REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-14)
Role of Pharmacists in Improving Immunization Rates
Resolution 212-I-12
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. To develop a comprehensive report that addresses the role of pharmacists in increasing immunization rates, summarizes state-level efforts authorizing pharmacists to administer vaccines, and promotes current guidelines and recommendations that apply to all vaccine providers. The report includes and expands upon Board of Trustees Report 1-I-13, which was referred.

Methods. English-language articles were selected from searches of the PubMed and Google Scholar databases from 2004 to July 3l, 2014 using the search terms "vaccine administration," "vaccine delivery," "vaccine provider," "vaccine safety," " immunization delivery," "immunization program," "pharmacist and vaccine," "pharmacy and vaccine," "nontraditional vaccine provider," in the article title and/or abstract. Internet sites managed by federal agencies and applicable health professional organizations and vaccine advocacy organizations also were reviewed for relevant information. Additional articles were identified from the manual search of reference lists contained in pertinent articles and other publications.

Results. Current low rates for administration of adult vaccines and some adolescent vaccines indicate that a strategy of delivering vaccinations to a high proportion of these populations solely through the medical home is suboptimal. A recent physician survey on adult vaccine delivery revealed that only 20% to 30% of internists and family physicians stocked all recommended vaccines for adults. Federal advisory groups and national medical specialty societies recognize the role of settings outside of the medical home, such as pharmacies, to increase immunization rates, particularly for individuals who have difficulty accessing a medical home. Survey data suggest that primary care physicians are generally accepting of the increased access that adults now have to vaccination services in pharmacy settings; physicians feel more strongly that vaccines should be administered in the medical home for pediatric patients, particularly children with chronic medical conditions. Pharmacists are authorized to administer vaccines in all 50 states. Differences exist among the states with respect to the age of people who can be immunized by a pharmacist, which vaccines can be provided, and the required level of physician oversight. All states require that pharmacists who administer vaccines have and maintain specific education and training in the provision of immunization services.

Conclusion. It is optimal for patients to receive vaccinations in their medical home. While pharmacists should support the importance of immunizations across the lifespan and share consistent messages about vaccine safety for all ages and populations, the primary mode of vaccine delivery for pediatric patients, and for adult patients with chronic disease and co-morbidities, should be the medical home to ensure coordination of care. When vaccines are administered in pharmacies, the information should be transmitted back to the individual's medical home and documented in the electronic health record and immunization registry (when one exists) so that a complete vaccination record is maintained. It is important to monitor current trends in vaccine administration to ensure that services do not become fragmented and place patients at risk. Mechanisms should be developed and implemented to ensure that communication and record sharing are optimized between pharmacists and primary care physicians. Physicians have a clear interest in ensuring that state laws on the qualifications of health care professionals who administer vaccines outside the medical home are sufficient to protect patient health and safety.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-I-14

Subject: Role of Pharmacists in Improving Immunization Rates (Resolution 212, I-12)

Presented by: Stuart Gitlow, MD, Chair

Referred to: Reference Committee K (Hugh Taylor, MD, Chair)

INTRODUCTION

At the 2013 Interim Meeting, the House of Delegates (HOD) referred Board of Trustees (BOT) Report 1-I-13, Pharmacist Administration of Immunizations, for further study and report back. The BOT report was written in response to Resolution 212-I-12 "Pharmacist Administration of Vaccines," submitted by the Louisiana Delegation and referred by the HOD. Resolution 212-I-12 recognizes the potential role that pharmacists can play in increasing immunization rates and specifies criteria, including the need for model legislation to ensure appropriate physician oversight and involvement in state-level efforts authorizing pharmacists to administer vaccines.

In referring BOT Report 1-I-13, the HOD identified several issues in need of clarification, including safety issues associated with immunization of pediatric populations, the safety of live vaccines, the appropriateness of pharmacist immunization of at-risk populations, the need to ensure communication with the treating physician, parity in requirements for reporting to immunization registries, and handling of adverse events.

Given the broad public health and clinical implications of these issues, the BOT determined that the issue of pharmacist administration of vaccines could benefit from a contemporary, collaborative review by relevant councils of our AMA. The Council on Science and Public Health agreed to take the lead in this endeavor and engaged the Council on Medical Service, Council on Legislation, and the Council on Long Range Planning and Development to develop a comprehensive report that is responsive to the public health imperative to immunize and protect all ages and populations from vaccine-preventable diseases, and reflects best practices for patient selection, management, and follow-up.

METHODS

This Council report includes and expands upon information presented in BOT Report 1-I-13. English-language articles were selected from searches of the PubMed and Google Scholar databases from 2004 to July 31, 2014 using the search terms "vaccine administration," "vaccine delivery," "vaccine provider," "vaccine safety," " immunization delivery," "immunization program," "pharmacist and vaccine," "pharmacy and vaccine," or "nontraditional vaccine provider" in the article title and/or abstract. Internet sites managed by federal agencies and applicable health professional organizations and vaccine advocacy organizations also were

Action of the AMA House of Delegates 2014 Interim Meeting: Council on Science and Public Health Report 4 Adopted, and Remainder of Report filed.

reviewed for relevant information. Additional articles were culled from reference lists contained in pertinent articles and other publications.

BACKGROUND

Vaccines are among the safest and most cost-effective measures to prevent infectious diseases.[1] Immunization recommendations in the United States currently target 17 vaccine-preventable diseases across the lifespan.[2,3] National vaccination rates for most recommended childhood vaccines are between 80% and 90%; and more than 99% of U.S. children have received at least one vaccination.[4] Vaccination coverage among adolescents (between 13 and 17 years of age) ranges from 78% for at least one dose of meningococcal vaccine to 95% for at least one dose of varicella vaccine; however, only 57% of girls and 35% of boys have received at least one dose of human papillomavirus (HPV) vaccine.[5] Population coverage for adult vaccines ranges from 2% to 70%, depending on the vaccine and the target population.[6,7] The CDC reports that less than half of eligible adults 18 years of age or older received an influenza vaccine last year.[6,7] Only 60% and 62% of adults 65 years of age or older received a pneumococcal or influenza vaccine, respectively; and only 20% of adults 60 years of age or older received a herpes zoster vaccine.[7] Each year, about 42,000 adults and 300 children in the United States die of vaccine-preventable diseases, mostly due to influenza.[8]

Primary care is the most appropriate setting for vaccine administration since it serves as the medical home. In the medical home, physicians have timely access to patient information to perform clinical assessments as well as timely access to other members of the health care team.[9] Each clinical encounter is an opportunity to enhance the physician/patient relationship and provide immunizations and other health services. Current success in improving pediatric immunization rates has been achieved largely as a result of the federal Vaccines for Children (VFC) Program, which has made it easier for eligible children and adolescents to receive vaccines in their medical homes by reducing financial barriers.[10]

Although the medical home is the ideal place to deliver vaccines, current low rates for administration of adult vaccines and some adolescent vaccines indicate that a strategy of delivering vaccinations to a high proportion of these populations solely through the medical home is suboptimal. Since 2000, the CDC Advisory Committee on Immunization Practices (ACIP) has expanded recommendations for adolescents to include vaccines protecting against HPV, meningococcal disease, and pertussis, as well as annual influenza vaccination for individuals older than six months of age. Implementing expanded vaccination recommendations, particularly for adolescent and adult patients, is a challenge for primary care physicians who administer the majority of vaccines in their practices. To improve immunization rates, community settings beyond the traditional medical home are increasingly being utilized (e.g., schools, student health services, employer sites, retail clinics, pharmacies), particularly for individuals who are unlikely to receive primary care medical services through conventional venues.

Physicians have a clear interest in ensuring that state laws on the qualifications of health care professionals who administer vaccines outside the medical home are sufficient to protect patient health and safety. Vaccine administration calls for verification and safety considerations, adherence to complex vaccination schedules, accurate medical history and record keeping, protocols for responding to allergic reaction or other adverse side effects, and overall monitoring of the individual's health and medical conditions. This includes having systems in place for assessing vaccination status of high-risk patients, including pregnant women and patients with renal failure, diabetes, cardiac disease, chronic lung disease, cancer, and immunocompromised individuals.

CHALLENGES TO INCREASING IMMUNIZATION RATES

Patient and Provider Attitudes and Beliefs

Vaccination decisions are influenced by an individual's perception of health, beliefs about vaccine-preventable diseases, perceptions about the risks of these diseases, perceptions about vaccine effectiveness and vaccine components, and trust in institutions. A recommendation from a physician or other health care provider is recognized as one of the most important predictors of receipt of vaccination, coupled with the ability to provide the recommended vaccine during the same clinical encounter.[11] Common reasons precluding adult vaccination include patient concerns about vaccine-associated side effects or vaccine-acquired illness, provider and patient belief that the vaccine is not effective, provider and patient lack of awareness that the vaccine is needed, and lack of a health care provider recommendation for the vaccine.[11-15]

The pediatric immunization schedule is particularly complex and benefits greatly from coordination within a medical home.[16] Parental attitudes, beliefs, and behaviors about the safety of vaccines have a considerable impact on decisions regarding vaccination. A consistent reason for vaccine refusal or delay among parents on behalf of their children is concern about vaccine safety.[17] While most parents adhere to the ACIP-recommended immunization schedule for their children, some are concerned, even in the absence of supporting evidence, that the schedule may present unnecessary risk because of the timing and number of vaccinations. With the currently recommended immunization schedule, children can receive up to 24 immunizations by two years of age, and up to five injections in a single office visit.

While many adolescents obtain some medical care (including vaccinations) from a primary care physician,[18] as adolescents age into their late teens, visits to primary care physicians decline substantially, reducing opportunities for immunization.[19,20] Adolescents should preferably be vaccinated during early or middle adolescence, when they are most likely to visit pediatricians and family practice physicians and more likely to have preventive visits than older teens.

Cost

Financial pressure from vaccine costs and inadequate reimbursement for vaccine purchase and administration challenge physicians' ability to provide vaccines to their patients, with some physicians opting out of providing vaccines or choosing not to vaccinate uninsured or underinsured patients.[21-24] A recent physician survey on adult vaccine delivery conducted by the Vaccine Policy Collaborative Initiative[*] revealed that only 20% to 30% of internists and family physicians stocked all 11 CDC-recommended vaccines for adults; 80% of survey respondents stocked seasonal influenza, pneumococcal, Td (tetanus, diphtheria), and Tdap (tetanus, diphtheria, pertussis) vaccines.[25] Survey respondents indicated they were less likely to stock more expensive vaccines like herpes zoster and hepatitis B, as well as "catch up" vaccines such as HPV, MMR (measles, mumps, rubella), and varicella. The survey revealed that most internists and family physicians refer patients elsewhere for vaccines they did not stock. The most commonly reported reasons for referring patients elsewhere for vaccines included insurance not covering the vaccine or inadequate insurance reimbursement. When they did not stock the vaccine, survey respondents most often reported referring patients to pharmacy/retail stores and public health clinics.

[*] The Vaccine Policy Collaborative Initiative at the University of Colorado Denver works with the CDC to perform rapid-turnaround surveys to assess physician attitudes about vaccine issues.

Access and Availability of Services

Presently, the United States faces a growing shortage or maldistribution of physicians, especially primary care physicians, which has significant implications for basic health care access.[26,27] These shortages are expected to persist or worsen, in light of current health system reform efforts that enable many more Americans to obtain health care insurance and seek health care services. The projected surge in patient volume is accompanied by an aging U.S. population and an increasing number of patients with chronic disease, who can benefit from immunizations and other medical services. To address this reality, supplementary venues (e.g., schools, student health services, worksites, retail clinics, pharmacies) are being utilized to provide immunization services. Increased immunization rates can be achieved by complementing the efforts of primary care physicians with efforts to deliver vaccines in other health settings, particularly settings that adolescents and adults tend to frequent.[28-30]

Convenience and proximity are important factors associated with the choice of vaccination setting, particularly for individuals who do not frequently visit physicians or do not have a regular source of care.[20,31] Reducing the distance from the vaccine setting to the target population, eliminating the need for making an appointment in advance and avoiding the waiting time often associated with a clinic or office visit, offering more convenient clinic hours, and reducing administrative barriers to vaccination are factors that increase vaccine-seeking behavior.[28] The potential benefit of expanded access to immunizations through nonphysician settings was demonstrated in a study showing that almost 31% of 6,250,402 immunizations administered over a one-year period at a large national pharmacy chain occurred during evenings, weekends, or federal holidays, when physician settings for vaccine delivery were less accessible.[32]

INTEGRATION OF IMMUNIZATION PROGRAMS IN PHYSICIAN AND NONPHYSICIAN SETTINGS

Integration of complementary (nonphysician-based) immunization programs with the traditional medical home provides the potential to increase vaccine coverage rates and decrease vaccine-preventable diseases. This includes expansion of services offered by pharmacists and other community providers.[11] According to the Infectious Diseases Society of America (IDSA), the proper use of complementary sites for immunization services can: (1) improve access to immunizations for many adolescents and adults who are otherwise unable to reach a primary care provider; (2) have the potential to eliminate barriers associated with seeking care in a primary care setting, such as making an appointment or long waiting times; (3) provide immunizations at lower costs, which may increase access for the uninsured or for people who have insurance that either does not cover immunizations or is associated with large deductibles or co-payments; and (4) increase opportunities to raise awareness and educate the public about the value of immunizations. In addition, new partnerships and alliances can be formed that can improve immunization outreach.[29]

AMA Policy H-160.921, Store-Based Health Clinics, is germane to the provision of immunizations and other health services in complementary settings with respect to the scope of clinical services provided, use of standardized protocols, access to and supervision by a physician as consistent with state law, continuity of care, and referral systems.

Surveys demonstrate that primary care physicians are generally accepting of the increased access that adults and school-age children now have to vaccination services outside of the medical home, particularly for influenza vaccination.[25,33-37] Some physicians may be reluctant to refer patients to complementary settings for vaccination services, citing concerns about the safety of vaccination in

immunization programs outside of the medical home or the ability of providers in other settings to properly screen patients for a wide range of vaccinations without access to a full patient history. Additional concern has been expressed that the provision of vaccinations outside the traditional medical home may interfere with the receipt of other preventive health care services that are typically received in traditional primary care settings.[20,38,39] No studies were identified suggesting that adults or adolescents forego preventive health care services provided in primary care settings if they receive vaccinations elsewhere or that administration of vaccines in complementary settings places patients at increased risk for adverse events.

Guidelines for Vaccine Administration in Nonphysician Settings

In 2009, the IDSA released clinical practice guidelines to address immunization services delivered in complementary settings.[29] The guidelines stipulate that health care professionals who administer vaccines in these settings adhere to quality standards, including the ability to appropriately manage vaccine-related adverse events, proper storage and handling of vaccines, appropriate record keeping, regulatory issues, and provision of education regarding both risks and benefits of immunizations. Furthermore, records of immunizations administered in these settings should be sent to primary care providers and to immunization information systems (registries). Vaccine recipients in such settings should be encouraged to see their primary care providers for other preventive and therapeutic services. These guidelines supplement quality standards and guidance issued in 2000 by the National Vaccine Advisory Committee (NVAC).[30] The most recent NVAC recommendations specify that all health care providers should assess the patient's immunization status and either administer needed vaccines or refer the patient to a provider who can provide vaccination services (see Appendix).[11]

PHARMACISTS' ROLE IN VACCINE ADMINISTRATION

Over the past two decades, pharmacies in the United States have increased their participation nationally in vaccination activities.[40,41] Although state laws vary regarding educational requirements, any pharmacist who wishes to administer vaccines must undergo additional training in immunization delivery. The most common educational requirements include completion of a state-specific course in vaccine administration, certificate programs in vaccine administration, and completion of a specified number of contact hours of continuing education related to immunizations. Most states also require basic life support or cardiopulmonary resuscitation certification.

More than 20 years ago, the American Pharmacists Association (APhA) developed and began delivering *Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists*, which was based on CDC, ACIP, NVAC and other published standards and guidelines.[42] The course involves 12 hours of self-study and 8 hours of seminar and demonstration with hands-on experience in intramuscular and subcutaneous vaccination techniques. Content includes education on vaccine-preventable disease epidemiology, vaccine characteristics, reporting and documentation, and emergency response to adverse events. In addition, participants must pass an exam, including demonstration of administration technique, and obtain certification in cardiopulmonary resuscitation. According to the APhA, more than 250,000 pharmacists in the United States have been trained to provide immunizations, primarily through the 20-hour APhA certificate training program.

In 2013, the APhA conducted a national Internet survey regarding pharmacy-based immunizations on behalf of the U.S. Department of Health and Human Services National Vaccine Program Office.[43] Responses from 2,351 pharmacy practice sites revealed that nearly all sites (97%) planned

to administer influenza vaccine to adults, 56% planned on administering the vaccine to adolescents (aged 10 to 18 years), and 22% planned to provide the vaccine to pediatric patients (between 2 and 9 years of age); only 4% of pharmacy practice sites planned to administer influenza vaccine to infants younger than 2 years of age. In addition to influenza vaccine, the majority of pharmacies surveyed administered pneumococcal (77%), herpes zoster (75%), and tetanus (57%) vaccines. Fewer than half of pharmacies administered hepatitis B vaccine (47%), hepatitis A vaccine (43%), meningococcal vaccine (43%), and HPV vaccine (37%). Only 10% of pharmacies surveyed reported that they administered pediatric vaccines. Only 3% of pharmacy practice sites reported that they did not offer immunization services.

Medical Society Recognition of Pharmacists' Role in Vaccine Administration

National medical specialty societies support the use of settings outside of the medical home to immunize target populations who have difficulty accessing a medical home; some of these societies specifically recognize the role of pharmacists in providing such services:

- The American Academy of Family Physicians (AAFP) strongly recommends that patients receive all immunizations recommended by the AAFP in their medical home.[44] When vaccines are administered elsewhere, all pertinent vaccine-related information should be transmitted back to the patient's primary care physician and their state registry when one exists so that there is a complete vaccination record. The AAFP supports arrangements in which pharmacists are part of an integrated, team-based approach to care but believes the interests of patients are best served when such care is provided by a physician or through an integrated practice supervised directly by a physician.
- The American Academy of Pediatrics (AAP) advocates that all children receive immunizations in a medical home,[45,46] but recommends that pediatricians assist in the identification of other venues in which vaccinations can be delivered if a significant number of children in a community do not have convenient access to a medical home or if existing medical homes are not able to meet the demand.[46] If sufficient pediatric medical homes are not available, additional venues for vaccine administration could include public health department clinics, Women, Infants, and Children Program offices, child care centers, school-based health clinics, and, in those states that allow it, pharmacies.
- The American College Physicians (ACP) supports pharmacists as immunization information sources, hosts of immunization sites, and immunizers, as appropriate and allowed by state law.[47]
- To improve adolescent and adult immunization rates, the IDSA urges states to develop standing order policies that allow nonphysicians to administer vaccines in certain circumstances, such as at schools, pharmacies, and walk-in clinics.[48] IDSA policy further urges states to require and promote the use of state-based immunization registries. Promotional efforts must reach immunization providers in nontraditional locations (retail and community settings) to increase participation in registries; information about immunizations administered in nontraditional settings should be conveyed to the patient's primary care provider.

Physician and Patient Perspectives on Pharmacists' Role in Vaccine Administration

Pediatricians and family physicians have expressed concern about pharmacists administering vaccines because they view this as inconsistent with medical home principles.[18,44,46] A particular concern is that pharmacist administration of vaccines would eliminate an opportunity for children and adolescents to receive much needed well-care visits in the critical pre-teen and teenage years. Medical homes are integral to both the delivery of immunizations and comprehensive care. Most

medical homes for children and adolescents involve primary care pediatric and family physician practices, although the role of these settings is diminished among older adolescents who are more likely to visit gynecologists or specialists or may not visit a health care provider at all.[18]

In a recent national survey, about 60% of general internal medicine and family physicians indicated that they "always," "often," or "sometimes" referred patients to a pharmacy/retail store for vaccinations.[25] About 70% of family physicians and 75% of general internal medicine physicians agreed that it was helpful to have pharmacists share a role in vaccinating adult patients.[25] While additional surveys indicate physician support for pharmacists in vaccinating adult patients,[34,36,38] physicians feel more strongly that vaccines should be administered in the medical home rather than a pharmacy for pediatric patients, particularly children with chronic medical conditions.[35,36,38]

Data are limited on patient and parental preferences for receipt of vaccination services in pharmacies and other settings outside the medical home. For the 2011-2012 influenza season, CDC data indicate that 65% of children between 6 months and 17 years of age received the influenza vaccine in a medical setting (i.e., physician office, health department, other health clinic/health center, or hospital); among nonmedical settings, pharmacies and other retail settings accounted for about 3% of influenza vaccinations delivered to this age group.[49] The percentage of vaccinated children who received the vaccine in a pharmacy or other retail setting was higher among children between 5 and 17 years of age than younger children. Among adults (18 years of age and older), about 57% reported that they received the influenza vaccine in a medical setting; with the majority reporting vaccination in a physician office.[49,50] Pharmacies and other retail settings accounted for 20% of influenza vaccinations administered to adults. Older adults (50 years of age and older), individuals with certain high-risk medical conditions (i.e., asthma, diabetes, cardiovascular disease, chronic obstructive pulmonary disease, emphysema, chronic bronchitis, and cancer), those having a checkup in the past year, and those having a primary care physician were more likely to have been vaccinated in a medical setting. Characteristics associated with an increased likelihood of receipt of vaccination in nonmedical settings were higher education; not having certain identified high-risk conditions; not having had a routine checkup in the previous 12 months; and not having a primary physician for health care.[50]

One published survey involving 420 adult patients in Iowa who presented to a family physician or pharmacy for receipt of the pneumococcal and influenza vaccines revealed greatest support for adult immunizations provided by physicians (85%), followed by pharmacists (64%), community health departments (38%), and school nurses (15%); little support was shown for vaccinations provided by chiropractors or dentists.[51] For childhood immunizations, adult respondents preferred to have their children vaccinated by physicians (99%) and community health departments (87%). About 10% of adults supported receipt of vaccines for children in a pharmacy setting.

A survey of 370 households in Colorado found that 78% of parents preferred that adolescents receive vaccines in the medical home.[52] For adolescents who need to seek care in settings outside of the medical home, a majority of parents were "definitely" or "probably" accepting of vaccination in public health clinics (74%), school health clinics (70%), and obstetrics and gynecology clinics (69%). Only 36% of parents indicated retail-based clinics as an alternative setting for adolescents who could not receive vaccinations in the medical home.

USE OF VACCINE ORDERS AND VACCINE PROTOCOL AGREEMENTS BY PHARMACISTS

Use of Protocol Agreements

In many states, pharmacists who are authorized to administer immunizations must do so under a written protocol agreement signed and dated by a licensed physician. Some states require jointly adopted rules by state medical and pharmacy boards to permit "authorized" pharmacists to administer selected vaccines to specified age groups via protocol under supervision of a physician. These joint rules specify what physicians must do to adequately supervise an authorized pharmacist, what the pharmacist must do to be authorized, and what the protocol must address. State regulations stipulate whether a physician is required to issue a written or verbal patient-specific prescription order for a particular vaccine administration, and whether a physician can prescribe vaccines for a group of patients via a non-patient-specific vaccine order contained in the protocol agreement. The vaccine protocol agreement includes a definitive set of treatment guidelines established by the physician and contains directives and provisions for immediate consultation between the pharmacist and the physician.

Use of Standing Orders

Standing orders authorize nurses, pharmacists, and other nonphysician healthcare personnel, where allowed by state law, to assess an individual's immunization status and administer vaccines according to the process approved by an institution, physician, or other authorized practitioner. Standing orders are typically institution-based, while vaccine orders in protocol agreements are used outside of institutions. Such procedures enable assessment and vaccination without the need for examination or direct order from the attending physician at the time of the interaction.

While standing orders have been shown to be an effective tool for increasing access to immunization services,[53,54] less than half of primary care physicians reported using standing orders for adult influenza vaccinations.[55] This was attributed to lack of awareness of recommendations and regulations for the use of these procedures and of evidence for the effectiveness of standing orders in improving vaccination rates. A recent national survey of pharmacists indicated that the main sources of vaccine protocols or standing orders were corporate physicians who are employed by an entity via contract or as consultants (33%), family physicians (29%), internal medicine physicians (21%), and public health departments (9%).[43]

STATE REGULATIONS FOR TYPES OF VACCINES ALLOWED FOR PHARMACIST ADMINISTRATION AND AGE RESTRICTIONS

All 50 states and the District of Columbia (DC) authorize pharmacies to administer vaccines at some level; variations exist regarding the type of vaccines that can be administered by pharmacists and the age of eligible individuals to whom pharmacists can administer vaccines.[56] All states and DC require that pharmacists who administer vaccines have and maintain specific education and training in the provision of immunization services. The AMA Advocacy Resource Center (ARC) maintains 50 state surveys that provide detailed information on the state laws and regulations that govern pharmacist immunization practice. These surveys are on file with the ARC and are available upon request by contacting arc@ama-assn.org.

Most states and DC allow pharmacists to administer any vaccine or a broad subset of vaccines recommended by the ACIP for adults and/or children through various processes. All states and DC allow pharmacists to administer the influenza vaccine. Most states and DC also allow pharmacists

to administer the zoster, pneumococcal, Td/Tdap, and HPV vaccines. The allowable age of individuals that pharmacists are authorized to vaccinate are outlined within the state statute or regulations:

- 19 states and DC allow pharmacists to vaccinate individuals of any age.
- 9 states allow pharmacists to administer vaccines only to individual 18 years of age or older.
- 22 states allow pharmacists to administer certain vaccines to individuals under the age of 18 (allowable age levels range from 3 years of age and older to 14 years of age and older).

Depending on the antigen or age of the patient, most states and DC require a prescription, protocol, standing order, consent of parent or guardian, or a combination of these factors prior to a pharmacist being authorized to administer vaccines. As of July 2014, 13 states allow pharmacists to administer some or all ACIP-recommended vaccines without a physician protocol or prescription for specified ages (see Table).

In the event of a declared public health emergency, which necessitates the rapid immunization of the population to respond to an infectious disease threat, states can authorize pharmacists to administer specified vaccines for the duration of the emergency declaration. Five states (Arizona, Kentucky, New Jersey, New York, Oregon) either reduce the age restriction or expand the types of vaccines that pharmacists can administer during public health emergencies.

VACCINE SAFETY

Vaccines, like other medications, are not without risk. Despite a credible body of scientific evidence supporting the safety and effectiveness of vaccines,[57-60] unsubstantiated concerns continue to be raised about possible associations between various vaccines and health conditions (e.g., MMR vaccine and autism).[61-63] While most people who are vaccinated suffer no effects or minor side effects, severe allergic reactions or other medical problems sometimes occur. A patient history of severe systemic hypersensitivity reactions (including anaphylaxis) to egg protein, gelatin, neomycin, or streptomycin are contraindications for vaccines that contain these products.[64]

To prevent serious adverse reactions to vaccines, vaccine providers should adhere to all quality standards for safe immunization.[64] This includes following standard precautions to prevent transmission of infection during immunization, such as proper hand hygiene prior to vaccination. Safety devices for vaccine administration should be used for safe disposal of needles and syringes. All vaccine providers should screen individuals for contraindications and precautions before administering a vaccine dose, and should be trained to manage adverse reactions that might occur. All vaccine providers should have procedures in place and be prepared for emergency care of an individual who experiences an anaphylactic reaction. Epinephrine and equipment for maintaining an airway should be available for immediate use. All vaccine providers should be familiar with the facility emergency plan and should be certified in basic life support and cardiopulmonary resuscitation.

Live Vaccines

Live attenuated vaccines may cause severe reactions or even death as a result of uncontrolled replication of the vaccine virus in patients with immunodeficiencies (e.g., from leukemia, treatment with immunosuppressive drugs, or infection with human immunodeficiency virus). Commonly administered live attenuated viral vaccines include measles, mumps, rubella, varicella, zoster, rotavirus, and influenza (intranasal). Oral polio vaccine is a live viral vaccine but is no longer available in the United States. Live attenuated bacterial vaccines are bacille Calmette-Guérin

(which is not currently available in the United States) and oral typhoid and cholera vaccines. However, since the theoretical possibility of fetal injury exists, live vaccines should not be administered routinely to women known to be pregnant. Live attenuated vaccines need to be refrigerated or frozen to maintain potency.[65] Appropriate vaccine storage, handling, and monitoring systems need to be in place for all vaccines. Manufacturer protocols, found in the manufacturer's product information and package inserts, should be referred to for specific and detailed information about storage and handling of specific vaccines.

Vaccine Adverse Event Reporting System

The National Childhood Vaccine Injury Act of 1986 requires health care providers and manufacturers to report any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine, or any adverse event listed in the Vaccine Adverse Event Reporting System (VAERS) "Table of Reportable Events Following Vaccination," which occurs within the specified time period after vaccination.[66] In addition to mandated reporting, health care providers are encouraged to report any clinically significant adverse event following vaccination. VAERS, which is administered jointly by the CDC and the Food and Drug Administration, is the spontaneous reporting system used to monitor vaccine safety. VAERS accepts reports of adverse events after vaccination from vaccine manufacturers, health care providers, vaccine recipients, and others.

During an 11-year surveillance period (1991-2001), VAERS received 128,717 reports, whereas more than 1.9 billion net doses of human vaccines were distributed.[67] Overall, the most commonly reported adverse event was fever, which appeared in 25.8% of all reports, followed by injection-site hypersensitivity (15.8%), rash (unspecified) (11.0%), injection-site edema (10.8%), and vasodilatation (10.8%). Serious adverse events were described in approximately 14% of all reports, which by regulatory definition include death, life-threatening illness, hospitalization or prolongation of hospitalization, or permanent disability. Considering that 1.9 billion doses of vaccines were distributed during this 10-year reporting period, the likelihood of any adverse event could be extrapolated at well below one percent. No evidence exists that the occurrence of adverse events differs based on whether the vaccine was administered in a physician or nonphysician setting.

VAERS generally cannot assess whether a vaccination caused an adverse event, but can identify possible vaccine safety problems for further investigation. Findings in VAERS need to be interpreted with caution. VAERS is prone to both over- and under-reporting (stimulated reporting has been observed following publicity around a potential adverse event).[68] Additionally, the information in VAERS reports can be incomplete or inconsistent in quality. VAERS does not collect data on the number of vaccinated individuals; therefore, rates and relative risks cannot be calculated. Although VAERS data must be interpreted with these limitations in mind, VAERS is a valuable system for detecting potential vaccine safety concerns or "signals" which can then be investigated in other epidemiological studies.[68]

INFORMATION EXCHANGE AND RECORDKEEPING

While surveys demonstrate that primary care physicians are generally accepting of the increased access that adults and adolescents now have to vaccination outside of the medical home, communication between alternate vaccine providers and primary care physicians is suboptimal. This problem extends to physicians in other medical specialties, who also do not always communicate vaccination information back to the primary care physician.[25] Communication and

coordination of care between primary care physicians and other vaccine providers (including physicians in other medical specialties) is an ongoing challenge.[25, 33-36, 38]

Current reporting practice for pharmacist administration of vaccines typically involves the pharmacy sending a fax or letter to the physician's office.[69] However, such practice may not always occur or be effective; in many cases, additional administrative work is required to transcribe the information into the patient record. Pharmacists may have to call or fax the physician or office staff with patient-related questions or prescription clarifications, which is impractical in a busy pharmacy or within the primary care office work flow. These interruptive, indirect, and relayed methods of exchanging patient health information are subject to misinterpretation, miscommunication, and inefficiencies that can affect vaccination delivery and patient safety.

Role of Vaccine Registries

Many recordkeeping tasks, as well as patient reminder/recall activities, can be simplified by participation in a population-based immunization information system, also known as an immunization registry.[70] Immunization registries are confidential, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geographic area (e.g., state). The Task Force on Community Preventive Services recommends immunization registries on the basis of strong evidence of effectiveness in increasing vaccination rates.[71] Specifically, the Task Force concluded that registries are directly related to increasing vaccination rates through their capabilities to create or support effective interventions such as client reminder/recall systems, provider assessment and feedback, and provider reminders. Registries also can be used to generate and evaluate public health responses to outbreaks of vaccine-preventable disease; facilitate vaccine management and accountability; determine patient vaccination status for decisions made by clinicians, health departments, and schools; and aid surveillance and investigations on vaccination rates, missed vaccination opportunities, invalid dose administration, and disparities in vaccination status. AMA Policy H-440.899 "Immunization Registries" encourages physicians to participate in the development of immunization registries in their communities and to use immunization registries in their practices.

Vaccine providers should understand how to access immunization registries as a source to check for vaccines that a patient has received or should receive.[70] The NVAC recommends that a record of receipt of vaccination be placed in the patient's electronic health record and that information be placed in immunization registries when available.[11] In addition, primary care providers should be informed of any vaccines given to their patients by alternative providers, and all patients should receive a written or electronic record of administered vaccines.

In 2012, 54 of 56 CDC immunization program grantees (representing 50 states, five cities, and the District of Columbia) reported that 86% of U.S. children under the age of six and 54% of adolescents between 11 and 17 years of age participated in an immunization registry.[72,73] While 53 of the registries are capable of recording vaccination data across the lifespan, adult participation remains low at 25%.[72] According to the CDC, challenges to increase adult participation in immunization registries include: (1) identifying and enrolling the diverse providers that serve adults; (2) a lack of adult immunization reporting mandates in many grantees' jurisdictions; and (3) competing priorities for state and local immunization programs. A national survey of general internal medicine and family physicians suggests that physician awareness and use of registries for adult vaccinations is limited.[25] Internists and family physicians reported that they rely on immunization registries 25% and 44% of the time, respectively, to assess whether their patients were vaccinated by alternate providers. However, only 8% of internists and 36% of family

physicians reported that they recorded adult vaccination information in a state or regional immunization registry.

A recent survey of pharmacy practice sites indicated that 55% of sites screen patients for needed vaccines; 91% reported that their practice sites maintained documentation of individuals receiving vaccinations in the pharmacy; 69% provided individuals with a copy of their consent form; and 53% entered the vaccination into the individual's medical record.[43] In addition, 63% of survey respondents reported that they provide documentation of an individual's vaccinations directly to a primary care physician. Overall, 35% of respondents entered an individual's vaccination data into an immunization registry; 11% indicated that they were not permitted to access state and local immunization registries.

CONCLUSION

Health care settings beyond the traditional medical home currently have an important role in the provision of vaccines, especially for adolescents and adults who do not receive primary care medical services through conventional venues. Improving immunization rates and reducing vaccine preventable illness across the lifespan requires a collaborative approach that engages physicians, public health agencies, and other community health care professionals, such as pharmacists, in identifying approaches that are most readily applicable to their communities. In the United States, the use of nonphysician (or complementary) vaccine delivery settings is most critical for vaccinating adult patients; however, even for the administration of pediatric vaccines, complementary settings may be needed to reach populations that have poor access to primary care. Collaboration should be pursued with pharmacists and other community health care professionals to educate patients about the importance of the medical home, as well as to coordinate efforts to improve vaccination rates and meet quality metrics and desired processes for communication. An essential step toward creating a more effective immunization infrastructure and improving national vaccination rates is to improve integration and data sharing of immunization efforts in physician and nonphysician settings.

Under the Affordable Care Act, millions of newly insured Americans will gain access to medical care services, which places increased demand on the current primary care workforce. The existing shortage or maldistribution of primary care physicians, exacerbated by this influx of newly insured Americans, underscores a real need to engage other health professionals who can administer vaccines safely and effectively, as well as expand where those vaccines are administered. For some individuals, the use of alternative settings, such as pharmacies, work sites, and school-based clinics, are an effective means for immunization delivery. More research is needed on immunization services provided in physician and nonphysician settings to assess patient preferences and reasons for receiving vaccines in these settings. Data characterizing individuals who do not receive vaccines and their reasons for not getting vaccinated also are needed. More research is needed to address the effectiveness of immunization programs in pharmacies and other nonphysician settings toward improving immunization rates. Results of such research can help clarify specific health system-based activities that may contribute most to improving patient and population immunization rates and the challenges that must be overcome to achieve success. Ongoing surveillance also is warranted to monitor the safety and quality of immunization services delivered in physician and nonphysician settings.

Pharmacists in all states are authorized to provide immunization services in accordance with state regulations. Differences exist among the states with respect to the age of people who can be immunized by a pharmacist, which vaccines can be provided, and the requirement for physician protocol agreements, prescriptions, or standing orders. All states require that pharmacists who

administer vaccines have and maintain specific education and training in the provision of immunization services. Such requirements should be based on ACIP recommendations and recognized standards and guidelines derived with input from physicians and pharmacists who have demonstrated expertise in this field. While pharmacists should support the importance of immunizations across the lifespan and share consistent messages about vaccine safety for all ages and populations, the primary mode of vaccine delivery for pediatric patients, and for adult patients with chronic disease and co-morbidities, should be the medical home to ensure coordination of care. Important components of quality care that impact vaccine administration in pharmacies include ability to screen individuals for needed vaccines, ability to handle adverse reactions, notification of the primary care physician or health department when vaccines are administered, provision of physician referral services, and providing education regarding other key preventive health measures. When vaccines are administered in pharmacies, the information should be transmitted back to the individual's medical home and documented in the electronic health record and immunization registry (when one exists) so that a complete vaccination record is maintained.

It is important to monitor current trends in vaccine administration to ensure that services do not become fragmented and place patients at risk. Mechanisms should be developed and implemented to ensure that communication and record sharing are optimized between pharmacists and primary care physicians. Important factors regarding recordkeeping include how to determine which individuals are in need of vaccines and how to prevent inappropriate revaccination. Federal, state, and local public health agencies are continuing efforts to improve immunization registries and to increase participation by physicians and other vaccine providers. Until electronic health records and immunization registries routinely include this information, the primary care physician and/or public health agency should be notified when a vaccine is administered in a pharmacy setting so that immunization records are updated appropriately.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following recommendations be adopted in lieu of Resolution 212-I-12 and that the remainder of the report be filed.

Our American Medical Association believes that:

1. Physicians and medical professional organizations should support state and federal efforts to engage pharmacists in vaccinating target populations that have difficulty accessing immunizations in a medical home. Before administration of a vaccine, pharmacists should assess the immunization status of the patient, which includes checking an immunization registry when one exists. Pharmacists should ensure that a record of vaccine administration is transmitted to the patient's primary care physician and documented in the immunization registry, and that written or electronic documentation is provided to the patient. (New HOD Policy)

2. Vaccination programs in pharmacies should promote the importance of having a medical home to ensure appropriate and comprehensive preventive care, early diagnosis, and optimal therapy. Physicians and pharmacists should work together in the community to: (a) establish referral systems to facilitate appropriate medical care if the patient's conditions or symptoms are beyond the scope of services provided by the pharmacies; and (b) encourage patients to contact a primary care physician to ensure continuity of care. (New HOD Policy)

3. State educational requirements for pharmacists who administer vaccines should be based on ACIP recommendations and recognized standards and guidelines derived with input from physicians and pharmacists with demonstrated expertise in immunization practices. (New HOD Policy)

4. Policy H-440.877, "Distribution and Administration of Vaccines," should be amended by addition and deletion to read as follows:

AMA policy is that:

(1) it is optimal for patients to receive vaccinations in their medical home to ensure coordination of care. This is particularly true for pediatric patients and for adult patients with chronic disease and co-morbidities. If a vaccine is administered outside the medical home, all pertinent vaccine-related information should be transmitted back to the patient's primary care physician and entered into an immunization registry when one exists to provide a complete vaccination record.

(2~~1~~) all physicians and other qualified health care providers who administer vaccines should have fair and equitable access to all ACIP recommended vaccines. However, when there is a vaccine shortage, those physicians and other health care providers immunizing patients who are prioritized to receive the vaccine based upon medical risks/needs according to ~~the~~ ACIP recommendations ~~of the ACIP~~ must be ensured timely access to adequate vaccine supply.

(3) physicians and other qualified health care providers should: (a) incorporate immunization needs into clinical encounters, as appropriate; (b) strongly recommend needed vaccines to their patients in accordance with ACIP recommendations and consistent with professional guidelines; (c) either administer vaccines directly or refer patients to another qualified health care provider who can administer vaccines safely and effectively, in accordance with ACIP recommendations and professional guidelines and consistent with state laws; (d) ensure that vaccination administration is documented in the patient medical record and an immunization registry when one exists; and (e) maintain professional competencies in immunization practices, as appropriate.

(~~2~~)(4) all vaccines should be administered by a licensed physician, or by a qualified health care provider ~~under the supervision of a physician~~ pursuant to a prescription, order, or protocol agreement from a physician licensed to practice medicine in the state where the vaccine is to be administered or in a manner otherwise consistent with state law.

(~~3~~5) patients should be provided with documentation of all vaccinations for inclusion in their medical record, particularly when the vaccination is ~~was~~ provided by someone other than the patient's primary care physician ~~provide~~r.

(6) physicians and other qualified health care providers who administer vaccines should seek to use integrated and interoperable systems, including electronic health records and immunization registries, to facilitate access to accurate and complete immunization data and to improve information-sharing among all vaccine providers.

~~(4)~~(7) ~~our AMA will work with~~ vaccine manufacturers, medical specialty societies, electronic medical record vendors, and immunization information systems should ~~to~~ apply

uniform bar-coding on vaccines based on standards promulgated by the medical community. (Modify HOD Policy).

5. That Policy H-440.899, "Immunization Registries," should be amended by addition to read as follows:

Our AMA encourages:

(1) physicians to participate in the development of immunization registries in their communities and use them in their practices for patients of all ages;~~.~~

(2) electronic health record (EHR) vendors to add features to automate the exchange of vaccination information in the patient EHR to state immunization registries to improve and help ensure completeness and accuracy of vaccination records. EHR vendors and registry administrators need to work with physicians and other health professionals to facilitate the exchange of needed vaccination information by establishing seamless, bidirectional communication capabilities for physicians, other vaccine providers, and immunization registries; and

(3) all states to move rapidly to provide comprehensive lifespan immunization registries that are interfaced with other state registries. (Modify HOD Policy)

6. That Policy H-160.921, "Store-Based Health Clinics," should be reaffirmed. (Reaffirm HOD Policy).

Fiscal Note: Less than $500

Table. States Allowing Pharmacists to Administer Vaccines without a Physician Protocol or Prescription (but in alignment with ACIP Recommendations)[†]

State	Provision
Arizona	Allows pharmacists to administer all ACIP-recommended vaccines to adults without a prescription order in compliance with rules and protocols adopted by the state pharmacy board; influenza vaccine can be administered to individuals 6 years of age and older.
California	Allows pharmacists to administer all vaccines for individuals 3 years of age and older according to ACIP recommendations and practice guidances without a physician-specific protocol or prescription.
Idaho	Allows pharmacists to administer all vaccines to a healthy individual 12 years of age and older without immunization contraindications pursuant to the latest recommendations by the CDC or other qualified government authority or to any individual 12 years of age and older pursuant to a prescription drug order issued by another prescriber.
Louisiana	Allows pharmacists to administer vaccine to individuals 17 years of age and older without a patient-specific prescription or medical order if "the vaccine is administered in conformance with the most current immunization administration protocol as set forth by the ACIP." Pharmacists must inform the vaccine recipient that the administration of the vaccine is not to be construed as being in lieu of an annual checkup with the individual's primary care physician.
Maine	Allows pharmacists to administer the influenza vaccine to individuals 9 years of age and older without a physician prescription or protocol.
Maryland	Allows pharmacists to provide influenza vaccine without a prescription to individuals 9 years of age and older without a physician prescription or protocol.
Montana	Allows pharmacists to administer the influenza, pneumococcal, Tdap, and zoster vaccines to specified ages without a physician specific protocol or prescription, and other vaccines pursuant to a physician protocol or prescription.
New Hampshire	Allows pharmacists to administer influenza, pneumococcal, and zoster vaccines without a physican prescription or protocol.
New Mexico	Allows pharmacists to administer all ACIP-recommended vaccines in accordance to a protocol filed with the state.
Oregon	Allows pharmacists to administer all vaccines in accordance to protocols issued by the state health authority.
Virginia	Allows a pharmacist to administer influenza vaccine to minors (6 months and older) who do not present a prescription, when acting in accordance with guidelines developed by the Virginia Department of Health.
West Virginia	Allows pharmacists to administer all ACIP-recommended vaccines to individuals 18 years of age and older in accordance with ACIP guidelines.
Wyoming	Allows pharmacists to administer all vaccines for healthy adults and influenza vaccine for individuals 7 years of age and older without a physician-specific protocol or prescription.

[†] Source: Personnel communication. Mitchel C. Rothholz, RPh, MBA, American Pharmacists Association, June 10, 2014 and Rebecca Snead, RPh, National Alliance of State Pharmacy Associations, June 11, 2014. The AMA Advocacy Resource Center (ARC) maintains 50-state surveys that provide detailed information on the state laws and regulations that govern pharmacist immunization practice. These surveys are on file with the ARC and are available upon request by contacting arc@ama-assn.org.

APPENDIX

Summary of 2013 National Vaccine Advisory Committee's Standards for Adult Immunization Practices[11]

The National Vaccine Advisory Committee (NVAC) was established in 1987 to advise and make recommendations to the Assistant Secretary for Health, who is the designated director of the National Vaccine Program. The NVAC recommends strategies to achieve optimal prevention of human infectious diseases through vaccine development, and provides direction to prevent adverse reactions to vaccines.

All providers should:

- Incorporate immunization needs assessment into every clinical encounter.
- Strongly recommend needed vaccine(s) and either administer vaccine(s) or refer patient to a provider who can immunize.
- Stay up-to-date on, and educate patients about, vaccine recommendations.
- Implement systems to incorporate vaccine assessment into routine clinical care.
- Understand how to access immunization information systems (i.e., immunization registries).

Immunizing providers should:

- Ensure professional competencies in immunizations.
- Assess immunization status in every patient care and counseling encounter and strongly recommend needed vaccine(s).
- Ensure that receipt of vaccination is documented in patient medical record and immunization registry.

Non-immunizing providers should:

- Routinely assess the immunization status of patients, recommend needed vaccine(s), and refer patient to an immunizing provider.
- Establish referral relationships with immunizing providers
- Follow up to confirm patient receipt of recommended vaccine(s).

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