

MODULE

7

PROVIDER COMPLIANCE AND MONITORING

Bureau of Immunization-Vaccines for Children Program

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MODULE 7 – Provider Compliance and Monitoring

Introduction

This module gives VFC providers information on the quality assurance requirements, which involve review and evaluation of VFC provider practices. Quality assurance is a legal requirement of the VFC Program implemented through site visits to VFC providers. Outcomes of provider site visits help program staff determine how well the VFC Program is being implemented at the individual provider site level, and individual evaluations assist with improving the overall VFC Program at the state level.

Quality assurance takes place during two types of site visits:

- VFC Provider Site Visits.
- Assessment, Feedback, Incentives, and eXchange (AFIX) Visits.

VFC Provider Site Visits

VFC provider site visits help determine if VFC vaccines are being distributed, handled, and administered in accordance with the laws and policies that govern the VFC Program. The VFC Program is required to conduct site visits to VFC providers in both the public and private healthcare sectors. The purpose of the site visit is to review children's immunization records through the VFC Program and to evaluate the provider's recordkeeping, vaccine handling and storage procedures, and compliance with the requirements of the VFC Program.

A Bureau of Immunization (BOI) field staff representative contacts the provider in advance to schedule the time and date for the site review, and advises the provider as to what the VFC Program expects during the site visit.

The site review will include:

- A. An inspection of VFC vaccine storage and handling practices, including a review of temperature logs and storage unit.
- B. An analysis of stock levels and expiration dates of VFC-supplied vaccines.
- C. A review of records, including vaccine documentation, of manufacturer, lot number, and publication dates of Vaccine Information Statements (VIS), as required by recommendations of the Advisory Committee on Immunization Practices (ACIP) and the National Childhood Vaccine Injury Act (NCVIA).

- D. A review of VFC vaccine accountability practices.
- E. An inspection of a sample of VFC client charts.
- F. A review of clinic policies and practices based on the *Standards for Child and Adolescent Immunization Practices* (see Appendix 7).
- G. The review will include feedback and, as necessary, requesting corrective actions and follow-up of identified problems.

If the practice sees a large number of VFC-eligible children, the reviewer may also conduct an immunization assessment to support the practice in increasing immunization coverage levels.

The following situations necessitate that the VFC Program conduct a VFC site visit more frequently:

- High-volume vaccine usage.
- Unusual ordering patterns.
- Healthcare providers who are outliers with respect to vaccine ordering.
- Reports of vaccine abuse or fraud.
- Medicaid billing inconsistencies.
- Unacceptable storage and handling practices.

Reviewing the findings

Upon completion of the site visit, the BOI field staff representative will discuss the outcomes in a face-to-face meeting with appropriate staff, either at the conclusion of the site visit or soon thereafter. This discussion should include a review of the visit findings and should address any recommended corrective actions for the provider site. The BOI field staff representative and the provider site staff should agree upon, and document in writing, a follow-up plan for addressing any issues of noncompliance or opportunities for improvement.

Within a few weeks following the review, the provider site staff will receive a written report from the BOI documenting the findings, recommendations, and/or corrective actions needed because of the visit. The BOI may ask the provider to respond to this report and describe any steps enacted to address compliance with VFC Program requirements.

Assessment, Feedback, Incentives and eXchange (AFIX)

AFIX includes four components: Assessment of immunization levels, feedback of immunization information to key staff, incentives to motivate and/or recognize outstanding performance, and exchange of information on best practices to improve immunization coverage levels. The goal of AFIX is to ensure that viable vaccines reach all children served by the provider site in accordance with the ACIP schedule. A successful AFIX process requires implementation of all four components.

Standards for Pediatric Immunization Practices

The Centers for Disease Control and Prevention (CDC) developed the *Standards for Child and Adolescent Immunization Practices*, resulting in collaboration with a 35-member working group representing 22 public and private agencies that had input from state and local health departments, physician and nursing organizations, and public and private providers involved in clinical care and prevention health services. The Standards represent the consensus of the National Vaccine Advisory Committee (NVAC) and the working group that address the most essential and desirable immunization policies and practices for an immunization service. *A Guide to Contraindications and Precautions to Immunization*, which reflects the current recommendations of the ACIP, as well as the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP), accompany the Standards.

Several medical and public health organizations have endorsed the Standards. These organizations encourage adherence to the *Standards for Child and Adolescent Immunization Practices* as a key element in our national strategy to administer vaccines more efficiently and effectively to the nation's children.

Providers can print a copy of *the Standards for Child and Adolescent Immunization Practices* from the CDC's website at <http://www.cdc.gov/vaccines/recs/vac-admin/rev-immz-stds.htm>.

The Standards

Ideally, providers should administer immunizations as part of comprehensive child health care. Overall improvement in our primary-care delivery system requires intensive effort and will take time. However, providing effective immunization programs should not depend on changes in this system before vaccinations are delivered more effectively to U.S. children. Current healthcare policies and practices in all settings result in the failure to deliver vaccines on schedule to many vulnerable preschool-age children. This failure is due primarily to barriers that impede vaccine delivery and missed opportunities during clinic visits. Changes in policies and practices can immediately improve coverage. The present system should be geared to "user-friendly", family-centered,

culturally sensitive and comprehensive primary health care that can provide rapid, efficient, and consumer-oriented services to the users, i.e., children and their parents. The failure to do so is evidenced by the recent resurgence of measles and measles-related childhood mortality, which may be a precursor of other vaccine-preventable disease outbreaks.

Adopting these Standards will improve the health and wellbeing of all children and adolescents.

A. Availability of Vaccines

1. Vaccination services are readily available.
2. Vaccinations are coordinated with other healthcare services and provided in a medical home when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

B. Assessment of Vaccination Status

1. Healthcare professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
2. Healthcare professionals assess for and follow only medically indicated contraindications.

C. Effective Communication about Vaccine Benefits and Risks

1. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

D. Proper Storage and Administration of Vaccines and Documentation of Vaccinations

1. Healthcare professionals follow appropriate procedures of vaccine storage and handling.
2. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
3. Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.

4. Healthcare professionals simultaneously administer as many indicated vaccine doses as possible.
5. Vaccination records for the patients are accurate, complete, and easily accessible.
6. Healthcare professionals report adverse events following vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the National Vaccine Injury Compensation Program (NVICP).
7. All personnel who have contact with patients are appropriately vaccinated.

E. Implementation of Strategies to Improve Vaccination Coverage

1. Systems are used to remind parents/guardians, patients, and healthcare professionals when vaccinations are due and to recall those patients who are overdue.
2. Office or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
3. Healthcare professionals practice community-based approaches.

More information on how to implement the Standards and improve child and adolescent immunization coverage is available at the CDC's website at <http://www.cdc.gov/vaccines/recs/vac-admin/rev-immz-stds.htm> or refer to Appendix 7.

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