



**OPERATION**

# IMMUNIZATION

STUDENT PHARMACISTS AND PRACTITIONERS PROTECTING THE PUBLIC HEALTH

**RESEARCH**

---



# Implementation of a Community Pharmacy-Based Influenza Vaccination Program

Michael E. Ernst, Carl V. Chalstrom, Jay D. Currie, and Bernard Sorofman

**Objective:** To increase accessibility of influenza vaccine in a rural community by establishing a community pharmacy-based influenza vaccination program. **Setting:** An independent pharmacy in a rural eastern Iowa community of 5,000 people. **Practice Description:** Protocols for identification and screening of patients, administration of vaccine, and treatment of emergencies were developed by the pharmacist and approved by the county health department medical director. Administration of vaccine began October 15, 1996, and was completed on December 6, 1996. **Practice Innovation:** Patients were prospectively and retrospectively identified to receive the vaccination. Informed consent was obtained. Vaccine was administered by the pharmacist after screening for contraindications and counseling the patient. Weekly vaccination records were forwarded to the collaborating physician to update patient charts. **Main Outcome Measurements:** To determine whether accessibility of influenza vaccine in the community was increased through pharmacist administration, the proportion of patients immunized in the pharmacy who were not vaccinated the previous year was determined. **Results:** The pharmacist administered 343 doses of vaccine. Two-thirds of the immunized patients (67.9%) reported also being immunized the previous year. These patients were generally older (65 years of age  $\pm$  13) than the previously nonimmunized patients (54 years of age  $\pm$  16). However, 60.8% of the patients not immunized the previous year reported either they would not have gone elsewhere for the immunization (45.3%), or were unsure (25.5%). **Conclusion:** The data collected suggest that pharmacist administration of influenza vaccination in a rural community pharmacy increases access and, possibly, immunization rates. This may be especially true among high-risk younger adults who are often overlooked and would not normally have received the immunization.

*J Am Pharm Assoc. 1997;NS37:570-80.*

Few preventive health care interventions are as favorable as immunization. Immunization saves millions of dollars annually that would otherwise be spent on treatment of vaccine-preventable diseases,<sup>1,2</sup> while reducing lost productivity and lowering morbidity and mortality rates. In recognition of these benefits, multifaceted strategies have been directed in recent years toward easing or removing such constraints to immunization as cost and accessibility. As part of this new initiative, alternative

vaccine-delivery systems are being examined, which include pharmacists playing integral roles in identifying, screening, and counseling patients, and administering vaccines.<sup>3</sup> For example, one study is examining whether pharmacists serving as immunization advocates improve vaccination rates among children in rural West Virginia.<sup>4</sup> A similar demonstration project in Mississippi is determining whether pharmacist administration of vaccines increases immunization rates among adults.<sup>5</sup>

Grabenstein demonstrated that community pharmacists can increase overall influenza immunization rates by simply advocating the vaccination.<sup>6</sup> In his study, community pharmacists in Durham County, N.C., sent personalized letters to 598 patients who were over 65 years of age or who were receiving prescription medications for heart or lung disease or diabetes. Immunization rates increased from 54.2% (130/240) in the control group, which received no letter, to 64.5% (156/242) in the intervention group. In a follow-up study, Grabenstein and colleagues constructed a decision tree of the consequences of implementing a pharmacy-based vaccine-advocacy program. They determined that routine advocacy of influenza immunizations by community pharmacists could substantially prevent morbidity and mortality and reduce health

Received December 12, 1996, and in revised form May 23, 1997. Accepted for publication June 17, 1997.

Michael E. Ernst, PharmD, was a PharmD student at the time of this writing; currently he is a specialty resident in family medicine, College of Pharmacy, The University of Iowa, Iowa City. Carl V. Chalstrom is a pharmacist at The Pharmacy on Main, Anamosa, Iowa, and adjunct clinical instructor, College of Pharmacy, The University of Iowa, Iowa City. Jay D. Currie, PharmD, is associate professor (clinical), College of Pharmacy, The University of Iowa, Iowa City. Bernard Sorofman, PhD, is associate professor, College of Pharmacy, The University of Iowa, Iowa City. All authors are from the Division of Clinical and Administrative Pharmacy.

Correspondence: Michael E. Ernst, PharmD, Department of Family Medicine, University of Iowa, 2133 Steindler Building, Iowa City, IA 52242. Fax: (319) 335-8302. E-mail: michael-ernst@uiowa.edu

care expenses.<sup>7</sup> The authors estimated that a vaccine-advocacy letter sent by pharmacists to 100,000 patients at risk for influenza would increase vaccine acceptance rates 10.3% above baseline. Assuming Medicare reimbursed pharmacists \$1.10 per patient for the letter, they predicted the total expenditure of \$110,000 would result in a cost savings of nearly \$300,000.

Personalized communications from pharmacists have previously been shown to be more effective at increasing the numbers of vaccinated individuals than using traditional vaccine advocates such as private physicians.<sup>7</sup> For example, Spruill et al. described a pharmacist-coordinated pneumonia and influenza vaccination program in an ambulatory care center located in a medically underserved area of Savannah, Ga.<sup>8</sup> After pharmacists identified 1,593 patients eligible for vaccinations, pneumococcal vaccine was administered to 474 patients, and a follow-up letter urging the need for influenza vaccination was mailed afterward. Of the 474 patients receiving the pneumococcal vaccine, 84% (397) also received the influenza vaccine as a result of the follow-up letter. Cost analysis of the data revealed an estimated \$47,260 savings over five years in treatment of pneumococcal pneumonia. This figure does not include the additional savings known to be associated with influenza vaccination.<sup>1</sup> Before implementation of the program by Spruill et al., a review of the vaccination status of 15,000 patients at their center determined that only 10 of the patients had received both the pneumococcal and influenza vaccine. It is unclear exactly why vaccine acceptance among patients is greater after pharmacist intervention. Perhaps it is a result of pharmacists being more successful at identifying patients who are highly motivated about their health care, or it could be due to the efficient and specific message of the pharmacist to the patient at risk, as Grabenstein has noted.<sup>7</sup>

Pharmacists are in a unique position to improve the delivery of immunizations to target populations. In Iowa, as in many other states, the pharmacist is often the most accessible health care provider

**Table 1. States That Allow Pharmacists to Administer Immunizations**

Alabama	Missouri
Alaska	Nebraska
Arkansas	New Mexico
California	Oklahoma
Georgia	South Carolina
Illinois	South Dakota
Indiana	Tennessee
Iowa	Texas
Kansas	Virginia
Kentucky	Washington
Michigan	West Virginia*
Mississippi	

\* In West Virginia, a pilot project partially funded by the Centers for Disease Control and Prevention is assessing the value of having health department nurses administer vaccinations in community pharmacies.

Source: APhA and Reference 10.

because of an aging population and the predominance of rural communities.<sup>9</sup> Currently, pharmacists are granted legal authority to administer vaccinations in 22 states, and one other state has implemented a limited program in which nurses administer vaccines in community pharmacies (Table 1).<sup>4,10</sup> Despite regulatory approval allowing pharmacists to provide this service, few pharmacists in Iowa are embracing the opportunity to expand their practice in this manner. The situation is similar in most other areas of the country. Previously, several barriers may have prevented pharmacists from administering vaccinations. For example, pharmacists may have been uninformed of the legal issues surrounding pharmacist administration in their particular state, or unfamiliar with the steps involved in implementing a pharmacy-based immunization program.

In an effort to improve vaccine delivery and awareness in our

**Table 2. Steps in Implementing a Community Pharmacy-Based Influenza Vaccination Program**

- Research the need in your community.
- Determine your role—administration of vaccine versus advocacy alone.
- Develop protocols for administration of vaccine and emergency procedures.
- Submit your program to a collaborating physician for approval.
- Apply for a Medicare provider number.
- Identify a goal for the number of vaccinations to administer and purchase appropriate vaccine and supplies.
- Establish a reimbursement schedule.
- Become certified in basic cardiac life support (BCLS) and cardiopulmonary resuscitation (CPR). Receive training on how to administer injections.
- Advertise your program—fliers, radio announcements, newspaper advertisements, word of mouth.
- Identify patients—both prospectively at time of prescription presentation and retrospectively through prescription review.
- Screen patients for precautions and contraindications. Obtain previous immunization history, if possible.
- Counsel on the vaccine and administer the injection.
- Document the immunization.
- Notify the physician of immunized patients.

rural Iowa community, we organized an influenza immunization program in our community pharmacy in the fall of 1996. This article outlines the research conducted and the steps used to implement the program (see Table 2) and provides a descriptive analysis of the outcomes.

## The Case for Influenza Vaccination

Influenza-associated morbidity and mortality account for 10,000 to 40,000 deaths annually in the United States at an estimated annual cost exceeding \$12 billion.<sup>1,11</sup> Ninety percent of these deaths occur in persons aged 65 years and older.<sup>11</sup> One of the national health objectives for the year 2000 is to achieve vaccination rates of at least 60% in noninstitutionalized patients at high risk for complications of influenza, including those aged 65 years and older.<sup>12</sup> The plan emphasizes the need for new methods of reaching people in need of immunizations, as well as new approaches to removing cost and accessibility constraints. Increasing the collaboration between the public and private sectors to improve awareness of the benefits of and opportunities for immunization is one tactic suggested. Yet, despite recommendations by the Advisory Committee on Immunization Practices (ACIP) for annual vaccination against influenza, nearly half of elderly Americans at risk for complications are not vaccinated.<sup>11</sup> The Centers for Disease Control and Prevention (CDC) reports that overall influenza vaccination rates for persons 65 years of age and older increased from 1989 (33%) to 1993 (52%); however, for high-risk persons younger than 65 years of age, rates are estimated to fall below 30%.<sup>11</sup>

Perceived and real barriers to the achievement of these goals include uncertainty about the efficacy and cost-effectiveness of immunization, financial barriers, missed opportunities on the part of health care providers to identify and recommend vaccination, and lack of convenient accessibility.<sup>1,13-15</sup> These barriers can be and are being removed. Medicare began reimbursing providers for influenza vaccine in 1993 after several studies established the cost-effectiveness of the vaccination.<sup>1,16</sup> This decision helped reduce the financial barriers that, in the past, may have prevented many elderly patients from being immunized. With regard to cost-effectiveness, one study concluded that immunization resulted in an average direct cost savings of \$117 per person vaccinated. Cumulative savings totaled nearly \$5 million for the 41,418 people immunized by reducing the number of hospitalizations for not only influenza, but pneumonia, acute and chronic respiratory conditions, and congestive heart failure, as well.<sup>1</sup>

Community pharmacists are well positioned to work with other health care professionals to overcome the accessibility barrier and implement new immunization strategies. The equivalent of the entire population of the United States (250 million people) walks into a pharmacy every week.<sup>17</sup> Moreover, the transition to pharmaceutical care as the practice standard of the profession is empowering pharmacists to implement immunization programs as part of their patient-centered practices.

Participation in a comprehensive training program can help pharmacists establish credibility with physicians and nurses when planning and implementing a pharmacy-based vaccination program. The state pharmacy associations in Washington and Georgia have offered programs to train pharmacists to administer immunizations. Recently, pharmacists in Mississippi (in the aforementioned demonstration project) completed a pilot training program developed by the American Pharmacists Association to prepare them to administer immunizations; pharmacists in Iowa attended a similar program in July.

## Researching the Need

The first step in establishing the immunization program at The Pharmacy on Main, Anamosa, Iowa, was to determine how the pharmacy could satisfy the immunization needs in the community. Clearly, the health care needs of patients in a rural Iowa community differ from those of patients in other geographic areas. In our community, for example, accessibility was an important consideration in confirming the need for another vaccination provider. The community health department offered flu vaccinations only once per week, at different sites each time. This irregular schedule made obtaining vaccination difficult for patients who missed the designated days. Patients then either had to make an appointment at the physician clinic in town, or drive to another community that offered the vaccination.

The low number of providers in the community was identified as an accessibility barrier, indicating that the flu vaccination needs of the community were possibly not being met. The only physician clinic in town is staffed by just one physician and two physician assistants. During previous flu seasons, the staff was often short-handed because of the many scheduled influenza vaccinations.

Next, using census information from the State of Iowa Department of Elder Affairs and State Library, we estimated the percentage of target individuals vaccinated each year for influenza in the county, to confirm the need for an additional provider. Census data for 1990 indicated that there were approximately 4,014 persons aged 60 years or older in the county, representing 20.6% of the population.<sup>18,19</sup> Our pharmacy supplies influenza vaccine to two of the three providers in the county. On the basis of pharmacy sales records from 1995, we estimated that approximately 1,300 to 1,400 doses were given in the county, or about 30 to 35% of the target population. Even if more doses had been given than estimated, vaccination rates would likely have remained below the desired 60% goal.

## Developing Protocols

Pharmacists in Iowa do not have prescriptive authority; therefore, those wishing to administer vaccines must collaborate with a physician. Protocols for administering influenza vaccine as well as coping with emergencies were written by the pharmacist. We modeled our protocols after those of Baggett Clinical Services in Levelland,

**Figure 1. Example: Standing Order and Protocol for Administration of Influenza Vaccine**

THE PHARMACY  
 MAIN ST.  
 RURAL, IA

**Authorizing Prescriber Statement for Influenza Vaccination**

J. Doe of The Pharmacy, and other licensed pharmacists or visiting nurses employed by The Pharmacy, acting as delegates for Dr. Physician according to and in compliance with Article 155A.3 and Article 155A.4 of the Iowa Pharmacy Practice Act, will administer injectable influenza vaccination on the premises of The Pharmacy only, and for a fee.

Influenza Virus Vaccine 0.5 mL IM may be given to consenting individuals at The Pharmacy. Vaccine may be given as early as September if necessary, but preferably late October/November.

**Criteria**

1. The vaccine is available to:
  - a. Adults with chronic disorders of cardiovascular or pulmonary system, or
  - b. Healthy individuals 60 years of age or older, or
  - c. Persons who have contact with high risk persons.
2. Each recipient will be made aware of the benefits and risks, and shall sign informed consent.
3. A standard form will be utilized to document immunizations and The Pharmacy will maintain a patient record of administration.
4. The Pharmacy will inform the prescribing physician of vaccinated individuals on a regular basis.

**Contraindications**

1. Febrile illness.
2. Severe allergy to eggs.

**Emergencies**

Use The Pharmacy Protocol and Standing Order for Management of Allergic and Anaphylactic Reactions for emergencies.

Date	Physician, MD Medical Director, County Health Department
Date	J. Doe, PharmD Chief Pharmacist, The Pharmacy

This authorization will be in effect for one year unless rescinded earlier in writing by either party. Any changes in protocol must be agreed upon by both parties.

Adapted with permission from Black Hawk County Health Department, Waterloo, Iowa.

Texas, and the Black Hawk County Health Department in Waterloo, Iowa (see Figures 1 and 2). The physician then approved and signed these documents, thereby authorizing the pharmacist to identify and screen patients, and administer the vaccine.

We developed the protocols before approaching the physician for approval in order to strengthen our position and demonstrate that we were fully prepared to implement this service. Protocols were

reviewed internally by the pharmacy staff before submittal to the physician for approval. The protocol for flu vaccine administration (see Figure 1) contained the following information: (1) statement from the prescriber authorizing the pharmacist to administer flu vaccine to consenting individuals, (2) criteria for administration, (3) criteria for identification of the target population, and (4) contraindications to receiving the vaccine.

Protocols were valid for one year from the date of signing by the pharmacist and physician. The protocol for treatment of allergic and anaphylactic reactions included information regarding the following (see Figure 2): (1) supplies to stock, (2) recognition of anaphylactic reaction, (3) emergency treatment procedures, and (4) weight- and age-based dosages of epinephrine and diphenhydramine. The protocol also served as the standing order to administer the medications if needed in the event of an anaphylactic reaction and was signed by the pharmacist and physician. The pharmacist was also trained to perform cardiopulmonary resuscitation (CPR) in the event of an emergency.

**Submitting a Proposal for Physician Authorization**

Once the research was completed, the need established, and the protocols written, we contacted the physician for authorization. We submitted our proposal

to the local physician, because he is also the medical director for the county health department. We presented our data showing suboptimal influenza vaccination rates for the county, and then discussed how our accessibility as community pharmacists might increase these rates. We were concerned that the physician might view the pharmacy as a competitor in the vaccination of patients, and not support the program. However, the physician embraced

our plan without reservation after we clearly documented the need for increased accessibility to the vaccine. We also informed the physician that we would send him weekly updates of which patients had been vaccinated in the pharmacy, so that clinic records could be kept current. The clinic reduced its influenza vaccine administration days to once per week after our program was approved and referred most of their patients to our pharmacy to receive the injection.

It is essential that any proposal for a community pharmacy-based immunization program be well researched, easily implementable, and clearly presented to the physician, so that he or she is aware that the program is in the best interest of the patient. Depending on the size of your community, approvals may be required from more than one physician. If approval of the program is difficult because of physician concerns for liability of patients for whom they are not their primary physician, one suggestion is to submit the proposal to the county health department medical director. County health department medical directors are charged with promoting health in the community. It is unlikely they would disapprove of such a program if the pharmacy demonstrates an active need for another vaccine provider, and the program is well researched. The physician should have the opportunity to make suggestions in implementation or protocol revisions before final approval.

## Implementation

### Publicizing the Program

Once the physician had approved the protocols, our next step was to publicize the program to pharmacy patients. The optimum time for influenza vaccination is usually from mid-October through early November. However, the vaccine can be given from September through December and remain effective against the circulating strains of influenza for that flu season. This is true because influenza in the United States usually occurs between late December and early March.<sup>11</sup> National Adult Immunization Week (October 19–25, 1997; October 18–24, 1998) and National Pharmacy Week in mid-October offer excellent promotional opportunities. With the new school year beginning in August and September, students and other persons living in dormitories or other institutionalized settings are encouraged to receive the vaccination.<sup>11</sup> These situations may present additional opportunities for pharmacists to promote their program and increase immunization awareness.

Various methods can be used to notify patients of the new program. Signs can be posted in the pharmacy and fliers placed in prescription bags. An advertisement in the local newspaper is an option that we found very useful. In fact, approximately one week after we began administering influenza vaccinations, the local newspaper ran an article describing this program,<sup>20</sup> which helped to increase community awareness without an added expense to the pharmacy. A review of prescription records can help identify potential candidates for vaccination. An invitational letter can then

be sent informing targeted patients of the benefits of vaccination and the availability of this service at your pharmacy.

One important consideration is whether immunization will be offered during normal business hours. Depending on the demand, extra staff may be required. We administered the vaccine during normal business hours in our pharmacy. However, we also advertised a special flu shot “drive” on the first day the vaccine was offered, and enlisted the assistance of a registered nurse to help with the increased demand on that day.

It is important to work with other agencies, such as community health departments, that may exist in your community. These agencies can be valuable sources of the local background information needed when researching and developing your program. Collaboration and cooperation, particularly in sponsoring vaccination drives, can strengthen the chances for success in your community.

The Visiting Nurses Association (VNA), community health departments, hospice organizations, charities, and ethnic organizations can all help identify patients in need of influenza vaccination. This may be especially true among lower income patients or ethnic minorities. After a small survey of 96 Vietnamese-American residents of a midsized midwestern city, Siganga and Huynh recently described recommendations for pharmacists to help improve pharmaceutical services to ethnic populations. Financial, language, physical illness, and transportation barriers were most commonly observed in the population studied. The authors suggest pharmacists form liaisons with local ethnic organizations, coordinate transportation services or information, and form partnerships to overcome physical illness barriers.<sup>21</sup> Financial barriers to influenza vaccine for non-Medicare patients could be reduced by offering a sliding-scale fee for the immunization. Certainly, collaboration with ethnic organizations and organizations such as VNA could help reduce physical illness and transportation barriers for patients in need of influenza vaccination.

### Expenses

Although it is difficult to estimate the number of doses that will be administered during the first year of any new immunization program, a target goal should be established after researching the local statistics. We felt that a reasonable estimate of our pharmacy’s potential contribution to the number of immunized persons in the county would be an additional 10% in the first year. With approximately 4,000 elderly people in our county receiving an estimated 1,400 doses in the previous year, we determined that an additional 10% would place our target goal at 140 doses.

Start-up costs for our program were mostly one-time fees. The vaccine cost the pharmacy \$1.90 per dose. Costs of supplies, such as syringes, gloves, and alcohol swabs (approximately \$0.75 per dose), advertising, and generation of patient record forms totaled approximately \$500. This figure does not reflect pharmacist training time and labor. Maintenance costs included the cost of additional vaccine and supplies ordered, and totaled approximately \$50 per month.

An important question is whether or not pharmacists who

administer vaccines will be charged increased professional liability insurance premiums. Our insurance premiums did not increase, because the Iowa Board of Pharmacy Examiners considers the administration of injectable medications to fall under the professional practice of a pharmacist as defined in the state pharmacy practice act. This should be true in any state that allows pharmacists to administer injections (see Table 1). Nevertheless, one should check with his or her individual insurance carrier to be sure.

## Identifying Patients

Prospective and retrospective review of prescriptions offers pharmacists a unique tool for identifying potential candidates for vaccination. The ACIP guidelines target the following specific groups for organized vaccination programs, because they are at increased risk for influenza-related complications<sup>11</sup>:

- Persons 65 years of age or older.
- Residents of nursing homes and other chronic-care facilities that house persons of any age with chronic medical conditions.
- Adults and children with chronic disorders of the pulmonary or cardiovascular systems, including children with asthma.
- Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications).
- Children and adolescents (6 months to 18 years of age) who are receiving long-term aspirin therapy and therefore might be at risk for developing Reye's syndrome after influenza.
- Any person who wishes to reduce the chance of becoming infected with influenza.<sup>11</sup>

We identified patients as potential influenza candidates if they were: (1) over 60 years of age, or (2) receiving prescriptions for

## Figure 2. Example: Standing Order and Protocol for Treatment of Emergencies

THE PHARMACY  
MAIN ST.  
RURAL, IA

### Protocol for ALLERGIC and ANAPHYLACTIC REACTIONS to Injectable Medications Administered at The Pharmacy

If an allergic reaction to injectable medication occurs at The Pharmacy, the following protocol will be followed.

#### Standing orders for management of ALLERGIC REACTION and ANAPHYLAXIS:

##### I. Supplies to stock

- A. Epinephrine Injection, USP, 1:1000. Preferably, this will be in pre-drawn syringes with 0.1 mL gradations on the barrel (Ana-Kit or equivalent). If pre-drawn syringes are not used, 1 cc tuberculin syringes with 1/2-inch or 5/8-inch 26 ga. needle will be used.
- B. Diphenhydramine hydrochloride injection.
- C. Blood pressure cuffs, pedi-size and adult regular, with stethoscope.

##### II. Recognition of anaphylactic reaction

- A. Sudden onset of itching, redness, with or without hives, within several minutes after injecting a vaccine. The symptoms may be localized or generalized.
- B. Angioedema (swelling of the lips, face, throat), anxiety, difficulty swallowing, syncope, fall in blood pressure, lightheadedness, paresthesia, flushing, sweating, palpitations.
- C. Bronchospasm, wheezing, tightness in chest, shock.

##### III. Emergency treatment

- A. If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for 30 minutes, watching for generalized symptoms. If none occur, go to **III. (G)**.
- B. If symptoms are generalized, activate the emergency response system (911) and notify the ordering physician. This should be done by another person, while the agent treats and observes the patient.
- C. Administer epinephrine according to dose in the table below, subcutaneously or intramuscular. Site of administration can be the anterior thigh or deltoid muscle.
- D. Administer diphenhydramine by IM injection according to the dose in the table below. DO NOT administer diphenhydramine or anything else by mouth if the patient is not fully alert or if patient has respiratory distress.
- E. Monitor the patient until EMS arrives; perform CPR and maintain airway if necessary.
  1. Keep patient in supine position unless there are breathing difficulties. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness.
  2. Monitor vital signs frequently.
- F. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 15 minutes.
- G. Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later.

medications treating any chronic cardiovascular, pulmonary, or metabolic disease. Identification was most commonly prospective—that is, when the prescription was received.

## Screening Patients

Once candidates were identified, we screened for precautions and contraindications, such as allergy to eggs, or current febrile illness. The pharmacist discussed the risks and benefits of the vaccine with the patient before obtaining informed consent. In addition, written information provided by CDC specific to the 1996 influenza vaccine was distributed to the patient.

Patients were asked to complete the Iowa Center for

**Figure 2 (continued). Example: Standing Order and Protocol for Treatment of Emergencies****Dosage of epinephrine**

Weight (kg)	(lb)	Dose (cc)	or	Age	Dose (cc)
3–16	6–35	0.1		0–24 mo.	0.1
17–25	36–55	0.2		2–8 yrs.	0.2
26–34	56–75	0.3		9 yrs +	0.3
35–45	75–99	0.4			
46 +	100 +	0.5			

**NOTE:** Most accurate dosage is based on weight, at 0.01 cc/kg body weight, with a maximum dose of 0.5 cc. Injections should be SC or IM. Doses over 0.3 cc should be based on weight, NOT age.

**Dosage of diphenhydramine**

Weight (kg)	(lb)	Dose (mg)	or	Age	Dose (mg)
3–16	6–35	10		0–24 mo.	10
17–25	36–55	20		2–8 yrs.	20
26–34	56–75	30		9 yrs +	30
35–45	76–99	40			
46 +	100 +	50			

**NOTE:** Dose is to be administered IM. Doses over 30 mg should be based on weight, NOT age.

Date	J. Doe, PharmD
Date	Physician, MD

This authorization will be in effect for one year unless rescinded earlier in writing by either party. Any changes in protocol must be agreed upon by both parties.

Adapted with permission from Baggett Clinical Services, Levelland, Texas.

Pharmaceutical Care patient history form and a general immunization screening form (see Figure 3) to help identify precautions and contraindications. If any contraindications existed, actual or potential, patients were referred to the physician for further evaluation to determine the appropriateness of the vaccination. All forms were kept in a patient-specific chart. When available, a copy of the patient's immunization record was placed with this chart. We developed a duplicate form for administration of influenza vaccine, which contains the billing information, admin-

istration record (lot number, expiration date, manufacturer, dose, administrator), and informed consent (see Figure 4). This form was completed and signed by the pharmacist and patient. One copy was filed with the patient's chart; the other copy was kept by the patient as a record of the immunization.

### Administering the Vaccine

Not all pharmacy schools train pharmacists to administer injections; hence it is likely that most pharmacists will need training to become proficient in administering injections. No certification program was available for pharmacists in Iowa at the time our program was first implemented; therefore, a registered nurse came to the pharmacy and gave the pharmacist an instructional seminar on vaccine administration. In addition, educational videos provided by CDC and other immunization agencies teach the techniques.

Once the screening process was completed and informed consent obtained, the vaccine was administered in the private counseling area. All patients were required to wait 20 minutes after receiving the vaccine to monitor for signs and symptoms of anaphylaxis and allergic reactions. As previously mentioned, it is imperative for pharmacists to be certified in CPR and thoroughly familiar with the protocol for treatment

of anaphylaxis and allergic reactions in the event of an emergency. Patients were not allowed to receive the injection if they were unable or unwilling to wait for this period of time.

### Documentation/Records

Documentation is an important component of the immunization program. We retain all screening forms, records, and

informed consent forms with the patient's chart. Administration information—lot number, expiration date, manufacturer, dose, and administrator—should be recorded to facilitate any searches necessary to identify patients who received vaccine with a certain lot number or expiration date. Software programs that track the immunization status of patients and assist in documentation of administered vaccines are available to health care providers. One example is VAC-TRAC 2.1, a value-added service available from SmithKline Beecham Pharmaceuticals.

Pharmacists have the responsibility to inform the patient's primary physician that the patient was vaccinated in the pharmacy. Sharing this information contributed to the success of our program. As mentioned previously, each week we sent a copy of our immunization log to the physician. We also sent preprinted adhesive notes containing the name of the patient, Medicare number, date of administration, lot number, expiration date, manufactur-

er, and dose, so that these could be placed with the patient's chart at the clinic. For patients whose primary physician was located outside the community, notification memos were sent directly to the physician so that the patient chart could remain current.

**Reimbursement**

Following determination of cost-effectiveness in 1993, Medicare has reimbursed Medicare-registered providers for administration of the influenza vaccine. Pharmacists are recognized in this group. Our pharmacy charged \$11 per vaccination, which included both the cost of vaccine and administration fee. We billed this amount directly to Medicare if the patient was a Medicare beneficiary or to the patient if the patient was not insured. Medicare reimbursement was \$8.13 per dose administered.

To be eligible to receive Medicare reimbursement for the cost of the vaccine and an administration fee, a pharmacy must apply

for a Medicare provider number. An application for a Medicare provider number can be obtained from the Medicare carrier office in each state. It took approximately two months to receive our provider number; therefore, to time immunization for influenza properly, the application should be filled out as early as possible. Billing was completed on a Health Care Financing Administration (HCFA) 1500 claim form for each patient or by roster billing. Roster billing allows providers to bill for five or more Medicare beneficiaries by attaching a list of beneficiaries to one HCFA 1500 claim form. Specific information on how to bill for administration of influenza vaccine and the specific codes used are included with the receipt of the Medicare provider number.

**Program Evaluation**

The influenza immunization program offered by our pharmacy received considerable support throughout the community. Immunizations were provided from October 15 to

**Figure 3. Example: General Immunization Screening Form**

THE PHARMACY  
MAIN ST.  
RURAL, IA

PLEASE READ THE LIST BELOW AND INDICATE YES OR NO FOR THE PERSON RECEIVING THE VACCINE TODAY

	YES	NO
1. Did this person receive a flu shot last year?	_____	_____
2. Has this person ever had a severe reaction to any vaccine which required medical care?	_____	_____
3. Is this person allergic to eggs, Baker's yeast, sulfites, thimerosal, streptomycin or neomycin?	_____	_____
4. Does this person have a fever, diarrhea or vomiting today?	_____	_____
5. Is this person or anyone in the home being treated with chemotherapy, radiation for cancer, have HIV/AIDS or any immune deficiency disorder?	_____	_____
6. Does this person smoke? If under 18 years of age, does anyone in the house smoke?	_____	_____
7. Is this person receiving treatment for any disease or illness?	_____	_____
8. Has this person been under a doctor's care in the past year?	_____	_____
9. Has this person had immune globulin or a blood transfusion in the past seven months?	_____	_____
10. Has this person had Guillain-Barrè Syndrome, a condition which causes paralysis?	_____	_____
11. Is this person pregnant or planning pregnancy in the next three months?	_____	_____
12. Is this person taking theophylline, warfarin, or phenytoin?	_____	_____
13. Would this person be willing to disclose their immunization records to the pharmacy to be kept in their chart?	_____	_____
14. List all prescription or over-the-counter medications this person is taking:		
_____		
_____		

Modeled after Gardner J, Sharp B. *Practicum Training Manual*. Washington State Pharmacists Assn. April 1995.

**Figure 4. Example: Administration Log and Informed Consent**

THE PHARMACY  
MAIN ST.  
RURAL, IA

INFLUENZA VACCINE ADMINISTRATION RECORD

INFORMATION ABOUT PERSON TO RECEIVE VACCINE (please print)

NAME last	first	middle initial	SOCIAL SECURITY NUMBER
ADDRESS	CITY	STATE	ZIP
BIRTHDATE	SEX	PHYSICIAN	

PAY TYPE

1. MEDICARE PART B

NAME AS IT APPEARS ON MEDICARE CARD. PLEASE PRINT (IF DIFFERENT FROM ABOVE)

MEDICARE NUMBER

2. NO INSURANCE/PRIVATE

CHARGE \$ \_\_\_\_\_

LOT #	EXP. DATE	MANUFACTURER	DOSE (mL)	ADMINISTRATOR

Please read the following three statements and sign below on the signature line. If statement 2 and/or 3 do not apply, cross out.

I have read or have had explained to me the information provided to me about influenza and influenza vaccine. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of influenza vaccine and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.

**RELEASE OF INFORMATION/ASSIGNMENT OF INSURANCE BENEFITS**

The Pharmacy may disclose all or part of the patient's immunization record to any person or corporation which may be liable under a contract to the pharmacy, patient, patient's family member, or patient's employer for all or part of the pharmacy's charge. This includes, but is not limited to worker's compensation carriers, self-insured organizations, mutual hospital associations, insurance companies, Medicare and its agents, and utilization review or managed care organizations. I authorize the release of information about my immunization status and health status for continuing health services and to the referring physician.

Medicare, I do hereby authorize The Pharmacy to release information and request payment. I certify that the information given by me in applying for payment under Medicare is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

X \_\_\_\_\_  
SIGNATURE OF PERSON TO RECEIVE VACCINE OR PERSON AUTHORIZED TO MAKE THE REQUEST (PARENT OR GUARDIAN)

DATE: \_\_\_\_\_

December 6, 1996. For purposes of this data analysis, each patient was considered an individual case. Data collected for each case included (1) age of patient, (2) gender, (3) total time required for counseling and administration of vaccine, (4) whether or not the patient received an influenza vaccination the previous year, (5) payment type (Medicare versus cash), and (6) the patient's response to the question "Would you have received the influenza vaccine elsewhere if not offered at the pharmacy?"

**Results**

Pharmacists administered 343 doses of vaccine; 82 doses were administered on the first day of the program alone. All patients immunized met ACIP guidelines for the administration of influenza vaccine. No adverse events were observed or reported. The patients immunized in the pharmacy ranged in age from 15 to 89 years (mean 61 ± 15). Nearly half (49.5%) were aged 65 years or older. Women accounted for slightly more of the vaccinated population (53.2%). Two-thirds of the immunized patients (67.9%) reported also being immunized in 1995. These patients were generally older (age 65 ± 13) than the patients not immunized in 1995 (age 54 ± 16). Patients younger than age 65 who were immunized in the pharmacy reported either having a chronic disease such as asthma or diabetes, or were caregivers for an elderly person, thus increasing their risk of acquiring or transmitting influenza.

Overall, nearly 75% of the patients reported that they

**Table 3. Results of the 1996 Immunization Program at The Pharmacy on Main**

Number of patients immunized in the pharmacy	343
Mean age	61 ( $\pm 15$ years)
Sex	53.2% female, 46.8% male
Source of payment for influenza immunization	50.4% Medicare, 49.6% cash
Were patients immunized in the previous year?	Yes: 67.9% (233/343) Number reporting they would have gone elsewhere*: 95.2% (222/233)
	No: 32.1% (110/343) Number reporting they would have gone elsewhere*: 29.2% (32/110)

**Summary**

- Older patients (mean age  $64 \pm 14$  years) were more likely than younger patients to indicate they would obtain the influenza immunization elsewhere if not offered at the pharmacy ( $t = 5.39$ ,  $df = 74.1$ ,  $p < 0.01$ ).
- Older patients (mean age  $64 \pm 14$  years) were more likely than younger patients to have been immunized in the previous year ( $t = 6.21$ ,  $df = 171.8$ ,  $p < 0.01$ ).
- Most patients not immunized in the previous year indicated they would not have gone elsewhere if the influenza vaccination were not offered at the pharmacy ( $\chi^2 = 160.1$ ,  $df = 1$ ,  $p < 0.01$ ).

\* If the vaccination were not offered at the pharmacy.

would have received the vaccination elsewhere had it not been offered at the pharmacy. Again, older patients (aged  $64 \pm 14$ ) were more likely to indicate that they would have received the immunization elsewhere than were younger patients (aged  $52 \pm 16$ ). However, 60.8% of the patients not immunized in 1995 reported they either would not have gone elsewhere for an immunization (45.3%) or were unsure (25.5%).

The uniform billing charge of \$11 per vaccination was reimbursed at \$8.13 for Medicare-eligible patients. Interestingly, half of the patients (49.6%) paid cash for the immunization. The vaccine cost the pharmacy \$1.90 per dose, leaving a \$9.10 fee from the \$11 charge paid by cash patients, and a \$6.23 fee with Medicare reimbursement. This program generated \$2,624.79 in income after subtracting the costs of the vaccine. However, this figure is closer to \$2,000 when start-up costs and the disposable supplies are figured. In all cases, the time required for the immunization transaction was between one and five minutes. Results of the program are summarized in Table 3.

## Discussion

The potential to increase the number of immunizations within the community is evident in the fact that one-third (32.1%) of the patients immunized in the pharmacy reported not having received an immunization in the previous year. Nearly two-thirds of these patients reported that they would not have gone elsewhere for the vaccination or were unsure. A wide age range of patients were immunized, not only elderly patients. Thus, based on our limited experience, high-risk younger patients are likely to benefit from pharmacy-based immunization campaigns. Our data suggest that pharmacist administration of influenza vaccination in a community pharmacy increases access and possibly immunization rates, especially for younger adults who

would not normally have received the immunization.

Pharmacists often express frustration about the time constraints involved in implementing new programs. However, careful planning should allow pharmacists to allocate their time in such a way that innovative programs can be incorporated into their practices. Our pharmacy staff consists of one full-time pharmacist and one technician, who dispense approximately 70 prescriptions per day while conducting patient follow-up and monitoring. This pharmacist was able to personally administer 341 of the 343 doses of vaccine in one and a half months. The other two doses were administered by the nurse on the first day of the program. Afterward, the pharmacist performed all injections. Use of technicians in supportive roles is a key element that allows pharmacists to devote adequate time to immunizing patients. The total time spent with the patient to administer a flu shot in our pharmacy never exceeded five minutes. Therefore, concern about time constraints should not prevent interested pharmacists from pursuing immunization programs. Pharmacist participation in influenza vaccination programs is an ideal way to position the pharmacy as a center for the provision of all immunizations. The success of the program has securely established the pharmacy as an additional provider of influenza immunizations in the community. The program will be continued each year. For the 1997 season, 500 doses of the vaccine have been ordered in anticipation of increased success.

## Conclusion

Preventive health care is an integral component of pharmaceutical care, and pharmacists have the ability to reach individuals whose vaccination needs might otherwise be neglected or overlooked by the health care system. Maintaining a current immunization profile on patients is also an important responsibility of the

pharmacist as a health care provider. Counseling patients about influenza and other vaccinations is an example of how pharmacists can participate in this level of practice and increase vaccine acceptance.<sup>22</sup> Pharmacists who choose not to administer vaccines personally may still identify potential candidates and advocate immunizations to those target populations. Whether or not a pharmacy equips itself to provide immunizations, at the very least pharmacists should become immunization advocates. Our data indicate that community-pharmacy-based influenza vaccination programs can increase accessibility and vaccine acceptance, especially among high-risk younger adults. Community pharmacy-based vaccination programs, especially in the case of influenza, are attractive solutions to reducing accessibility barriers to immunization and allow pharmacists to continue their active role in promoting public health.

## References

- Nichol KL, Margolis KL, Wuorenma J, et al. The efficacy and cost effectiveness of vaccination against influenza among elderly persons living in the community. *N Engl J Med.* 1994;331:778-84.
- Willems JS, Sanders CR. Cost-effectiveness and cost-benefit analysis of vaccines. *J Infect Dis.* 1981;144:486-93.
- Grabenstein JD, Hayton BD. Pharmacoepidemiologic program for identifying patients in need of vaccination. *Am J Hosp Pharm.* 1990;47:1774-81.
- West Virginia to study pharmacists' impact on immunization rates. *Pharmacy Today.* 1996;2(2):10.
- Mississippi to train, pay pharmacists to immunize. *Pharmacy Today.* 1996;2(10):1.
- Grabenstein JD. Community pharmacists as immunization advocates: a clinical pharmacoepidemiologic trial. Chapel Hill: University of North Carolina; 1991. Thesis.
- Grabenstein JD, Hartzema AG, Guess HA, et al. Community pharmacists as immunization advocates: cost-effectiveness of a cue to influenza vaccination. *Med Care.* 1992;30:503-13.
- Spruill WJ, Cooper JW, Taylor WJR. Pharmacist-coordinated pneumonia and influenza vaccination program. *Am J Hosp Pharm.* 1982;39:1904.
- Knapp K, Paavola F, Sorofman B. Distribution of pharmacists in rural areas: a mapping study with implications for access and forming interdisciplinary teams. American Pharmacists Association Annual Meeting. Nashville; March 10, 1996. Abstract.
- 1996-1997 National Association of Boards of Pharmacy. Survey of pharmacy law. Park Ridge, Ill: 1996.
- Advisory Committee on Immunization Practices. Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices. *MMWR.* 1996;45 (RR-5):1-24.
- Public Health Service. *Healthy people 2000: national health promotion and disease prevention objectives.* Washington, DC: U.S. Department of Health and Human Services, Public Health Service; 1991:122-3; DHHS publication no. (PHS)91-50213.
- Williams WW, Hickson MA, Kane MA, et al. Immunization policies and vaccine coverage among adults: the risk for missed opportunities. *Ann Intern Med.* 1988; 108:616-25.
- Ohmit SE, Furumoto-Dawson A. Influenza vaccine use among an elderly population in a community intervention. *Am J Prev Med.* 1995;11:271-6.
- Ives DG, Lave JR, Travern ND, et al. Impact of Medicare reimbursement on influenza vaccination rates in the elderly. *Prev Med.* 1994;23:134-41.
- Implementation of the Medicare influenza vaccination benefit—United States, 1993. *MMWR.* 1994;43(2):771-3.
- "Every month should be immunization month...until everyone is vaccinated. A call to action to use every resource and every setting to solve America's immunization deficit." American Pharmacists Association; November 9, 1993. Press Release.
- State of Iowa Department of Elder Affairs. Clemens Building, 3rd floor. 200 Tenth Street, Des Moines, Iowa 50309-3609. (515) 281-4651. Information on file.
- State of Iowa Library Information Services. E. 12th and Grand, Des Moines, Iowa 50319. (515) 281-4350. Information on file.
- "Chalstrom becomes one of first to administer flu shots." *Anamosa Journal-Eureka* (Iowa). 1996, 24 October: 5.
- Siganga WW, Huynh TC. Barriers to the use of pharmacy services: the case of ethnic populations. *J Am Pharm Assoc.* 1997;NS37:335-40.
- Kirk JK, Grabenstein JD. Interviewing and counseling patients about immunizations. *Hosp Pharm.* 1991;26:1006-10.





# A Practical Guide to Establishing Vaccine Administration Services in Community Pharmacies

Jacqueline S. Gardner

**Objective:** This article describes requisite components of a community pharmacy-based vaccine administration program and provides resources for obtaining training and materials to facilitate implementation in the pharmacy. **Data Sources:** Published medical literature accessed via Medline; interviews of pharmacists who initiated vaccine administration programs; government publications; professional publications including manuals and newsletters; and the resources of the Washington State Board of Pharmacy. **Data Synthesis:** Pharmacists in several states have initiated vaccine-administration programs for adults, adolescents, and children within their pharmacies with acceptance by patients, third party payers, and other health professionals. In some states, collaborative prescribing agreements between physicians or nurse-practitioners and pharmacists enable pharmacists to implement high-volume immunization clinics as well as individual patients services. Standardized training is available from several sources, and in most settings vaccine administration services can be implemented with low initial investment. **Conclusion:** Vaccine administration may soon become an integral function in community pharmacists' responsibilities for the health and well-being of patients.

*J Am Pharm Assoc. 1997;NS37:683-93.*

Pharmacists in 23 states now have authority to administer vaccines under collaborative prescribing protocols. In many of those states and others, nonpharmacist health care providers administer vaccines in community pharmacies or their associated retail settings during immunization campaigns.<sup>1</sup> Because of the high demand for these services in community settings, immunization offers pharmacists an opportunity to venture into an area of pharmaceutical care in which positive precedents exist. This article describes how community pharmacists have successfully incorporated vaccine administration services into their practices, what steps may be taken to establish those services in the community pharmacy, and where to obtain the needed assistance. Many articles have already described how pharmacists may become immunization advocates<sup>2,3</sup> and may facilitate patients' access to vaccines administered by other providers<sup>4,5</sup>; therefore, this article will not revisit those subjects.

## Immunization—A National Effort

In recent years, national attention has been focused on the reemergence (e.g., measles during 1989-1991) or continued prevalence (e.g., pneumococcal disease and influenza) of vaccine-preventable diseases in the United States despite the availability of safe and effective vaccines and federally subsidized programs for vaccination. Analysis of the reasons for this unsettling situation reveals several interrelated problems pertaining to the cost of and access to vaccines.<sup>6</sup> Often, insurance carriers do not reimburse for vaccination. Many of the same barriers that prevent more widespread immunization also restrict access to other health care services, and include the need for an appointment, restricted clinic hours, inaccessible clinic locations, and language barriers.<sup>7</sup>

In light of the national goals for reduction of vaccine-preventable diseases, as articulated in *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*<sup>8</sup> (Table 1), multiple federal initiatives have been undertaken to increase vaccine coverage of target groups. In 1981 the Health Care Financing Administration (HCFA) authorized payment for pneumococcal vaccines and their administration to Medicare enrollees.<sup>9</sup> That coverage was extended to influenza virus vaccine in 1993. The National Vaccine Injury Compensation Program (VICP), authorized by Congress in 1988, became the arbiter of claims of injury resulting from the childhood vaccines, whether as a result of adverse reaction to the vaccine itself or a misadventure related to its administration.<sup>10</sup> In 1993, at the urging of the Clinton Administration, Congress authorized the Vaccines For Children

Received August 8, 1997, and in revised form September 4, 1997. Accepted for publication September 4, 1997.

Jacqueline S. Gardner, PhD, is associate professor, University of Washington School of Pharmacy, Seattle.

Acknowledgments: Many thanks to Don Downing for editorial review.

Correspondence: Jacqueline S. Gardner, PhD, School of Pharmacy, University of Washington, H-364 Health Science Center, Box 357631, Seattle, WA 98195. Fax:(206) 685-9297. E-mail: jsgardne@u.washington.edu

(VFC) program in conjunction with the Comprehensive Childhood Immunization Initiative Act.<sup>11</sup> Under this program, designed to remove cost as a barrier to childhood immunization, the federal government purchases vaccines from manufacturers and distributes them free to private and local government health care providers. The objective was to exceed the *Healthy People 2000* goal, and to have immunized at least 90% of all 2-year-olds against nine targeted vaccine-preventable diseases by 1996. This objective was met for all of the routinely recommended vaccines.<sup>12</sup>

Assessment of vaccination status and administration of vaccines for adults at age 50 is recommended by the Advisory Committee on Immunization Practices (ACIP), the American College of Physicians, and the Infectious Disease Society of America.<sup>13</sup>

Tetanus and diphtheria vaccine should be brought up to date, and people at high risk (e.g., adults over age 65 and those with chronic pulmonary or cardiovascular disease) should have at least one pneumococcal vaccination in their lifetime and should be vaccinated for influenza every fall. Many adults need "childhood" vaccines that were developed recently or that need periodic booster doses to maintain potency. Adults who have no history of infection with chicken pox or herpes zoster should consider receiving the two-dose varicella vaccine series, because the disease is more severe in adults than in children. A review of risk factors for hepatitis A is also indicated for adults, and the two-dose vaccine should be obtained if needed.

In 1996, the ACIP, the American Academy of Pediatrics (AAP), the American Academy of Family Physicians, and the American Medical Association issued recommendations that vaccine status should be assessed for all adolescents (11–21 years of age) during routine visits to a health care provider. As needed, the adolescent patient should be vaccinated against varicella virus and hepatitis B, and should receive the second

dose of measles-mumps-rubella (MMR) vaccines, the booster Td toxoids, and influenza and pneumococcal vaccines (for high-risk patients).<sup>14</sup> As with adults, adolescents should be evaluated for their risk of exposure to hepatitis A and vaccinated as needed.

## Need for Pharmacy-Based Vaccine Providers

A study published in 1995 by the U.S. General Accounting Office found that states varied in their preparedness to initiate and maintain VFC programs through private providers and local health departments.<sup>15</sup> In most states, in part because of the federal initiatives, priority was placed on increasing the protection of children with the inadvertent effect being the near exclusion of elderly and other high-risk patients.<sup>16</sup> However, recognizing the cost-effectiveness of immunization programs for these high-risk groups,<sup>17,18</sup> in 1995-96 HCFA placed new emphasis on outreach programs targeting those people and their caregivers.<sup>19</sup> Nursing home administrators in particular were being urged to increase the protection of their residents to meet the goal of immunizing at least 80% of the institutionalized Medicare population by the year 2000. Since the publication of *Healthy People 2000* through the present day, new vaccines with increased safety and efficacy have broadened the scope of protection against vaccine-preventable diseases. These have included vaccines targeting diseases most likely to be encountered by international travelers.<sup>20</sup> This expanded emphasis on vaccines has created a demand for additional qualified providers with competence in screening patients and administering vaccines, and with knowledge of vaccine effects.

This circumstance has opened the door for pharmacy-based immunization services, and that opening continues to widen. Although pharmacists have practiced immunization advocacy and facilitation in hospitals<sup>21</sup> and long-term-care facilities for some time,<sup>22</sup> community pharmacists are now implementing mobile immunization services to senior centers and retirement residences<sup>23</sup> as well as providing services directly in pharmacies.<sup>24</sup>

### CE Credit

#### CE Credit

To obtain two hours of continuing education credit (0.2 CEU) for completing "A Practical Guide to Establishing Vaccine Administration Services in Community Pharmacies," complete the assessment exercise and CE registration form and return it to APhA. A certificate will be awarded upon achieving a passing grade of 70% or better. Pharmacists completing this article by December 31, 2000, can receive credit.



The American Pharmacists Association is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education.



APhA provider number is: 202-000-97-069-H04.

"A Practical Guide to Establishing Vaccine Administration Services in Community Pharmacies" is part of the continuing education program on Value Added Services for pharmacists appearing in the *Journal of the American Pharmacists Association*. Developed by the American Pharmacists Association, the series is edited by Janet P. Engle, PharmD, FAPPM, acting associate dean for academic affairs and clinical professor of pharmacy practice, University of Illinois at Chicago, and supported by an educational grant from Merck Human Health.



### Learning Objectives

After reading this article, the pharmacist should be able to:

- List three key immunization objectives of *Healthy People 2000*.
- List three requisite practice features for a vaccine administration program.
- Describe the procedures necessary to obtain Medicare reimbursement for vaccine administration.
- Describe how community pharmacists have successfully marketed vaccine administration services.
- List four sources of free patient education materials related to immunization.

**Table 1. National Goals for Reduction of Vaccine-Preventable Diseases by 2000\***

Disease	1987 or 1988 Baseline	2000 Target
Congenital rubella syndrome	6 cases	0 cases
Diphtheria among people age 25 and younger	1 case	0 cases
Epidemic-related pneumonia and influenza deaths among people age 65 and older	9.1/100,000	≤ 7.3/100,000
Hepatitis A	31/100,000	23/100,000
Hepatitis B	63.5/100,000	40/100,000
Hepatitis C	18.3/100,000	13.7/100,000
Measles	3,058 cases	0 cases
Mumps	4,866 cases	500 cases
Pertussis	3,450 cases	1,000 cases
Polio (wild-type virus)	0 cases	0 cases
Rubella	225 cases	0 cases
Tetanus among people age 25 and younger	3 cases	0 cases

\* Adapted from Reference 8.

## Authorization to Administer Vaccines

State laws vary in the flexibility granted to pharmacists to initiate therapy and to administer drugs. Pharmacists should be prepared to cite the language in their state's practice act authorizing them to administer vaccines. For example, in Washington State the "Practice of Pharmacy" includes "...the compounding, dispensing, labeling, administering, and distributing of drugs and devices..."<sup>25</sup> with "administer" defined as "the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject."<sup>26</sup> This definition clearly authorizes injection of vaccines for individual patients under prescription. The language is similar in the practice acts of Delaware, Mississippi, and Texas.<sup>27</sup>

## Collaborative Prescribing Protocols

In many states legislative codes permit pharmacists and prescribers to enter into agreements that authorize pharmacists to identify patients in need of immunization, to administer vaccines, and to notify the prescriber of the action taken. Here again state-specific requirements vary, but generally a pharmacist who wishes to initiate services under a collaborative prescribing protocol must obtain an agreement with a prescriber and complete the requisite documentation with the state board of pharmacy. Components of a collaborative prescribing protocol and sample wording are shown in Figure 1<sup>28,29</sup>; others, including a protocol covering emergency management, are provided by Ernst et al.<sup>24</sup>

Pharmacists' experiences in establishing collaborative prescribing protocols have been varied. Pharmacists who have good work-

ing relationships with individual prescribers often find the latter eager to broaden their patients' options for receiving vaccines, and more than willing to sign mutually agreed-on prescribing protocols.<sup>24</sup> However, pharmacists intending to administer vaccines to children have reported difficulty in identifying a cooperative prescriber. This difficulty appears to stem from the AAP's 1992 initiative to ensure that every American child has a "medical home," that is, a primary care practitioner responsible for his or her health, by the turn of the century.<sup>30</sup>

Pediatricians who object to pharmacist-administered immunization may believe that such programs fragment care for children, separating their basic immunizations from other well child care and compromising the establishment of a true medical home. Pharmacists who wish to provide childhood immunization programs should be prepared to address this concern not only with pediatricians being approached to approve collaborative protocols, but also in direct communication with other professionals or by way of advertising or public relations messages.

## Training Opportunities

The key to general patient and professional acceptance of pharmacist-immunizers is competence. At present, most pharmacists feel that they have not had adequate training to initiate a comprehensive immunization program. Even those who are trained to administer drugs by injection may need additional training both in the hands-on and pharmaceutical care aspects of managing vaccine-preventable diseases. Therefore, education about the targeted vaccine-preventable diseases for both children and adults, and specific training relevant to administration of the selected vaccines, are critical components of establishing competence.

Standardized training is available from three sources. The national standard for didactic training in immunization is the Centers for Disease Control and Prevention (CDC) continuing education course, Epidemiology and Prevention of Vaccine-Preventable Diseases, which is offered semiannually in four three-hour segments via interactive satellite transmission. Registration for this course is free or nominal, and subject to space availability. The course manual may be ordered separately at no charge.<sup>31</sup> Information about schedules and locations is posted on the CDC World Wide Web site (Table 2) or available from state immunization coordinators. This course offers comprehensive coverage of the vaccine-preventable diseases targeted by CDC for reduced incidence or eradication in the United States, with particular emphasis on childhood diseases. There is no practicum component, and this course is attended by vaccine providers in all health professions. CDC-based faculty often conduct the course on site at the request of provider organizations.

Using the CDC-based faculty (whenever possible) and videotapes of a CDC training session for pharmacists, the Washington State Pharmacists Association (WSPA) offers certification courses that emphasize the adult and adolescent vaccines. These courses are intended to complement CDC training in childhood vaccines. The practicum component provides hands-on experience in administra-

**Figure 1. Sample of Collaborative Prescribing Protocol**

XYZ Pharmacy and John Doe, MD/PA/RNP  
Administration of Vaccines

*Purpose*

This protocol describes how pharmacists, through their unique access to patients, can exercise their role as public health advocates in screening for and administering needed immunizations.

*Patient Population*

Children under school age, adolescents and adults at high risk due to comorbidities or other factors increasing susceptibility to vaccine-preventable diseases, and healthy adults in positions of caretaker or critical professional responsibilities are the primary targets of concern.

*Training and Procedures*

Each pharmacist will be trained and certified in adherence to the guidelines and recommendations of the Advisory Committee on Immunization Practices (ACIP). The procedures utilized for immunization in the pharmacy comply with the Standards for Immunization Practices recommended by the National Vaccine Advisory Committee. Community surveillance programs and communication with and referral to other health care providers are emphasized.

*Drugs to be Administered*

- Diphtheria, tetanus toxoids, and pertussis (DPT)
- Diphtheria, tetanus, and acellular pertussis (DtaP)
- Oral poliovirus (OPV)
- Inactivated poliomyelitis (IPV)
- Measles, mumps, and rubella (MMR) *Haemophilus influenzae B* (HIB)
- Influenza virus
- Pneumococcal polyvalent
- Varicella
- Other vaccines and biologic agents as mutually agreed by authorizing prescriber and authorized pharmacist

The administration of vaccines follows the recommendation of the ACIP and the Committee on Infectious Diseases (Red Book). The protocol includes the Centers for Disease Control and Prevention *Guide to Contraindications to Childhood Vaccinations*.

*Guidelines for Prescriptive Authority Decisions*

The pharmacist will follow algorithms for administration of vaccines, take patient histories, and consult with previous medical providers as appropriate.

The pharmacy will document all immunizations on an immunization record provided to the patient or the patient's parent or guardian. The pharmacy will maintain patient immunizations records on a standard form.

*Feedback and Review*

The authorizing prescriber will review quarterly the activities of the pharmacists providing immunizations and will provide feedback.

*Authorizing Prescriber Statement*

XYZ Pharmacy and John Doe, MD/PA/RNP  
Administration of Vaccines

I, \_\_\_\_\_ MD/PA/RNP licensed in the State of \_\_\_\_\_, do hereby authorize \_\_\_\_\_, PharmD, of XYZ Pharmacy and other certified pharmacists employed by XYZ Pharmacy to prescribe and administer vaccines to infants, children, and adults in accordance with the laws (\_\_\_\_\_) and regulations (\_\_\_\_\_) of the State of \_\_\_\_\_. In exercising this authority the pharmacists shall comply with the recommendations of the Advisory Committee on Immunization Practices. The pharmacist will document all vaccines administered as required by statute, and on each patient's personal immunization record. As the authorizing prescriber I will, on a quarterly basis, review the activities of the pharmacists administering vaccines.

This authorization will be in effect for two years, unless rescinded earlier in writing to the State Board of Pharmacy by either party. Any significant changes in the protocol must be agreed on by the participants and submitted to the Board.

Date \_\_\_\_\_

Prescriber Signature \_\_\_\_\_ License # \_\_\_\_\_

Pharmacist Signature \_\_\_\_\_ License # \_\_\_\_\_

Pharmacist Signature \_\_\_\_\_ License # \_\_\_\_\_

**Table 2. Resources for Immunization Information**

Organization	Web Site/Description
American Pharmacists Association	<a href="http://www.aphanet.org">http://www.aphanet.org</a>
CDC Travel Information	<a href="http://www.cdc.gov/travel/travel.html">http://www.cdc.gov/travel/travel.html</a>
Centers for Disease Control and Prevention	<a href="http://www.cdc.gov">http://www.cdc.gov</a>
Immunization Action Coalition/Hepatitis B Coalition	<a href="http://www.immunize.org">http://www.immunize.org</a>
National Coalition on Adult Immunization	<a href="http://www.medscape.com/Affiliates/NCAI/index.html">http://www.medscape.com/Affiliates/NCAI/index.html</a>
Pharmacists' Immunization Network	<a href="mailto:pi-net@listserv.oit.unc.edu">pi-net@listserv.oit.unc.edu</a>
U.S. Food and Drug Administration	<a href="http://www.fda.gov/fdahomepage.html">http://www.fda.gov/fdahomepage.html</a>
Washington State Pharmacists Association	<a href="http://PharmCare.org">http://PharmCare.org</a>
Immunization Action Coalition 1573 Selby Avenue, Suite 229 St. Paul, MN 55104 (612) 647-9009 Fax (612) 647-9131	Newsletter Needle Tips and the Hepatitis B Coalition News; best all-around patient information source; membership is \$50/year and provides all materials free for copying; includes CDC information resources and order blanks
St. Anthony Publishing 11410 Isaac Newton Square Reston, VA 20190 (703) 904-3900 Fax (703) 707-5700	Publishers of <i>Coding and Reimbursement Guide for Pharmacists &amp; Pharmacy Reimbursement and Disease Management Report</i>

tion by injection as well as instruction in emergency procedures, practice implementation strategies, and reimbursement options. The WSPA Web site (see Table 2) describes enrollment information, self-study alternatives, practicum training sites, and schedules. This information may also be obtained by calling (425) 228-7171.

In summer 1997, the American Pharmacists Association (APhA) launched a certificate program called "Pharmacy-Based Immunization Delivery." The course is designed to provide pharmacists the necessary training to establish and promote a successful immunization specialty service; among other topics, the program covers the identification of at-risk patient populations and maintenance of immunization records. The program comprises a self-study component and a one-and-one-half day training symposium, including practicum experience and practice implementation strategies. Course registration information is posted on the APhA Web site (Table 2) or can be obtained by calling (800) 237-APhA, ext. 4867.

Many pharmacists offer travel vaccines as part of their comprehensive immunization services. In certain areas of the world, travelers risk infection with malaria, typhoid fever, yellow fever, and other communicable diseases, for which additional vaccines and other prophylaxis are recommended. Current country-specific recommendations for travel vaccines can be obtained from the Travelers Health Section of the CDC Web site (Table 2) and from CDC publications. In addition, CDC offers a short training course in travel vaccines.

## Practice Requirements for Immunization Services

The basic physical requirements for initiating vaccine administration services are as follows:

- Space with at least minimal privacy for administering injections.

tions.

- Room to manage an emergency situation, including performance of cardiopulmonary resuscitation (CPR). The pharmacist should be certified in CPR. For pharmacists who will be immunizing children, health professional certification must include care for infants and toddlers.
- An arrangement that minimizes the risk of injury if a patient should experience syncope and fall.<sup>32</sup>
- A refrigerator with freezer adequate to maintain the vaccine supplies.

Through creative arrangement of furniture, the use of movable screens, or both, many pharmacies provide adequate privacy without the need for reconstruction. Sufficient seating space to allow a firm grip on the patient's arm can minimize the risk of a fall. When vaccinating infants and children, places for a parent to sit and hold the child, or for the child to lie down or be supine will be needed. Sound buffers may be advisable, because small children may cry.

## Supplies and Equipment

It is advisable to store all vaccination supplies in the same area. The Immunization Clinic Kit for Pharmacy, a starter kit of supplies, forms, and order blanks in a compact container, can be purchased from WSPA. Ordering information is available on the WSPA Web site (Table 2). Table 3 lists basic supplies for any vaccine administration program; these supplies can be obtained from medical suppliers or wholesalers.

## Occupational Safety Considerations

Pharmacists who administer vaccines are at risk of needlestick

**Table 3. Basic Supplies for a Vaccination Program**

- Alcohol swabs
- Bandages
- Consent forms, if needed
- Disposable gloves
- Emergency kit containing blood pressure cuff and stethoscope, epinephrine (e.g., EpiPen), tourniquet
- Gauze squares
- Hazardous waste disposal bags
- Lifetime Immunization Records
- Sharps container
- Syringes, needles of varying sizes
- Vaccine Information Statements
- Vaccines

injuries and exposure to bloodborne pathogens. Studies of needlestick injuries in health care settings have shown that the vast majority of injuries occur during or after use of the needle or during disposal, and that one-third occur in the process of recapping needles.<sup>33</sup> The risk of acquiring hepatitis B virus infection from a single percutaneous exposure to positive blood has been estimated at between 6–30%; similarly, the risk of exposure to the hepatitis C virus has been estimated at between 0–7%. The risk of HIV exposure is approximately 0.3%.

The practicum sessions of standardized training programs address the management of immunization services to minimize the potential for harm to pharmacists and other employees. The programs include recommendations based on the principle of “universal precautions,” that is, that blood, as well as certain other body fluids and tissues, should be considered potentially infectious.<sup>33</sup> The following general recommendations apply regardless of the setting or the type of vaccine being administered:

- All pharmacists administering drugs by injection should have received a complete series of hepatitis B vaccine; employing pharmacies must offer the hepatitis B vaccine to employees at risk of infection.<sup>34</sup>
- All staff, interns, and volunteers working around the immunization service area should be alerted to universal precautions in handling used needles and syringes, and all must be provided with gloves by the employing pharmacy.
- Physical arrangements allocated for the administration of vaccines should allow for unimpeded access to a sharps container in one direct motion following removal of a needle from a patient.
- Workflow should be managed so that vaccines are not being administered in an atmosphere of pressure to hurry through procedures.
- Pharmacists giving injections should be diligent in avoiding recapping used needles before disposing of them in sharps containers.
- A postexposure protocol should be available to each employee

or posted in the pharmacy; this protocol should include procedures for promptly reporting and evaluating exposures; and recommended follow-up and management of the exposed worker, including the possible use of postexposure prophylaxis.<sup>33</sup>

Employing pharmacies are responsible for all medical evaluations, procedures, counseling, and where necessary, postexposure prophylaxis in the event of a needlestick injury. Prevention of needlestick injuries is the key to safety, and every effort should be made to inform pharmacists administering vaccines and other personnel assisting with the services about the proper technique for avoiding these injuries.

## Marketing Immunization Services

Pharmacists have mounted successful marketing campaigns for immunization services, targeting both patients and prescribers. For adult vaccines, particularly influenza, a simple but effective means is to post an 8 ½" × 11" sign announcing “Flu Shots Given Here.” Alternatives include banners with the same message or buttons with the phrase “Ask me about flu shots.” These simple strategies have produced excellent results.<sup>35</sup> Other pharmacists have made in-person, telephone, and mail contact with prescribers in their areas, apprising them of the new service and soliciting referrals. In some areas, messages from coalition-based immunization campaigns include pharmacists in the list of health care providers who administer vaccines. Pharmacists have targeted local businesses offering to bring influenza vaccines to the worksite. Most pharmacists who have given vaccines recognize word-of-mouth as a primary means of expanding their practices.

Marketing messages to adult patients have positioned the pharmacy as an accessible and convenient location to receive a vaccination. Information could include local or national statistics on morbidity and mortality from vaccine-preventable diseases, as well as the cost-effectiveness of vaccines, but these messages may not be necessary to motivate individuals who find the pharmacy convenient. Marketing messages to parents may require personal contact rather than more generalized promotion. Authorization is also important. Although responsive to the message of convenience, parents may want to be assured that their physicians have given permission to vaccinate children outside of the physician’s office.<sup>35</sup>

Marketing messages to prescribers have positioned the pharmacist as a collaborator in the shared mission to immunize all at-risk patients. Thus, the pharmacist, having been well trained to immunize patients through the same program that all vaccine providers receive, can extend the prescriber’s reach into the community. Prescribers have responded to this message in several ways: with relief that target groups are less likely to fall through the cracks; with relief that patients can be vaccinated without needing to make an office visit; with concern that introduction of an additional hands-on health care provider may fragment patient care; with concern that pharmacists might reduce prescribers’ immunization-

associated revenues; and with concern that pharmacists and pharmacies are not adequately equipped to manage medical emergencies arising from vaccine administration.\* Pharmacists should be prepared to address such responses. Concise protocols for communication between the pharmacist and the primary care physician about the vaccines administered and any adverse reaction will help to address the concern for fragmentation of care. Emphasizing the extent of pharmacists' training, including the management of vaccine-associated emergencies, will alleviate other concerns.

Marketing materials should also point out that pharmacists can make a positive contribution to providers' compliance with requirements of the National Committee for Quality Assurance (NCQA) Health Plan Employer Data and Information Set (HEDIS 3.0). HEDIS, a set of standardized measures used to evaluate the performance of managed care plans, specifies adolescent and childhood immunization and flu shots for older adults as criteria for measurement of quality of care.<sup>36</sup> HEDIS also specifies adults' access to preventive and ambulatory health services as a criterion for the quality of access to care, another performance quality measure. Provider organizations that are evaluated according to HEDIS measures are continually seeking cost-effective alternatives to meet the various quality standards, and may be receptive to pharmacists' offers of assistance in these areas.

## Reimbursement

Pharmacists receive professional fees for administering vaccines. In some instances retail pharmacies offer free flu shots as a marketing device to attract customers. However, that practice is strongly discouraged as undermining the professional role of pharmacists in patient care and public health promotion.

## Patient Payment

Pharmacists in Washington State have found that most patients who have the means are willing to pay out-of-pocket for influenza and travel vaccinations. Even patients of managed care organizations that include vaccine coverage in their plans are often willing to pay for the convenience of receiving vaccines in the community pharmacy. If patients intend to bill their insurance carrier for the vaccination, pharmacists give them an invoice that includes the appropriate Physicians' Current Procedure Terminology (CPT) and HCFA Common Procedure Coding System (HCPCS) codes<sup>†</sup> as well as the amounts charged and paid (see Table 4).<sup>37</sup>

\* R. Shafer. Personal communication.

† Health Care Financing Administration procedure codes used to describe to payers the services rendered to patients by health care professionals. For complete information and specific codes, see *Coding and Reimbursement Guide For Pharmacists*, St. Anthony Publishing and the American Pharmacists Association, 1996, or contact the appropriate state Medicare provider organization.

## Medicare Payment

Pharmacists have applied for and received Provider Identification Numbers (PIN) from HCFA to bill Medicare Part B for influenza and pneumococcal vaccine administration and products. The Medicare Provider/Supplier Enrollment Application (HCFA 855 Form) for a HCFA PIN may be obtained from the local Medicare contractor (listed on the HCFA Web site or in the local telephone book).

Pharmacists can bill for vaccine administration using a HCFA 1500 Health Insurance Claim Form for each patient, or via a simplified "roster" billing option, whereby patients sign a log with their name, date of birth, and Medicare number. For the latter, the entire page is attached to a single HCFA 1500 Form containing minimal information, and sent to the carrier. Both influenza and pneumococcal vaccine administration can be billed to HCFA using the roster system. Individual state Medicare representatives will answer questions about the procedures.

The relevant Medicare billing codes for administration of influenza, pneumococcal, and hepatitis B vaccines are listed in Table 4. The amount reimbursed varies according to state.

## Other Third Party Payment

Pharmacists receive reimbursement for vaccines that are included in the formularies of insurance plans, billing through normal channels by National Drug Code (NDC) code.<sup>29</sup> Pharmacists have had some success in receiving reimbursement for vaccine administration when billing private payers using the HCFA 1500 Form with associated codes, and inserting the patient's medical card number in Item 1a. A fully itemized statement, prepared on the pharmacy's letterhead and attached with the completed form, increases the likelihood of reimbursement. Some pharmacists elect not to become involved in the billing process, instead collecting fees from patients and providing them with itemized statements for their insurers.

## Vaccine Acquisition

### Vaccines For Children (VFC) Program

VFC provides free vaccination for children up to 18 years of age

**Table 4. Medicare Billing Codes Required for Reimbursement of Vaccine Administration\***

Procedure	ICD-9 Code	CPT Code	HCFA Procedure Code
Administer influenza virus vaccine	V04.8	90724	G0008
Administer hepatitis B vaccine	V05.3	90746	G0010
Administer pneumococcal vaccine	V05.82	90732	G0009

\* Adapted from Reference 37.

who are eligible for Medicaid, who are Native Americans, or who are uninsured or (in some settings) underinsured.<sup>15</sup> VFC provides state health departments with vaccines against the following diseases: measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, hepatitis B, *haemophilus influenzae*, and varicella for all eligible children. VFC provides the following vaccines for high-risk children: pneumococcal (children 2 to 19 years), influenza (children 6 months to 19 years), and hepatitis A. The states have various methods for free distribution of these vaccines under contract with qualified providers. The states determine whether pharmacists qualify to receive free vaccines under the program, from the standpoint both of policy and of demand for vaccine provider services. In some states the decision is relegated to local health officers, who can allocate resources based on the needs of their local communities. In some instances, a small administration fee may be charged, but no child can be turned away for inability to pay.

State or local health department immunization coordinators or the National Immunization Program Public Health Advisor listed in the appendices of the CDC training manual can advise pharmacists in a given area on their eligibility for VFC vaccines. These are federal requirements. Providers who are eligible to receive free vaccines under the VFC program

- May not charge for vaccines, but may charge for vaccine administration; the amount allowable varies by state.
- May not refuse to administer vaccine on the basis of ability to pay, and must publicly display a sign to that effect.
- Must provide the patient and/or guardian a copy of the CDC-developed Vaccine Information Statement (VIS) for each vaccine administered.
- Must comply with the recordkeeping requirements of the VFC program.

Also, each state may impose contractual requirements on pharmacists and other vaccine providers for VFC program implementation.

## Distributors

Vaccines can be purchased through wholesalers that supply prescription drugs; vaccine availability should be discussed with a pharmacy's regular supplier. Vaccines can be purchased by direct mail from several catalog wholesalers. The vaccine manufacturers offer direct purchase options to pharmacies, and this mechanism may be faster and less expensive than ordering through wholesalers.

## Patient Education Materials and Records

Standardized VISs for basic childhood and adult vaccines are available in several languages at no charge from CDC and state health departments. A large variety of patient information materials, including posters, forms, and consent templates (in various languages) is available from the Immunization Action Coalition,

either at no charge or at nominal charge for nonmembers (membership is \$50 a year). The National Coalition for Adult Immunization also has excellent materials available. The Web site addresses for these organizations are listed in Table 2. Some of these materials can be downloaded from the Internet, and all may be reproduced. Vaccine manufacturers are also excellent sources of patient education materials.

Individual immunization recordkeeping forms are available at no charge from state and local health departments and other agencies advocating immunization. Records take many forms, from lifetime record formats for children to wallet-sized cards for adults. To document vaccine delivery in the pharmacy, pharmacists can use their patient management software or one of the vaccine tracking software packages available at no charge from vaccine manufacturers. Twenty U.S. health departments have established multi-user immunization monitoring systems under the All Kids Count project. These systems are administered by a national program office in Atlanta<sup>38</sup> and are available generally through dial-up access.<sup>39</sup> Pharmacists can obtain PINs to access these databases and share immunization status of patients with other vaccine providers.

There is no externally imposed requirement for signed patient consent to administer vaccines. In deciding whether to use signed consent procedures, pharmacists should be guided by practice policy; the procedures used in local/community health departments; ethical principles of ensuring patient, parent, or caregiver comprehension of procedures and rationale; and sound risk management.

## Legal Liability

The question periodically arises of the increased risk of litigation against pharmacists who administer vaccines, prescribers who authorize them to do so, health departments who declare them eligible to receive VFC vaccines, and even pharmaceutical companies who knowingly sell vaccines to be administered by community pharmacists. These concerns, however legitimate, threaten to deter pharmacist-provided immunization services. Although there have been no instances of litigation against pharmacists regarding vaccine administration, the possibility cannot be ruled out. Still, in states where the pharmacy practice act includes drug administration, appropriately trained pharmacists who practice within the legal guidelines are at no greater risk of litigation for that function than for any other authorized by the practice act. The Vaccine Injury Compensation Program further reduces the risk by arbitrating and settling vaccine injury claims for diphtheria; tetanus; pertussis; polio; measles, mumps, and rubella (MMR); *Haemophilus influenzae B* (HIB); hepatitis B; and varicella antigens. Beyond that, risk of litigation is low, because the risk of adverse reactions to vaccines, including anaphylaxis, is low.<sup>40</sup> On the other hand, there is a precedent of lawsuits brought against physicians who failed to provide vaccines, and as pharmacists become established as vaccine providers, that responsibility could be extended to them as well.<sup>41</sup>

## Conclusion

Each year more community pharmacists elect to initiate vaccine administration programs. Although this activity is still extraordinary, it is likely to eventually become a standard of professional practice along with other health promotion functions such as smoking cessation, weight reduction, and chronic disease prevention programs. Schools of pharmacy are expanding training in prevention of infectious diseases through immunization services, and more students will graduate with the expectation that vaccine advocacy and administration are basic to their professional responsibility. In the interval, supplementary training and certification, sensitivity to the perceptions of patients and other professionals, and insistence on compensation for professional services will build an expanding corps of pharmacist role models who accept responsibility for the health of their patients and the community.

## References

1. *National Pharmacy Compliance News*. National Association of Boards of Pharmacy Foundation, Inc. April, 1995
2. Grabenstein JD. Counseling your patients about vaccines. *Am Pharm*. 1992;NS32:54-5.
3. ASHP technical assistance bulletin on the pharmacist's role in immunization. *Am J Hosp Pharm*. 1993;50:501-5.
4. Knoell KR, Leeds AL. Influenza vaccination program for elderly outpatients. *Am J Hosp Pharm*. 1991;48:256-9.
5. Spruill WJ, Cooper JW, Taylor WJR. Pharmacist-coordinated pneumonia and influenza vaccination program. *Am J Hosp Pharm*. 1982;39:1904-6.
6. Freed GL, Bordley WC, DeFriesse GH. Childhood immunization programs: an analysis of policy issues. *The Milbank Quarterly*. 1993;71:65-96.
7. The National Vaccine Advisory Committee. The measles epidemic: the problems, barriers and recommendations. *JAMA*. 1991;266:1547-52.
8. *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*. Washington, DC: U.S. Public Health Service; U.S. Department of Health and Human Services. 1991;511-6.
9. *Immunization: HHS Could Do More to Increase Vaccination Among Older Adults*. Washington, DC: U.S. General Accounting Office. GAO/PEMD 95-14. 1995.
10. Evans G. Vaccine liability and safety: a progress report. *Pediatr Infect Dis J*. 1996;15:477-8.
11. Robinson CA, Evans WB, Mahanes JA, et al. Progress on the childhood immunization initiative. *Public Health Rep*. 1994;109:594-600.
12. Centers for Disease Control and Prevention. Status report on the Childhood Immunization Initiative: national, state, and urban area vaccination coverage levels among children aged 19-35 months in the United States, 1996. *MMWR*. July 1997; 46:657.
13. Centers for Disease Control and Prevention. Assessing adult vaccination status at age 50 years. *MMWR*. 1995;44:561-3.
14. Centers for Disease Control and Prevention. Immunization of Adolescents. *MMWR Recommendations and Reports*. 1996;45.
15. *Vaccines for Children: Reexamination of Program Goals and Implementation Needed to Ensure Vaccination*. Washington, DC: U.S. General Accounting Office. PEMD-95-22. 1995.
16. Lee JS. Adult immunization priorities in the United States. *Milbank Quarterly*. 1996;74:285-307.
17. Nichol KL, Margolis KL, Wuorenma J, et al. The efficacy and cost effectiveness of vaccination against influenza among elderly persons living in the community. *N Engl J Med*. 1994;331:778-84.
18. Mullooly JP, Bennett MD, Hornbrook MC, et al. Influenza vaccination programs for elderly persons: cost-effectiveness in a health maintenance organization. *Ann Intern Med*. 1994;121:947-52.
19. Centers for Disease Control and Prevention. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 1997;46(No.RR-9):9.
20. Grabenstein JD. Status and future of vaccines for adults. *Am J Health Syst Pharm*. 1997;54:379-87.
21. Fedson DS. Hospital-based immunization: a leadership role for hospital pharmacists. *Am J Hosp Pharm*. 1990;47:521.
22. Morton MR, Spruill WJ, Cooper JW. Pharmacist impact on pneumococcal vaccination rates in long-term-care facilities. *Am J Hosp Pharm*. 1988;45:73.
23. Ray S. Innovative practitioners create a new future for pharmacy. *Washington Pharmacist*. 1997;39:25.
24. Ernst ME, Chalstrom CV, Currie JD, Sorofman B. Implementation of a community pharmacy-based influenza program. *J Am Pharm Assoc*. 1997;NS37:570-80.
25. Revised Code of Washington (RCW) 18.64.011(11)
26. Revised Code of Washington (RCW) 18.64.011(23).
27. National Association of Boards of Pharmacy. NABPLAW (CD ROM). Version 2.0. 1995
28. Fuller TS. *Handbook of Collaborative Drug Therapy Management*. Seattle: Washington State Pharmacists Association; 1996.
29. Vaccination services present payment opportunities to pharmacists. Pharmacy Reimbursement and Disease Management Report 1996;1:3-7. Reston, Va: St. Anthony Publishing and the American Pharmacists Association.
30. American Academy of Pediatrics Ad Hoc Task Force on Definition of the Medical Home. The medical home. *Pediatrics*. 1992;90:774.
31. Atkinson W, Furphy L, Gantt J, et al. Epidemiology and Prevention of Vaccine-Preventable Diseases. Washington DC: U.S. Public Health Service; U.S. Dept. of Health and Human Services. 1996.
32. Braun MM, Patriarca PA, Ellenberg SS. Syncope after immunization. *Arch Ped Adolesc Med*. 1997;151:255-9.
33. Cardo DM, Bell DM. Bloodborne pathogen transmission in health care workers: risks and prevention strategies. *Inf Dis Clin No Am*. 1997;11:331-46.
34. Department of Labor, Occupational Safety and Health Administration: 29 CFR Part 1910.1030. Occupational exposure to bloodborne pathogens: final rule. *Federal Register* 56(235)64004, 1991.
35. Schaefer B, Darrah T. Oral presentation. National Community Pharmacists Association, RxExpo. San Diego, May 6-9, 1997.
36. <http://www.ncqa.org/news/hedismeas.htm>. National Committee for Quality Assurance, HEDIS 3.0.
37. American Pharmacists Association. *Coding and Reimbursement Guide for Pharmacists*. Reston, Va: St. Anthony Publishing; 1996.
38. Task Force for Child Survival and Development. All Kids Count Immunization Monitoring and Follow-up Systems: Program Fact Sheet. Atlanta, Ga. April 1995.
39. Inkelas M, Wood D, Borenstein P, et al. Lessons learned in planning for community child immunization registries. *Am J Prev Med*. 1997; 13:7-11.
40. Centers for Disease Control and Prevention. Update: vaccine side effects, adverse reactions, contraindications, and precautions—recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 1996;45(No.RR12):8.
41. Immunization Action Coalition Hepatitis B Coalition. *Needle Tips*. September-December 1994.

