Updates from CDC’s Immunization Safety Office (CDC-ISO): What Public Health Officials and Healthcare Providers Need to Know
Maria Cano, Theresa Harrington

Summary of Topic:
The CDC’s Immunization Safety Office (CDC-ISO) in collaboration with partners, conducts post-licensure vaccine safety monitoring for U.S.-licensed vaccines. During this session, we will provide updates on CDC-ISO activities focusing on Vaccine Adverse Event Reporting System (VAERS) and Clinical Immunization Safety Assessment (CISA) Project activities and CDC-ISO inquiry response functions.

Description of Session:
Title: Updates from CDC’s Immunization Safety Office (CDC-ISO): What Public Health Officials and Healthcare Providers Need to Know

The session will focus on updates about CDC-ISO VAERS activities. We will also describe two ISO service functions: the vaccine safety inquiry response program and the Clinical Immunization Safety Assessment (CISA) Project clinical consultation service.

VAERS is a national spontaneous reporting system co-managed by CDC and the Food and Drug Administration (FDA) for monitoring the safety of U.S.-licensed vaccines. On June 30, 2017, CDC and FDA implemented a new VAERS reporting form and a new process for submitting reports to VAERS. Members of the public wanting to report adverse events to VAERS can now submit reports directly using the VAERS 2.0 online reporting tool or they can download and complete the writable and savable VAERS 2.0 form and submit it using an electronic document upload feature. The VAERS 2.0 form has new data elements, such as pregnancy status, race and ethnicity. Prior to VAERS 2.0, adverse event reports were submitted using a paper reporting form or through a legacy online reporting process. Upgrades to the VAERS website were completed in the first half of 2017 to allow the new options for VAERS 2.0 reporting. A video on how to complete and submit the VAERS 2.0 form is available on YouTube (https://www.youtube.com/watch?v=sbCWhcQADFE).

The CDC-ISO vaccine safety inquiry activity is a service that responds to questions from the public, healthcare providers, media, and government officials. In recent years, approximately 400 inquiries have been received annually. During the period January 1 through December 4, 2017, 53% of inquiries were from healthcare providers or health departments, 33% were from the general public, and 5% were from the media. The vaccines asked about most frequently were all childhood vaccines in general (29%), influenza vaccine (22%), human papillomavirus vaccine (12%) and measles-mumps-rubella vaccine (8%). The primary reasons for inquiries were to obtain general vaccine safety-related information (59%) and VAERS data (18%). During the session, examples of inquiries will be discussed.

CISA is a national network of vaccine safety experts from CDC-ISO, seven medical research centers, and other partners, which provides a comprehensive vaccine safety public health service to the nation. The CISA Project conducts high-quality vaccine safety clinical research. CISA also provides consultation to U.S. clinicians who have vaccine safety questions about a specific patient residing in the United States, including guidance about future vaccinations. Reviews may be for a serious or unusual adverse event following immunization (AEFI) or because of concern that a patient might be at increased risk for an AEFI. Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. This part of the presentation will focus on the CISA clinical consultation service, criteria
and processes for requesting a consultation, and assessments of causality of adverse events according to a published algorithm. Case examples from CISA reviews will also be provided.