Excerpt from "The Immunization Encounter: Critical Issues" satellite broadcast, originally broadcast June 27, 2002.

Written by Donna Weaver, RN, MN, Judy Schmidt, RN, EdD, and William Atkinson, MD, MPH, with contributions by Jean Popiak and Robert Pless, MD, National Immunization Program, Centers for Disease Control and Prevention

Vaccine Injury Compensation Program and Vaccine Adverse Events Reporting System Segment

ATKINSON:
Our last topic is vaccine adverse events and the Vaccine Injury Compensation Program. We- YOU- administer millions of childhood vaccines each year, and millions more to adults. Only a tiny fraction of these results in potentially serious adverse events. The Vaccine Injury Compensation Program, or VICP, is in place to address legal claims for these rare, but serious, events. Judy, will you tell us more about the VICP?

SCHMIDT:
Sure Bill. The VICP is a no- fault federal compensation program. It serves as an alternative to the traditional tort legal system for resolving vaccine injury claims. VICP was established by the National Childhood Vaccine Injury Act of 1986, and began operation in 1988. It is jointly administered by the Department of Health and Human Services, the United States Court of Federal Claims, and the Department of Justice.

There are eleven specific antigens included in the Vaccine Injury Compensation Program. They are tetanus, pertussis, measles, mumps, rubella, polio, Haemophilus influenza type B, hepatitis B, varicella, and rotavirus. A combination vaccine containing any of these antigens is also covered, such as DTAP or MMR. Pneumococcal conjugate vaccine is currently covered under the broad category of New Vaccines.

The types of injuries covered by VICP are published in a Vaccine Injury Table. Here is the most current version of the table. For each vaccine listed in the first column, there are specific adverse events named in the second column. Each of these events is associated with a time period shown in the last column. For instance, tetanus containing vaccines list the adverse event of anaphylaxis occurring within a 4 hour time frame. This means that there must be evidence that anaphylaxis caused by a tetanus containing product occurred within 4 hours of receiving the vaccine in order to qualify for this particular compensation.

When a specific vaccine injury occurs that appears on the table and meets the time criteria, there is a "presumption of cause". That means the vaccine is presumed to have caused the injury, unless the Court determines the event was due to a cause unrelated to the vaccine. If the specific injury does not appear on the Vaccine Injury Table, proof must be shown that the vaccine caused the condition or significantly aggravated a pre-existing condition.

There are specific time frames for filing a claim. The claim for injury must be filed with the court within 36 months after the first symptoms appeared. The injury must have lasted at least six months after the vaccine was given. OR the injury must have resulted in a hospital stay and surgical intervention. If a death occurs, the claim must be filed within 24 months of the death and within 48 months of the vaccine event that caused death.

In addition to the information in the table, there are detailed definitions, descriptions, and instructions that accompany the table. This information is extremely useful for health care providers as well as the person filing the claim.

There is an important point about reporting adverse events I want to mention here. The National Vaccine Injury Act REQUIRES health care professionals and vaccine manufacturers to report adverse events that appear on the Vaccine Injury Table. These adverse events should be reported as soon as possible after their occurrence.

In 1990, a reporting system was put into place to assist providers and families with this requirement. The system is called the Vaccine Adverse Events Reporting system, or VAERS. VAERS accepts spontaneous reports of all the required events. But it will also accept any event a health care professional, patient, or parent suspects may be related to the vaccine. It's important that you understand how VAERS works and what it does. We asked Doctor Robert Pless, a vaccine safety expert in the National Immunization Program, to tell us about the system.

PLESS:
The Vaccine Adverse Event Reporting System, or VAERS is a program co-managed by the Centers for Disease Control and Prevention, and the Food and Drug Administration. I hope you will remember two important take home messages. First, VAERS is the cornerstone of efforts to monitor the safety of vaccines, and second, your contributions to VAERS are absolutely vital. VAERS is a unique

surveillance system that relies most on health care providers, but also patients and parents, to report cases of adverse events that they think might be related to vaccination. The CDC and FDA continually monitor the safety of vaccines by collecting and evaluating these cases.

VAERS is really the only system in place that does safety surveillance on an ongoing basis. It is automatic, unlike a clinical trial or a study, it does not need to be set up to monitor a new vaccine. VAERS relies on reporting from the users and recipients of vaccines, so it cannot work without you!

VAERS was established in 1990 after Congress passed the National Childhood Vaccine Injury Act. VAERS merged two different systems that had been collecting case reports separately from private and public health care providers. Although, the Childhood Vaccine Injury Act mandates that health care providers report the events listed on a table of designated Reportable Events.

VAERS depends on the reporting of ALL clinically significant events, most of which are not listed on the Table of Reportable Events and are therefore voluntary. Any event that you suspect MIGHT have been due to a vaccination, or if you are not SURE but feel it is important to let VAERS know, should be reported.

Now let's talk about how VAERS works. I hope that most vaccine providers have heard of VAERS and have seen a copy of the VAERS reporting form. Almost 200,000 copies are sent each year to pediatricians, nurses and family physicians.

The form can be obtained from the VAERS website at www.vaers.org or by calling the telephone number found on every Vaccine Information Statement. The VAERS form is self-mailing and postage-paid, with the address and instructions on the back. When folded and sealed, it, in fact, becomes its' own envelope. The completed form can, of course, be faxed to a toll free number. In addition, reporting through a secure web site is available at www.VAERS.org. This website provides excellent information about VAERS including a continuing education module. The module gives continuing education credits for physicians, nurses, and other professionals.

Once VAERS receives a report, a letter is sent out to the person who submitted it. The letter provides a thank you, the assigned VAERS ID number, and, if needed, requests additional information.

A team of nurses conducts personal follow up on all reports

considered serious. This follow up is done to obtain more complete clinical information about the reported event. In addition to the VAERS form, VAERS welcomes hospital or clinic summaries or other additional medical information. The additional medical information is useful informing a complete history.

To show you how VAERS works, let me give two examples of why collecting reports that are merely suspected to be related to a vaccination, is important.
In the past, there was a concern that Sudden Infant Death Syndrome, or SIDS, was related to vaccination. When parents and physicians reported cases of SIDS within a few days of a vaccination, they thought that this close timing between the vaccination and SIDS suggested an association. Careful studies were conducted with control groups, and repeatedly showed that the risk of SIDS following a vaccination is no greater than if the vaccination had not been given. We now know that vaccines do not cause SIDS. Reports of SIDS are still submitted and followed up, but reassurance is given to parents that this tragic event was not because they had their baby vaccinated.

Now, let's examine the story of the rotavirus vaccine. Before the rotavirus vaccine was licensed in the fall of 1998, investigators did note a few cases of a bowel disorder called intussusception in both vaccine recipients and those who received a placebo. Although the rate among vaccine recipients was slightly higher, it was not significant. Therefore, the vaccine was licensed, but intussusception was included in product information among the list of reported adverse reactions.

Once the vaccine was widely distributed, VAERS began to receive adverse event case reports, including cases of intussusception. The number of cases reported relative to the number of doses distributed turned out to be high compared to what was expected. This suggested, but did not confirm, a problem that we call a signal. Subsequent rigorous studies did confirm that the risk of intussusception was higher after vaccination, and the rotavirus vaccine was withdrawn. VAERS did its' job! The rotavirus problem was uncovered through VAERS and confirmed, and then appropriate action was taken. These stories of SIDS and Rotavirus highlight the importance of reporting events even when the person reporting may be unsure that the vaccine was responsible. Vaccine safety concerns raised by VAERS will be carefully evaluated before any action is taken.

So, as the cornerstone of the country's vaccine safety monitoring system, VAERS is always "on call" to receive case reports of any

adverse event suspected to be related to any vaccine distributed.

A few important points: VAERS accepts all reports of adverse events. Events that are related, as well as those that are unrelated to vaccination, end up in VAERS. VAERS reports are screened and evaluated as they are received. Concerns are flagged and further assessed, as illustrated by the examples of intussusception and SIDS.

VAERS relies on the astute health care provider to notice and report adverse events that may be related to vaccination. VAERS is a focal point of all sorts of questions related to vaccine safety. By being that focal point, it ensures that concerns have a much better chance to be heard and evaluated. This is like when a restaurant outbreak occurs. Everyone may go to a different emergency room, but the different hospitals all call the public health department! That way the pieces are put together and the outbreak is discovered and managed.

Thank you for this opportunity to discuss the Vaccine Adverse Event Reporting System. Because in the end, it relies on you to help make sure that vaccines continue their exceptional track record of safety. The VAERS program welcomes feedback on what can be done to make the reporting process easier. And remember: when in doubt, report it!

SCHMIDT:
Now that we have reviewed the vaccine adverse event reporting system as well as the vaccine injury compensation program, it's important to remember that these are two separate systems, managed by different agencies. Filing a VAERS report is not the same as filing a vaccine compensation claim. A VAERS report is NOT a compensation claim. A compensation claim is filed separately from the VAERS report. A VAERS report may be appropriate where a compensation claim is not. There is more information about the Vaccine Injury Compensation Program and VAERS on the broadcast resource website.

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