Instructions for Completing the Immunization Quality Assurance On-Site Evaluation Report (Electronic Template)

The 2007 Texas Department of State Health Services (DSHS) Immunization Quality Assurance (QA) On-Site Evaluation Report is a dual-purpose QA monitoring tool to be used by both DSHS Immunization QA reviewers and TMF TVFC reviewers. The report tool is based on a Microsoft Excel format, and consists of 61 items.

The general instructions are divided into 6 main topic areas:

1. **Getting Started** -What do I need to get started? How do I open and view the different sections of the report tool?
2. **Navigating and Entering Data** -How do I move electronically through the tool and enter data correctly?
3. **Collecting Information and Data** -What general methods and sources can I use to collect the information needed to complete the tool?
4. **Providing Feedback, Education and Intervention** -What general methods and sources can I use to provide appropriate feedback and/or education to clinic staff? Which items are critical enough to require immediate intervention? What corrective actions and/or comments should be shared with the provider in order to assist the provider in improving the quality of their services?
5. **Completing the Header: Step-by-Step Instructions**. How do I fill out the header section?
6. **Completing the Numbered Items: Step-by-Step Instructions**. How do I address and record the answer to each specific item? Does this item require intervention (calls to DSHS, etc.)? What instructions, education and Resources can I provide to clinic staff for each item topic?

All of the items for review in the VFC only On-Site Evaluation Report have pre-developed corrective actions (and some items have pre-developed comments) which may be selected by the reviewer by left-clicking in a checkmark box next to the corrective action or comment statement. One or more corrective action and/or comment statements may be selected. All items provide the opportunity for the reviewer to type in corrective actions and/or comments in a text box area titled 'Other Comments'. Corrective action statements and/or comments were incorporated into the survey tool to:

- Make it easier and more user-friendly for the reviewer to complete the form.
- Collect data to determine which areas are more problematic for providers in general, or for certain providers in particular.
- Provide an opportunity for newer reviewers to learn about the review process without having to search through the Reviewer Manual.

GETTING STARTED

To complete the On-Site Evaluation Report, you will need:

- A laptop computer with the On-Site Evaluation tool loaded (Microsoft Excel format).
- Information from the Monthly Biological Reports (C-33).
- Results from the Clinical Assessment Software Application (CoCASA) tool, Immunization Record Review Tool (IRRT), the Gain/Loss Calculation Table and the 60-day Stock Level calculations. You will need the results from these tasks to answer specific items on the On-Site Evaluation Report.
- Reference information: TVFC Resources Reviewers Manual 2007, TVFC Provider Tool Kit, and CDC Vaccine Storage and Handling Toolkit (website).

Open the DSHS Imm QA On-Site Evaluation Report template

- From your desktop: Double-click on the DSHS Imm QA Survey 2007 icon, or
- From the START menu: Click 'Start' → 'All Programs' → 'DSHS Immunization Division' → 'QA Survey 2007Template'.
- At the window prompt, **click to select the 'Enable Macros' button**: Note this is NOT the default, so you need to move your cursor to the 'Enable Macros' button and then click once. This is essential, so that you don't run into serious problems as you use this tool.

The On-Site Evaluation Report (Site Survey Template) is a dual purpose report. There are two report types:

- The "Full Survey" is conducted on all provider sites who are on contract with DSHS
- The "VFC Only" is composed of only critical VFC components and is conducted on provider sites who are not on contract with DSHS. **This is the report that the TMF reviewer will use.**

There are 6 report sections. When you open the On-Site Evaluation Report file, you will see a set of 6 tabs at the bottom of the screen window. You can maneuver through the reports by clicking on the desired tab:

- 1st tab: Header – general information
- 2nd tab: Site Survey – main report (On-Site Evaluation Report)
- 3rd tab: IRRT – 10 chart review
- 4th tab: Vaccine Gain/Loss – vaccine Gain/Loss Calculation Table
- 5th tab: Follow-Up – for follow-up by local health department (LHD) or the health service region (HSR) staff
- 6th tab: Software Usage – software usage information

***NOTE: From this point on, the instructions address how to complete the "Site Survey" main report section only. To complete the CoCASA, IRRT or the Gain/Loss Calculation Table, refer to other tabbed sections in this manual.

NAVIGATING AND ENTERING DATA

To make the On-Site Evaluation Report easier to view and enter data into, you can:

- Adjust the % view (zoom): Click on View, Zoom, and select the desired level. Most reviewers like this set at 100-125% to view larger sections of the report at one time.

Colors act as a guide to completing the report

- Blue: Full Survey items – This means the file is in the "Full Survey" mode.
- Pink: Needs information filled in. There are 2 reasons for pink cells:
  - Original color is pink: Must be filled in.
  - Changes to pink: There has been an entry of "n" or "na" in the item's answer column, which triggers a need for information or explanation in the 'Corrective Actions', 'Comments', and/or 'Other Comments' areas (turns from white → pink).

Completed reports should have no "pink boxes"

- Pink → to Green, Orange or White:

  Generally, when information is entered into pink boxes, they change to white, which means that no further information is needed. However, when pink boxes in the 'answer' column are filled with different answers, the cell will change to one of 3 colors:
  - Answer "y": Pink → turns green (no intervention required)
  - Answer "n": Pink → turns orange (needs selection of 'Corrective Actions', 'Comments', and/or entry in 'Other Comments' areas)
  - Answer "na":Pink → turns white (needs selection of 'Comments' and/or entry in 'Other Comments' areas to explain)
- Red Triangles

  These small triangles in the upper right corner of some cells alert you to a hint for filling the cell in. To reveal the hint, hover the cursor over the triangle. To see the hints on the cells for the phone and fax numbers in the Header tab, you may need to scroll over to the right.

Drop-Down Menus alert you to a selection of possible answers

Some cells have an arrow box on the right side, which alerts you to a drop-down menu to select information from. The arrow for the drop-down box will appear when the cell is entered. Examples in the Header include Type of Practice, County, and Tool Kit.

Pop-Up Hints automatically appear in some header cells

There are several cells in the Header tab that have pop-up hints for data entry. These cells have red triangle tabs, but you do not have to hover the cursor over the triangle to see the hint – moving the cursor over any part of the cell triggers the hint to pop up on the right.

Navigating within the Site Survey Report

- You can use your mouse (or touch pad) to move your cursor to any desired cell or answer box. Simply click once on the cell to open it for data/text entry. If you want to change or add to existing text in a cell, then you must double-click in the desired cell. This will place a blinking cursor there and allow you to change existing text.
- Using the Arrow, Enter and Tab keys:

  These keys work in all of the report sections, except in the far left column that contains data entry boxes (directly under the item questions):

  - Arrow keys:The ↑ and ↓ keys will move you up and down directly in the same column. The →and ← keys will move you directly across each row, left or right.
  - Tab key:The Tab key will move you (right) directly across each row to the end, and then down and over (left) to the first answer column in the next row.
  - Enter key:The Enter key will move you down directly in the same column.

Navigating and entering data in the far left column (answer boxes below item statement)

- The ONLY way to move to and from the answer boxes in the far left column is to use the mouse (or touch pad) to move the cursor and click directly on or off the box. The Arrow, Tab and Enter keys will not work here. To enter data, you must click directly in the box. If you click on the box, but:
  - Nothing happens (cannot enter data) – Check to see if you have a flashing cursor in another cell on the right. If so, use your arrow keys or the tab key to move out of that cell into another cell on the right, which will eliminate the flashing cursor. Then try moving your cursor and clicking on the box in the left column again.
  - The box appears highlighted with little circles, like an inserted picture or drawing canvas (cannot enter data) – In this case, the template has reverted to "design mode". This happens as a result of cutting or copying and pasting cells within the spreadsheet. **DO NOT CUT OR COPY AND PASTE CELLS. IN ORDER TO FIX THIS, CALL YOUR TVFC CONSULTANT**.

Entering Data in the Site Survey report

- Entering text in a cell:
  - To enter text in a blank cell, just click on the cell (highlights cell – dark border appears), and you can begin typing text in the cell.
  - To edit text in a text-filled cell, double-click in the cell (creates blinking cursor) and move the cursor to the spot you want to edit. You can use the delete and backspace keys to delete sections of text.
  - **DO NOT CUT OR COPY and PASTE** any text from one cell into other cells. This action can cause the program to copy the cell formula, which then triggers the spreadsheet to switch to design mode – making it impossible for you to enter data in some other cells.
- Marking a Box or a Button:
  - To select or mark a box or a button, point to the box or button and left click once. This will place a checkmark in the box, or a dot in the button.
- Correct formatting and writing:
  - Text formatting: Please enter all text in typical report writing format with capitals and small letters (not all CAPS).
  - Grammar: Use brief, but complete statements. Provide enough information that someone else reading your comments will be able to understand what you're trying to convey.
  - Spelling & punctuation: Please check your spelling and punctuation – remember, this is a professional report, and we have to correct it if you don't check it.

- Publications: Any published Resources you give out should be noted correctly: Instead of "Gave After the Shots," checkmark a box if applicable, or enter "Provided After the Shots information sheet" in the 'Other Comments' area.
- Abbreviations and acronyms: Common immunization program-related abbreviations or acronyms are acceptable, however, please do not cut or abbreviate words in ways you wouldn't normally do in a report.

- Content: Your answers, coupled with corrective actions and comments should give our client (DSHS) a good idea of the situation related to that item. The three elements you may need to address are:
  - What is your source of information?
    - Some items are based on the results of other data analysis tools, such as the IRRT, Gain/Loss Table and the CoCASA. Some of these results are automatically linked to the Site Survey and will appear in the boxes of the corresponding item. In this case, you will need only to correctly answer the item by check-marking a box and/or adding any applicable comments.
    - For other items, sometimes it is good to note the clinic staff member who supplied the information if this person is different from your contact. For example, if the provider actually talks to you about his reasons for not following true contraindications, you might want to NOTE: "Dr. Jones states he also holds vaccines for ...", in the 'Other Comments' area.
  - Why did the clinic receive an "n" or "na" on this item?
    - If the reason for the "n" is obvious, like a temperature out of range, then you don't need to write this – it would be repetitive. However, there are several items where there could be multiple reasons for an answer. You would need to, make the appropriate selection(s) in the 'Corrective Actions'/'Comments' area, and/or comment in the 'Other Comments' area.
    - If the clinic receives an "na" on an item, select a Comment and/or provide an explanation in the 'Other Comments' area.
    - If you answer "n" to an item, there should always be a Corrective Action(s) selected, or entered in the 'Other Comments' area, and education. However if you answer "y", do not mark any of the pre-developed Corrective Actions.
    - Make sure the corrective action(s)/education matches the CAUSE of the problem/need. For example, WHY is the CcCASA rate so low? Is it because of incomplete histories, non-active patients entered into CoCASA who should have been designated as Moved/Going Elsewhere (MoGE), or missed opportunities to give simultaneous vaccines?
    - Did you note any clear relationships between missed vaccinations (low % for certain vaccines) that could point to a process change? For example, if the DTaP4 rate is only 80%, yet the MMR1 rate is 98%, you might ask if the clinic is missing getting the children back in at 15-18 months. If this is a possibility, then you might advise the clinic to give children the DTaP4 at the same visit as the MMR1 (usually at 12 months), as long as it has been at least six months since the DTaP3 was given. If they aren't amenable to that suggestion, you might want to advise they perform chart audits for patients who are 15 months old or institute a stronger recall for this age group.
  - What corrective action/education did you do?
    - The key is: Be specific in your suggestions about causes and interventions you gave – "Advised on raising imm rates" used as a stock phrase in all your site visit comments does not give much useful information. Remember, YOU are the expert – so think about how you educate and what you document.
    - Document "extra" education: There are many times you will educate clinic staff and/or give out resources as you perform the review, or upon request. Don't forget to take credit for this and note it either in the 'Other Comments' area or 'Overall Review Comments' area at the end of the site survey report.
    - Be complete, but don't repeat the obvious – i.e., if the item's answer is "n" then you don't have to write "clinic doesn't ….". For example, if you answered "y" for the item "provides vaccines regardless of ability to pay," then you don't have to write, "never refuses vaccines to those who can't pay." However, you could write, "works out a payment plan or writes off vaccine cost" to explain HOW this is done, if you choose. Also, if the same corrective action or comment typed

into the 'Other Comments' area applies to more than one item, you can type "See comment for item #" in the 'Other Comments' area where you would otherwise make the same comment.

- **ON REFRIGERATION ISSUES:**
  - Regional staff
    - If there is a refrigeration issue, you MUST take immediate action. You may need to call the DSHS-AO Pharmacy Branch at 512-458-7500. Items on the site survey that might require contact are 48a, 50a, 50c, 50d, 51b, and 51c. If the appropriate action is to remove the vaccine please note that in the 'Other Comments' area.
  - TMF
    - If there is a refrigeration issue, you MUST contact the health department contact while still at the site. Items on the site survey that require contact are 48a, 50a, 50c, 50d, 51b, and 51c. Use your list of LHD and HSR contacts. Try first to speak to the LHD contact if there is one. If you can't talk directly to the local contact, leave a message (voicemail), then call the HSR contact. If you are unable to talk directly to the HSR contact, leave a message (voicemail) and then call TMF. We can help contact DSHS or give advice on the next step - You MUST speak to someone directly so that they can immediately act on the refrigeration issue. ***DO NOT ASK THE CLINIC STAFF TO CONTACT THE LHD or HSR – CONTACT IS YOUR RESPONSIBILITY***.
    - When you contact the LHD and/or HSR, make sure you NOTE in the 'Other Comments' area:
    - WHOM you left messages with, and
    - WHOM you spoke to directly, and
    - What time you spoke with or left message with the contact. Ex: "Left voicemail message for Donna Smith, LHD. Spoke with Mary Abrams at HSR #7 office via phone at 11:30 a.m."
- Overall Review Comments: The 'Overall Review Comments' section at the end of the On-Site Evaluation Report should contain only a very brief overview of important things that relate to your clinic visit, yet have not been addressed anywhere else in the tool. You might want to come up with a format for writing these comments so they are consistent and complete. Here is one suggestion:

"The Happy Shots Clinic is a small rural family practice with two MDs; Few clients under 18; Complete staff turnover in the past month; Staff contact was new nurse with limited experience with TVFC; Staff very responsive to teaching and interested in attending future DSHS TVFC training."

It's very important to write clearly and briefly, as the text allotment for this area is small.

- Completing and reviewing the report
  - The general rule is: NO PINK IN THE ANSWER, CORRECTIVE ACTIONS OR COMMENT COLUMN. Please verify that all the questions have been answered and all needed corrective actions/comments have been added before you submit your report.
  - Check that the "Totals" area just before the 'Overall Review Comments' box shows the "Blank" row as "0."
  - Double-check your supporting information.

CoCASA: Are the # of records reviewed, # of records > 24 months of age, and resulting percentages correct?

IRRT: Have you referenced all 9 indicators? The 2007 version populated the number of records into the tool (for the appropriate questions) automatically.

Vaccine Gain/Loss: If the gain/loss is significant, did you double-check your calculations? If correctly calculated, did you explain the gain or loss?

COLLECTING INFORMATION AND DATA

Gathering Information

There are several ways to gather the information needed to answer the On-Site Evaluation Report items. These methods are listed as 5 columns immediately to the right of the answer column.

- (O)--Observation: Observe the process in the site/clinic.
- (IS)--Interview with Staff: Interview the clinic staff.
- (IC)--Interview with Client: Interview a client.
- (R)--Review Resource Materials or Documents: Review any written policies or other documents (policy & procedure manuals, posted materials, staff memos; note references in the comments).
- (D)--Review Documentation of Immunizations: Review of any documentation of immunizations (e.g., medical records, files and/or databases with individual/group immunization records).

For each item, you will note some of the source column cells are pink, and some gray. Pink means that method is an acceptable way to collect the information needed to answer that item. Gray means that method is not appropriate. Use as many suggested methods as you are able to, to get an accurate response to the particular statement.

For each method that has a pink box, put a "y" for "yes" or an "n" for "no" to indicate that you did or did not use that method to get the information needed to arrive at your response to the item. You can use either upper or lower case.

There may be several reasons that you were unable to answer an item, e.g., the key contact person was ill and other staff members could not answer your question. Before submitting the report, please attempt to call the clinic back to obtain the information over the phone. If you are still not able to answer the item contact Austin.

Collecting Data from Other Reports:

- The results from the IRRT, and Gain/Loss Calculation Table all feed into the Site Survey. In addition, you can gather information from CoCASA, the C-33's and Re-Enrollment Forms. Though you will find you need to be flexible in gathering information, there is nothing wrong with a good plan of attack.
- Since all of these data sources are needed to complete the Site Survey, and also give you added insight into potential issues, it would be to your advantage to complete them as early on as possible during the site visit.
- In addition, we recommend you initially review the Re-Enrollment Form when you first meet with the clinic contact. This is to make sure they have the form signed (or prompt them to get the form signed), and also to verify the client population. This form should be the basis for posing, and answering questions about VFC fees, under-insured fees, eligibility, and CoCASA records. If what the clinic staff contact tells you does not match their enrollment information, then find out why not. You should be verifying these forms are complete and accurate.
- Also, performing the CoCASA early will help you get a good overview of the clinic's approach to immunization policies. This is because, as you perform the CoCASA, you will get a much better idea of how the immunization documentation is set up, and be alerted to potential issues in immunization documentation. For example, if you have difficulty finding histories in the CoCASA records, you know this would be an item to address in improving immunization rates – you don't need to just use the IRRT results.

PROVIDING FEEDBACK, EDUCATION AND INTERVENTION

The spirit of the site visit is educational and focuses on a customer service approach. Each site visit is viewed as DSHS's opportunity to "reach out" and touch base with their providers, so we want their experience to be good. Finally, you are representing TMF and DSHS, so it is important you appear professional, knowledgeable and helpful. If the site is using out-dated documentation (e.g., VIS) or doesn't have the necessary documentation relating to a particular question, be prepared to show the clinic where this information is in the TVFC Provider Tool Kit or your resource Manual and/or assist the clinic in obtaining those documents during the site visit. If you provide the clinic with the necessary and/or current documentation (VIS), still check the "n" or "Outdated" area for the item(s) but note their provision in the 'Other Comments' area.

COMPLETING THE HEADER: STEP-BY-STEP INSTRUCTIONS

- Click on the '**Header' tab** at the bottom of the screen.
- Use the down arrow key to enter the first column of information in the header.
- **Provider Identification Number (PIN**): Enter the PIN for the clinic being reviewed. (Be sure to enter all 6 digits of the PIN **WITHOUT dashes**: Example: "070333")**.**

- **Provider/Clinic Name**: Fill in the full name of the provider or clinic. Check this against the Provider Re-Enrollment Form to verify the name and spelling. Use the same name in this field that you use for the CoCASA Assessment Site.
- Immediately after you enter these two fields (PIN and Provider/Clinic Name), click on the 'Save' icon. In the File Name box, enter the PIN, and then a single space followed by the clinic name, e.g., "555555 Pediatric Clinic of Anywhere".
- Then click on 'Save'. This will save your file for this clinic in the 'My Documents' folder, so that you can later copy it onto a disk. Note that the file name is now in the top blue bar on your computer screen. Also, the file name cannot be greater than 70 characters.
- **Contact**: Type in the name of the person you worked with to coordinate the site visit or the person you worked most closely with during the site visit. This is usually the nurse, vaccine manager, or office manager. This should be the same person as the name on the Provider Enrollment Form, unless the usual contact was not available.
- **Type of Practice**: Check this against the Provider Enrollment Form to verify the type of practice. Use the drop-down list to select the words that describe the type of site visited. In other instances, choose the "other publics" category for sites such as schools, hospitals, youth facilities, etc. Be sure to type in a descriptor in the "Type if Other" cell. If there is any question about the type of practice, check the TVFC Provider Enrollment Form or call the LHD, HSR, or TMF for clarification.
- **HSR or LHD conducting review**: (TMF Health Quality Institute is listed as the default.)
- **Reviewer Name**: Type in your full name.
- **Reviewer Title**: Type in your job title or credentials, e.g., RN, LVN, RHIA, RHIT, etc., can be used instead of your title.
- **Address**: Enter the street address, including suite number if appropriate.
- **City**: Enter the name of the city.
- **Zip**: Enter the zip code.
- **County**: Use the drop-down list to enter the name and number of the county where the clinic is located.
- **Phone and Fax Numbers**: Use the format of 999-555-5555 to type in the phone and fax numbers for the clinic. Be sure to include area code.
- **Review Date**: Use the format of MM-DD-YY to enter the site visit date. If the review spans two days, list only the date that the site visit was completed.
- **Total Time Spent**: Enter the total amount of time you spent conducting the site visit.
- **Tool Kit Provided**: Use the drop-down list to identify if the Provider Tool Kit was:
  - Provided
  - Already provided
  - Not provided

  In the date column, insert the clinic visit date if you provided the TVFC Provider Tool Kit, or type in the approximate date that the clinic received a TVFC Provider Tool Kit (month and year are sufficient).
- Use the Tool Kit Comments section to note any of the following:
  - The clinic staff's reaction to receiving the Provider Tool Kit.
  - Additional and/or replacement materials provided to the clinic during the site visit.
  - The reason that a clinic without a Provider Tool Kit did not receive one during the site visit.
- **Reminder/Recall Kit Provided:**
  - Enter date Reminder/Recall "Shot Box" was provided if applicable

COMPLETING THE NUMBERED ITEMS: STEP-BY-STEP INSTRUCTIONS

Here are some general parameters for completing the tool.

- All of the statements require a "Yes," "No" or sometimes an "NA" response. Enter a "y" for yes, an "n" for no or an "na" for not applicable. You can use either upper or lower case.
- A "y" answer is the preferred response to all questions. Although you do not have to add any comments for a "y" answer, you can use the 'Other Comments' area to provide relevant information specific to the clinic you are reviewing. Do not mark any of the pre-developed Corrective Actions.
- An "n" response will result in the 'Corrective Action' and 'Other Comments' area turning pink, meaning that you need to identify the problem along with the recommended solution(s). This is applicable to all items except for #15a and #15b.
- An "na" response will result in the 'Comments' and/or 'Other Comments' area turning pink, meaning that you need to need to make the appropriate selection and/or enter the necessary comments to explain.
- It is critical to state the recommended solution(s) in the form of a corrective action. The appropriate corrective action can be chosen from the check box (for a "n" answer) or a specific answer can be typed in 'Other Comments' area (for a "y" or "na" answer), if necessary, or when the 'Other' box is checked. Many of your corrective actions should emphasize the "3 Rs":
    - Record-keeping (especially complete histories),
    - Recall systems, and
    - Reminder systems.
- The 'Other Comments' area is limited to only 1000 characters, so please be concise. If after finishing an entry, the text is not all visible, even when the cell has expanded, then go back and edit to the best of your ability. You can put any deleted text of a critical nature in the Other Review Comments box at the end of the Site Survey. The "na" should be reserved ONLY for TVFC items that do not apply to that particular site. Be sure to enter an explanation in the 'Other Comments' area as to why the item is not relevant.

Specific Instructions for Numbered Items on the DSHS IMM QA On-Site Evaluation Report

Item 1 Suspected Cases of Vaccine-Preventable Diseases Reported

Prior to program review, obtain status report from Infectious Disease Control Unit (IDCU) on all suspected cases of vaccine-preventable diseases reported from the county or area under review. This report can be detailed (name and demographics) or can be aggregate counts only. IDCU can also provide the name of the person in local agency responsible for coordinating disease reports, as well as the name of the person responsible for investigating suspected diseases.

Sources of information

- (IS) Interview Staff; Sample questions (provider)
  - Ask staff for names and telephone numbers of local doctors, hospitals, clinics, laboratories, schools, child-care facilities, etc. There should be a system in place to collect disease reports routinely from these groups/individuals; make a brief note of their reporting system.
- (R) Review Resource Materials or Documents: Review local morbidity reports and files and compare with state data. Review list of local reporting sources or sentinels.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Suspected cases of vaccine-preventable disease are reported
- Mark this item "n" if:
  - Suspected cases of vaccine-preventable disease are not reported

Resources

- Infectious Disease Control Unit (IDCU) at DSHS-AO:
  - Notifiable Conditions in Texas (#6-101A)
  - Rules and Regulations Governing the Control and Reporting of Notifiable Conditions (#E6-106)
  - Vaccine-Preventable Disease Surveillance Guidelines (#E-106)

Item 2a Timely Initiation of Disease Investigations

Disease Investigations are initiated within 24 hours of initial report.

For example, investigation of rash/fever illnesses must begin immediately to control spread of measles and initiation of prophylaxis can avert spread of pertussis among close contacts

Sources of information

- (IS) Interview Staff; Sample questions (provider)
  - Interview staff to ascertain their knowledge of the importance of prompts vaccine-preventable disease investigation.
- (R) Review Resource Materials or Documents: Review dates on case investigation forms on file locally.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Initiation of investigation is within 24 hours of initial report.
- Mark this item "n" if:
  - Initiation of investigation is not within 24 hours of initial report.

Resources

- Infectious Disease Control Unit (IDCU) at DSHS-AO:
  - Notifiable Conditions in Texas (#6-101A)
  - Rules and Regulations Governing the Control and Reporting of Notifiable Conditions (#E6-106)
  - Vaccine-Preventable Disease Surveillance Guidelines (#E-106)

Item 2b Timely Completion of Disease Investigations

Some of these data can be obtained from IDCU prior to program review.

Sources of information

- (IS) Interview Staff; Sample questions (provider)
  - Who is locally responsible for providing completed case investigation forms to IDCU--and how often?
- (R) Review Resource Materials or Documents: Review local morbidity files for completeness of case investigation forms.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Completion of investigation is within 30 days.
- Mark this item "n" if:
  - Completion of investigation is not within 30 days.

Resources

- Infectious Disease Control Unit (IDCU) at DSHS-AO:
  - Notifiable Conditions in Texas (#6-101A)
  - Rules and Regulations Governing the Control and Reporting of Notifiable Conditions (#E6-106)
  - Vaccine-Preventable Disease Surveillance Guidelines (#E-106)

Item 3 Active Surveillance

Provider has an active system in place where specific reporting sentinels are contacted by telephone and reports of vaccine-preventable diseases are solicited.

Sources of information

- (R) Review Resource Materials or Documents: Review list of reporting sentinels and procedures for active surveillance.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Provider has active system in place.
- Mark this item "n" if:
  - Provider does not have active system in place.

Resources

- Infectious Disease Control Unit (IDCU) at DSHS-AO:
  - Notifiable Conditions in Texas (#6-101A)
  - Rules and Regulations Governing the Control and Reporting of Notifiable Conditions (#E6-106)
  - Vaccine-Preventable Disease Surveillance Guidelines (#E-106)

Item 4 True Contraindications Followed

National Vaccine Advisory Committee (NVAC) Standards for Child and Adolescent Immunization Practices Standard 6: Health care professionals assess for and follow only medically accepted contraindications.

Providers should follow only true contraindications as outlined by the most current Advisory Committee on Immunization Practices (ACIP) recommendations.

Misperceptions about true contraindications to immunizations are common. Health care professionals and parents often believe that immunizations should be delayed when a child is sick or is running a fever. As seen on the documents in the resource sleeves, mild to moderate illness and low-grade fever are not contraindications to providing an immunization when it is due.

Sources of information

- (O) Observe client interview prior to immunization.
- (IS) Interview Staff; Sample questions (provider)
  - Under what circumstances or for what conditions would you not provide an immunization for a child who is due for vaccination during that visit?
  - Are children immunized in your clinic when they have: 1) a cold 2) a low grade fever 3) recently been exposed to an infectious illness 4) mild diarrhea 5) been convalescing from an acute illness? This requires an answer of yes or no for each condition. Mark the box if the answer is yes.
  - What do you consider contraindications to giving a vaccine during a visit, and how do you assess for this? What about precautions?

Entry of Results into the Site Survey

- Under the statement "Children are immunized when they have:" for each of the five conditions noted, determine either 'yes' or 'no' (see Sources of Information above).
- When reviewing a newborn nursery, mark the appropriate box in the "Comments" section
- If special circumstances are involved, enter a comment in the 'Other Comments' area, as needed.
- Mark this item "y" if:
  - The clinic follows true contraindications for the population served.
  - The clinic follows true contraindications when vaccines are due but not provided due to a parent's request/refusal.
  - The clinic has answered 'yes' to all five conditions noted under "Children are immunized when they have:" and a checkmark has been placed in each box.
- Mark this item "n" if:
  - The provider withholds vaccines for any reason other than a true contraindication for the population served.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standards #6, 9
  - MMWR General Recommendations on Immunization, pages 8-11
- TVFC Provider Tool Kit, Section 10: Vaccine Safety Information
  - Contraindications & Precautions to Immunizations poster

Item 5 Possible Adverse Events Explained

NVAC Standards for Child and Adolescent Immunization Practices Standard 7: Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Providers should provide a current and appropriate Vaccine Information Statement (VIS) before the administration of each vaccine. Providing a copy of the VIS to read before the administration of the vaccine is acceptable but if the responsible party wants to take a copy with them, the clinic must provide a copy.

Legal Ward / Texas Youth Commission

When a child is a ward of the state, e.g., housed at a youth correctional facility, boot camp or State School, the VIS should be given to the legal representative of the child. This would be the state employee and/or nurse accompanying the client on the medical visit. When a resident enters any Texas Youth Commission (TYC) or State School, that entity assumes full guardianship as appointed by the courts. The TYC and State School staff is essentially assuming the role of guardian, and therefore would be the ones who need to read and understand the VIS on behalf of the child. In addition, policy at TYC sites does not allow residents to own possessions, including paper (printed or blank). Therefore, the staff is not able to give the residents copies of the VIS statements. Since there are some residents who are 18 years of age, it may be advisable for the staff to allow the resident to read the VIS, provided the resident is able to read and comprehend the VIS. They do not have to allow the resident to retain the copy. Even in these circumstances, it is a federal requirement to record the VIS

publication date on the child's immunization record. Therefore, when performing a site visit on a TYC facility or State School, you should check to see if there are current versions of the VISs available for the staff. You should also ask whether they understand the VIS information well enough to accept the VIS on behalf of the child. If these criteria are met, mark this item as "y".

School-based Clinics

At school-based clinics, parents must be given the VIS before the immunization is given, e.g., the VIS should be sent home with the child prior to the vaccination or given to the parent when the immunization is given. It is not acceptable to send the VIS home with the child after the immunization has been given.

Sources of Information

- (O) Observe client interview and teaching regarding immunizations.
- (IS) Interview Staff; Sample questions (provider)
    - What information do you get from the parent before giving an immunization?
    - What information is given to parents prior to an immunization?

Entry of Results into the Site Survey

- If the initial answer to the item statement is no, mark the statement that most appropriately describes what the clinic is doing; comments may be entered in the 'Other Comment' area as needed.
- Mark this item "y" if:
    - The clinic reports/demonstrates they question parents, etc. about contraindications, and informs them of specific risks & benefits through VIS review BEFORE administering vaccines.
    - This is a school-based provider that sends the VIS home with the child prior to the date of immunization if the parent is not present when the immunization is given.
    - This is a college-based provider that questions students about contraindications and provides and explains the VIS BEFORE administering vaccines.
    - This is a state school, juvenile detention center, youth correctional facility, etc., where the child is in custody and the staff receives the VIS information on the child's behalf. At these facilities, the staff is the guardian for the child.
- Mark this item "n" if:
    - The clinic does not report or give evidence of performing the above actions – or does not do this BEFORE administering vaccines. NOTE: If the clinic does not have updated teaching materials, offer copies of resources and note which materials you give them in the 'Other Comments' area.
    - This is a school-based provider that does not send the VIS home with the child prior to the date of immunization when the parent is not present at the time of immunization.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
    - Standards for Child and Adolescent Immunization Practices, Standard #7
    - MMWR General Recommendations on Immunizations, pages 8-11
- TVFC Provider Tool Kit, Section 9: Vaccine Adverse Events Reporting System (VAERS)
- TVFC Provider Tool Kit, Section 8: Vaccine Information Statements

Item 6 Information Provided on Reporting Adverse Events

NVAC Standards for Child and Adolescent Immunization Practices Standard 13: Health care professionals report adverse events following vaccination promptly and accurately to the Vaccine Adverse Event Reporting System (VAERS) and are aware of a separate program, the National Vaccine Injury Compensation Program (VICP).

According to this standard, providers must report adverse events following immunization promptly, accurately, and completely. In order to do this, providers must inform parents or legal guardians about how to report any adverse events following immunizations, including providing a phone number.

Sources of Information

- (O) Observe client interview and teaching regarding immunizations. Note what information (VIS, pamphlets, etc.) is given to the client/parent.
- (R) Review teaching materials used for client teaching: VISs and other handouts ("After the Shots…" is a common information sheet used by clinics.)
- (IS) Interview Staff; Sample questions (provider)
  - What information do you provide to parents about adverse events and how to report them?
- (IC) Interview Client; Sample questions (client)
  - What information was provided to you about reaction your child may have to a vaccine and what to do?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic reports or demonstrates they inform parents how to report adverse events AND provides a phone number for reporting.
  - This is a school-based provider that sends the contact information for reporting adverse events home with the child when the immunization is given.
  - This is a college-based provider that informs students about how to report adverse events AND provides a phone number for reporting.
  - This is a state school, juvenile detention center, youth correctional facility, etc., where the child is in custody and the staff receives the information on the child's behalf. At these facilities, the staff is the guardian for the child.
- Mark this item "n" if:
  - The clinic does not report or demonstrate they perform the above actions OR does not have or provide a phone number for reporting.
  - This is a school-based provider, which does not send the contact information for reporting adverse events directly to the parent or home with the child when the immunization is given.
  - This is a college-based provider, which does not inform students about how to report adverse events OR does not provide a phone number for reporting.

Resources:

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standards #7,9,13
- TVFC Provider Tool Kit, Section 8: Vaccine Information Statements (VIS)
- TVFC Provider Tool Kit, Section 9: Vaccine Adverse Events Reporting System (VAERS)

Item 7 Reporting of Adverse Events

NVAC Standards for Child and Adolescent Immunization Practices Standard 13: Health care professionals report adverse events following vaccination promptly and accurately to the Vaccine Adverse Event Reporting System (VAERS) and are aware of a separate program, the National Vaccine Injury Compensation Program (VICP).

Sources of Information

- (R) Review Resource Materials or Documents: Check with VAERS Coordinator in IDCU at DSHS-AO prior to scheduling on-site visit to see if area is reporting adverse events. Review written policy.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Clinic is reporting adverse events.
- Mark this item "n" if:

- Clinic is not reporting adverse events.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 13
- TVFC Provider Tool Kit, Section 9: Vaccine Adverse Events Reporting System (VAERS)
  - Information packet on VAERS
  - Vaccine Adverse Event Reporting System (VAERS) Form (#C-76)

Item 8 Display of Clinic Hours

Public clinics must display clinic hours according to standing orders.

Sources of Information

- (R) Review Resource Materials or Documents: Verify that clinic hours are displayed.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Clinic hours are displayed according to standing orders.
- Mark this item "n" if:
  - Clinic hours are not displayed according to standing orders.

Item 9 Walk-in Immunization Services

NVAC Standards for Child and Adolescent Immunization Practices Standard 3: Barriers to vaccination are identified and minimized.

Barriers to receiving vaccines include delays in scheduling appointments, requiring a well-care visit, long waiting periods in the office, and lack of culturally and age-appropriate educational materials. A physical exam, while an important part of well care, should not be required before administering vaccines: simply observing the patient and questioning about the patient's health status, immunization history, and vaccine contraindications are sufficient. In addition, vaccination-only visits should be available.

Ensure that immunization services are available on a walk-in basis **each working day** for both routine and new enrollee visits.

Sources of Information

- (O) Observe client interview, process or explanation about walk-in immunization services.
- (R) Review resource materials; Ask to see a copy of policy/procedure regarding immunizations
- (IS) Interview Staff; Sample questions (providers)
  - When are immunizations services offered?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Walk-in immunization services are available.
- Mark this item "n" if:
  - Walk-in immunization services are not available.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 1
  - Standards for Child and Adolescent Immunization Practices, Standard 3

Item 10 Non-Business Hours for Immunization Services

NVAC Standards for Child and Adolescent Immunization Practices Standard 3: Barriers to vaccination are identified and minimized.

Barriers to receiving vaccines include delays in scheduling appointments, requiring a well-care visit, long waiting periods in the office, and lack of culturally and age-appropriate educational materials. A physical exam, while an important part of well care, should not be required before administering vaccines: simply observing the patient and questioning about the patient's health status, immunization history, and vaccine contraindications are sufficient.

Vaccination-only visits should be available during non-traditional working hours. For example, in large urban areas, public immunization clinic services should be available daily, 8 hours per day. In smaller cities and rural areas, clinics may operate less frequently. To be fully responsive, providers in many locations should consider offering immunization services each working day, as well as, during some off-hours (e.g., weekends, evenings, early mornings, or lunch hours).

Sources of Information

- (IS) Interview with Staff: Ask when if immunization services are offered?
- (R) Review resource materials: Note other hours or schedules when immunization services are offered.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Provider offers alternative hours for immunization services.
- Mark this item "n" if:
  - Provider does not offer alternative hours for immunization services.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 1
  - Standards for Child and Adolescent Immunization Practices, Standard 3

Item 11 Language Needs of Clients

NVAC Standards for Child and Adolescent Immunization Practices Standard Reference Standard 7: Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Sources of Information

- (IS) Interview with Staff; Sample questions (providers)
  - Other than English what languages do patients in this clinic speak?
- (R) Review Resource Materials or Documents: Check the immunization literature to see that it is available in the appropriate language(s).

Entry of Results into the Site Survey

- Mark this item "y" if:
  - All language needs are met.
- Mark this item "n" if:
  - All language need are not met.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 3
  - Standards for Child and Adolescent Immunization Practices, Standard 7

Item 12 Vaccine Provided Regardless of Ability to Pay

NVAC Standards for Child and Adolescent Immunization Practices Standard 4: Patient costs are minimized; TVFC Provider Enrollment Form, Item #7; SB 266 – 73rd Legislature.

State and federal laws guarantee access to vaccines by providers utilizing TVFC vaccine regardless of ability to pay. When providers sign the TVFC Provider Enrollment Form, they agree to follow the DSHS guidelines for fees when administering vaccines. The Provider Enrollment Form (revision 08/2006, item #7), states the following:

- This office/facility will not deny administration of TVFC vaccine to a child because of the inability of the child's parent or guardian/individual of record to pay an administration fee.

If the physician is a patient's designated primary health provider, he/she should not refer the patient to the health department (or any other provider) for vaccines because of inability to pay an administration fee. In addition, a primary provider also cannot tell a patient to come back when they can pay the administration fee. It is acceptable for the provider to set up a payment plan, for the administration fee with the parent when they provide the immunization to the child.

Sources of Information

- (O) Observe client interview, process or explanation about payment for immunizations.
- (R) Review resource materials; Ask to see a copy of the billing/fee policy/procedure regarding immunizations, or examine client invoices with billing codes/payment schedules.
- (IS) Interview Staff; Sample questions (providers)
  - How do you handle providing immunizations for patients who are unable to pay an administration fee?
  - If you have a patient that comes in for a visit, but cannot afford to pay your immunization administration fee at that time, what do you do? Is this policy the same for all patients? If not, how does it differ?
- (IC) Interview Client; Sample questions (clients)
  - How much money will you have to pay, yourself, for your child's immunizations?
  - What have you been told about paying for your child's immunizations here? Have you ever been unable to pay – how has this been handled?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic reports or shows a policy stating TVFC vaccines are not denied based on inability to pay an administration fee.
  - The clinic provides the immunization to the child and sets up a plan for the parent to pay the administration fee.
- Mark this item "n" if:
  - The clinic, if a designated primary provider, reports they refer children who cannot pay an administration fee to another provider (LHD, etc.) or tells them to come back when they can pay the administration fee.
  - Note in the 'Other Comments' area what is currently being done (where the clinic is referring).

Resources

- TVFC Provider Tool Kit, Section 1: Introduction & Enrollment
  - Provider Enrollment Form, item #7
- TVFC Provider Tool Kit, Section 4: Standards for Child and Adolescent Immunization Practices, Standard #4

Item 13 Inability to Pay Poster

NVAC Standards for Child and Adolescent Immunization Practices Standard 4: Patient costs are minimized; most current Texas Department of State Health Services fee policy.

Sources of Information

- (O) Observation: Look for the "inability to pay" poster.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - "Inability to Pay" poster is present.
- Mark this item "n" if:
  - "Inability to Pay" poster is not present.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 4

Item 14 Vaccine Administration Fee

NVAC Standards for Child and Adolescent Immunization Practices Standard 4: Patient costs are minimized; most current Texas Department of State Health Services fee policy.

When providers sign the TVFC Provider Enrollment Form, they agree to follow the DSHS guidelines for fees when administering vaccines. The Provider Enrollment Form (revised 08/2006) contains the following statements regarding fees:

- This office/facility will not charge for vaccines supplied by DSHS and administered to a child who is eligible for TVFC.(item #5)
- This office/facility may charge a vaccine administration fee. This office/facility will not impose a charge for the administration of the vaccine in any amount higher than the maximum fee established by DSHS. Medicaid patients cannot be charged for the vaccine, administration of vaccine, or an office visit associated with Medicaid services.(item #6)

For this item, to "charge" means to ask for an "out of pocket" payment from the client or the client's parent or legal representative:

- Out-of-Pocket: An "out-of-pocket" cost is what the clinic asks the client or his/her legal representative to actually pay, out-of-pocket
- Billed: A "billed" cost is one that has been submitted to the client's insurer in the client's name – however, the client IS NOT responsible for personal payment of these charges. This can be confusing, however, as many clinics will tell you they "bill the client" – meaning they submitted the fees to the insurer for reimbursement. Be sure to clarify this if the clinic tells you that they charge the Medicaid/CHIP client, because clinics are not allowed to charge the Medicaid/CHIP client any out-of-pocket fees. They may be telling you the amount that they actually bill the Medicaid program.

This item specifically refers to "out-of-pocket" fees for vaccine administration for TVFC-eligible children. The best way to determine whether the clinic is complying with this standard is to methodically ask about each fee, and how each "category" of TVFC-eligible patient is assessed a fee. To do this, use the Re-Enrollment Form as the basis for your knowledge on what population(s) the clinic serves.

Before you ask, know your immunization fees.

Because staff is often unclear about what fees the clinic is charging, it is important you are clear about what fee you are asking. There are 3 types of fees you might see charged for immunization-related services:

- Cost of Vaccine Fee:
  - The actual cost of the vaccine (product). Since TVFC/state-supplied vaccines are provided at no cost to the provider, any agency or provider using these vaccines cannot charge the client, insurer, or Medicaid for the actual cost of the vaccine. Though the survey items do not ask about cost of vaccine fees, we would like you to ask whether the clinic charges for the cost of TVFC vaccines. Children receiving TVFC-supplied vaccine should not be charged for vaccine. If the clinic is

charging a fee for TVFC-supplied vaccines, then you should educate them on not charging for the vaccine, and note this by making a comment in the 'Other Comments' area.

- Vaccine Administration Fee
  - Often referred to as a "nurse fee" or "professional fee". This fee is assessed for services or supplies required to administer the immunization.
  - TVFC providers may charge administration fees. Fee allowances differ according to the TVFC eligibility category of the child (see guidelines below). If the office is charging more than $5-10 per vaccine, ask if this is actually an office visit fee.
- Office Visit Fee
  - Usually referred to as an office visit fee, appointment fee or exam fee. This is the per-visit service fee many clinics charge to account for the general clinic services, maintenance and provider time. Providers may charge office visit fees in most cases (except Medicaid – see below). They typically range from $20 to $40. There is no "maximum office fee" regulation by TVFC at this time.

Guidelines for allowable administration fees (TVFC-eligible only)

- Medicaid/CHIP
  - Patients may not be charged any out-of-pocket fees, either for vaccines or for administration of the vaccines. Providers can charge an administration fee to the Medicaid/CHIP program, but NOT to the client.
- Uninsured/Under-insured/Native American/Alaskan Eskimo
  - An administration fee can be charged at the provider's discretion. If administration fees are collected, they should be kept to a maximum of $14.85 per vaccine for VFC. This fee is "per vaccine" fee, not "per visit". If the clinic charges a "per visit" fee, then it still cannot exceed the "per vaccine" fee – since a child could have only one vaccine given in one visit.

Sources of Information

- (O) Observe client interview, process or explanation about payment for immunizations.
- (R) Review resource materials; Ask to see a copy of the billing/fee policy/procedure regarding immunizations, or examine client invoices with billing codes/payment schedules.
- (IS) Interview Staff; Sample questions (provider)
  - Some clinics charge an administration, or "professional service/supply fee" to cover the cost of administering the vaccine. Do you charge this fee? If so, I would like to ask you about how you handle payment of this fee, based on these types of patients:
  - For children enrolled in Medicaid, whom do you bill the administration fee to? How much? Does the patient have to pay any part of this fee out of his/her pocket? How much?
  - What about children with CHIP, Uninsured, Under-insured, Native American, Alaskan Eskimo & Non-TVFC?
  - What fees do you charge for vaccinations? If "yes," what is the fee and what does it cover? If "yes," is the fee charged for each vaccine given or is the fee charged once, regardless of how many vaccines the child receives during that visit? If greater than $20, is this an office visit fee?
- (IC) Interview Client; Sample questions (client)
  - How much money will you have to pay for your child's immunizations?
  - What have you been told about paying for your child's immunizations here?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Medicaid/CHIP patients pay NO out-of-pocket administration fees and, for all others, the clinic does not charge more than $14.85 per vaccine. Remember, the total can still be $14.85 times the number of vaccines administered, which could be a much higher total and still be okay.
- Mark this item "n" if:

  - The clinic charges Medicaid/CHIP patients an out-of-pocket fee OR charges over the maximum allowable administration fee to non-Medicaid/CHIP VFC eligible clients
  - The provider is charging all patients a set administration fee, regardless of eligibility. (Note: You are most likely to encounter this when a school-based clinic, a mobile clinic, a pharmacy, or a walk-in clinic is not doing eligibility screening and is charging a standardized fee to everyone).

- Mark this Item "na" if:
  - The clinic does not charge a fee ($0.00)
- Document the amount of the administration fee in the box, even if the amount is "0". When you leave that field, the program will automatically convert the number into a dollar format. Make sure you use the drop-down list to specify if the amount charged is "per vaccine" or "per visit". You will notice most clinics charge "per vaccine".
- If a clinic charges a graduated fee based on the number of vaccinations provided at the same visit, put the highest amount charged per vaccine in the administration fee box. Then, include this information in the 'Other Comments' area. For example, "Clinic charges $10 for 1st vaccine, $7 for 2nd vaccine and $5 for additional vaccines provided at the same visit." If the highest amount charged is more than $14.85, mark this item as "n"

Resources

- TVFC Provider Tool Kit, Section 1: Introduction & Enrollment
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #4

Item 15a Immunization-only Visits

NVAC Standards for Child and Adolescent Immunization Practices Standard 3: Barriers to vaccination are identified and minimized.

The NVAC Standards state, "Barriers to receiving vaccines include delays in scheduling appointments, requiring a well-care visit, long waiting periods in the office, and lack of culturally and age-appropriate educational materials. A physical exam, while an important part of well care, should not be required before administering vaccines. Simply observing the patient and questioning about the patient's health status, immunization history, and vaccine contraindications are sufficient. In addition, vaccination-only visits should be available."

While some clinics allow patients to come in for immunization-only visits, other clinics always require the patient to have a well-child check-up along with immunizations. Find out which system the clinic uses and mark this answer accordingly.

Sources of Information

- (IS) Interview Staff; Sample questions (provider)
  - Do you allow or encourage parents to bring their children to the clinic for immunizations only?
  - Do you provide immunizations-only visits without a well-child check-up?
  - Do you require every child that comes in for immunizations to also have a physical exam or check-up?
- (R) Review resource materials; Ask if there is a written policy or procedure that demonstrates scheduling and/or coding of immunization-only visits.

Entry of Results into the Site Survey

- NOTE: This item is not included in the "Critical Entries" count at the end of the Site Survey. Either a "y" or an "n" is acceptable, and an "n" response does not require a note in the 'Other Comments' area.
- Mark this item "y" if:
  - The clinic offers immunization-only visits.
- Mark this item "n" if:
  - The clinic does not offer immunization-only visits.

  - You are reviewing a hospital newborn nursery, or youth correctional facility. Checkmark "Hospital newborn nursery" or "Youth correctional facility" in the 'Comments' area.

- Since this is a non-critical item, no corrective action is required for an "n" response; it would still be appropriate to mark the corrective action statement on this item, and discuss with the clinic.

Item 15b Office Visit Fee for Immunization-only Visits

This is not a critical item: The information is for data collection purposes only. Answer this item only if you answered #15a as "y" (yes). If you marked #15a as "n" (no), the 'Answer' column for this item (#15b) is automatically filled in as "na" and requires no comment.

The office visit fee is a general "cost of business" fee. This fee is usually left to the discretion of the clinic, as there are no state or federal guidelines pertaining to the collection of an office fee for vaccinations. However, we have been asked to collect information on office visit fees for "immunization-only" visits.

When you inquire about office visit fees, first make sure your contact person understands you are asking only about the office visit fee, not vaccine administration fees. If might be helpful to say, "and so you charge $x for the clinic visit fee, plus $x for the vaccine administration fee, for a total of $x?" Also, you are asking for the "out-of'-pocket" fee the clinic charges – not what is billed to Medicaid, etc.

Sources of Information

- (O) Observe client interview or explanation about payment of office visit fee for immunization-only visits.
- (R) Review resource materials; Ask to see a copy of the billing/fee policy/procedure regarding immunizations, or examine client invoices with billing codes/payment schedules.
- (IS) Interview Staff; Sample questions (provider)
  - For immunization-only visits, do you charge an office visit fee? If yes, what is the amount of that fee? Is your fee the same for all groups of patients?
- (IC) Interview Client; Sample questions (client)
  - Are you charged for an office visit fee when you bring your child in just to have his immunizations given? How much?

Entry of Results into the Site Survey

- NOTE: This item is not included in the "Critical Entries" count at the end of the Site Survey. Either a "y" or an "n" is acceptable, and an "n" response does not require a corrective action or a note in the 'Other Comments' area.
- Mark this item "y" if:
  - The clinic collects an office fee when the child "comes in only for immunizations." Enter the amount of the fee in the box labeled 'Specify fee'. If the fee is different for different populations, then enter the highest fee and note exceptions in the 'Other Comments' area.
- Mark this item "n" if:
  - The clinic does not charge an office visit fee when the child comes in only for immunizations. This does not require a corrective action or a comment.
  - The clinic charges an office visit fee, but it is NOT paid out-of-pocket by the client (i.e., billed to Medicaid, CHIP, insurance company).
  - The clinic charges only a vaccine administration fee for immunization-only visits.
- Although "na" is an answer choice, please be aware that:
  - If 15a is answered with "n", 15b will automatically be pre-populated with "na" and you do not need to re enter the reason in the "Comments" section.
- Since this is a non-critical item, no corrective action is required for an "n" response, however you may mark the corrective action statement if discussed with the clinic, or note in the 'Other Comments' area if there are variations in office visit fee structure.

Item16a Under-insured Children Vaccinated Using TVFC Vaccine

Under-insured children are vaccinated at this clinic/practice with Texas Vaccines for Children (TVFC) vaccine.

For TVFC, the term under-insured is used to describe children less than 19 years of age whose insurance:

- Does not pay for vaccine;
- Has a co-pay or deductible that the family cannot meet; or
- Provides for limited wellness or prevention coverage.

These children are eligible to receive TVFC vaccines at all participating offices. Ensure that children eligible as "under-insured" are not being referred to another location for vaccination. There are two important questions to ask before answering this item:

- Is the clinic screening for and identifying under-insured children? How?
    - Make sure you find out HOW the screening is done (interview, form, insurance co-pay data) and WHAT the criteria are (insurance doesn't pay, family reports unable to pay). Put the answer to HOW the screening is done in the "Identify Criteria" box.
- Is the clinic offering TVFC vaccines to identified under-insured children?

Sources of Information

- (O) Observe "client with insurance" screening process for determination of ability to pay even if parent is unable to pay the co-pay or administration fee.
- (IS) Interview Staff; Sample questions (provider)
    - Do you ever give TVFC vaccines to insured children? How do you decide if they are eligible?
    - How do you handle children who have insurance, but the insurance doesn't cover immunization? What about if the parents say they can't afford the co-pay?
    - Do you know that children with insurance can be eligible for TVFC vaccine? If yes, what type of screening tools do you use determine that these children are TVFC- eligible?
- (R) Review resource materials; Ask to see a copy of the billing/fee policy/procedure regarding immunizations, or examine client invoices with billing codes/payment schedules. Also check the re-enrollment form to see if the clinic reports children in the under-insured category.

Entry of Results into the Site Survey

- Mark this item "y" if:
    - The clinic is identifying under-insured children and vaccinating them. In the "Identify criteria" box, document how the clinic identifies these children: e.g., "interview, form, insurance co-pay data, etc."
- Mark this item "n" if:
    - The clinic reports they are NOT identifying under-insured children or they cannot show you their criteria for identifying under-insured children. You mark this "n" because if the clinic is not screening adequately for these children, then they are inadvertently not offering them the TVFC vaccine
    - The clinic sees under-insured children but the child is being referred somewhere else (LHD or other clinic).
    - The clinic reports they are giving TVFC vaccines only to children on Medicaid, CHIP or children with no health insurance.
- Mark the answer as "na" if:
    - This is a juvenile detention center, state school, youth correctional facility, etc., where the child is in custody. These children are considered publicly insured (by some public program). Note the type of facility in the 'Other Comments' area.
    - The clinic does not see under-insured children, i.e., the clinic population is 100% Medicaid and/or CHIP. Type "100% Medicaid/CHIP" in the 'Other Comments' area. Make sure you verify this with the Patient Profile section of the Re-enrollment Form.

Resources

- TVFC Provider Tool Kit, Section 1: Introduction & Enrollment

Item 16b Under-insured Children Referred To FQHC or RHC

In previous years, DSHS has identified specific vaccines that when given to an under-insured child, must be given in a Federally Qualified Health Center (FQHC), or Rural Health Center (RHC). As of January 1, 2007, per DSHS all vaccines can be given to an under-insured child without referring them to an FQHC or RHC. Therefore, for 2007, until/unless otherwise notified, the answer to this question will always be "na".

Item 17 Uncollected Administrative Fees

NVAC Standards for Child and Adolescent Immunization Practices Standard 4: Patient costs are minimized; TVFC Provider Enrollment Form, Item #7; SB 266 – 73rd Legislature.

Uncollected Administrative fees are billed at a later date.

State and federal laws guarantee access to vaccines by providers utilizing TVFC vaccine regardless of ability to pay. When providers sign the TVFC Provider Enrollment Form, they agree to follow the DSHS guidelines for fees when administering vaccines. The Provider Enrollment Form (revision 10/2005),(item # 7), states the following:

- This office/facility will not deny administration of TVFC vaccine to a child because of the inability of the child's parent or guardian/individual of record to pay an administration fee.

If the physician is a patient's designated primary health provider, he/she should not refer the patient to the health department (or any other provider) for vaccines because of inability to pay an administration fee. In addition, a primary provider also cannot tell a patient to come back when they can pay the administration fee. It is acceptable for the provider to set up a payment plan with the parent when they provide the immunization to the child.

Sources of Information

- (O) Observe client interview, process or explanation about payment for immunizations.
- (R) Review resource materials; Ask to see a copy of the billing/fee policy/procedure regarding immunizations, or examine client invoices with billing codes/payment schedules.
- (IS) Interview Staff; Sample questions (providers)
  - How do you handle providing immunizations for patients who are unable to pay an administration fee?
  - If you have a patient that comes in for a visit, but cannot afford to pay your immunization administration fee at that time, what do you do? Is this policy the same for all patients? If not, how does it differ?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic provides the immunization to the child and sets up a plan for the parent to pay the administration fee.
  - The clinic bills for administrations fees after the visit.
- Mark this item "n" if:
  - The clinic does not bill for administrative fees.

Resources

- TVFC Provider Tool Kit, Section 1: Introduction & Enrollment
  - Provider Enrollment Form, item #7
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 4

Item 18 Immunization Services in Conjunction with Other Services

NVAC Standards for Child and Adolescent Immunization Practices Standard 2: Vaccinations are coordinated with other health care services and provided in a medical home when possible.

Sources of Information

- (IS) Interview with Staff: sample questions (provider)
  - When does clinic offer immunization service?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic provides immunization services in conjunction with other health care services like acute care.
- Mark this item "n" if:
  - The clinic does not provide immunization services in conjunction with other health care services.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 2
  - Standards for Child and Adolescent Immunization Practices, Standard 5
  - Standards for Child and Adolescent Immunization Practices, Standard 7

Item 19 Residency Status

Reference Contract*:* Individuals cannot be denied services based on residency (i.e., city, county, state, country, etc.). This is a requirement for all financial assistance contracts with DSHS Immunization Branch.

Sources of Information

- (IS) Interview Staff; Sample questions (provider)
  - Is the client asked about residency status?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic provides immunization services regardless of residency status.
  - The clinic provides immunization services and does not ask about residency status.
- Mark this item "n" if:
  - The clinic does not provide immunization services if client is out of area.
  - This clinic uses residency status to determine eligibility for immunization services.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 3

Item 20 Immunization Status Review at Every Visit

NVAC Standards for Child and Adolescent Immunization Practices Standard 5: Health care professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated. Texas State Law: SB-266- Rule 97.101

Providers should make it a practice to review immunization status at every patient encounter. The best approach to assessing this item is to ask the staff contact what triggers an immunization review – every visit, only well-child checks, etc.? Avoid using a closed question like, "Do you perform a review every visit?" because most staff will give you a blanket "yes" to this type of question.

Most clinics that consistently review immunization status at each encounter use a one-page "immunization history." Without this form, it would be difficult to consistently and efficiently document and review immunizations. If the clinic does not use one, suggest they consider implementing the use of a one-page form. Members of the American Academy of Pediatrics can get copyrighted forms free of charge through their membership. Resource sleeve #20 contains the one-page Vaccine Administration Record for Children and Teens from the Immunization Action Coalition, and you can hand out a copy to clinics as a suggested form. This is not copyrighted, so they can copy them as much as they want. Also included is one example of how to fill out this form.

Though a one-page form is preferable, it is NOT required – as long as the clinic reports and explains how they perform the review and updates, you can mark the item "y".

Sources of Information:

- (O) Observe the process of the immunization status review and update during a patient encounter (which would include looking for a summary form).
- (IS) Interview Staff; sample questions (provider); If you are using only the staff interview as the sole source to answer this question, ask about the process they use to ensure screening.
    - When, and how often, is a client's immunization status reviewed and updated?
    - How do you make sure your client records are reviewed and updated so his/her immunization status is current?
    - Avoid asking a closed question, like, "Do you review status at every encounter...," because staff might be reluctant to say "no."
- (D) Review documentation of immunizations; Review the child's medical record to see documentation of status checks, audits or updates.

Entry of Results into the Site Survey

- Mark this item "y" if:
    - The clinic reports and explains how they review and update immunization status at every patient encounter/visit, even if they do not have documentation in the record (take their word if it if they can describe a process).
    - This is a school based clinic (immunization status is reviewed upon school entry).
- Mark this item "n" if:
    - The clinic does not perform immunization status review at every patient encounter/visit.
    - The clinic reports they perform review and update, but cannot describe or show evidence of a policy /process for performing this task.
- Mark this item "na" if:
    - The clinic is a newborn nursery (make sure you check the 'newborn nursery' comment box on the site survey tool).

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
    - Standards for Child and Adolescent Immunization Practices, Standards #1, 5 & 9.

Item 21 Current VISs in Appropriate Languages

NVAC Standards for Child and Adolescent Immunization Practices Standard 7: Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language, and most current Vaccine Information Statements (VIS)

The National Childhood Vaccine Injury Act requires all immunization providers (not just TVFC) to give a current VIS for each vaccine administered to a client every time a vaccine is given. In the case of children, the VIS should be given to the parent/guardian or other responsible adult who presents the child for immunization.

In addition, providers must take reasonable steps to provide the VIS information in languages most appropriate to the clinic population. It is important the information be provided and presented in a way to ensure that a client with limited English proficiency is effectively informed.

LEGAL WARD/TEXAS YOUTH COMMISSION

When a child is a ward of the state, e.g., housed at a correctional facility, boot camp or State School, the VIS should be given to the legal representative of the child or sent home to the parent. This would be the state employee and/or nurse accompanying the client on the medical visit. When a resident enters any Texas Youth Commission (TYC) or State School, that entity assumes full guardianship as appointed by the courts. The TYC and State School staff is essentially assuming the role of guardian, and therefore would be the ones who would need to read and understand the VIS on behalf of the child. In addition, policy at TYC sites does not allow residents to own possessions, including paper (printed or blank). Therefore, the staff is not able to give the residents copies of the VIS statements. Since there are some residents who are 18 years of age, it may be advisable for the staff to allow the resident to read the VIS, provided the resident is able to read and

comprehend the VIS. They do not have to allow the resident to retain the copy. Even in these circumstances, it is a federal requirement to record the VIS date on the child's immunization record. Therefore, when performing a site visit on a TYC facility or State School, you should check to see if there are current versions of the VISs available for the staff. You should also ask whether they understand the VIS information well enough to accept the VIS on behalf of the child. If these criteria are met, mark this item as "y".

School-Based Clinics

At school-based clinics, parents must be given the VIS before the immunization is given, e.g., the VIS should be sent home with the child prior to the vaccination or given to the parent when the immunization is given. It is not acceptable to send the VIS home with the child after the immunization has been given.

Documentation that the VIS was provided

Regardless of the type of setting you are reviewing, the only required documentation regarding the VIS is that staff document the publication date of each VIS used for every dose of vaccine provided. In Texas, the VIS forms printed by DSHS have a second page addendum. This addendum included a half-page section for staff and client signatures to acknowledge VIS receipt and informed consent, and other items required for documentation of each vaccine administered (see item #32).

If you encounter clinics using the Texas VIS with the addendum, you might want to advise them that filling out this section is not required, if the required information is documented somewhere else in the record. In addition, there is no requirement to put a copy or part of the VIS in the client's record.

Most typically, clinics document this information on a consolidated immunization history record form, like the American Academy of Pediatrics form, DSHS Vaccine Information Documentation Form (#C-100) or site-developed form. If the clinic does not use a consolidated form that contains all the required documentation, they can document the VIS information on the Medical Administration Record (MAR); this would be most appropriate for hospital nurseries and schools. However, you may want to suggest the clinic institute use of a one-page immunization record to consolidate immunization-related documentation and ease record reviews and updates.

Combination Vaccines

There are currently no VISs for the combination vaccines. The provider must use the VIS for each component of the vaccine, e.g, 3 VISs for each dose of Pediarix given (DTaP +Hep B+ IPV).

Review to Assure that Provided VISs are Current

To answer this item, you will need to compare each VIS the clinic uses with a list of the most current VISs available for each vaccine. A matrix of the most current VISs at this time has also been placed in the Manual resource section in sleeve #21. However, to insure that you are using the most current VIS, be sure to check the matrix on the DSHS website periodically: http://www.dshs.state.tx.us/immunize/vischart.shtm. Encourage any clinic with internet access to also check this website periodically.

VISs and instructions on how to use them can also be obtained from the CDC website:

www.cdc.gov/nip/publications/vis

VISs in other languages can be obtained from the Immunization Action Coolition website:

www.immunize.org/vis

Current VISs

Here are the most current VISs with issue dates. Make sure the provider is using the current statement. Please recycle old copies.

Interim VISs are available for download from the web only, DSHS will not print.

Chickenpox (Varicella)- **(Interim available on line only)** revised 01/10/07	DTaP, DT- revised 07/30/01
Hib- revised 12/16/98	Hepatitis A- revised 03/21/06
Hepatitis B- revised 07/11/01	HPV- **(Interim available on line only)** revised 09/05/06
IPV-revised 01/01/00	MMR- revised 01/15/03
Meningococcal- **(Interim available on line only)** revised 11/16/06	PCV- revised 09/30/02
PPV-revised 07/29/97	Rotavirus - **(Interim available on line only)** revised 04/12/06
Td-revised 06/10/94	Tdap- **(Interim available on line only)** revised 07/12/06

- If the clinic is using any outdated VISs, help them access a current copy in any of the following ways:
  - Provide the clinic with a copy.
  - Help the clinic staff access the DSHS, CDC, or IAC website to download the current VIS, or
  - Have clinic staff use the 'Literature and Forms' order sheet from Section #7 of the Tool Kit.
  - Per DSHS, as of April 1, 2007 the current VIS for meningococcal must be dated 11/16/06 to receive a yes.
  - Per DSHS, as of May 1, 2007 the current VIS for varicella must be dated 01/10/07 to receive a yes.
  - If HPV is stock the current VIS dated 09/05/06 must be given.

Sources of Information

- (O) Observe the process for VIS-related teaching and consent; note if the VIS is offered to client.
- (IS) Interview Staff; sample questions (provider):
  - How and when are VIS forms used and /or given out to clients?
  - In this practice, what are the languages most used? Do you supply VISs in these languages?
- (IC) Interview Client; sample questions (client):
  - What information was discussed and offered to you before your child received his/her immunizations? (Client can show you the VIS received.)
- (R) Review resource materials; Ask to see all the VISs that the clinic currently uses. Compare the dates on the federal portion of each VIS with the DSHS Matrix (see resource sleeve #21). If any VIS is outdated or not used, mark the corresponding box, provide the most current version, and make a notation of which specific VIS and what language was replaced in the 'Other Comments' area. If the clinic does not carry the vaccine, mark the box "NA."

Entry of Results into the Site Survey

- First, compare each VIS the clinic currently uses with your matrix of the most current VISs. In the boxes next to each vaccine listed:

- Mark the "current" box if the clinic uses a current VIS for that vaccine.
- Mark the "outdated" box if the clinic uses an outdated VIS for that vaccine.
- Mark the "none used" box if the clinic does not have a VIS for that vaccine. Clarify the reason for "none used" in the 'Other Comments' area.
- Mark the "NA" box if the clinic does not stock the vaccine.
- Select "Other" and write in the name of the vaccine if a vaccine is added to this list after January 2007.

- Next, determine whether this item, overall, should be marked as "y" or "n":
- Mark this item "y" if:
  - All of the VISs are current and in the appropriate language for the vaccines stocked.
- Mark this item "n" if:
  - Any of the VISs are outdated for the vaccines stocked.
  - Any of the VISs are absent for the vaccines stocked.
  - The clinic has a significant non-English speaking population, yet does not supply VISs in the appropriate language, or they are outdated (if language available).

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #7
- TVFC Provider Tool Kit, Section 8: Vaccine Information Statements (VIS)
- Immunization Action Coalition www.immunize.org/vis/

Item 22 Proof of Relationship Does Not Create a Barrier

Staff does not create a barrier by requiring documentation or proof of a relationship allowing the adult accompanying a child to consent to immunization.

- Persons authorized to consent for immunization are listed in Texas law:
  - TX Family Code §151.001 states that parents have the right to consent to a child's medical and dental care.
  - TX Family Code §32.101 states that in addition to parents, a grandparent, an adult sibling, aunt or uncle, or a step parent may consent to immunization. Consent may be delegated by a parent, managing conservator, guardian, or another person authorized by the law of another state or by a court order. Delegation can be made to an educational institution in which the child is enrolled or another adult who has care, control and possession of the child.
  - 25 TAC §97.91 defines information that must be available when consent is delegated: the signature of the parent, managing conservator, guardian or other person authorized to give consent; the name and birth date of the child; the name of the adult giving consent for immunization, and the relationship of this adult to the child.

Sources of Information

- (IS) Interview with Staff: sample questions (provider):
  - Who may bring child in for immunizations?
  - Is proof of relationship required for immunizations services?
- (R) Review Resource Materials or Documents: Review policy on who can consent for immunization services.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Staff does not create barriers.
- Mark this item "n" if:
  - Staff creates barriers.

Resources

- Texas law noted above

Item 23a Staff Training on Emergency Procedures/Equipment

NVAC Standards for Child and Adolescent Immunization Practices Standard 10: Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive on-going education.

Sources of Information

- (IS) Interview with Staff: sample questions (provider)
  - When are trainings on Emergency procedures and equipments conducted?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Staff has received training.
- Mark this item "n" if:
  - Staff has not received training on emergency producers and equipment.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 10

Item 23b Current and Operational Emergency Equipment

NVAC Standards for Child and Adolescent Immunization Practices Standard 10: Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive on-going education.

Sources of Information

- (O) Observation: Ensure that emergency drugs are not outdated.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Equipment operational and current.
- Mark this item "n" if:
  - Equipment is not operational or drugs are expired.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 10

Item 24 Update of Standing Delegation Orders

NVAC Standards for Child and Adolescent Immunization Practices Standard 9: Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.

Standing delegation orders for vaccine administration and emergencies are updated at least on an annual basis or as changes occur.

Sources of Information

- (R) Review Resource Materials or Documents: Review written policy, standing delegation orders or protocols.
- (IS) Interview Staff; sample questions (provider):
  - How often are standing delegation orders updated?

Entry of Results into the Site Survey

- Mark this item "y" if:

- Standing delegation orders are updated annual or when changes occur.

- Mark this item "n" if:
  - Standing delegation orders are not updated annual or when changes occur.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 9

Item 25 Accessibility of Standing Delegation Orders

NVAC Standards for Child and Adolescent Immunization Practices Standard 9: Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.

Standing delegation orders are accessible to all staff

Sources of Information

- (R) Review Resource Materials or Documents: Review written policy, standing delegation orders or protocols.
- (IS) Interview Staff; sample questions (provider):
  - Where are the standing delegations orders located?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - All staff has access to standing delegation orders.
- Mark this item "n" if:
  - All staff does not have access to standing delegation orders.
  - Only limited staff has access to standing delegation orders.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 9

Item 26 Properly Trained Vaccine Administrators

NVAC Standards for Child and Adolescent Immunization Practices Standard 10: Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive on-going education.

Sources of Information

- (IS) Interview Staff; sample questions (provider):
  - How were you trained to administer vaccines?
  - What type of training is offered for the administration of vaccine?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Staff has received proper training on techniques to administer vaccines.
- Mark this item "n" if:
  - Staff has not received proper training on techniques to administer vaccine.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 10
  - Giving All the Doses Chart
- TVFC Provider Tool Kit, Section 11: Other Resources
  - "Vaccine Techniques" video

Item 27 Current Vaccine Schedule

Most current ACIP/AMERICAN ACADEMY OF PEDIATRICS (AAP)/AMERICAN ACADEMY OF FAMILY PHYSICIANS (AAFP) harmonized immunization schedule (January 2007)

For 2007 CDC has changed the harmonized immunization schedule. They have separated the schedule by age groups, 0-6 years and 7-18 years. Providers should have a copy of the most current ACIP/AAP/AAFP harmonized age appropriate immunization schedule(s) for their population served. In addition, this schedule should be posted for easy review. To answer this item, you will simply check to see if the provider has a copy of the most current schedule posted somewhere (or easily accessible). You are NOT examining whether he/she actually complies with it. In addition, show the clinic staff how to access the most current schedule on the DSHS website at: http://www.DSHS.state.tx.us/immunize/imm_sched.shtm.

DSHS allows a grace period of two months (January 1, 2007 through February 28, 2007) for clinics to obtain and post the most current childhood and adolescent immunization schedule (2007). Clinics are expected to have obtained and posted the 2007 schedule by March 1, 2007.

Sources of Information

- (O) Observe what schedule is posted in the clinic or provided to patients.
- (IS) Interview Staff; sample questions (provider):
  - What version of vaccination schedule does your clinic use as its primary resource for staff and patients?
- (R) Review resource materials; Ask the clinic staff where copies of the vaccine schedule are placed, posted or used. Check these locations for the version of schedule used. If the schedules are outdated or not consistent, advise the clinic to develop a process for keeping all schedules consistent and up to date.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The provider has a copy of the 2006 or 2007 ACIP/AAP/AAFP harmonized immunization schedule prior to a March 1, 2007 site visit.
  - Provider has 2007 schedule(s) posted that covers population served.
- Mark this item "n" if:
  - The provider does not have a copy of the 2007 ACIP/AAP/AAFP harmonized immunization schedule as of site visits conducted on March 1, 2007 or later.
  - Provider does not have age appropriate schedule(s) posted (for population served).

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
- TVFC Provider Tool Kit, Section 5: Immunization Requirements: School Law
- NOTE: The current version of the recommended schedule can also be obtained on the CDC website at http://www.cdc.gov/nip/menus/vaccines.htm#Schedules. Click on the appropriate schedule to get the most updated schedule.

Item 28 All TVFC Vaccines Routinely Recommended

Standard: TVFC Provider Enrollment Form

When providers enroll in TVFC, they agree to comply with the appropriate vaccination schedule, dosage, and contraindications, as established by the ACIP.

- Note that this will vary according to ages of the population served. The TVFC recommended vaccines are listed in Item #28.
- Though the item heading asks for "vaccines routinely recommended," you are verifying what vaccines the clinic actually stocks and administers to children. The best way to appraise this is to review the C-33 to see what vaccines are actually stocked. In addition, examine the Vaccine Gain/Loss Calculation Table and note if there are any vaccines stocked at a very low level compared to others. This might alert you to opportunities for the provider to be more proactive about offering certain vaccines.

Routinely recommended vaccines for specific populations:

- Clinic Populations: Before answering this item, find out what populations (age range) the clinic generally serves. Ask staff and/or review the Patient Profile section on the TVFC Provider Enrollment form for the population (age groups) served at this clinic. Next, compare the population to the vaccines stocked, using the chart below and/ or the current ACIP vaccination schedule. For example, if a clinic does not see children under 6 years of age, they do not need to stock Hib or PCV7 (e.g., most school-based clinics and some family practices). If the site does not stock or offer one of the vaccines listed, first ask why they do not carry it. Note specific population-based exceptions in the 'Other Comments' area.

	Hospital Nursery	**Ages 0-5 years**	**Ages 6-18 years (schools, youth correctional facilities, state-run facilities, colleges)**
Vaccines	**Hep B** (may also stock others, like DTaP & HIB for preemies, but not routine in most cases)	**DTaP/ DT** **Hep A** **Hep B** **Hib** **IPV** **MMR/MMR-V** **PCV7** **rotavirus** **varicella**	**Tdap/Td** **Hep A** **Hep B** **IPV** **MCV4** **MMR/MMR-V** **varicella** **HPV**

HPV is available for TVFC providers effective 01/07. After May 1, 2007 providers who serve HPV population will have to have vaccine in stock to receive a yes.

- Colleges and universities: If the facility only stocks hepatitis B and Td/Tdap vaccines, mark this item as "y." Encourage the facility to consider stocking varicella, hepatitis A, MCV4 and HPV to ensure fully protected students. New students may not have had chickenpox disease nor had the vaccine.

Refrigerator/Freezers: The clinic is not exempt from offering all the recommended vaccines just because it does not have the correct equipment or space to keep specific vaccines. For example, if a clinic does not have a freezer to correctly stock varicella, the clinic should be reminded of the enrollment contract and encouraged to obtain a freezer for stocking varicella (and this item would be marked "n").

Be sure that the specific vaccines checked in this statement correlate with the vaccines shown as provided on theC-33, as reflected on the Vaccine Gain/Loss Calculation Table.

Sources of Information

- (O) Check the stock in the refrigerator to see what vaccines are stocked. Observe what vaccines the provider/staff member recommends to a client.
- (R) Review resource materials; Review the Patient Profile section of the TVFC Provider Enrollment form to determine the population served and examine the C-33 and Gain/Loss Calculation table to assess what vaccines are stocked, and the relative numbers of vaccines stocked and administered.
- (IS) Interview Staff; sample questions (provider)
  - What vaccines do you routinely offer? Are there any vaccines your clinic does not stock or offer and for what reason?

Entry of Results into the Site Survey

Note: The boxes are now for the vaccines the clinic does <u>not</u> routinely recommend

- Mark this item "y" if:
  - The clinic stocks and administers all routinely recommended vaccines for the population served.
  - The clinic is a hospital nursery and stocks only hepatitis B. Note that some nurseries may stock other vaccines for prolonged hospital stays or use in the pediatric unit. (check the 'newborn nursery' comment box on the site survey tool)
- Mark this item "n" if:

- The clinic does not stock and administer all routinely recommended vaccines for the population served.
- The clinic does not carry varicella because they do not have a freezer.

- If the answer to the initial item question is "no", mark the specific routinely recommended vaccines that are not being administered for the population seen.

Item 29 Needed Vaccines Simultaneously Administered

NVAC Standards for Child and Adolescent Immunization Practices Standard 11: Health care professionals simultaneously administer as many indicated vaccine doses as possible

According to NVAC 2003 Standards for Child and Adolescent Immunization Practices, administering vaccines simultaneously (at the same visit), in accordance with recommendations from the ACIP, AAP and AAFP, is safe, effective and indicated. TVFC recommends that providers simultaneously administer all vaccine doses a child is eligible to receive within the time frame of each visit, unless there is a true contraindication. This item asks the reviewer to assess, based on medical record review (IRRT), whether the provider is generally following the practice of administering vaccines simultaneously.

When a provider does not practice simultaneous vaccination, he misses the opportunity:

- to decrease the number of visits needed.
- to avoid potential doses missed.
- to enable earlier protection for the child, and
- to raise overall vaccination rates.

Some providers do not administer vaccines simultaneously because they:

- do not want to conflict with clients fearful of multiple vaccine interactions.
- think there is a higher potential for side effects.
- are concerned about increased risk of adverse reactions, and/or
- are concerned it would be difficult to isolate the cause of adverse reactions.

There is no scientific evidence to support the theory that giving simultaneous vaccinations causes more harm or decreases the efficacy of each vaccine. In fact, there is evidence that simultaneous vaccination may even enhance the immune response to vaccination.

To determine whether the provider is actively following the practice of giving simultaneous vaccinations, use the results (% compliance) from the IRRT indicator #2: "All indicated vaccine doses are simultaneously administered." See the IRRT instructions of this Manual for directions on how to complete this. These results are automatically linked to this item, and should appear in "%" field of item #29. They reflect what percentage of patients, in general, have had multiple vaccines simultaneously administered. In order to mark this answer as "y", the results should be 60% or above.

Ask the provider what the maximum number of injections are administered at a single visit and enter this number in the field provided (drop down list). This data will be tracked to determine whether the provider needs follow-up education in the future.

The "Number of records reviewed" field is automatically populated from the IRRT. Normally 10 medical records are used to complete the IRRT. If less that 10 records were used, note why less than 10 were used in the 'Other Comments' area.

Sources of Information

- (O) Observe what vaccinations the clinic recommends or offers for each well-child visit or age frame. Does this take advantage of simultaneous administration opportunities?
- (IS) Interview Staff; sample questions (provider)
  - What is your clinic's approach to simultaneously administering vaccines?
  - If the IRRT results are less than 60%, ask: The record review results indicate you may be missing opportunities to simultaneously administer some vaccines. What barriers or beliefs affect your decision to limit that number of vaccines provided at the same visit?

- (D) Review documentation of immunizations; Use the "% simultaneous vaccination" results from IRRT indicator #2 to determine whether to mark this item "y" or "n". See the IRRT instructions for more information.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The results of IRRT indicator #2 show at least 60% of the records indicate simultaneous administration of vaccinations.
- Mark this item "n" if:
  - The results of IRRT indicator #2 show that less than 60% of the records indicate simultaneous administration of vaccinations.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - "Giving All The Doses" information sheet
  - Standards for Child and Adolescent Immunization Practices, Standard #11
  - MMWR General Recommendations on Immunization, pg. 4

Item 30 Discussion of Next Immunization Visit and Bringing Records

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

To educate parents about the importance of timely vaccination future visits should be discussed before client leaves the office.

- Encourage parents to schedule future appointments before leaving.
- Identify when next visit should occur.

Providers can use several methods to obtain more complete immunization histories:

- Encourage clients to bring their children's immunization records with them on the first visit and all subsequent visits.
- Request and make copies of immunization records from other providers to place in a dedicated section of the patient's medical record.
- Review and update immunization histories with the parents at each encounter.
- Encourage parents to take the child's immunization documentation to every health care encounter, so that it can easily be updated as immunizations are provided.

Sources of Information

- (IS) Interview Staff; Sample questions (provider)
  - At time of visit are future immunization appointments discussed?
  - What types of reminders are given to parent to help remind them to bring immunization cards to all visits?
- (IC) Interview with Client: Interview a client.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Next immunization visit and immunization record are discussed during visit.
- Mark this item "n" if:
  - Next immunization visit and immunization record are not discussed during visit.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 12
  - Standards for Child and Adolescent Immunization Practices, Standard 3

Item 31a Appropriate Vaccine Administration Techniques

Reference current "ACIP General Recommendations on Immunization," regarding appropriate administration techniques/sites of vaccines.

A nurse or medical professional must be on the review team, to determine compliance for this item through personal observation of professional administering the vaccine.

Sources of Information

- (O)Observe staff's vaccine administration techniques.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Appropriate vaccine administration techniques are observed.
- Mark this item "n" if:
  - Appropriate vaccine administration techniques are not observed.
- Mark this item "na" if:
  - If no nurse or medical professional is available on the review team, this item should not be reviewed and the comment that "No nurse/medical professional on the review team" recorded.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 10

Item 31b Appropriate Vaccine Administration Techniques

Staff is trained in vaccine administration techniques, dosage, and site selection.

Reference current "ACIP General Recommendations on Immunization," regarding appropriate administration techniques/sites of vaccines.

Sources of Information

- (IS) Interview Staff; Sample questions (provider)
  - When was the last training for vaccine administration techniques you attended
- (R) Review Resource Materials or Documents: During the interview, note date(s) of training or presentations.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Training for vaccine administration techniques can be documented.
- Mark this item "n" if:
  - Training for vaccine administration techniques cannot be documented.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 9
  - Standards for Child and Adolescent Immunization Practices, Standard 10
  - Giving all the Doses Chart
  - How to Administer Chart

Item 32 Accurate and Complete Recording of Vaccinations

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

The 1986 National Childhood Vaccine Injury and Compensation Act requires providers nationwide to record specific information in the medical record each time a vaccine is administered. The following information is required:

- Vaccine given
- Vaccination date ("at birth" or "at hospital" is not an acceptable date designation)
- Name of vaccine manufacturer
- Vaccine lot number
- Signature and title of person administering the vaccine
- Organization name and address of clinic location (where records are kept)
- The publication date of the VIS provided
- Note: Parent's signature required by Texas Family Code Chapter 32 Subchapter B. This is an educational piece and will not be documented on the IRRT.

The following items are **not** required but are recommended:

- Site and route of administration
- Information collected about the clinic's documentation on these items is for informational purposes only.

To determine how to answer this item, you will use the data from indicators on the IRRT:

- Indicator #4: Vaccine lot # and manufacturer for each vaccine are recorded
- Indicator #5: Nurse's signature, title, and date of vaccination given are recorded
- Indicator #6: Clinic name and address are stamped or written on each immunization chart
- Indicator #7: The publication date from the VIS is recorded for each vaccination given

Refer to the IRRT instructions on how to complete these indicators. These results are automatically linked to this item and should appear in several text boxes. They reflect what percentage of patients, in general, have each of these items correctly documented. In order to mark this answer as "y", the results FROM ALL FOUR INDICATORS should EACH be 60% or above. If ANY one of these results is less than 60%, mark the item "n".

The boxes for the number of records reviewed will automatically be populated from the IRRT. If less that 10 records were used, note why less than 10 were used in the 'Other Comments' area.

The best way to help clinics improve their compliance with immunization documentation requirements is to advise them to utilize a consolidated immunization history form that includes all these elements. If the clinic does not use one, suggest they consider implementing the use of a form that includes all these elements. Members of AAP can get copyrighted forms, free of charge, through their membership. Resource sleeve #20 contains the one-page Vaccine Administration Record from the Immunization Action Coalition (IAC), copies of which you can hand out to clinics as a suggested form. This is not copyrighted, so they can copy them as much as they want. Also included is one example of how to fill out this form.

Sources of Information

- (O) Observe what process the clinic uses for documentation
- (D) Review documentation of immunizations; Use the % compliance results of indicators 4, 5, 6, and 7 from the IRRT. Refer to the IRRT instructions for answering these items.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The results from ALL FOUR of the IRRT indicators 4, 5, 6, and 7 individually are a 60% or higher. For example, you cannot give a "y" if one of the IRRT indicators = 50%, even if each of the other three are 100%.
- Mark this item "n" if:
  - ANY ONE of the IRRT indicators 4, 5, 6, or 7 is less than 60% (50% or below). For the indicators less than 60%, comment in the 'Other Comments' area on the possible reason (e.g., "nurse initials but no space for signature on form"). Use the 'Other Comments' area to indicate which recording procedures or processes are lacking.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Childhood and Adolescent Immunization Practices, Standards #9,12

Item 33a Complete Immunization Histories

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

When accepting immunization record data from adults, the provider should confirm that prior doses of vaccines have actually been administered. Providers can use several methods to obtain more complete immunization histories:

- Encourage new clients to bring their children's immunization records with them on the first visit.
- Request and make copies of immunization records from other providers to place in a dedicated section of the patient's medical record.
- For children who present with no immunization record, query the ImmTrac statewide tracking registry to obtain any immunizations in the registry.
- Encourage local hospital(s) to provide parents with specific information about the child's first hepatitis B vaccination. Request new parents bring their child's hospital discharge summary to their first visit.
- Review and update immunization histories with the parents at each encounter.
- Encourage parents to take the child's immunization documentation to every health care encounter, so that it can easily be updated as immunizations are provided.

If a child presents with no immunization record and the history cannot be obtained, the provider should administer age-appropriate vaccinations during that visit to avoid a missed opportunity.

To determine how to answer this item, use the results (% compliance) of indicator #3 on the IRRT. This reflects if the clinic has been adequately retrieving and transcribing vaccinations given elsewhere. Documentation for each vaccine given should include:

- The name of the provider or clinic where the vaccine was given.
- The date the vaccine was given.

Refer to the IRRT instructions on how to complete this indicator. These results are automatically linked to this item and should appear in a text box of item #33a. In order to mark this item "y", at least 60% of the records reviewed should have this information for every vaccine given to date.

The box for the number of records reviewed will automatically be populated from the IRRT. If less that 10 records were used, note why less than 10 were used in the 'Other Comments' area.

Hospital Nurseries: If you are reviewing a hospital nursery, there should be no history to note, so checkmark 'Hospital newborn nursery' in the 'Comments' area. If they are not already doing so, encourage the staff to provide documentation of the newborn's hepatitis B immunization to the parent to take to the child's primary care provider.

Cross-referencing this Item's results with the CoCASA Results

Notice the results you find on this item compared to item #32 (accurate and complete recording of vaccinations) and to the CoCASA results. This might alert you to opportunities to educate staff on improving administrative and documentation processes. A typical example is the clinic that does not either obtain or document the exact date and location of administration of the first hepatitis B vaccine (given usually at birth). This results in first dose not being entered into the CoCASA for that child, which results in the child being "late" in his vaccination schedule. If this is an ongoing problem, this could seriously decrease the vaccination rates for that clinic.

Sources of Information

- (D) Review documentation of immunizations; Use the % compliance results from indicator #3 on the IRRT. This requires examining 10 patient records, usually pulled for the CoCASA. Refer to the IRRT instructions for answering this item.

Entry of Results into the Site Survey

- Mark this item "y" if:

- The results of IRRT indicator #3 show that at least 60% of the records reviewed have the required documentation for the immunization history.

- Mark this item "n" if:
  - The results of IRRT indicator #3 shows less than 60% of the records reviewed have the required documentation for the immunization history. If you notice a trend in missing documentation, note this in the 'Other Comments' area.

- Mark this item "na" if:
  - You are reviewing a hospital nursery. Mark 'Hospital newborn nursery' in the 'Comments' area; leave the # of records reviewed box pink—no entry.

Resources

- TVFC Provider Tool Kit, Section 4:Immunizations: Guidelines & General Recommendations
  - Standards for Childhood and Adolescent Immunization Practices, Standards #9, 12.
  - MMWR Morbidity & Mortality Weekly Report, pg. 8.

Item 33b Issuing Immunization Record

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

If an immunization record is not brought to the clinic, another containing all immunizations on file is issued.

Sources of Information

- (IS) Interview Staff; Sample questions (provider)
  - How is a missing immunization cards handled?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - A new card with complete history on file is issued to client.
- Mark this item "n" if:
  - A new card with complete history on file is not issued to client

Resources

- TVFC Provider Tool Kit, Section 4:Immunizations: Guidelines & General Recommendations
  - Standards for Childhood and Adolescent Immunization Practices, Standard 12

Item 33c Consolidated Immunization Records Are Provided

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

As part of record assessment, all available sources of child immunization records are reviewed and a consolidated record is provided (if needed).

Sources of Information

- (R) Review Resource Materials or Documents: Note procedures used to access child immunization history. Available resources may include clinic hard files, clinic electronic files, ImmTrac, TWICES and a local registry.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - All resources are used to access childhood immunizations history and a consolidated record is provided if needed.
- Mark this item "n" if:
  - All resources are not used to access childhood immunizations history and a consolidated record is provided if needed.

- A consolidated record is not provided when needed.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Childhood and Adolescent Immunization Practices, Standard 12

Item 34 Easily Accessible Immunization Records

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

Immunization records are easily accessible to clinic staff.

Sources of Information

- (D) Review Documentation of Immunizations: Review immunization records for accessibility

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Records are accessible to all staff.
- Mark this item "n" if:
  - Access to records is limited.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 12

Item 35a Recall System

NVAC Standards for Child and Adolescent Immunization Practices Standard 15: Systems are used to remind parents/guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.

The goal of a recall system is to keep clients on the recommended immunization schedule. A recall system is an essential component for maintaining or improving immunization rates within a clinic. In fact, it is commonly referred to as one of the three "Rs" of increasing immunization rates - Recall, Reminder and Record-keeping. In general, clinics with a good recall system tend to have better overall vaccination rates.

ImmTrac, the Texas immunization registry, is an important component of Texas' strategy to improve vaccine coverage rates. ImmTrac is designed to consolidate immunization records from multiple sources throughout the State, and offers many benefits to health care providers and their patients. ImmTrac allows providers easy internet access to immunization histories on participating patients, and offers recall capability. ImmTrac is available, free of charge, to authorized health care providers.

Recall Tracking System

- A system that tracks and notifies clients with missed appointments and due or overdue immunizations: e.g., recalls clients who may be missing scheduled immunizations.
- To perform recall activities, the clinic needs to be able to: 1) develop a method to alert the clinic when patients are due (or overdue) for vaccinations, and 2) employ a method to contact and follow-up on patients.
- For example, at the end of each clinic visit the patient is asked to make an appointment for the next visit. If the child does not appear for that appointment, the clinic "recalls" the parents to arrange another appointment. If the appointment is not made at the end of a particular clinic visit, the child's information is placed in a monthly tickler file for recall, at the time the vaccinations are due.
- Document the type of system used by checking one or more of the boxes. If the clinic has a current system, use the 'Other Comments' area to document any advice or suggestions you provided to improve the recall effort.
- Unless a patient has requested that information be provided in a specific confidential manner, HIPAA regulations allow physician's offices or pharmacists to leave messages for patients at their home answering machine, with a family member or via a postcard to remind them of an appointment or the need for immunizations. Professional judgment should be used to disclose the least amount of information possible

to achieve the intended purpose. For access to questions and answers regarding privacy under HIPAA, refer to **www.hhs.gov/ocr/hipaa/privacy.html**.

- If a clinic says that they do not have sufficient staff to implement a recall system, encourage them to select a specific age population, e.g., children between 9 and 15 months of age, to target with recall postcards. This population is especially at risk for not receiving their MMR and/or the 4th DTaP.

Exceptions:

- Walk-in clinics should have a recall system, since they should keep track of clients they have seen, to make sure they are getting the next vaccine.
- Hospital nurseries do not need to have a recall system.

Sources of Information:

- (R) Review resource materials; Examine clinic policies/procedures for description and process of a recall system. NOTE: This may be a software product manual, etc.
- (D) Review documentation of immunizations; Examine client medical records for documentation on client contact for missed appointments, overdue immunizations and upcoming appointments.
- (IS) Interview Staff; sample questions (provider)
  - Describe your process for tracking and contacting clients with missed immunization appointments and/or clients with overdue immunizations.
  - How reliable is this system?
  - What process or systems do you use to make sure children stay up-to-date with the vaccination schedule?
- (IC) Interview Client; sample questions (client)
  - Have you ever missed an appointment, and then been contacted to reschedule?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic has a consistent recall system - Mark the type(s) used in the boxes.
  - This is a walk-in clinic that has a recall system.
- Mark this item "n" if:
  - The clinic does not have a consistent recall system. Do not mark any box since there is NO system in place. In the 'Other Comments' area describe why the clinic has not adopted a system.
  - This is a walk-in clinic that does not have a client recall system. Explain to them that they should be tracking past clients (children) who received immunizations at their clinic to prompt them to stay on schedule.
  - Offer the 'Reminder/Recall' training to the provider. If they accept, mark the appropriate selection under the "comments" area (*either that you conducted the training or provider expressed interest and will schedule later with DSHS* – See Reminder/Recall training protocol).
- Mark this item "na" if:
  - This is a hospital nursery. Mark the box 'Hospital newborn nursery' in the 'Comments' area.
  - This is a youth correctional facility. Mark the box 'Youth correctional facility' in the 'Comments' area.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #15.

Item 35b Reminder System

NVAC Standards for Child and Adolescent Immunization Practices Standard 15: Systems are used to remind parents/guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.

The goal of a reminder system is to keep clients on the recommended immunization schedule. A reminder system is an essential component for maintaining or improving immunization rates within a clinic. In fact, a reminder system is commonly referred to as one of the three "Rs" of increasing immunization rates - Recall, Reminder and Record-keeping. In general, clinics with a good reminder system tend to have better overall vaccination rates.

ImmTrac, the Texas immunization registry, is an important component of Texas' strategy to improve vaccine coverage rates. ImmTrac is designed to consolidate immunization records from multiple sources throughout the State, and offers many benefits to health care providers and their young patients. ImmTrac allows providers easy internet access to immunization histories on participating patients, and offers reminder capability. ImmTrac is available free of charge to authorized health care providers.

Reminder System

A system that ensures client contact a few days before a scheduled appointment: e.g., reminds clients they have an appointment coming up to avoid missing scheduled immunizations.

To perform reminder activities, the clinic needs to be able to: 1) access scheduled appointments ahead of time, and 2) employ a method to contact patients 1-3 days ahead of the anticipated appointment date.

Providing a "next appointment" card for the next visit at the end of the current clinic visit is NOT considered a reminder system.

Document the type of system(s) used by marking one or more of the boxes. If the clinic has a current system, use the 'Other Comments' area to document any advice or suggestions you provided to improve the reminder effort.

Unless a patient has requested that information be provided in a specific confidential manner, HIPAA regulations allow physician's offices or pharmacists to leave messages for patients at their home answering machine, with a family member or via a postcard to remind them of an appointment or the need for immunizations. Professional judgment should be used to disclose the least amount of information possible to achieve the intended purpose. For access to questions and answers regarding privacy under HIPAA, refer to **www.hhs.gov/ocr/hipaa/privacy.html**.

If a clinic says that they do not have sufficient staff to implement a reminder system, encourage them to select a specific age population, e.g., children between 9 and 15 months of age, to target with reminder phone calls. This population is especially at risk for not receiving their MMR and/or the 4th DTaP.

Exceptions

- Walk-in clinics do not need to have a reminder system, since appointments are not scheduled ahead of time (so they cannot remind anyone).
- Hospital nurseries do not need to have a reminder system.

Sources of Information

- (R) Review resource materials; Examine clinic policies/procedures for description and process of a reminder system. NOTE: This may be a software product manual.
- (D) Review documentation of immunizations; Examine client medical records for documentation on client contact for missed appointments, overdue immunizations and upcoming appointments.
- (IS) Interview Staff; sample questions (provider)
  - Describe your process for tracking and contacting clients who have scheduled appointments coming up.
  - How reliable is this system?
  - What process or systems do you use to make sure children stay up-to-date with the vaccination schedule?
- (IC) Interview Client; sample questions (clients)
  - Does the clinic ever contact you a few days before an appointment to remind you to come in?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic has a consistent reminder system. Mark the appropriate box(es) to describe the type of system(s).
- Mark this item "n" if:
  - The clinic does not have a consistent reminder system. Do not mark any box since there is NO system in place. In the 'Other Comments' area describe why the clinic has not adopted a system. Suggest what the clinic could do to overcome any barriers and also note this in your comments. Emphasize the value of reminder systems in keeping children up to date on their vaccines.
  - The clinic reports they use only "next appointment cards": These are not acceptable, as they are not a timely reminder. DO NOT mark any box. Note in the 'Other Comments' area what the clinic is currently doing, plus any education you provide.
  - Offer the 'Reminder/Recall' training to the provider. If they accept, mark the appropriate selection under the "comments" area (*either that you conducted the training or provider expressed interest and will schedule later with DSHS* – See Reminder/Recall training protocol).
- Mark this item "na" if:
  - This is a hospital nursery: Mark the 'Hospital newborn nursery' box in the 'Comments' area.
  - This is a walk-in clinic: Mark the 'Walk-in clinic' box in the 'Comments' area.
  - This is a youth correctional facility (children live on premises, so wouldn't normally call parents to remind). Mark the 'Youth correctional facility' box in the 'Comments' area.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #15

Item 36 Parents (legal guardian or managing conservator) Informed about Immunization Registry (ImmTrac)

Parents (legal guardian or managing conservator) are informed and educated regarding the statewide immunization registry, ImmTrac, and a local registry if applicable.

Texas Department of State Health Services Immunization Registry (ImmTrac)

The DSHS ImmTrac Registry contains demographic information and immunization records for enrolled children. The goal of immunization registries is to provide a centralized database for immunization records. With appropriate consent, these records can be made available to ImmTrac authorized entities such as health departments, schools, child-care facilities and private physicians as needed. Please note that this item is not about whether the provider actually uses ImmTrac. Though providers are not required to offer parents (legal guardian or managing conservator) the opportunity to consent for their child to participate in ImmTrac, it is highly encouraged, and providers are required to report all immunizations administered to persons under 18 years of age to ImmTrac.

To complete this item, ask the staff if they are informing parents (legal guardian or managing conservator) about the statewide registry, and local immunization registry, if applicable. If not, use this opportunity to educate the provider on the benefits of registry participation. This item is not included in the "Critical Entries" count at the end of the On-Site Evaluation Report.

City of Houston sites: The City of Houston sites (PIN beginning with 25-) participate in a separate local registry. Therefore, this question will address the local registry, Houston Harris County Immunization Registry (HHCIR), as well as ImmTrac.

Sources of Information

- (O) Observe a staff member offering information to a client about ImmTrac Registry.
- (IS) Interview Staff; sample questions (providers)
  - What do you tell parents (legal guardian or managing conservator) about ImmTrac, the statewide immunization registry?

- Does your clinic encourage ImmTrac participation? If so, how do you inform and educate parents (legal guardian or managing conservator) on the registry?

- (R) Review resource materials; Ask for a copy of policies/procedures relating to staff education about ImmTrac, and/or client information materials relating to the ImmTrac Registry.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The provider/staff report that they inform and educate parents (*legal guardian or managing conservator, e.g. a Youth Correctional facility*) about ImmTrac (and the local registry, if in the City of Houston).
- Mark this item "n" if:
- The provider/staff report that they do not inform parents (*legal guardian or managing conservator*) about ImmTrac (and the local registry, if in the City of Houston).

Resources

- ImmTrac Website: www.ImmTrac.com
- TVFC Provider Tool Kit, Section 6
  - "Love Them Protect Them" pamphlet in English and Spanish (#6-202)
  - "Love Them Protect Them" poster in English and Spanish (#6-202P)

Item 37a Checking Status of, Obtaining, and Submitting Consent to DSHS for Immunization Registry (ImmTrac) Participation

The status of consent for the child's immunization information to be added to ImmTrac (and a local registry if applicable) is checked prior to submitting signed consent forms to DSHS for creation of a new record in ImmTrac.

Texas Department of State Health Services Immunization Registry (ImmTrac) Consent Form

Recent changes were made in the state law to relieve health care providers from the responsibility of tracking and maintaining written parental consent for registry participation. It is now the responsibility of DSHS to verify that parental consent has been granted for a child to participate in the registry prior to including that child's information in ImmTrac. However, providers still play a significant role in obtaining consent only for those children not currently participating in ImmTrac. This item is not included in the "Critical Entries" count at the end of the On-Site Evaluation Report. Note: This item is not about whether the provider actively uses ImmTrac, although providers are required to report immunizations to the ImmTrac Registry.

As a result of a collaborative effort between ImmTrac and the Vital Statistics Unit of DSHS, the Texas Electronic Registrar (TER) birth registration system generates the Immunization Registry (ImmTrac) Registration Form so that hospital/birth registrar staff can offer parents the opportunity to either grant consent for ImmTrac participation or request exclusion from the registry during the birth registration process. The parent simply checks either option and signs the form. The birth registrar faxes the "checked" and signed form to VSU for processing and reporting (electronically) to ImmTrac. In 2003, over 94% of Texas newborns registered for ImmTrac during the birth registration process.

To determine how to answer this item for providers who are not hospital nurseries, begin by asking if the provider is registered with ImmTrac (and/or a local registry that reports to ImmTrac) or is using the Texas-Wide Integrated Client Encounter System (TWICES). If the provider answers "no," give him or her a copy of the ImmTrac Provider Information sheet {#11-12152}, review with them the basic information regarding the law, and encourage the provider to contact ImmTrac Customer Service at (800) 348-9158 for additional information.

If the provider is registered with ImmTrac or is using TWICES, ask if they are checking either system to see if there is documentation of consent for inclusion of the immunization data in ImmTrac. If the child is not consented, the provider will have an opportunity to print out a consent form from the ImmTrac or TWICES systems and have the parent sign it (or refuse to sign it). Signed consent forms should be faxed to DSHS for new record creation in ImmTrac.

Sources of Information

- (O) Observe a staff member searching for a client's record in ImmTrac or TWICES, obtaining consent to enter the child's immunization information in ImmTrac, or faxing completed and signed, necessary consent forms to DSHS.
- (IS) Interview Staff; sample question (providers)
  - Are you currently registered with ImmTrac or using TWICES in this clinic?
  - If you are registered with ImmTrac or using TWICES, are you checking either system to see if the consent has already been obtained for a child? If consent has not been obtained, are you printing out an ImmTrac or TWICES generated consent form, presenting it to the parent, then faxing signed consent forms to DSHS for new record creation in ImmTrac?
  - How do you obtain consent from parents for ImmTrac Registry participation?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Hospital/birth registrar staff is using the Texas Electronic Registrar (TER) generated Immunization Registry ImmTrac Registration Form to offer parents the opportunity to either grant consent for ImmTrac participation or request exclusion from the registry during the birth registration process, then faxing completed forms to DSHS Vital Statistics.
  - The provider already has access to ImmTrac or TWICES, is checking to see if consent has been obtained on each child, is obtaining consent for those children not currently in ImmTrac, and faxing only those new consents to DSHS for creation of a new record in ImmTrac.
- Mark this item "n" if:
  - Hospital/birth registrar staff is not offering parents the opportunity to either grant consent for ImmTrac participation or request exclusion from the registry during the birth registration process.
  - The provider already has access to ImmTrac or TWICES, but is not checking the status of consent on each child before submitting parent-signed consent forms to DSHS.
  - The provider already has access to ImmTrac or TWICES, is checking consent status on each child, but is not obtaining consent for those children not currently in ImmTrac.
- Mark this item "na" if:
  - The provider is not registered with ImmTrac or does not have access to TWICES. Make sure you check the 'Provider not registered to use ImmTrac' comments box.

Resources

- ImmTrac Website: www.ImmTrac.com
- TVFC Provider Tool Kit, Section 6
  - "Love Them Protect Them" pamphlet in English and Spanish (#6-202)
  - "Love Them Protect Them" poster in English and Spanish (#6-202P)

Item 37b Provider Submitting Immunizations to Registry

Provider is reporting immunization records to the statewide immunization registry, ImmTrac, or a local registry if applicable.

Texas Department of State Health Services Immunization Registry (ImmTrac) Provider Recruitment Materials

This item is intended to help determine whether providers are actively reporting immunization data to the statewide immunization registry, ImmTrac. Texas law requires that **all** health care providers must report **all vaccines administered to a child under 18 years of age** to DSHS **within 30 days** of administering the vaccine, regardless of knowledge of parental consent for ImmTrac participation. Since this requirement became effective January 1, 2005, the DSHS ImmTrac Group would like to use the TVFC site visit as an opportunity to provide information about this requirement and to more actively promote provider reporting to the ImmTrac registry.

If the provider is not currently reporting immunizations to ImmTrac, DSHS would like to have TVFC reviewers hand out promotional materials regarding the registry. As a TVFC reviewer, you have the opportunity to educate providers about the registry on a more personal level.

To answer this question, ask the provider if they are actively using ImmTrac, which means they are registered for access to the registry and they regularly report vaccinations to ImmTrac. If the provider is registered, but uses the registry only for gaining past immunization histories, the provider would not be considered "actively reporting" (you would mark this question "n" and add "registered but not reporting" to the 'Other Comments' area. If the provider is not actively using ImmTrac, ask why they aren't and note the reason in the 'Other Comments' area.

In addition, there may be some providers who report vaccination information to other immunization related systems, which in turn, report the information to ImmTrac. For example, a provider might report information to:

- the Vital Statistics Unit (e.g., hospital/birth registrar staff, as part of the birth certificate application process).
- TWICES (a public health client encounter system, which private providers may have access to in the near future).
- A local registry that reports data to the ImmTrac registry (e.g., Houston-Harris County Immunization Registry, Tarrant County).

If the provider reports vaccination information in this manner, they are considered to be actively reporting vaccinations to the ImmTrac registry (mark this item "y" and note which system the provider submits through in the 'Other Comments' area).

In the past, use of the U6 modifier on the Medicaid billing was necessary in order to feed information about immunizations to ImmTrac. However, this is no longer the case. Please inform clinics about this change. Clinics with questions about this should be referred to ImmTrac Customer Support at (800)-348-9158.

This item is not included in the "Critical Entries" count at the end of the On-Site Evaluation Report.

Sources of Information:

- (IS) Interview Staff; sample questions (providers)
  - Is your clinic registered with the ImmTrac registry? If so, are you actively reporting vaccinations to the registry?
  - Is your clinic currently reporting immunization information to another system that directly links with ImmTrac?
  - If your clinic isn't currently reporting immunization data to the ImmTrac registry, why not?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic is actively reporting vaccinations directly to the ImmTrac registry. This could be done via on-line entry in the ImmTrac application, electronic transfer from an EMR or EHR system, or submission on the ImmTrac Paper Reporting Forms.
  - The clinic is actively reporting vaccinations (electronically or via paper) to another immunization system or local registry that reports this information directly to the ImmTrac registry (e.g., TWICES, Tarrant County Immunization Registry, Houston-Harris County Immunization Registry, WINWIC).
  - This is a hospital and they are documenting the administration of the hepatitis B vaccination on the birth certificate application submitted to the Vital Statistics Unit. If the hospital also gives out vaccines other than the initial at-birth dose of Hep B, they also need to be reporting the other vaccines (e.g., immunizations provided in the ER or the pediatric unit) to ImmTrac also.
- Mark this item "n" if:
  - The clinic is not reporting immunization data to any system.
  - The clinic is registered with ImmTrac, but does not actively report vaccinations to the registry. Note the reasons they are not reporting vaccinations in the 'Other Comments' area.
  - This is a hospital (or hospital nursery) and they are not documenting the administration of the hepatitis B vaccination on the birth certificate application submitted to the Vital Statistics Unit, or are not reporting other post-birth doses of vaccines (e.g., immunizations provided in the ER or the pediatric unit) to ImmTrac or another immunization system that directly report into ImmTrac.

- The clinic is registered with a local registry that reports to ImmTrac but is not actively reporting vaccinations to the local registry.

Resources

- ImmTrac Website: www.ImmTrac.com
- TVFC Provider Tool Kit, Section 6
  - "Love Them Protect Them" pamphlet in English and Spanish (#6-202)
  - "Love Them Protect Them" poster in English and Spanish (#6-202P
  - "Protect Texas Children" brochure (#6-218)

Item 38 ImmTrac

This question is no longer applicable due to implementation of HB 1921 and should not be addressed during a site visit.

Item 39 Outbreak Control Measures

Vaccine Preventable Disease Surveillance Guidelines are used to determine appropriate control measures. Close contacts to suspected cases of vaccine-preventable diseases are identified within 24 hours of initial report, and their vaccine status is determined.

For example, measles vaccine is administered to susceptible close contacts of persons with rash/fever illness within 72 hours of exposure. Prophylaxis is prescribed for or provided to close contacts of suspected pertussis cases.

Sources of Information

- (R) Review Resource Materials or Documents: Review procedures for active surveillance and control measures.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Disease Surveillance Guidelines are followed.
- Mark this item "n" if:
  - Disease Surveillance Guidelines are not followed.

Resources

- Infectious Disease Control Unit (IDCU) at DSHS-AO:
  - Rules and Regulations Governing the Control and Reporting of Notifiable Conditions (#E6-106)
  - Vaccine-Preventable Disease Surveillance Guidelines (#E-106)

Item 40 Immunization Rates Equal To or Greater Than State Rate

Texas State Immunization Rate vs. Site-Specific Immunization Rate

This item compares site-specific immunization rates, obtained through the CDC Comprehensive Clinical Assessment Software Application (CoCASA) program to the current published 4:3:1:3:3:1 immunization rate of 76% for the state of Texas. States will be reporting the 4:3:1:3:3:1 to the CDC in 2007.

If the site has a rate equal to or greater than the Texas state rate of 76% you will answer the item "y"; if not, then "n". You will determine the clinic's immunization rate by performing an analysis of medical records using the CoCASA. CoCASA is a database tool designed to help assessors estimate the percent of immunizations successfully delivered (according to a recommended schedule) at different age points in clinic populations. For TMF site survey purposes, a CoCASA of 50 records is performed on children in the age range of 19-35 months of age. A minimum of 10 records in the age range of 24-35 months is required for a CoCASA. If the clinic cannot provide the reviewer with ten records in this age range, or if the clinic does not have children in the CoCASA age range, you will use the results of the IRRT indicator #1 "percent of children up to date on immunizations."

If the provider does not have enough records pulled to qualify for a CoCASA, let them know as soon as possible so they are given the opportunity to locate any additional qualifying records. Once you have given the provider this opportunity, and they still can not pull enough records for a CoCASA, explain that a CoCASA will not be performed and this question will be answered using only the IRRT results.

Because you will be using the 4:3:1:3:3:1 rate, you will also need to review the medical records for documentation of varicella vaccination or history of varicella infection ("chickenpox"). Be sure to ask your clinic contact how to find documentation of varicella infection in the medical record. In addition, you will need to make sure your CoCASA input variables include "Has had chickenpox."

To perform the CoCASA and/or the IRRT, follow the steps below and refer to the CoCASA/ IRRT instructions in the applicable sections of this manual.

Following are the steps for completing this item:

- Determine the tool to be used, based on the client population (usually done when scheduling):
  - Clinic sees children in the 19-35 month age range and has at least 10 records in the 24-35 month age range: Complete a CoCASA report (up to 50 records).
  - Complete a CoCASA report on children in 19-35 month age range; the confirmation letter will have requested that of clients' records in the 19-35 month age range pulled for review, no less than 10 and at least 50% should be of clients 24-35 months of age. The following scenarios will help illustrate the situation:
  - We request 75 records in the age range of 19-35 months, with no less than 10 and at least 50% of the records pulled to be those of children 24-35 months of age, if possible. The clinic pulls 40 records, and 25 (*more than 50%)* are 24-35 months, 15 are less than 24 months (19-24 months),we review all 40 records.
    - Same request for the clinic; the clinic pulls 60 records, and 25 are 24-35 months, 35 are less than 24 months (19-24 months). We review the 25 records (*50% of 50*) of the 24-35 month age, **but only 25** of the 19-24 month age, for a total of 50 records.
    - Same request for the clinic; the clinic pulls 50 records, and 20 are 24-35 months, 30 are less than 24 months (19-24 months). We review the 20 records of the 24-35 month age (50% of 40), **but only 20** of the 19-24 month age, for a total of 40 records.
    - Same request for the clinic; the clinic pulls 25 records, and 9 are 24-35 months, 15 are less than 24 months (19-24 months). Since there are not at least 10 records in the 24-35 month age range, **NO CoCASA will be performed**. You will use IRRT data to answer this question.
  - **If the Clinic does not treat or immunize children in 19-35 month age range**: Do not complete CoCASA report. Instead, use the results from IRRT indicator #1 "percent of children up to date on immunizations" (10 records or less – see IRRT instructions).
- Prior to discussing the record review, ask the physician or contact person for his/her estimate of the percent of 2-year-old children in the practice who are up-to-date for immunizations, or if the clinic does not see 2-year-old children, the percent of children in their practice who are up-to-date on their immunizations. You may need to present a percentage, e.g., the state rate, and ask them if they think they are higher or lower than that rate. Exception: no rate is needed for a hospital newborn nursery.
- Obtain the records and complete the CoCASA and/or IRRT: See the CoCASA or IRRT instructions sections of this Manual. Don't forget to ask where you would find documentation of history of varicella (chickenpox), if the child has not received varicella vaccine. When completed, you should have the results of the CoCASA Diagnostic Report (4:3:1, 4:3:1:3:3 and 4:3:1:3:3:1 rates) or the results from IRRT transcribed on to a Site Assessment Summary form.
- Fill in the rates as indicated in Item #40:
  - **Estimated Immunization Rate**: Enter the self-reported estimated immunization rate supplied by the provider or contact person.
  - **Assessor**: Click the appropriate box
  - **19 through 35 months old**: If you did a CoCASA report for the age range of 19-35 months, then mark the '19 through 35 months old' button and fill in the 4:3:1, 4:3:1:3:3 and 4:3:1:3:3:1 rates from the CoCASA Summary Report.

- **IRRT Rate**: Mark this button if you did not have enough records to do a CoCASA or the clinic does not see children in the 19-35 month age range. The percentage rate from the IRRT will automatically populate. Make sure you have answered the question as "na".
- **Total number of records reviewed:**
  - Fill in the total number of records reviewed for CoCASA, including any MoGE'd records, in this box.
  - If you did not have enough records to do a CoCASA or the provider does not see children in the age range for conducting a CoCASA (e.g., a hospital or school), put the number of records reviewed for the IRRT in this box. Typically this will be 10 records but can be less than 10. Remember that records from any age can be used for the IRRT.
  - If you did not review 50 records, indicate the number reviewed and the reason this number is less than 50 in the 'Other Comments' area.
- **Number of records reviewed 24-35 months**:
  - Fill in the number of records reviewed for 24-35 month-old patients If you did a CoCASA, you can find this number on the CoCASA Summary report.
  - If a CoCASA was not performed because there were not enough records in the 24-35 month age range, put the number of records that you did review in the 24-35 month age range (this number could be as little as 0 [for a newborn nursery] or as many as 9 [maybe for a school]).

Sources of Information

- (IS) Interview Staff; Ask the physician or contact person for his/her estimate of the percent of 2-year-old children in the practice who are up-to-date for immunizations, or, if the clinic does not see preschool children, the percent of children in their practice who are up-to-date on their immunizations.
- (R) Review resource materials; Reviewer Manual with published Texas State Immunization Rate.
- (D) Review documentation of immunizations; Client medical records pulled for CoCASA and IRRT with documentation of immunizations and history of varicella.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The CoCASA 4:3:1:3:3:1 rate is equal to or greater than the state 4:3:1:3:3:1 rate of 76%.
- Mark this item "n" if:
  - The CoCASA 4:3:1:3:3:1 rate is less than the state 4:3:1:3:3:1 rate of 76%. Inform the clinic that a follow-up CoCASA may be conducted by DSHS in 6 months.
- Mark this item "na" if:
  - The clinic only sees children under 2 years of age (including newborn nursery) or only children more than 3 years of age.
  - Make sure you check the 'IRRT' button and the IRRT indicator #1 percent results will automatically populate.
  - Check the 'This site does not see children in the CoCASA age range' box in the Comments area.
  - The clinic did not allow you to review any records for a CoCASA. Document the reason a CoCASA record review was not done in the 'Other Comments' area.

Corrective Actions/Comments

The CoCASA assessment is a major part of the site survey and the results are affected by several aspects of the clinic's overall immunization program. Your individual comments and/or selections in the 'Corrective Actions/Comments' area should address any areas that may have affected the CoCASA results. In addition, your comments/selections should indicate some critical thinking and be specific to the clinic you are reviewing. Your corrective action selection(s) (and advice) should address specific factors that may have influenced the clinic's individual and overall CoCASA rates.

Some possible areas to address in the 'Corrective Actions/Comments' area, or in the 'Other Comments' area:

- The nature of the clinic and types of clients seen in this clinic, e.g.

- Clinic only sees patients over "XX" years of age (for example, no children in CoCASA age range).
- Clinic population is transient or high turnover.
- Clinic provides only episodic care (walk-in clinic, fire dept, pharmacy).

- Any problems or restrictions with the number of records reviewed, e.g.
  - Clinic pulled "X#" records, but only "Y#" of these were in the correct age range for CoCASA review.
  - Clinic population includes very few children, so only "X#" records were reviewed for the IRRT.
- Results from other items that apply to the CoCASA results:
  - Record-keeping: Obtaining complete histories & documenting accurately (IRRT)
  - Recall & reminder: Maintaining effective recall and/ or reminder systems
- Following immunization practices that promote avoiding "missed opportunities" by:
  - administering simultaneous immunizations (IRRT)
  - adhering to true contraindications
  - following the recommended immunization schedule
  - minimizing barriers by screening for TVFC eligibility (free vaccine), offering vaccine regardless of ability to pay, and offering immunization-only visits
- Specific data from CoCASA rates, e.g.:
  - If the DTaP #3 rate at 12 months is high, but DTaP #4 rate at 24 months is low – clinic is not getting the child back in for the 4th DTaP (usually at 15-18 mos). If the MMR #1 rate is higher than the DTaP #4 rate, then you can suggest the clinic have the child receive the DTaP#4 when they come in for the MMR #1 (usually at 12 mos). The key to this is making sure the DTaP4/MMR appointment is scheduled at least 6 months after the DTaP3 immunization.
  - If the Hep B #2 rate is high at 12 months, but the Hep B #3 rate is low at 24 months AND you notice there is limited documentation in the records of the "at birth" Hep B dose, then you can recommend the clinic develop a better method for obtaining and transcribing immunization records from the hospital nursery.
  - If the 4:3:1:3:3 rate is significantly higher than the 4:3:1:3:3:1 rate, then the clinic is obviously not vaccinating the children for varicella. This may due to the clinic's lack of storage capabilities (e.g., no freezer for varicella) or lack of recommendation. Also, it may be these children have had chickenpox, but it has not been documented in a place in the record where you can find it easily. Address the specific reason in your advice, for example: "Suggested purchase of freezer to store varicella to improve rate."

Resources:

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations

Item 41 MOGE

NVAC Standards for Child and Adolescent Immunization Practices Standard 12: Vaccination records for patients are accurate, complete, and easily accessible.

Up-to-date records are important for accurate CoCASA rates. Any client considered inactive should have their medical records inactivated using the provider's Moved Or Gone Elsewhere policy.

Sources of Information

- (IS) Interview Staff; Sample questions (provider)
  - How are records handled when clients are not active?
- (R) Review Resource Materials or Documents: Review agency MOGE (Moved Or Gone Elsewhere) policy.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Appropriate MOGE policy is used.
- Mark this item "n" if:

- Provider has no MOGE policy.
- Provider does not inactivate client records.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 12

Item 42 Employee Immunization Policy

NVAC Standards for Child and Adolescent Immunization Practices Standard 14: All Personnel who have contact with patients are appropriately vaccinated.

Agency has developed and implemented an employee immunizations policy in accordance with ACIP recommendations.

Sources of Information

- (R) Review Resource Materials or Documents: Review employee immunization policy for the agency.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The provider has an immunization policy in accordance with ACIP recommendations and has implemented it.
- Mark this item "n" if:
  - The provider does not have an immunization policy in accordance with ACIP recommendations.
  - The provider has a policy but has not implemented it.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 14

Item 43 Documentation of Employee Immunization

NVAC Standards for Child and Adolescent Immunization Practices Standard 14: All Personnel who have contact with patients are appropriately vaccinated.

Employee immunization records should be separate from client records.

Sources of Information

- (D) Review Documentation of Immunizations: Pull the employee immunization records for all clinic staff present on the day of your visit and ensure compliance with the employee immunization policy.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Employee immunization records are compliant with employee immunization policy
- Mark this item "n" if:
  - Employee immunization cards are not compliant with policy.
  - There are no employee immunization cards at the clinic.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 14

Item 44 Annual Training on Minimum State Vaccine Requirements

Offers to provide seminar or training session at least annually, including information on the Recommended Childhood and Adolescent Immunization Schedule and DSHS Minimum Vaccine Requirements, to TVFC providers and WIC programs in the service area.

Sources of Information

- (R) Review Resource Materials or Documents: During the interview, note date(s) of training or presentations.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - At least one training session has been offered or conducted.
- Mark this item "n" if:
  - No trainings have been offered.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Recommended Childhood and Adolescent Immunization Schedule
  - Standards for Child and Adolescent Immunization Practices, Standard 10
- TVFC Provider Tool Kit, Section 5: Immunization Requirements: School Law
  - State of Texas Immunization Requirements for Children & Students
  - Minimum State Vaccine Requirements for TX School Entrance/Attendance
  - Minimum State Vaccine Requirements for TX Child-Care Facilities

Item 45 Annual Training on Immunization/Disease Surveillance

NVAC Standards for Child and Adolescent Immunization Practices Standard 10: Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive on-going education.

Sources of Information

- (R) Review Resource Materials or Documents: During the interview, note date(s) of training or presentations.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Documentation of annual training can be found.
- Mark this item "n" if:
  - No documentation of annual training can be found.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 10

Item 46 Designated Personnel for Vaccine Management

NVAC Standards for Child and Adolescent Immunization Practices Standard 10: Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive on-going education.

Sources of Information

- (R) Review Resource Materials or Documents: Review standard operating procedures for vaccine management.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - A designated person can be identified.
- Mark this item "n" if:
  - No personnel have been designated responsible for vaccine management.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations

- Standards for Child and Adolescent Immunization Practices, Standard 10

Item 47 Staff Training on Vaccine Management

NVAC Standards for Child and Adolescent Immunization Practices Standard 10: Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive on-going education.

This item focuses on staff training regarding vaccine management. There should be written policies regarding the storage and handling of vaccines, which should be communicated to staff. The CDC Vaccine Management wall poster, when posted in a prominent location, is a very good educational tool and can be used as the "policy" for vaccine management.

To answer this item, ask the staff contact about how new staff is oriented and how vaccine management in the clinic is reviewed or updated with current staff. Ask about how both formal (in-services, training meetings, outside training & seminars) and informal (individual staff training, referral to resources) training is done. Also ask about updates – how often are staff updated, as a whole. In order to mark this item as a "y," the clinic simply needs to report there is a process for staff education, whether individual or group, formal or informal.

Sources of Information

- (O) Observe whether the vaccine management poster is posted on wall. Observe a part of a staff training video or presentation.
- (R) Review resource materials; Examine written policies/procedures or memos on vaccine management and staff training records (e.g., in-services, seminars, etc.)
- (IS) Interview Staff; sample questions (providers)
  - How are new staff oriented on vaccine management and handling?
  - How is vaccine management training for current staff accomplished? Is it formal or informal? How often is training updated?
  - What does the training address and how do you document the contents of the training?
  - How do you document who attends staff training?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The staff contact reports or shows evidence of formal or informal staff training for vaccine management. Note that verbal confirmation is acceptable, but encourage the clinic to document training through a sign-in list, agendas of staff meetings, and/or documentation of new staff orientation. Note date(s) of staff training or evidence of orientation in the 'Other Comments' area.
- Mark this item "n" if:
  - The clinic does not provide staff training or orientation on vaccine management.
  - The clinic does not report or show evidence of training on vaccine management. Encourage the clinic to develop policies, procedures and reference materials, and to develop a process for ensuring that staff is educated on correct vaccine management.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standards # 8,9,10
  - MMWR Morbidity & Mortality Weekly Report, pg 15

Item 48a Appropriate Refrigerators/Freezers

NVAC Standards for Child and Adolescent Immunization Practices Standard 8: Health care professionals follow appropriate procedures for vaccine storage and handling.

In order for the clinic to effectively store all TVFC recommended vaccines, both refrigerator and freezer storage space should be available. Since vaccines should be stored at specific temperature ranges to insure stability

and viability, the CDC requires that all vaccine storage refrigeration units contain separate refrigerator and freezer compartments, each of which should have a separate exterior door.

The most common problem in vaccine storage occurs with varicella storage. Some clinics make the mistake of storing varicella in a freezer that is actually an inner compartment of a refrigerator – not truly a separate compartment. Although the freezer appears to have a "separate door" inside, this does not offer enough freezer temperature control. Varicella should never be stored in an "internal freezer" section of a dormitory-sized refrigerator, even if it's the only vaccine kept in that unit. The freezer unit does not need to have its own thermostat – what is important is that it has its own door to the exterior and that the temperature can be maintained in the proper range. Also, be aware that the MMR vaccine can also be stored in a freezer, if it arrives already frozen. It cannot be thawed, and then re-frozen. MMR vaccine distributed from DSHS is NOT shipped frozen. For this reason DSHS recommends storing MMR in the refrigerator.

If the clinic does not stock varicella or frozen MMR, a separate freezer compartment is not required. However, since varicella is a routinely recommended TVFC vaccine, you would want to encourage the clinic that sees children between 2 and 18 years of age to obtain a freezer unit acceptable for varicella storage.

Sources of Information

- (O) Observe what type of refrigeration unit is used for vaccine storage.
- If you are reviewing a site with multiple refrigerators, ask to see each and record the number and types of units (you will then mark more than one box and explain types/locations in the 'Other Comments' area).
    - If you are reviewing a hospital nursery, you should ask if the vaccine is also stored in the pharmacy. If so, you will need to check the pharmacy storage unit (you will then mark more than one box and explain types/locations in the 'Other Comments' area).

Entry of Results into the Site Survey

Mark the appropriate box(es) to indicate what type of refrigeration unit(s) you observed in the clinic.

The types of vaccine storage units are listed below:

- Combined refrigerator/freezer with separate exterior refrigerator and freezer doors (regardless of size)- NOTE: There is NO size limit – this can be as small as a dorm-sized refrigerator, as long as there are SEPARATE OUTSIDE doors. THIS UNIT IS ACCEPTABLE FOR VACCINES – THE FREEZER IS O.K. FOR VARICELLA AND MMRV.
- Stand-alone refrigerator (no freezer unit included)- THIS UNIT IS ACCEPTABLE FOR ALL VACCINES EXCEPT VARICELLA AND MMRV- NO FREEZER.
- Stand-alone freezer (no refrigerator unit – can be regular or dorm-sized freezer)- THIS UNIT IS ACCEPTABLE FOR VARICELLA , MMRV AND FROZEN MMR ONLY – NO FRIDGE FOR OTHER VACCINES.
- Combined refrigerator/freezer with a single exterior door (freezer not acceptable for varicella storage)- THIS UNIT IS ACCEPTABLE FOR REFRIGERATED VACCINES BUT THE FREEZER IS NOT ACCEPTABLE FOR VARICELLA OR MMRV STORAGE.

If the clinic has multiple refrigerator/freezer combinations, you may mark as many types on the list as applicable and explain your selection(s) in the 'Other Comments' area. For example: "3 dorm-sized combined fridge/freezers with single ext. doors in nurse stations for each MD; all MDs share central stand-alone freezer for varicella." If you are reviewing a hospital nursery, then you will most likely need to check the pharmacy storage unit as well as the nursery unit.

Note that dorm-size refrigerators or ones with internal freezer compartments are NOT acceptable, even if the only thing kept in the unit is varicella. Some clinics will use dormitory-sized fridge/freezer combinations this way, reporting that the unit is set so the temperature stays in the "acceptable freezer limit" for varicella. However, CDC research has shown that these units do not keep freezer temperatures stable, so they are not recommended for varicella storage.

Finally, if the clinic does not stock varicella, then freezer type is not an issue. However, if the clinic does not stock varicella because they don't have an appropriate freezer, then you might advise them to consider purchasing one if they see children between 2 and 18 years of age. To encourage them, you might want to highlight that schools now require varicella, so the administration fees gained over time from administering varicella could certainly finance the cost of the storage unit upgrade.

- Mark this item "y" if:

- The clinic stocks varicella or frozen MMR/MMRV and uses an ACCEPTABLE unit.
- The clinic does not stock varicella or frozen MMR/MMRV and has some type of refrigerator for other vaccines (any type).

- Mark this item "n" if:
  - The clinic stocks varicella or frozen MMR/MMRV but uses an UNACCEPTABLE unit. If the clinic is not stocking varicella or MMRV, but is freezing MMR, you can suggest the clinic refrigerate the MMR.

NOTE: IF YOU MARKED THIS ITEM "n": You must take immediate steps to determine vaccine viability and safeguard vaccine supply.

TMF reviewers: See the instructions below for the DSHS notification process.

This MUST be done BEFORE you leave the clinic.

Instructions for Notifying DSHS for Vaccine Storage Problems

- Use the city/county LHD and HSR Immunization Contact List (sleeve #48) to determine the appropriate person to call while you are still at the clinic site. If the city or county health department column is filled in, call that person first**.** If you are unable to speak to this person (or an acceptable substitute) directly, you can leave a voice mail, but it is also essential that you call the person named in the DSHS Regional Contact column. You should speak to this person (or an acceptable substitute) directly. If this is not possible, please call TMF and speak to either your designated TMF Review Coordinator, Sue Welch, or Geri Bischoff directly. Make sure to note who you spoke with in the 'Other Comments' area.
- Remember, YOU are responsible for notifying the appropriate contacts regarding refrigeration issues. DO NOT ask the clinic staff or provider to perform this task. You must speak directly to a responsible person at one of these levels before you leave the clinic site, so that the refrigeration issue can be dealt with immediately. Because this is a problem of a critical nature, do not substitute an email after you get home for a phone call from the clinic.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8

Item 48b Vaccine Stored in Central Area of Refrigerator

NVAC Standards for Child and Adolescent Immunization Practices Standard 8: Health care professionals follow appropriate procedures for vaccine storage and handling.

Proper storage of vaccine includes having the vaccine placed in the central area of the body of the refrigerator. Vaccine should be placed so that the cold air can circulate around it, not in a closed container or against the walls of the unit. This means that there should be space between the stack and side/back of the unit to allow cold air to circulate around the vaccine. Vaccine should not be stored in the doors, vegetable bins or meat drawers because these areas can have different temperatures from the central area of the unit, which is the area monitored by the thermometer. Vaccine dilutent can be stored in the door.

To answer this item, check the vaccine storage unit(s) to see that the vaccine is in the central area of the body of the refrigerator. If there is any vaccine being stored in the door, the vegetable bins, and/or the meat drawer, help the staff move it into the refrigerator body. Suggest removing the vegetable bins and meat drawers and putting water bottles or Pedialyte in these areas to discourage placement of vaccine in these areas. It is acceptable, although not encouraged, for clinics to store vaccines in the area where vegetable bins used to be, as long as the vaccine is placed on a rack at least 1" high to allow for air circulation. Also, signs could be posted to remind staff not to place vaccine in undesirable areas.

Sources of Information

- (O) Observe where the vaccines are placed in the refrigerator. There should be no vaccine in the door, the vegetable bins, or the meat drawer.

Entry of Results into the Site Survey

If the vaccine is not properly stored in the central area of the refrigerator, mark the box corresponding to what the problem is (vaccine in door, vaccine in bin or drawer, no air space around vaccine).

- Mark this item "y" if:
    - The vaccine is being stored in the central area of the refrigerator, and is stored in such a fashion as to allow air to circulate freely around it.
- Mark this item "n" if:
    - The vaccine is stored in the door of the refrigerator.
    - The vaccine is stored in a vegetable bin or meat drawer.
    - The vaccine in stored in a closed container, or in such a fashion as to obstruct the flow of air around it.

NOTE: If you mark the item "n", advise the staff to move the vaccine to the central area of the refrigerator, and discourage the placement of vaccines in the door. Note these interventions in the 'Corrective Actions', Comments', or 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
    - Standards for Child and Adolescent Immunization Practices, Standard # 8

Item 48c Vaccine Stored in Central Area of Freezer

NVAC Standards for Child and Adolescent Immunization Practices Standard 8: Health care professionals follow appropriate procedures for vaccine storage and handling.

Proper storage of vaccine includes having the vaccine placed in the central area of the body of the freezer. Vaccine should be placed so that the cold air can circulate around it, not in a closed container or against the walls of the unit. This means that there should be space between the stack and side/back of the unit to allow cold air to circulate around the vaccine. Vaccine should not be stored in the door; this area can have different temperatures than the central area of the freezer, which is the area monitored by the thermometer.

To answer this item, check the vaccine storage unit(s) to see that the vaccine is in the central area of the body of the freezer. If there is any vaccine being stored in the door, help the staff move it into the freezer body. Signs could be posted to remind staff not to place vaccine in undesirable areas.

Sources of Information

- (O) Observe where the vaccine is placed in the freezer. There should be no vaccine in the door.

Entry of Results into the Site Survey

If the vaccine is not properly stored in the central area of the freezer, mark the box corresponding to what the problem is (vaccine in door, no air space around vaccine).

- Mark this item "y" if:
    - The vaccine is being stored in the central area of the freezer, and is stored in such a fashion as to allow air to circulate freely around it.
- Mark this item "n" if:
    - The vaccine is stored in the door of the freezer.
    - The vaccine in stored in a closed container, or in such a fashion as to obstruct the flow of air around it.

NOTE: If you mark the item "n", advise the staff to move the vaccine to the central area of the freezer, and discourage the placement of vaccines in the door. Note these interventions in the 'Corrective Actions', 'Comments', or 'Other Comments' area.

- Mark this item "na" if:
    - The clinic does not stock varicella, or does not have a freezer. Mark the appropriate statement in the 'Comments' area. However, if the clinic sees preschool children, encourage the staff to stock varicella and obtain an appropriate freezer, if necessary, to do so. Note this in the 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
    - Standards for Child and Adolescent Immunization Practices, Standard # 8

Item 49a Plug Guards

Plug guards are effective tools in preventing the unintentional disconnecting of a refrigerator or freezer in which vaccines are stored. All refrigerator/freezers storing vaccine should have plug guards installed. Whether or not the plug is accessible does not matter – even an electrical outlet blocked by a refrigerator can inadvertently be unplugged during cleaning or maintenance. TVFC policy states that a provider may be held liable for loss of vaccine due to improper storage, e.g., if a refrigerator or freezer is unplugged when it didn't have a plug guard on it.

To answer this item, visually check the plug outlets of all vaccine storage units for plug guards. If you can't observe each outlet, ask the staff if a plug guard has been installed and record their response (take their word for it). If one is missing, provide one for the site, if available from DSHS. The plug guard should be installed while you are in the clinic, if possible. However you are not required to help the clinic do this. You may simply give the clinic the plug guard, give a short explanation of how it is installed, and advise them to call DSHS if they have any questions.

Note that surge protectors, power strips, and extension cords are not substitutes for a plug guard. If a plug guard is on the cord plugged into an outlet, but that cord is plugged into a surge protector, power strip, and/or extension cord, educate the clinic about the true intent of using a plug guard (to prevent unintentional disconnecting of the electrical supply) and encourage them to place a "Do Not Unplug" sign at any electrical connection and on the power strip on/off switch. Alternative actions could include taping the connections, taping over the on/off switch, and/or tying the two sections of the cord together before plugging one end into the other.

Plugging the refrigerator and/or freezer into an outlet connected to a generator (typically the red outlets in a hospital, etc.) is helpful in case of a power outage, but does not substitute for use of a plug guard. The cord plugged into these outlets should still have a plug guard on them, if it will fit.

Newer appliances often have a flat plug, which does not allow for installation of the state-issued plug guard. In these circumstances, "Do Not Unplug" signs should be posted near the outlet and the cord of the appliance should be taped to the wall. Providers should be encouraged, but are not required, to purchase a plug guard that will fit the flat plug (these are available at major hardware stores).

Sources of Information

- (O) Observe all vaccine storage unit electrical outlets for plug guards.

Entry of Results into the Site Survey

- Mark this item "y" if:
    - All refrigerators/freezers used for vaccine storage have plug guards installed.
    - You can't visualize the plug guard, but staff states it is present.
- Mark this item "n" if:
    - A refrigerator/freezer storing vaccine does not have a plug guard installed.
    - You can't visualize the plug guard and staff states it is not present or they do not know if one is present.
    - Even if a plug guard is installed during the site visit, this item should still be marked "n" because the guard was not in place at the beginning of the visit.
- Mark this item "na" if:
    - The appliance has a flat plug and the DSHS supplied plug guard does not fit. If a new plug guard is available, have the provider check to see if the new plug guard can be used. If the new plug guard does not fit, be sure to check the '*Plug guard does not fit."* box, in the Comments section. Encourage the staff to tape the appliance cord to the wall near the outlet and post a "Do Not Unplug" warning sign near the outlet and document this in the "Other Comments" section. Encourage provider to contact HSR for newer plug guard if unavailable at time of visit.

- The building management will not allow the clinic to install a plug guard. Encourage the staff to tape the appliance cord to the wall near the outlet and post a "Do Not Unplug" warning sign near the outlet. Be sure to note these circumstances in the 'Other Comments' area.
- See the notations above re: surge protectors, power strips and extension cords. Be sure to note these circumstances in the 'Other Comments' area and the education you provided about additional measures to insure that all electrical connections are protected.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8

Item 49b Alarm System on Vaccine Refrigerators/Freezers

Temperature-sensitive alarm systems are an effective way to help reduce vaccine lost when unexpected events occur.

Sources of Information

- (R) Review Resource Materials or Documents: Review the emergency contingency plan. Check the numbers being called and ensure the validity. Obtain the telephone number of alarm and name of person responsible for monitoring. Review documentation of monitoring.

Note in the "Comments" section of the tool how often the alarm is checked.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - A temperature-sensitive alarm monitors vaccine refrigerators/ freezers.
- Mark this item "n" if:
  - No temperature-sensitive alarm monitors vaccine refrigerators/freezers.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard 8

Item 49c Warning Sign Posted by Each Vaccine Storage Unit

Clinics are encouraged to use plug guards, duct tape or other measures to prevent unintentional disconnecting of a refrigerator or freezer in which vaccines are stored. However, providing an additional safeguard, like a "Do Not Unplug" sign by all refrigerator/freezers storing vaccine is strongly encouraged. This is a quick and easy way to alert staff and outsiders not to disconnect the appliance. This is especially important when the storage unit is enclosed in an area where the plug is not easily visible or a plug guard is not installed.

To answer this item, ask the clinic staff if they post "Do Not Unplug" signs for each vaccine storage unit. If so, ask to see where they are posted. Observe whether the signs are posted near the location of each outlet. In some cases, the sign may be posted on the wall, cabinet or directly on the appliance, depending on whether the outlet is easily accessible. Use your common sense to decide if the sign is posted appropriately to alert people to avoid unplugging the unit. .Also, make sure there is a sign for each unit in which vaccines are stored. Note that even if a clinic has a plug guard, there should still be a "Do Not Unplug" sign posted. Any size sign from any source (TVFC Provider Tool Kit Section 3, IAC, CDC, or even hand-written) is acceptable**.**

If the clinic has not posted "Do Not Unplug" signs, give the clinic signs to post and assist them to post the signs while you are at the clinic. Even if a "Do Not Unplug" sign is posted during the site visit, this item should still be marked "n" because the sign was not in place at the beginning of the visit, and note that you assisted them in posting signs as a corrective action**.**

Sources of Information

- (O) Observe all vaccine storage units for "Do Not Unplug" signs.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - All refrigerators/freezers used for vaccine storage have "Do Not Unplug" signs posted by the outlet areas or on the storage unit.
- Mark this item "n" if:
  - Any refrigerator/freezer storing vaccine does not have a "Do Not Unplug" sign posted by the outlet area or on the storage unit.
  - The "Do Not Unplug" sign(s) is not posted in an area by the outlet or on the storage unit, e.g., the sign is not close enough to the outlet or storage unit to naturally alert staff to stop and consider whether they should unplug the unit.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling.
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8

Item 50a Refrigerator/Freezer Temperature Recording Form

The DSHS Temperature Recording Form (DSHS form # C-105) is available for the past three months.

The modified live viruses, bacteria or protein derivatives in vaccines are particularly subject to variations in temperature. Temperatures must be documented twice daily on the C-105, which is submitted to DSHS monthly. Completion of the DSHS form is required – no other temperature recording form may be used. Twice daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. All storage units should have temperature recording forms to document temperatures twice daily when vaccine is present in unit. The clinic is required to make the refrigerator/freezer C-105 (for the past three months) available to the site surveyor for review. For example, if the survey is taking place in April 2007, the C-105s for January, February, and March of 2007 should be available.

Review the C-105 to verify that the clinic has made the C-105s available from the past three months. If the three C-105s are not available, mark on the tool whether the missing C-105 is refrigerator, freezer, or both.

If the C-105s are not available, follow the process to notify the LHD or HSR (see below).

Continuous Recording Devices

DSHS has distributed, to some TVFC providers, thermometers with continuous graphing/recording capability, or digital data logging capability. These are helpful for monitoring refrigerator temperatures when the clinic is not open. However, they do not replace the need for a standard thermometer. The clinic staff still needs to review and record the actual refrigerator temperature on C-105 twice a day.

Sources of Information

- (R) Review resource materials; Examine the C-105s for the past 3 months.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic has made the C-105s available for the past three months.
- Mark this item "n" if:
  - The clinic has not made the C-105s available for the past three months.

NOTE: IF YOU MARKED THIS ITEM "n": You must take immediate steps to determine vaccine viability and safeguard vaccine supply.

TMF reviewers: See the instructions below for the DSHS notification process.

This MUST be done BEFORE you leave the clinic.

Instructions for Notifying DSHS for Vaccine Storage Problems

- Use the LHD and HSR Immunization Contact List (sleeve #48) to determine the appropriate person to call while you are still at the clinic site. If the city or county health department column is filled in, call that person first**.** If you are unable to speak to this person (or an acceptable substitute) directly, you can leave a voice mail, but it is also essential that you call the person named in the DSHS Regional Contact column. You

should speak to this person (or an acceptable substitute) directly. If this is not possible, please call TMF and speak to either your designated TMF Review Coordinator, Sue White, or Geri Bischoff directly. Make sure to note who you spoke with in the 'Other Comments' area.

- Remember, YOU are responsible for notifying the appropriate contacts regarding refrigeration issues. DO NOT ask the clinic staff or provider to perform this task. You must speak directly to a responsible person at one of these levels before you leave the clinic site, so that the refrigeration issue can be dealt with immediately. Because this is a problem of a critical nature, do not substitute an email after you get home for a phone call from the clinic.

Resources

- CDC Vaccine Storage and Handling Toolkit; Chapter 6. http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 50b Refrigerator Temperature Recording

NVAC Standards for Child and Adolescent Immunization Practices Standard 8: Health care professionals follow appropriate procedures for vaccine storage and handling

DSHS requires all providers storing vaccines to monitor refrigerator temperatures twice daily. Temperatures should be documented on the C-105, which is submitted to the DSHS monthly. Completion of the DSHS form is required; no other temperature recording form may be used. The clinic may choose whether to record temperatures in Fahrenheit or Centigrade/Celsius.

Review the clinic copies of the C-105s to verify the temperature is being checked and recorded twice daily. Documenting the actual time of the temperature readings from the refrigerator is also required.

Continuous Recording Devices

(See 50a)

Sources of Information

- (R) Review resource materials; Examine the C-105s for the past 3 months to verify whether the temperature is recorded twice daily, as required.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic is recording the refrigerator temperature twice per day on the C-105.
- Mark this item "n" if:
  - The clinic is not recording the refrigerator temperature twice per day on the C-105 (days the clinic is closed are exempt). Once per day is not enough.
  - The clinic is not recording on the C-105 because they use a continuous temperature recording device in lieu of this. Even if the device is capable of printing out a log, DSHS still requires twice daily refrigerator recording on the required C-105.
  - The clinic is not completing the C-105 as instructed. See instructions on back of C-105.
- If the answer to the initial item statement is "no", mark the button to indicate whether they are recording 1) once per day, or 2) less than once per day.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8
- CDC Vaccine Storage and Handling Toolkit; Chapter 6 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Items 50c Refrigerator Temperature Range

NVAC Standards for Child and Adolescent Immunization Practices Standard 8: Health care professionals follow appropriate procedures for vaccine storage and handling.

DSHS requires all providers storing vaccines to monitor refrigerator temperatures twice daily. Temperatures should be documented on the C-105, which is submitted to the DSHS monthly.

A good way to advise clinics on maintaining appropriate refrigerator temperatures is to use the adage, "Aim for 40": This means that if the clinic aims for 40 degrees Fahrenheit, then the chances are less that the temperature will vary enough to be out of range.

To complete this item, first check the current temperature of the refrigerator. If this is a hospital nursery (with a pharmacy storage unit) or a clinic with multiple storage locations, find out where the vaccine is stored the longest. This unit should be considered Unit 1 (sole or primary unit). If there is a second refrigerator where vaccine is stored, this unit should be considered Unit 2 (secondary). Describe the locations of the unit(s) within the clinic/office in the 'Other Comments' area.

Use your thermometer to check the current temperature. If you do not have one available, you can use the clinic's thermometer.

Place the thermometer in the central area of the refrigerator, next to the clinic's thermometer, and wait a minimum of five minutes. Enter the current temperature in Fahrenheit in the appropriate space on the site survey report. This must be recorded in Fahrenheit on the site survey report.

- If the clinic is recording the temperatures in centigrade, use the Fahrenheit-centigrade conversion table in sleeve #50 (PLEASE DO NOT ENTER THE TEMPERATURE IN THE CENTIGRADE SCALE). The temperature should be in the accepted temperature range of 36 to 46 degrees F. You will repeat this process with the freezer compartment (Item 51b). The temperature you document in the "current temperature" box should be the reading from your thermometer (unless your thermometer is not accurate; see the thermometer discrepancy section below.)

Record the highest and lowest temperatures (Fahrenheit) for Unit 1, for the past 3 months, in the respective fields provided on the site survey report. Repeat this process for Unit 2 if applicable.

If "n" is selected (any of the recorded or currently taken temperatures are out of the range), document how many times the temperature is recorded above the maximum, and/or how many times the temperature is recorded below the minimum, for the past three months recordings, in the space(s) provided on the site survey report. Ask the provider what actions were taken at the time a refrigerator temperature recording was taken and noted to be out of range; mark the action taken on the site survey report.

Thermometer discrepancies: If your thermometer temperature reading is significantly different from the clinic's thermometer (>5 degree F), you should check both thermometers, using either of the methods presented below:

- The first method is to use a third thermometer. Ask the clinic if they have an additional thermometer or simply use the freezer thermometer. Place all three thermometers side-by-side and compare the results. Whichever thermometer matches the third thermometer most closely is probably the most accurate. In this case, use the most accurate for your current temperature readings.
- The second method to check accuracy of a thermometer is to place it in ice water that has stabilized (add ice to water and wait 5 minutes – ice cubes should still be present). The temperature should read 32 degrees F.
- If these tests show the clinic thermometer is grossly inaccurate, advise the clinic to obtain a new thermometer, preferably certified by the National Institute of Standards and Technology (NIST) or American Society for Testing and Materials (ASTM). These can usually be purchased from a medical supply or other professional refrigeration vendor.

Continuous Recording Devices

(See 50a)

Sources of Information

- (O) Observe the actual current temperature of the refrigerator from your thermometer.
- (R) Review resource materials; Examine the C-105s for the past 3 months.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - During the past three months, all recorded refrigerator temperatures were within the recommended range (2-8°C/36-46°F).
- Mark this item "n" if:

- **Any** of the recorded refrigerator temperatures (current, lowest, or highest) are out of the recommended range.

NOTE: IF YOU MARKED THIS ITEM "n": You must take immediate steps to determine vaccine viability and safeguard vaccine supply!

TMF reviewers: See the instructions below for the DSHS notification process.

This MUST be done BEFORE you leave the clinic

Instructions for Notifying DSHS for Vaccine Storage Problems

- Use the LHD and HSR Contact List (sleeve #48) to determine the appropriate person to call while you are still at the clinic site. If the city or county health department column is filled in, call that person first. If you are unable to speak to this person (or an acceptable substitute) directly, you can leave a voice mail, but it is also essential that you call the person named in the DSHS Regional Contact column. You should speak to this person (or an acceptable substitute) directly. If this is not possible, please call TMF and speak to either your designated TMF Review Coordinator, Sue White, or Geri Bischoff directly. Make sure to note who you spoke with in the 'Other Comments' area.
- Remember, YOU are responsible for notifying the appropriate contacts regarding refrigeration issues. DO NOT ask the clinic staff or provider to perform this task. You must speak directly to a responsible person at one of these levels before you leave the clinic site, so the refrigeration issue can be dealt with immediately. Because this is a problem of a critical nature, do not substitute an email after you get home for a phone call from the clinic.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8

Item 50d Working Thermometer in Central Area of Refrigerator

There should be a working thermometer in the middle of the refrigerator even if there is a continuous monitoring device. The thermometer may be a standard mercury-type thermometer (scale or dial read) or a digital display thermometer, with or without a probe. If the thermometer has a probe, the probe should be placed in the central area of the refrigerator, near the vaccine. If you are unsure about the thermometer's reliability or accuracy, refer to the instructions in Item 50c for checking the accuracy of a clinic thermometer.

If a working thermometer was not found in the central area of the refrigerator, mark the appropriate button to note that 1) no thermometer was found, 2) a working thermometer was found, but it was not in the central area of the refrigerator or 3) a thermometer was found but it was not working properly.

Sources of Information

- (O) Observe a working thermometer in the central area of the refrigerator.
- (R) Review resource materials; Check any equipment logs that note testing of thermometer working condition and accuracy.

Thermometer discrepancies

(see 50c)

Continuous Recording Devices

(See 50a)

Entry of Results into the Site Survey

- Mark this item "y" if:
  - There is a working thermometer placed in the central area of the refrigerator.
- Mark this item "n" if:
  - The refrigerator does not have a thermometer, even if they have a 24-hour continuous monitoring device.
  - The thermometer is not working or is grossly inaccurate.

- The thermometer or probe is placed in the door of the refrigerator.
- The thermometer or probe is placed against any inside wall of the refrigerator.

NOTE: IF YOU MARKED THIS ITEM "n": You must take immediate steps to determine vaccine viability and safeguard vaccine supply.

TMF reviewers: See the instructions below for the DSHS notification process.

This MUST be done BEFORE you leave the clinic.

Instructions for Notifying DSHS for Vaccine Storage Problems

- Use the LHD and HSR Immunization Contact List (sleeve #48) to determine the appropriate person to call while you are still at the clinic site. If the city or county health department column is filled in, call that person first**.** If you are unable to speak to this person (or an acceptable substitute) directly, you can leave a voice mail, but it is also essential that you call the person named in the DSHS Regional Contact column. You should speak to this person (or an acceptable substitute) directly. If this is not possible, please call TMF and speak to either your designated TMF Review Coordinator, Sue White, or Geri Bischoff directly. Make sure to note who you spoke with in the 'Other Comments' area.
    - Remember, YOU are responsible for notifying the appropriate contacts regarding refrigeration issues. DO NOT ask the clinic staff or provider to perform this task. You must speak directly to a responsible person at one of these levels before you leave the clinic site, so that the refrigeration issue can be dealt with immediately. Because this is a problem of a critical nature, do not substitute an email after you get home for a phone call from the clinic.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
    - Standards for Child and Adolescent Immunization Practices, Standard #8
- CDC Vaccine Storage and Handling Toolkit; Chapter 4 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 50e Bottles of Water in the Refrigerator

Refrigerator temperatures should remain as constant as possible to protect vaccine viability. A simple and inexpensive way to help maintain refrigerator temperatures in the proper range is to place several bottles of water in the refrigerator. All TVFC providers should keep bottles of water in refrigerators that are stocked with vaccines. If the clinic has multiple vaccine storage units, all units should be checked. This includes hospital nurseries where vaccines are kept in the pharmacy unit prior to being transported to the nursery.

Stress to clinic staff that filling up the door and part of the shelves with multiple, large bottles of water is the idea. Even though the clinic will receive a "y" answer for this item with only one container present, in truth, only one 16oz bottle is not going to make much difference. Having the door filled with bottles of water will also prevent the door from being used for storage of vaccines, which should be on a shelf in the center of the refrigerator. Removing the vegetable bins and meat drawers and putting water bottles or Pedialyte in these areas can discourage placement of vaccine in these undesirable areas. Some clinics may complain that dorm-sized refrigerators are too limited to place water bottles, but there is still door space available in these units to fill with water bottles to stabilize temperatures.

Gel packs, such as those the clinic receives with their vaccine shipment, can also be used. However, the vaccine should NOT be placed directly on top of gel packs or containers of water. In addition, Pedialyte bottles or IV bags with solution can be used instead of water.

To avoid any problems with regulations from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Clinical Laboratories Improvement Amendments (CLIA) regulations, encourage the staff to remove any labels identifying the original contents of the container and label the container with "do not drink" or "not for consumption." These actions are not necessary if the clinic uses the gel packs sent with the vaccine shipments.

Sources of Information

- (O) Observe whether at least one bottle of water or comparable gel- or water-filled container has been placed in the refrigerator to maintain temperature.
- (R) Review resource materials; Examine a written policy or procedure for placement of water/gel packs in the refrigerator.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - At least one bottle of water or comparable gel- or water-filled container has been placed in the refrigerator to maintain temperature. *Be sure to check the Comment "Encouraged to place additional bottles of water in refrigerator" if they only have one bottle placed*.
- Mark this item "n" if:
  - There are no gel- or water-filled containers in the refrigerator.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8
- CDC Vaccine Storage and Handling Toolkit; Chapter 4 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 51a Freezer Temperature Recording

NVAC Standards for Child and Adolescent Immunization Practices Standard 8: Health care professionals follow appropriate procedures for vaccine storage and handling

DSHS requires all providers storing vaccines to monitor freezer temperatures twice daily. Actual temperatures should be documented on the C-105, which is submitted to the DSHS monthly.

Review the clinic copies of the C-105 (for the past three months) to verify the temperature is being checked and recorded twice per day. Documenting the actual time of the temperature readings from the freezer is also required.

Continuous Recording Devices

DSHS has distributed continuous recording devices to some TVFC providers. These are helpful for monitoring refrigerator temperatures when the clinic is not open. However**,** they should not to be used in freezers.

Sources of Information

- (R) Review resource materials; Examine the C-105s for the past 3 months to verify whether the freezer temperature is recorded twice daily, as required.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic is recording the actual freezer temperature and time twice per day on the C-105.
- Mark this item "n" if:
  - The clinic is not recording the actual freezer temperature and time twice per day on the C-105 (days the clinic is closed are exempt). Once per day in not enough.
  - The clinic is not completing the C-105 as instructed. See instructions on back of C-105.
- If the answer to the initial item statement is "no", mark the button to indicate whether they are recording 1) once per day, or 2) less than once per day.
- Mark this item "na" if:
  - The clinic does not stock varicella, or does not have a freezer. Mark the appropriate statement in the 'Comments' area. However, if the clinic sees preschool children, encourage the staff to stock varicella and obtain an appropriate freezer, if necessary, to do so. Note this in the 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8

- CDC Vaccine Storage and Handling Toolkit; Chapter 6. http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 51b Freezer Temperature Range

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling

DSHS requires all providers storing vaccines to monitor freezer temperatures twice daily. Actual temperatures should be documented on the C-105, which is submitted to the DSHS monthly.

Use your thermometer to check the current temperature. If you do not have one available, you can use the clinic's thermometer. Place the thermometer in the central area of the freezer, next to the clinic's thermometer, and wait a minimum of five minutes. Record the current temperature in Fahrenheit in the appropriate space on the site survey report. If the clinic is recording the temperatures in centigrade, use the Fahrenheit-centigrade conversion table in sleeve #50 (PLEASE DO NOT ENTER THE TEMPERATURE IN THE CENTIGRADE SCALE). The temperature should be below the recommended maximum of -15°C/5°F. The temperature you document in the "Current temperature" box should be the reading from your thermometer (unless your thermometer is not accurate – see the thermometer discrepancy section 50c.) Record the highest temperature (Fahrenheit) in the appropriate field provided on the site survey report. IF EITHER THE CURRENT OR HIGHEST TEMPERATURE IS OUT OF RANGE, MARK THIS ITEM "n".

If "n" is selected (**any** of the recorded or currently taken temperatures are out of the range), document how many times the temperature is recorded above the maximum for the past three months recordings, in the space(s) provided on the site survey report. Ask the provider what actions were taken at the time a freezer temperature recording was taken and noted to be above the maximum; mark the action taken on the site survey report.

Thermometer discrepancies (see 50c)

Please note:

- To enter a negative number, you have to enter the number first, and then the minus sign, e.g., "5-". The program will convert it to a negative number.
- The acceptable freezer range is at or below 5 degrees Fahrenheit.
- Mark this item as "na" if the clinic does not stock varicella or does not have a freezer. However, if the clinic sees children age 2-18 years of age, encourage the staff to stock varicella, and obtain an appropriate freezer. Note this in the 'Other Comments' area.
- Some clinics use the "penny test" as an additional indicator that the proper temperature has been maintained in the freezer. The staff could put a cup of water in the freezer until it freezes, and then place a penny on top of the ice. If the penny is ever found to recede into the ice, this means the temperature at some point warmed up enough to question the viability of the varicella. Though the penny test is useful, it CANNOT be substituted for the required daily monitoring using a thermometer.

Sources of Information

- (O) Observe the actual current temperature of the refrigerator from your thermometer.
- (R) Review resource materials; Examine the C-105s for the past 3 months.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - During the past three months, all recorded freezer temperatures were at or below the recommended maximum temperature (-15°C/5°F)
- Mark this item "n" if:
  - **Either** of the recorded freezer temperatures (current or highest) are above the recommended maximum temperature (-15°C/5°F)

NOTE: IF YOU MARKED THIS ITEM "n": You must take immediate steps to determine vaccine viability and safeguard vaccine supply.

TMF reviewers: See the instructions below for the DSHS notification process.

This MUST be done BEFORE you leave the clinic!

Instructions for Notifying DSHS for Vaccine Storage Problems

- Use the LHD and HSR Contact List (sleeve #48) to determine the appropriate person to call while you are still at the clinic site. If the city or county health department column is filled in, call that person first. If you are unable to speak to this person (or an acceptable substitute) directly, you can leave a voice mail, but it is also essential that you call the person named in the DSHS Regional Contact column. You should speak to this person (or an acceptable substitute) directly. If this is not possible, please call TMF and speak to either your designated TMF Review Coordinator, Sue White, or Geri Bischoff directly. Make sure to note who you spoke to in the 'Other Comments' area.
- Remember, YOU are responsible for notifying the appropriate contacts regarding refrigeration issues. DO NOT ask the clinic staff or provider to perform this task. You must speak directly to a responsible person at one of these levels before you leave the clinic site, so that the refrigeration issue can be dealt with immediately. Because this is a problem of a critical nature, do not substitute an email after you get home for a phone call from the clinic.
- Mark this item "na" if:
  - The clinic does not stock varicella, or does not have a freezer. Mark the appropriate statement in the 'Comments' area. However, if the clinic sees preschool children, encourage the staff to stock varicella and obtain an appropriate freezer, if necessary, to do so. Note this in the 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8

Item 51c Working Thermometer in Central Area of Freezer

There should be a working thermometer in the central area of the freezer. The thermometer may be a standard mercury-type thermometer (scale or dial read) or a digital display thermometer, with or without a probe. If the thermometer has a probe, the probe should be placed in the central area of the freezer, near the vaccine. The thermometer should NOT be sitting directly on ice or ice packs.

If a working thermometer was not found in the central area of the freezer, mark the appropriate button to note that 1) no thermometer was found, 2) a working thermometer was found, but it was not in the central area of the freezer or 3) a thermometer was found, but it was not working properly.

To complete this item, refer to the instructions and Resources for Item #50d – Working Thermometer in Central Area of Refrigerator. Repeat the procedure for the freezer, except for the following difference:

All other aspects of the instructions are the same as #50d – Working Thermometer in Central Area of Refrigerator.

Sources of Information

- (O) Observe for a working thermometer in the central area of the freezer.
- (R) Review resource materials; Check any equipment logs that note testing of thermometer working condition and accuracy.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - There is a working thermometer placed in the central area of the freezer.
- Mark this item "n" if:
  - The freezer does not have a thermometer, even if they have a 24-hour continuous monitoring device.
  - The thermometer is not working or is grossly inaccurate.
  - The thermometer or probe is placed in the door of the freezer.
  - The thermometer or probe is placed against any inside wall of the freezer.

NOTE: IF YOU MARKED THIS ITEM "n": You must take immediate steps to determine vaccine viability and safeguard vaccine supply.

TMF reviewers: See the instructions below for the DSHS notification process.

This MUST be done BEFORE you leave the clinic.

Instructions for Notifying DSHS for Vaccine Storage Problems

- Use the LHD and HSR Immunization Contact List (sleeve #48) to determine the appropriate person to call while you are still at the clinic site. If the city or county health department column is filled in, call that person first**.** If you are unable to speak to this person (or an acceptable substitute) directly, you can leave a voice mail, but it is also essential that you call the person named in the DSHS Regional Contact column. You should speak to this person (or an acceptable substitute) directly. If this is not possible, please call TMF and speak to either your designated TMF Review Coordinator, Sue White, or Geri Bischoff directly. Make sure to note who you spoke with in the 'Other Comments' area.
    - Remember, YOU are responsible for notifying the appropriate contacts regarding refrigeration issues. DO NOT ask the clinic staff or provider to perform this task. You must speak directly to a responsible person at one of these levels before you leave the clinic site, so that the refrigeration issue can be dealt with immediately. Because this is a problem of a critical nature, do not substitute an email after you get home for a phone call from the clinic.
- Mark this item as "na" if:
    - The clinic does not stock varicella or does not have a freezer. Mark the appropriate statement in the 'Comments' area. However, if the clinic sees preschool children, encourage the staff to stock varicella and obtain an appropriate freezer, if necessary, to do so. Note this in the 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
    - Standards for Child and Adolescent Immunization Practices, Standard #8

Item 51d Icepacks in the Freezer

Freezer temperatures should remain as constant as possible to protect vaccine viability. A simple and inexpensive way to help maintain freezer temperatures in the proper range is to keep several icepacks in the freezer. All TVFC providers should keep icepacks in freezers that are shipped with vaccines.

Encourage the clinic to have multiple icepacks (even zip lock bags filled with water) in the freezer. Having the freezer door filled with icepacks will also prevent the door from being used for storage of vaccines, which should be on a shelf in the center of the freezer. Gel packs, such as those the clinic receives with their vaccine shipment, can also be used. If the clinic has multiple vaccine storage units, all units should be checked.

Stress to clinic staff that filling up the freezer door and part of the shelves with multiple ice or gel packs is the idea. Even though the clinic will receive a "y" answer for this item even if they have only one container present, in truth, only one pack is not going to make much difference.

Sources of Information

- (O) Observe at least one icepack has been placed in the freezer to maintain temperature.
- (R) Review resource materials; Examine a written policy or procedure for placement of icepacks in the freezer.

Entry of Results into the Site Survey

- Mark this item "y" if:
    - At least one icepack has been placed in the freezer to maintain temperature. Be sure to check the Comment "Encouraged to place additional icepacks in the freezer" if they only have one in placed.
- Mark this item "n" if:
    - There are no gel- or water-filled icepacks in the freezer.
- Mark this item "na" if:
    - The clinic does not stock varicella or does not have a freezer. Mark the appropriate statement in the 'Comments' area. However, if the clinic sees preschool children, encourage the staff to stock

varicella and obtain an appropriate freezer, if necessary, to do so. Note this in the 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage & Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8
- CDC Vaccine Storage and Handling Toolkit; Chapter 4 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 52 Vaccine Storage and Handling Chart

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

To ensure TVFC providers and their staff are aware of vaccine storage and handling recommendations, each clinic should have a CDC Vaccine Management poster (DSHS poster 6-26P) posted prominently in the vaccine storage area. The most current DSHS version has a revision date of January 2005.

To answer this item, check to see if the clinic has a CDC Vaccine Management poster (DSHS version) displayed in the vaccine storage area(s). The CDC Vaccine Management poster (DSHS version) is in the TVFC Provider Tool Kit Section 3.

- **Hospital Nurseries**: If you are reviewing a hospital nursery that stocks only hepatitis B vaccine and also has only a small storage unit (not large enough to display the entire poster), you may suggest they fold or cut the poster to display only the hepatitis B related recommendations. However, since some nurseries occasionally give other vaccines, you should recommend this only if it is the only feasible solution.

Sources of Information

- (O) Observe; Ask the staff contact where vaccines are stored and observe whether the CDC Vaccine Management poster (DSHS version dated January 2005) is posted prominently in all vaccine storage areas.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic has a CDC Vaccine Management poster (DSHS version dated January 2005) posted in the vaccine storage area(s)
- Mark this item "n" if:
  - The clinic does not have a CDC Vaccine Management poster (DSHS version dated January 2005) posted in the vaccine storage area(s). Assist the clinic staff with ordering of the DSHS poster. Encourage staff to post the most current DSHS poster available while you are at the clinic.

Resources

- TVFC Provider Tool Kit, Section 1: Introduction & Enrollment
- TVFC Provider Tool Kit, Section 2: Vaccine Ordering & Vaccine Accountability
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines & General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8
- CDC Vaccine Storage and Handling Toolkit, Chapter 8, Selected Biologicals; http://www2a.cdc.gov/nip/isd/shtoolkit/content.html
- CDC Vaccine Management Recommendations for Storage and Handling of Selected Biologicals (June 2005) document (http://www.cdc.gov/nip/publications/vac_mgt_book.pdf

Item 53 Refrigerators/Freezers Contain No Food or Beverages

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

Clinics should have a refrigerator/freezer dedicated to vaccine and medicinal storage. This means refrigerators containing vaccines should not contain any food or beverages. Pedialyte is considered medicinal and can be kept with vaccines. Patient specimens and blood-based lab controls may also be kept in vaccine-containing refrigerators, ideally stored below the level of the vaccines. The refrigerator/freezer may have large containers of water/icepacks placed against the walls or in the door racks to help maintain a stable temperature and provide extra cold reserves in the event of a power failure. Note: if the freezer is not used for vaccine storage, it may contain food items.

Sources of Information

- (O) Observe; Check the refrigerator/freezer where vaccines are stored for food or drinks.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - Food and beverages are not stored in vaccine storage units.
- Mark the item "n" if:
  - The clinic is storing food or beverages with vaccines in the refrigerator/freezer. Educate the clinic staff on vaccine storage requirements and help them transfer the unacceptable items to an acceptable location. Note what items were found in the 'Other Comments' area.

The clinic should <u>not</u> get an "n" if storing patient and blood-based lab controls.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage and Handling
- TVFC Provider Tool Kit, Section 4; Immunizations: Guidelines and General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8.
- CDC Vaccine Storage and Handling Toolkit; Chapter 5 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 54a Vaccine Stock Rotation

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

TVFC providers are expected to make every effort to manage their vaccine inventory wisely. To avoid vaccine waste, providers should routinely rotate stock by expiration date and notify the LHD or HSR of short-dated stock not likely to be used so it can be utilized by other providers needing stock (see Item #54b).

To answer this item, inspect the refrigerator stock to ensure the clinic is using short-dated vaccine first. The expiration dates on the stock in the front should be nearer than the expiration dates on the stock in the back. Note that this is a different concept than "first in, first out," which is based on the date when the order was received at the clinic. Even though you may interview staff about vaccine rotation, you should also observe the stock directly to check rotation. If you notice any short-dated or expired vaccine, discuss with the staff handling of expiring or expired vaccine (see Item #54b instructions).

When you review the C-33, note if there is a history of wasting vaccine. Compare this to your results for Item #56, which examines the clinic's maximum recommended stock levels. Use this information and your observations to discuss better vaccine management with the clinic staff.

Sources of Information

- (O) Observe the vaccine stock in the refrigerator for rotation based on expiration date. Observe for short-dated (expiring) and expired vaccines.
- (IS) Interview Staff; sample questions (providers)
  - How do you ensure vaccine stock is rotated by expiration date?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic staff rotates vaccine stock by expiration date.
- Mark this item "n" if:

- The clinic staff report they do not practice or understand the process for rotation of vaccine stock.
- You observe older-dated stock being used before shorter-dated stock.

NOTE: If you mark this item "n," make sure to document any interventions you undertake to handle expiring or expired vaccines.

Resources

- TVFC Provider Tool Kit, Section 2; Vaccine Ordering and Accountability
- TVFC Provider Tool Kit, Section 3; Vaccine Storage and Handling
- TVFC Provider Tool Kit, Section 4; Immunizations: Guidelines and General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8.
- CDC Vaccine Storage and Handling Toolkit; Chapter 9; http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 54b Handling of Expired/Expiring Vaccine

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

Due to federal laws and contract changes, DSHS requires that all unopened, expired, or unused vials of vaccines/toxoids/biologicals be returned. Vaccine manufacturers reimburse Texas for the federal excise tax portion of the cost of the vaccine, and in some cases, for the total cost of the vaccine.

If short-dated vaccines cannot be used before expiration, the provider should notify their LHD and HSR 60 days in advance of expiration, so the vaccine can be moved to another clinic where it can be used. If a TVFC provider does not provide this notification to the LHD or HSR in sufficient time, the provider could be charged for the cost of lost vaccine. A provider should not simply "give" the vaccine to another provider, unless specifically directed to do so after consultation with the LHD or HSR. Transfers should be documented with, the appropriate contact names and amounts on the C-33.

To answer this item, review the clinic's policy and/or standard operating procedures and discuss them with the appropriate clinic staff. If you observe short-dated vaccine, discuss how the clinic intends to handle this. Assist them to notify the LHD or HSR if it is evident they will not be able to use the vaccine before it expires.

City of Houston sites: If the clinic is in the City of Houston (PIN 25- sites), they should fax the loss form to the City of Houston 60 days prior to expiration of the vaccine**.**

Sources of Information

- (O) Observe a staff member performing LHD or HSR notification of expiring stock.
- (R) Review resource materials; If the clinic has returned expired vaccine, review a log or C-33 that documents this process.
- (IS) Interview Staff; sample questions (providers)
  - What policies or procedures does your clinic follow to minimize wastage of expiring or expired vaccine?
  - How do you handle expired or expiring stock?
  - When do you notify and/or return TVFC stock to LHD or HSR?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic staff demonstrates they understand and follow the practice of notifying the LHD, HSR or City of Houston of short-dated vaccine not being used.
- Mark this item "n" if:
  - The clinic shows a history of allowing TVFC vaccines to expire without notifying the LHD or HSR.
  - The clinic staff cannot verbalize the process for notifying the LHD or HSR when expiring vaccines may be unused.
  - The clinic staff report lending or transferring short-dated vaccines to other providers without consulting and explicit directions from a LHDor HSR representative.

NOTE: If you mark this item "n," make sure to document any interventions you undertake to handle expiring or expired vaccines.

Resources

- TVFC Provider Tool Kit, Section 2; Vaccine Ordering and Accountability
- TVFC Provider Tool Kit, Section 3; Vaccine Storage and Handling
- TVFC Provider Tool Kit, Section 4; Immunizations: Guidelines and General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8**.**
- CDC Vaccine Storage and Handling Toolkit; Chapter 9 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 55 Monthly Vaccine Inventory

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

All TVFC providers are required to submit C-33 to DSHS. Each monthly report includes vaccine doses reported as received, administered, wasted, returned, and transferred. In addition, a physical count of the "ending inventory" should be performed. Any discrepancy between the physical count and the recorded count should be noted on the C-33. To ensure these reports are completed and counts are consistently performed, it is recommended a designated staff member be assigned to monitor vaccine inventory.

To complete this item, the clinic should supply you with copies of the C-33s for the past 12 months, or, if reporting for less than 12 months, from the point the clinic became a TVFC provider**.** Keep these copies for submission with your site survey report. Be sure you are not taking the clinic's original C-33.

Review the reports to see if all months are included, and if each report is complete. If possible, interview the staff member responsible for completing these reports. Ask about how the physical inventory is checked and documented on the report. You DO NOT need to actually inventory the stock yourself in order to see if the report is accurate. Because you will be examining the accuracy of inventory accounting on the C-33 for Item #57, you may find obvious errors that have been transcribed over a number of months. This indicates physical counts are probably not being done on a regular basis. If this occurs, you should suggest the staff perform monthly inventories. Also, because the reports demonstrate a lack of accounting, you would answer this item "n".

If a physical inventory is not performed monthly, mark the appropriate button related to how often an inventory is performed (never, more frequently than monthly, at least quarterly, before the order is placed).

If the site is a school, and a monthly physical inventory is conducted when vaccine is stocked at school answer "yes", and mark 'School' under 'Comments' area.

Questions about ordering the combination vaccines (e.g., Pediarix , MMRV and Comvax), or decreasing ordering of single vaccines because of these vaccines, should be referred to the LHD or HSR contact. (See sleeve #48).

Sources of Information

- (R) Review resource materials; Obtain and examine copies of the past 12 months of C-33s.
- (IS) Interview Staff; sample questions (providers)
  - What is your process for completing the C-33 and submitting them?
  - How do you train staff to document items on the C-33? How do you check this documentation against the actual inventory?
  - How often do you perform a physical count of the vaccines and check it against the recorded inventory? What do you do when it doesn't match?

Entry of Results into the Site Survey

- Mark the item "y" if:
  - The staff reports they perform a monthly physical inventory, AND the clinic has a complete set of C-33s for the past 12 months or for the period since TVFC enrollment AND the reports appear to be complete and accurate.
  - A physical inventory is performed more frequently than monthly.

  - The site is a school, and a monthly physical inventory is conducted when vaccine is stocked at school. Mark "School" in the 'Comments' area.

- Mark this item "n" if:
  - The clinic is missing any C-33 or does not supply any for review.
  - The C-33 are obviously incomplete or inaccurate. This might be evidenced by the results of the gain/loss Calculations Table results.
  - The staff does not perform any actual physical inventory counts, or performs them less frequently than monthly.
- If the item statement is answered as "no", mark the box in the item column that indicates when the physical inventory is performed.
- Mark this item "na" if:
  - No vaccines are stored

Resources

- TVFC Provider Tool Kit, Section 1: Introduction and Enrollment
- TVFC Provider Tool Kit; Section 2: Vaccine Ordering and Accountability
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines and General Recommendations
  - Standards for Child and Adolescent Immunization Practices, Standard #8.
- CDC Vaccine Storage and Handling Toolkit; Chapter 9 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 56 Appropriate Stock Levels Maintained

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling

Clinics should strive to maintain appropriate stock levels of vaccines so that the clinic:

- Has enough of each vaccine to provide to children in a timely manner.
- Does not have more vaccine than it can use before the vaccine expires.
- Minimizes potential for vaccine loss in case of power failure.

Clinics can manage their vaccine stock more efficiently by actively monitoring and maintaining stock levels of vaccines based on actual usage. To help a clinic determine what their appropriate stock level should be, a recommended 60-day stock level can be calculated using the past usage data from the C-33.

To answer this item, first calculate the recommended 60-day stock level for each of the TVFC vaccines the clinic stocks **(**Refer to "Calculating the Recommended 60-Day Stock Level" in the 'Gain/Loss' section of this Manual):

- Enter the calculated recommended stock level, per vaccine, in the fields under "Doses Recommended".
- The number for the "Doses on Hand Previous Month" field is automatically populated from the Gain/Loss Calculation Table (Doses On Hand At End of Month).
- The recommended stock levels should be compared with the actual doses kept to get an idea of how well the clinic manages stock levels.

The results from calculating the 60-day stock levels are compared against the current stock being kept by the clinic. Based on this, the reviewer should determine whether the clinic is keeping appropriate levels of vaccines. Keep in mind that vaccine use may be seasonal (e.g., higher volumes are typically used from July through September). Also consider whether the clinic population has changed.

If the current inventory (# doses) for most of the vaccines is reasonably close to the recommended 60-day stock level for each, mark this item as "y". If there is a significant difference (>2-3x greater/lesser) between the amount on hand and recommended stock levels for at least 3 vaccines, mark this statement as "n". When comparing actual and recommended stock levels, use your best judgment and common sense, consider whether the vaccine doses are kept in multi-dose or single dose vials.

For example, if the clinic orders a vaccine supplied in 10 dose vials, but the average 60-day level is 3 doses, there will obviously be a significant overage the clinic can't avoid. What is significant is when a recommended level is 30 doses and the clinic has 100 doses on hand.

Also consider that if the current stock level is higher than the recommended level for a vaccine, take the clinic's CoCASA rate into perspective. If the immunization rates are low and you are recommending ways that they can increase rates, then you might not want to recommend they decrease stock levels. Instead, focus on watching expiration dates (rather than return stock). The 'Corrective Action' area includes a corrective action statement to this effect.

There are several reasons you could mark this item "n"; be sure to explain your answer either by marking a corrective action statement(s), or providing an explanation by documenting in the 'Other Comments' area. Note whether the problem is an overage (too much) or underage (too little) or both.

If the clinic has had any problems with vaccine delivery, encourage them to contact their LHD or HSR immunization contact.

Some clinics may be using the Pharmacy Inventory Control System (PICS). The primary purpose of PICS is to provide the state with "real-time" inventories, apply minimum and maximum stock levels for each antigen, automate vaccine orders, improve vaccine administrative data, inventory control and recall/quarantine measures, and reduce emergency orders. PICS uses minimum/maximum levels. The PICS roll-out schedule for private providers begins with a pilot process in region 07 in 2007, and is to gradually roll-out to the remainder of the state through 2008. The roll-out schedule is always subject to revision. If a clinic is using PICS, mark the answer as "na", and mark the appropriate comment in the 'Comments' area.

Sources of Information

- (O) Observe stock on hand.
- (R) Review resource materials; Examine any policies or procedures the clinic uses to calculate inventory orders or stock levels. Does the clinic use the maximum 60-day stock levels already?
- (R) Examine the C-33s to assess what vaccines are stocked, and the relative numbers of vaccines stocked and administered.
- (IS) Interview Staff; sample questions (providers)
    - How does your clinic determine how much vaccine to order and keep on hand?
    - What seasonal variations do you account for when ordering vaccines? Are the past month's levels indicative of your typical stock levels at this time of year?
    - Has your clinic had any difficulty managing stock levels? If so, why?
    - Is your clinic using the PICS to account for vaccine doses?

Entry of Results into the Site Survey

- Mark this item "y" if:
    - The clinic's most recent stock levels are reasonably consistent with the 60-day stock level recommendations.
- Mark this item "n" if:
    - If there is a significant difference (>2-3x greater/lesser) between the amount on hand and recommended stock levels for at least 3 vaccines, even considering seasonal fluctuations.
- Mark this item "na" if:
    - The clinic does not have any C-33s on hand. Originals have been sent to DSHS or cannot find the records. Since this has been addressed in Item #55, write "See #55" in the 'Other Comments' area. Remind the staff that TVFC providers are required to keep copies of C-33s for at least 1 year.
    - The clinic is using PICS; checkmark the appropriate comment in the 'Comments' area.

Resources

- Refer to the "Calculating the Gain/Loss and Maximum 60-Day Stock Levels" in the 'Gain/Loss' section in this Manual.
- TVFC Provider Tool Kit, Section 2: Vaccine Ordering and Accountability

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines and General Recommendations
    - Standards For Child and Adolescent Immunization Practices, Standard #8
- CDC Vaccine Storage and Handling Toolkit; Chapter 9 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 57 Vaccine Gain or Loss

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

Understanding the Site Survey Approach to Vaccine Gain or Loss

When TVFC providers submit C-33 to DSHS, these reports should be complete and accurate. This vaccine gain/loss indicator addresses how accurately the clinic accounts for vaccine doses. When there is a discrepancy between the calculations on paper and the actual ending inventory, then a "gain" or "loss" occurs. A clinic **with reasonable accounting practices should have an overall percent gain or loss less than 5%. Any gain or loss above 5% may signal problems with vaccine documentation, calculation or monitoring.**

The key to approaching this item is to understand you are evaluating the clinic's vaccine dose accounting practices, not their vaccine management practices. In other words, "vaccine losses" are number losses due to poor documentation or calculation errors, e.g., these are not vaccines "lost" due to waste or expiration. As long as the number of vaccine doses received, administered, wasted, returned, etc. all add up correctly to match ending inventories, there should be no gains or losses recorded.

To perform the gain/loss calculations, refer to the "Instructions for Completing the Gain/Loss Calculation Table" in the 'Gain/Loss' section of this manual.

Examine the "% gain" and "% loss" results from the Gain/Loss Calculation Table. These results are automatically linked to this item on the site survey. Based on these results, mark this item "y" if the gain or loss is less than 5% or mark this item "n" if it is greater than 5%.

Advise the clinic if the gain/loss results are high, and if you noticed any errors, omissions or discrepancies observed on the C-33. Educate the clinic staff as indicated on improving their inventory and vaccine accounting practices, and encourage them to perform physical counts on a regular basis.

Sources of Information

- (R) Review resource materials; Examine the C-33 to complete the Vaccine Gain/Loss Calculation Table and Gain/Loss form.
- (IS) Interview Staff; sample questions (providers)
    - Who is responsible for maintaining and checking the accuracy of the C-33?
    - What process do you have to verify the accuracy of the reports?
    - Has your clinic had any difficulty keeping track of vaccine doses or reconciling the inventory sheets? If so, why?

Entry of Results into the Site Survey

The results of the Gain/Loss Calculation Table are automatically linked to fill in the boxes labeled "Overall gain (%)" and "Overall loss (%)" in the far left column of Item on #57 of the Site Survey. Use the pull-down list to select the number of months that you used to calculate these values. If you were not able to use 12 months of data due to one or more missing C-33s, note the actual months used, e.g., November 2006 – May 2007 in the 'Other Comments' area and explain why some reports were missing.

- Mark this item "y" if :
    - Both the gain and loss results are each less than 5%.
- Mark this item "n" if:
    - Either the gain or loss is equal to or greater than 5%. If you found an obvious error or errors leading to the excessive gain/loss, then note this in the 'Other Comments' area.
- Mark this item "na" if:
    - Only one, or no C-33 is available.

- The clinic is using PICS, s*ee item 56 for more information*; checkmark the appropriate comment in the 'Comments' area.

Resources

- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines and General Recommendations
  - Standards of Child and Adolescent Immunization Practices, Standard #8

Item 58 Vaccine Management Protocol for Power Failure

NVAC Standards for Child and Adolescent Immunization Practices #8: Health care professionals follow appropriate procedures for vaccine storage and handling.

Each clinic should have a written plan for vaccine storage to minimize vaccine losses in case of a power failure. This should include, at a minimum:

- The names and phone numbers of people who should be contacted.
- The plan for movement of vaccine to a proper storage facility (in case of outage).
- The specific location where the vaccine will be stored. This should be a location with a generator, e.g., a hospital, pharmacy or grocery store.

TVFC providers may be required to reimburse the state for vaccine losses that occur from improper transportation of vaccine (not on ice or dry ice) or for improper maintenance of recommended refrigerator and freezer temperatures.

To answer this item, check to see if the clinic has a written vaccine contingency plan. This plan should be accessible to appropriate staff members. If the clinic does not have a written plan, encourage them to develop one. Offer the staff a copy of the Vaccine Storage Contingency Plan, as an example that they can customize for their circumstances.

Sources of Information

- (R) Review resource materials; Check to see if the clinic has a written vaccine contingency management plan.
- (IS) Interview Staff; sample questions (providers)
  - What would you do with your vaccine in the event of a power failure?
  - What does your vaccine contingency plan include?
  - Who is responsible for the plan, and how is it communicated to all employees?

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The clinic has a written vaccine contingency plan that is communicated to appropriate staff members.
- Mark this item "n" if:
  - The clinic does not have a written vaccine contingency plan. In this case, make the provider and staff aware they could be liable for lost vaccine, and encourage them to develop a written plan.

NOTE: Always encourage the clinic to develop a written plan that can be posted prominently on the refrigerator. Offer a copy of the Protocol for Vaccine Storage Contingency Plan (sleeve #58) to use and document this intervention in the 'Other Comments' area.

Resources

- TVFC Provider Tool Kit, Section 3: Vaccine Storage and Handling
- TVFC Provider Tool Kit, Section 4: Immunizations: Guidelines and General Recommendations
  - Standards of Child and Adolescent Immunization Practices; Standard #8.
- CDC Vaccine Storage and Handling Toolkit; Chapter 2 http://www2a.cdc.gov/nip/isd/shtoolkit/content.html

Item 59 TVFC Vaccines Distinguished from Private Vaccines

TVFC vaccines should be distinguishable from private vaccines, since TVFC vaccine is ordered and inventoried separately.

To complete this item, ask the staff contact to describe how TVFC vaccine is distinguished from private vaccine, and visually inspect the vaccine stock to see if this is clearly evident. Methods to separate public vaccines and private vaccines include:

- Keeping the vaccines on separate shelves in the refrigerator/freezer or separate units in the refrigerator/freezer.
- Keeping the vaccines on separate sides of the same shelf.
- Marking the boxes of the public vaccine in some way, e.g., with a colored sticker.

As long as the system for separating the two sources of vaccine is consistent and observable, mark this item "y". If you are reviewing a hospital nursery and they do not carry any private vaccine, ask how they have determined their population is 100% TVFC. If they cannot show some form of eligibility screening, note this in Item #61a. In addition, encourage them to begin screening and consider carrying private vaccine for patients not eligible to receive TVFC vaccine.

Sources of Information

- (O) Visually check that the TVFC vaccine is distinguished from private vaccine.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - The TVFC vaccines can be distinguished from private vaccines.
- Mark this item "n" if:
  - The TVFC vaccines cannot be distinguished from private vaccines.
- Mark this item "na" if:
  - There is no private vaccine carried (100% TVFC clinic). Mark the appropriate box in the 'Comments' area.

Item 60 Current Enrollment and Profile Forms

Current enrollment and profile forms for each TVFC provider under this agency are maintained

Reference Provider Enrollment and Profile Forms. Current enrollment and profile forms should be updated annually.

Sources of Information

- (R) Review resource materials; Examine TVFC Provider Enrollment Form.

Entry of Results into the Site Survey

- Mark this item "y" if:
  - All TVFC Provider Enrollment Forms are current.
- Mark this item "n" if:
  - Not all TVFC Provider Enrollment Forms are current (older than 15 months).
- Mark this item "na" if
  - This agency is not responsible for any TVFC providers.

Resources

- TVFC Provider Tool Kit, Section 1:
  - Enrollment Packet
- TVFC Operations Manual

Item 61a TVFC Eligibility Screening

All clients are screened for eligibility.

All TVFC providers should screen all children for TVFC eligibility, regardless of past history or coverage.

To answer this item, utilize the data from indicator #8 and #9 on the IRRT. These fields from the IRRT are automatically linked to the corresponding fields for this question and you will not have to enter this data. If for some reason the numbers are not populated, just click on the "refresh" button. For specific instructions on completing the IRRT, refer to the "Completing the IRRT" section in this Manual.

Screening for eligibility -Indicator #8 on the IRRT addresses whether the provider is actively screening children for TVFC eligibility.

- 100% should have evidence of screening ("y" answers) to receive a "y" for this item.
- Since typically only TVFC-eligible records will be used for completing the IRRT, this item will often be marked as "y" with a 100% screening rate.
- Note that clinics are not required to use the TVFC eligibility screening form. However, they must be able to verbalize their screening method and show you evidence in the medical record of a screening process.
- Children who are on Medicaid and the Children Health Insurance Plan (CHIP) program are automatically eligible for TVFC and do not need a completed TVFC Patient Eligibility Screening Record in their medical record.
- Special note: School-based clinics must conduct TVFC Eligibility Screening. However, they may vaccinate all children, regardless of their eligibility.

- **Eligibility category** – Indicator #9 on IRRT addresses the category of TVFC eligibility (see table below).
  - NOTE regarding residents of a state youth facility or detainees in a juvenile detention center: Even if the court system has declared the child an adult, he or she is eligible for TVFC vaccines based on age (through age 18).

Eligibility Category Number & Name		Eligibility Types Included	Acceptable Documentation
1	**Medicaid/CHIP**	Medicaid, Texas Health Steps, CHIP, Star program or other local indigent health program	Enrollment in Medicaid, CHIP or other program documented somewhere in the medical record (generally billing/ Medicaid enroll forms). **TVFC eligibility form NOT required if proof of Medicaid, etc.
2	**Uninsured**	No insurance coverage and no indication of other enrollment in HMO, health plan, etc.	TVFC eligibility form or comparable eligibility form or documentation (ask staff).
3	**Native American/ Alaskan Native**	Self-proclaimed classification of Native American or Alaskan Native	TVFC eligibility form or comparable eligibility form or documentation (ask staff).
4	**Under-insured**	"Underinsured" = parents cannot afford to pay for immunization because insurance co-pay, deductible or lack of coverage for immunizations.	TVFC eligibility form or comparable eligibility form that serves for TVFC screening – or – written statement/ documentation that child is underinsured (cannot afford vaccines).
5	**Not TVFC-eligible**	Insurance covers immunizations and/ or parent reports coverage adequate. **If eligibility is unclear, place child in this category.	TVFC eligibility form or proof of insurance – generally in billing/ insurance section.

Documentation that demonstrates the child is not eligible (e.g., has private insurance) is still considered a determination of eligibility. If the child has Medicaid and also has insurance that covers immunizations, Medicaid is always used first, so mark the eligibility as category #1.

Sources of information

- (O) Observe the process for screening for TVFC eligibility.
- (IS) Interview Staff; sample question (provider)
  - How are you screening for TVFC eligibility?

Entry of Results into the Site Survey

- The "Number of Records By Category", is automatically populated based on the IRRT indicator #9 results.
- Mark this item "y" if:
  - The screening rate is 100%.
- Mark this item "n" if:
  - The screening rate is less than 100%. Find out why the clinic is not screening all clients for eligibility, or at least not documenting it.
  - If the provider doesn't carry private vaccine and you find out by talking to staff that they are using TVFC vaccines for all children and are not screening for TVFC eligibility.

Resources

- TVFC Provider Tool Kit, Section 1: Introduction and Enrollment

61b TVFC Eligibility Screening

The clinic/practice screens for eligibility at every encounter.

All TVFC providers should screen for TVFC eligibility at every encounter, regardless of past history or coverage. This is legislated in the Omnibus Budget Reconciliation Act (OBRA) which established the VFC Program. Appropriate sections of the legislation are printed in Appendix 1 of the VFC Progam Operations Guide, and state that "before administering a qualified pediatric vaccine to a child, the provider will ask the parent of the child such questions as are necessary to determine whether the child is a federally vaccine-eligible child…"

Sources of information

- (O) Observe the process of screening for TVFC eligibility
- (R) Review resource materials; Examine the patient record for evidence of eligibility screening
- (IS) Interview Staff; sample question (provider)
  - How are you screening for TVFC eligibility?
  - Are you screening for TVFC eligibility at every encounter?

Entry of Results into the Site Survey

- Mark this item "y" if:
- The clinic staff states they screen for TVFC eligibility at every encounter.
- Mark this item "na" if:
  - The provider is a youth correctional facility. Check the 'Youth correctional facility' box in the Comments section.
- Mark this item "n" if:
  - The clinic staff states they are not screening for TVFC eligibility at every encounter.
  - Screening is not performed at every encounter, checkmark the appropriate box 1) Sreened at initial visit only, 2) Does not screen for eligibility, or 3) Other (requires comment in the 'Other Comments' area)

Resources

- TVFC Provider Tool Kit, Section 1: Introduction and Enrollment

General Comments About The TVFC Site Visit

The open space at the end of the report ("**Overall Review Comments**") can be used to make general comments about the clinic and the site visit that should be shared with everyone who reviews the report.

Examples of what might be important to write here include:

- Positive comments about the site visit

- Cooperation from the staff
- Interest of the staff in complying with the TVFC requirements
- General comments about the organization of clinic functions

- The name, title and organization of anyone who accompanied you on this site visit
- Any other problems or issues that might explain the clinic's performance, not directly applicable to one item
  - New TVFC provider
  - High education needs of clinic staff (high turnover, new TVFC contact, few resources, etc.)
  - Extenuating circumstances or major changes in clinic operations (change of leadership/MDs, new location, recent emergencies or catastrophes, etc.)