NATIONAL PBM BULLETIN

OCTOBER 19, 2009

**VETERANS HEALTH ADMINISTRATION (VHA) PHARMACY BENEFITS MANAGEMENT SERVICES (PBM),
MEDICAL ADVISORY PANEL (MAP), CENTER FOR MEDICATION SAFETY (VA MEDSAFE),
& OFFICE OF PUBLIC HEALTH STRATEGIC HEALTHCARE GROUP**

INFLUENZA VACCINE ADVERSE EVENT REPORTING

I. ISSUE

VA has strengthened efforts to actively monitor safety associated with influenza immunization administration through provider- and patient-reported adverse drug events (ADE) entered into two spontaneous ADE systems currently active in the VA:

- the Allergy/Adverse Reaction Tracking (ARTS) Package, which is part of the VA electronic medical record and houses all allergies and adverse drug reactions entered into CPRS by providers; and
- the VA Adverse Drug Event Reporting System (VA ADERS), a web-based spontaneous adverse drug event reporting system within the VA.

II. BACKGROUND

Recipients of influenza vaccinations may experience possible side effects. Adverse events related to the live attenuated influenza vaccine most commonly consist of nasal congestion, headache, myalgias, and fever.   Adverse events most commonly reported with the inactivated influenza vaccine include local injection site reactions such as soreness and redness. Fever and malaise have ensued as well, but with less frequency.[1] The relationship between influenza vaccination and Guillian-Barré Syndrome (GBS) remains unclear; past studies have suggested an association.[1] The Centers for Disease Control and Prevention (CDC) reports the following as risks for developing GBS:

- approximately 1-2 cases per 1 million recipients for seasonal influenza vaccine[2];
- approximately 1 per 100,000 recipients of the 1976 swine influenza vaccine.[2]
- approximately 1 per 100,000 annually for the general public regardless of receiving an influenza vaccination .[2, 3]

As newer influenza vaccines become available, adequate reporting and tracking of observed adverse events can help to characterize the safety profile and elucidate potential side effects associated with the use and administration of recently approved vaccines. For complete and appropriate vaccine surveillance, VA is encouraging that ALL providers report ANY adverse event (regardless of severity) seen with influenza vaccinations to the ARTS system, VA ADERS, and the Vaccine Adverse Event Reporting System (VAERS[4,5], which is the national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA).

III. PROVIDER RECOMMENDATIONS

FOR PROVIDERS WHO REGULARLY ENTER ADE INFORMATION INTO THE ARTS SYSTEM:

- Right click on the "Allergies/Adverse Reactions" box at the top middle section of the Cover Sheet in CPRS.
- Select 'Enter new allergy' to create a reactant record.
- Enter 3 to 5 letters of the vaccination product name (e.g., "INFLU") and click on SEARCH.
- Select an agent by left clicking on it. When the term has been selected, click on 'OK'.
- Signs/Symptoms are recorded by making a selection from the list on the Template. More than one can be selected. If appropriate, enter a comment.
- Please make sure when reporting a newly noted adverse reaction to click "Observed" (unless you are reporting an old influenza vaccine adverse event [e.g. from prior years] in which case choose "Historical"); also choose a severity level (mild, moderate, severe).
- When finished, click on 'OK' and the record will become active.
- Once active, the adverse reaction may be found on the 'Cover Sheet' under Allergies/Adverse Reactions; clicking on the drug name provides further information.
- An overview of how to enter an adverse drug event into the ARTS package is available at: http://www.pbm.va.gov/VACenterForMedicationSafety-AdverseEventTrackingTools.aspx under "DEFINITIONS AND FREQUENTLY ASKED QUESTIONS ON ENTERING ADEs IN VA CPRS" in a link entitled "HOW TO ENTER AN ALLERGY OR ADVERSE DRUG EVENT".

FOR CLINICIANS WITH ACCESS TO VA ADERS WHO REGULARLY ENTER ADE INFORMATION INTO THIS SYSTEM:

- All healthcare personnel who administer the influenza vaccine should document any associated adverse reactions (regardless of severity) as a VA report to VA ADERS at https://medora.va.gov/adr.
- Select your VISN and facility from the available drop-down list and log into VA ADERS using your CPRS Access and Verify Codes.
- Click onto the "ENTER NEW REPORT" tab on the left-hand side of the page.
- Select patient(s) in the same manner as you would within CPRS, either by name or social security number.
- When asked if this report will be sent to MedWatch, click "No". *[A dual report needs to be completed and submitted to VAERS[4,5].]*
- Enter Reporter Information in appropriate section of VA ADERS as directed.
- Enter Patient Information in appropriate section of VA ADERS as directed.
- Enter Suspect Agent in appropriate section of VA ADERS as directed. When a vaccine is selected as the suspect agent, a Med Alert Box will appear providing an external link for VAERS (http://www.cdc.gov/vaccinesafety/vaers/)[4,5] so that the clinician can create a separate report. [This can be done during the time that the event is entered into VA ADERS, or after completion of the VA ADERS report. VA ADERS and VAERS are not currently linked, so dual reporting is necessary to submit adverse event information with respect to vaccine use to VAERS at this time.]
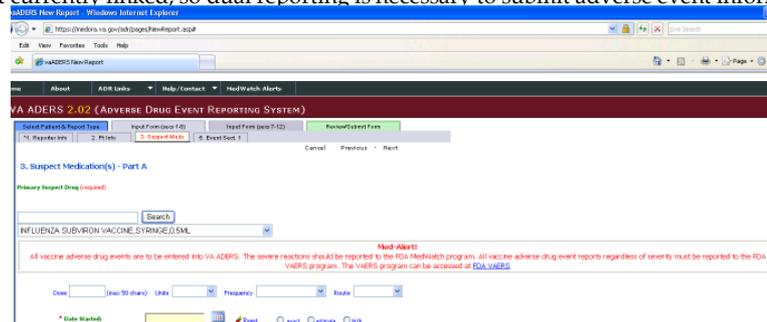
- Enter Adverse Event Information in appropriate section of VA ADERS as directed. If symptoms do not appear on lists provided, click "Other" and enter a description of up to 255 characters.
- Complete Sections 7-12 of VA ADERS as directed and submit report by clicking on the "SAVE" button.
- Use external link provided in Med Alert Box to access VAERS[4,5] and enter requested information regarding vaccine-related adverse event.
- VA ADERS staff will monitor vaccine-related submissions on a daily basis and will contact the reporter to verify that the VA ADERS report was also submitted to VAERS[4,5].
- An overview of VA ADERS and how to enter an adverse drug event is available at: https://medora.va.gov/vaaders/MedSafe_portal/training.asp .

FOR VA EMPLOYEE INFLUENZA VACCINATIONS ADMINISTERED BY EMPLOYEE HEALTH:

- Enter adverse event information in appropriate section(s) of the Occupational Health Record Keeping System (OHRS).
- Visit http://www.cdc.gov/vaccinesafety/vaers/ and enter requested information regarding vaccine-related adverse event into VAERS (FDA and CDC vaccine surveillance).
- A third entry for VA ADERS is not required.

IV. REFERENCES

1. Fiore AE, Bridges CB, Cox NJ. *Seasonal influenza vaccines*. Curr Top Microbiol Immunol. 2009; 333:43-82.
2. http://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm . Accessed October 16, 2009.
3. Ropper AH. The Guillain-Barre syndrome. N Engl J Med 1992; 326:1130–6.
4. http://www.cdc.gov/vaccinesafety/vaers/ . Accessed October 12, 2009.
5. http://www.cdc.gov/H1N1flu/vaccination/statelocal/letter_template_HCP.htm . Accessed October 8, 2009.

ACTIONS:

- **Facility Director** *(or physician designee): Report completion of actions to the VISN Director.*
- **Facility COS and Chief Nurse Executives:** *Forward this document to all appropriate providers who prescribe/use/handle this agent (e.g., **primary care providers, nursing staff, and pharmacy**, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.*
- **ACOS for R&D:** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*
- **VISN Directors:** *Within 10 business days of receipt (due 11/2/2009), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*