

WOMEN'S INTERAGENCY HIV STUDY

SECTION 35: VACCINATION CARD PROTOCOL

A. STUDY PURPOSE

The purpose of the WIHS Vaccination Card Protocol is to improve the accuracy of self-reported vaccination since last visit for all of the vaccinations inquired about in Form 22 MED.

B. RESEARCH GOALS

Hypothesis 1: The accuracy of reported vaccination will improve with the assistance of the vaccination card as compared to self-report alone.

Specific aim 1.1: The accuracy of the reported *type* of vaccination will improve with the assistance of the vaccination card as compared to self-report alone.

Specific aim 1.2: The accuracy of the reported *date* of vaccination will improve with the assistance of the vaccination card as compared to self-report alone.

Hypothesis 2: Influenza vaccinations will be more frequently obtained in non-healthcare settings as compared to healthcare settings.

C. BACKGROUND

Little is known about indicators of vaccination in HIV-infected women. Using vaccination cards to improve the accuracy of self-reported vaccination is important to identifying predictors of vaccination.

D. PARTICIPANT ELIGIBILITY

All WIHS participants will receive a vaccination card and instructions on its use.

E. OVERVIEW OF DISTRIBUTION

Wallet-sized vaccination cards (printed on pink cardstock) will be distributed to all sites that perform WIHS core visits. The cards will need to be folded like a letter in a business envelope before distribution to WIHS participants (i.e., folding the bottom 1/3 of the card towards the top of the card; folding the top 1/3 of the card towards the bottom of the card). Once folded, the card will be the size of a credit card.

Sites should attempt to distribute the vaccination cards to all WIHS participants before the 2006 influenza season. They can be distributed via U.S. mail, or in-person at a core or substudy (e.g., Cardiovascular, Metabolic, etc.) visit. WDMAC suggests the following methods for distribution:

- If a participant had her WIHS core visit during October 2006 (prior to distribution of the cards to sites) and is not scheduled to return to the clinic for a substudy visit, please mail a vaccination card and instructions to the participant, if a mailing address is available.
- If a participant is scheduled to have a WIHS visit (core or substudy) during November 2006, please distribute a vaccination card and instructions during this visit.
- If a participant is scheduled for a visit between December 2006 and March 2007, it is preferable if a vaccination card and instructions are mailed to the participant, if a mailing address is available. However, if a participant cannot be reached via U.S. mail, she should receive a vaccination card at her earliest clinic visit (either core or substudy) during the visit 25 window.

During WIHS visits 25 and 26, **all** participants should be asked if they received a vaccination card and given a card if they have not yet received one.

A brief, written explanation of the use of the vaccination card will be distributed to participants with the vaccination card. The participant is asked to keep the card in a convenient, secure place, such as a pocketbook. If a participant receives a vaccination, she should be instructed to ask the health care professional administering the vaccination to complete the necessary information on the vaccination card. The participant is reminded all vaccinations should be recorded, even vaccinations not administered in a healthcare setting (such as receiving a flu shot in a grocery store or superstore). If a participant loses or damages her card, a replacement card can be provided, as all sites will receive extra vaccination cards. The participants are asked to write their name and the date the card was given to them in the indicated boxes on the card. A WIHS staff member may also write the participant's name and the date the card was given to the participant on the card if the WIHS staff member distributes the card during a WIHS visit.

F. DATA COLLECTION

The Vaccination History (VAC) form is a data collection instrument that will be used to capture information from completed vaccination cards so that these data can be entered into APOLLO. The format of the form was designed to parallel that of the vaccination card, although the VAC form includes one additional vaccine, *Twinrix*, which is a combination of the Hepatitis A and B vaccinations. If a participant reports having received a *Twinrix* vaccination in the Hepatitis A or B sections of the vaccination card, only *Twinrix* (question B1) should be filled in on the VAC form – not the separate Hepatitis A (question B2) and B (question B3) sections, unless she also received individual Hepatitis A and/or B vaccinations.

The VAC form can be filled out by a clinician, interviewer or site coordinator, either during or after completion of the interview. If done while the participant is present, the person completing the VAC form can just copy the information from the actual vaccination card to the VAC form, and then return the vaccination card to the participant when done. If the form will be completed after the interview has concluded, there are different options for collecting the data from the vaccination card. The person completing the form can scan or make a photocopy of the vaccination card at the time of the interview, give the original vaccination card back to the participant, and then complete the VAC form at a later time using the photocopy. Another option is to collect and keep the completed vaccination card and give the participant a new card to bring in at her next visit. Sites that do not wish to collect the participant's original vaccination card and do not have access to a photocopier may use a small scanner, such as a mobile or business card scanner (available at Office Depot, CompUSA, etc.), to copy the card. Scans, photocopies and/or original vaccination cards (if kept by the site) should be stored in the participant's chart.

Starting at visit 26, the data recorded on the VAC form for the current visit should be compared to that from the participant's previous visit. Care should be taken to ensure that information appearing on the previous visit's VAC form is not re-recorded during the present visit.

After completion, the VAC form should be entered into APOLLO.

APPENDIX A: INSTRUCTIONS TO PARTICIPANT

Dear WIHS participant:

To help make reporting vaccinations easier, we have created a vaccination card for your use. It should fit in your pocketbook and we encourage you to keep it with you. When you receive a vaccination, we ask you give the card to the health care provider administering the vaccine and ask them to fill out the information requested on the card. We ask that you do this even if you get a vaccination in a non-healthcare setting, such as getting an influenza vaccination in a supermarket or a pharmacy.

Please write your name and the date you received this card clearly in the indicated boxes on the card. There is no information linking you to the WIHS study is on this card.

Please bring this card with you to all future WIHS study visits. If you lose the card, we will be able to give you another one, but we ask that you keep it in a safe and convenient place.

Thank you!

APPENDIX B: VACCINATION CARD

	Type	Date given mm/dd/yy	Location administered	Date next dose due
Hepatitis A Type: Hep A				
Hepatitis B Type: Hep B				
Hep A-Hep B combination vaccines should always be documented under each antigen				
HPV Type: Bi-valent Quadra-valent				
Varicella Type: Var				
Pneumococcal Type: PPV				
Tetanus Types: Td, Tdap				
Influenza Types: TIV (inactivated) LAIV (live, attenuated)				
Other				

First name	Last name						
<p>Always carry this card with you. If you receive a vaccination, ask the healthcare professional giving you the vaccination to record the vaccination in this card.</p> <p align="center">Adult Immunization Record</p>							
<p align="center">This card was given to you on the following date:</p> <table border="1" style="margin: auto;"> <tr> <td style="width: 30px; height: 30px;"></td> <td style="width: 30px; height: 30px;"></td> <td style="width: 30px; height: 30px;"></td> </tr> <tr> <td align="center">month</td> <td align="center">day</td> <td align="center">year</td> </tr> </table> <p align="center">Thank you for your participation!</p>					month	day	year
month	day	year					
<p align="center">Dear Health Care Professional,</p> <p>Please complete one line on this immunization record for each vaccination you administer. The abbreviations for the available types of vaccinations are noted below the vaccine-preventable disease. Please write legibly.</p> <p align="center">Thank you.</p>							