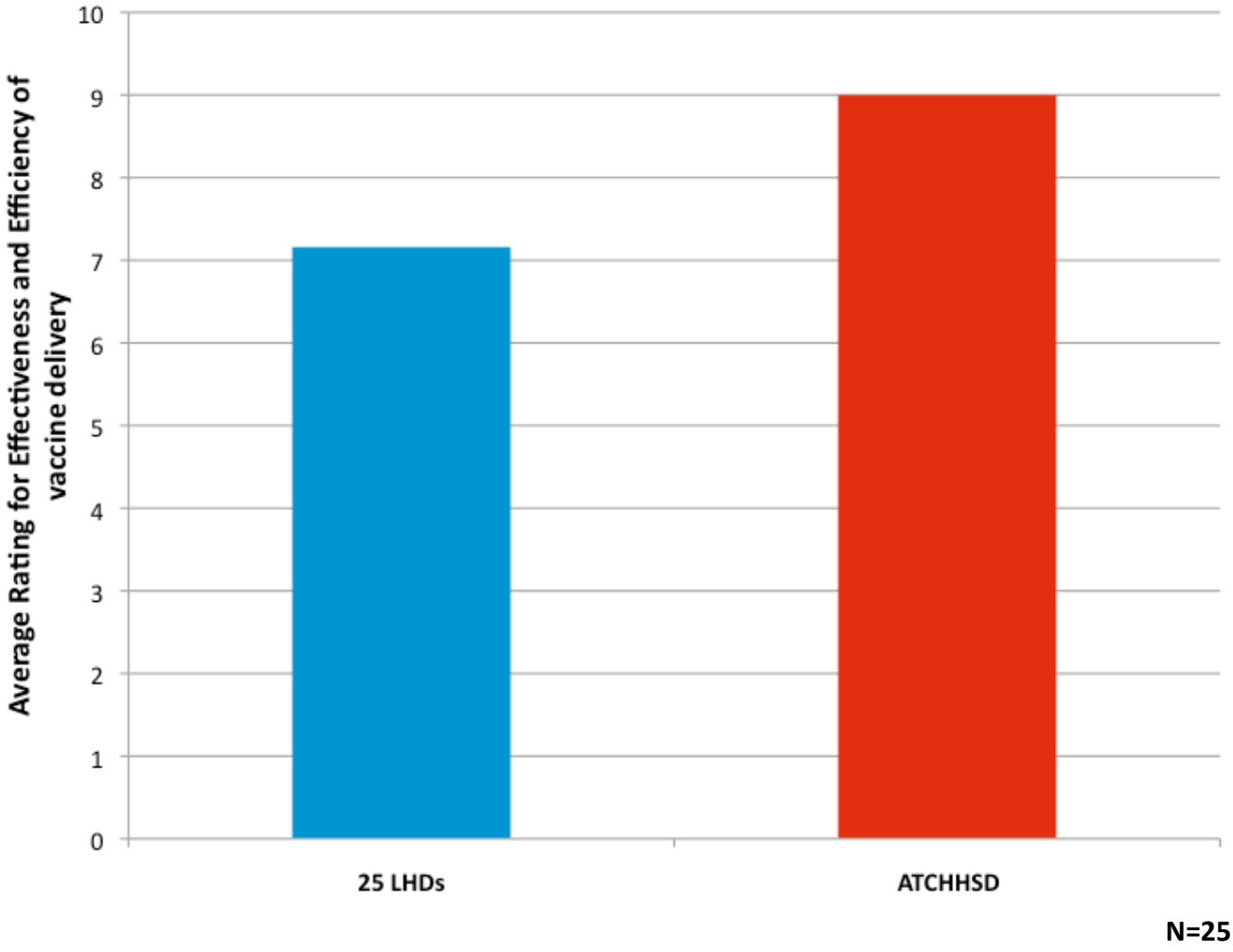


Figure 13. Self-reported Effectiveness and Efficiency of Influenza Vaccine Delivery



TABLES

Table 1. Months of Flu Vaccine Delivery by Delivery Type for 15 LHDs

Month	Permanent clinics	Massive clinics and strike teams	Outreach clinics for at-risk populations	Vaccine distribution through partners	Others	Total
Aug-June	1					1
Sept and on	6	1	2	1	1	11
Oct and on	4	4	3	2	1	14
Nov-Jan	1	1	1		0	3
Year-round	1	0	0	1	0	2
Total	13	6	6	4	2	31

N=15

Table 2: Insurance Types Accepted

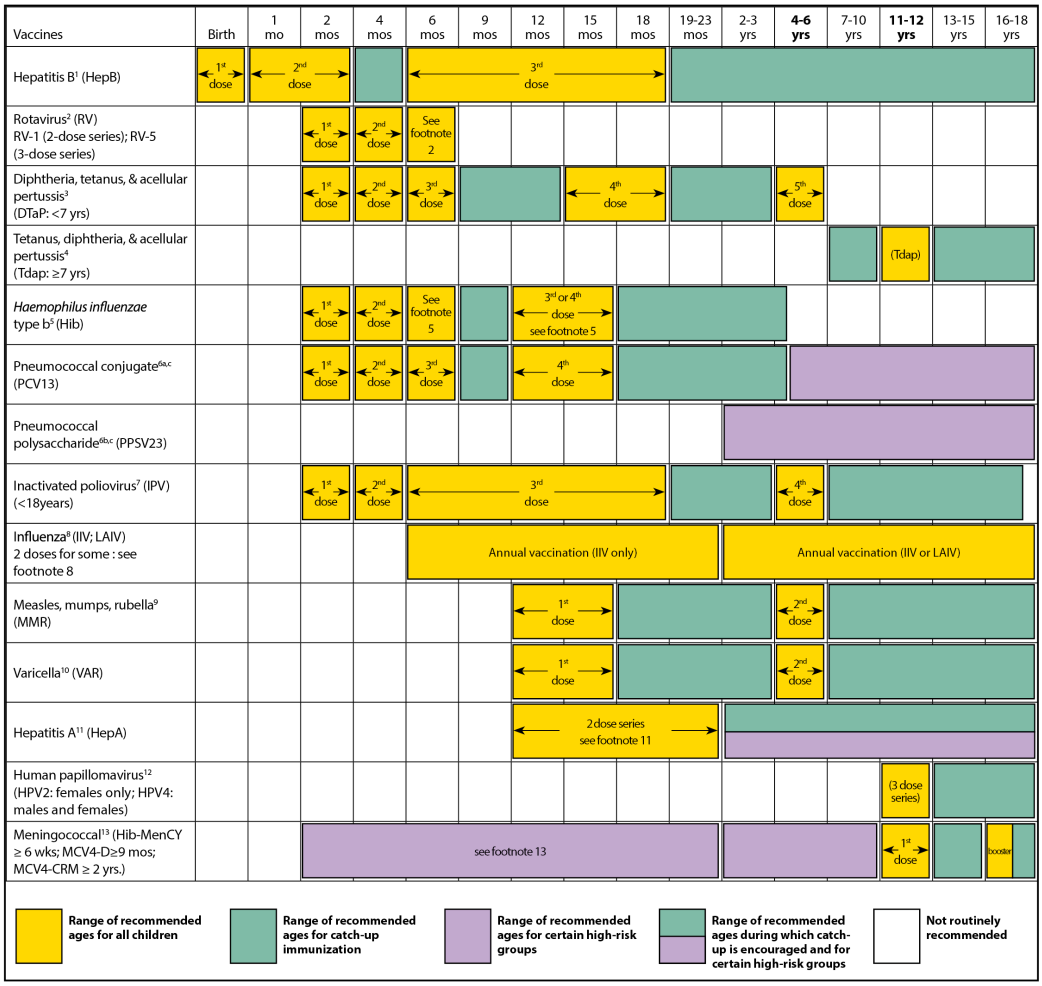
	Medicare	Medicaid	Private Insurance
25 LHDs	20%	25%	36%
ATCHHSD	100%	100%	0%

APPENDICES

Appendix A. 2013 CDC Recommended Child Immunization Schedules

FIGURE 1. Recommended immunization schedule for persons aged 0 through 18 years —2013 (for those who fall behind or start late, see the catch-up schedule [Figure 2])

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.



This schedule includes recommendations in effect as of January 1, 2013. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes on pages 6–8.

Appendix B: 2013 CDC Recommended Adult Immunization Schedule

Recommended Adult Immunization Schedule—United States • 2013

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group[1]

VACCINE ▼ AGE GROUP ▶	19–21 years	22–26 years	27–49 years	50–59 years	60–64 years	≥65 years
Influenza [2,*]	1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella [4,*]	2 doses					
Human papillomavirus (HPV) Female [5,*]	3 doses					
Human papillomavirus (HPV) Male [5,*]	3 doses					
Zoster [6]					1 dose	
Measles, mumps, rubella (MMR) [7,*]	1 or 2 doses					
Pneumococcal polysaccharide (PPSV23) [8,9]	1 or 2 doses					1 dose
Pneumococcal 13-valent conjugate (PCV13) [10]	1 dose					
Meningococcal [11,*]	1 or more doses					
Hepatitis A [12,*]	2 doses					
Hepatitis B [13,*]	3 doses					

*Covered by the Vaccine Injury Compensation Program

- For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; Zoster vaccine recommended regardless of prior episode of zoster
- Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)
- No recommendation

Appendix C. Counties and Contact Information for LHDs that Agreed to Participate

Counties	Name	email	phone #
Philadelphia	Nichole McLaughlin	nichole.mclaughlin@phila.gov	(215) 685-6837
Alameda	Leslie Greenwood	leslie.greenwood@acgov.org	(510) 268-2330
Middlesex	Michele Canfield	michele.canfield@co.middlesex.nj.us	(732) 745-4879
Sacramento	Kaitlin Mccaughly	N/A	(916) 875-7468
Cuyahoga	Cindy Modie	cmodie@ccbh.net	(216) 201-2040
Hillsborough	Kevin Argote	kevin_argote@doh.state.fl.us	(813) 307-8077
Allegheny	Sharon Silvestri	ssilvestri1@achd.net	(412) 578-8304
Oakland	Shane Bies	biess@oakgov.com	(248) 858-1409
Franklin	Terry Ann Bugg	tabugg@franklincountyohio.gov	(614) 525-3160
Orange	Tammy Gay	N/A	(407) 836-2502
Hennepin	Mary Skube	mary.skube@co.hennepin.mn.us	(612) 348-5618
Fairfax	Jessica Ong	jessica.ong@fairfaxcounty.gov	(703) 246-2411
Contra Costa	Paul Leung	pleung@hsd.cccounty.us	(925) 313-6740
Salt Lake	Sharon Moon	smoon@slco.org	(385) 468-4144
St. Louis	Eleanor Peters	epeters@stlouisco.com	(314) 615-1630
Montgomery	Debra Aplan	debra.aplan@montgomerycountymd.gov	(240) 777-1512
Pima	Edmee Botwright	edmee.botwright@pima.gov	(520) 243-7770
Honolulu	martha yamada	martha.yamada@doh.hawaii.gov	(808) 974-6025
Westchester	Suzanne Calvallo	sxc5@westchestergov.com	(914) 813-5000
Milwaukee	Fred Radmer	fradme@milwaukee.gov	(414) 286-8034
Cook	Connie Linchangco	pclinchangco@cookcountyhhs.org	(708) 633-8014
Fresno	Natalia Vargas	nvargas@co.fresno.ca.us	(559) 600-3550
Shelby	Marie Evans	marie.evans@shelbycountytn.gov	(901) 222-9332
Fulton	Juliet Cooper	juliet.cooper@fultoncountyga.gov	(404) 612-1211
Mecklenburg	Jeanine Williams	jeanine.williams@carolinahealthcare.org	(704) 336-4744
Erie	Karen Menza	karen.menza@erie.gov	(716) 858 -2373
Dupage	Beverly Govednik	bgovedni@dupagehealth.org	(630) 682-7400.
Fairfield	Sands Cleary	scleary@town.fairfield.ct.us	(203) 256-3020
Pinellas	Andrea Castillo	andrea_castillo@doh.state.fl.us	(727) 824-6900
Maricopa	Brenda Jones	Brenda.jones@azdhs.gov	(602) 364-3635
San Diego	Heidi Unruh	heidi.unruh@sdcounty.ca.gov	(866) 358-2966
Palm Beach	Phyllis Diana	phyllis_diana@doh.state.fl.us	(561) 840-4568
Henderson	Candace Piersol	N/A	(828) 694-6018
San Luis Obispo	Christine Gaiger	cgaiger@co.slo.ca.us	(805) 781-5577
Pulaski	Amanika Duncan	amanika.duncan@arkansas.gov	(501) 280-3160
D.C.	Charlissa Quick	charlissa.quick@dc.gov	(202) 442-9338
Suffolk	Julia Gunn	jgunn@bphc.org	(617) 534-5050
Oklahoma	Diane Clark	diane_clark@occhd.org	(405) 427-8651
Tulsa	Priscilla Haynes	phaynes@tulsa-health.org	(918) 582-9355
Franklin, KY	Vicky Poplin	vickyl.poplin@ky.gov	(502) 564-7647
Northern Kentucky	Sonya Moseley	sonya.moseley@nkyhealth.org	**(859) 341-4264**
OK State	Susan Mendez	susanm@health.ok.gov	(405) 271-4073
Cabarrus	TL Staehler	tlstaehler@cabarrushealth.org	(704) 920-1000
West Allis	Shelyn Zagdel	szagdel@westalliswi.gov	(414) 302-8600

Appendix C. continued

Texas Counties	Patty Batchelor	pbatcheler@hcphes.org	
Harris	Patricia Cook	pacook@dallascounty.org	(214) 819-2164
Dallas	Florastine Mack	FMack@tarrantcounty.com	(817) 321-4700
Tarrant	Vivian Flores	Vivian.flores@sanantonio.gov	(210) 207-8794
Bexar	Diana Garcia	dgarcia@immunizeelpaso.org	(915) 857-2474
El Paso	Amy Lawrence	lawrea@co.comal.tx.us	(830) 221-1150
Travis	Debbie Tucker	Debbie.Tucker@austintexas.gov	

Appendix D. Qualtrics Questionnaire Distributed to Participants

The Austin/Travis County Health and Human Services Department is researching best practices for flu vaccine delivery. By completing this survey, your local health department (LHD) will be contributing to a study on US flu vaccination efforts. Results will be shared with you, so that you can compare your LHD's practices with others and consider adopting novel flu delivery approaches next flu season.

	Contact Name	Title	Address, City, Zipcode	Telephone	Fax	e-mail address
Program Information						

Please record your responses to the following flu vaccination delivery options about your LHD by matching the column to the row. For example, if your LHD does not have strike teams or conduct drive-through clinics, leave those columns blank. All information provided should be from the 2011-2012 flu season.

	regular LHD clinics	massive flu clinics by appointment	massive flu clinics by walk-in	drive-through clinics	strike teams	outreach clinics for at-risk populations	vaccine distribution through partners	other	none
What methods of flu vaccination did your local health department use to vaccinate community members? (Write "X" for all that apply).									
number of clinics									
number of flu vaccines administered per day									
months of the year when conducted									
duration (hours per day)									
number of employees/volunteers									
fee charged per vaccine (indicate free or price that was charged)									
fee charged per vaccine administration (indicate free or price that was charged)									
acceptance of Medicaid (indicate yes or no)									
acceptance of Medicare (indicate yes or no)									
acceptance of private insurance (indicate yes or no)									
average throughput per client (answer in minutes)									

If you indicated "Other" to methods of flu vaccination, please list what types of flu delivery methods your LHD coordinates.

If you indicated "yes" to partnering with other organizations to administer flu vaccines, please select all categories that apply or select other.

independent school districts	non-profits	hospitals	private practices	pharmacies	pharmaceutical companies	None	Other
☒	☒	☒	☒	☒	☒	☒	☒

Please indicate the names of the organizations your local health department partnered with to distribute flu vaccines.

How did your local health department promote flu immunization for the 2011-2012 flu season? (Select all that apply)

radio	television	newspaper	personal invitation by phone	personal invitation in person	Facebook	Twitter	Other social media	Other
☒	☒	☒	☒	☒	☒	☒	☒	☒

How would you rate your health department's efficiency and effectiveness in delivering flu vaccines to the community? Drag the scale to indicate the desired number. (1 being poor and 10 being excellent)

What is the primary reason for your rating in the previous question?

What, if anything, do you find novel or exemplary about your LHD's mass flu clinics?

Hypothetically, if you had all the necessary resources, what would you improve upon, in terms of your local health department's flu vaccination delivery efforts?

Please press the "SUBMIT" button once you have answered the questions. Thank you for your time and participation!

Appendix E. LHD officials That Completed the Questionnaire

Contact Name	County, State	Title	Address, City, Zipcode
Amanika Duncan	Pulaski, AR	Nurse Manager	3915 w 8th st Little rock AR 72204
Shane Bies	Oakland, MI	Public Health Nursing Services Administrator	1200 N. Telegraph Rd. Pontiac MI 48341
Jennifer Birchett	Oklahoma State	Immunization Field Consultant	1904 Gordon Cooper Drive Shawnee OK 74801
A. Lawrence	Comal, TX	Office Mgr/Vaccine Program Manager	178 East Mill, Suite 210 New Braunfels, TX 78130
Patricia Cook	Dallas, TX	Immunization Supervisor	2377 N. Stemmons Fwy. Dallas, TX 75207
Vivian Flores	Bexar, TX	Program Manager	332 W. Commerce, San Antonio, 78205
Cindy Modie	Cuyahoga, OH	Supervisor Vaccine Services	5550 Venture Dr. parma, ohio 44130
Edmee Botwright	Pima, AZ	Mgr. Vaccine Preventable Disease	3950 S. Country Club
Eleanor Peters	St. Louis, MO	Epidemiology Specialist	6121 N. Hanley Road, St. Louis, MO, 63134
Michele Canfield, RN-BC	Middlesex, NJ	Head Clinic Nurse	75 Bayard Street, 5th fl. New Brunswick, NJ 08901
Paul Leung	Contra Costa, CA	Immunization Coordinator, Contra Costa Public Health	597Center Avenue, Suite 200-A, Martinez, 94553
Charlissa Quick, RN, MSA	D.C	Interim Bureau Chief, CASH, DC/DOH	899 North Capitol Street, NE, 3rd Floor, Wash DC 20002
Mary Ellen Dragicevich	Fairfield, CT	Public Health RN	100 Mona Terrace, Fairfield, CT 06824
Bev Govednik	Dupage, IL	School Health Supervisor	111 N County Farm Road, Wheaton, IL 60187
Vicky L. Poplin	Franklin, KY	RN	40601
Frederick Radmer	Milwaukee, WI	Health Project Coordinator	841 N Broadway, Milwaukee WI 53202
Becky Grubb, RN,MPH	Tulsa, OK	Manager, Immunization Program, Tulsa Health Department	5051 S 129 East Avenue, Tulsa, OK 74134
Florastine Mack	Tarrant, TX	Division Manager	1101 S. Main Street, Fort Worth, TX 76104
Christine Gaiger	San Luis Obispo, CA	Immunization Coordinator	2191 Johnson Ave , San Luis Obispo, 93401
Karen Menza	Erie, NY	Immubnization Specialist, RN	608 William St., Buffalo, NY 14206
Diana Garcia	El Paso, TX	Clinic Manager	1580 George Diter Suite 102
Mary Skube	Hennepin, MN	Public Health Nurse	525 Portland Avenue South, MC 963, Minneapolis, MN 55415
Tammy Gay	Orange, FL	Immunization Program Manager	
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Eva Valilis is graduating from the University of Texas at Austin in May 2014 with a B.S. Public Health Honors degree. A student in the Dean's Scholars Honors Program in the College of Natural Sciences, Eva began research as a freshman in Freshman Research Initiative. She continued her research in Dr. Karen Browning's lab the summer following her first year. She completed her public health internship her third year at Austin/Travis County Health and Human Services Immunization Unit. She also studied abroad in Madrid, Spain, for two months before starting her final year at UT.

Eva is also actively involved in extracurricular organizations on campus. She has been on Dean's Scholars Council for three years and helps plan events for the honors program. She has also served as a College of Natural Sciences student ambassador and was an undergraduate teaching assistant for Dr. Sacha Kopp's Research Methods class. Eva is also a member of the spirit organization Texas Sweethearts and a member of the honorary female service organization Orange Jackets. She is vice president of a new organization on campus Delete Blood Cancer, which hosts bone marrow registration swab drives and raises awareness about blood cancers.

Eva is attending medical school next year at UT Houston Medical School. She plans on obtaining a Masters in Public Health to use as a clinician interested in community health.