35. Treanor JJ, Kotloff K, Betts RF, et al. Evaluation of trivalent, live, cold-adapted (CAIV-TT) and inactivated (TIV) influenza vaccines in prevention of virus infection and illness following challenge of adults with wild-type influenza A (H1N1), A (H3N2), and B viruses. Vaccine. 2000;18:899–906.
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Trade Name</th>
<th>Abbreviation</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>BioThrax</td>
<td>AVA</td>
<td>Emergent BioSolutions</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Tetanus &amp; diphtheria toxoids and acellular pertussis vaccine.</td>
</tr>
<tr>
<td>DTaP</td>
<td>Daptacel</td>
<td>DTaP</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Tetanus &amp; diphtheria toxoids and acellular pertussis vaccine.</td>
</tr>
<tr>
<td></td>
<td>Infanrix</td>
<td>DTaP</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Tetanus &amp; diphtheria toxoids and acellular pertussis vaccine.</td>
</tr>
<tr>
<td></td>
<td>Tripedia</td>
<td>DTaP</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Tetanus &amp; diphtheria toxoids and acellular pertussis vaccine.</td>
</tr>
<tr>
<td>DT</td>
<td>Generic</td>
<td>DT</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Pediatric formulation (through age 6).</td>
</tr>
<tr>
<td>DTaP/Hib</td>
<td>TriHIBit</td>
<td>DTaP/Hib</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>ActHIB reconstituted with Tripedia. Licensed for 4th dose of DTaP &amp; Hib series.</td>
</tr>
<tr>
<td>DTaP–IPV</td>
<td>Kinrix</td>
<td>DTaP-IPV</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Bacterial &amp; Viral</td>
<td>IM</td>
<td>Licensed for 5th (DTaP) and 4th (IPV) booster at 4-6 years.</td>
</tr>
<tr>
<td>DTaP–HepB-IPV</td>
<td>Pediari×</td>
<td>DTaP-HepB-IPV</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Bacterial &amp; Viral</td>
<td>IM</td>
<td>Licensed for doses at 2, 4, &amp; 6 months (through 6 years of age). Not licensed for boosters.</td>
</tr>
<tr>
<td>DTaP-IPV/Hib</td>
<td>Pentacel</td>
<td>DTaP-IPV/Hib</td>
<td>sanofi</td>
<td>Inactivated Bacterial &amp; Viral</td>
<td>IM</td>
<td>Licensed for 4 doses at 2, 4, 6, and 15-18 months.</td>
</tr>
<tr>
<td>Haemophilus influenzae type b (Hib)</td>
<td>PedvaxHIB</td>
<td>Hib</td>
<td>Merck</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>PRP-OMP. Polysaccharide conjugate (mening. protein carrier). 2-dose primary series.</td>
</tr>
<tr>
<td></td>
<td>ActHIB</td>
<td>Hib</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>PRP-T. Polysaccharide conjugate (tetanus toxoid carrier). 3-dose primary series.</td>
</tr>
<tr>
<td></td>
<td>Hiberix</td>
<td>Hib</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Polysaccharide conjugate (tetanus toxoid carrier). Booster only.</td>
</tr>
<tr>
<td>Haemophilus influenzae type b – hepatitis B</td>
<td>Comvax</td>
<td>Hib-HepB</td>
<td>Merck</td>
<td>Inactivated Bacterial &amp; Viral</td>
<td>IM</td>
<td>Should not be used for hepB birth dose.</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Havrix</td>
<td>HepA</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Pediatric (&lt;18) and adult formulations. Pediatric = 720 EL.U., 0.5mL Adult = 1,440 EL.U., 1.0mL Minimum age = 1 year</td>
</tr>
<tr>
<td></td>
<td>Vaqta</td>
<td>HepA</td>
<td>Merck</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Pediatric (&lt;18) and adult formulations. Pediatric = 25 U. 0.5mL Adult = 50 U. 1.0mL Minimum age = 1 year</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Trade Name</td>
<td>Abbreviation</td>
<td>Manufacturer</td>
<td>Type</td>
<td>Route</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------------</td>
<td>---------------------</td>
<td>-------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Engerix-B</td>
<td>HepB</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Pediatric (≤19) and adult formulations. Pediatric formulation not licensed for adults.</td>
</tr>
<tr>
<td></td>
<td>Recombivax HB</td>
<td>HepB</td>
<td>Merck</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Pediatric (≤19), adult, and dialysis formulations. Two pediatric doses may be substituted for an adult dose.</td>
</tr>
<tr>
<td>Hepatitis A - Hepatitis B</td>
<td>Twinrix</td>
<td>HepA-HepB</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Pediatric dose of HepA + adult dose of HepB. Minimum age = 18 years. 3-dose routine series (4-dose alternate schedule for rapid protection).</td>
</tr>
<tr>
<td>Herpes Zoster (Shingles)</td>
<td>Zostavax</td>
<td>ZOS</td>
<td>Merck</td>
<td>Live Attenuated Viral</td>
<td>SC</td>
<td>Licensed for age 50 and older.</td>
</tr>
<tr>
<td>Human Papillomavirus (HPV)</td>
<td>Gardasil</td>
<td>HPV4</td>
<td>Merck</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Quadrivalent (types 6, 11, 16, 18). Licensed for males and females 9 through 26 years.</td>
</tr>
<tr>
<td></td>
<td>Cervarix</td>
<td>HPV2</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Bivalent (types 16, 18). Licensed for females 10 through 26 years.</td>
</tr>
<tr>
<td>Influenza (Trivalent, types A &amp; B)</td>
<td>Fluarix</td>
<td>TIV</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Minimum age = 3 years.</td>
</tr>
<tr>
<td></td>
<td>Fluvirin</td>
<td>TIV</td>
<td>Chiron</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Purified surface antigen. Minimum age = 4 years.</td>
</tr>
<tr>
<td></td>
<td>Fluzone</td>
<td>TIV</td>
<td>sanofi</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Subvirion. Minimum age (multidose vial) = 6 mo. Age range (0.25mL prefilled syringe) = 6 through 35 mo. Minimum age (0.5mL prefilled syringe) = 3 years.</td>
</tr>
<tr>
<td></td>
<td>Fluzone High-Dose</td>
<td>TIV</td>
<td>sanofi</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Licensed for age 65 and older.</td>
</tr>
<tr>
<td></td>
<td>Fluzone Intradermal</td>
<td>TIV</td>
<td>sanofi</td>
<td>Inactivated Viral</td>
<td>Intradermal</td>
<td>Age range 18 through 64 years. 0.1 mL dose.</td>
</tr>
<tr>
<td></td>
<td>FluLaval</td>
<td>TIV</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Minimum age = 18 years.</td>
</tr>
<tr>
<td></td>
<td>Afluria</td>
<td>TIV</td>
<td>CSL</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Minimum age = 6 months.</td>
</tr>
<tr>
<td></td>
<td>Agriflu</td>
<td>TIV</td>
<td>Novartis</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Minimum age 18 years.</td>
</tr>
<tr>
<td>Japanese encephalitis</td>
<td>Ixiaro</td>
<td>JE</td>
<td>Novartis</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td>Licensed for age 17 and older. 2-dose series.</td>
</tr>
<tr>
<td>Measles, Mumps, Rubella</td>
<td>M-M-R II</td>
<td>MMR</td>
<td>Merck</td>
<td>Live Attenuated Viral</td>
<td>SC</td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>Trade Name</td>
<td>Abbreviation</td>
<td>Manufacturer</td>
<td>Type</td>
<td>Route</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------</td>
<td>--------------</td>
<td>-------------------</td>
<td>---------------------------</td>
<td>-------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Measles, Mumps, Rubella, Varicella</td>
<td>ProQuad</td>
<td>MMRV</td>
<td>Merck</td>
<td>Live Attenuated Viral</td>
<td>SC</td>
<td>Age range = 1 through 12 years.</td>
</tr>
<tr>
<td></td>
<td>Menactra</td>
<td>MCV4</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Polysaccharide conjugate (diphtheria toxoid carrier, serogroups A, C, Y, W135). Age range = 9 months through 55 years.</td>
</tr>
<tr>
<td></td>
<td>Menveo</td>
<td>MCV4</td>
<td>Novartis</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Polysaccharide conjugate (diphtheria toxoid carrier, serogroups A, C, Y, W135). Age range = 2 through 55 years.</td>
</tr>
<tr>
<td></td>
<td>Pneumovax 23</td>
<td>PPSV23</td>
<td>Merck</td>
<td>Inactivated Bacterial</td>
<td>SC or IM</td>
<td>Polysaccharide (contains 23 strains). Minimum age = 2 years.</td>
</tr>
<tr>
<td></td>
<td>Prevnar 13</td>
<td>PCV13</td>
<td>Wyeth</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Polysaccharide conjugate (diphtheria protein carrier, contains 13 strains).</td>
</tr>
<tr>
<td>Polio</td>
<td>Ipol</td>
<td>IPV</td>
<td>sanofi</td>
<td>Inactivated Viral</td>
<td>SC or IM</td>
<td>Trivalent, Types 1, 2, 3</td>
</tr>
<tr>
<td>Rabies</td>
<td>Imovax Rabies</td>
<td></td>
<td>sanofi</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RabAvert</td>
<td></td>
<td>Chiron</td>
<td>Inactivated Viral</td>
<td>IM</td>
<td></td>
</tr>
<tr>
<td>Rotavirus</td>
<td>Rota Teq</td>
<td>RV5</td>
<td>Merck</td>
<td>Live Viral</td>
<td>Oral</td>
<td>Pentavalent. First dose between 6 weeks and 14 weeks 6 days; complete 3-dose series by 8 months 0 days.</td>
</tr>
<tr>
<td></td>
<td>Rotarix</td>
<td>RV1</td>
<td>GlaxoSmithKline</td>
<td>Live Viral</td>
<td>Oral</td>
<td>Monovalent. First dose between 6 weeks and 14 weeks 6 days; complete 2-dose series by 8 months 0 days.</td>
</tr>
<tr>
<td>Tetanus – (reduced) Diphtheria</td>
<td>Decavac</td>
<td>Td</td>
<td>sanofi</td>
<td>Inactivated Bacterial Toxoids</td>
<td>IM</td>
<td>Adult formulation (age 7 and older).</td>
</tr>
<tr>
<td></td>
<td>(Generic)</td>
<td>Td</td>
<td>Massachusetts Biological Labs</td>
<td>Inactivated Bacterial Toxoids</td>
<td>IM</td>
<td>Adult formulation (age 7 and older).</td>
</tr>
<tr>
<td>Vaccine</td>
<td>Trade Name</td>
<td>Abbreviation</td>
<td>Manufacturer</td>
<td>Type</td>
<td>Route</td>
<td>Comments</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------</td>
<td>--------------</td>
<td>--------------</td>
<td>------------------------</td>
<td>-------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Tetanus – (reduced) Diphtheria</td>
<td>Boostrix</td>
<td>Tdap</td>
<td>GlaxoSmithKline</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Tetanus and diphtheria toxoids &amp; pertussis vaccine. Age range 10 through 64 years.</td>
</tr>
<tr>
<td>(reduced) Pertussis</td>
<td>Adacel</td>
<td>Tdap</td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Tetanus and diphtheria toxoids &amp; acellular pertussis vaccine. Age range 11 through 64 years.</td>
</tr>
<tr>
<td>Tetanus toxoid</td>
<td>(Generic)</td>
<td>TT</td>
<td>sanofi</td>
<td>Inactivated Bacterial Toxoid</td>
<td>IM</td>
<td>May be used for adults or children.</td>
</tr>
<tr>
<td>Typhoid</td>
<td>Typhim Vi</td>
<td></td>
<td>sanofi</td>
<td>Inactivated Bacterial</td>
<td>IM</td>
<td>Polysaccharide</td>
</tr>
<tr>
<td></td>
<td>Vivotif Bema</td>
<td></td>
<td>Bema</td>
<td>Live Attenuated Bacterial</td>
<td>Oral</td>
<td>Ty21a strain.</td>
</tr>
<tr>
<td>Varicella</td>
<td>Varivax</td>
<td>VAR</td>
<td>Merck</td>
<td>Live Attenuated Viral</td>
<td>SC</td>
<td></td>
</tr>
<tr>
<td>Vaccinia (Smallpox)</td>
<td>ACAM2000</td>
<td></td>
<td>Acambis</td>
<td>Live Attenuated Viral</td>
<td>Percutaneous</td>
<td></td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>YF-Vax</td>
<td>YF</td>
<td>sanofi</td>
<td>Live Attenuated Viral</td>
<td>SC</td>
<td>Minimum age = 9 months.</td>
</tr>
</tbody>
</table>

The abbreviations on this table (Column 3) were standardized jointly by staff of the Centers for Disease Control and Prevention, ACIP Work Groups, the editor of the *Morbidity and Mortality Weekly Report (MMWR)*, the editor of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the *Pink Book*), ACIP members, and liaison organizations to the ACIP.

These abbreviations are intended to provide a uniform approach to vaccine references used in ACIP Recommendations and Policy Notes published in the *MMWR*, the *Pink Book*, and the American Academy of Pediatrics *Red Book*, and in the U.S. immunization schedules for children, adolescents, and adults.

A dash (-) in an abbreviation for a combination vaccine indicates products that are supplied in their final form by the manufacturer and do not require mixing or reconstitution. A slash (/) indicates products that must be mixed or reconstituted by the user.
Legal and Regulatory Issues

Every state has its own regulations about who can and cannot prescribe and administer vaccines. State law directs separately who has authority to prescribe and who has authority to administer the drugs. Each vaccine is a prescription drug, with all the attendant requirements.2

To administer a vaccine, student pharmacists need

1. Confirmation of their legal eligibility to administer medications. (Ask your state board of pharmacy for the state’s definition of the scope of pharmacy practice.)

2. An authorization to administer the drug. (In most states this involves a prescription [written or oral] or a collaborative protocol or standing orders to administer vaccines. In a few states, pharmacists may have independent prescribing authority for vaccines.)

To illustrate, the Mississippi Practice Act (Section 73-21-73[aa]) states that the “Practice of pharmacy...shall mean a health care service that includes, but is not limited to, the compounding, dispensing and labeling of drugs or devices; interpreting and evaluating prescriptions; administering and distributing drugs and devices...” [emphasis added].

Prototype practice protocols or standing orders appear at the end of the section. The Clinical Considerations section offers a prototype protocol for managing severe allergic reactions. These templates can be customized according to local conditions and the relationship you establish with your collaborating physician. For example, you and the physician might agree to a longer or shorter list of vaccines or a longer or shorter duration than in the template.

To conduct an immunization program in Mississippi, the state board of pharmacy requires the pharmacist to (1) have competency in vaccination procedures gained through specific immunization training; (2) be able to deal with anticipated adverse events (e.g., administer cardiopulmonary resuscitation [CPR] and administer epinephrine); (3) establish a collaborative agreement with a physician or clinic to support the immunization program and handle emergencies; and (4) have a sponsoring physician or county medical director give written guidelines authorizing the pharmacist to administer vaccines.3

Liability

This section provides an overview of some laws and regulations associated with immunization delivery. Legal issues are complex and vary from state to state. This brief review does not cover every nuance of the law. This section does not constitute legal advice. If you have specific questions, ask your chapter advisor and state board of pharmacy before making decisions.

Malpractice risks for health care providers who immunize are low. Because of some federal programs, the risks are especially low for those who immunize children. Vaccine providers are typically protected by a strong set of legal provision, but no law provides absolute protection from liability for harm.5

The best defenses against liability are good training and competent performance. The cause of successful medical malpractice suits very often is negligence by the provider. Another common theme in vaccine litigation is “failure to warn.”5

44 | APhA-ASP Operation Immunization
When vaccines are dispensed on a physician’s order or through a protocol, the physician is usually not liable if the person (historically, a nurse) giving the vaccines administers them negligently. In this case, the nurse is engaged in the practice of nursing and acting under the authority of a nursing license. Courts have held that physicians are not liable for nurses who negligently practice nursing, just as they are not liable for laboratories that negligently perform tests. In many states, drug administration is explicitly included within the scope of practice of a pharmacist. Analogously, the same relationships between physician and pharmacist would operate as in the physician-nurse example. The physician should satisfy him or herself that the pharmacist can competently administer an immunization (e.g., has been trained in proper injection technique). Physicians are not liable for pharmacists who negligently practice pharmacy, such as in making a dispensing error. Unless state law directs to the contrary, physicians do not need to delegate the administration of vaccines to nurses or pharmacists if nurses and pharmacists can administer the vaccine under the authority of their own licenses.\

Nonetheless, it is wise for the pharmacy and the practicing pharmacist to carry liability insurance. Some pharmacists interviewed for this module carry a minimum of $1 million of coverage per occurrence, with an aggregate coverage of $3 million per policy interval.

Both the commercial pharmacy policy and the individual policy will provide protection only if the pharmacists act within the scope of pharmacy laws in the state where they practice. The pharmacy or the pharmacist should not administer drugs unless it is legal for them to do so in their state and is covered by their insurance policies.

Also consider general business liability. People seeking immunizations are classified as invitees, more specifically as business visitors. The normal duty of property owners is the same with immunizations as with everyday business—to remove effects or dangerous conditions on the premises, or warn invitees about them. Businesses are normally covered under a standard commercial coverage for accidents caused by some conditions of the premises to persons on the premises for immunization. Each business should verify its coverage.

**The Vaccine Injury Compensation Program**

In the early 1980’s, pharmaceutical companies and health care providers were overwhelmed by lawsuits based on alleged severe adverse events in children (e.g., alleged permanent brain damage; death allegedly caused by vaccination). Companies were on the verge of withdrawing their vaccines from the United States market, which would have left children in this country unprotected against many devastating diseases. Consequently, in 1986, the United States Congress enacted the National Childhood Vaccine Injury Act, which authorized the VICP.

This act levies an excise tax on many vaccines sold in the United States. The revenue goes into a type of no-fault insurance fund to cover injuries listed in the Vaccine Injury Table (VIT) that are temporally associated with immunization. If one of the events in this table occurs or some other event is proved to be caused by the vaccine, the claimant can be awarded damages from a federal trust fund. The VICP has the advantage of being national in scope and covering any authorized vaccine provider.
The following vaccines are covered under VICP:

- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT)\(^1,7\)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Human papillomavirus (HPV)
- Influenza (TIV, LAIV) [given each year during the flu season]
- Measles, mumps, rubella (MMR, MR, M, R)
- Meningococcal (MCV4, MPSV4)
- Polio (OPV or IPV)
- Pneumococcal conjugate (PCV)
- Rotavirus (RV)
- Varicella (VZV)
- Any combination of the vaccines above
- Additional vaccines may be added in the future

Health care providers cannot be sued while allegedly vaccine-injured people and their families pursue redress under VICP. If a petitioner accepts an award under the VICP, a malpractice claim cannot be brought later in the tort system. Petitioners can reject an award made under VICP and pursue their remedy at tort law, but few do. Even so, providers can later be found negligent, such as vaccinating despite an obvious contraindication.

In exchange for this simplified, no-fault proceeding, petitioners give up the right to file claims for punitive damages or family claims. VICP balances individual risk with society’s benefit from having good immunization coverage that reduces disease transmission. Through VICP, a burden is lifted from families with alleged vaccine injury and from the manufacturers and providers.\(^1,7\)

If you encounter someone who claims a vaccine-induced injury, refer him or her to the VICP. The person can call VICP at (800) 338-2382 or (301) 443-6593 for information on how to file a claim, eligibility criteria, and documentation requirements.

It is interesting to note that the Immunization Action Coalition reports an accumulating series of court cases where negligence is claimed for *failing* to vaccinate. Such cases, which are frequently settled out of court, suggest that all health professionals have a responsibility to protect their patients against preventable infection.

**Three Requirements of VICP**

The VICP provides protection for any patient, regardless of age, receiving a vaccine containing any of the following antigens: diphtheria, tetanus, pertussis, poliovirus, measles, mumps, rubella, hepatitis A, hepatitis B, *Haemophilus influenzae* type b, influenza (trivalent inactivated or live attenuated), meningococcal, pneumococcal conjugate, human papillomavirus, rotavirus, or varicella.\(^{11}\)

The VICP protects any authorized vaccine provider who meets the following requirements. Vaccine administrators must:
1. Provide a copy of the most up-to-date version of the Vaccine Information Statement (VIS) to the patient or the patient’s caregiver before administering the vaccine. VISs are standardized forms developed by the Centers for Disease Control and Prevention (CDC) that provide an overview of the benefits and risks of a vaccine. A VIS is available for each vaccine on the market and the particular VIS given to the patient must match the vaccine to be administered. Current versions of VISs (in English and translations in a variety of foreign languages) can be obtained from the CDC (www.cdc.gov/vaccines/Pubs/vis/default.htm) or the Immunization Action Coalition (IAC) (www.immunize.org/vis).

2. Permanently record the following information for all vaccines covered by the VICP:
   - Patient name.
   - Date vaccine administered.
   - Vaccine manufacturer and lot number.
   - Name, address, and title of person administering the vaccine.
   - Date printed on the VIS.
   - Date the VIS is given to the vaccine recipient or that person’s legal representative.

3. Report the occurrence of any adverse event listed in the VIT to the Vaccine Adverse Event Reporting System (VAERS) (www.vaers.hhs.gov). These events include but are not limited to: anaphylaxis, brachial neuritis, encephalitis, chronic arthritis, thrombocytopenic purpura, vaccine-strain measles infection in an immunodeficient recipient, and paralytic poliomyelitis.

Three Steps to Reduce Liability

To reduce the likelihood of liability, pharmacists administering immunizations should educate their patients, receive specialized training, and emulate local safeguards.

- **Educate and inform patients and their families.** To help patients, their parents, or their guardians understand the risk as well as the benefits of immunization, the Centers for Disease Control and Prevention (CDC) has prepared Vaccine Information Statements (VIS) explaining most vaccines. Copies are available through local health clinics, CDC state immunization coordinators and at www.cdc.gov/vaccines/pubs/vis. For their names and phone numbers, contact your state department of health. A common theme in many cases of vaccine litigation is the failure to warn. It is wise to read through the VIS with patients to be vaccinated or have them read the form independently. Some vaccine providers hand the patients a form to sign indicating that they have read the information and agree to the vaccination. In some states, documentation of informed consent is required for some patients and some vaccines. Ask your health department for local expectations.

- **Receive specialized training in immunization delivery from a source acknowledged by professional peers and regulators.** Training offered or endorsed by the CDC is an excellent way to expand your immunization expertise. Immunization policies change frequently, so be sure to stay up to date.

- **Follow standards and safeguards adopted to minimize liability as used by the county health clinic.** You can ensure you abide by community expectations if you have your patients under observation for anaphylaxis for the same length of time as would your local public clinic.
Similarly, follow the types of interviewing for contraindications, record-keeping and informed consent procedures, and other clinical and administrative procedures.

**OSHA and Avoiding Blood Exposure**

Implementing an immunization program requires compliance with good clinical practices and several regulations of the Occupational Safety and Health Administration (OSHA). Many of these requirements are designed to reduce the risk of exposure to blood-borne pathogens, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and others. A general approach is known as universal precautions, an infection control principle that treats all human blood and other potentially infectious materials as infectious. OSHA regulations became more stringent in 2001, as OSHA wrote the regulations to implement the Needle Stick Safety and Prevention Act of 2000. The revised standard clarifies the need for employers to select safer needle devices and to involve employees in identifying and choosing these devices. The updated standard also requires employers to maintain a log of injuries from contaminated sharps.

Any chapter member handling sharp devices or equipment such as hypodermic needles is at risk. As many as one-third of all “sharps” injuries involves the disposal process. The CDC estimates that 62% to 88% of sharps injuries can potentially be prevented by the use of safer medical devices. Needle-stick and other sharps-related injuries are an important public health concern.

Keep the work area clean. Wearing gloves is not generally required to give injections. However, it may be prudent to follow the policy used at the local health clinic, and student pharmacists are encouraged to consider wearing gloves.

Plan for safe handling and disposal before beginning any procedure using needles. Do not separate syringes and needles, or recap or clip them after use. Instead, place them in a special sharps or biohazard container. Consult applicable state regulations concerning disposal of these containers. Often, calling a waste-disposal company listed in the telephone book is sufficient to determine any special handling requirements. At least one vendor offers a through-the-mail service for disposing of used needles and syringes.

The Needle stick Safety and Prevention Act requires all health care employers to provide safety-engineered sharp devices and needle-less systems to employees to reduce the risk of occupational exposure to HIV, hepatitis C, and other blood-borne diseases. Other requirements involve exposure-control plans and maintaining a sharps-injury log. The law does not recommend the use of specific devices but requires employers to conduct their own evaluations of available safety devices.

Safety needles/lancets follow two general approaches: (a) those that cover the surface of a used needle or lancet to reduce the chance of touching blood-laden surfaces (e.g., needles that retract into the syringe or sliding needle shields), and (b) those that reduce one’s ability to reuse a needle (e.g., self-blunting).

Immunizing pharmacists should have a current needle stick policy, perhaps mirroring that of a local hospital or health clinic. As student pharmacists, be sure to check with your chapter advisor regarding policies for your school or college of pharmacy. Also, be sure to work with the site coordinator to learn
about the policies of that specific institution. A thorough policy should address pre-exposure vaccination, post-exposure management (e.g., hepatitis B vaccine, HBIG), as well as medications appropriate for acute post-exposure management of HIV-infected blood. As with many other aspects of immunization delivery, mimicking the practices of your local health department will provide a general guide to standards of practice. With the evolving nature of the safety-needle situation, pharmacists will want to assure that their health department has considered the new, stricter standards.

For more information on need stick prevention, be sure to visit: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

**Keeping Immunization Records**

Careful record-keeping, essential for any immunization program and will help ensure that patients receive the proper immunizations based on their health and age and that immunization occurs at the right time. Records help clinicians know what vaccinations the patient received and allow vaccine recipients to be tracked in the unlikely event of a manufacturer product recall. Records are required for compliance with the National Childhood Vaccine Injury Act and for participation in the *Vaccines For Children* program. When you prepare good records today, you help other providers, parents, schools, employers, etc., obtain accurate records far into the future.

Some states require a Release of Information (ROI) to obtain a patient’s records. Pharmacists should check with the state in which they practice to determine their requirements.

Additionally, the Health Insurance Portability and Accountability Act (HIPAA) which went into effect in April 2003 requires that patients be notified of your pharmacy’s privacy practices and that your pharmacy not disclose patient specific information to anyone other than insurance companies for the purpose of obtaining payment for a claim and other health care providers directly involved in the care of the patient. Other exempt communications also are allowed for under HIPAA. For specific guidance on ways to comply with HIPAA and meet national quality standards for immunization registries and activities, consult the CDC’s Web site at http://www.cdc.gov/vaccines/.

Immunization records should track:

- Patient’s name *
- Patient data; for example, indications for vaccination, contraindications, chronic medical problems
- Vaccination date *
- Name, address, and title of practitioner administering the vaccine *
- Trade or generic name of the vaccine, manufacturer, and lot number *
- Signed informed consent forms, if required locally, for the length of time recommended by your local health department.

**Missing Vaccination Records**

People with no vaccination records may ask for vaccination for themselves or their children. Should the pharmacist vaccinate? The answer is “yes” in most cases, but first, do a bit of investigating.
If people say they have had some shots, ask them to look again for the records, checking the desk, the bottom of the junk drawer, a kitchen shelf, a baby book, a shoe box full of their children’s art work and scout badges, and so on. Next, ask the people to contact their parents, guardians, previous immunization providers, schools or day care centers, or the public health department in the state where they grew up.

If reasonable attempts fail to produce an accurate vaccination record, the CDC recommends vaccination. A duplicate dose will do no harm other than a sore arm, while a missed dose could result in a life-threatening infection. Waiting too long while searching for records increases the interval when the person is vulnerable to the dangerous infection. Work with the prescribing physician or the health department to establish a procedure for these situations.

Vaccine Storage and Handling

Vaccines are biological preparations and require special care in order to retain potency. The term cold chain is often used when referring to vaccine storage and handling, meaning that at all stages—manufacturing, shipping, and storage—most vaccines must be kept between 2° C and 8° C. A few vaccines require storage in a freezer. Store diluents at controlled room temperature. Vaccines that get warmer or colder quickly lose potency and may no longer be able to offer protection, even though the product may look normal.  

Some vaccines must be protected from light. Reconstituted measles, mumps, and rubella vaccines are light sensitive and should not be stored outside the refrigerator after reconstitution. Administer them promptly after reconstitution.

Vaccine storage is extremely critical so that these valuable drugs do not lose their potency. Vaccine manufacturers often ship vaccines in insulated containers with ice packs with temperature monitoring cards attached. These cards indicate when temperatures have gone too high or too low during shipping. Vaccines shipped by airplanes are met by refrigerated trucks, and the vaccine is transferred promptly to its ultimate destination.

Vaccine stability is only as good as the weakest link in the “cold chain,” the sequence of storage conditions between vaccine manufacture and administration to the patient.

Maintain the Cold Chain

Arrange for vaccines to be delivered only when someone trained in their handling will be present to receive them. Unpack the vaccine immediately once the vaccine reaches the pharmacy. Check the temperature indicators in the shipping case. If there are no indicators, check that the ice packs have not thawed. If the monitors indicate that the vaccine has been exposed to temperatures outside of the recommended range, or if the ice packs thawed, call the distributor. Quarantine the vaccine in the refrigerator or freezer (as appropriate), but do not use the vaccine without guidance from the manufacturer. Document each of these steps as part of your quality-control practices. For more detailed guidelines, consult references.  

Special diligence with the pharmacy refrigerator will help protect vaccine potency. If possible, have a
separate refrigerator for vaccines to reduce the number of times the door is opened and how much the temperature is allowed to vary. Keep maximum/minimum thermometers in the refrigerator; monitor them daily; and keep a chart on the refrigerator door to track daily temperatures. Attach an alarm that indicates when a door is left open or alerts you to a power outage. Keep ice packs in the freezer and water bottles in the refrigerator, especially in the door if possible, to act as thermal buffers in the event of power failures.10

Store the vaccines in the middle of the refrigerator, not in the door or on the bottom shelf. Put a sign on the refrigerator door that tells everyone that the refrigerator contains vaccines and opening the door should be minimized. Make sure that everyone in the pharmacy is aware of the special vaccine storage and handling requirements.

Three vaccines are routinely stored in the freezer: varicella (and zoster) vaccine, and yellow fever vaccine. These vaccines are the exception to the no-freeze rule; they must be stored in the freezer. Dormitory-style freezer compartments are not cold enough for vaccine storage. Lyophilized varicella vaccine can be stored in the refrigerator for up to 72 hours, but if it is not used within that time, it must be discarded.1,10,11 Once reconstituted, varicella (and zoster) must be used within 30 minutes to avoid loss of potency. Yellow fever vaccine must be used or discarded within 60 minutes of reconstitution. Zoster must be stored in a manual defrost freezer and maintained at a temperature of −15°C.

**Manage Inventory Appropriately**

Order only the vaccine needed until the next scheduled delivery. A 1- or 2-week supply is a good rule of thumb. You can also consider purchasing influenza vaccine with a return policy. The amount will vary with the season—for example, the demand for influenza vaccine will be high in the fall but low in the early spring.1,10,11

Every vial of vaccine carries an expiration date. The **oldest** vaccine should be placed at the front of the row so that it will be administered first, with the **newest** vaccine vials stored toward the back of the shelf. This stock rotation will help ensure every patient receives fully potent vaccine. Do not use vaccine beyond its expiration date.1,10,11

**Design Your Immunization Area**

Pharmacies that offer immunizations typically use consultation areas or waiting rooms to administer injections. If possible, privacy should be provided for patients who need to remove or adjust clothing to free the injection site (e.g., adult women adjusting sweaters or blouses to bare their upper arms). A pipe and drape screen or moveable office partitions may suffice. Redesign may also help muffle noises.

Arrange the space to allow for fainting without injury, plus access to a hard surface if CPR is needed. Vaccinating toddlers, teens, and adults requires little more than a sturdy chair.

Syringes, needles, latex gloves, alcohol wipes, cotton balls, and bandages should be conveniently located for ready access. Consider keeping a stock of non-latex gloves on hand for patients with latex allergy. If conducting mass immunizations, icepacks and/or coolers may be necessary. Waste receptacles and sharps containers should also be nearby. While not essential, a supply of rewards to help ease children’s
tears is a good idea; lollipops or brightly colored stickers work well. Even adult vaccines appreciate these items. It is also essential to keep a supply of materials necessary to handle adverse reactions to immunizations.
ACTION PLAN
APhA-ASP Operation Immunization
Getting Started

Operation Immunization offers a unique opportunity for student pharmacists to take an active role in the profession. Not only can you increase public awareness through media campaigns and immunization events, but you may also advocate for student pharmacists’ right to immunize if it is not already allowed in your state. All of these activities will in turn increase immunization rates and awareness.

As the Project Coordinator, the first step to implementing a successful event is to schedule a meeting with your APhA-ASP Chapter Advisor, other interested faculty, and your APhA-ASP Chapter Officers to set chapter goals for your chapter to accomplish through Operation Immunization. This meeting will give you the opportunity to discuss your ideas, brainstorm, and set the direction of your Operation Immunization events. This is the time to decide how you will participate in this patient care project. Contact your state board of pharmacy and find out the laws governing pharmacists and student pharmacists immunizing rights. Depending on whether you choose to hold an actual event, or advocate on behalf of the profession will change how you use this planning guide. There are two sections to the Action Plan; one to outline planning an event/media campaign and another to educate you on how to advocate on behalf of the profession. You are not limited to only participating in one way, and you are, in fact, encouraged to be creative. The two sections are provided as a way to help you attain your goals, and ease your way towards success. The methods lined out in both sections are meant to be a general guide, and will need to be adjusted based on your situation.

Planning Events

This section of the Action Plan will assist you, the Project Coordinator, in planning an event to educate the public as well as an event when immunizations are performed. The process of recruiting students to participate should start early to increase the opportunities for participation. You can hold an interest meeting to outline projects and brainstorm. The interest meeting will offer you the opportunity to assess student interest and begin forming committees. Forming committees will increase involvement and encourage participation in future events. These committees can be responsible for such areas as public relations, publicity, immunization sites, and reports. Each of these committees will have specific tasks and responsibilities. These are just a few suggestions for committees, and can be adjusted as seen fit by the Project Coordinator. An example of the specific duties of each of these committees is outlined later in this section, and as stated above you can tailor the number and responsibilities of these committees to fit your chapter needs. The practical considerations section of this planning guide is a great resource in assisting your planning, and should be an available reference for your committees. This Preparation should begin at least 6 weeks before the Patient Care Project.

Project Organization

Event days can be conducted throughout the year and can be held in conjunction with other events and patient care projects. Hosting multiple patient care projects at one time allows you to offer screenings for multiple disease states to patients at one event. Don’t forget October is American Pharmacists month, and is a great time to promote the profession. Continue utilizing the Operation Immunization Planning Guide materials and establish a timeline to facilitate your planned event and education day.

Enlist the support of a faculty project advisor (e.g. either the APhA-ASP Chapter Advisor or another interested faculty member). Your faculty project advisor can assist you in coordinating a training
session, and also be a supportive contact in case you encounter challenges during the project. The faculty project advisor will need to be well informed about the activities going on with the project in order to ensure the project’s success.

Begin developing your media contacts in the community. Also contact your state pharmacy association to see if they are interested in becoming involved with your project. Allow yourself about 2 weeks to complete this portion, and don’t forget to utilize your committees.

**Pharmacist Recruitment & Initial Publicity**

Pharmacists have been continually recognized as one of the most approachable healthcare providers, and you are at an advantage for finding these practitioners to participate in the event. During this two week period, you will need to identify the pharmacists who are interested in participating. Meet with these individuals to discuss the campaign and review plans for implementation of the campaign. The pharmacists will need to be present on the day of the event, and give immunizations or observe student pharmacists giving immunizations if allowed by local law. You will also collaborate with the pharmacist to make sure the proper vaccinating supplies are ordered and available for the event. You can also utilize your chapter’s New Practitioner Mentor as a resource for events.

**Mass Publicity and Supply Procurement**

This is also the time to start contacting radio and TV show producers and send a “pitch” letter indicating that you would like an interview to promote this community service project. A pitch letter is used to introduce yourself to an editor or producer and suggest story ideas. There is information about pitch letters and other media tools in the “Promotion” section of this planning guide.

To ensure the success of your event, getting the word out to the public is a vital part of the project. You will make your big advertising push to the public starting about 3-4 weeks prior to the event. Get your posters and flyers out to the identified locations, and make follow-up phone calls to media outlets to arrange interviews. Get in touch with local newspapers, radio, and TV stations to inform them about your event and when it will occur. Invite the public to attend. Another great tool to reach patients is a radio public service announcement (PSA). Deliver the PSA to the public service director of the stations. Contact the venue to find out what supplies and equipment is available. Work with your committees to ensure that the appropriate supplies have been ordered to provide immunization education and immunization services to patients. Use new and innovative ways to reach your target audience.

By utilizing the tools provided in the planning guide, student pharmacists can assist the patients in effectively educating and preventing disease. Be sure to check out the health literacy resources on www.pharmacist.com/students.

**Final Preparation**

Now that you are in the homestretch, keep in touch with media contacts and distribute literature throughout the community. Send news releases to local newspapers if they are not planning to run a feature article on the project. Make copies of fact sheets, consent forms, surveys and all other documentation forms and handouts to be distributed at the event site. Ensure you have immunization cards and other necessary documentation for the event.
Help your faculty advisor organize a training session for the immunization events. Have the faculty advisor refer to the “Diseases & Vaccines” section to see the educational material provided. The training session can take place during your lunch hour or another time that is convenient for students participating in the event. Topics for the training session should cover an overview of immunizations, as well as how students should interact with the patients. The Operation Immunization event is also a great time to help your patients fill out a Personal Medication Record along with their immunization card that they can take home, and the training session is a great time to familiarize student pharmacists with the form. The planning guide provides great resources that should also be introduced to students during this session so that they may familiarize themselves on how to best screen, educate, and treat the public.

**Day of Project**

Implement Operation Immunization! Hand out the literature you’ve prepared, educate the public, and administer immunizations. Radio stations should be running the PSAs as well as other advertisements. Newspapers should run stories covering your event this week. TV interviews should discuss the event and invite the public.

You are now prepared to raise patients’ awareness about the impact of preventable disease. The event is an extension of your recent media campaign, and gives you the chance to personalize the education to the public. Through presentations to groups and one-on-one patient counseling, student pharmacists will focus their efforts on those individuals at the event site.
**Project Coordinator Checklists**

The checklists below are provided as an example for the Project Coordinator to follow. The individual tasks can be assigned to committees and adjusted to fit the project’s needs. These timelines are suggestions and should be modified to fit the needs of your events.

**Eight Weeks to Target Date**

- Review the materials and timeline for Operation Immunization and make adjustments as needed to facilitate your school, APhA-ASP plans.
- Organize a planning meeting with your APhA-ASP Chapter Officers and APhA-ASP faculty advisor.
- Hold a student interest meeting to overview projects and brainstorm on event dates and locations.
- Select a target date and location.
- Form working committees and outline the tasks of each for your specific needs.
- Develop a list of names, addresses, phone numbers, fax numbers, and e-mail addresses of media contacts in your community.
- Contact your state and/or local pharmacy associations to seek involvement in the project.
- Contact your state pharmacy association to participate in the campaign and place advertisements and articles describing Operation Immunization in your state pharmacy journal.

**Six Weeks to Target Date**

- Identify pharmacists who will participate and pharmacies where immunization services will be provided. Meet with these individuals to discuss the campaign and review plans for implementation of the campaign.
- Identify radio and TV show producers and send information on Operation Immunization with a “pitch” letter indicating that you would like an interview to promote this community service project.
- Contact state/local health departments to inform them of Operation Immunization.
- Produce promotional flyers and a promotional display for the event site.
- Identify a source for all equipment necessary for the event, and acquire equipment.

**Four Weeks to Target Date**

- Distribute posters and flyers to identified target locations advertising when and where immunization services will be provided.
__ Make follow-up phone calls to radio and TV producers to arrange an interview to discuss Operation Immunization.

__ Send out a media advisory to local newspapers, radio, and TV stations explaining Operation Immunization. Provide dates and times that immunization services will be available at participating pharmacies.

__ Send out radio public service announcements (PSAs) to the public service director of the stations. Personal delivery of PSAs is better, so try to make an appointment with the PSA director and bring along the Operation Immunization Media Kit. If you cannot get an appointment, follow up with a telephone call to make sure the PSA made it to the right person.

__ Contact the pharmacists and other health care professionals involved in the campaign to ensure that the appropriate supplies have been ordered to provide immunization services to patients.

__ Send out education and screening day sign-up sheets to students.

**Two Weeks to Target Date**

__ Continue making media contacts and distributing flyers and posters throughout the community.

__ Send news release to local newspapers detailing Operation Immunization if they are not planning to run a feature article on the project.

__ Make copies of fact sheets and immunization schedules to be distributed at the immunization sites, health fairs, and/or local pharmacies.

__ Enlist a faculty member to perform a 1-hour basic training session for all participating student pharmacists.

__ If local newspapers are not planning to run a feature article on the project, send a news release to them detailing the Operation Immunization event.

__ Remind participating students to wear lab coats, nametags, and professional attire to the screening event.

**Operation Immunization Event Day**

__ Deliver equipment and have it set-up at least ½ hour before the event.

__ Hand-out brochures/bag stuffers and information on adult immunizations at the pharmacies where immunization services are being provided.

__ Radio stations should be running the PSA’s as well as other Operation Immunization advertisements.

__ Newspapers should run story covering Operation Immunization this week.

__ TV interviews should be discussing Operation Immunization and inviting the public to attend.
ACTION PLAN

___ Collect all documentation and assessment forms, and complete the screening summary results form.

___ Clean up, tear down, and return equipment at the conclusion of the event.

Post Event Follow-Up and Report Submission

** Within one week after project**

___ Send out “Thank You Notes” to:
   ___ All media who promoted Operation Immunization
   ___ Business locations that promoted Operation Immunization
   ___ Pharmacists and other health care professionals involved in the campaign
   ___ Your school Dean, faculty, advisor, and other supporters
   ___ State and local pharmacy associations that promoted the event

___ Complete project report on Operation Immunization activities and send into APhA Headquarters for award recognition judging. Reports must be submitted electronically to the FTP site no later than July 15. Late reports will not be accepted for award consideration under any circumstance.
**Operation Immunization Committees Outline**

Promotions Committee Assignments

Action Items:

1) Select committee chairperson.
2) Select committee members.
3) Assign committee tasks to members for action.

Specific Tasks:

1. Seek out support of state and local pharmacy associations, and the state board of pharmacy.
   - Find out the names of key contact persons (i.e. executive director, president, etc.) and when the next organizational board meeting will be held. Asked to be placed on the agenda to inform the group of the Operation Immunization campaign and ways in which they can assist your chapter with its efforts.

2. Prepare an outline to present at these meetings.
   - Remember to tailor it to the target audience because each organization will likely play a different role.
   - The local pharmacy association may provide names of pharmacists/pharmacies that are interested in participating in the Operation Immunization campaign. The state pharmacy association may also be able to do this, and may additionally provide publicity support through the association’s journal or newsletters.
   - The board of pharmacy should be made aware of your project plans to ensure compliance with all state pharmacy laws and regulations.
   - Compile a list of all contact persons identified in this step that can be shared with the advertising committee. Each of your key organization contact persons should be provided with copies of all consumer advertising materials and kept abreast of your promotion and event activities so as to maximize your support from these organizations.

3. Attend meetings and ask for support from these organizations.
   - It is your responsibility to make sure there is the appropriate number of pharmacists are at the event, so make sure you have commitments from pharmacists to participate.

4. Meet with pharmacists and other health care professionals who have committed to assist with your project.
   - Provide more detail to them on the Operation Immunization event and your plans for the project. Ask for their ideas and suggestions on how to make your project even more successful.
5. Encourage chapter members to participate.
   - Dedicate time at a chapter meeting early in the planning period to promote participation in Operation Immunization to general members.
   - Ask interested members to sign up so that they can be included in the planning process.
   - Send out education and screening day sign-up sheets to the students 2 to 4 weeks before the event.
   - You will need enough students to counsel/immunize the patients with a reasonable waiting time. If students cannot immunize under your local law, they can still assist by educating the public, passing out literature, and possibly drawing up doses.
   - Ask students to sign up to participate and provide them with educational material covering immunizations that will be offered at your event.
   - Only enlist students for education and immunizing shifts if they have completed training conducted by the training committee on the proper patient education/counseling techniques.

6. Student Pharmacist Training
   - One to two weeks before the event, organize a time with your faculty advisor to have a 1-hour informational session for all participating students, provide an overview of immunization and education recommendations and to prepare the students to answer questions from the community.
Advertising Committee Assignments

Action Items:

1) Select committee chairperson.

2) Select committee members.

3) Assign committee tasks to members for action.

Specific Tasks:

1. Keep in communication with the promotion committee.

   - Get a list of the people to contact on the state and local pharmacy associations, and board of pharmacy from the promotion committee.
   - Once the contacts have been established, begin to communicate with these organizations to learn of ways they may be able to assist you in getting the word out to the public about your Operation Immunization event. For example, they may already have established contacts with local newspapers, radio, and television stations. Ask the organizations for their help advertising. They may be able to assist in preparing press releases or in getting ad placement in key newspapers.

2. Consult with pharmacists who have committed to be a part of your project.

   - The promotion committee should be able to provide you with the names of those who have committed. Ask these pharmacists for their assistance in brainstorming ideas for promotion of the event to the public.
   - These pharmacists may also be able to distribute bag stuffers or flyers with each prescription they dispense or with each front-end pharmacy sale. They may also be willing to post flyers or posters in their pharmacies as a way of promoting your upcoming event.

3. Produce promotional materials.

   - Flyers including the date, time, and location(s) of your Operation Immunization event(s) should be created.
   - Use brightly colored paper and bold lettering on your flyers to increase their visibility.
   - If pharmacies will be distributing the flyers as bag stuffers or at the checkout counter, be sure to provide an adequate supply to each pharmacy (500 flyers per pharmacy is probably sufficient).
   - Your local or state pharmacy association, participating pharmacies, or school may be willing to assist with copying of the flyers to help offset expense.

4. Start posting promotional materials in the area of the site at least 2 weeks prior to the event.

   - If your education and screening site is a pharmacy or other retail outlet, be sure to provide an extra supply of flyers for distribution to every patient and customer of the store.
5. Work with pharmacy organizations to aggressively inform the media of the event.

- Submit press releases, develop public service announcements for radio and TV stations, and arrange interviews with radio, newspaper, and TV reporters 1 to 2 months before your event if possible.
- Try to get TV coverage on the day of your event by inviting local celebrities to take part in the Operation Immunization education and screening day.

6. Continue to advertise to the radio and television all the way up to the day of the event.

- Follow up regularly with the pharmacy organizations and the media to inform them of your progress. Keep trying, sometimes the media cannot commit until the last minute, and be prepared in case they show up without notice.

7. Create a promotional display.

- Create a promotion exhibit on a corkboard (bulletin board) or poster board to display at the site the day of the event to attract uninformed passers-by of the event.
**Immunization Site and Equipment Committee Assignments**

**Action Items:**

1) Select committee chairperson.

2) Select committee members.

3) Assign committee tasks to members for action.

**Specific Tasks:**

1. Determine a location for the education and screening site.

   - The promotion committee should be able to provide contact information of pharmacists interested in participating in the event. The pharmacists should be consulted for recommendations of host sites.
   - If pharmacists are not authorized or trained to administer vaccines in your state, this subcommittee could identify physicians, public health nurses or other authorized healthcare professionals to participate in the program.
   - Talk to faculty, local pharmacists that may not be participating in the event, and fellow students about any site that may be available for use.
   - You will need a site large enough to accommodate 3 to 4 tables, 10 student pharmacists, and 2 pharmacists at any given time during the education and immunization event.
   - Adequate space for patients that does not interfere unnecessarily with the site’s business operations is also required, as well as for patient privacy.

2. Identify a source for all equipment necessary to perform your Operation Immunization project and acquire equipment. Please see following pages for equipment check-off list. This committee is also responsible for ensuring that needed supplies are ordered and available for the event. This committee should be referred to the practical considerations section of this planning guide regarding the “Cold Chain”, and their responsibility to ensure proper temperature for the vaccines.

3. Deliver equipment and set-up the day of the event. Tear down and return equipment at the conclusion of the event.

**Operation Immunization Equipment**

You will need the following specific items:

(Note: depending upon the nature of your event, additional items may be necessary and some recommended items may be unnecessary for your particular event)

- Four, 6-foot tables
- 20 folding chairs
- Pens, markers, and pencils
- Power strip/electric extension cord
- Tape to cover any extension cords
- Patient education materials
- Blank Immunization Cards
- Blank Screening Documents
| __ | Blank Personal Medication Records                          | __ | Disposable gloves (1 set/patient)                          |
| __ | Brochures                                                    | __ | Epinephrine                                                 |
| __ | Contact information for patients                             | __ | Diphenhydramine                                             |
| __ | Clipboards (4-6)                                             | __ | Medication refrigeration/ freezer                           |
| __ | Vaccines                                                     | __ | Blood pressure cuffs                                        |
| __ | Syringes (1-3 ml)                                            | __ | Stethoscope                                                 |
| __ | Needles (22- to 25-gauge)                                    | __ | Tourniquets                                                 |
| __ | Red “sharps” containers (replace at 2/3 full)                | __ |                                                            |
| __ | Hazardous waste bags                                         | __ |                                                            |
| __ | Alcohol wipes                                                | __ |                                                            |
| __ | Cotton balls                                                 | __ |                                                            |
| __ | Adhesive bandages                                           | __ |                                                            |
| __ |                                                           | __ |                                                            |
| __ |                                                           | __ |                                                            |
| __ | Other:____________________________________________________ | __ |                                                            |
| __ |                                                           | __ |                                                            |
| __ |                                                           | __ |                                                            |
| __ |                                                           | __ |                                                            |
| __ |                                                           | __ |                                                            |
Training Committee Assignments

Action Items:

1) Select committee chairperson.
2) Select committee members.
3) Assign committee tasks to members for action.

Specific Tasks:

1. Consult with the Promotion Committee and find out the date of the event, as well as the names of all pharmacists who have committed to participate in the event. Find out the names of all students who have been enlisted to assist with the event.

2. Enlist a faculty member (either the chapter advisor or another faculty member) to perform a 1-hour basic training session for all participating student pharmacists.
   - Training should occur 1 to 2 weeks prior to the scheduled education and screening event. The faculty member should provide an overview of the education and screening tools, recommendations, how to help a patient fill out a personal medication record (this is Medication Therapy Management!), the presentation and tips on good patient counseling.
   - Invite participating pharmacists to attend this brief educational session as well. This is a good opportunity to familiarize the students with the handouts and educational materials that will be utilized on your event date.

3. Provide participating pharmacists with copies of all patient education materials that have been acquired by the Site and Equipment Committee.
   - Also provide the participating pharmacists with a listing of all students who will be participating in the event and information on the types of devices that will be used for screening. Determine from the pharmacist if he or she needs any additional information before the education and screening event.

4. Remind participating students to wear lab coats, nametags, and professional attire to the education and screening event.
   - This is for the purpose of projecting a professional image to patients, pharmacists, professional association representatives, and media representatives that may be present for the event.
Reporting Committee Assignments

Action Items:

1) Select committee chairperson.
2) Select committee members.
3) Assign committee tasks to members for action.

Specific Tasks:

1. Photocopies.
   - Patient consent forms, assessment forms, personal medication record, and any other handouts or education material deemed appropriate. (Refer to the “Forms” section.)
   - Consult with participating pharmacists and the Advertising Committee to gauge whether additional copies beyond the recommended number may be necessary.
     - Vaccine Information Statements
     - Consent forms (if required)
     - Personal immunization record forms
     - HCFA Form 1500
     - CDC text and ACIP recommendations
     - Reference materials

2. Ensure you have an adequate supply of Adult Immunization Cards.

3. Collect all documentation and assessment forms at the conclusion of the event. (See Forms section)

4. Complete the screening summary results form (see Forms section) and submit the form with the Chapter Operation Immunization Report. All reports are due to APhA headquarters by January 5:

5. Send thank you letters to:
   - Participating pharmacists
   - Participating/supporting faculty members and administration
   - Participating organizations (i.e. local and state associations)
   - Participating student pharmacists
   - Site host(s)
   - Media contacts that provided event coverage
Project Report Committee Assignments

Action Items:

1) Select a committee chairperson, who will also serve as the person responsible for assembling the final report for submission to APhA headquarters.

2) Select committee members. The committee should be made up of one representative from all activity committees (i.e. Promotion, Advertising, Site and Equipment, Training, and Documentation Committees).

3) Assign committee tasks to members for action.

Specific Tasks:

1. Each representative from the aforementioned committees should provide the committee chair with details necessary to complete the chapter’s final project report to APhA headquarters.

2. Remember, your chapter will be considered for an award and recognition based upon the details provided in your report, so try not to leave any important details out of the report. Include photographs, copies of news clips, and supporting letters if possible. It is strongly required that your chapter submits the report through the APhA-ASP File Transfer Protocol (FTP) Site.

3. Reports that are submitted after 11:59pm July 15 will not be considered. There will be no exceptions.

4. Chapters that submit their report on time will receive a plaque of recognition for participation.

5. Awards will be presented during the APhA-ASP Opening General Session at the APhA Annual Meeting & Exposition.
**Immunization Process**

In the immunization delivery process, pharmacists and student pharmacists can play several roles: to advocate, to facilitate, and to immunize. All three roles are equally important in facilitating immunization delivery to needed populations. All states currently allow pharmacists to immunize, and twenty-nine allow student pharmacists to immunize under pharmacist supervision. The remaining states, however, also have a mission to fulfill. Pharmacists and student pharmacists are encouraged to actively advocate and facilitate the immunization process in order to help increase immunization awareness and delivery. The information in this section is intended to be used to assist you in portraying the need for pharmacists and student pharmacists to immunize.

Immunization advocacy spans the life-cycle from newborns to the elderly. Pharmacy’s impact can involve educating parents and caregivers on the importance of maintaining immunization records and adhering to immunization schedules. Pharmacists and student pharmacists can help communities meet their immunization goals. Currently pharmacy’s activities focus on providing vaccinations and immunization information to adolescents and adults. The adult community is currently the population most likely not to receive immunizations for several reasons. For example, many adults may find it difficult to schedule appointments at a clinic because it takes them away from work and other obligations they have. In today’s society, people are more likely to partake in an activity if it is convenient to them.

Pharmacies are avenues that are noted to be more accessible and convenient than other offices or public health clinics for some people. Extended hours in the evenings and on the weekends and locations in the same proximity as the patients’ neighborhoods help make pharmacists readily available to the public. People also depend on pharmacists, known to be one of the most trusted healthcare professionals, for information and advice. Therefore, pharmacists possess a great opportunity to provide patients with resources they need to become active in preventative healthcare.

Many people may be more apt to receive immunizations if they can do so at their own convenience. This especially includes those who struggle with transportation problems. By expanding the scope of immunization delivery to include pharmacists, more adults are reached and are given information on immunizations. Increasing the number of adults immunized is the ultimate result.

Pharmacists do possess a unique opportunity to reach populations. A National Vaccine Advisory Committee report on Adult Immunization Programs in Nontraditional settings (March 24, 2000) stated that many adults are not receiving immunizations. Therefore, in order to increase the number of adults being immunized, vaccine delivery, and information must be readily available. Pharmacists have the ability to provide these services. By examining patients’ medication profiles, pharmacists may identify high-risk patients who would benefit from receiving immunizations. For example, adults 50 years and older should be vaccinated against influenza. Patients who are taking medications for congenital or adult heart disease, diabetes, chronic pulmonary disease, or other similar disease states are also high risk patients who should be informed about the importance of being immunized.

Pharmacists’ access to patients provides an excellent opportunity to reach at-risk patients through the use of reminders, bag inserts, and other educational materials. As an advocate, pharmacists should identify high-risk patients and offer them immunization information that will help patients protect their health.
Another area for immunization advocacy for students to advocate is in the area of immunization education. Students are taught in the classroom how to immunize, but many states restrict students from practicing immunizations outside of the classroom setting. Only 29 states allow student pharmacists to practice their immunization skills outside the classroom under the supervision of a pharmacist.

Pharmacists should keep informed about immunizations. Immunization resource information is provided in the resource section of this resource guide. By keeping up-to-date, pharmacists can correct misconceptions their patients may have. This can be done during counseling sessions with patients, writing letters to the editor, or speaking to local community groups. These activities help pharmacists serve the community and promote individual health care.

Many opportunities are also available for pharmacists to facilitate the immunization process. Pharmacists and student pharmacists can collaborate with other healthcare professionals (ie. nurses, physicians, physician assistants, etc.) who have the authority to immunize. Pharmacists could host one of these healthcare professionals in their pharmacy to administer immunizations while they provide the patients with vaccine education and answer patients’ questions. Pharmacists with the ability to immunize can also work with these individuals and provide immunizations when clinics are not scheduled. Some health care professionals may be leery of involving pharmacists in the immunization process.

However, Together Everyone Achieves More . . . TEAM. According to Grabenstein’s doctoral dissertation, 7 June 1999, University of North Carolina, society as a whole can benefit from pharmacists’ involvement in immunization delivery. People benefit by having greater access to vaccinations and information; healthcare providers benefit by seeing a general increase in the interest and acceptance of adult vaccinations.

In order for pharmacists to become immunizers, they must have the authority to immunize from the state in which they practice. Authorization can come from the language in the state pharmacy practice act, from an interpretation by a state agency, or from a statement by the Attorney General. After authorization is granted, pharmacists should participate an intensive immunization training program, such as the American Pharmacists Association’s Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists.
People Who Need Influenza and Pneumococcal Vaccines

Influenza and pneumococcal vaccines are indicated for people in these groups:

- Adults, adolescents, and children (<2 years of age) with chronic disorders of the pulmonary or cardiovascular systems. For influenza vaccine, this includes children >6 months of age with asthma.
- Adults, adolescents, and children who needed regular medical follow-up or hospitalization during the previous year for chronic metabolic diseases—including diabetes mellitus, renal dysfunction, problems related to hemoglobin, or any form of immunosuppression, including that caused by medications.
- Residents of nursing homes and other chronic care facilities housing people of any age with chronic medical conditions.
- People aged 65 years or more should get both vaccines, even if otherwise healthy. In addition, influenza vaccine is recommended for everyone 50 years and older. Patients older than 65 account for >80% of pneumococcal and influenza deaths. About two-thirds of those who died had been hospitalized in the previous year but were not vaccinated. More than 90% had visited an outpatient clinic or private physician in the preceding year. But again, their clinicians did not take advantage of these opportunities to protect them from deadly infection.

For influenza vaccine only:

- Children and teenagers (6 months to 18 years of age) who receive long-term aspirin therapy and therefore may be at risk of developing Reye’s syndrome if they contract influenza.
- Staff and visitors at nursing facilities with residents at increased risk of influenza.

(See the Immunization Resources section for more information and the dates of the program.)

Immunizations in many states may be provided via a written or verbal prescription, standing order or protocol/collaborative agreement, and may be issued by an individual practitioner or health department.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Representative Medications Indicating Vaccine Need</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease (e.g., congestive heart failure, myocardial infarction, heart anomalies)</td>
<td>Digoxin, warfarin, nitroglycerin, diuretics, antidyshrythmics, others</td>
</tr>
<tr>
<td>Lung disease (e.g., emphysema, COPD, asthma)</td>
<td>Albuterol, zafirlukast, theophylline, chronic inhaler use, chronic corticosteroids, others</td>
</tr>
<tr>
<td>Metabolic (e.g., diabetes)</td>
<td>Insulin, oral hypoglycemics, others</td>
</tr>
<tr>
<td>Healthy people ≥ 65 years (≥ 50 for influenza vaccine)</td>
<td>Any or none</td>
</tr>
<tr>
<td>Kidney disease (e.g., renal dysfunction, nephrotic syndrome)</td>
<td>Various</td>
</tr>
<tr>
<td>Juvenile rheumatoid arthritis</td>
<td>Children on chronic aspirin therapy</td>
</tr>
<tr>
<td>HIV infection</td>
<td>Various antiviral therapies, others</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>Coagulation factors, others</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Rifampin, pyrazinamide, others</td>
</tr>
<tr>
<td>Hemoglobinopathies (e.g., sickle-cell disease)</td>
<td>Hydroyurea, others</td>
</tr>
<tr>
<td>Cancers (e.g., Hodgkin’s disease, lymphoma, multiple myeloma)</td>
<td>Alkylating agents, antimetabolites, interferons, mitotic inhibitors, others</td>
</tr>
<tr>
<td>Immunosuppression, various</td>
<td>Immune globulin intravenous, cyclosporine, others</td>
</tr>
</tbody>
</table>

These authorizations apply not only to vaccines, but also epinephrine. Most state practice acts include the term “administer” with the definition of the scope of practice.

Some state medical practice acts allow physicians to delegate any activity they wish including the provision of immunization by pharmacists, and may be another avenue to grant the authority to pharmacists.
The following material is excerpted from “Pharmacy-Based Immunization Delivery: A Certificate Program for Pharmacists” - Copyright 2007 American Pharmacists Association

Starting Your Pharmacy-Based Immunization Program

Immunization advocacy happens at the pharmacy counter, the counseling center, the patient’s bedside, in meeting rooms, or anywhere you find a pharmacist interacting with patients. In a community pharmacy, the consultation area is often the most appropriate place to give vaccine doses.

Infant and toddler immunizations are needed throughout the year, making immunizations a year-round concern. Even so, some months involve more immunization activities than others. National Infant Immunization Week falls during the last full week of April each year, and summer offers the opportunity to focus on getting older children caught up on the missed immunizations needed to attend school. August has been designated National Immunization Awareness Month by the National Partnership for Immunization. Immunization in October usually centers on efforts to vaccinate people against influenza. Because October is also American Pharmacists Month, there is a particularly strong opportunity for pharmacists to reach the un-immunized and under-immunized. Never forget, however, pneumococcal disease kills people all year long. The same is true for tetanus and hepatitis B. Immunize the susceptible people whenever you find them.

Guidelines for Pharmacy Immunization Advocacy

Every pharmacist can and should warn patients who are vulnerable to vaccine-preventable infections. In 1996 at APhA’s 143rd Annual Meeting in Nashville, the Association called on pharmacists to adopt one of three roles in immunization advocacy: educator, facilitator, or immunizer. The level of involvement will vary depending on the resources, time, and interest of the pharmacist. See Table 1 for a description of each level.

Student pharmacists at sites acting at level 2, hosting others who vaccinate, still have professional responsibilities as hosts. Student pharmacists should assure the providers who administer the vaccines follow CDC guidelines, giving priority to those at greatest risk, have professional liability coverage, and are otherwise conducting a professionally responsible immunization delivery program. For example, programs might give precedence to senior citizens or at least offer them a seating area during extensive waiting periods.

In August 1997, the APhA Board of Trustees adopted the following guidelines for pharmacy-based immunization advocacy and administration. As you begin to consider participating in Operation Immunization, incorporate these principals as student pharmacists and use these principals as reference when advocating for the profession.

<table>
<thead>
<tr>
<th>TABLE 1 Levels of Pharmacist’s &amp; Student Pharmacists Immunization Advocacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1: Advocate</td>
</tr>
<tr>
<td>Immunization motivator</td>
</tr>
<tr>
<td>Level 2: Facilitator</td>
</tr>
<tr>
<td>Level 1 activities, plus hosting others who vaccinate</td>
</tr>
<tr>
<td>Level 3: Immunizer</td>
</tr>
<tr>
<td>Level 1 activities, plus giving vaccinations yourself</td>
</tr>
</tbody>
</table>
Guideline 1: Priority to Prevention—

Pharmacists should protect their patients’ health by being vaccine advocates. Pharmacists should adopt one of three levels of involvement in vaccine advocacy:

1. Pharmacist as advocate (motivating people to be immunized);
2. Pharmacist as facilitator (hosting others who immunize); and
3. Pharmacist as immunizer (protecting vulnerable people, consistent with state law).

Pharmacists should:

- focus their immunization efforts on diseases that are the most significant sources of preventable mortality among the American people, such as influenza and pneumococcal and hepatitis B infections;
- routinely determine the immunization status of patients, then refer patients to the most appropriate provider for immunization;
- identify high-risk patients in need of targeted vaccines and develop an appropriate immunization schedule; and
- protect themselves and prevent infection of their patients by being appropriately immunized themselves.

Guideline 2: Partnership—

Pharmacists who administer immunizations do so in partnership with their community.

Pharmacists should:

- support the immunization advocacy goals and other educational programs of health departments in their cities, counties, and states;
- collaborate with community prescribers and health departments;
- assist their patients in maintaining a medical home, including care such as immunization delivery;
- consult with and report immunization delivery, as appropriate, to primary care providers, state immunization registries, and other relevant parties;
- identify high-risk patients in hospitals and other institutions and ensure that appropriate vaccination is considered either before discharge or in discharge planning; and
- identify high-risk patients in nursing homes and other facilities and ensure that needed vaccinations are considered either upon admission or in drug regimen reviews.

Guideline 3: Quality—

Pharmacists must achieve and maintain competence to administer immunizations, and should administer vaccines only after:

- being properly trained and evaluated in disease epidemiology, vaccine characteristics, injection technique, and related topics;
be properly trained in emergency responses to adverse events; they should provide this service only in settings equipped with epinephrine and related supplies;
- they question patients and their families about contraindications and inform them in specific terms about the risks and benefits of immunization; and
- they receive additional education and training on current immunization recommendations, schedules, and techniques at least annually.

Guideline 4: Documentation—
Pharmacists should document immunizations fully and report important events appropriately.

Pharmacists should:
- maintain perpetual immunization records and offer a personal immunization record to each patient; and
- report adverse events following immunization to any appropriate primary care provider and to the Vaccine Adverse Event Reporting System (VAERS).

Guideline 5: Empowerment—
Pharmacists should:
- educate patients about immunizations and respect patients’ rights;
- encourage appropriate vaccine use through information campaigns for health care practitioners, employers, and the public about the benefits of immunizations;
- educate patients and their families about immunization in readily understood terms; and
- before immunizing, document any patient education provided and obtain written informed consent as recommended in their state.

Advantages of the Pharmacy Immunization Center
One of the major advantages of the pharmacy as the immunization center is its extended hours of availability. For busy parents who cannot take time from work to get themselves or their children to a health clinic or a pediatrician, immunizations offered at a pharmacy may be very attractive.

Even if there are plenty of resources in your community for delivering poliovirus, pertussis, measles, and other routine childhood vaccines, ask if anyone is taking responsibility for identifying the children who need influenza vaccine. Those with diabetes, sickle-cell anemia, and other chronic diseases need this vaccine and pneumococcal vaccine as well.

Pharmacies offer major advantages as places to administer immunizations: access, convenience, and knowledge of the individuals most in need. The unique contributions of pharmacy to immunization delivery are:
- Identification of specific people who need vaccines based on their medication use or knowledge of patient-specific disease-based risk factors.
- Extended hours of access in the evening and on weekends, if immunizations are offered throughout those times.
- Proximity to the patients’ own neighborhoods.
• Computerized records, facilitating the delivery of reminders (e.g., postcards with encouraging messages).
• Pharmacists repeatedly are cited among America’s most trusted professionals.
• Pharmacists offer a useful bridge between patients and physicians for referrals and health advocacy. As with all health care services, high levels of quality are needed to protect the patients’ interests and maintain their trust.
• Pharmacists are adept at electronic communications, using modems, and electronic claims processing.
• Pharmacists are experienced in product storage, handling, and safeguarding inventory.
• Pharmacists are responsible for the effective use of all medications.

Depending on whether you practice in a rural, suburban, or urban setting, offer services that will meet the greatest needs around you. The same is true whether you are in a community, nursing home, or hospital-based practice. For example, it may be more convenient for a patient to stop by the neighborhood pharmacy rather than travel to a health department or other immunization site. This is especially true for people with few transportation options.

Meet Your Local Needs

What you do should depend in large measure on what is needed in your area. Ask your county health director or the immunization division of your state health department what their greatest needs are. It will vary for adults, adolescents, and children. Explain your interest in joining the multidisciplinary team that keeps your community healthy.

One of pharmacy’s greatest contributions to the public health may come in rural areas.29,40,42 Similarly, regions with shortages of health professionals might stand to benefit most from pharmacists and student pharmacists who expand the clinical services they provide.29

Emphasize that pharmacists bring unique capabilities to the multidisciplinary immunization delivery team. Vaccines are drugs, and pharmacists help people achieve the best outcomes from all drugs. If a patient suffers a preventable infection, it is a drug-related problem that a pharmacist could have helped prevent.49

Information Is Essential

Most people believe that vaccines work, or they are easily persuaded when offered the facts. Nonetheless, some myths persist, such as “Oh, I always get the flu from a flu shot.” Explaining the manufacturing method of mixing influenza viruses with formaldehyde can help dispel this myth. Many individuals do not realize the differences between influenza and the common cold. Some return and complain that the vaccine did not work because immediately after being vaccinated they came down with a cold. Pharmacists can educate the public about vaccines and associated misconceptions.

Perhaps the most important contribution the pharmacist can make is simply informing the person or parent of disease risk. The pharmacist can then encourage immunization at any of several locations as soon as possible. Experience from a variety of settings shows that between 50% and 94% of people will act on the basis of the pharmacist’s vaccine recommendation.1, 3, 47, 52–56
Vaccines are prescription drugs. If vaccines are not on the list of drugs authorized for pharmacists to prescribe in your state, work with your local health department. Consider asking for authority to act in collaboration with the county medical director, a physician, provided that you ask the same screening questions as the nurses who administer vaccines at the public health clinic. In most cases, people immunized in public clinics do not see a physician; he or she is called in only to consult on unusual cases. For your practice, develop an emergency response plan and have the necessary resources (e.g., epinephrine, CPR, and ambulance availability) in the event of an anaphylactic response.

Some current vaccine providers may object to pharmacists delivering immunizations, often on the basis of competition. This obstacle may be best countered by pointing out the tremendous number of people who are vulnerable and die of vaccine-preventable infections each year. Something extra is needed to protect these people and keep them alive. There are so many vulnerable people currently unimmunized, so much unmet demand, that competition is not really an issue.

Others are justifiably concerned whether pharmacists provide high-quality immunization care. These concerns can often be satisfied by pointing out that the pharmacists’ procedures emulate the controls and precautions adopted at local health clinics. Show how your practice abides by the guidelines for pharmacy based immunization advocacy described earlier. Invite them to visit.

If pharmacists in your state do not have the explicit authority to administer immunizations, work with your state pharmaceutical association and board of pharmacy to change your state’s pharmacy practice act, so pharmacists can more fully protect the public’s health.

Remember that pharmacists should join the immunization activities of their community as an enhancer, not as a competitor, especially in the case of children.

Ideas for Immunization Advocacy:

- Cooperate with local high schools to educate students and parents about immunizations needed during adolescence and especially those recommended before college. Parent-teacher conferences provide an excellent time to have access to parents, and students can be reached during the school day.
- Write articles or short passages in residence hall newsletters to warn these high-risk students of meningococcal disease and educate them about the availability of the meningococcal and influenza vaccines.
- Target the immunization status of younger children by providing information at PTO meetings or at preschools and kindergartens.
- Use health fairs and other pharmaceutical care activities to take time to educate patients regarding the importance of proper immunizations.
- Educate university students, faculty, and staff by holding informational sessions in the evenings and staffing booths in the student union, dining halls, or residence halls. This can be done as a part of another large university event such as homecoming or as part of American Pharmacists Month to educate about immunizations and the patient care roles of pharmacists.
- Promote Operation Immunization at state pharmacy association meetings to gather overall support and assemble a list of practitioners willing to assist students in the project.
- Learn about the legislative process to see if you need to change a law or a regulation in your state to be able to effectively practice your immunization skills while you are still in school.
Ideas for Immunization Facilitation:

- Find out about immunization clinics already scheduled in your area (including those at pharmacies) and ask to help promote their clinic and assist on-site. Aid in promotion through radio and print advertisements, fliers and posters, announcements, lollipop reminders, etc. On-site, students can prepare the patient for immunization by going through the screening questionnaires, taking patient histories, assessing patient appropriateness for vaccination, advising patient of vaccine benefits/adverse events, filling out Medicare billing forms, handing out immunization record cards, providing vaccine information statements, and generally counseling patients. Remind your chapter members that providing patient counseling is a way to practice providing Medication Therapy Management.

- Collaborate with other well-known health care organizations that administer immunizations in your area. Examples include the American Red Cross, Department of Public Health, state pharmacy associations, and other healthcare-related student organizations.

- Collaborate with the student health services at your university to encourage and facilitate their immunizations campus-wide.

- Find a large company in your area interested in immunizing its employees, and arrange to hold several clinics there. Find immunizing pharmacists, nurses, or public health officials to come give the immunizations.

- Correlate Operation Immunization activities with classroom experiences by having faculty members administer immunizations as part of a lecture about immunization providers or by having students on experiential rotations facilitate immunizations with their preceptors.

Sources of Immunization Information:

There are a wide variety of resources to turn to for information on new recommendations, products, programs, and materials. See “Resources” section.

Common Questions

Q: If I can’t immunize why should I participate?

As a student pharmacist, it is important to advocate for patients’ healthcare. By helping identify high-risk patients in your pharmacy and informing them on immunization benefits, you are helping patients take preventative health care measures. Experiences and interactions you have with people will also help you better understand the information you’ve learned in the classroom. You can also learn about the legislative process to see if you need to change a law or a regulation in your state to be able to effectively practice your immunization skills while you are still in school.

Q: I’m only a student, how can I possibly make a difference?

Student pharmacists do make a difference! Over 25,000 people were immunized and thousands received information on immunizations in the inaugural year of Operation Immunization (1997). Over 51,000 immunizations were administered in 1998 and over 53,000 in 1999. In eleven years, student pharmacists and practitioners provided over 750,000 immunizations nationwide. Your chapter’s participation can only help increase the number of people being immunized!

Q: What can I do if I can’t give immunizations?
• Even though you may not be able to administer immunizations, you can still impact the immunization delivery process by promoting and encouraging people to receive vaccinations. Be an advocate of immunizations! Use the resources found in this resource guide to provide information to the public about the importance of immunizations.
• Collaborate with an organization that offers immunizations (such as the Red Cross, local health departments, community groups, etc.) and assist them in providing information and answering questions on immunizations.
• Host a nurse in your local pharmacy to administer immunizations and provide the patients with information.
• Contact a local nursing program or hospital for potential participants.
• Send a letter to them explaining you would like to work with them to provide immunizations delivery. Share your excitement about wanting to assist them in providing vaccine information and potential side effects to patients.
• Develop a schedule where and when the immunizations will be offered.
• Recruit student pharmacists who will provide information and counsel patients.
• Organize appropriate brochures and materials that will be available to patients at the sight.
• Thank the immunizer for letting you participate.
• Distribute brochures to high-risk patients.
• Send letters to the editors of local papers explaining the importance of immunizations. (Samples are in the resource section.)
• Encourage your pharmacy manager to invest in auxiliary labels, for example, “Are your immunizations up to date?”
• Create bag stuffers to include with high-risk patients’ medications. Samples are in the resource section.

How can I help student pharmacists in my state receive authority to immunize?
• CHECK with State Pharmacy Association to determine activity, if any, that has occurred on this issue.
• If current activity, volunteer to assist in the effort
• If no activity, determine the Association’s interest level in pursuing the issue and volunteer to develop a plan for securing the authority. The plan would be presented to the Association.

CONCEPT DEVELOPMENT

1) Items to Acquire

a) copy of the state Pharmacy Practice Act and Regulations.

b) copy of the state Medical and Nursing Practice Acts and Regulations.

c) immunization rates for the state, including demographic statistics (ie. at risk populations).

d) gather examples of existing immunization programs being conducted in your state that could be used for comparison purposes (ie. Visiting Nurses programs).
e) gather examples of pharmacist provided patient focused care programs in your state today (include examples from independent, chain, supermarket, ambulatory care, acute care, long term care and other settings).

f) current school of pharmacy curriculum and continuing education requirements in your state.

g) identify current immunization standards in your state related to registries and documentation (ie. Reporting immunizations to public health department, physicians and/or patients).

h) identify and join immunization coalitions in your state / local community. Offer to promote public education and other programs.

i) Find out if state association has APhA’s immunization resource packet. Contact APhA’s State Relations.

2) Determine method to obtain authority:

   a) Legislature

   b) Regulation

   c) Attorney General or other official opinion

3) Draft language for Bill/Regulation

   a) Statute/Regulation Components

      i) Practice of Pharmacy Definition

      ii) Education and Training Requirements

      iii) Patient Populations Affected

      iv) Protocol/Standing Orders Use and Procedures

      v) Documentation Requirements

      vi) National Immunization Standards (follow ACIP, NVAC and APhA Immunization Standards)

OBTAINING SUPPORT:

Present your proposal to the following groups and listen to their concerns. Where appropriate, modifications may be made. However, there may be some issues where a compromise cannot be reached.
BILL INTRODUCTION

1) Once feedback is obtained and modifications, if any, are made to the proposed bill, work with the state pharmacy association to obtain a House or Senate sponsor. Provide sponsors with a complete background packet. The packet should include the material gathered during the concept development, a list of organizations/individuals who you met with in developing the bill, action taken on comments received, and any concerns/issues that still exist with the bill. The sponsors of the bill will be your champion during the legislative process.

2) Create a student task force on the immunization legislation to work with the state pharmacy association.
   
   a) make sure each student knows who their state Representative and Senator is and how to contact them.
   
   b) Identify students who have special relationships with their legislator (ie. relative, close friend, worked campaign, etc.)

3) Conduct a briefing / presentation on the legislation at an APhA-ASP meeting to be conducted by the state pharmacy association and/or initiative leaders.
   
   a) provide students with a one-page bullet point document highlighting the important components of the legislation.
   
   b) Invite school faculty and Board of Pharmacy to participate.

4) When notified by the state pharmacy association that the bill is to be heard by a committee or the full legislature, mobilize the student body to contact the appropriate legislators in order to educate them on the benefits of the bill to citizen’s public health.
   
   a) offer to coordinate a visit to the state capitol by students to meet with individual legislators.

PASSAGE OF THE BILL:

1) In most states both the House and Senate must pass the legislation.
2) The passed bill is sent to the Governor’s office for consideration (signature, no action which equals passage, or veto)

   a) if necessary, contact may need to be made with the Governor’s office to encourage the signature of the bill

Promulgation of Rules

Even though the legislation may have been passed by the legislature and signed by the Governor, rules must be adopted before a student pharmacist would be allowed to provide immunizations.

1) depending upon the process established within the statute for implementation of the new law, the timeframe for establishing rules can vary. (ie. if need to utilize joint pharmacy / medicine board, etc.)

2) communicate with the Board of Pharmacy to determine the procedure they will follow. Plan to have a student representative at any open hearings.

3) Once rules have been adopted, conduct a seminar for students on the new law and rules. Invite state pharmacy association and board of pharmacy representatives to participate.

 NOTE: even after passage and rule adoption, pharmacists and their state association need to be cautious of attempts to eliminate immunization authority by those opposed to pharmacists partaking in this activity. Pharmacists and student pharmacists should adhere to the established standards and do what’s right for the patients they serve.

APhA has compiled the following information to assist individuals and organizations interested in passing legislation/regulations on pharmacists’ administration of immunizations. The observations/suggestions made are based upon APhA’s experience with several state legislative and regulatory processes. Fell free to utilize this information to best meet the needs of your state. APhA staff is available to assist you in your efforts.

Empowerment Language

Many states have included the term “administer” within the definition of the practice of pharmacy. Then, within the regulations they identify the procedures pharmacist must follow to partake in this activity.

Regulatory Language

1) Ideally, having a physician or public health department official establish a protocol with the pharmacist is preferred. This approach is the recommended approach since the intent of pharmacists’ involvement in this activity is to increase access, not divert patients or disrupt the medical home. “A rising tide lifts all boats” —increased public awareness of the need to be immunized will increase immunization rates throughout the entire system (documented in a June 1999 Ph.D. dissertation work by John Grabenstein, Ph.D.). The protocol establishes which vaccines may be administered, record keeping/reporting requirements and emergency procedures. Regulations might describe these protocols a follows: “Written protocol” means a physician’s order, standing medical order, standing delegation order or other order or protocol as defined by _______ and contains:
a) statement identifying the individual authorized to prescribe drugs who has delegated the activity.

b) statement identifying the individual pharmacist authorized to administer the vaccine

c) statement identifying the types of vaccines that the pharmacist is authorized to administer

d) statement of the procedures, decision criteria or plan the pharmacist should follow when exercising the administration authority, including when to refer the patient to the physician

e) statement of the procedures for emergency situations, and statement of record keeping and documentation procedures

**Training Program:**

Successfully complete an immunization training program recognized by the state Board of Pharmacy. The current guidelines and recommendations of the Center for Disease Control and Prevention for pediatric, adolescent and adult patients and the APhA Guidelines for Pharmacy-based Immunization Advocacy. The course of study shall include, at a minimum, the following:

1) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration

2) immunization schedules (pediatric, adolescent and adult)

3) immunization screening questions, informed consent, record keeping, registries and reporting mechanisms/requirements of state

4) vaccine storage

5) biohazard waste disposal and sterile techniques

6) establishing protocols/standing orders

7) immunization coalitions and other community resources available

8) mechanism for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS)

9) reimbursement procedures and vaccine coverage by federal, state and local entities

10) administration techniques

In addition, current cardiopulmonary resuscitation/Basic Life Support (CPR certification) should be part of the requirements for immunization providers.

*The primary focus of pharmacists’ immunization activities is the adult population (those individuals who are 14 years old and above), where the greatest need for increasing immunization rates exist. In communities where increasing providers and access have been identified by the public health department or local physicians, pharmacists could become providers of immunizations to additional...