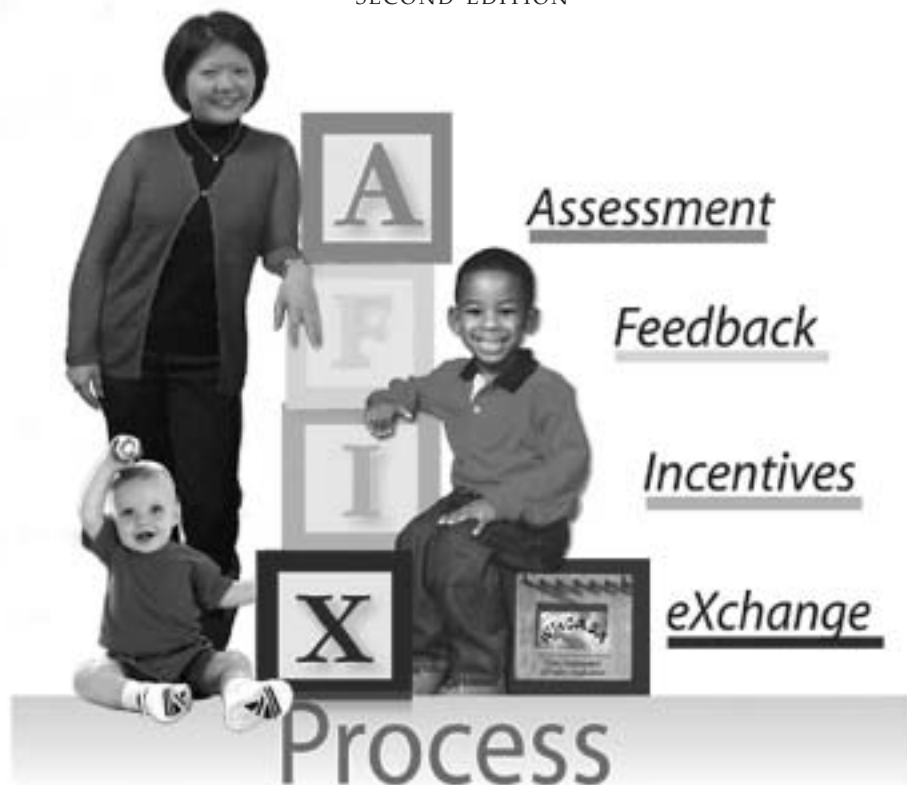


Core Elements *for* AFIX Training and Implementation

SECOND EDITION



April 2004

www.cdc.gov/nip/afix



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Please send comments and feedback on this document to:

Nancy Fenlon, *NFenlon@cdc.gov*

or

Amy Kirsch, *AKirsch@cdc.gov*

Thank you.

Index

Introduction	3
Acknowledgements	5
Assessment (“A”)	6
Methodology	6
Preparation for Visit	8
The Visit	9
Organize and Analyze Data	10
Feedback (“F”)	11
Preparing for Feedback Session	11
Methods of Conducting Feedback Session	12
Concluding a Feedback Session	13
After Conclusion of Feedback Session	13
Incentives (“I”)	14
Informal Incentives	14
Formal Incentives	14
Funding and Partnering for Incentives	14
eXchange of Information (“X”)	15
Comparison of Immunization Coverage Levels	15
Successful Processes/Systems Implemented by Other Practices	16
Ideas for Removing Barriers	16
Encouraging Ownership of This Initiative	17
Offer Additional Education Opportunities	18
Resources	18
Final Advice	18
Appendix A – List of High Risk Conditions	19
Appendix B – Hybrid Assessment Method	23
Appendix C – Examples of Pre-Assessment Forms and Letters	27
Appendix D – Public Health Implications of the Health Insurance Portability and Accountability Act (HIPAA)	35
Appendix E – Examples of Confidentiality Information	43
Appendix F – Methods for Selecting a Random Sample	47
Appendix G – Using Registries for Immunization Assessment	51
Appendix H – Examples and Tips on Partnering	55
Appendix I – Graphical Representation of Immunization Coverage Levels Between Practices	59
Appendix J – Examples of Vaccine Administration Records for Medical Records	63
Appendix K – Additional Resources	71
Appendix L – Glossary of Terms	75

Introduction to Core Elements For AFIX Training and Implementation

AFIX (Assessment, Feedback, Incentive, and eXchange) is a continuous quality improvement tool that consists of:

- 1) assessment of the health care provider's vaccination coverage levels and immunization practices;
- 2) feedback of the results to the provider along with recommended strategies to improve coverage levels;
- 3) motivating the provider through incentives to improve vaccination coverage levels;
- 4) and exchanging health care information and resources necessary to facilitate improvement.

The AFIX methodology is a comprehensive and effective tool for improving the vaccination coverage levels and immunization practices of health care providers. The improved outcomes produced by AFIX through implementation of recommendations and best immunization practices can be quantified through successive AFIX participation over time. The efficacy of AFIX has been documented in published and unpublished studies. Perhaps the greatest potential value of AFIX is when a majority of providers in a community participates in the AFIX process. This is because vaccine preventable disease risk declines when higher rates of immunization coverage confer higher levels of immunity to these preventable diseases.

For several years, state and local immunization programs have been utilizing the AFIX methodology in public health clinics where many childhood immunizations had been previously administered. Over the past decade, however, there has been a shift to the private sector for comprehensive health care and immunization services. Programs such as Vaccines for Children (VFC), Medicaid, the State Children's Health Insurance Program (SCHIP), and the impact of the managed care industry have been responsible for these

changes, resulting in more than 80% of children receiving some or all of their recommended vaccines in private primary care settings. State and local public health immunization programs are strongly encouraged to provide their AFIX services to all health care providers that provide any type of immunization services, regardless of VFC participation.

Although AFIX has traditionally been conducted to assess immunization delivery systems for children, several states are applying the AFIX process to assess adolescent and adult populations. In this edition of the Core Elements, we have generalized the AFIX process so that it can be applied to any age group. When differences between populations do exist with respect to the AFIX process, we have clearly identified the difference and provided helpful strategies for modifying the AFIX methodology.

The CDC Task Force on Community Preventive Services has endorsed the AFIX methodology as an effective quality improvement activity to improve immunization coverage levels in persons of all ages. With this endorsement, CDC convened a work group consisting of local, state, and federal participants. A subcommittee of the Clinic Provider Assessment Work Group (CPAWG) developed this document and the CDC AFIX committee recommends these core elements be used as guidelines when providing AFIX education and training in any health care setting, whether public or private. One activity that the group determined to be a priority was the development of these guidelines to ensure AFIX activities are conducted in a standardized fashion. The use of these core elements should assist any health care provider to improve immunization practices. CPAWG continues to meet bi-annually to develop an agenda of priority activities on which to focus.

To ensure proper use of the core elements, training sessions to conduct AFIX visits are essential. The core elements will provide guidance in:

- Training key staff to conduct AFIX visits
- Creating AFIX process protocols

This document is intended to be used by individuals and immunization programs that plan to utilize the AFIX methodology. Individual users will find this methodology to be flexible for their specific needs while statewide programs can use these same

concepts in their settings, as well. AFIX users need to be reminded that facilitating immunization practice (behavior) changes in the health care provider offices requires skillful collaboration. In all cases, health care providers should be encouraged to take ownership of the initiative by being active participants in making decisions through all phases of the process, from assessment to exchange. The use of AFIX has been demonstrated to change immunization practice behaviors and improve outcomes in any health care setting.

Acknowledgements

The development of this document was made possible by the hard work and dedication of the following individuals and their organizations:

R. Clinton Crews

Eastern Virginia Medical School
Center for Pediatric Research
Norfolk, Virginia 23510

Nancy Fenlon

Program Operations Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

Stephanie Sanchez

Communicable Disease and Immunization
Division
Michigan Department of Community Health
Lansing, Michigan 48909

Shelley Vaughn

San Diego County Infant Immunization
Initiative
County of San Diego Immunization Program
San Diego, California 92186-5222

Shannon Stokley

Health Services Research and Evaluation
Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

Judy Schmidt

Education Information and Partnership Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

John Stevenson

Health Services Research and Evaluation
Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

Lisa Luna

Oregon Department of Human Services
Oregon Health Division
Portland, Oregon 97232

Ruby Jones

Arkansas Department of Health
Division of Communicable Disease/
Immunization
Little Rock, Arkansas 72205-3867

Judy Yates

Mississippi Department of Health
Division of Immunization
Jackson, Mississippi 39215

Ken Anderson

Program Support Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta, Georgia 30333

Amy Kirsch

Program Operations Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta Georgia 30333

The second edition revisions to this document were made possible by the input of the following individuals and their organizations:

Nathan Crawford

AFIX Coordinator
Immunization Program
Oregon Department of Health Services
Portland Oregon, 97232

Andrew Chilkatowsky

Division of Disease Control
Philadelphia Department of Public Health
Philadelphia, PA 19146

Terry Adams

Indiana VFC Program
Indiana State Health Department
Indianapolis, IN 46204

Marcia Levin

VFC Program Supervisor
Chicago Department of Public Health
Chicago, IL 60612

Carolyn Bachino

Fellow, Health Services Research and
Evaluation Branch
National Immunization Program
Centers for Disease Control and Prevention
Atlanta Georgia 30333

Assessment (“A”)

The “A” in AFIX stands for *Assessment* of immunization coverage levels and immunization delivery patterns at the practice level. The Advisory Committee on Immunization Practices (ACIP) recommends the regular assessment of vaccination rates for both public and private providers. Assessment should include qualitative and quantitative observations.

Although the activities listed below can be applied to an assessment of any population, there are some differences between pediatric and adult assessments. These differences have been explained when appropriate.

I. METHODOLOGY

A. Choose Assessment Method

Assessment methods supported by CDC include:

1. *Chart Based*

a. *Standard*

The standard method for conducting an assessment is to randomly select a number of patient charts and calculate vaccination coverage rates based on the information obtained from the charts. Different methods can be used for selecting charts (see section III-B).

b. *Hybrid*

The hybrid assessment method may be used for conducting assessments. This method typically involves reviewing 30 charts. Results from the hybrid method allow the assessor to classify a provider as having coverage levels above or below a specific level but do not produce actual vaccination coverage rates.

2. *Registry Based*

A registry-based methodology is one in which all data used come from an immunization registry. This method generally assesses a pre-defined population rather than a sample of that population.

B. Determine Assessment Parameters

The following parameters should all be determined prior to conducting any assessment.

1. *Define active patient*

The definition of an active patient is at the discretion of the project conducting the assessment. The project may wish to use the number of office visits within a given time period for their definition. An alternative is to ask the clinic manager what his/her definition of an active patient would be, however, definitions may not be consistent across practices.

2. *Age range to be assessed*

Age range to be assessed can vary.

Common options are:

PEDIATRIC (Infants & Adolescents)	ADULT
12-23 months	Adults are considered any person 19 years of age or older
19-35 months	
24-35 months	19–49
combination of the above	50+
11-18 years	65+

3. *Sample size*

Determine a sample size that is realistic for your resources (this includes personnel and time).

PEDIATRIC (Infants & Adolescents)	ADULT
If using standard assessment method, it is recommended to review 50-200 charts.	If using standard assessment method, it is recommended to review 50 charts, although more may be reviewed. (Estimate that each adult chart will take approximately 15 minutes to assess.)
If using hybrid assessment method, the sample size is 30 charts.	If using hybrid assessment method, the sample size is 30 charts.

4. *Define flu season of interest*

If influenza vaccine is among the vaccines of interest for your assessment, it is important to determine the flu season of interest. A flu season is typically defined as October through March, but this may be altered based on the provider's situation or the date on which you are doing the assessment. For example, if the purpose of the assessment is to evaluate the 2001/2002 flu season coverage, but the provider did not receive vaccine supply until November, then you may define the flu season as November 1, 2001–March 30, 2002. More than one flu season may be evaluated during an assessment.

5. *High-risk conditions*

Many vaccine recommendations are risk based and/or age based. For example, a person with the high risk condition of asthma is recommended to receive the influenza vaccine each year. Depending on your quality

improvement goals, you may decide to do the assessment only for patients with a particular risk factor. For a list of high risk medical conditions and their recommended vaccines, refer to **Appendix A***.

6. *If using the hybrid assessment method, determine the threshold level.* (See **Appendix B**)

C. **Identify Data Fields**

Identify data fields (as determined by your project) to be collected during assessments. Standardizing the variable order may increase speed and accuracy of data entered over time.

1. Patient demographic information (sex, race/ethnicity, etc.)
2. Insurance status
3. Disease/medical history (e.g. varicella history, heart disease, asthma, etc.)
4. Social/behavioral risk factors (if applicable)
5. Other variables of interest (if applicable) to enable data collection and reporting of additional information (e.g. zip code, dates of first and last visits).
6. Type of vaccine
7. Date of vaccine
8. Comments and observations: during the assessment, assessors may identify issues with chart organization, documentation problems, etc. A designated space on the data abstraction form (or a separate form) should be made available for documenting comments and observations.

D. **Choose Data Collection Method**

Choose the method of data collection that will be used. Options include:

1. Laptop computer: abstracting data from a chart and directly entering into a computerized database
2. Paper and pencil: abstracting data from a chart and recording onto a data abstraction form
3. Import registry data or electronic patient information system data into

software system that analyzes immunization histories (e.g. CASA, ACASA)

E. Supplies

The supplies for staff to take to an AFIX provider site visit may include:

1. Computer and supplies (if applicable)
2. Data abstraction forms (if applicable)
3. Reference sheets
(e.g. list of high risk conditions)
4. Sampling instructions/tally sheets
(if applicable)
5. Post it notes
6. Pens/pencils
7. Calculator
8. Information for providers
(e.g. updated VIS statements)

II. PREPARATION FOR VISIT

A. Provider Selection

Identify providers that your program would like to target for AFIX activities. Provider selection may be based on a variety of variables. Some of the strategies for choosing providers are:

1. Actively promote AFIX to your network of immunization partners and professional contacts (e.g. state or local AAP, AAFP, or AARP chapter; immunization coalitions; etc)
 - a. Ask them to participate in your program
 - b. Ask them to help you recruit providers
2. Recruit practices with the largest target patient populations first
3. Recruit from all levels of practices
 - a. Promote your program to physician groups
 - b. Contact office managers
 - c. Contact medical group administrators or quality assurance personnel
4. Use several sources for the development of your recruitment list
 - a. VACMAN (vaccine ordering system) provider profiles
 - b. Local medical society and professional associations (AAP, AAFP)
 - c. Health plan provider lists
 - d. Medical group provider lists
 - e. Referrals from other providers
 - f. Providers with poor immunization practices
 - g. Geographic area of need
5. If doing a registry-based assessment, the participation level of the interested clinics in the registry should be considered.

B. Scheduling the Assessment and/or Feedback

The approach you take for scheduling the site visit will set the tone for the visit itself.

1. Call the office manager and explain exactly what you will be doing, how long it will take, and what you will need when you get there. (Refer to **Appendix C** for examples of

pre-assessment forms and letters from several state programs.)

2. Identify a mutually convenient date and time for the assessment.
(Coordinate with the VFC site visit if appropriate.)
3. Arrange for a workspace out of the flow of traffic with a table, chairs, and an electrical outlet for the computer (if applicable).
4. Ask for a computer-generated list of patients in the identified age range and pre-select the sample, if possible.
5. Determine staffing requirements and length of time for assessment based on sample size, file selection method, and workspace availability.
6. Confirm the date and time of the assessment with a follow-up letter and/or phone call.
7. Confirm office address and directions—if unfamiliar with area.
8. Communicate when and how the assessment results will be reported back to the office.

C. Confidentiality

The confidentiality of a provider's patients is often an important issue for the provider.

1. Be prepared to discuss concerns providers have with the issue of confidentiality. Some may ask for documentation showing your assessors have the right to extract information from their patients' medical records and that assessments will maintain the confidentiality of the information. Others may ask about state or federal regulations such as HIPAA (Health Insurance Portability & Accountability Act). For more information on HIPAA, please review **Appendix D** or go to <http://www.cms.hhs.gov/hipaa>. Additionally, the *Morbidity and Mortality Weekly Report (MMWR)* has published information on the privacy rule at <http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm>.
2. Address the issue of confidentiality with those conducting the assessments.

Have assessors sign an oath of confidentiality to be kept on file in your office. (Refer to **Appendix E** for state program examples of confidentiality statements).

3. Establish and follow procedures for distribution, handling and disposal of confidential information

III. THE VISIT

A. Make a Good Impression

There are a number of ways to make a good impression when making a provider site visit:

1. Be prompt; give the office a 15-30 minute time range for arrival
2. Smile and be friendly
3. Let everyone know who you are and what you are doing
4. Wear professional attire
5. Carry identification (business card and/or badge)
6. Provide immunization information and resources
7. Consider bringing food if resources allow

B. Chart Selection

Methods for selecting patient charts for review include:

1. *Pre-select the sample from a computer-generated list of patients*
2. *Shelf selection:* computerized lists of eligible patients may not be available; thus the shelf selection method may be the only method appropriate for selecting a sample of patients. Several options for using the shelf selection method can be seen in **Appendix F**.
3. *Registry-based assessment chart selection:* When doing a registry-based assessment, it is crucial to first determine how the clinic population will be defined, because this will drive how the patients are selected. Then, a request is made to the registry for an extract of those patients and their

immunizations. It is also important to include in that request the date-of-birth range of interest. Please refer to **Appendix G** for a full discussion of the use of registry data for assessments.

C. Data Extraction

The following guidelines will assist you in developing a method of extracting data from the charts:

1. Review completely all sections of the first few charts to become familiar with the system in the office. If more than one person is extracting data, agreement must occur on how to interpret immunization issues.
2. Ask office staff for clarification of documentation procedures for immunizations.
3. If documentation is inadequate, do further follow up to verify doses were given. This may include further chart review or office staff consultation.
4. Note problems for office staff to correct and put records aside for review.
5. Perform the quality assurance review, whereby spot checks are performed to assure data were correctly extracted.

D. Wrap Up—Leave a Good Impression

The way you end your visit is just as important as how you begin it. Improve your chances of gaining re-entry to a provider office by following these guidelines:

1. Offer to replace the records
2. Collect all materials
3. Leave the workspace tidy
4. Thank the staff for their hospitality
5. Avoid discussion of results until data can be appropriately analyzed

IV. ORGANIZE AND ANALYZE DATA

A. Select Reports and Feedback Methods

Determine what data to share with provider. Projects may customize reports or use standardized reports available in various software programs (i.e. CASA, ACASA). Report results and on-site observations may include:

1. Vaccine coverage levels of the target population
2. Single antigen coverage levels
3. List of patients with incomplete immunizations
4. Quality of record documentation
5. Missed opportunities including failure to simultaneously administer all needed immunizations
6. Frequency of invalid doses

B. Prepare Reports

Some things to consider when preparing reports for providers:

1. Present data in user-friendly format (graphs, pie charts...)
2. Retain provider confidentiality when presenting data comparing providers to each other
3. Identify areas of strength
4. Identify areas for improvement

C. Summarize Each Assessment for Internal Program Purposes

1. Document methods and parameters
2. Document program planning
3. Document results of each provider assessment for comparison over time
4. Document recommendations/goals and follow-up activities with provider

Feedback (“F”)

The “F” in AFIX stands for *Feedback*, the process of informing immunization providers about their performance in providing vaccines to a specifically defined population. It provides information on immunization coverage levels for a particular office or provider. Feedback provides a forum to discuss with the office how to improve its immunization delivery system and improve immunization coverage levels. The feedback process requires time, flexibility, creativity and knowledge of immunization recommendations and standards of practice. The feedback process is given in a sensitive, respectful manner that assures provider confidentiality. The person conducting the feedback session needs well-developed skills for dealing with people in a range of situations.

Feedback is a two-way conversation. It encourages the application of knowledge, attitudes and practice improvement in the immunization delivery system. You must get input from the provider to find out what changes are reasonable for the practice to institute.

I. PREPARING FOR FEEDBACK SESSION

A. Helpful Hints for the Feedback Session

Suggestions for designing your feedback session:

1. Schedule your feedback session at a mutually convenient time for the office and yourself if session is to occur separately from the assessment visit
2. Determine presentation mode and needed equipment and/or materials: handouts, PowerPoint presentation, easel and flip chart, overhead and transparencies, etc.
3. Use visual aids if possible for presenting data, especially key points
4. Be comfortable in presenting information—practice feedback session(s) in front of your office staff
5. Bring resources to improve immunization delivery
 - a. Immunization record for medical charts
 - b. Vaccine Information Statements (VIS)
 - c. Most current ACIP schedule
 - d. Vaccine oriented educational materials for provider and patients
6. If incorporating food at feedback session, coordinate with caterer, and consider space, time available, clean up, etc.

B. Develop Feedback Plan

Use the following as a guide for preparing your feedback session:

1. Who will be present for the feedback session?
 - Have at least one key decision maker present (office manager, provider, nurse or other staff) and encourage as much staff participation as possible
2. Be aware of time limits and keep within the limit for the session

3. What information will you present in the session?
 - a. Outline key points of assessment findings
 - i. Coverage level
 - ii. Diagnostic information
 - iii. Observation of office practices
 - b. Highlight office's strengths
 - c. Identify areas for improvement
 - i. Documentation
 - ii. Missed opportunities
 - iii. Reminder/recall
 - iv. Patient education
 - v. Provider education
 - vi. Vaccine handling and storage issues
4. Brainstorm with practice on improvement strategies that can be adopted
 - a. Include "easy fixes"
 - b. Target areas that provide the "biggest bang for the buck"
 - c. Be empathetic and supportive to office concerns
 - d. Outline and discuss follow up activities
 - e. Foster an environment of change in practice
 - f. Utilize incentives and exchange of Information during feedback session

II. METHODS OF CONDUCTING FEEDBACK SESSION

When and how will you present the feedback session? There is no one ideal method for feedback. Do what works best for your program and/or the providers you are working with to improve coverage levels.

A. Feedback conducted at a later scheduled date (after day of assessment)

Pros: Allows time for analysis and development of feedback plan
Ensures key players are available to participate in feedback session
Uses both verbal and written formats

Cons: Time and labor intensive

Situations best suited to this feedback

method: Large, high priority practices

B. Feedback conducted on day of assessment

Pros: Immediate information provided back to office
Staff interest in immunizations may be at highest level

Cons: May not be able to get "key" players to attend
Limited prep time for presentation
Lack of prep time may limit discussion on improving immunization practices
Time constraints: If assessment runs long, time available for feedback is decreased

Situations best suited to this feedback

method: Difficult to reach providers who are unlikely to schedule a follow-up feedback session; small volume practices

Providers who request immediate feedback session at conclusion of assessment

C. Written feedback report mailed to office after assessment as sole feedback method.

Pros: No additional time required by office staff
Since feedback is not immediate, allows for more thoughtful analysis of data

Office has hard copy of findings—
does not rely on memory of what
went on in feedback meeting
and/or notes taken during meeting

Cons: Information may never be read or
shared with appropriate staff
Limits incentives and exchange of
information
Difficult to develop working
relationship with office

**Situations best suited to this feedback
method:** Limited project resources.
Repeat assessments in high
performing offices with limited,
identified areas for improvement

III. CONCLUDING A FEEDBACK SESSION

Before leaving the office, remember to:

- Thank the office for participation in program
- Leave office work area clean and neat
- Review key findings of assessment
- Review agreed upon follow-up activities

IV. AFTER CONCLUSION OF FEEDBACK SESSION

Additional activities

A. Written follow-up report to provider

Include the following items as appropriate
in the written report to the provider:

1. Summary of results
2. Agreed upon short-term goals
3. Clear and concise outline of follow-up
activities to be conducted and respon-
sible party
4. Retain a copy of the follow-up report
for your own records for future follow-
up with each provider

**B. Periodic follow-up telephone contact
with office**

Allows project staff to follow up on
progress of immunization activities with
provider on specific issues

Incentives (“I”)

The “I” in AFIX stands for the *Incentives* to motivate providers and practices to improve immunization coverage levels. The key to this part of the AFIX process is to provide effective motivational rewards for positive change and improvement in immunization services and rates. Incentives promote change and reward achievement.

Incentives may be informal or formal. Informal incentives can be as simple as providing contact names and numbers for local, state and federal immunization resources. Formal incentives may be as elaborate as providing funding to send office staff to training at state or national immunization conferences.

The purpose is to motivate and encourage all staff to accept improving immunization coverage levels as “part of their job.” Public recognition of positive changes, as well as acknowledging high performing practices, is encouraged. When considering the following examples of incentives, be aware that practice characteristics such as provider type, size and location will influence what incentives are effective, relevant, and genuinely motivating to the provider.

I. INFORMAL INCENTIVES

Some examples of informal incentives used at the practice level include:

- Free immunization materials
- Educational in-services for staff
- On-going immunization updates
- Assistance with developing an immunization quality improvement plan for the office
- Letters of Commendation

II. FORMAL INCENTIVES

Some examples of formal types of incentives include:

- Certificates of Participation, Improvement and Collaboration
- Plaques
- Promotion of clinics/offices as “Immunization Champions” or role models
- Recognition of clinics/offices with significant improvement or high coverage levels at local or state conferences, educational seminars, professional meetings
- Celebration lunches for the winners within the project’s service area
- Recognition of clinics and offices in feature articles in various state and local professional newsletters and journals
- Catered lunch/breakfast in-services for staff
- Grants to improve immunization delivery services using evidence-based strategies
- Scholarships to local, state and/or national immunization conferences

III. FUNDING AND PARTNERING FOR INCENTIVES

To fund some of the more involved and/or costly incentives, consider partnering with other agencies or organizations with similar goals. Explore non-traditional partners as well. If unable to provide financial support, seek support to promote AFIX. Potential funding sources include:

- Immunization coalitions
- State chapters of professional organizations
- Health maintenance organizations
- Pharmaceutical manufacturers
- State medical societies

(Refer to **Appendix H** for examples and tips on partnering)

eXchange of Information (“X”)

The “X” in AFIX stands for the *eXchange* of information. The “X” can interact with both the Feedback (“F”) and the Incentive (“I”) components of AFIX. Information can be exchanged during feedback of assessment results to provider and staff as well as in many other settings where health professionals might meet, such as professional meetings. The exchange of information section will include examples of efforts that have been successfully implemented in practices and clinics. Exchanging information should reinforce the strengths of practices (acknowledge what the practice is doing well), as well as make recommendations for changes in their immunization practices. This exchange of information can be applied to individual practices, professional organizations and health systems.

I. COMPARISON OF IMMUNIZATION COVERAGE LEVELS

A. National levels and goals

Comparing provider immunization coverage levels to national levels and goals gives providers a broad context for their immunization level and where they stand.

B. State levels and goals (if available)

State levels and goals can give a provider a picture of how their coverage levels compare to others in the state.

C. Provider practice levels

Public providers can be shown their progress in relation to other providers by using a blinded rank order (refer to **Appendix I** for examples of how programs present comparison coverage levels). There are two things to keep in mind to maintain professional confidentiality if you choose to do this:

1. **DO NOT** identify specific practices without their permission
2. Do not generalize rates for practices in geographic areas or by practice type

II. SUCCESSFUL PROCESSES/ SYSTEMS IMPLEMENTED BY OTHER PRACTICES

A. Mentoring or testimony by an immunization champion

Using a local provider or immunization champion to speak with area providers is one method of educating providers. Local immunization staff may provide expertise as an immunization advocate and in identifying other immunization champions.

B. Evidence-based strategies

Another method of immunization coverage improvement is to show providers how implementing quality-assurance methods in other practices improved the coverage levels for those providers. For examples of evidence-based strategies to improve immunization coverage, go to the Task Force on Community Prevention Website at <http://www.thecommunityguide.org/vaccine/default.htm>

C. Competition

Friendly competition can be used as a motivator for increasing immunization coverage levels. For example, this can be done between staff at a large practice or among clinics or offices within a larger health system. This may be effective in conjunction with incentives discussed in the prior section.

D. Share success stories

It is important that immunization programs and providers do not try to reinvent the wheel. There are numerous examples of success stories at the provider level. Projects need to communicate about what has worked for programs, and encourage providers to contact each other to do the same.

E. Share experiences that have not worked

It is equally important that states and providers share experiences that have not been successful to collectively address barriers. Remember that while some strategies work well in a local area, strategies may not be universally successful.

III. IDEAS FOR REMOVING BARRIERS

A. Standard vaccine documentation

1. Standard immunization record in chart

A standard immunization record in each client's chart is an efficient and accurate way to review a client's immunization status (refer to **Appendix J** for examples of vaccine administration records for medical charts).

2. Vaccination records for patients that are accurate, complete, and easily accessible

This is standard #12 in the 2003 *Standards for Child and Adolescent Immunization Practices* developed by the National Vaccine Advisory Committee. This standard states, "Vaccination records for patients should be recorded on a standard form in an easily accessible location in the medical record to facilitate rapid review of vaccination status." Accurate record keeping ensures that only needed vaccinations are given. The medical record maintained by the primary care provider should document all vaccines received including those received at a specialist's office or in another health care setting. The Standards for child and adolescent immunization practices were published in *Pediatrics*, Volume 112 Number 4, October 2003. Additionally, the Standards are available on the National Immunization Program's website at www.cdc.gov/nip/recs/rev-immz-stds.htm.

3. Legal requirements

Providers are required by federal law (42 US Code 300aa-25) to ensure that records for each vaccine given contain the date the vaccine was given (month, day, year), the name of the manufacturer of the vaccine, the lot number, the signature and title of the person who gave the vaccine, and the address where the vaccine was given. In addition, providers should record on the client's personal immunization record

card what vaccine was given, the date the vaccine was given and the name of the provider. Additional state statutes may apply.

B. Assess immunization status at all encounters

Providers should use all clinical encounters to screen and, when indicated, immunize clients.

C. Tracking, reminder and recall

Operating a tracking system that produces reminders of upcoming immunizations as well as recall notices for clients who are overdue is another strategy for overcoming barriers to immunizations. The tracking system may be automated or manual and may include, but is not limited to, mailed or telephone messages.

IV. ENCOURAGING OWNERSHIP OF THIS INITIATIVE

A. Determine who makes decisions

Determine who in the practice can authorize changes in protocol.

B. Changes in immunization practice patterns can make clinical time more efficient

Give examples of how improving immunization practice patterns will enable the practice to operate more efficiently.

C. Discuss potential changes

Encourage the decision-maker to explore what immunization activities the practice is willing to implement to improve coverage levels. Determine some changes that may improve assessment results.

D. Liability

Discuss potential liability situations related to immunizations such as failure to use the most current VIS statements.

E. Maintaining and continuing improvement

Discuss the option of periodic return visits for reassessment to measure the success of practice changes. Practices should be encouraged to set realistic improvement goals.

V. OFFER ADDITIONAL EDUCATION OPPORTUNITIES

- A. CDC conferences and satellite courses**
Inform staff of dates and times of CDC conferences and satellite courses.
- B. State/regional/national immunization conferences**
Inform staff of dates and times of other immunization conferences.
- C. Inservices for office staff**
Provide in-services for nursing and office staff on immunization topics.
- D. Provide in-services for medical providers**
Provide inservices for medical providers on immunization topics.
- E. Consider offering CEUs for participation in AFIX visits**

VI. RESOURCES

Develop a list of immunization resources for your providers. Following are some examples to include:

- Yourself
- Local/county health department
- State immunization program
- CDC “Hotline”
- Immunization coalitions in area
- Website addresses
- Vaccine manufacturers

(Refer to **Appendix K**, Additional Resources, for websites and telephone numbers)

VII. FINAL ADVICE

Some final points to keep in mind:

- Be empathetic/supportive
- Encourage creativity
- Expect and accept mistakes
- Allow for candid opinions
- Offer positive feedback
- Offer appreciation for a job well done

With all the components in place, your program will be successful in private provider practices participating in your assessment process. As a result of using the AFIX process to its full extent, you will see an increase in properly immunized populations. The process never ends, and vigilance must be kept to achieve our goal:

*Protect Vulnerable Populations
from Vaccine Preventable Diseases*

Appendix A



List of High Risk Conditions

*This is a list of common high-risk medical conditions
that are indications for obtaining a certain vaccination.*

*It is not an all-inclusive list of
who should be vaccinated against certain conditions.*

High Risk Conditions

Heart Disease

Influenza Vaccine

- 394 Diseases of mitral valve
- 395 Diseases of aortic valve
- 396 Diseases of mitral and aortic valves
- 398.91 Rheumatic heart failure (congestive)
402.01, .11, .91
Hypertensive heart disease with CHF
- 404.01, .03, .11, .13
Hypertensive heart and renal disease with CHF
- 410 Acute myocardial infarction
- 411 Other acute and subacute forms of ischemic heart disease
- 412 Old myocardial infarction
- 413 Angina pectoris
- 414 Other forms of chronic ischemic heart disease
- 416 Chronic pulmonary heart disease
- 425 Cardiomyopathy
- 428 Heart failure
- 440 Artherosclerosis

Pneumococcal Vaccine

- 398.91 Rheumatic heart failure (congestive)
402.01, .11, .91
Hypertensive heart disease with CHF
- 404.01, .03, .11, .91, .93
Hypertensive heart and renal disease with CHF
- 416 Chronic pulmonary heart disease
- 425 Cardiomyopathy
- 428 Heart failure

Cancer/HIV/Organ Transplantation

Influenza Vaccine

- 042 Human immunodeficiency virus (HIV) disease
- V42.0 Kidney transplant
- V42.1 Heart transplant
- V42.6 Lung transplant
- V42.7 Liver transplant
- V42.8 Bone marrow transplant
- V58.0 Radiation therapy
- V58.1 Chemotherapy

Pneumococcal Vaccine

- 042 Human immunodeficiency virus (HIV) disease
- V42.0 Kidney transplant
- V42.1 Heart transplant
- V42.6 Lung transplant
- V42.7 Liver transplant
- V42.8 Bone marrow transplant
- V58.0 Radiation therapy
- V58.1 Chemotherapy
- 200 Lymphosarcoma and reticulosarcoma
- 201 Hodgkin's disease
- 202 Other malignant neoplasms of lymphoid and histiocytic tissue
- 203 Multiple myeloma and immunoproliferative neoplasms
- 204 Lymphoid leukemia
- 205 Myeloid leukemia
- 206 Monocytic leukemia
- 207 Other specified leukemia
- 208 Leukemia of unspecified cell type

Liver Disease

Pneumococcal Vaccine and Hepatitis A Vaccine

571, 572, 573.0

Chronic liver disease and cirrhosis

Hepatitis A Vaccine

Hepatitis C positive antibodies

Cerebrospinal Fluid (CSF) Leak

Pneumococcal Vaccine

V45.2 CSF drain

Travel

Hepatitis A Vaccine

(certain countries—refer to ACIP recommendations)

Hepatitis B Vaccine

(certain countries—refer to ACIP recommendations)

Nursing home/ Long Term Care Facility Resident

Influenza Vaccine

Health Care Occupation

Influenza Vaccine

Lung Disease Other than Asthma

Influenza Vaccine

491 Chronic bronchitis

492 Emphysema

494 Bronchiectasis

496 Chronic airway obstruction, NEC

506.4 Chronic respiratory conditions due to fumes and vapors

518 Compensatory emphysema

Pneumococcal Vaccine

491 Chronic bronchitis

492 Emphysema

494 Bronchiectasis

496 Chronic airway obstruction, NEC

506.4 Chronic respiratory conditions due to fumes and vapors

518 Compensatory emphysema

Alcoholism

Pneumococcal Vaccine

291 Alcoholic psychoses

303 Alcohol dependence syndrome

Asthma

Influenza Vaccine

493 Asthma

Diabetes

Influenza Vaccine

250 Diabetes mellitus

Pneumococcal Vaccine

250 Diabetes mellitus

Renal Disease

Influenza Vaccine and Hepatitis B Vaccine

585 Chronic renal failure

Pneumococcal Vaccine and Hepatitis B Vaccine

581 Nephrotic syndrome

585 Chronic renal failure

Blood Disorders

Influenza Vaccine and Hepatitis A Vaccine

282.4 Thalassemias

282.6 Sickle-cell anemia

Pneumococcal Vaccine and Hepatitis A Vaccine

282.6 Sickle-cell anemia

Asplenia

Pneumococcal Vaccine

759.0, 746.87

Asplenia, asplenia with mesocardia

Behavioral

Hepatitis A Vaccine and Hepatitis B Vaccine

Men who have sex with men (MSM)

Intravenous (IV) Drug Use

Hepatitis A Vaccine

Non-Injecting Drug Use

Hepatitis B Vaccine

Drug use—type unknown

High-risk sexual activity
(defined as >2 sex partners in 6 months)

Health care occupation

Race

Pneumococcal Vaccine

American Indian

Alaskan Native

Pregnancy

(2nd or 3rd trimester during flu season)

Influenza Vaccine

Appendix B



Hybrid Assessment Method

Hybrid Assessment Method

What is the Hybrid Method?

The hybrid method is a screening tool to help determine if a provider's immunization coverage level is at or below a specific threshold. The hybrid method uses small sample sizes so it takes less time to conduct. Unfortunately, the hybrid method does not have diagnostic capabilities to determine why a provider might have low immunization coverage levels. The hybrid method incorporates the best of each method. It maintains the small sample size of Lot Quality Assurance (LQA) while providing some diagnostic information from a traditional assessment method. Please keep in mind that the hybrid method is not designed to determine the actual immunization coverage level for the practice but to determine if the practice is performing above or below a specific level.

Terms Used

The following is a list of terms that are used throughout the protocol.

Threshold Level:

The standard against which the provider is evaluated. If the threshold level is set at 70%, then the assessment will determine if the provider has immunization coverage level above or below 70%. Use existing information to determine the appropriate threshold level for your area (for example: NIS estimates, public health center or private provider assessment information).

Reference Number:

The number of children in the sample allowed to be not up-to-date (UTD). If the number of children in the sample not UTD exceeds the reference number, then the provider has an immunization coverage level below the threshold level.

Steps for Conducting a Hybrid Assessment

Use the following protocol when using the hybrid method for the assessment.

1. Prior to conducting the assessment, determine the threshold level and use the table below to identify the appropriate reference number. We will use a sample size of 30 charts, regardless of where the threshold level is set.

THRESHOLD LEVEL	REFERENCE NUMBER
90%	1
85%	2
80%	3
75%	4
70%	5
65%	6
60%	7

2. Select charts.

To be eligible for inclusion in the hybrid sample, a child must:

- be 19-35 months of age
- have made at least 2 visits to the practice
- have no documentation in the chart of having moved or gone elsewhere for services

We recommend selecting an extra 10-15 charts so that there will be the appropriate number of charts remaining after excluding ineligible children. If more than 30 charts remain after removing the ineligible children, just review the first 30 charts in the group.

Use one of the following methods to select a random sample of charts:

1. If possible, obtain a listing of all age-eligible patients of the practice prior to conducting the assessment and randomly select 45–50 children.
2. If obtaining a list of patients is not possible, use the "shelf" method. Divide the sample size by the number

of shelves holding patient charts. This will determine the number of charts to pull per shelf (i.e., if there are 10 shelves and the sample size is 30, select 3 charts per shelf). Randomly select a starting point on the shelf and sequentially review each chart until you find the appropriate number of charts from each shelf.

3. As a last resort, review the appointment book to identify children. Select each age-eligible child who visited the practice during the month prior to the assessment until the appropriate sample size is met. You may need to extend the time period in order to select the appropriate number of children.
3. Define up-to-date (UTD) for the assessment.
4. In the immunization input screen, enter the child's name, date-of-birth and the number of doses of vaccine the child received. If you wish to do so, you may choose the Immunization History option to enter the actual date of each immunization. We recommend doing this only if the child is not UTD (this information is used for the diagnostic evaluation of missed opportunities and other causes of being not UTD).
5. Separate the charts of children who are not UTD for the feedback session with the provider.
6. When you have completed inputting information for the sample, select the option to run the Final Report. The Final Report will state the number of children UTD and not UTD in the sam-

ple, whether or not the practice has passed the Hybrid assessment based on the selected threshold level, as well as provide a listing of each child included in the sample.

The hybrid software determines if the provider passed the assessment based on the number of children not UTD in the sample:

- If this number is less than or equal to the reference number that corresponds to your selected threshold level, then the practice has a high probability of having coverage *above the threshold level*.
 - If this number is greater than the reference number that corresponds to you selected threshold level, then the practice has a high probability of having coverage below the threshold level.
7. After running the Final Report, you will be prompted if you want to select a further analysis of the not UTD children. If you select "yes," the hybrid method will provide a listing of children not UTD along with their immunization histories and comments describing the reason for being not UTD.
 8. During the feedback session, present results to the provider. Indicate whether or not the practice has an immunization coverage level above the threshold. Present the final report along with the analysis of the children not UTD. Use the charts of the children who are not UTD as a tool to discuss strategies for improving coverage.

Appendix C



Examples of
Pre-Assessment Forms and Letters

Private Provider Initial Contact Form

Provider name _____

Address _____

Contact person (*name and title*) _____

Phone # _____ Fax # _____

Number of children served _____ Number in age range _____

Patient age range in practice _____

What kind of record keeping system for immunization records is used?

Computer Medical Records Card File Other (*Specify*) _____

How can we access records? (computer printout, pulled files, etc.)

How are completed records reported?

Immunization cards

Summary form

Other (specify)

Immunization screening policy used (ACIP, AAP, etc.) How long has this policy been used?

When is DTP #4 given? _____

When is MMR given? _____

IPV schedule? _____

Varicella, PCV-7, Hep A given? _____

Type of insurance accepted: _____

Percentage Medicaid _____

How are active/non-active patients defined? _____

Are they separate? _____

Best day/time to do audits? _____

Number of non-English speaking clients? _____

What languages are spoken?

How many staff ? (MD, RN, PA, MA, etc.)

Computer system? _____

Software: _____

Notes:

Department of Human Services: Immunization Offices

AFIX Application and Enrollment Profile

Thank you for your interest in AFIX and for your interest in improving immunization rates and practices in your clinic. Please fill out **all fields** on both of these forms and submit them to X (fax: xxx-xxx-xxxx). You will need to **complete a separate Part B** for each clinic site in your practice. We will contact you shortly by phone to discuss the next steps in the AFIX process.

Part A: General Practice Information

1. Name of practice or organization: _____
2. Are there multiple sites for this practice? Yes No
If yes, please list each clinic or site name:
 1. _____
 2. _____
 3. _____
 4. _____
 5. _____
3. Does this practice or organization participate in the immunization registry?
 Yes No
If yes, how often is immunization data submitted to the immunization registry?

4. By which method is this data submitted?
 Barcodes
 Electronic file transfer from practice billing system
 Electronic file transfer from medical records system
 Public clinic: automated data entry
5. Please describe general impressions of the immunization registry within your practice or organization:

6. Does this practice or organization participate in the Vaccines for Children (VFC) program?
 Yes No

For Office Use Only:

Current

Future

Time Frame

Part B: Specific Clinic Site Location Information

Please fill out a separate Part B for each clinic or site location within your practice.

- 1. Clinic or site name: _____
- 2. Clinic specialty: *(Check one)*
 Pediatric Family practice Both Neither/other: _____
- 3. Clinic type: (please check one)
 Private, non-FQHC Private, FQHC
 M/CHC County health department
 WIC site Other public agency
 Tribal agency Other: _____

4. Clinic contact information:

Street address: _____

City/State: _____ Zip code: _____

County: _____

Clinic phone: _____ Clinic fax: _____

Clinic e-mail: _____ Clinic website: _____

5. Clinic Practitioners:

Number of pediatricians at this clinic: _____

Number of family physicians at this clinic: _____

Number nurse practitioners at this clinic: _____

Number physician assistants at this clinic: _____

Number nursing staff (RN, LPN, CNA, etc.): _____

Number office staff at this clinic: _____

- 6. Approximate the number of children under 3 years old seen at this clinic: _____

—Please complete next page—

7. Who will be designated as the primary AFIX contact?

First name: _____ Last name: _____

Title: _____ E-mail: _____

Phone: _____ Fax: _____

Hours at this phone number (ex: M, W, F, 9am - 2:30pm): _____

8. Who is designated as the primary VFC contact?

First name: _____ Last name: _____

Title: _____ E-mail: _____

Phone: _____ Fax: _____

Hours at this phone number (ex: M, W, F, 9am - 2:30pm): _____

9. Who is the lead physician overseeing immunizations in this clinic?

First name: _____ Last name: _____

Title: _____ E-mail: _____

Phone: _____ Fax: _____

Hours at this phone number (ex: M, W, F, 9am - 2:30pm): _____

Authorizing signature
of physician: _____

By authorizing this application, I confirm that this practice recognizes AFIX as a continuous improvement process for immunization practices and is in the best interest of our practice and our patients.

Thank you for completing these forms.

Please return to:

Department of Community Health Immunization Record Assessment Confirmation

Thank you for your request to participate in an immunization record assessment, and for your interest in improving immunization rates and practices in your clinic. Please verify the information on this profile, make corrections as necessary, and sign the confirmation where indicated. Please fax the completed confirmation to _____ . The immunization assessment office will mail a letter to your office that will confirm the scheduled dates for the chart review and the feedback meeting.

NAME OF PRACTICE: _____

DATE OF CHART REVIEW: _____

DATE OF FEEDBACK MEETING: _____

TIME OF FEEDBACK MEETING: _____

The primary contact for the immunization record assessment is:

Name: _____ Title: _____

Phone: _____ Fax: _____

E-mail: _____

Hours at this phone number (ex: M, W, F, 9am – 2:30pm): _____

This practice recognizes the X immunization record assessment as a continuous improvement process for immunization practices that is in the best interest of our practice. By signing this confirmation, the practice 1) agrees to participate in the immunization record assessment, 2) grants X permission to review the immunization data for the provider in the X Childhood Immunization Registry, and 3) commits to have medical staff in attendance at the feedback meeting on *Feedback Date* at *Feedback Time*. The list of patients with birth dates *Birth Date Age Range*, being generating by this practice, will be **faxed to X within the next five business days**.

Signature of primary contact person: _____

Provider ID: _____

The immunization assessment staff will conduct a chart review for immunization data and review the immunization data for the provider in the registry. All information abstracted from the charts will be treated as confidential.

The immunization record assessment for "PracticeName" is supervised by XX Immunization Assessment Coordinator. XX can be contacted at XXX-XXXX or by e-mail at _____

(Date)

PROVIDER ADDRESS INFO

Dear CONTACT PERSON:

Thank you for your interest in the Immunization Record Assessment. The chart review date is scheduled for *Date of Chart Review*. The list of patients with dates of birth from *Birth Date Age Range* has not yet been generated by your practice. When the list of children is generated, please call our office to let us know you have the list and then fax the list of children to the X Immunization Assessment office, attention XX at . *Name of Assessor*, a Department of Community Health Immunization Assessment Specialist, will arrive at your office at approximately *ARRIVAL TIME* and will be conducting the chart review for approximately 4 hours. During the chart review *Name of Assessor* will need a table or empty desk upon which she may place a lap top computer and a full-size keyboard. An electrical outlet is also required in an adequate space to review the charts (i.e., conference room, break room, empty desk, etc.). When we receive a faxed copy of your list of children, you will be instructed on which charts to pull before the assessor's arrival.

After the chart review, the immunization assessment staff will compare the immunization data in the X Childhood Immunization Registry with the data collected at the chart review. The results of this data review will be discussed at the feedback meeting.

The Assessment Feedback meeting is scheduled for *Feedback Date* at *Time of Feedback*. All clinical staff is to attend this 1-hour meeting. *Name of Presenter*, Immunization Assessment Specialist, will present this feedback meeting. The immunization coordinator from your local health department, the regional staff and the X immunization field representative are interested in increasing immunization levels for your practice, and they will be invited to attend the feedback meeting.

If you have any questions concerning the methods used to assess your records or need to reschedule, please feel free to call me at . Otherwise, we look forward to seeing you on *Date of Chart Review*. Your continued partnership is critical to our efforts to ensure the health and well being of children in our state through the administration of age-appropriate immunizations.

Sincerely,

XXX, Immunization Assessment Coordinator
Communicable Disease and Immunization Division
Bureau of Epidemiology

cc: *Immunization Coordinator*, County County Health Department
Field Rep, Immunization Field Representative

Appendix D



Public Health Implications of the
Health Insurance Portability and Accountability Act (HIPAA)

Informational Memo and Fact Sheet

A Product of the National Immunization Program

**MEMORANDUM**

Date: August 11, 2003

From: Director, National Immunization Program

Subject: Public Health Implications of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

To: Immunization Program Managers
State Epidemiologists

Dear Colleague:

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which went into effect April 14, 2003, is having unintended consequences on some of the core functions of public health. The intent of HIPAA is to establish national standards for consumer privacy protection and insurance market reform. Unfortunately, a lack of information and misinterpretation of some HIPAA provisions has begun to hamper the conduct of time-honored public health activities. In some instances, confusion about the intent and implementation of the rules has resulted in health care providers refusing public health officials access to patient records for immunization assessment and surveillance purposes. We recognize that providers are concerned about compliance and they need clear and accurate information about the practical application of the HIPAA Privacy Rule on public health practices.

The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) is working closely with Health and Human Services (HHS) Office for Civil Rights, which is the lead agency for interpreting and enforcing HIPAA, and the CDC legal counsel to clarify public health provisions of the Privacy Rule and disseminate information to our partners at the state and local levels. Due to the complexity of the HIPAA Privacy Rule, NIP plans to develop periodic advisories regarding policy issues and interpretation of confidentiality provisions that may affect public health activities. Some principal areas on which states have requested clarification deal with access to patient records to conduct VFC and AFIX site visits, participation in immunization registries, and disease surveillance and epidemiologic follow-up as part of outbreak investigation.

The first of a series of HIPAA guidance statements is attached with this mailing. The one page "HIPAA and Public Health Factsheet" provides a brief summary of HIPAA and Privacy Rule definitions. The "HIPAA and Public Health Site Visits: Access to Patient Records during AFIX and VFC Visits" provides responses to specific questions asked by the states regarding disclosure of patient health information without prior authorization during VFC and AFIX provider site visits. The responses to these questions were prepared by the CDC Office of General Counsel, which provides legal advice for CDC programs on issues such as implementation of HIPAA. Additional information is available on the Office for Civil Rights website at <http://www.hhs.gov/ocr/hipaa> and in the MMWR, HIPAA Privacy Rule and Public Health: <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>.

Page 2 - Dear Colleague/Public Health Implications - HIPAA

We hope you will find this information helpful as you educate your provider groups and work with your respective legal offices on HIPAA issues. We are encouraged that all of the written and oral questions NIP has submitted to HHS about the impact of HIPAA on immunization activities have affirmed NIP's position that state and local health agencies may continue to carry out routine public health activities while remaining in full compliance with HIPAA.

/ Original Signed By /

Walter A. Orenstein, M.D.

Attachment

cc:

Chair, Association of State and Territorial Health Officials

Chair, Association of Immunization Managers

Health Insurance Portability and Accountability Act and Public Health Factsheet

What is HIPAA?

The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) established a national floor of consumer privacy protection and marketplace reform. Some key provisions include: insurance reforms, privacy and security, administrative simplification, and cost savings.

What is the HIPAA Privacy Rule?

HIPAA required Congress to enact privacy legislation by August 1999 or the Secretary of DHHS was to develop regulations protecting privacy. The HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) sets national minimal standards for protected health information.

Implications for Public Health

The Privacy Rule strikes a balance between protecting patient information and allowing traditional public health activities to continue. Disclosure of patient health information without the authorization of the individual is permitted for purposes including but not

limited to 1) disclosures required by law (45 CFR § 164.512(a)) or 2) for “public health activities and purposes.” This includes disclosure to “a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events. . . , and the conduct of public health surveillance, . . . investigations, and. . . interventions.” (45 CFR § 164.512(b)(i))

Definition of Public Health Authority

Defined as “an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandates.” (45 CFR § 164.501)

HIPAA and Public Health Site Visits

Access to Patient Records during AFIX and VFC Visits

Responses to Frequently Asked Questions about AFIX and VFC

This guidance is intended to give health care providers and public health agencies specific information regarding the HIPAA Privacy Rule and access to patient records during Assessment, Feedback, Incentives, Exchange (AFIX) and Vaccines for Children (VFC) site visits. Several frequently asked questions posed to the CDC legal counsel for interpretation are presented below. Additional sources of information and reference materials available on the internet are also included.

- Q1. Can patient records be reviewed by health department staff, or their contractual agents such as the American Academy of Pediatrics (AAP) or the Visiting Nurses Association (VNA), for the purpose of conducting AFIX provider site visits?**
- A1.** Yes. Under 45 CFR § 164.512(b) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes. AFIX, authorized under section 317 of the Public Health Service Act, is a public health strategy to raise immunization coverage levels and improve standards of practices at the provider level. AFIX providers, as covered entities, may share patient records with health department staff or their contractors because a health department is a public health authority authorized by law to review patient records for AFIX purposes, or because health department contractors are acting under a grant of authority from a public health authority. In addition, state health departments may have authority under applicable state law to collect this information.
- Q2. Can patient records be reviewed by health officials or their agents for the purpose of conducting VFC provider site visits?**
- A2.** Yes. As explained in A1. above, under 45 CFR § 164.512(b) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes. VFC is a public health program that provides vaccines for children in certain eligibility groups. The VFC program was authorized under Section 1928 of the Social Security Act and has been delegated to CDC to administer. VFC providers, as covered entities, may share patient records with health officials or their agents because a health department is a public health authority authorized by law to review patient records for VFC purposes, or because contractors are acting under a grant of authority from a public health authority.
- Q3. Are VFC providers required to allow health officials access to the immunization records of children in their practice to determine compliance with VFC requirements?**
- A3.** The HIPAA Privacy Rule permits providers to share immunization records with public health officials for public health purposes as otherwise authorized by law. Under the VFC statute, at 42 U.S.C. 1396s(c)(2), as a condition of participation in the VFC program providers must share immunization records with health officials to verify compliance with VFC program requirements, including:

1. screening of all children in their practice to determine VFC eligibility
2. to determine provider compliance with the VFC immunization schedule regarding the appropriate periodicity, dosage and contraindications applicable to the vaccines
3. to determine provider compliance with applicable State law, including any such law relating to any religious or other exemption
4. to verify that VFC vaccine-eligible children are not being charged for the cost of the vaccine
5. to verify that any administration fees being charged do not exceed the caps established by CMS;
6. to verify that the provider does not deny administration of vaccine to vaccine-eligible children due to the inability of the child's parent to pay an administration fee.

Q4. Can health care providers, daycare operators, Head Start and school officials share immunization information with another provider or school to update missing immunization history or bring children into compliance with daycare, Head Start and school requirements?

A4. Health care providers (or other covered entities) may share immunization information with other health care providers as needed to make treatment decisions, such as to give further immunizations. Providers may also disclose immunization information to schools, without authorization, if permitted or required by State law. These State laws would not be preempted by the Privacy Rule. (45 CFR 160.203(c)). In the absence of such a State law, it appears that such disclosures to schools will require individual authorization.

Immunization records held by day care centers and schools are not protected health information under the Privacy Rule. Disclosures of immunization information by schools is covered by the Family Educational Rights and Privacy Act (FERPA). (45 CFR 164.501).

Q5. Can patient identifiers, including name and birthdate, be collected and stored electronically, incidental to AFIX or VFC visits?

A5. Yes. Under 45 CFR § 164.512(b) of the HIPAA Privacy Rule, covered entities may disclose protected health information—including name, birthdate, and other individually identifiable health information—to public health authorities that are authorized by law to collect such information for public health purposes. However, other requirements of the Privacy Rule (including minimum necessary, verification of identity, and accounting requirements) may apply to covered entities making these disclosures. For a full explanation of these requirements, see the website of the Office for Civil Rights (www.hhs.gov/ocr/hipaa) (responsible for enforcing the Privacy Rule), or CDC/HHS guidance on the Privacy Rule and Public Health, available at <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>. Once protected health information has been disclosed to a public health authority for a public health activity pursuant to section 164.512(b) of the Privacy Rule, the information may be stored in whatever way is reasonable for conducting the public health activity, including electronically, so long as the storage is consistent with other applicable state and federal law.

Links to additional sources of information may be found on the CDC website at www.cdc.gov/nip/registry

Appendix E



Examples of Confidentiality Information

Examples based on state program forms

Statement of Confidentiality Immunization Survey Data

(Date)

Pursuant to Section *N* of the Health and Safety Code regarding immunization data gathered during the conduct of surveys or studies:

(insert law here)

Immunization data collected during the conduct of clinic assessments and/or special immunization studies shall be released as aggregate statistics only to maintain confidentiality. Assessed entities shall be provided individual immunization histories of their clients upon request and for the purpose of identifying persons who may be in need of immunizations.

Director of Health

Confidentiality Statement for Review of Private Patient Information During VFC Site Reviews

During the VFC Site Review, the VFC Field Representative enters immunization information of a sample of your private and VFC-eligible patients into a laptop computer in order to obtain an overall evaluation of your immunization coverage rates. The data gained in this process allow VFC staff to offer tailored solutions to the problems of missed opportunities to vaccinate and under-vaccination.

Private patient immunization data, in addition to VFC-eligible patient data, is used to obtain more accurate results, for better feedback to VFC providers about ways to maximize immunization levels in their practices.

VFC staff will use these data solely for the purpose of statistical analysis. VFC's reports will not reflect any patient information obtained by VFC staff from a provider. To the extent permitted by law, VFC staff will distribute only information from site review assessments in aggregate form. VFC staff intends to use patient identifiers solely for the purpose of avoiding duplication of data entry.

The analysis of immunization data from both private and VFC-eligible patients is a critical component in providing an accurate evaluation of immunization rates within this state. Thank you for your cooperation. Please contact, _____, Provider Services Specialist, if you have any questions.

Appendix F



Methods for
Selecting a Random Sample

A Menu of Options for Sampling Plans

The clinic's choice of a sampling plan depends on the type of record keeping system already in place.

A. Census or Complete Enumeration

If a clinic has a computerized data system, it would be relatively easy to do a census or complete enumeration of the records in the system. Assessment becomes a simple matter of accessing the computer files, selecting all eligible 2-year-olds, and counting the number of these children who are up-to-date on vaccinations at their second birthday and at earlier age markers. Similarly, if a clinic has fewer than 50 2-year-olds, the time spent doing a complete enumeration may not be much more than the time it would take to do a survey. In both clinics, sampling error would no longer be an issue—an advantage that a complete enumeration has over a sample survey. However, a census could still be subject to nonsampling error.

In other clinics, it would be difficult, time-consuming, and expensive to do a complete enumeration. In these clinics a sample survey needs to be done. This involves deciding on a sampling procedure, calculating sample sizes, selecting the sample, and computing the appropriate estimates and the corresponding sampling error. Following are some options for the sampling procedure.

B. Simple Random Sampling

With simple random sampling (SRS), every possible sample of n children from a population of size N has the same chance of being chosen. Following are the steps to be taken when selecting a simple random sample.

Step 1 Label the children in the survey population from 1 to N .

Step 2 Take n random numbers between 1 and N . The selection must be done without replacement; i.e., if

a number is the same as any one of the previous numbers selected, discard it and continue until n *different* numbers between 1 and N have been chosen. (Use either a table of random numbers like Table 1 or a computerized random number generator.)

Step 3 Select the children corresponding to the n numbers generated in step 2.

Example

Suppose that we need to select 10 records from a collection of 100 clinic records. We number the records in the sampling frame from 1 to 100. Then, using a table of random numbers such as in Table 1, we pick 10 random numbers. Because we want numbers between 1 and 100, we read off three digits at a time. Reading from left to right and from top to bottom, the first two numbers (332 and 767) are discarded because they are larger than 100. The next number, 099, is chosen. The second number selected is 034. All numbers read that fall between 1 and 100 are in boldface (Table 1). Note that 099 is selected twice, but we include it only once. The number 34 is also read twice but is included only once. Hence, the 10 numbers selected are 99, 34, 15, 81, 43, 25, 1, 5, 85, and 100. We then pull out the 1st, 5th, 15th, 25th, 34th, 43rd, 81st, 85th, 99th and the 100th records from our files.

Conceptually, SRS is the simplest type of sampling plan. At the implementation stage, however, SRS may present some problems. In some clinics, it may be difficult to construct a list of all the N children before sampling and to train personnel to generate n random numbers. In these situations, systematic sampling may be easier to implement.

Table 1
A Portion of a Table of Random Numbers

33276	70997	79936	56865	05859	90106
03427	49626	69445	18663	72695	52180
92737	88974	33488	36320	17617	30015
85689	48237	52267	67689	93394	01511
08178	77233	13916	47564	81056	97735
51259	77452	16308	60756	92144	49442
60268	89368	19885	55322	44819	01188
94904	31273	04146	18594	29852	71685
58586	23216	14513	83149	98736	23495
09998	42698	06691	76988	13602	51851
14346	09172	30163	90229	04734	59193
74103	47070	25306	76468	26384	58151
24200	13363	38005	94342	28728	35806
87308	58731	00256	45834	15398	46557
07351	19731	92420	60952	61280	50001

C. Systematic Sampling

Systematic sampling is easy to apply because it simply involves taking every k th child after a random start. The following are steps to be taken when selecting a 1-in- k systematic sample.

Step 1 Divide the population size N by the required sample size n to get the sampling interval k ,

$$k = N/n.$$

If k is not an integer, round it down to the nearest integer, i.e., truncate the number.

Step 2 Take a random number between 1 and k to determine the first child to be included in the sample.

Step 3 Add into the sample every k th child after the random start in the preceding step.

Example

Suppose that we need a sample of 5 out of 28 records. Then $k=28/5=5.6$, not an integer, and hence we round it down to

the nearest integer, 5. Using a table of random numbers, select a number between 1 and 5, say 2. The random start is 2, and the second record is selected first. Starting with the third record, count from 1 to 5 and pull the last record, i.e., the seventh record from the file is selected. Repeat the procedure until 5 records are selected or the end of the file is reached. Thus, with a random start of 2 and a sampling interval of 5, the 2nd, 7th, 12th, 17th, 22nd, and 27th records are selected. Note that because we rounded the sampling interval down to the nearest integer, we get a sample size of 6 instead of the intended size of 5. This process is illustrated in Table 2. Note that the 1-in- k systematic sampling essentially divides the population into groups of k ($k=5$ in our example) and one record is selected from each group. The random start fixes the position of the record selected within each group; in our example, every 2nd record in a group of 5. If the selection process got interrupted, it is helpful to know that the j th selection is determined by the formula

$$j\text{th selection} = (\text{random start}) + (j-1) \times (\text{sampling interval}).$$

For example, the 3rd selection will be $2+(3-1)(5)=12$ and the 6th selection will be $2+(6-1)*5=27$.

D. Two-step shelf method

Step 1 Determine total number of eligible patients in the practice

1. Choose one typical shelf in the practice. Review each chart on that shelf to identify the number of patients meeting your eligibility criteria.
2. Count the total number of shelves in the office.
3. Complete the following formula:

$$\left(\frac{\text{\# eligible on 1 shelf}}{\text{\# shelves total}} \times \text{\# shelves total} = \text{\# eligible in practice} \right)$$

Step 2 Select a sample of eligible patients

1. Randomly select a shelf
2. Pull each eligible chart from the shelf (use the table below to keep track of the number of charts pulled from each age group)
3. Repeat steps 1 and 2 until you have selected the number of charts required for your assessment (e.g. 100 charts)

Age Group	Birth date range for eligibility	Number of eligible charts abstracted for data in each age group
18-49	__ / __ / __ - __ / __ / __	
50-64	__ / __ / __ - __ / __ / __	
>65	__ / __ / __ - __ / __ / __	

When you have reached your quota of eligible charts, complete the following:

Total # eligible patients sampled:

18-49 _____
 50-64 _____
 >65 _____

Table 2
A 1-in-5 Systematic Sampling from 28 Records Using a Random Start of 2

Record Number	Record to be selected in the sample
1	
2	x
3	
4	
5	
.....	
6	
7	x
8	
9	
10	
.....	
11	
12	x
13	
14	
15	
.....	
16	
17	x
18	
19	
20	
.....	
21	
22	x
23	
24	
25	
.....	
26	
27	x
28	

Appendix G



Using Registries for Immunization Assessment

Using Registries for Immunization Assessment

The purpose of this appendix is to provide guidance on how to begin using registry data for assessments and crucial issues to first address.

What is a registry-based assessment?

A registry-based assessment is one in which all data come from the immunization registry rather than clinic charts.

Why use a registry-based assessment methodology with AFIX activities?

As immunization registries grow to be more complete, advantages become available for AFIX visits. Such advantages include:

- Capability to target provider site visits to clinics with low coverage rates or problematic practice issues
- Ease of assessing longitudinal impact of AFIX activities
- Assistance in building synergy amongst providers and immunization registry efforts in the pursuit of achieving 2010 goal of 90% immunization coverage
- Reduction in time spent extracting and replacing medical records, and entry of immunization data
- Incorporating key registry functions into AFIX Feedback visits that will help assist providers in their pursuit of increasing immunization coverage levels of their patient population (i.e. reminder/recall systems)

What are some key initial data issues?

(to be addressed when first thinking about going to a registry-based assessment)

- **Define the denominator** *(the patients to be included from that site)*
 - > All patients who have ever received at least one immunization
 - > All patients who have received an immunization in the past year
 - > Those patients who were last seen at a particular location
 - > Other

Defining the denominator and being able to describe the rationale for it is one of the most important steps. The definition of choice should, in part, be based on what information will be most valuable to the providers receiving the assessments.

- **Denominator analysis** *(checking the chosen denominator definition)*
 - > How do the denominators showing up in the registry-based assessments relate to what is known about the population of the related clinics? (i.e., Does a clinic with 100 patients have a denominator of 1000?) There must be a reasonable answer for the denominator before the data are used.
 - > Compared with other sources of data for this same age group, how do the denominators compare in terms of numbers and patient characteristics?

What are the differences between a chart-pull assessment and a registry-based assessment? *(Differences will largely depend on how each project has defined its methodology, but these are some potential differences)*

Registry-based	Chart-pull based
Allows for true population-based rates	Rates are based on a sample
True missed opportunities cannot be discussed unless all visits (not just immunization visits) are recorded	Missed opportunities can be discussed
Records entered electronically	Records entered manually
Provides opportunities to study impact of AFIX activities longitudinally with relative ease	Research opportunities available but more time intensive
Time can be devoted to feedback, since the assessment is relatively fast and not resource intensive	Time must be split between the assessment and the feedback, both of which may be time intensive

(Note that providers are unreliable sources of information on denominators—they are often not sure how many children between 1 and 3 that they see.)

- **Understand the differences between the current methodology (chart-pull) and what the registry-based assessment will provide.**

- > Denominator differences
- > Resource differences

Understanding these and other differences will be important to communicating the assessment methodology to providers. Also, understanding these differences will enable providers to better understand the assessment results.

- **Determine a method to quantify the consistency, timeliness, and accuracy with which different providers send data to the registry.**

- > When given the name of a particular provider, do you have a way of knowing how well they submit/enter data?
- > Are you and providers confident in the accuracy of your method?

Registry participation can significantly affect the results of the assessment, so this is an important step. Knowing how well a provider participates in the registry becomes a tool to better understand and communicate the results of the assessment.

Not being able to quantify this information should not stop one from continuing, but this information will become important with more registry-based assessments.

As part of feedback sessions, it is wise to devote time to discussing registry participation with the practice.

- **Foster a good relationship with the registry staff.** This will be a crucial component and communicating regularly and openly will be important.
- **Understand how the registry maintains internal data quality.**
 - > What is the frequency of and process for data deduplication?

- > How are data merged from various sources?
- > What is the registry doing about merging immunization records?
- > How is the registry actively involved in improving data quality?
- > Does the registry allow providers regular access to the reported data (i.e. monthly registry reports) for the purpose of appropriate feedback?

These are all key issues to understand, because they can affect the quality of the assessments. Developing a strong relationship with the registry staff can begin to uncover these and other important data issues.

Also, it is important to communicate to the registry staff that AFIX can be a useful feedback tool that can help provide the registry with valuable information about its data quality.

Key Data Quality Checks

Issues of reliability and validity must be addressed, because providers will inevitably ask questions about these issues.

In general, be prepared to take the time to critically assess the registry-based assessments *before* beginning to provide them to clinics.

- **Historical and concurrent data analysis** (use as many sites as possible)
 - > Up-to-date rates (compare rates as well as differences in rates; are the registry-based rates lower than the chart-pull assessments by a consistent percentage over time?)
 - > Do several registry-based assessments provide similar trend information (drop-offs, late starts, etc) as the chart-review assessments?
 - > If reliable historical coverage rates are available for many clinic sites, compare registry-based assessments with these data. Look for individual practice and group differences. When ranked highest to lowest with the reliable historical data, do the

registry-based assessments show similar rankings (keeping confidence intervals in mind)?

- > When doing quartile analysis (box-plots) with the registry assessments, do clinics remain in the same quartiles in which they were previously placed?

There will likely not be a perfect correlation between chart-review assessments and registry-based assessments, but that isn't necessary to begin using the data (see General Philosophy of Registry Data Use for more on this).

Once the above issues have been addressed and you are able to articulate the process, you may be ready to begin using the data in assessments.

Selling Providers on the Benefits of Registry Participation

Promoting registry participation should become an integral part of a registry-based AFIX program. Part of promoting the registry involves showing providers how assessments are only one advantage among many of participating in a registry.

The following are important benefits to participating in a registry:

- Allows for free and easy assessment of immunization rates and practices
- Allows for access to more complete histories
- Allows schools and other authorized users to view the immunization information rather than calling the provider for the information
- When needing to recall a certain patient population, the registry becomes a powerful tool
- Registry-based reminder/recall becomes a possibility

General Philosophy of Registry Data Use

- Use the data, and it will get better
- Use it or lose it
- Show providers tangible results of the data they are submitting to the registry
- Improving immunization practice is more important than improving rates, and rates will improve with practice (focusing less on the rates will help providers focus more on discussing practice rather than debating the pros/cons of the data itself)
- Be willing to admit that the data are not perfect
- Use registry data for assessments only when able to articulate the methodology to providers. Do careful analyses and be confident
- Communicate to providers the strengths of the registry-based assessments

Appendix H



Examples and Tips on Partnering

Partnering to Implement AFIX

AFIX has primarily been a health department initiated activity. However, a variety of partners could be involved in the various parts of the AFIX process. Please consider the following suggestions for partnering when implementing AFIX.

Assessment: This is often the most labor intensive part of AFIX and can provide opportunities to partner with a variety groups or organizations such as VFC programs, immunization coalitions, managed care organizations, insurers, local chapters of the AAP & AAFP, service clubs, and colleges and universities. These partners may assist by extracting data, pulling/re-filing charts, enlisting private practices to participate, and preparing reports.

Feedback: Within the feedback process, opportunities to partner are limited due to the sensitive and confidential nature of this part of the process. However, partners like immunization coalitions, managed care

organizations, insurers, vaccine representatives, local chapters of the AAP & AAFP and service clubs may be able to assist by providing resources (food, space, funds to cover reproduction costs for reports) to support the feedback session.

Incentives: Most AFIX programs have minimal resources to provide incentives. Therefore, partnering with other organizations to offer incentives is recommended. Please refer to the Incentive section for incentive ideas.

eXchange of Information: Partnering is useful during this part of AFIX. Identifying partners that are willing to reinforce the strengths and monitor the recommended changes of practices can lead to increased commitment by practices and sustain improvement in immunization rates over time. Immunization coalitions, local AAP/AAFP chapters and insurers are good partners for this activity.

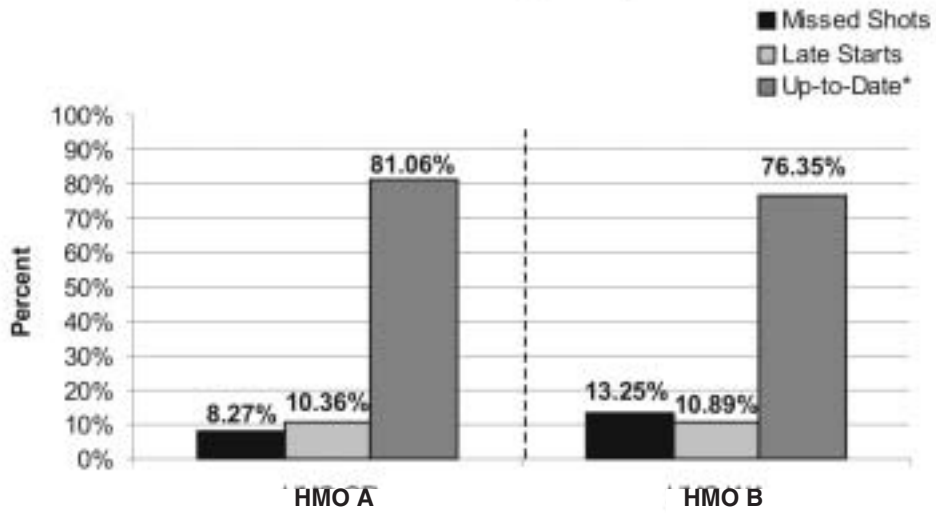
Appendix I



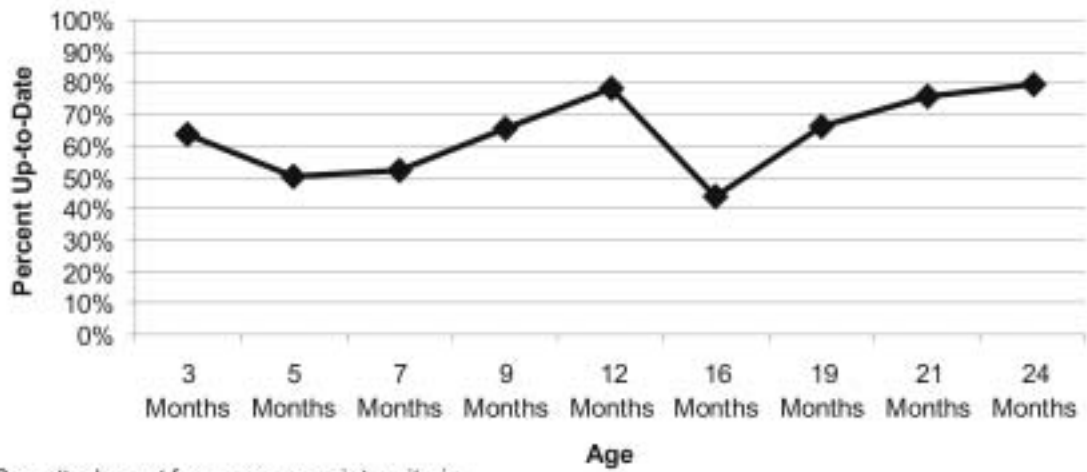
Graphical Representation of Immunization Coverage Levels Between Practices

Examples based on state program graphics

Factors Affecting an Up-to-Date Rate

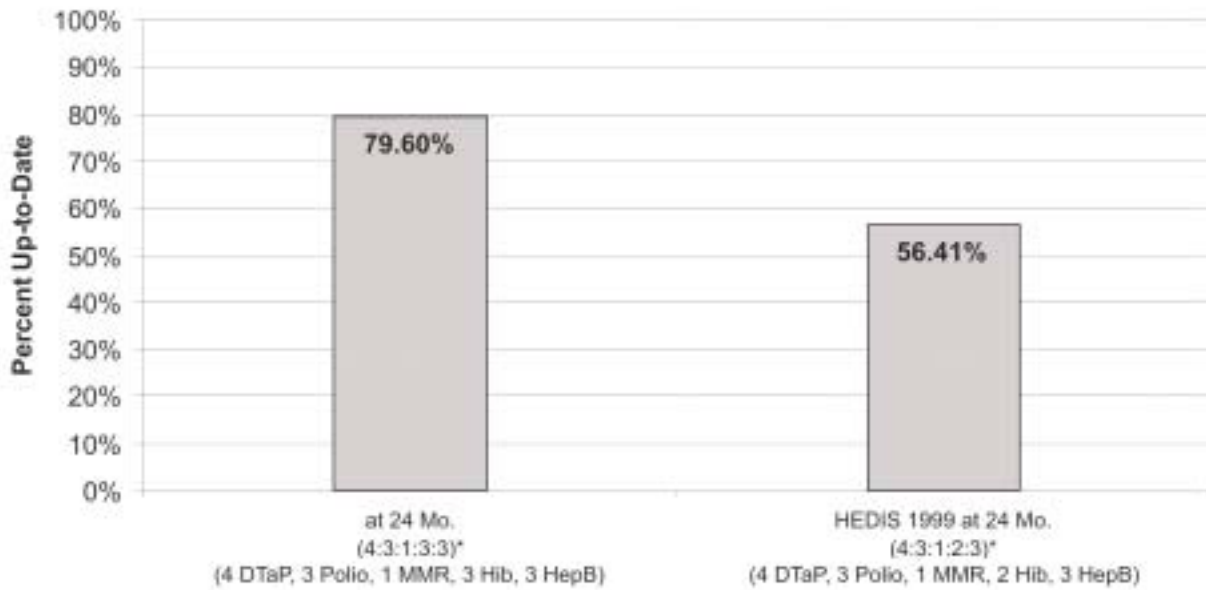


Age-Appropriate* Up-to-Date Rates: HMO Average



*See attachment for age-appropriate criteria

Percent of Kids Up-to-Date by 24 Months:



Appendix J



Examples of Vaccine Administration Records for Medical Charts

*Examples provided by
Immunization Action Coalition
<http://www.immunize.org/>*

Vaccine Administration Record for Children and Teens

Patient name: _____

Birthdate: _____

Chart number: _____

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS [§]	Date given [§]	
Hepatitis B [†] (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)			IM						
			IM						
			IM						
			IM						
Diphtheria, Tetanus, Pertussis [†] (e.g., DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
Haemophilus influenzae type b [†] (e.g., Hib, Hib-HepB, DTaP-Hib)			IM						
			IM						
			IM						
			IM						
Polio [†] (e.g., IPV, DTaP-HepB-IPV)			IM-SC						
			IM-SC						
			IM-SC						
			IM-SC						
Pneumococcal conjugate (PCV)			IM						
			IM						
			IM						
			IM						
Measles, Mumps, Rubella (MMR)			SC						
			SC						
Varicella (Var)			SC						
			SC						
Hepatitis A** (HepA)			IM						
			IM						
Influenza** (Flu)			IM						
			IM						
			IM						
			IM						
			IM						
Other**									
Other**									

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), not the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/

guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

Vaccine Administration Record for Children and Teens

Patient name: Victoria Johnson

Birthdate: December 2, 2002

Chart number: 1234567

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS [§]	Date given [§]	
Hepatitis B [†] (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)	HepB	12/02/02	IM	RT	0651A	MARK	7/11/01	12/02/02	JTA
	Hib-HepB	2/02/03	IM	RT	1051A	MARK	7/11/01	2/02/03	DCP
	Hib-HepB	4/02/03	IM	RT	1051A	MARK	7/11/01	4/02/03	DCP
	Hib-HepB	12/02/03	IM	RT	1051A	MARK	7/11/01	12/02/03	DLW
Diphtheria, Tetanus, Pertussis [†] (e.g., DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)	DTaP	2/02/03	IM	LT	667A2	GJK	7/30/01	2/02/03	DCP
	DTaP	4/02/03	IM	LT	667A2	GJK	7/30/01	4/02/03	DCP
	DTaP	6/02/03	IM	LT	667A2	GJK	7/30/01	6/02/03	DLW
	DTaP	3/02/04	IM	RA	667A2	GJK	7/30/01	3/02/04	RLV
	Hib-HepB (Comvax)		IM						
			IM				1 shot, 2 different VIS dates		
Haemophilus influenzae type b [†] (e.g., Hib, Hib-HepB, DTaP-Hib)	Hib-HepB	2/02/03	IM	RT	1051A	MARK	12/16/98	2/02/03	DCP
	Hib-HepB	4/02/03	IM	RT	1051A	MARK	12/16/98	4/02/03	DCP
	Hib-HepB	12/02/03	IM	RT	1051A	MARK	12/16/98	12/02/03	DLW
			IM						
Polio [†] (e.g., IPV, DTaP-HepB-IPV)	IPV	2/02/03	IM-SC	LT	40123-4	AVP	1/01/00	2/02/03	DCP
	IPV	4/02/03	IM-SC	LT	40123-4	AVP	1/01/00	4/02/03	DCP
	IPV	3/02/04	IM-SC	LT	40123-4	AVP	1/01/00	3/02/04	DLW
			IM-SC						
Pneumococcal conjugate (PCV)	PCV	2/02/03	IM	LT	489-835	WYE	9/30/02	2/02/03	DCP
	PCV	4/02/03	IM	RT	489-835	WYE	9/30/02	4/02/03	DCP
	PCV	6/02/03	IM	LT	489-835	WYE	9/30/02	6/02/03	DLW
	PCV	3/02/04	IM	LA	501-245	WYE	9/30/02	3/02/04	RLV
Measles, Mumps, Rubella (MMR)	MMR	12/02/03	SC	LA	0857A	MARK	1/15/03	12/02/03	DLW
			SC						
Varicella (Var)	Var	12/02/03	SC	LA	0799A	MARK	12/16/98	12/02/03	DLW
			SC						
Hepatitis A** (HepA)			IM						
Influenza** (Flu)			IM						
			IM						
Other**									
Other**									

How to record Hib-HepB
combination vaccine

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), not the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/

guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

Vaccine Administration Record for Children and Teens

Patient name: Sara Smith
 Birthdate: December 2, 2002
 Chart number: 2345678

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ Initials of vaccinator
					lot #	mfr.	Date on VIS ⁵	Date given ⁵	
Hepatitis B [†] (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)	HepB	12/02/02	IM	RT	065TAM	MERK	7/11/01	12/02/02	JTA
	DTaP-HepB-IPV	2/02/03	IM	RT	635A2	GJK	7/11/01	2/02/03	DCP
	DTaP-HepB-IPV	4/02/03	IM	RT	712A2	GJK	7/11/01	4/02/03	DCP
	DTaP-HepB-IPV (Pediarix)	06/02/03	IM	RT	712A2	GJK	7/11/01	06/02/03	DLW
Diphtheria, Tetanus, Pertussis [†] (e.g., DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)	DTaP-HepB-IPV	2/02/03	IM	RT	635A2	GJK	7/30/01	2/02/03	DCP
	DTaP-HepB-IPV	4/02/03	IM	RT	712A2	GJK	7/30/01	4/02/03	DCP
	DTaP-HepB-IPV	6/02/03	IM	RT	712A2	GJK	7/30/01	6/02/03	DLW
	DTaP-Hib	3/02/04	IM	RA	P0897AA	AVP	7/30/01	3/02/04	RLV
DTaP-Hib (Trihibit)		IM							
Haemophilus influenzae type b [†] (e.g., Hib, Hib-HepB, DTaP-Hib)	Hib	2/02/03	IM	LT	4A744AA	AVP	12/16/98	2/02/03	DCP
	Hib	4/02/03	IM	LT	4A744AA	AVP	12/16/98	4/02/03	DCP
	Hib	6/02/03	IM	LT	4A744AA	AVP	12/16/98	6/02/03	DLW
	DTaP-Hib	3/02/04	IM	RA	7172AA	AVP	12/16/98	3/02/04	RLV
Polio [†] (e.g., IPV, DTaP-HepB-IPV)	DTaP-HepB-IPV	2/02/03	IM-SC	RT	635A2	GJK	1/01/00	2/02/03	DCP
	DTaP-HepB-IPV	4/02/03	IM-SC	RT	712A2	GJK	1/01/00	4/02/03	DCP
	DTaP-HepB-IPV	6/02/03	IM-SC	RT	712A2	GJK	1/01/00	6/02/03	DLW
Pneumococcal conjugate (PCV)	PCV	2/02/03	IM	LT	489-835	WYE	9/30/02	2/02/03	DCP
	PCV	4/02/03	IM	RT	489-835	WYE	9/30/02	4/02/03	DCP
	PCV	6/02/03	IM	LT	489-835	WYE	9/30/02	6/02/03	DLW
	PCV	3/02/04	IM	LA	501-245	WYE	9/30/02	3/02/04	RLV
Measles, Mumps, Rubella (MMR)	MMR	12/02/03	SC	RA	0857M	MERK	1/15/03	12/02/03	DLW
Varicella (Var)	Var	12/02/03	SC	LA	0799M	MERK	12/16/98	12/02/03	DLW
			SC						
Hepatitis A** (HepA)			IM						
Influenza** (Flu)			IM						
			IM						
Other**									
Other**									

How to record DTaP-HepB-IPV and DTaP-Hib combination vaccines

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), not the trade name.
[†]For combination vaccines, fill in the row for each individual antigen composing the combination.
[‡]Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/

guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.
 **Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

Vaccine Administration Record for Children and Teens

Patient name: Jack Jones

Birthdate: October 15, 1989

Chart number: 3456789

Before administering any vaccines, give the parent/guardian all appropriate copies of Vaccine Information Statements (VISs) and make sure they understand the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA, RT, LT)	Vaccine		Vaccine Information Statement		Signature/ initials of vaccinator
					lot #	mfr.	Date on VIS ³	Date given ³	
Hepatitis B ¹ (e.g., HepB, Hib-HepB, DTaP-HepB-IPV)	HepB (1.0 mL)	6/02/02	IM	RA	0651M	MARK	7/11/01	6/02/02	TAA
	HepB (1.0 mL)	1/02/03	IM	RA	0651M	MARK	7/11/01	1/02/03	TAA
	2-dose adult HepB for adolescents								
				IM					
Diphtheria, Tetanus, Pertussis ¹ (e.g., DTaP, DT, DTaP-Hib, DTaP-HepB-IPV, Td)	DTP	12/15/89	IM	RT	326-912	LED	1/01/88	12/15/89	DCP
	DTP	2/15/90	IM	RT	326-912	LED	1/01/88	2/15/90	DCP
	DTP	4/15/90	IM	RT	326-912	LED	1/01/88	4/15/90	DLW
	DTP	4/15/91	IM	RA	326-912	LED	1/01/88	4/15/91	RLV
	DTP	4/15/94	IM	RA	326-912	LED	10/15/91	4/15/94	JTA
Haemophilus influenzae type b ² (e.g., Hib, Hib-HepB, DTaP-Hib)	Hib	12/15/89	IM	LT	1492L	MARK	6/01/89	12/15/89	DCP
	Hib	2/15/90	IM	LT	1492L	MARK	6/01/89	2/15/90	DCP
	Hib	10/15/90	IM	LT	1492L	MARK	6/01/89	10/15/90	DLW
			IM						
Polio ² (e.g., IPV, DTaP-HepB-IPV)	OPV	12/15/89	IM-SC	Oral	0678A	LED	3/01/83	12/15/89	DCP
	OPV	2/15/90	IM-SC	Oral	0678A	LED	3/01/83	2/15/90	DCP
	OPV	4/15/91	IM-SC	Oral	0896A	LED	3/01/83	4/15/91	RLV
	OPV	4/15/94	IM-SC	Oral	0987A	LED	10/15/91	4/15/94	JTA
Pneumococcal conjugate (PCV)			IM						
			IM						
			IM						
			IM						
Measles, Mumps, Rubella (MMR)	MMR	1/15/91	SC	RA	0857M	MARK	1/01/88	1/15/91	DLW
	MMR	10/15/01	SC	LA	0946M	MARK	1/01/88	10/15/01	PWS
Varicella (Var)	Var	10/15/01	SC	LA	0799M	MARK	12/16/98	10/15/01	PWS
			SC						
Hepatitis A** (HepA)			IM						
Influenza** (Flu)									
			IM						
Other**									
Other**									

How to record adult HepB vaccine
given to 11-15 year olds

*Record the generic abbreviation for the type of vaccine given (e.g., DTaP-Hib, PCV), not the trade name.

¹For combination vaccines, fill in the row for each individual antigen composing the combination.

³Record the publication date of each VIS as well as the date it is given to the patient. According to federal law, VISs must be given to patients (or parent/

guardian of a minor child) before administering each dose of DTaP, Td, Hib, polio, MMR, varicella, PCV, or HepB vaccine, or combinations thereof.

**Influenza, pneumococcal polysaccharide (PPV23), hepatitis A, and/or meningococcal vaccines are recommended for certain high-risk children.

Vaccine Administration Record for Adults

Patient name: _____

Birthdate: _____

Chart number: _____

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA)	Vaccine		Vaccine Information Statement		Signature/ Initials of vaccinator
					lot #	mfr.	Date on VIS [§]	Date given [§]	
Tetanus and Diphtheria (e.g., Td)			IM						
			IM						
			IM						
			IM						
			IM						
Hepatitis A [†] (e.g., HepA, HepA-HepB)			IM						
			IM						
			IM						
Hepatitis B [†] (e.g., HepB, HepA-HepB)			IM						
			IM						
			IM						
Measles, Mumps, Rubella (MMR)			SC						
			SC						
Varicella (Var)			SC						
			SC						
Pneumococcal** (PPV)			IM+SC						
			IM+SC						
Influenza (Flu)			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
			IM						
Other									
Other									

*Record the generic abbreviation for the type of vaccine given (e.g., PPV, HepA-HepB), not the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the

patient. According to federal law, VISs must be given to patients before administering each dose of Td, MMR, varicella, or hepatitis B vaccine.

**Some high-risk patients need a one-time revaccination with pneumococcal polysaccharide vaccine (PPV).

Vaccine Administration Record for Adults

Patient name: Mohammed Sharik
 Birthdate: April 15, 1978
 Chart number: 06-732543

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks and benefits of the vaccine(s). Update the patient's personal record card or provide a new one whenever you administer vaccine.

Vaccine	Type of Vaccine* (generic abbreviation)	Date given (mo/day/yr)	Route	Site given (RA, LA)	Vaccine		Vaccine Information Statement		Signature/initials of vaccinator
					lot #	mfr.	Date on VIS [§]	Date given [§]	
Tetanus and Diphtheria (e.g., Td)	Td	8/01/02	IM	LA	40376AA	AVP	6/10/94	8/01/02	JTA
	Td	9/01/02	IM	LA	40376AA	AVP	6/10/94	9/01/02	PWS
	Td	3/01/03	IM	LA	40376AA	AVP	6/10/94	3/01/03	TAA
			IM						
1 shot, 2 different VIS dates									
Hepatitis A [†] (e.g., HepA, HepA-HepB)	HepA-HepB	8/01/02	IM	RA	HAB239A4	GSK	8/25/98	8/01/02	JTA
	HepA-HepB	9/01/02	IM	RA	HAB239A4	GSK	8/25/98	9/01/02	TAA
	HepA-HepB	2/01/03	IM	RA	HAB239A4	GSK	8/25/98	2/01/03	TAA
Hepatitis B [†] (e.g., HepB, HepA-HepB)	HepA-HepB	8/01/02	IM	RA	HAB239A4	GSK	7/11/01	8/01/02	JTA
	HepA-HepB	9/01/02	IM	RA	HAB239A4	GSK	7/11/01	9/01/02	TAA
	HepA-HepB	2/01/03	IM	RA	HAB239A4	GSK	7/11/01	2/01/03	TAA
Measles, Mumps, Rubella (MMR)	MMR	8/01/02	SC	RA	0025L	MRK	6/13/02	8/01/02	JTA
	MMR	11/01/02	SC	RA	0025L	MRK	6/18/02	11/01/02	PWS
Varicella (Var)			SC						
Pneumococcal** (PPV)	PPV	10/01/02	IM+SC	LA	0443A	MRK	7/29/97	10/01/02	TAA
			IM+SC						
Influenza (Flu)	Flu	10/01/02	IM	RA	4088211	AVP	6/26/02	10/01/02	PWS
			IM						
			IM						
			IM						
			IM						
			IM						
(This is a record for a 25-year-old health care worker with diabetes who is planning to travel to Saudi Arabia for the annual Hajj.)									
<div style="border: 1px solid black; border-radius: 15px; padding: 10px; width: fit-content; margin: 0 auto;"> How to record combination vaccines given to adults (i.e., HepA-HepB) </div>									
Other	Men	11/01/02	IC	LA	484148A	AVP	3/31/00	11/01/02	PWS
Other									

*Record the generic abbreviation for the type of vaccine given (e.g., PPV, HepA-HepB), not the trade name.

†For combination vaccines, fill in the row for each individual antigen composing the combination.

§Record the publication date of each VIS as well as the date it is given to the

patient. According to federal law, VISs must be given to patients before administering each dose of Td, MMR, varicella, or hepatitis B vaccine.

**Some high-risk patients need a one-time revaccination with pneumococcal polysaccharide vaccine (PPV).

Appendix K



Additional Resources

Helpful Resources for You and Your Providers

TELEPHONE NUMBERS:

National Immunization Hotline:

(English) 1-800-232-2522
(Spanish) 1-800-232-0233
(TTY) 1-800-243-7889

FREQUENTLY USED IMMUNIZATION WEBSITES:

National Immunization Program
<http://www.cdc.gov/nip>

AFIX
<http://www.cdc.gov/nip/afix>

National Partnership for Immunization
<http://www.partnersforimmunization.org/>

Immunization Action Coalition
<http://www.immunize.org/>

The Children's Hospital of Philadelphia
<http://www.vaccine.chop.edu/>

National Network for Immunization Information
<http://www.immunizationinfo.org/>

Every Child by Two
<http://www.ecbt.org>

American Academy of Pediatrics' Childhood Immunization Support Program
<http://www.cispimmunize.org>

HIPAA (MMWR 2003)
<http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm>

CONTINUING EDUCATION CREDENTIALING ORGANIZATIONS:

International Association for Continuing Education and Training
<http://www.iacet.org/> and
<http://www.iacet.org/index2.htm>

American Nurses Credentialing Center of American Nurses Association
<http://www.ana.org/ancc/reviews.htm>

Accreditation Council for Continuing Medical Education
www.accme.org

National Commission for Health Education Credentialing, Inc (CHES)
<http://www.nchec.org/newhome.htm>
http://www.nchec.org/continuing_education%20map.htm

American Association of Medical Assistants, Inc.
<http://www.aama-ntl.org/ed/pprm.html>

National Center for Competency Testing – National Certified Medical Office Assistant (NCMOA)
<http://www.ncctinc.com/reference/onlineCEU00.htm>

Appendix L



Glossary of Terms

Glossary

- ACASA** The Adult (and Adolescent) Clinic Assessment Software Application (ACASA) to facilitate obtaining immunization data on adults and adolescents. Like its pediatric counterpart, CASA, ACASA is a tool for assessing immunization practices within a clinic, private practice, or any other environment where immunizations are provided.
- ACIP** Advisory Committee on Immunization Practices (ACIP) is a panel of experts who make recommendations on the use of vaccines in the United States. The panel is advised on current issues by representatives from the Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health, American Academy of Pediatrics, American Academy of Family Physicians, American Medical Association and others. The recommendations of the ACIP guide immunization practice at the federal, state and local level.
- Administrative Data**
Information on medical procedures such as immunizations that is collected, processed and stored in automated information systems.
- AFIX** Acronym for the continuous quality improvement strategy of Assessment of immunization coverage levels, Feedback of coverage level to provider and staff, Incentives to improve coverage levels and eXchange of information of how to make changes in immunization service delivery to improve coverage levels.
- AARP** American Association of Retired Persons is a nonprofit membership organization dedicated to addressing the needs and interests of persons 50 and older. The organization seeks to enhance the quality of life for all by promoting independence, dignity and purpose. www.aarp.org
- AAP** The American Academy of Pediatrics (AAP) and its member pediatricians are dedicated to the health, safety and well-being of all infants, children, adolescents and young adults. The AAP has members in the United States, Canada and Latin America. Members include pediatricians, pediatric medical sub specialists and pediatric surgical specialists. www.aap.org/
- AAFP** The American Academy of Family Physicians is the national association of family doctors. It is one of the largest national medical organizations, with members in 50 states, D.C., Puerto Rico, the Virgin Islands, and Guam. www.aafp.org/
- Assessment**
The Standardized collection, analysis and summary of how well a provider is delivering immunizations. Both qualitative (office workflow, interaction with patients) and quantitative (immunization coverage levels) data should be collected during this component of AFIX.
- CASA** Clinical Assessment Software Application a menu driven software program developed by the National Immunization Program/Centers for Disease Control (CDC) to assist in the assessment component of AFIX.
- Continuous Quality Improvement (CQI)**
A process which continually monitors performance on specific measure such as immunizations. When a problem is identified, CQI develops a new method of implementing services related to the measure and monitors the success of the intervention.
- CMS** Centers for Medicare & Medicaid Services (CMS), the federal agency that runs the Medicare program. In addition, it works with the States to run the Medicaid program. CMS works to make sure that the beneficiaries in these programs are able to get high quality health care.
- Centers for Disease Control and Prevention (CDC)**
The Centers for Disease Control and Prevention is the lead federal agency for protecting the health and safety of Americans. CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability.

EPSDT Early, Periodic Screening, Diagnosis and Treatment Program. The comprehensive well child program available to children enrolled in Medicaid under the age of 21 years.

Exchange of Information

Providing access to more experience than individuals can accumulate by themselves. Exchanging information maybe done formally or informally and should be included in the feedback session. The gold standard for information exchange is peer to peer with an immunization champion. Informal methods used during the feedback can be very effective in certain situations.

Feedback The process of informing immunization providers about their performance in providing vaccines to a specifically defined population. It must be a two way conversation between the assessment staff and the provider and office staff to determine what interventions can realistically be implemented in that office.

Health Employer Data and Information Set (HEDIS)

A set of standard performance measures that can provide information on the quality of care provided generally at a Health Plan level.

HHS Department of Health and Human Services is the United States government's principal department for protecting the health of all Americans and providing essential human services. CDC and CMS are located within DHHS.

HIPAA A Federal law that allows persons to qualify immediately for comparable health insurance coverage when they change their employment relationships. Title II subtitle F of HIPAA (Administrative Simplification) gives HHS, the authority to mandate the use of standards for the electronic exchange of health care data; and among other items to specify the types of measures required to protect the security and privacy of personally identifiable health care information. Public law 104-191.

Incentives

Something that motivates individuals to make changes in practices. Incentives may be either formal or informal.

Managed Care Organizations

Entities that provide health care services to enrolled members through a network of employed or affiliated providers. The term may include Health Maintenance Organizations, Preferred Provider Organizations and Point of Service Plans. These organizations integrate the financing and delivery of appropriate health care services to enrolled members.

Medicaid A joint federal and state program that helps with the medical cost of certain low income individuals. Medicaid programs vary from state to state.

National Committee for Quality Assurance (NCQA)

An organization that accredits managed care organizations. NCQA maintains the HEDIS reporting system.

Network A group of doctors, hospitals, pharmacies and other health care providers hired by a health plan to take care of its members.

Random Sample

A group of people or items with some common attribute arbitrarily selected for study from a larger group of people with the same attribute.

Vaccines for Children Program (VFC)

A Federal program that provides public purchased vaccine, for eligible children, at no charge to public and private providers in all states and territories based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and approved by the Centers for Disease Control and Prevention (CDC). Saves parents and enrolled providers out-of-pocket expenses for vaccine. Eliminates vaccine cost as a barrier to immunizing eligible children. Reduces the practice of referring children from the private sector to the public sector for vaccination, thereby keeping children in their medical home for comprehensive health care.

SCHIP

The Balanced Budget Act of 1997 created a new children's health insurance program under Title XXI of the Social Security Act called the State Children's Health Insurance Plan (SCHIP). This program enabled States to initiate and expand health insurance coverage for uninsured children. States could create a separate insurance

program, expand Medicaid, or combine both approaches.

Invalid dose

A vaccination administered before the ACIP recommended age for receipt or when a dose of vaccine is given before the minimal time interval has elapsed for an individual to receive that vaccine and be considered a valid dose.

VIS

Vaccine Information Statements provide information on the vaccine to be received by the patient. VIS's are required to be given prior to the administration of the vaccine in accordance with the National Childhood Vaccine Injury Act. The most current VIS must be given prior each and every vaccination.

