



Promoting Access and Lowering Costs in Health Care:

The Case of Empowering Pharmacists to Increase Adult Vaccination Rates

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+ Introduction

The U.S. health care debate typically focuses on reforming the payment system, all but ignoring beneficial reforms to the practice of medicine. However, there are many opportunities to improve the quality of health care in the U.S. by improving patients' access to health care services. One example is the barriers that overly-restrict the administration of vaccines.

Vaccines are often referred to as one of the greatest advancements in public health – only clean water being more important.¹ Vaccinations reduce the rates of sickness and improve overall lifespans by: controlling the spread of infectious diseases; helping to eradicate diseases, where possible; mitigating the severity of diseases; and, helping to protect unvaccinated people, importantly those who may not be able to be vaccinated due to contraindications, so long as a large enough percentage of the population is vaccinated.

Although vaccines create important health benefits, public health officials believe that U.S. vaccination rates are too low. For instance, according to a study by *The Economist*, the U.S. measles vaccination rate has fallen below the “herd immunity threshold” (the rate of people, 95 percent, who must be vaccinated to stop the spread of a disease).² As Meissner (2015) describes, exceeding the herd immunity threshold is particularly important to “various segments of our society: to children too young to be vaccinated, to immunosuppressed patients who cannot be vaccinated, to elderly people who cannot mount an optimal immune response to a vaccine, to people in whom vaccine-induced immunity has waned, to people who have inadequate access to immunizations, and to people who remain unvaccinated by choice.”³

Ensuring that there is adequate vaccination coverage against Adult Vaccine-Preventable Diseases (VPDs) is an important public health issue in the United States, including diseases such as influenza, shingles, and pneumonia. Nevertheless, the Centers for Disease Control and Prevention (CDC) has also noted that the adult vaccination coverage in the U.S. is unacceptably low.⁴ Specifically, the CDC recommends people receive vaccines “throughout life to prevent vaccine-preventable diseases and their sequelae [consequences]. Adult vaccination coverage, however, remains low for most routinely recommended vaccines and well below Healthy People 2020 targets.”⁵ For example, the Healthy People 2020 target pneumococcal vaccination rate for people 65 and older is 90 percent. Less than 64 percent of adults 65 and older have received pneumococcal vaccines.⁶ Today, influenza and pneumonia represent the eighth leading cause of death among U.S. adults.⁷

Importantly, there are indications that improving adults' access to vaccines can meaningfully improve the adult vaccination rate. Toward this end, enhancing the ability of pharmacists to provide patients with vaccination services can meaningfully reduce the current access barriers. The purpose of this analysis is to present the potential benefits that empowering pharmacists to provide vaccination services can create.

The first section documents the inadequate adult vaccination rates and the resulting potential health consequences. Once the problem of an inadequate vaccination rate in the U.S. has been established, this problem will be linked, in part, to the restrictive environment for administering vaccines. Specifically, each state imposes restrictions on pharmacists regarding the vaccines that they can administer. Many of

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these restrictions are excessive, despite the evidence that pharmacists can administer vaccines safely and effectively. Since pharmacists are an important provider for administering vaccines, these restrictions are, effectively, an access barrier in the delivery of vaccinations.

The costs from these access barriers are even more problematic because the evidence shows that pharmacists are cost-effective vaccine providers. Consequently, due to the restrictions on pharmacists, costs (in both time and money) of vaccines are higher than necessary. The expected outcome from greater supply restrictions and higher demand costs is a smaller-sized market, which is precisely what is observed with respect to vaccines.

The final section will suggest reforms that will increase access to vaccines. These reforms should contain several components. First, the CDC maintains a recommended list of vaccines for adults.⁸ Pharmacists should have the authority to independently screen, assess, and administer all CDC recommended adult vaccines without a protocol or a prescription from a physician on a national basis, while being held to the same accountability and reporting requirements as other providers. Second, the federal government should establish nationally consistent reporting requirements that lower pharmacies' compliance costs (in terms of time and money). And third, pharmacists should have access to patients' vaccination history, enabling pharmacists to educate patients regarding potential the benefits of vaccines. The expected benefits from these proposed reforms are higher adult vaccination rates and improved overall public health.

+ Adult Vaccination Rates Remain Inefficiently Low

Every year people in the U.S. become sick, are hospitalized, and even die from vaccine-preventable diseases. According to the CDC:

- + Since 2010, flu-related hospitalizations in the United States have ranged from 140,000 to 710,000 and flu related deaths have ranged from 12,000 to 56,000.
- + About 900,000 people get pneumococcal pneumonia every year, leading to as many as 400,000 hospitalizations and 19,000 deaths.
- + 700,000 to 1.4 million people suffer from chronic hepatitis B, with complications such as liver cancer.
- + HPV causes over 27,000 cancers in women and men each year. About 4,000 women die each year from cervical cancer.⁹

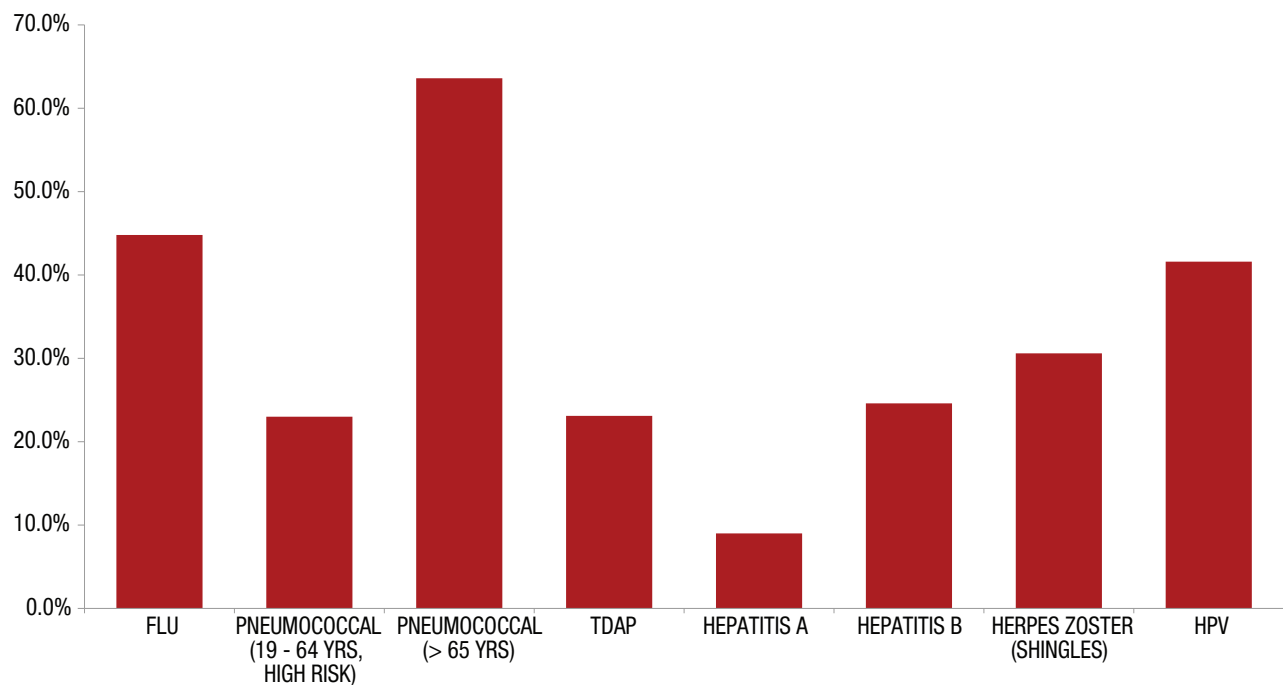
There are also economic costs from these diseases. According to the National Foundation for Infectious Diseases, “the cost of a moderately severe seasonal influenza outbreak may be \$10 billion or more, not including the value of lost years of life. Projected lost earnings due to influenza illness and loss of life are more than \$16 billion.”¹⁰

Improved vaccination rates can help reduce these adverse consequences from vaccine-preventable illnesses, which is why one goal of the CDC's Healthy People 2020 is to “increase immunization rates and reduce preventable infectious diseases.”¹¹ This drive to increase vaccination rates has led to some recent improvements. Based on the National Health Interview Survey (NHIS) data, adult vaccination rates for influenza, pneumococcal, Tdap, Herpes Zoster (shingles), and Hepatitis B (for health care professionals, HCP) all

increased between 2014 and 2015.¹² Yet, despite these improvements, a CDC analysis of this NHIS data concluded that the “adult vaccination coverage remains low for most routinely recommended vaccines.”¹³

Figure 1 presents the adult vaccination rates for the typically recommended vaccines. Putting these data into perspective, Williams et al. (2017) concluded that “vaccination coverage estimates for three of the four vaccines in this report that are included in Healthy People 2020 (influenza, pneumococcal, and hepatitis B [for HCP] vaccines) were below the respective target levels, including among insured adults and adults with multiple health care visits in the past year. Herpes zoster vaccination coverage in 2015 was 0.6 percentage points above the Healthy People 2020 target of 30 percent. Racial/ethnic differences in vaccination coverage persisted for all seven vaccines discussed in this report. These data indicate multiple missed opportunities for vaccination and the need to increase routine assessment of adult vaccination needs.”¹⁴

FIGURE 1 U.S. ADULT VACCINATION RATES - 2015¹⁵

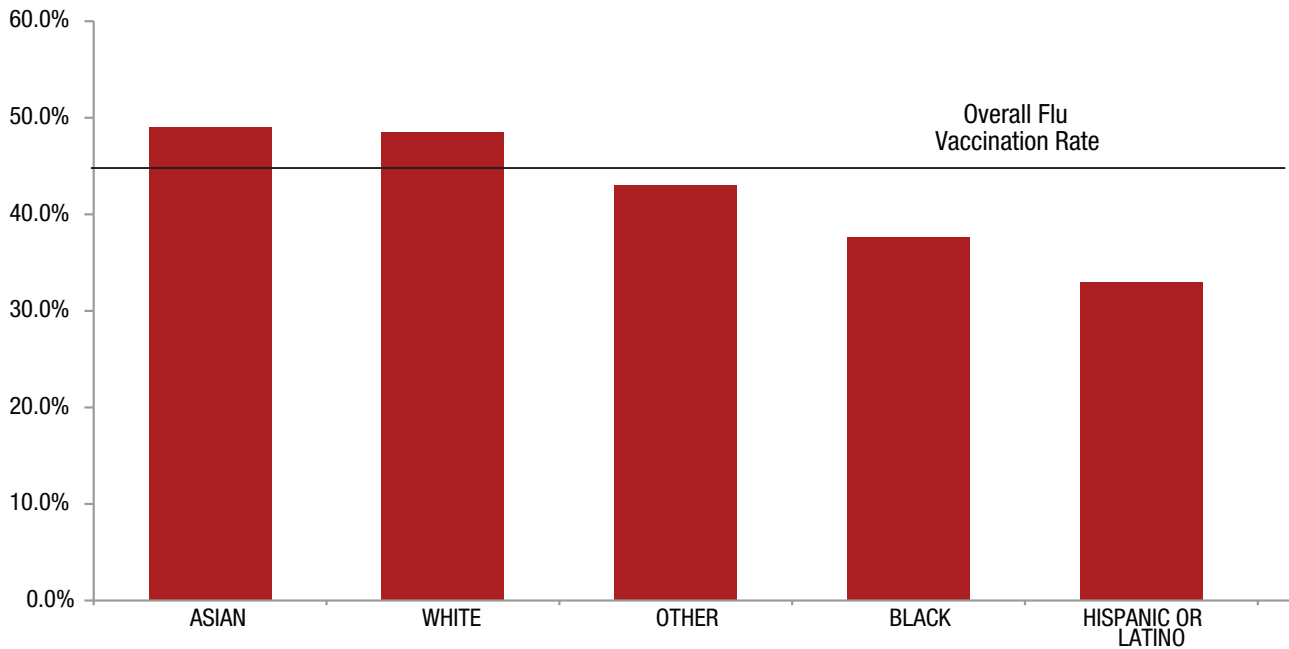


Source: CDC

Lu et al. (2015) confirm the findings of racial disparities referenced by Williams et al. (2017), concluding that “vaccination coverage was significantly lower among non-Hispanic blacks, Hispanics, and non-Hispanic Asians compared with non-Hispanic whites. However, racial and ethnic differences in vaccination levels narrow when adjusting for socioeconomic factors analyzed in this survey, but are not eliminated...”¹⁶ Logan (2009) has linked the lower vaccination rates to higher incidences of vaccine-preventable diseases among ethnic minority groups and higher fatality rates from these illnesses.¹⁷

Figures 2 and 3 illustrate these discrepancies based on the data from the 2015 *National Health Interview Survey*. Figure 2 illustrates that Asians have the highest flu vaccination rate, whites have an above average vaccination rate, blacks have a below average vaccination rate, and, Hispanics or Latinos have the lowest vaccination rate.

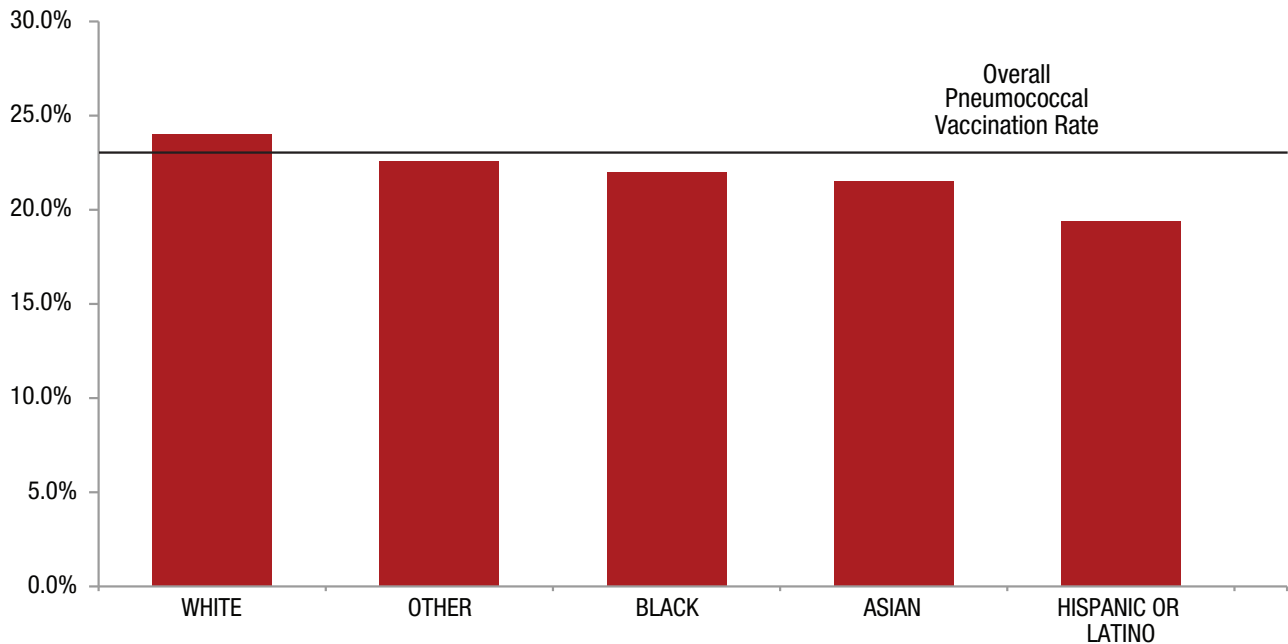
FIGURE 2 U.S. FLU VACCINATION RATES BY ETHNICITY - 2015¹⁸



Source: CDC

Figure 3 presents the vaccination rates by demographic group for the pneumococcal vaccine, which has a slightly different demographic breakdown. In the case of the pneumococcal vaccine, whites have the highest vaccination rate, followed by blacks, and Asians. Hispanics or Latinos once again have the lowest vaccination rate.

FIGURE 3 U.S. PNEUMOCOCCAL VACCINATION RATES BY ETHNICITY - 2015 (19 – 64 YEARS, HIGH RISK INDIVIDUALS)¹⁹



Source: CDC

Researchers have also noted vaccination discrepancies between rural areas and urban areas, and between the insured and the uninsured. For example, Talbert et al. (2018), found that as of 2014, there was “a significant disparity in pneumococcal vaccine service delivery...between rural and urban areas across the nation, with a 60 percent lower vaccination rate observed in rural communities.”²⁰ Williams et al. (2017) found that adults without health insurance reported lower vaccination rates than adults with health insurance, even after accounting for ethnicity and geographical factors.²¹

+ Pharmacists as a Means to Improve Access

Effectively improving the vaccination rate requires identifying the barriers and costs that are preventing too many adults from getting vaccinated. It logically follows that policies geared toward improving vaccination rates will be more successful if they account for the needs of the under-vaccinated patient populations, particularly patients who are part of the ethnicities with below average vaccination rates, patients who live in rural areas, and uninsured patients.

Typically, patients who do not obtain the recommended vaccines cite issues such as: information barriers (e.g., not understanding the importance of vaccines or underestimating the risks of not being vaccinated); the costs of vaccines; insurance status; language barriers; fear of needles; and, a mistrust of the health care system.²² Recommendations to address these barriers include education programs to increase awareness and improve demand for vaccines,²³ and increased access to vaccination services at lower costs.

Providers also cite barriers that limit the number of vaccines they offer, with the most-oft cited barrier being the costs to stock the vaccines. Summarizing the results from a 2012 survey of doctors, “only 31 percent of family physicians and 20 percent of general internists reported stocking all 11 adult vaccines that were recommended for routine use in 2012. The most important barrier to stocking and administering vaccines was financial for both family physicians and internists. Physicians in private practice, those with fewer than 5 members in a practice, physicians from the South, West (for family physicians only), and Midwest, and those who had a higher proportion of patients with Medicare part D (internists only) reported the most financial barriers.”²⁴

The most important barrier to stocking and administering vaccines was financial for both family physicians and internists.

Studies have shown that pharmacies are well placed to address these barriers as they tend to be more effective, lower-cost providers of vaccinations. In a 2014 analysis, Singhal and Zhang examined the direct medical costs for alternative vaccinations across different medical settings.²⁵ These direct medical costs “included the health plan and enrollee paid amounts for the product; vaccine administration; dispensing fee; and, where applicable, the visit.”²⁶ Table 1 reproduces their results.

**TABLE 1 AVERAGE DIRECT MEDICAL COSTS PAID PER ADULT VACCINATION
VARIOUS MEDICAL SETTINGS**

	Physician Offices	Other Medical Settings	Pharmacies
Zoster (shingles)	\$208.72	\$209.51	\$168.50
Pneumococcal	\$65.69	\$72.11	\$54.98
Influenza	\$29.29	\$24.30	\$21.57

Source: Singhal and Zhang (2014)

As Table 1 illustrates, the average vaccination costs in pharmacies were less than the average vaccination costs in either physicians’ offices or other medical settings. Summarizing these results, Singhal and Zhang (2014) state “the average direct costs paid per adult vaccination were lower in pharmacies compared with physician offices and other medical settings by 16 percent-26 percent and 11 percent-20 percent, respectively. These results were mostly consistent across geographic regions and types of health plans.”²⁷

Confirming the Singhal and Zhang (2014) results, Fontanesi et al. (2010) examined the cost and efficiency of providing vaccination services at different care settings in San Diego, finding that “pharmacist-provided vaccination services had the lowest unit cost, as well as the best productivity and efficiency indexes of the 3 vaccination strategies studied. Pharmacists also proved more consistent in following Advisory Committee on Immunization Practices national guidelines [the recommendations from a CDC advisory group of medical and public health experts on the use of vaccines]. Given the number of pharmacists in the United States, optimizing their vaccination capacity could double the nation’s vaccination capacity.”²⁸

In addition to lower direct costs, pharmacies also offer greater convenience including expanded hours of operation, more flexible scheduling than physicians’ offices or public health clinics, and multiple locations (located near where people live). These convenience benefits have been linked to increased vaccination results. In fact, these improvements to vaccination rates were due, in part, to pharmacies providing vaccination services during non-working hours that are more convenient for many adults.

As an example of this increased availability, Goad et al. (2013) reviewed the vaccination data of a national pharmacy chain finding that 30.5 percent of the more than 6 million vaccine doses dispensed were administered during nights, weekends, and holidays.²⁹ Additionally, more than one million vaccinations (17.5 percent of all vaccinations) were administered during lunch hours (11am-1pm); and uninsured patients were more likely to be vaccinated during these off-clinic hours than individuals with insurance.³⁰

Burson et al. (2016) performed a systematic review of the literature (47 articles in total) to assess “the feasibility, acceptability, and effectiveness of community pharmacies as sites for adult vaccination.”³¹ Their review found “that pharmacy-based immunization services (PBIS) have been facilitated by state regulatory changes and training programs that allow pharmacists to directly provide vaccinations. These services are widely accepted by both patients and pharmacy staff and can improve access and increase vaccination rates. However, political and organizational barriers limit the feasibility and effectiveness of vaccine delivery in pharmacies.”³²

The lower costs and greater efficiencies associated with pharmacies have also been linked with higher adult vaccination rates. As one example with respect to the flu vaccine, Drozd et al. (2017) found direct evidence linking increased immunization rates to policies that allowed pharmacists to administer vaccines.³³ Summarizing their findings, Drozd et al. (2017) stated:

The present study suggests that regulations implemented to expand pharmacists' role in health care delivery through the administration of seasonal influenza immunizations have had a positive impact on the national efforts to increase immunization rates. Our findings show that states had significantly higher long run seasonal influenza immunization rates among most nonelderly adults after policy changes allowed pharmacists to administer immunizations. For example, in 2013, we estimated that 4.1 million additional adults were immunized for seasonal influenza.³⁴

Pharmacists are also well placed to address the disparities in racial and geographical vaccination rates. Pattin (2017) reviewed studies that addressed the challenges associated with access to vaccines among minority populations. Overall, the review found that enabling pharmacists to provide vaccines has helped to reduce the vaccination disparities of minority populations.³⁵

Similarly, pharmacists have been linked to improvements in the rural-urban divide. As an example, Talbert et al. (2018) found

that almost a quarter of U.S. adults who reported receiving an annual influenza vaccine indicated they received those services from a pharmacy-based store. A significantly greater proportion of pneumococcal vaccine services are delivered by pharmacy providers in rural areas compared to urban areas, and regression models indicate that pharmacy providers have a significant impact on pneumococcal vaccine delivery in rural areas. Given that over 50 percent of the nation's primary care health professional shortage is in rural areas, access to primary care providers may limit delivery of pneumococcal vaccination services in that setting, resulting in a shift to service delivery in pharmacies as shown in this study. Rural pharmacies play a key role in access to pneumococcal vaccinations for Medicare patients. Engaging community pharmacists who are already embedded in rural communities may help address the need for increasing rural populations' access to health care and improving vaccination rates across all demographic sectors.³⁶

In recognition of these realities, many physicians already refer their patients to pharmacies to receive vaccinations. Lowry (2014), for example, noted that "most physicians reported that they refer patients to get the vaccines they did not stock, most often to a pharmacy or public health department. ...the physicians also thought the pharmacist played an important role in vaccinating adults."³⁷

Despite the benefits, which are summarized in Table 2, and as noted by Burson et al. (2016), barriers still exist that limit the ability of pharmacies to vaccinate patients. Due to their positive impact on increasing adult immunization rates, policy reforms should eliminate these "political barriers" that unnecessarily restrict pharmacies' ability to provide vaccines.

TABLE 2 SUMMARY OF BENEFITS FROM ENHANCING PHARMACISTS' ABILITY TO ADMINISTER VACCINES

1. Pharmacies typically have lower costs and higher productivity in administering vaccines.
2. Pharmacies offer patients greater time and locational convenience.
3. Pharmacies are well positioned to serve under-vaccinated populations, particularly in rural communities.
4. Pharmacists are well positioned to educate patients on the benefits from vaccines.

+ Identifying the Political Barriers That Restrict Pharmacies' Vaccination Services

Two decades ago, pharmacists were not allowed to administer vaccines in most states – only nine permitted the practice.³⁸ As of 2017, all states now permit pharmacists to administer vaccines to some extent. Further,

many states initially authorized pharmacists only to administer the influenza vaccine, that authority has expanded to other vaccines in most states.

Nearly all states now allow pharmacists to administer all or almost all vaccines, including routine adult vaccines like herpes zoster and pneumococcal and travel vaccines, although most states impose burdensome restrictions. Since 2012, seven states have allowed pharmacists to administer all vaccines.³⁹

While all states grant pharmacists the ability to administer vaccines, the authority varies across the states.

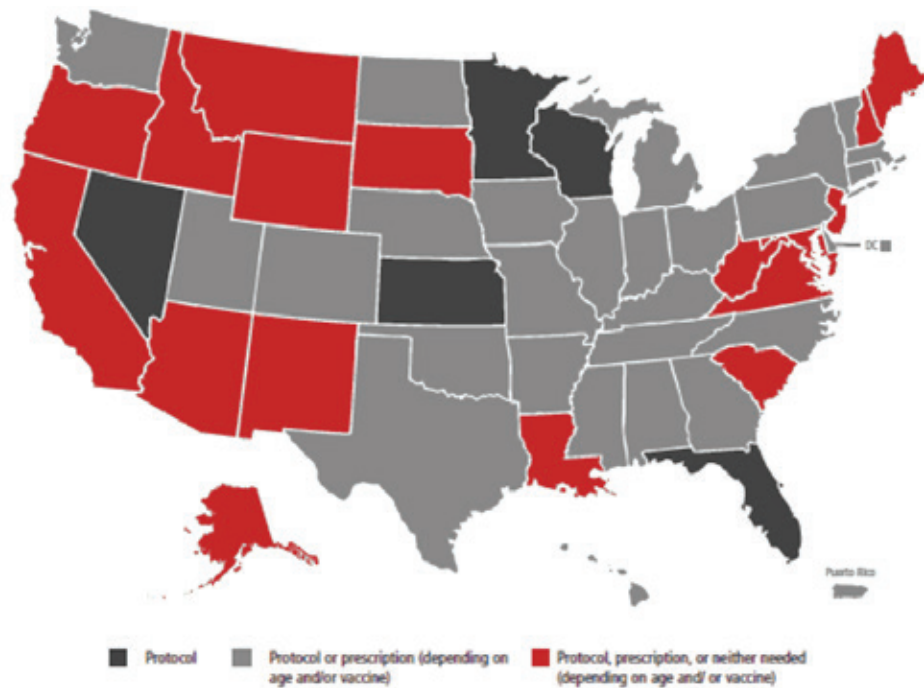
Reflecting these realities, obtaining an immunization certification is now a required element of any accredited Doctor of Pharmacy curriculum. Further, all pharmacists that administer vaccines are trained on the CDC's national immunization standards and recommendations.⁴⁰

While all states grant pharmacists the ability to administer vaccines, the authority varies across the states. The state authorizations for pharmacists to administer immunizations, which can vary within a state by type of vaccine, can be categorized into three primary policy types (Xavioer 2017 refers to these policy types as models):⁴¹

- + ***States that require a prescription from a physician:*** The state requires that patients obtain prescriptions from physicians before vaccines can be administered at a pharmacy.
- + ***States that require a vaccination protocol:*** The protocol stipulates which vaccines, under which conditions, and which procedures to follow for pharmacists administering vaccines. In several states, the protocols must be agreed to by a physician or, in some cases, a state public health department.
- + ***States that empower pharmacists to independently vaccinate without a prescriber's order or a protocol:*** The state grants pharmacists the authority to directly screen, assess, and administer vaccines autonomously without a protocol or a prescription from a physician.

Figure 4, which is reproduced from Xavioer, 2017 categorizes the states by these three policy types.

FIGURE 4 STATES CATEGORIZED BY PHARMACIST POLICY TYPE - JULY 2016 ⁴²



Source: Xavier (2017)

As illustrated in Figure 4, seventeen states empower pharmacists to independently administer certain vaccines without a prescriber’s order or a protocol. Since this policy environment imposes no excessive regulatory costs, these policies enable pharmacies to provide patients with vaccination services most efficiently. If applied to all adult vaccines recommended by the CDC, then this policy will create the largest positive incentive to encourage greater adult vaccination rates.

As an illustration of the benefits this policy model can enable, a pilot study in Washington State found that vaccination rates improved when pharmacists were given access to the necessary data and had the authority to act on the information.⁴³ Specifically, Blum (2018) examined the impact from eight community pharmacies in Washington State who were granted access to the patients’ vaccination history. Not only did the pharmacists have access to information, they were empowered to identify for the patients their unmet vaccination needs (e.g. the pharmacists directly addressed the informational barriers identified above).

The results of the pilot program were encouraging. During the pilot program, the eight community pharmacies increased the number of vaccines administered by 41.4 percent over the 6-month period.⁴⁴ These results are dependent on pharmacists having the authority to “screen, assess, and administer vaccines autonomously without a protocol or a prescription from a physician.”⁴⁵

While the results of Blum (2018) illustrate the potential benefits that can be gained when pharmacists are empowered to independently administer vaccines, many of these 17 states impose limits on the vaccines that pharmacists can independently administer. For example, several states only authorize pharmacists to administer the annual flu vaccine; other states restrict pharmacists to vaccinations for flu, pneumococcal, and zoster. In other instances, there are age restrictions. Therefore, many of the states with independent authority regulations do not effectively implement them.

The regulations imposed in the other 33 states (the states that require a prescription and the states that require a vaccination protocol) impose even greater restrictions. How restrictive will vary, sometimes widely, across the states and typically differ based on the patient's age and the specific vaccine being administered.

In five of these states, pharmacists must first obtain a prescriber-issued protocol before they can administer the vaccine, which is an even more burdensome form of these regulations.⁴⁶ Due to these restrictions, pharmacists in these states cannot, for all intents and purposes, administer vaccines unless they have formed a collaborative agreement with local physicians.⁴⁷

Requiring prescriptions and protocols are problematic because they impose unnecessary costs and obstacles on the pharmacist providers, increase the time required before a vaccine can be administered, and decrease the convenience of obtaining a vaccine from a pharmacy. In short, imposing prescriptions and protocols

Having to comply with the overly-restrictive regulations promulgated by these states imposes excessive costs on pharmacies, and may even effectively eliminate the convenience, efficiency, and education services the pharmacies can offer patients.

reduce the value that the pharmacists can provide. Further, pharmacists may need to turn patients away who have prescriptions but do not qualify for immunization under the written protocols, or if a protocol hasn't been established. Many states also impose more than one regulatory structure at the same time, indicating that different vaccines will have different approval requirements. Levying multiple models increases the regulatory complexity for pharmacies, further decreasing their ability to be effective vaccination providers.

In comparison to these policy environments, states that do not require prescriptions nor protocols remove the time-consuming barrier of obtaining a physician prescription or practicing under a site-specific protocol. Having to comply with the overly-restrictive regulations promulgated by these states imposes excessive costs on pharmacies, and may even effectively eliminate the convenience, efficiency, and education

services the pharmacies can offer patients. In either scenario, the benefits from expanded access are lost due to these overly-restrictive policy environments.

In addition to these issues, states also impose varying degrees of reporting requirements. The variation in how to report immunization information to the states, and the varying consent requirements pharmacists must obtain from patients, have been noted by pharmacists as major challenges that require a substantial amount of staff time that frequently understaffed pharmacies do not have. According to a 2014 survey of pharmacists of the American Immunization Registry Association:

For pharmacies, the greatest challenges are restrictions on the type of files that IIS [Immunization Information Systems] are willing or able to accept (e.g. pharmacy can generate a flat file but state requires HL7 or vice versa). These restrictions lead to expensive development efforts, duplicate data entry by pharmacy staff, or requirements for the pharmacy to contract out for intermediary messaging services. When interfaces are pursued, limited staffing resources and infrastructure on the IIS side can lead to a lengthy onboarding process – sometimes six months to a year or longer before an interface goes live. State vari-

ations in the IIS specifications were also cited by almost all of the pharmacy chains as being a major challenge (specifically required fields, reporting methods supported, reporting timelines). State variations require a substantial amount of effort on behalf of pharmacy staff resources to configure, compile, and transmit pharmacy data on a weekly basis. A final challenge shared by almost all pharmacies was IIS consent requirements mandated through state/local law. Pharmacies generally do not have a systematic way to capture or transmit consent requirements of the IIS. In most cases, the pharmacies are hard coding a consent field in the transmission file to whatever default is most conservative (e.g. opt out).⁴⁸

Pharmacists have noted that these costs have led to an underutilization of pharmacists to administer vaccines. More broadly, eliminating the barriers that are currently inhibiting pharmacists from being an effective provider of vaccines can increase access and help reduce the size of the unvaccinated population.

+ Empowering Pharmacists to Improve Vaccination Rates

The evidence shows that pharmacists, when effectively empowered, play a valuable role in reducing the inadequate adult vaccination rate. Pharmacists provide vaccinations at lower costs, and with greater convenience, for many patients. They also provide valuable education services, particularly with respect to the other CDC recommended immunizations that a patient should receive.

Establishing a policy environment that “effectively empowers” pharmacists is the key. The lessons from the current regulatory environment illustrate that an effective policy will contain the following components:

- + Grant pharmacists the authority to independently screen, assess, and administer all CDC recommended adult vaccines without a protocol or a prescription from a physician on a national basis, while holding pharmacists to the same accountability and reporting requirements as other providers;
- + Create streamlined, nationally consistent, reporting requirements to lower the costs (in terms of time and money) that pharmacies must pay to comply with the regulations; and
- + Enable pharmacists to have access to patients’ vaccination history, enabling pharmacists to educate patients regarding potential benefits of vaccines.

Reforms such as these will reduce the unnecessary regulatory costs imposed on pharmacists and increase the choices patients have with respect to vaccination services. Empowering pharmacists to administer vaccines also serves as an important case study for the broader health care system. Increasing access across the health care system can provide patients with more choices, increase overall health care quality, and effectively “bend the health care cost curve”.

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The National Adult and Influenza Immunization Summit (https://www.izsummitpartners.org/content/uploads/2016/01/NAIIS_Adult_Immunization_Disparities-4-01-2015.pdf) also summarized interventions that can improve the demand for vaccines. The suggested interventions include: using reminder/recall systems; using standing orders for vaccination; assessing vaccination coverage among provider practices; using immunization information systems (“registries”); and improving public and provider awareness on the importance of vaccines for adults.

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