Walgreens
There's a way

March 28, 2012

Re: Pharmacists – Administration of Vaccinations – Expanded Authority HB 817

**Dear Chairwoman Harhart, Chairman Readshaw, Members of the House Professional Licensure Committee:**

I am Al Carter with the Pharmacy Services Division of Walgreens. I am also a certified immunizing pharmacist and I thank you for the opportunity to express my support of HB 817.

Walgreens Co. (Walgreens) operates over 7,800 drugstores in 50 states, the District of Columbia and Puerto Rico. Walgreens operates approximately 119 retail pharmacies in Pennsylvania to help meet the healthcare needs of the citizens of the Commonwealth. We have locations in both urban and rural areas of the state.

Walgreens is committed to promoting public health by improving the accessibility of vaccines. To meet the goal of increasing access to care and affordability for consumers, Walgreens' pharmacists administer vaccines to patients in pharmacies in 49 states, including Pennsylvania, at any time the pharmacy is open. This vital public health service increases immunization rates in the community. For example, flu vaccination rates increase up to 5% for those under 65 and over 10% for seniors[1] when pharmacists are allowed to administer vaccination. In Pennsylvania, Walgreens pharmacists alone administered over 67,000 vaccinations in 2011. Over 52,000 of those were for the flu.

As the Committee is aware, the law in Pennsylvania allows for pharmacists to administer the full Centers for Disease Control and Prevention (CDC) approved vaccines to patients 18 and older without a prescription. While current law is a step in the right direction, it unduly restricts access to vaccination for residents of the state under the age of 18. Sixteen states already allow for pharmacists to administer all Centers for Disease Control and Prevention (CDC) approved vaccines with certain age limitations. This national trend is one that the Commonwealth should promote and allow. As noted earlier, data has shown that states that have expanded immunization authority to pharmacists see an increase in vaccination rates.

Walgreens pharmacists are trained to be able to administer any vaccine to patients aged three years and above. Walgreens pharmacists go through either the "Pharmacy-Based Immunization Delivery" certificate training program by the American Pharmacists Association and recognized by the CDC, or a state approved equivalent program. In addition to immunization training, all participating pharmacists are required to become certified in adult and child CPR and take OSHA blood-borne pathogens training.

Not only are Walgreens pharmacists trained and able to administer vaccines to improve public health, they greatly increase access to care for many patients. Walgreens employs nationally, over 27,000 pharmacist immunizers, 415 in Pennsylvania, who can provide vaccines at anytime to patients. With over 70% of Americans living within 5 miles of a Walgreens, and 85% of African-Americans and 86% of Latino-Americans living within 5 miles of a Walgreens, the access that Walgreens pharmacists provide for the community should be leveraged by the state. Furthermore,

[1] Steyer TE, et al. The role of pharmacists in the delivery of influenza vaccinations. Vaccine. 2004; 22: 1001-6.

pharmacist immunizations increase accessibility to vaccines for Americans living in Medically Underserved Area (MUAs) and Health Professional Shortage Areas (HPSAs), with over a third of the flu vaccine being administered by pharmacists in these areas[2]. In essence, pharmacists' ability to immunize makes the number of those immunized greater, not less.

In addition, research has shown that every $1 spent on immunizations saves $6.30 in direct costs (i.e hospitalizations). This amounts to annual aggregate direct cost savings of $10.5 billion. When indirect costs (i.e. lost wages) are taken into account, every $1 spent on immunizations saves $18.40, resulting in aggregate savings of $42 billion[3]. Therefore, we know that vaccinating a population saves healthcare dollars but moreover, providing vaccines in a pharmacy setting, saves the patient and the healthcare system even more.

Walgreens automatically sends Physician Notification Letters (PNL) for all vaccines (excluding Vivotif as we only dispense this with a prescription) to the patient's primary care physician (PCP) within 48 hours of administration via one of three methods: email, fax, or mail. A blank PNL is attached for your reference. Just this week, at the 2012 National Immunization Conference, my company presented the results of an in-depth internal analysis of all vaccinations administered from August of 2010 through July of 2011. Of the many important items in the presentation, a few are very relevant to the discussion here today. Namely, a large proportion of community pharmacy patients receive vaccinations during evening, weekend, and holiday hours when traditional vaccine providers are unavailable. In fact, of those aged 18-64 years, nearly a third received vaccinations during off-clinic hours, potentially minimizing disruptions in work schedules and ultimately decreasing illness and absenteeism, while increasing presenteeism.

In June of 2011, the Official Journal of the American Academy of Pediatrics released their study entitled, "How Effectively Can Health Care Settings Beyond the Traditional Medical Home Provide Vaccines to Adolescents?" The study cited that as long ago as 1994, the Federal Department of Health and Human Services made a recommendation that, "pharmacists' competencies include vaccine education and mobilization, vaccine distribution, vaccine access and administration, and participation in vaccine registries and tracking systems." The study went on to say that "the number and distribution of pharmacies throughout the nation make them a unique resource. Pharmacies are readily accessible to and frequently visited by adolescents. Many of them have extended hours on evenings and weekends, and they are a particularly important source of health care in rural communities." Clearly, the need exists for pharmacies to be included in the network of health care providers that may administer vaccination to adolescents. It is important to note that Walgreens company policy, as well as this bill, forbids the administration of vaccine to patients under the age of 18 without the consent of a parent or legal guardian.

We at Walgreens believe in providing the best care to our patients and improving public health. As such, Walgreens supports a less-restrictive environment for vaccinations by pharmacists. I respectfully ask that you move HB 817 out of the Committee.

Many thanks to Rep. Grove for sponsoring this bill and to Representatives Harhart and Readshaw and the committee members for the opportunity to testify today.

Al Carter
Pharmacy Services
Walgreen Co.

[2] Murphy, PA, et al (in press). Access to preventative health: The impact of a community pharmacy on influenza immunizations. Journal of American Pharmacists Association, 2012.

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

# How Effectively Can Health Care Settings Beyond the Traditional Medical Home Provide Vaccines to Adolescents?

Stanley J. Schaffer, John Fontanesi, Donna Rickert, John D. Grabenstein, Mitchel C. Rothholz, Susan A. Wang and Daniel Fishbein

*Pediatrics* 2008;121;S35
DOI: 10.1542/peds.2007-1115E

SUPPLEMENT ARTICLE

# How Effectively Can Health Care Settings Beyond the Traditional Medical Home Provide Vaccines to Adolescents?

**Stanley J. Schaffer, MD, MS[a], John Fontanesi, MEd, PhD[b], Donna Rickert, MA, PhD[c]†, John D. Grabenstein, PhD[d], Mitchel C. Rothholz, RPh, MBA[e], Susan A. Wang, MD, MPH[f], Daniel Fishbein, MD[c], for the Working Group on Complementary Settings**

[a]Department of Pediatrics, University of Rochester School of Medicine and Dentistry, Rochester, New York; [b]Center for Management Science in Health, University of California School of Medicine, San Diego, California; [c]National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; [d]US Army Medical Command, Military Vaccine Agency, Falls Church, Virginia; [e]American Pharmacists Association, Washington, DC; [f]National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

Financial Disclosure: Dr Grabenstein is now employed by Merck. The other authors have indicated they have no financial relationships relevant to this article to disclose.

## ABSTRACT

OBJECTIVES. Our goal was to evaluate the capacity of various health care settings to supplement the activities of the traditional medical home by delivering vaccines to adolescents.

METHODS. A group of experts in the fields of adolescent-immunization delivery and the provision of preventive care in various health care settings summarized the available literature, considered setting-specific factors, and assessed the ability of various health care settings beyond the traditional medical home to conform to the immunization quality standards set by the National Vaccine Advisory Committee, report vaccination information for the quantitative assessment of vaccine-coverage rates, be likely to offer vaccines to adolescents, and be viewed by adolescents as acceptable sites for receiving vaccinations.

RESULTS. Seven candidate settings were evaluated: pharmacies, obstetrics-gynecology practices, sexually transmitted disease clinics, hospital emergency departments, family planning clinics, teen clinics, and local public health department immunization clinics. The panel concluded that all could safely provide vaccinations to adolescents but that vaccination efforts at some of the settings could potentially have a markedly greater impact on overall adolescent-immunization rates than could those at other settings. In addition, for adolescent-vaccination services to be practical, candidate settings need to have a clear interest in providing them. Conditional on that, several issues need to be addressed: (1) funding; (2) orienting facilities to provide preventive care services; (3) enhancing access to immunization registries; and (4) clarifying issues related to immunization consent.

CONCLUSIONS. With supporting health policy, health education, and communication, health care settings beyond the traditional medical home have the potential to effectively augment the vaccination efforts of more traditional settings to deliver vaccines to adolescents. These health care settings may be particularly well suited to reach adolescents who lack access to traditional sources of preventive medical care or receive fragmented medical care.

www.pediatrics.org/cgi/doi/10.1542/peds.2007-1115E

doi:10.1542/peds.2007-1115E

†Deceased.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the funding agency.

Dr Fishbein's current affiliation is National Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA.

Dr Grabenstein's current affiliation is Merck Vaccine Division, West Point, PA.

**Key Words**
adolescent vaccination, settings

**Abbreviations**
STD—sexually transmitted disease
CDC—Centers for Disease Control and Prevention
Ob-Gyn—obstetrics-gynecology
NVAC—National Vaccine Advisory Committee
ACOG—American College of Obstetricians and Gynecologists
ACEP—American College of Emergency Physicians
VFC—Vaccines for Children

Accepted for publication Aug 22, 2007

Address correspondence to Stanley J. Schaffer, MD, MS, Division of General Pediatrics, University of Rochester Medical Center, 601 Elmwood Ave, Box 777, Rochester, NY 14642. E-mail: stanley_schaffer@urmc.rochester.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275). 

THE SUCCESSFUL INTRODUCTION of a new adolescent vaccine (such as the recently recommended meningococcal conjugate, pertussis, and human papillomavirus vaccines[1–3]), requires careful consideration of a range of issues including, but not limited to, the capacity of health care systems to achieve high coverage levels and adolescent health care utilization patterns. Although many adolescents obtain some medical care from a primary care physician, significant proportions of them, especially in mid- or late

adolescence, infrequently (or never) seek preventive care services from traditional sources.[4–6] Hence, high overall immunization coverage rates can potentially be achieved by complementing the efforts of primary care physicians with efforts to deliver vaccines in other health care settings that adolescents tend to frequent. Efforts to vaccinate adolescents in those settings may be of particular benefit for subpopulations who lack access to a medical home or segment their medical care. However, the ability to implement adolescent-immunization services in these settings has not been studied adequately.

One key to success will be the ability of the medical home and other health care settings to successfully coordinate their efforts. A vaccine such as the human papillomavirus vaccine that prevents sexually transmitted diseases (STDs) is best administered in early to mid-adolescence, before the initiation of sexual activity; hence, that is when administration of this vaccine is recommended. Other vaccines are recommended for early adolescence, in part to promote the use of routine preventive care services.[7] Although young adolescents may be more likely to strengthen their relationship with a pediatric or family practice medical home, in part as a result of the new vaccine recommendations, the need to administer several vaccines to adolescents nevertheless represents a major challenge for providers, particularly for multidose vaccines. In addition, older adolescents will need catch-up vaccination, which increases the number of adolescents who must be served in the near term. Thus, to achieve uniformly high adolescent-immunization rates, the combined efforts of the medical home and other health care settings and providers are likely to be necessary.

The Institute of Medicine recognizes that current systems of medical care are not meeting the complex needs of the US adolescent population and has called for the development of innovative programs for the achievement of better health outcomes.[8] Can other health care settings plausibly supplement the adolescent-vaccination efforts of the traditional medical home? The National Immunization Program (now a part of the National Center for Immunization and Respiratory Diseases) of the Centers for Disease Control and Prevention (CDC) convened a working group of individuals with expertise in immunization research and adolescent health care to address this question. This report summarizes the group's findings about what is presently known and what has yet to be determined about the ability of such settings to function as effective providers of vaccines to adolescents.

## METHODS

The working group established successive agendas, identified the candidate health care settings to be considered, defined terms, assigned individual scientific review and evaluation tasks, and assessed the results of the reviews over a 4-month period from February through May of 2005. The candidate health care settings were defined as sites that tend to offer services in nontraditional settings or offer limited or episodic health care services, in contrast to the coordinated, comprehensive services offered in the traditional medical home. The settings selected for evaluation were (1) pharmacies, (2) obstetrics-gynecology (Ob-Gyn) practices, (3) STD clinics, (4) hospital emergency departments, (5) family planning clinics, (6) teen clinics, and (7) public health department immunization clinics. School-based and school-linked clinics were not included, because they represented the exclusive focus of a separate working group. In addition, walk-in clinics located inside retail businesses were not addressed, because they are a new phenomenon for which there is insufficient information with which to permit an evaluation of their potential effect on adolescent-immunization efforts.

Key components of this evaluation included comparative assessments of the candidate settings in terms of their:

- capacity to meet the 7 quality standards established by the National Vaccine Advisory Committee (NVAC) to

**TABLE 1 NVAC Quality Standards**

| Quality Standard | Description |
|---|---|
| Information and education for vaccine recipients | Culturally and linguistically appropriate information about the risks and benefits of vaccination (including CDC-developed Vaccine Information Statements) must be provided before vaccination |
| Vaccine storage and handling | Must adhere to vaccine-handling and -storage standards noted in vaccine package inserts |
| Prevaccination screening | Prevaccination screening interviews must include immunization history, existing health conditions, allergies, and history of adverse events |
| Contraindications | Must have the ability to assess true vaccine contraindications before vaccination |
| Record keeping | A permanent record including the vaccine recipient's name, age, contact information, preexisting medical conditions, type of vaccine given, dose, site, route of administration, name of vaccine provider, date of vaccination, manufacturer, lot number, and date that next vaccination is due must be recorded; when a vaccine is administered by a health care provider other than the vaccine recipient's primary care provider, a record of the vaccination should be provided to the primary care provider and the vaccine recipient |
| Vaccine administration | Must have the legal authority to provide vaccines and be appropriately trained and licensed in all aspects of vaccine administration |
| Adverse events | Must be able to recognize and treat adverse reactions, and the equipment to do so must be on site |

ensure the quality of vaccination in these settings (described in detail in Table 1)*;

- previous experience with providing adolescent vaccines, alignment of adolescent-vaccination efforts with the primary mission of each setting, resource issues, and likelihood that decision-makers in each setting would elect to have the facility provide some or all of the vaccines to adolescents;
- overall client mix and the characteristics of adolescents receiving services in each setting, including sociodemographic features, frequency and continuity of contact in these settings, and acceptability and attractiveness of these settings as resources for the receipt of preventive health services;
- capacity to report or refer clients to a primary care physician, to provide educational materials about the importance of other preventive health care measures, and to recover or sustain the additional costs of adolescent-immunization services; and
- capacity to report vaccine-related adverse events and contribute data to assist in community assessments of adolescent vaccine-coverage rates.

A subjective matrix that summarizes these key components and provides a structure for comparing the candidate sites was developed and is shown in Table 2.

In many cases, the working group found a dearth of published data concerning the experience of the candidate settings in providing vaccines to adolescents. In those instances, the working group had to depend on as-yet-unpublished data or base its conclusions on information related to the settings' experiences in providing vaccinations to adult populations. It should be noted that these settings' experiences with vaccinating adult populations are not always applicable to the adolescent population, particularly with respect to adolescent-specific issues (eg, securing parental consent for vaccination) that are not faced by facilities when providing vaccinations to adult populations.

A draft of the initial findings was presented in June 2005 at the National Stakeholders' Meeting: Strengthening the Delivery of New Vaccines for Adolescents, a national conference in Washington, DC, cosponsored by the National Vaccine Program Office and the CDC, during which participants were invited to submit comments. Those comments were evaluated and incorporated as appropriate. The findings presented here summarize what is presently known and not known about the ability and capacity of health care settings beyond the medical home to provide immunizations to adolescents; barriers that might impede efforts to provide immunizations in these settings are also identified.

## RESULTS

### Pharmacies

Increased recognition of the role of pharmacies in population-based vaccination services is reflected in the Department of Health and Human Services' 1994 recommendation, made in a meeting with Secretary Shalala, that pharmacists' competencies include vaccine education and mobilization, vaccine distribution, vaccine access and administration, and participation in vaccine registries and tracking systems. In 1996, the American Pharmacists Association published *Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists*, which was based on CDC, Advisory Committee on Immunization Practices, and NVAC standards.[10,11] The program includes practice-management skills and vaccine-administration techniques and teaches pharmacists the functions and responsibilities associated with providing vaccination services.[12] According to the American Pharmacists Association, the program has been used to train ~25 000 student pharmacists and professionals as of 2006. A study published in 2004 indicated that 77% of pharmacists who completed the certification program directly administered vaccines, of whom 96% administered influenza vaccine, 77% administered pneumococcal vaccine, 55% administered hepatitis vaccines, and 19% administered the combined childhood diphtheria and tetanus toxoids and acellular pertussis vaccine.[13]

Pharmacists' commitment to providing vaccine services was demonstrated in recent surveys of pharmacists who had completed vaccination training. Respondents reported that they had done so because of their commitment to improving the health of the public rather than for business or financial reasons or for continuing education credit.[13–15] Various published studies have also shown that most consumers trust pharmacy vaccination services and are attracted to this type of setting because of the convenience that pharmacies offer their customers.[16,17] These findings are consistent with a recent review that concluded that pharmacist-administered vaccination, particularly for adult patients, has become routinely accepted as an important role of the pharmacist.[15] Nevertheless, to date, there is little experience with administration of vaccines to adolescents in the pharmacy setting.

The number and distribution of pharmacies throughout the nation make them a unique resource. Pharmacies are readily accessible to and frequently visited by adolescents. Many of them have extended hours on evenings and weekends, and they are a particularly important source of health care in rural communities.[18]

At present, 46 states grant pharmacists statutory permission to administer vaccinations[19]; most such efforts in the past have centered on the provision of influenza vaccine. Although a few states have not yet authorized pharmacists to administer vaccines, explicit statements from public health authorities that encourage immunization-trained pharmacists to take proactive roles in immunization delivery would likely prompt these states to support increased pharmacist involvement in this aspect of public health.

### Ob-Gyn Practices

Obstetrician-gynecologists have unique opportunities to deliver vaccines to women of all ages. They serve as the first and most frequent point of contact for young women who seek medical consultation for reproductive

**TABLE 2 Characteristics of Candidate Settings That May Affect Their Ability to Provide Vaccines to Adolescents**

| | Pharmacies | Ob/Gyn Practices | STD Clinics | Hospital Emergency Departments | Family Planning Clinics | Teen Clinics | Health Department Immunization Clinics |
|---|---|---|---|---|---|---|---|
| Capacity to meet NVAC quality standards | | | | | | | |
| Provide information and education for vaccine recipients | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform |
| Vaccine storage and handling | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform |
| Prevaccination screening | May have limited access to vaccination records | May have limited access to vaccination records | May have limited access to vaccination records | May have limited access to vaccination records | May have limited access to vaccination records | May have limited access to vaccination records | May have limited access to vaccination records |
| Evaluation of contraindications | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform |
| Record keeping | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform |
| Vaccine administration | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform |
| Recognition and management of adverse events | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform | Able to perform |
| Likely interest in providing vaccines to adolescents | High | High for vaccines to prevent STDs | High for vaccines to prevent STDs | May be limited | High for vaccines to prevent STDs | High for all adolescent vaccines | High for all adolescent vaccines |
| Orientation toward providing preventive care services | Limited but increasing | Yes, but often limited to reproductive care | Generally not oriented toward providing many preventive care services | Generally not oriented toward providing many preventive care services | Yes, but often limited to reproductive care | Yes | Yes, but limited to immunizations |
| Demographic characteristics | | | | | | | |
| Age range of clientele | All ages | ≥16 y | ≥16 y | All ages | ≥16 y | ≥13 y | All ages |
| Gender distribution of clientele | Males and females | Females | Primarily symptomatic males | Males and females | Females | Males and females | Males and females |
| Logistic characteristics | | | | | | | |
| Approximate number of sites | 58 000 | 32 000 | 2900 | 2000 | 3150 | 300 | 3000 |
| Frequency/continuity of contacts with clients | Moderate to High | Moderate | Limited | Limited | Moderate | Moderate | Limited to vaccination visits |
| Case management/tracking capabilities | Not routine | Routine | Routine | Not routine | Not routine | Routine | Routine |
| Perceived acceptability as a vaccination site by adolescents | Unknown | High | High | Unknown | High | High | High |
| Link to immunization-information system | May be limited | May be limited | May be limited | May be limited | May be limited | Most participate | Most participate |
| Ability to contact the medical home | Yes | Yes | Yes, but may be limited by privacy concerns | Yes | Yes, but may be limited by privacy concerns | Yes | Yes |
| Specific vaccination training | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Legal constraints on provision of vaccines in setting | Allowed in all but 4 states, some state-specific limitations exist based on age and antigen | None | None | None | None | None | None |
| Parental consent required? | In most states | In most states | In most states | In most states | In most states | In most states | In most states |
| Ability to be reimbursed by insurers for vaccine purchase and administration and to obtain vaccines from the VFC program | Able to bill insurers; are not currently able to be VFC providers in most states | Able to bill insurers; few are currently VFC providers | Able to bill insurers; few are currently VFC providers | Ability to bill insurers may vary; may not be reimbursed for providing preventive care services; few are currently VFC providers | Able to bill insurers; few are currently VFC providers | Able to bill insurers and obtain vaccine from the VFC program | Able to bill insurers and obtain vaccine from the VFC program |

health and as primary caregivers for many nonpregnant women who have little or no other contact with the health care system.[20] The vast majority of obstetrician-gynecologists serve both adolescents and adults.[20] Although few adolescents under 15 years of age see obstetrician-gynecologists,[5] one third of all medical visits for women aged 17 to 21 years are to obstetrician-gynecologists.[21] Indeed, obstetrician-gynecologists provide more office-based, general medical examinations to women aged ≥15 years than either family practice or internal medicine specialists.[22] Most young women who see obstetrician-gynecologists are or have been sexually active.

Nationwide, 64% of obstetrician-gynecologists have reported that they work in practices that offer at least 1 vaccine, with rubella (52%) and influenza (50%) vaccines being the most commonly offered, followed by hepatitis B vaccine (35%) and tetanus toxoid-diphtheria vaccine (32%).[20] Yet, fewer than 60% of obstetrician-gynecologists report that they routinely obtain patient vaccination or infection histories. Barriers that have been commonly noted by obstetrician-gynecologists who do not vaccinate their patients include the costs associated with vaccination (44%), the belief that vaccinations should be provided by other primary care providers (41%), and lack of adequate vaccine-storage and -handling facilities (32%).[20] Nevertheless, studies have shown that most obstetrician-gynecologists feel that the provision of vaccines should be within the scope of their responsibilities.[21] As noted previously, human papillomavirus vaccine and vaccines that are currently being developed to prevent other sexually transmitted infections primarily target early and middle adolescents before sexual debut. In contrast, obstetrician-gynecologists see relatively few women before mid- to late adolescence[5] and, thus, have relatively few opportunities to vaccinate women before the initiation of sexual activity.

Studies have demonstrated interesting patterns associated with the administration of vaccine in Ob-Gyn practices. One survey noted a wide range in knowledge level among obstetrician-gynecologists regarding vaccine-preventable diseases, immunization recommendations, and vaccine safety.[21] In another recent survey of obstetrician-gynecologists, provision of vaccines was associated with working in a multispecialty practice and identifying oneself as a primary care provider.[20] Almost all of the respondents indicated a willingness to administer vaccines to adult women to prevent human papillomavirus–associated cervical cancer and infections caused by genital herpes simplex virus (92% and 91%, respectively). Recommendations from the American College of Obstetricians and Gynecologists (ACOG) were viewed as the strongest determinant of practice-specific decisions on the use of newly licensed vaccines. Although vaccination has not traditionally been stressed by obstetrician-gynecologists,[20] >90% of respondents felt that the ACOG should make the development of educational tools related to vaccination of obstetrician-gynecologists' patients a priority, which suggests a willingness among obstetrician-gynecologists to integrate immunization more formally into their routine practice guidelines.[20] Hence, support from the ACOG will be key in determining whether more obstetrician-gynecologists adopt immunization services as part of their routine scope of care and offer vaccinations to adolescents.

### STD Clinics

STD clinics serve a high-risk population that tends to be poor, relatively young, male, and uninsured. Although most have access to primary care, their clients commonly seek STD-clinic services because of the availability of walk-in services, low cost of care, privacy or confidentiality concerns, convenience, or the expertise of STD-clinic providers in treating sexually transmitted infections.[23] In response to recommendations from the Advisory Committee on Immunization Practices, the Institute of Medicine, and the CDC, many STD clinics have successfully implemented hepatitis B immunization programs,[24–29] which suggests that such clinics may represent an effective capture point at which some adolescents at high risk might also be able to receive vaccinations to prevent other sexually transmitted infections such as human papillomavirus.[24,30,31] However, some of the difficulties encountered in efforts to institute hepatitis B vaccination in STD clinics may also apply to other vaccination initiatives that may be proposed for these settings. Studies have found that approximately half of STD program managers nationally do not view hepatitis B vaccination as a project responsibility.[24,29] Major barriers that have prevented some STD clinics from instituting hepatitis B vaccination programs include lack of adequate funding for procurement of vaccines and inadequate resources to implement effective vaccination efforts.[24] In addition, in typical underfunded and understaffed STD clinics, prevention strategies that require personal counseling or injections may be relegated to secondary status.[32] Other specific issues encountered with hepatitis B vaccination efforts in STD clinics include difficulty tracking clients who are highly mobile and who value anonymity,[24,32] variable rates of completion of the immunization series,[24,32] and relatively low vaccine acceptance rates.[32,33]

There are several challenges related to the potential provision of new vaccines to adolescents through STD clinics. As the range of vaccines recommended for adolescents increases, it is hard to know whether many STD clinics will consider providing vaccines to prevent conditions other than sexually transmitted infections or whether they will limit their efforts to vaccines such as hepatitis B and human papillomavirus vaccines that prevent diseases commonly acquired by sexual contact. The ~2-to-1 male/female ratio among STD-clinic clients[23] limits the number of individuals receiving services at STD clinics who could directly benefit from the human papillomavirus vaccine. In addition, although STD clinics see young adults and some older adolescents,[23] they are unlikely to have much contact with the young adolescents who are the primary target group for most adolescent-immunization efforts. Funding sources and vaccine-procurement efforts also must be ensured for vaccination efforts to be successful in STD clinics. Finally, STD clinics serve a small, defined population,[23]

which limits the potential impact of vaccination efforts in this setting on overall adolescent-immunization rates. Nevertheless, despite these considerations, STD clinics can play an important role in efforts to vaccinate the particularly high-risk group of adolescents that they serve.[34] As such, they should not be overlooked as comprehensive strategies are developed to vaccinate as many adolescents as possible.

### Hospital Emergency Departments

In 1995, the American College of Emergency Physicians (ACEP) published a policy statement recognizing that underimmunization of children is a serious problem in the United States and that populations at greatest risk, including the urban poor and racial and ethnic minorities, often use emergency departments as their principal source of primary care.[35] A subsequent study has noted that 5% of all adolescents nationally and 7% of nonwhite adolescents report that emergency departments are their only source of medical care.[36] Adolescents are particularly likely to use emergency departments for episodic medical care,[37–39] and the vaccine they currently are most likely to receive there is the tetanus-diphtheria toxoid booster.[40] For other vaccines, emergency departments usually refer adolescents to primary care providers.

Although the 1995 ACEP policy statement and its 2000 revision encouraged an active role by emergency department personnel in childhood vaccination efforts (including awareness of currently recommended immunization recommendations, screening of immunization status, education of parents, referral of patients with deficient immunizations, and administration of vaccinations in certain circumstances),[35,41,42] the ACEP has not published specific policy recommendations concerning the vaccination of adolescents in emergency departments. Furthermore, the potential for large-scale routine provision of adolescent vaccinations in emergency departments has not been systematically evaluated but would most likely not be cost-effective from an institutional perspective. Because emergency departments are generally not reimbursed for the provision of preventive care services, vaccine-purchase costs incurred by emergency departments and administration fees associated with vaccination would not necessarily be reimbursed by all insurers. As a result, emergency departments would have to absorb or shift vaccine costs for some patients. Furthermore, although emergency departments may enroll in the federal Vaccines for Children (VFC) program, administration costs related to providing vaccines in emergency departments are believed to significantly exceed VFC reimbursement levels for vaccine administration.[42] In addition, unreimbursed personnel time and decreased operating efficiencies that result from provision of vaccinations would constitute opportunity costs for emergency departments that consider broad vaccination initiatives.

Although emergency departments are able to participate in adolescent-vaccination programs, their core mission of providing acute care is inconsistent with the routine provision of preventive health services. Although some pilot studies have demonstrated the efficacy of vaccinating hard-to-reach populations in emergency departments,[43–45] the impact of those efforts has been questioned because of a lack of sustained programmatic success. In addition, a limited ability to ascertain adolescents' immunization status in the emergency department and a general reluctance of parents to allow their children to be vaccinated during emergency department visits, especially if immunization records are not readily available, continue to be barriers that hinder efforts to provide vaccinations there.[46,47] Hence, it is unlikely that the routine administration of vaccines to adolescents in emergency departments will soon become a widespread practice or will have a substantial impact on adolescent-immunization rates. Nevertheless, because emergency departments provide services to large numbers of adolescents who do not routinely receive preventive care elsewhere,[36] their potential to contribute to adolescent-vaccination efforts should be explored further. With more widespread access to immunization-information systems, adequate reimbursement, and potential support from the ACEP, efforts to provide routine vaccinations to some adolescents during emergency department visits may eventually become more feasible.

### Family Planning Clinics

Approximately 3100 Title X and other family planning clinics provide gynecologic care and contraceptive management to US adolescents and adults, often focusing on economically disadvantaged and high-risk populations. They primarily serve young women who seek confidential family planning services.[48] Nationally, the population of clients of family planning clinics is 61% non-Hispanic white, 19% black, 14% Hispanic, and 7% Asian or of another race.[49] Overall, 30% of all women served at family planning clinics are younger than 20 years. Minority and economically disadvantaged patients are more likely to receive services at family planning clinics that are run by hospitals, public health departments, and community or migrant health centers than at independent or Planned Parenthood facilities.[48–50] Many family planning clinics are located in rural communities and serve otherwise hard-to-reach patient populations.

Family planning clinics' orientation toward serving young, economically disadvantaged women and those who do not have easy access to other sources of care could potentially contribute significantly to vaccination efforts among these populations of adolescents. Moreover, many family planning clinics have successfully implemented previous recommendations to provide hepatitis B vaccinations to their adolescent and high-risk adult clients.[51–53] Such efforts are likely to serve as a model for them if they expand their efforts to immunize adolescents and young women by providing other vaccines as well. Furthermore, the human papillomavirus vaccine may be particularly well suited to be provided to women who obtain care in this setting, because it is licensed for administration to women up to age 26 and the timing of vaccination can be coordinated with their regular return visits for Depo-Provera injections or oral contraceptive refills. However, there are some potential

challenges associated with efforts to immunize adolescents in family planning clinics. As is also the case with Ob-Gyn practices, almost all women who receive services at family planning clinics are sexually active, which makes it unlikely that family planning clinics would be able to vaccinate many adolescents before their sexual debut. Patients' confidentiality concerns may dissuade family planning clinics from notifying their clients' primary care physicians that they have provided vaccinations.[48,50] Requirements for parental consent or notification before vaccination may also be a barrier. In addition, family planning clinics may not be inclined to be a setting for the provision of vaccines to prevent conditions other than those that are specifically associated with sexually-transmitted infections. Nevertheless, family planning clinics can certainly contribute to adolescent-immunization efforts, particularly in rural areas and for adolescents who are unlikely to receive preventive health care services elsewhere.

### Teen Clinics

Teen clinics are facilities that provide services exclusively to adolescents. They are usually staffed by community health centers, local health departments, hospitals, managed care organizations, or nonprofit agencies. Most teen clinics receive some federal funding. The majority of their vaccine supplies come from the VFC program. Many operate as drop-in clinics that neither require clients to make appointments nor require that they have an established relationship with the facility. A survey in 1 community found that 15% of urban youth received services at a teen clinic, with higher percentages found among older adolescents than younger adolescents.[54] Nationally, the proportion of adolescents who use teen clinics is unknown. However, 24% of US adolescents usually obtain primary care services from some sort of health center or clinic[36]; of these, presumably many are seen in teen clinics.

Teen clinics predominantly serve economically disadvantaged and uninsured teens who choose to receive medical services there because of convenience of scheduling and location, ease of access, low cost, the desirability of receiving services at a facility that is exclusively oriented to teens, or the perceived expertise of clinic staff or who seek assurance of confidentiality (particularly around the onset of sexual activity).[55–59] Although some adolescents consider a teen clinic to be their medical home, others maintain a medical home elsewhere and only use the teen clinic on an episodic basis.[54,59]

Almost all teen clinics offer adolescents the hepatitis B vaccine.[52,53] They are likely to also offer most of the other vaccines that have recently been recommended for adolescents. Although teen clinics have been very successful in their vaccination efforts, they have reported that their most significant difficulties are in (1) getting their patients to complete vaccination series that require multiple injections and (2) frequent unavailability of up-to-date immunization records.[52,53] These hurdles are not specific to teen clinics and have not prevented many of them from successfully offering vaccinations. Thus, teen clinics are likely to remain important venues for adolescent vaccination as the number of vaccines recommended for adolescents increases.

### Public Health Department Immunization Clinics

Vaccination is a shared responsibility between private providers, publicly funded clinics, and public health departments.[60] Currently, health departments continue to play an important role in vaccine-related efforts, particularly as a safety-net provider of immunizations for those who cannot afford the cost of vaccinations or do not have an established medical home.[61–63] Ninety-eight percent of health departments continue to provide adolescent-vaccination services.[64] In addition, health departments help coordinate efforts to immunize hard-to-reach populations and improve community-wide immunization rates.

Fifty-six percent of public health department immunization clinics use tracking and recall systems, and 38% use vaccination reminder systems.[65] Fifty-five percent have reported using medical charts to store vaccination histories, and 83% store vaccination information in an electronic database.[65] However, only 5% of clinics routinely communicate vaccination activities to primary care providers.[65]

As a result of shifting responsibilities and funding sources, the role of community health department immunization programs has changed from one of the traditional "vaccinator of choice" to that of "safety-net provider." This role is likely to continue with the advent of new adolescent vaccines.

## COMPLIANCE WITH THE NVAC QUALITY STANDARDS

Table 2 describes the ability of candidate health care settings outside the traditional medical home to comply with the 7 NVAC quality standards (which are described in detail in Table 1). Each of the candidate settings evaluated has a basic capacity to meet these standards, although the extent to which they do so varies.

## CHALLENGES AND BARRIERS TO PROVIDING VACCINATIONS TO ADOLESCENTS

Table 2 also summarizes how site capacity and other constraints may affect the ability of the various settings to provide vaccinations to adolescents. Of particular importance is that sites have an orientation toward the provision of preventive care services to adolescents and demonstrate a willingness to assume responsibility for providing routine immunizations to adolescents. These 2 crucial attributes will affect the contribution that health care settings outside the traditional medical home can make to adolescent-immunization efforts.

## EXPECTED HEALTH OUTCOMES

Additional study will be required to determine how consistently each site is able to meet the 7 NVAC quality standards. It should be noted that sites' organizational imperatives may not be consistent with, or may even conflict with, core competencies (eg, confidentiality constraints may conflict with data-sharing needs, and an

emphasis on treating acute conditions may conflict with an emphasis on providing preventive care).

Implicit in efforts to offer adolescents a host of new vaccines in a variety of settings is the requirement for information sharing among health care professionals. Electronic immunization-information systems (registries) that are widely accessible are crucial if these efforts are to be successful. At present, ~85% of CDC-funded immunization-information systems include adolescents (D. Bartlett, MPH, personal communication, CDC, April 13, 2006). However, relatively few health care facilities outside the traditional medical home report that they have access to immunization-information systems.[52,53] This is especially likely to be the case for those health facilities (eg, Ob-Gyn offices, STD clinics, and family planning clinics) that primarily serve an adult population. Now that data specifications for immunization-information systems have been defined,[66] future efforts should focus on enrollment and participation of providers working in health care settings beyond the traditional medical home.

In addition to the provision of vaccine, the capability of health care settings beyond the traditional medical home to collect and report data regarding vaccine-coverage rates and vaccine-related adverse events must be examined. Successful data-collection efforts depend not only on a site's capability and willingness to collect and report data but also on the ability of the local public health department to collect and analyze them. As has occurred with community-based immunization-information systems, collaboration is facilitated by clearly defined business rules that define what type of data are to be shared, who shares the data and with whom, and the preferred data-exchange format. Each of the candidate sites examined has the capacity to provide data, but not all of them are equally capable of providing the many types of information of interest.

Another variable that must be considered when determining the potential to deliver vaccines at each site is cost. The average unit cost for delivering adolescent vaccinations can be calculated for each specific delivery setting by analyzing standard workflow and using econometric methods. Pharmacies and public health clinics are already engaging in this process. Costs for patients will affect vaccination uptake. Although some sites participate in the VFC program, expanding VFC participation to additional facilities is a crucial component if efforts to vaccinate adolescents are to be successful.

Some have expressed concern 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.[67] However, there is limited evidence that adolescents forego preventive health care services provided in primary care settings if they receive vaccinations elsewhere.[68] The risks and benefits must be weighed. Data from the 2003 National Survey of Children's Health indicate that ~60% of adolescents do not receive care from a medical home.[69] Thus, it is likely that many of the adolescents who seek services in the settings described in this article cannot identify a primary care provider[36] and, thus, would be unlikely to receive vaccinations elsewhere, whereas others who have primary care physicians seek care outside the traditional medical home out of convenience or because they want the assurance of confidentiality.[57–59] Minorities, immigrants, and persons who engage in high-risk behaviors are particularly likely to use health care settings outside the traditional medical home[58,59,69]; these groups would benefit from having vaccination services available in such settings. In addition, many adolescents use more than 1 site of care[59]; making vaccinations available to these patients at various sites could significantly increase the likelihood that they will be vaccinated. The key to such an approach is ready access to vaccination records through the expansion of immunization-information systems to include all adolescents by increasing the participation of providers outside of the traditional medical home.

Statutory requirements that necessitate parental consent for adolescents' receipt of preventive care services and immunizations diminish the ability of adolescents to receive vaccines outside of the traditional medical home.[70] Adolescents who seek medical care in such settings often are unaccompanied by a parent or guardian. Although states generally allow adolescents to consent to receive confidential reproductive care, few states have statutes that specifically allow adolescents to provide their own consent for routine preventive medical care services or vaccinations.[71] Most states' laws do not explicitly determine if vaccines to prevent sexually transmitted infections fall under parental consent rules or would be exempt from those rules; hence, this remains a gray area. In addition, federal law requires that a parent or legal guardian be provided with an approved vaccine-information statement before vaccines can be given to unemancipated minors. These factors limit the extent to which vaccines can be provided to adolescents who seek confidential medical care and should be addressed if widespread adolescent-vaccination efforts are to succeed.

## CONCLUSIONS

Each type of setting evaluated in this article has strengths and weaknesses with regard to its ability to deliver vaccines to adolescents. Some serve hard-to-reach groups of individuals at high risk, whereas others serve those who seek specialized or confidential services. In addition, many adolescents obtain medical care in more than 1 type of setting.[58,59] Hence, an approach that provides easy access to immunization records and allows adolescents to be vaccinated in multiple settings would be beneficial if high immunization rates are to be achieved in this population. Because conditions and patterns of health care utilization vary geographically and according to community characteristics, local health authorities should consider the following factors when evaluating how best to provide vaccines to adolescents in their communities:

1. demographic characteristics of the community and local patterns of health care utilization;
2. availability and utilization of health care settings outside of the traditional medical home;
3. ability of vaccination sites to meet NVAC practice standards;
4. volume capacity of each site;
5. extent of participation in immunization-information systems; and
6. whether the provision of immunizations corresponds with the core mission of potential sites.

In most communities, immunization-delivery systems that combine the resources of the traditional medical home and other health care settings are necessary to achieve optimal adolescent-immunization rates. A collaborative approach that enlists public health departments and community providers representing all of these settings would benefit local adolescent-immunization efforts by identifying approaches that would most readily be applicable to specific communities.

Health care settings beyond the traditional medical home have an important role to play in the provision of vaccines to adolescents, especially for those who are unlikely to receive primary care medical services through conventional venues. Although several challenges exist, these health care settings can serve a pivotal and complementary role in ensuring that all adolescents receive recommended vaccinations.


## ACKNOWLEDGMENTS

We acknowledge the contributions of Duane Kilgus, Nicole Liddon, and Mark Sawyer to the work of the Complementary Settings Working Group. This article is dedicated to the memory of our colleague and friend, Donna Rickert, MA, PhD.


## REFERENCES


1. Bilukha OO, Rosenstein N; National Center for Infectious Diseases, Centers for Disease Control and Prevention. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2005;54(RR-7):1–21
2. Broder KR, Cortese MM, Iskander JK, et al. Preventing tetanus, diphtheria, and pertussis among adolescents: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines—recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2006;55(RR-3):1–34
3. Markowitz LE, Dunne EF, Saraiya M, Lawson HW, Chesson H, Unger ER. Quadrivalent human papillomavirus vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2007;56(RR-2):1–24
4. Rickert D, Deladisma A, Hussain Y, Averhoff F, Brink E, Shih S. Adolescent immunizations: are we ready for a new wave? *Am J Prev Med.* 2004;26:22–28
5. Rand CM, Shone LP, Albertin C, Auinger P, Klein JD, Szilagyi P. National health care visit patterns of adolescents: implications for delivery of new adolescent vaccines. *Arch Pediatr Adolesc Med.* 2007;161:252–259
6. Albertin CS, Rand CM, Fryer GE, Shone LP, Schaffer SJ, Szilagyi PG. Adolescent healthcare utilization across the U.S.: who may be reached for immunization [abstract]. E-PAS2006: 59:2747.4. Presented at 2006 Annual Meeting of the Pediatric Academic Societies, San Francisco, CA, April 29–May 2, 2006
7. Centers for Disease Control and Prevention. Immunization of adolescents: recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association. *MMWR Recomm Rep.* 1996;45(RR-13): 1–16
8. Institute of Medicine. *Vaccines for the 21st Century: A Tool for Decisionmaking.* Washington, DC: National Academy Press; 2000
9. Postema AS, Breiman RF; National Vaccine Advisory Committee. Adult immunization programs in nontraditional settings: quality standards and guidance for program evaluation. *MMWR Recomm Rep.* 2000;49(RR-1):1–29
10. Grabenstein JD. Pharmacists and immunization: increasing involvement over a century. *Pharm Hist.* 1999;41:137–152
11. Hogue MD, Foster SL, eds. *Pharmacy-Based Immunization Delivery: A National Certificate Program for Pharmacists.* 9th ed. Washington, DC: American Pharmacists Association; 2004
12. APhA promotes pharmacists' role. *Am Pharm.* 1994;NS34: 71–72
13. Neuhauser MM, Wiley D, Simpson L, Garey KW. Involvement of immunization-certified pharmacists with immunization activities. *Ann Pharmacother.* 2004;38:226–231
14. Grabenstein JD, Guess HA, Hartzema AG, Koch GG, Konrad TR. Attitudinal factors among adult prescription recipients associated with choice of where to be vaccinated. *J Clin Epidemiol.* 2002;55:279–284
15. Hogue MD, Grabenstein JD, Foster SL, Rothholz MC. Pharmacist involvement with immunizations: a decade of professional advancement [published correction appears in *J Am Pharm Assoc (Wash DC).* 2006;46:308]. *J Am Pharm Assoc (Wash DC).* 2002;46:168–179; quiz 179–182
16. Ndiaye SM, Madhavan S, Washington ML, et al. The use of pharmacy immunization services in rural communities. *Public Health.* 2003;117(2):88–97
17. Grabenstein JD, Guess HA, Hartzema AG, Koch GG, Konrad TR. Effect of vaccination by community pharmacists among adult prescription recipients. *Med Care.* 2001;39:340–348
18. Ernst ME, Chalstrom CV, Currie JD, Sorofman B. Implementation of a community pharmacy-based influenza vaccination program. *J Am Pharm Assoc (Wash DC).* 1997;37:570–580
19. Immunization Action Coalition. States authorizing pharmacists to vaccinate. Available at: www.immunize.org/laws/pharm.htm. Accessed August 9, 2007
20. Schrag SJD, Fiore AE, Gonik B, et al. Vaccination and perinatal infection prevention practices among obstetrician-gynecologists. *Obstet Gynecol.* 2003;101:704–710
21. Gonik B, Jones T, Contreras D, Fasano N, Roberts C. The obstetrician-gynecologist's role in vaccine-preventable diseases and immunization. *Obstet Gynecol.* 2000;96:81–84
22. Leader S, Perales PJ. Provision of primary-preventive healthcare services by obstetrician-gynecologists. *Obstet Gynecol.* 1995; 85:391–395
23. Celum CL, Bolan G, Krone M, et al. Patients attending STD clinics in an evolving health care environment: demographics, insurance coverage, preferences for STD services, and STD morbidity. *Sex Transm Dis.* 1997;24:599–605
24. Wilson BC, Moyer L, Schmid G, et al. Hepatitis B vaccination in sexually transmitted disease (STD) clinics: a survey of STD programs. *Sex Transm Dis.* 2001;28:148–152
25. Centers for Disease Control and Prevention. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through childhood vaccination—recommenda-

tions of the Immunization Practices Advisory Committee (ACIP). *MMWR Recomm Rep.* 1991;40(RR-13):1–25
26. Centers for Disease Control and Prevention. Update: recommendations to prevent hepatitis B virus transmission: United States. *MMWR Morb Mortal Wkly Rep.* 1995;44:574–575
27. Institute of Medicine. *The Hidden Epidemic: Confronting Sexually Transmitted Diseases.* Washington, DC: National Academy Press; 1997
28. Centers for Disease Control and Prevention. 1998 guidelines for treatment of sexually transmitted diseases. *MMWR Recomm Rep.* 1998;47(RR-1):1–118
29. Gilbert LK, Bulger J, Scanlon K, Ford K, Bergmire-Sweat D, Weinbaum C. Integrating hepatitis B prevention into sexually transmitted disease services: U.S. sexually transmitted disease program and clinical trends—1997 and 2001. *Sex Transm Dis.* 2005;32:346–350
30. Klausner JD, Shaw H, Williams-Taki D, Taylor F, Bolan G. The changing epidemiology of hepatitis B vaccination follow-up compliance in patients at San Francisco City STD clinic, 1995–1996 [abstract]. Presented at: the 31st National Immunization Conference; May 19–May 22, 1997; Detroit, MI. Abstract 62
31. Weinstock HS, Bolan G, Moran JS, Peterman TA, Polish L, Reingold AL. Hepatitis B vaccination trials in sexually transmitted disease clinics: implications for program development [abstract]. *Program and Abstracts of the 26th National Immunization Conference Proceedings.* June 1–5, 1992; St. Louis, MO; 1992: 107–109
32. Handsfield HH. Hepatitis A and B immunization in persons being evaluated for sexually transmitted diseases. *Am J Med.* 2005;118:69S–74S
33. Samoff E, Dunn A, VanDevanter N, Blank S, Weisfuse I. Predictors of acceptance of hepatitis B vaccination in an urban sexually transmitted disease clinic. *Sex Transm Dis.* 2004;31: 415–420
34. Centers for Disease Control and Prevention. Hepatitis B vaccination among high-risk adolescents and adults: San Diego, California 1998–2001. *MMWR Morb Mortal Wkly Rep.* 2002;51: 618–621
35. American College of Emergency Physicians. Policy statement: immunization of the pediatric patient. *Ann Emerg Med.* 1995; 26:403–404
36. Klein JD, Wilson KM, McNulty M, Kapphahn C, Collins KS. Access to medical care for adolescents: results from the 1997 Commonwealth Fund Survey of Health of Adolescent Girls. *J Adolesc Health.* 1999;25:120–130
37. McCaig L, Burt CW. National Ambulatory Medical Care Survey: 2001 emergency department summary. *Adv Data.* 2003;(335):1–29
38. Ziv A, Boulet JR, Slap GB. Emergency department utilization by adolescents in the United States. *Pediatrics.* 1998;101: 987–994
39. Wood DL, Hayward RA, Corey CR, Freeman HE, Shapiro MF. Access to medical care for children and adolescents in the United States. *Pediatrics.* 1990;86:666–673
40. Pallin DJ, Muennig PA, Emond JA, Kim S, Camargo CA Jr. Vaccination practices in U.S. emergency departments, 1992–2000. *Vaccine.* 2005;23:1048–1052
41. American College of Emergency Physicians. Policy statement: immunization of pediatric patients. Available at: www3.acep.org/practres.aspx?id=29520. Accessed July 30, 2007
42. Robinson PF, Gausche M, Gerardi MJ, et al. Immunization of the pediatric patient in the emergency department. *Ann Emerg Med.* 1996;28:334–341
43. Cunningham SJ. Providing immunizations in a pediatric emergency department: underimmunization rates and parental acceptance. *Pediatr Emerg Care.* 1999;15:255–259
44. Pappano D, Humiston S, Goepp J. Efficacy of a pediatric emergency department-based influenza vaccination program. *Arch Pediatr Adolesc Med.* 2004;158:1077–1083
45. Slobodkin D, Kitlas J, Zielske P. Opportunities not missed: systematic influenza and pneumococcal immunization in a public inner-city emergency department. *Vaccine.* 1998;16: 1795–1802
46. Rodewald LE, Szilagyi PG, Humiston SG, et al. Effect of emergency department immunizations on immunization rates and subsequent primary care visits. *Arch Pediatr Adolesc Med.* 1996; 150:1271–1276
47. Callahan JM, Reed D, Meguid V, Wojcik S, Reed K. Utility of an immunization registry in a pediatric emergency department. *Pediatr Emerg Care.* 2004;20:297–301
48. Frost JJ. Family planning clinic services in the United States, 1994 [published correction appears in *Fam Plann Perspect.* 1996; 28:173]. *Fam Plann Perspect.* 1996;29:92–100
49. Frost JJ. Public or private providers? U.S. women's use of reproductive health services. *Fam Plann Perspect.* 2001;33:4–12
50. Frost JJ, Bolzan M. The provision of public-sector services by family planning agencies in 1995. *Fam Plann Perspect.* 1997;29: 6–14
51. Slonim AB, Roberto AJ, Downing CR, et al. Adolescents' knowledge, beliefs, and behaviors regarding hepatitis B: insights and implications for programs targeting vaccine-preventable diseases. *J Adolesc Health.* 2005;36:178–186
52. Schaffer SJ, Szilagyi PG, Ambrose S, et al. Hepatitis B vaccine availability in complementary health-care settings [abstract]. *Pediatr Res.* 2004;55:317A. Abstract 1798
53. Schaffer SJ, Szilagyi PG, Ambrose S, et al. Availability of hepatitis B vaccine for high-risk teens [abstract]. Presented at: the 38th National Immunization Conference; May 12, 2004; Nashville, TN. Available at http://cdc.confex.com/cdc/nic2004/techprogram/paper_4938.htm. Accessed December 11, 2006
54. Aten MJ, Siegel DM, Roghmann KJ. Use of health services by urban youth: a school-based survey to assess differences by grade level, gender, and risk behavior. *J Adolesc Health.* 1996; 19:258–266
55. Hedberg VA, Byrd RS, Klein JD, Auinger P, Weitzman M. The role of community health centers in providing preventive care to adolescents. *Arch Pediatr Adolesc Med.* 1996;150:603–608
56. Cheng TL, Savageau JA, Sattler AL, DeWitt TG. Confidentiality in health care: a survey of knowledge, perceptions, and attitudes among high school students. *JAMA.* 1993;269: 1404–1407
57. McKee MD, Karasz A, Weber CM. Health care seeking among urban minority adolescent girls: the crisis at sexual debut. *Ann Fam Med.* 2004;2:549–554
58. Brindis C, Park MJ, Ozer EM, Irwin CE. Adolescents' access to health services and clinical preventive health care: crossing the great divide. *Pediatr Ann.* 2002;31:575–581
59. Klein JD, McNulty M, Flatau CN. Adolescents' access to care. Teenagers' self-reported use of services and perceived access to confidential care. *Arch Pediatr Adolesc Med.* 1998;152: 676–682
60. Santoli JM, Rodewald LE, Maes EF, Battaglia MP, Coronado VG. Vaccines for Children program, United States, 1997 *Pediatrics.* 1999;104(2). Available at: www.pediatrics.org/cgi/content/full/104/2/e15
61. Lieu TA, Smith MD, Newacheck PW, Langthorn D, Venkatesh P, Herradora R. Health insurance and preventive care sources of children at public immunization clinics. *Pediatrics.* 1994;93: 373–378

62. Starfield B. Public health and primary care: a framework for proposed linkages. *Am J Public Health*. 1996;86:1365–1369
63. Santoli JM, Setia S, Rodewald LI, O'Mara D, Gallo B, Brink E. Immunization pockets of need: science and practice. *Am J Prev Med*. 2000;19(3 suppl):89–98
64. Centers for Disease Control and Prevention. Selected characteristics of local health departments: United States, 1992–1993. *MMWR Morb Mortal Wkly Rep*. 1994;43:839–843
65. National Association of County and City Health Officials. *Research Brief: Preliminary Result From the 1997 Profile of U.S. Local Health Departments*. Washington, DC: National Association of County and City Health Officials: 1998
66. Centers for Disease Control and Prevention. IIS: 2001 minimum function standards for immunization registries. Available at: www.cdc.gov/nip/registry/st_terr/tech/stds/min-funct-stds2001.htm. Accessed June 27, 2006
67. Schaffer SJ, Humiston SG, Shone LP, Averhoff AM, Szilagyi PG. Adolescent immunization practices: a national survey of US physicians. *Arch Pediatr Adolesc Med*. 2001;155:566–571
68. Rew L, Resnick M, Beuhring T. Usual sources, patterns of utilization, and foregone health care among Hispanic adolescents. *J Adolesc Health*. 1999;25:407–413
69. US Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau. *The National Survey of Children's Health 2003*. Rockville, Maryland: US Department of Health and Human Services: 2005
70. Farrell RM, Rome ES. Adolescents' access and consent to the human papillomavirus vaccine: a critical aspect for immunization success. *Pediatrics*. 2007;120:434–437
71. Center for Adolescent Health and the Law. *State Minor Consent Laws: A Summary*. 2nd ed. Chapel Hill, NC: Center for Adolescent Health and the Law; 2003

# How Effectively Can Health Care Settings Beyond the Traditional Medical Home Provide Vaccines to Adolescents?

Stanley J. Schaffer, John Fontanesi, Donna Rickert, John D. Grabenstein, Mitchel C. Rothholz, Susan A. Wang and Daniel Fishbein

*Pediatrics* 2008;121;S35
DOI: 10.1542/peds.2007-1115E

Walgreens There's a way to stay well. | take care clinic℠

**Vaccine Administration Record (VAR) Informed Consent for Vaccination For All Health Care Providers***
**PATIENT: COMPLETE SECTIONS A, B, C**

IMMUNIZATION LOCATION

**SECTION A** *Please print clearly.*

Home Phone | Date of Birth | Age | Gender ☐ Male ☐ Female

First Name | MI | Last Name

Home Address | City | State | Zip Code

Email Address | Medicare Part B Number (if applicable)

Primary Care Physician Name (If known) | Physician Phone

Physician Address | City | State

**SECTION B** *The following questions will help us determine your eligibility to be vaccinated today. For All Vaccines: Please answer questions 1-12. For Live Vaccines (e.g. Flu Nasal Spray or Shingles): Please answer questions 1-19.*

| | | YES | NO | DON'T KNOW |
|---|---|---|---|---|
| ALL VACCINES | 1. Which vaccines are you requesting to have administered today? **Please check all requested vaccines:** ☐ **Flu Shot** ☐ **Flu Nasal Spray** (live – ages 2 to 49 only) ☐ **Pneumonia** ☐ **Shingles** ☐ **Other** _____ | | | |
| | 2. Do you feel sick today? | | | |
| | 3. Do you have allergies to medications, food or vaccines? (Examples: Eggs, Bovine Protein, Gelatin, Gentamicin, Polymyxin, Neomycin, Phenol or Thimerosal) **If yes, please list the allergies:** | | | |
| | 4. Have you received any vaccinations in the past 4 weeks? **If yes, please list the vaccination:** | | | |
| | 5. Have you ever had a serious reaction to an influenza vaccine or any other vaccine in the past? | | | |
| | 6. Have you ever had a seizure disorder for which you are on seizure medication(s), a brain disorder, Guillain-Barre Syndrome (a condition that causes paralysis) or other nervous system problem? | | | |
| | 7. Are you 65 years of age or older? | | | |
| | 8. Do you smoke? | | | |
| | 9. Do you have a chronic condition or long term health problem? **If yes, please check all that apply.** ☐ Anemia ☐ Asthma ☐ Diabetes ☐ Heart disease ☐ Kidney disease ☐ Liver disease ☐ Lung disease ☐ Other_____ | | | |
| | 10. If you answered YES to question #7, 8 or 9, have you ever had a pneumonia vaccination? | | | |
| | 11. Are you a health care worker? | | | |
| | 12. For women: Are you pregnant or considering becoming pregnant in the next month? | | | |
| LIVE VACCINES | 13. Do you have cancer, leukemia, lymphoma, HIV/AIDS or any other immune system disorder or are you in contact with anyone who has a severely weakened immune system? | | | |
| | 14. Are you currently on home infusions, weekly injections and/or taking medications such as Remicade®, Enbrel®, Humira® or Kineret®? Please refer to your health care provider if unsure about medication history. | | | |
| | 15. Do you take cortisone, prednisone, other steroids, anticancer drugs or have you had radiation treatments? | | | |
| | 16. Have you received a transfusion of blood or blood products, or been given a medicine called immune (gamma) globulin in the past year? | | | |
| | 17. Are you receiving aspirin therapy or aspirin-containing therapy? (18 years of age and younger only) | | | |
| | 18. If the patient receiving vaccine is under 5 years old, does he/she have a history of asthma or wheezing? (for FluMist® only) | | | |
| | 19. Does the patient have a nasal condition serious enough to make breathing difficult, such as a very stuffy nose? (for FluMist® only) | | | |

**SECTION C**

I certify that I am: (i) the Patient and at least 18 years of age; (ii) the parent or legal guardian of the minor Patient; or (iii) the legal guardian of the Patient. Further, I hereby give my consent to the health care provider of Walgreens or Take Care Health Services, as applicable, to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the Vaccine Information Statements on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering health care provider. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless Walgreens or Take Care Health Services, as applicable, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that: (a) I understand the purposes/benefits of my state's immunization registry ("Registry"); (b) I may, if my state permits, object to Walgreens disclosing my immunization information to the Registry by providing Walgreens with a state approved Registry disclosure opt out form (which I may request and obtain from Walgreens, if permitted by my state); and (c) unless I provide Walgreens with an approved opt out form, I have elected to participate in the Registry and consented to Walgreens reporting my immunization information, I authorize Walgreens or Take Care Health Services, as applicable, to (i) release my medical or other information, including my communicable disease (including HIV), mental health and drug/alcohol abuse information, to my health care professionals, Medicare, Medicaid, or other third party payor as necessary to effectuate care or payment, (ii) submit a claim to my insurer for the above requested items and services, and (iii) request payment of authorized benefits be made on my behalf to Walgreens or Take Care Health Services, as applicable, with respect to the above requested items and services. **I further agree to be fully financially responsible for any co-sharing amounts, including co-pays, coinsurance, and deductibles, for the requested items and services as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if Walgreens or Take Care Health Services invoices me after the time of service, upon receipt of such invoice.**

**Patient Signature:** _____ **Date:** _____
(Parent or Guardian, if minor)

**SECTION D (HEALTH CARE PROVIDERS ONLY)** *The following section is to be completed by the health care provider only.*

Immunizer Name (print): _____ Immunizer Signature: _____ RPh/PharmD/RN/LPN/LVN/NP/PA (circle one)

If applicable, Intern Name (print): _____ Administration Date: _____ Date VIS given to Patient: _____

| Vaccine | Lot # | Exp Date | Manufacturer | Dosage | Circle Site of Injection | VIS Date | Date PNL Sent |
|---|---|---|---|---|---|---|---|
| Inactivated influenza ☐-PF | | | | 0.5 ml | L / R Deltoid IM | 7/26/2011 | |
| Pneumococcal polysaccharide | | | | 0.5 ml | L / R Deltoid IM | | |
| | | | | | | | |

*Health care providers can be an immunization certified pharmacist or a registered nurse, licensed practical nurse, licensed vocational nurse, nurse practitioner or physician's assistant.

**Patient care services at Take Care Clinics are provided by Take Care Health Services℠, an independently owned professional corporation whose licensed healthcare professionals are not employed by or agents of Walgreen Co. or its subsidiaries, including Take Care Health Systems℠, LLC.