Vaccines in Community Practice: Business Considerations

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Upon successful completion of this continuing education activity, the pharmacist should be able to:
1. Identify the factors which contribute to the cost of implementing a vaccine service into a community pharmacy practice.
2. Discuss the revenue potential associated with offering comprehensive vaccine services in the community pharmacy.
3. Describe the difference between reimbursement for a vaccine product and compensation for the service of administering vaccines in an immunization practice.
4. Identify the needs for baseline training of pharmacists and pharmacy staff before starting an immunization service.
5. Identify appropriate information resources for vaccines and immunization services, especially related to inventory management, storage, and compensation.

Introduction

As of 2009, pharmacists in all states except Maine have the explicit authority to administer immunizations. In many states the availability of flu shots in community pharmacies has become a welcome convenience for the public. Medicare Part D routinely reimburses pharmacies more easily than physicians for varicella zoster (shingles) vaccine, resulting in many community pharmacies becoming the center of immunization activity in local communities. State pharmacy practice acts detail which immunizations can be provided by protocol, which need physician orders, and those a pharmacist may not administer. The scope of each pharmacists’ immunization practice will vary by legal limitations and business considerations. This article seeks to outline the business considerations for offering a wide range of immunization services through the pharmacy and makes the case that with proper preparation and minimal investment in marketing and other areas, immunization services can almost certainly add to the profitability of the community pharmacy.

Background

Independent community pharmacy practice continues to be a viable, profitable business for entrepreneurs largely because of the emphasis that pharmacists who practice in this setting place on relationships. Patients have come to trust pharmacists immensely and are happy to have their pharmacist immunize them. It is through strong patient relationships that pharmacists are able to identify niche markets within their communities for new products and services or improvement of existing services.

Despite these strong relationships, vaccine needs may remain unrecognized in many communities. For example, the most recent (2007) National Immunization Survey conducted by the Centers for Disease Control and Prevent-
tion (CDC) of adults found that in the population age 65 and over, more than 30 percent of Caucasian adults, and more than 55 percent of African Americans, were not immunized in the previous flu season despite recommendations that all persons in this age group receive the vaccine.

Unfortunately, influenza immunization rates in this age group represent the bright spot among recommended vaccines. Immunization rates for pneumococcal disease are half that of influenza, in some populations, the number of people 65 or older who have received their tetanus booster within the previous 10 years is only about 45 percent. These data provide a reminder to health care professionals that we have important work yet to do in protecting our communities against preventable diseases. Pharmacists are among the most accessible health care professionals and can help improve access to vaccines. However, despite the public health importance of this service, we must also recognize that pharmacies are businesses and must justify services based upon solid business principles.

**ANALYZING THE COST OF VACCINE SERVICES**

Table 1 (page 45) provides a listing of several costs to consider as part of the investment in an immunization service. Discussion of each of these items is worthwhile for more in-depth understanding.

**Training Costs**

Because vaccines are immunologic agents, there is some risk associated with their administration. As a result, a prudent pharmacist must be well-prepared to offer vaccines in his or her practice ensuring that only patients who should receive the vaccine(s) do and that patients receive comprehensive evaluation to determine all vaccine needs. During the last decade many graduates from schools and colleges of pharmacy have entered practice with a detailed skill set to offer vaccines as part of a comprehensive pharmacy service. Some others have not, and many practitioners may need to refresh their knowledge base on the appropriate use and administration of vaccines. Thus, before beginning any immunization practice, it is highly recommended that the pharmacist administering vaccines complete an advanced training program in the subject. In fact, some states require that pharmacists complete such training and others require continuing education in the subject matter annually or semi-annually. Many associations offer immunization training for pharmacists, as do many state organizations. The cost of completing this training ranges from free, to about $500 for the training itself (depending upon the provider and available sponsorship), plus one to two days away from the practice, which may require the hiring of a relief pharmacist, overnight hotel accommodations, and travel expenses.

Following this initial investment, most pharmacists can stay current with immunization knowledge by subscribing to one of several free immunization list-services via e-mail. Several state and national pharmacy organizations also offer CE programming at professional meetings and through their organizational Web sites. The CDC’s “Pink Book,” otherwise known as “The Epidemiology and Prevention of Vaccine-Preventable Diseases,” is the gold standard book for immunizations and is available for purchase or free download at the CDC Web site (www.cdc.gov/). It has a wealth of information regarding immunizations and should be on every pharmacy’s bookshelf.

Along with the baseline training in vaccines and immunology, the Occupational Safety and Health Administration (OSHA) requires as part of federal regulations that all individuals with potential occupational exposure to blood-borne pathogens (e.g. HIV, hepatitis) complete an annual one-hour OSHA training program. This can be in any format, and there are a variety of OSHA programs available at little or no cost via the Internet. OSHA also requires that every person with potential blood-borne pathogen exposure be offered immunization against Hepatitis B free of charge to the employee. Thus, a pharmacy owner will need to determine which individuals in the practice may come in contact with the sharps container (including any housekeeping staff) and offer the vaccine free of charge to the employee. The cost of a three-dose series per employee is approximately $120 to $150, and employees must have received at least the first dose before an immunization service is offered in the pharmacy.

The last item for training to consider is the cost associated with receiving training in cardio-pulmonary resuscitation (CPR). Many local fire
and police departments, as well as local chapters of the American Red Cross, offer CPR certification courses for $25 to $50 per person. This certification must be renewed every year or two, depending on whether it is the American Red Cross, or American Heart Association certification. Several state boards of pharmacy require that pharmacists have active CPR certification as a condition to offering an immunization service.

Inventory Costs

The second major expense associated with an immunization service is the investment in inventory, and the storage of the inventory. Vaccines, being biological agents, require strict adherence to storage and handling requirements listed by the manufacturer on the product labeling. This may require a pharmacy to purchase an updated refrigerator and/or freezer for storage, although most pharmacies likely already have sufficient cold storage available. The CDC offers detailed information on the storage and handling of vaccines through their Web site (www.cdc.gov/vaccines/pubs/vac-mgt-book.htm.)

Vaccine inventory is generally handled differently from other drug inventory. For starters, most vaccines are ordered directly from the manufacturer. For influenza vaccine, manufacturers pre-book orders in the late winter and early spring for the following fall influenza season. The manufacturing process for influenza vaccine takes several months, and manufacturers gauge the number of doses to produce by the pre-booking orders. Often vaccine that is ordered through pre-booking can be secured at a discount over vaccine ordered later in the production cycle or during the
current influenza season. It is difficult to gauge how much vaccine should be ordered in the initial season of offering influenza vaccine. One vial of inactivated influenza vaccine typically holds 10 doses of vaccine; and many pharmacists tend to be conservative in their first year of offering vaccine services (ordering 10 to 30 vials), and increasing the amount ordered during the subsequent season based upon demand in the first season. A reasonable amount to order for the first season is 200 doses. Influenza vaccine is generally not returnable for credit. Thus if the vaccine is not administered and is unused, it becomes wasted inventory.

Most other vaccines routinely used for adults, including tetanus-containing vaccines, varicella zoster vaccine, hepatitis A vaccine, hepatitis B vaccine, combination hepatitis A-hepatitis B vaccine, and pneumococcal vaccine may be ordered either direct from the manufacturer or through most major U.S. drug wholesalers. This allows for just-in-time inventory management similar to that used for other drugs. However, as pharmacists develop their immunization practice, planning ahead and anticipating vaccine demand for the practice can allow the owner to order larger quantities from the manufacturer and participate in certain discounts that may be offered. Return policies for vaccines other than influenza are more liberal; however, some manufacturers will not allow the return of expired vaccine regardless of type. Most pharmacists will begin their immunization business with influenza and pneumococcal vaccines, as these can be given at the same time. When patients come to the pharmacy for their influenza vaccine, they should all be assessed for the need for a pneumococcal vaccine and offered if applicable. This may double your income with no additional marketing expense. Plus pneumococcal vaccine is given year round to those who are eligible.

With regard to vaccines containing multiple antigens, it is important to note that unless there is a shortage of a particular vaccine, the pharmacist should only purchase vaccines containing all of the antigens currently recommended for adult patients by the CDC. For example, the CDC’s current recommendation for preventing tetanus recommend that the triple-antigen tetanus-diphtheria-acellular pertussis (Tdap) vaccine be used for the first booster dose in most adult patients. However, both single antigen tetanus toxoid vaccine (TT) and dual antigen tetanus-diphtheria (Td) vaccine are available from the manufacturer. Td continues to be recommended preferentially in certain patients (including those with a history of uncontrolled seizure disorders, and over 65), but for the majority of patients Tdap should be used. For single antigen vaccines, such as pneumococcal vaccine, the product choice is much more straightforward. Always be sure to follow current CDC recommendations for all vaccines. Purchasing the appropriate vaccine for your patients can minimize unnecessary vaccine doses in the future, prevent many illnesses, and can establish a practice as a reputable source for vaccine services.

Another inventory cost to consider is that of purchasing a sufficient supply of epinephrine to have on hand in the event a patient has a serious adverse reaction to a vaccine dose. Unfortunately, epinephrine has a very short shelf life compared to many other drugs. A minimum of four Epi-Pens or an equivalent amount of epinephrine in single use or multidose vials should be kept on hand at all times an immunization service is being offered.

Supply Costs
Supplies for vaccine services include syringes, needles, sharps containers, cotton balls, plastic strips (such as Band-Aids), alcohol prep pads, and gloves. OSHA requires that sharps with engineered sharps injury protections (often referred to as “safety needle devices) be assessed for use by health care professionals. There is significant variation in the cost of these devices, depending upon the volume purchased and the manufacturer, and in nearly all cases these devices are significantly more expensive than standard non-safety devices commonly used by patients at home for administration of insulin or other self-care injectables. Pharmacists should contact their wholesaler or independent buying group for detailed pricing information. Each of the other supplies (not including sharps containers) listed are of minimal cost, contributing a total of 5 cents to 10 cents per vaccine administered.

Sharps containers and their disposal are an important consideration for pharmacists. A variety of sizes and shapes of sharps containers are available. These must be used and disposed of according to OSHA regulations. For pharmacists with a large volume of immunizations being pro-
vided each month, contracting with your current refuse disposal company for additional medical waste disposal may be the most cost-effective approach. For others administering a smaller number of vaccines, utilizing a sharps container which can be mailed (via U.S. Postal Service) to a disposal company after the container is full may be the most cost-effective approach, as opposed to paying a monthly medical waste disposal fee. Sharps medical waste disposal and mailing disposal costs vary based upon volume, but can range from as low as $20 per month or per container, to as much as $50 or more for very large volumes or multiple pick-up locations.

Beyond administration supplies, immunizing pharmacists will also need to have available current vaccine information statements (available from the CDC at www.cdc.gov/vaccines), along with screening questionnaires and patient consent forms (available from the Immunization Action Coalition at www.immunize.org). NCPA has also created an immunization resource center that provides many of the necessary forms. Printing a sufficient quantity of these statements and for provision to patients should add no more than three cents to nine cents per vaccine administered. While not required in each state, a method to notify the patient’s physician that they have received an immunization is viewed as professional courtesy. This can be through an e-mail, fax, or mail notification. Wallet cards should be printed and given to the patient with the addition of any immunization given on that date. These cards can be designed and printed in house.

The pharmacy will need to provide a semi-private area for immunization, so that a patient can remove their arm from their sleeve, if needed, to access the deltoid muscle. Also, the patients will need to be observed for 30 minutes after the immunization to watch for allergic reactions. This needs to be in the general vicinity of the pharmacy, so that the patient can be observed from the pharmacy area. A waiting area with chairs should be provided for this. Also needed is an area large enough for the patient to fully recline in case of fainting or allergic reactions.

Policies and procedures need to be in place for emergencies such as fainting, adverse and anaphylactic reactions, and accidental needle sticks, to name a few.

**Personnel Costs**

As with any new service offering in pharmacy, personnel costs often represent the single greatest expense. With practice, it takes approximately the same amount of time to provide an immunization to a patient as it does to prepare and counsel on a new oral medication prescription. Thus, many pharmacists have found that the most efficient way to incorporate immunizations into practice is to process immunization requests just as any other prescription is processed in the pharmacy. For example, as the patient comes to the pharmacy drop-off window and asks for an immunization, the technician will put it down in writing and enter it into the prescription queue. While waiting for the pharmacist to get to that “vaccine prescription,” the technician will give the patient a clipboard with the screening questionnaire, vaccine information sheets, and any other paperwork deemed necessary. Patients can fill these out while waiting their turn in the prescription queue. The technician can also draw up the syringe with vaccine and get other needed supplies ready for the injection. When pharmacists get to the “vaccine prescription” in the queue, they will greet the patient, go over the paperwork and precautions, and administer the vaccine. After the immunization, the information regarding the vaccine, (such as lot number, injection site) should be recorded in the pharmacy dispensing system. This routine will require no additional personnel, until the volume, prescription and vaccine, deems it necessary to hire additional staff.

Certainly provision of immunizations (influenza) during a mass immunization event will require significantly greater human resources to ensure delivery of accurate and efficient immunization services. During these time periods it may be necessary to arrange for a nurse or pharmacist to assist with the event. If planning to hold a mass influenza immunization event, be sure that there are enough personnel available to cover both dispensing activities, while also having enough staff who can focus exclusively on immunizations.

**Profit Potential**

In any discussion of immunization services, it must first be recognized that the pharmacist is providing two distinct and individually billable items. First, is the vaccine product. The
second is vaccine administration. It is customary practice in the United States for payers to calculate remuneration for immunization services for the product and administration service separately, even if they require that they always be billed together on the same date. For example, a pharmacist providing a flu shot to a Medicare recipient in Alabama during the 2008-09 influenza season is reimbursed $16.88 for the vaccine, and $18.25 for the administration of the vaccine.

While pharmacists don’t typically advertise or market these separately, pharmacists must consider what their usual and customary charges for the vaccine are separately from the administration of the vaccine. Usual and customary charges should take into account the expenses outlined earlier in this article and per square foot overhead of the pharmacy, plus some reasonable profit. When submitting claims for reimbursement for vaccines and their administration, it is important that pharmacists submit their usual and customary price (the price a cash customer would pay). While the insurer may not remunerate at this rate, billed U&C is used by many insurers (including CMS) to calculate future reimbursement rates for services. CMS reimburses for influenza and pneumococcal vaccine administration at different rates depending upon the location of the provider in the United States, while the vaccine (product) reimbursement rate is the same across the United States.

Maximizing Profitability

Maximal profitability in immunization services is only achieved when the pharmacist is comprehensively reviewing all patients for vaccination needs on every visit to the pharmacy. Data from the CDC shows that far too many Americans who should be immunized against preventable diseases are not. For example, nearly half of all African American seniors 65 and over report never having received a pneumococcal vaccine, although all seniors should have this vaccine. The potential for adding to a pharmacy’s net margin through a comprehensive vaccination program are substantial.

For example, the 2008 NCPA Digest, sponsored by Cardinal Health, reports that the average community pharmacy practice operated with a 3 percent profit margin on just more than $3.6 million in total sales. These sales are almost exclusively product (prescription, non-prescription drug, non-drug items). A pharmacy in Alabama offering influenza vaccination incorporated into the normal workflow of the business (not via a mass immunization clinic) and which pre-purchased from the manufacturer 500 doses of vaccine for the 2008-09 influenza season would have seen the following: a cost of goods of approximately $9,230 (based upon the CDC’s published influenza vaccine price list, plus overhead and supplies as described in Table 1), a vaccine reimbursement rate of $8,440 (based upon $16.88/vaccine rate), and administration reimbursement of $9,125 (based upon $18.25 rate), for an estimated net profit of $8,335 (Revenue—COGS; $17,565 – $9,230) and profit margin of slightly more than 47 percent.

While these figures are based entirely on 2008-09 CMS reimbursement rates for Medicare beneficiaries, this illustrates the potential impact an influenza vaccination service alone can have on the net profits of a community pharmacy. Projections for other vaccines can be calculated using CMS reimbursement rates.

SUMMARY

Pharmacy-based immunization services are becoming the standard of practice in many states. However, even in those states where vaccines are often being given in pharmacies, it is likely that many pharmacists are missing opportunities for increasing their profit potential through implementing more comprehensive programs. Immunization services are a profitable and professionally rewarding addition to community pharmacy practice.

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Editor’s Note: To obtain the complete list of references used in the article, contact Chris Linville at NCPA (703-838-2680), or at chris.linville@ncpnet.org.
CONTINUING EDUCATION QUIZ

Select the correct answer.

1. Providing vaccines for patients in a community pharmacy can be both a service for patients and a profit making venture.
   a. True
   b. False

2. In 2007 just more than half of patients 65 and older had received their pneumococcal vaccine, according to the National Immunization Survey.
   a. True
   b. False

3. When establishing an immunization service, all of the following costs must be factored in EXCEPT:
   a. Immunization training for pharmacists
   b. CPR training
   c. Full page newspaper ads and TV spots
   d. Administration supplies
   e. Vaccine inventory

4. Which of the following represents a correct statement regarding the reimbursement for herpes zoster vaccine through Medicare Part D plans?
   a. Zoster vaccine is not reimbursable through pharmacies.
   b. Zoster vaccine and its administration are generally billed together by the same entity.
   c. Zoster vaccine may be dispensed at the pharmacy, and administered at the physician’s practice with each entity billing separately.
   d. Zoster vaccine is not billable through Medicare Part D, regardless of provider.

5. Which of the following statements is TRUE regarding pharmacy-based immunization services.
   a. The vaccine product and its administration are separately billable items.
   b. The vaccine product and its administration are reimbursed by most insurers at a single, bundled rate.
   c. Pharmacists and pharmacies are not eligible to become stand-alone Medicare Part B mass immunization providers.
   d. Pharmacies must bill the vaccine product to Medicare Part D and the administration fee to Medicare Part B.

6. Most pharmacist liability policies cover immunization services so it is not necessary to double check before providing immunizations.
   a. True
   b. False

7. CMS reimburses influenza immunization providers:
   a. Equally in all locations in the United States for a bundled service
   b. Equally in all locations in the United States for the vaccine, and varyably based upon location for the administration fee
   c. Equally in all locations in the United States for the administration fee, and varyably based upon location for the vaccine cost
   d. CMS does not reimburse for influenza vaccine.

8. Pharmacists offering immunization should consult which of the following organization’s Web sites for more information about blood-borne pathogen standards?
   a. Food and Drug Administration
   b. Centers for Medicare and Medicaid Services
   c. Occupational Safety and Health Administration
   d. Immunization Action Coalition

9. When assessing the best option for sharps container disposal, often times it may be with your local disposal company.
   a. True
   b. False

10. According to 2007 data from the National Immunization Survey, what percent of the population 65 and older reports had received a tetanus antigen-containing vaccine in the past 10 years?
    a. 25 percent
    b. 35 percent
    c. 45 percent
    d. 55 percent
11. Pharmacy based immunization services are becoming the standard of practice in many areas of the country.
   a. True
   b. False

12. When setting up a pharmacy for immunization delivery, all of the following items need to be included EXCEPT:
   a. Semi-private area for immunization administration
   b. Emergency kit containing epinephrine, bandage strips, cotton balls, smelling salts, etc.
   c. Decorations announcing the immunization area
   d. Seating for patients to be observed after the immunization

13. Supplies for conducting a vaccination program include all of the following EXCEPT:
   a. Epinephrine
   b. Sharps container
   c. Dobutamine
   d. Disposable gloves

14. Pharmacies are ideal locations to offer immunizations because of their:
   a. Convenient location
   b. Extended hours of operation
   c. No appointment is needed by patients
   d. All of the above make pharmacies ideal locations to immunize

15. Before implementing a pharmacy-based immunization program, pharmacists must do all of the following EXCEPT:
   a. Become certified in CPR
   b. Check with your state board of pharmacy for state rules
   c. Set up an area for administering the vaccines
   d. The pharmacist must do all of the above before starting their program

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Last 4 digits of SSN  MM/DD of birth
Name

Pharmacy name

Address

City State ZIP
Phone number (store or home)

Store e-mail (if avail.) Date quiz taken

Quiz: Shade in your choice

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Quiz: Circle your choice

16. Is this program used to meet your mandatory C.E. requirements?
    a. yes  b. no

17. Type of pharmacist:  a. owner  b. manager  c. employee

18. Age group:  a. 21–30  b. 31–40  c. 41–50  d. 51–60  e. Over 60

19. Did this article achieve its stated objectives?  a. yes  b. no

20. How much of this program can you apply in practice?
    a. all  b. some  c. very little  d. none

How long did it take you to complete both the reading and the quiz? ______ minutes

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