Ensuring Vaccine Safety

Vaccination is considered to be one of the most important public health interventions of the last century. With the continued emergence of bacterial and viral pathogens that are resistant to commonly used antibiotic and antiviral agents, vaccines are poised to become even more important during the current century. An expansion in the number of anticancer vaccines, as well as development of vaccines against debilitating neurological conditions, will further enhance the role of this important intervention.

A strong commitment to addressing concerns regarding vaccine safety during the long history of vaccine development has led to the availability of safer and more effective vaccines. The transition from a smallpox vaccine that was propagated in pooled humanized lymph banks to one that was propagated in the skin of calves and sterilized with glycerine is one historical example of a change that improved vaccine safety. The transition from whole cell pertussis vaccines to acellular pertussis vaccines currently in use is a modern day example.

Vaccine Safety Standards

While high safety standards are set for all medicinal products, a higher level of safety is expected for vaccines because they are given to millions of healthy infants, children, adolescents, and adults every year to prevent disease.

Continued on page 2

inSPOTLA Website Updated and Expanded

inSPOTLA http://www.inspotla.org, a pioneering STD/HIV partner notification website, has been updated and expanded. The website, launched in December 2005, allows individuals diagnosed with an STD or HIV to send an e-card (electronic postcard) to their partners notifying them that they may have been exposed. Originally tailored to men who have sex with men, the website has been revised and expanded to appeal to women and heterosexual men as well.

Continued on page 5
Ensuring Vaccine Safety...from page 1

Medications are given to proportionately smaller numbers of people to treat illnesses. During the pre-licensure stage of development, vaccines, as well as other pharmaceutical products, undergo extensive safety and efficacy studies, initially using in-vitro laboratory systems, animal studies, and then, phased human trials. World-wide standardized case definitions for assessing adverse events, the use of data and safety monitoring boards, and the increased number of trial subjects, have all enhanced the effectiveness of vaccine pre-licensure studies in identifying problems at an early stage.4

Because rare and delayed vaccine reactions or reactions in subpopulations are usually only seen after hundreds of thousands of vaccine doses have been administered, post-licensure or post marketing studies are also very important. Such post-marketing studies that are undertaken by vaccine manufacturers and academic research centers are supplemented by the Vaccine Safety Data Link, a network of large health maintenance organizations where all patient outcomes over time are matched with immunization histories. Because the Vaccine Safety Data Link follows a very large number of vaccine recipients, it has proven to be especially valuable in assessing vaccine safety. 4

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a post-licensure assessment system in which every health care provider should participate. VAERS was implemented jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in 1990 in order to provide a unified national process for the reporting of specific post-vaccination events. The National Childhood Vaccine Injury Act of 1986 requires this reporting. Visit www.vaers.hhs.gov/pubs.htm or call VAERS at 800-822-7967 for a list of required reportable events. VAERS also provides a mechanism for reporting other clinically significant events occurring after vaccination whether or not they were suspected to be the result of vaccination.

Key Facts about VAERS

• VAERS is a passive reporting system that accepts reports from patients and their parents as well as health care providers.

• There is no restriction on the interval between vaccination and symptoms that can be reported.

• Suspected events should be reported on a preaddressed and postage-paid VAERS form. Online web-based reporting is also available by clicking on the VAERS web site: www.vaers.org.

• All immunization providers that receive vaccines through the Los Angeles County Department of Public Health Immunization Program (LACIP) should send their VAERS reports to LACIP. Reports will be reviewed by LACIP to identify immediate concerns that may need to be addressed. All reports are then forwarded to the national system.

Continued on page 4
The World Health Assembly of International Health Regulations, referred to as IHR 2005, were adopted officially by the USA on July 17, 2007. The regulations define a “public health emergency of international concern” (PHEIC) as an extraordinary event that may constitute a public health risk to other countries through international spread of disease and which requires a coordinated international response.

Acute Communicable Disease Control (ACDC) asks that you report immediately any conditions that may potentially fall under the reporting requirements. ACDC staff will investigate and then consult with the California Department of Public Health and the U.S. Centers for Disease Control and Prevention (CDC) which will make the final determination about the need to report to the World Health Organization (WHO).

Most such situations are already reportable under Title 17 of the California Code of Regulations. Examples of the kinds of events that might constitute a PHEIC include:

1. A single case of smallpox, poliomyelitis due to wild type poliovirus, human influenza caused by a new virus subtype, or severe acute respiratory syndrome (SARS)

2. A case or cases of cholera, pneumonic plague, yellow fever, viral hemorrhagic fevers (Ebola, Lassa, Marburg), or other diseases of special national or regional concern, such as dengue fever, Rift valley fever, or meningococcal disease

3. Any event of potential international public health concern including those of unknown causes or sources

Conditions in the first category above always constitute a PHEIC and should be reported immediately; these are already reportable in California. Conditions in the second and third categories above will need some additional information to determine if they need to be reported to CDC on an urgent basis. In considering whether to report cases as PHEIC in categories two and three, ACDC will consider the following questions:

- Is the public health impact of the event serious?
- Is the event unusual or unexpected?
- Is there significant risk of international spread?
- Is there significant risk of international travel or trade restrictions?

If the response to two of the four questions is yes, then ACDC will report the event to CDPH immediately. If there is some uncertainty about the responses to the questions, then CDPH will be consulted immediately and additional consultation with CDC may be required.

For example, a case of pneumonic plague acquired in an endemic area of California with exposure only to family members who have been given prophylaxis and are under surveillance should be reported immediately to ACDC under Title 17, but would not constitute a PHEIC. A case of pneumonic plague in an airline passenger arriving from a country with an ongoing or recent undiagnosed respiratory outbreak would be of serious concern and should be reported immediately to ACDC as a PHEIC. Most meningococcal cases in California are of local importance only and would not constitute a PHEIC unless there is some link to a possible epidemic in a foreign country. An example from the third category would be the monkeypox outbreak in 2003 that led to restrictions on the importation of certain animals from Africa.

Resources


For questions or additional information, please contact ACDC at 213-240-7941.

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Acute Communicable Diseases Control Program
Los Angeles county Department of Public Health
• Healthcare providers in this category can: a) fax their VAERS reports to 213-351-2782, attention Epidemiology and Surveillance or b) mail the reports to LACIP at 3530 Wilshire Boulevard, Suite 700, Los Angeles, CA, 90010-2340, attention: Epidemiology and Surveillance.

VAERS works!

VAERS has helped to ensure that the benefits of vaccines far outweigh the risks. Since 1990, VAERS has received over 123,000 reports, the majority of which describe mild side effects such as fever. Reporting has also identified several associations between significant events and vaccination, which in turn has prompted further investigation.

Recent VAERS Success Stories

• The identification of a rare but significant association between intussusception and the 1998 rotavirus vaccine, that led to an immediate halt to the vaccine’s use and ultimately to its recall from the U.S. market in the fall of 1999.

• The identification of a cluster of Guillain–Barre Syndrome (GBS) cases following vaccination with meningococcal conjugate vaccine (MCV4) in the summer of 2005. This led to several assessment studies that were inconclusive in determining the relationship between GBS and MCV4. Nevertheless, these studies prompted the CDC and the Advisory Committee on Immunization Practices to make “past history of GBS” a precaution when assessing a client’s eligibility for receipt of MCV4.

VAERS is a very important part of a comprehensive system that ensures vaccine safety. It is critical that all healthcare providers use it to report clinically significant events that occur after vaccination. For more information about VAERS, please visit the web site: www.vaers.org, or call 1-800-822-7967.

Resources

7. CDC. Notice to readers: recommendation from the Advisory Committee on Immunization Practices (ACIP) for use of quadravalent meningococcal conjugate vaccine (MCV4) in children aged 2-10 years at increased risk for invasive meningococcal disease. MMWR. 2007/56(48);1265-1266.

Alvin Nelson El Amin, MD, MPH
Immunization Program
Los Angeles County Department of Public Health
inSPOTLA users can send an e-card to up to 6 partners at a time. Users can select a specific STD for their card (including HIV) from a pull-down menu.

The new expanded pull-down menu includes cervicitis, Chlamydia, gonorrhea, hepatitis A, hepatitis B, hepatitis C, HIV, lymphogranuloma venereum, non-gonococcal urethritis, syphilis, and trichomoniasis. The e-cards can be sent anonymously or not, and they can also include a personal note from the sender. Recipients of e-cards can click back to the website, where they can get more information about the STD for which they were notified, and choose among the 75 L.A. County clinics offering STD and HIV testing. The 75 clinics now include a number of family planning and women’s clinics.

Since 2005, there have been over 270,000 visitors to inSPOTLA, with over 35,000 e-cards sent. This includes 9,916 e-cards sent in 2006 and 2,782 e-cards sent in 2007. A promotion campaign is planned for 2008 to increase awareness and use of the website. inSPOTLA was developed by I.S.I.S., Inc., with design by Primatial; the site is sponsored by AIDS Healthcare Foundation, and co-sponsored and funded by the LAC Sexually Transmitted Disease Program.

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Sexually Transmitted Disease Program
Los Angeles County Department of Public Health

Coccidioidomycosis or Valley Fever: New Diagnostic Criteria

Coccidioides immitis or C. posadasii. Spores are naturally soil dwelling, but if disturbed, become airborne and may infect humans and many animals when inhaled. The disease is not directly transmitted from person to person or from animals to humans, and those infected do not need to be isolated. Interestingly, dogs appear to have a susceptibility similar to that of humans. For acute infection, the incubation period is 1 – 4 weeks. Disseminated cases may occur insidiously and may appear as reactivation years after the primary infection.

Sixty percent of people infected with Coccidioides have little to no symptoms. More severe illness can present with a febrile influenza-like or pneumonia illness. In less than 1% of cases, dissemination occurs in multiple organ systems causing erythema nodosum or erythema multiforme, bones or joint infection, and meningitis, and can also lead to death. Most people who contract the illness have an excellent chance of full recovery and infection is thought to provide life-long immunity.

Risk factors for cocci include activities and occupations with exposure to dirt such as farming, construction, military work, and archaeology. People who are at risk for disseminated disease include those who are immuno-

Continued on page 6
suppressed, the elderly, African-Americans, Asians, and women in the third trimester of pregnancy.

In most cases, cocci resolves without treatment. Antifungals such as amphotericin B, ketoconazole and miconazole may be life-saving for disseminated cases. Currently, no vaccine is available, but development is underway.

In the State of California, reporting of cocci cases to the Public Health Department is mandated by Title 17, section 2500. Case reports can be called to 888-397-3993 or faxed to 888-397-3778.

Merle S. Baron, RN, BSN, PHN
Acute Communicable Disease Control Program
Los Angeles County Department of Public Health

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**The new 2007 Council of State and Territorial Epidemiologists (CSTE) case definition of coccidioidomycosis:**

- Influenza-like signs and symptoms (e.g., fever, chest pain, cough, myalgia, arthralgia, and headache)
- Pneumonia or other pulmonary lesion, diagnosed by chest radiograph
- Erythema nodosum or erythema multiforme rash
- Involvement of bones, joints or skin by dissemination
- Meningitis
- Involvement of viscera and lymph nodes

**Laboratory Criteria for Diagnosis**

A confirmed case must include at least one of the following laboratory criteria for diagnosis:

- Cultural, histopathologic, or molecular evidence of presence of Coccidioides species, or
- Positive serologic test for coccidioidal antibodies in serum, cerebrospinal fluid, or other body fluids by:
  - Detection of coccidioidal immunoglobulin M (IgM) by immunodiffusion, enzyme immunoassay (EIA), latex agglutination, or tube precipitin, or
  - Detection of coccidioidal immunoglobulin G (IgG)* by immunodiffusion, EIA, or complement fixation, or
- Coccidioidal skin-test conversion from negative to positive after onset of clinical signs and symptoms

Confirmed Case: A case meeting the clinical definition that is laboratory confirmed.

*The 2007 case definition now accepts a single significant IgG titer as laboratory confirmation of infection in the presence of compatible clinical findings.*
The Five Components of Fitness
A Resource For Patients

When thinking about acquiring optimal physical fitness, many people tend to imagine themselves running numerous laps on a track or pumping iron in the gym. Although these activities represent a few of the components of fitness, there are additional components to fitness that should not be overlooked. The American College of Sports Medicine (2006) has identified five components of physical fitness, these include: cardiovascular endurance, muscular strength, muscular endurance, flexibility and body composition. Below we explore each component.

First, **Cardiovascular Endurance** is the ability of the body’s circulatory and respiratory systems to supply fuel during sustained physical activity. To help improve cardiovascular endurance, an individual should participate in activities that keep their heart rate elevated at a safe level for a sustained length of time. Some examples of such activities include walking, swimming, and cycling. These activities and similar activities can benefit the heart, lungs, muscles and the circulatory and endocrine systems as a result of the increase in oxygen transportation and utilization and are often referred to as aerobic exercises. Aerobic means “with oxygen” and indicates the energy produced to perform the work utilizes an oxygen system. Best of all, these activities help reduce the incidence of cardiovascular disease.

Second, **Muscular Strength** is the ability of a muscle to exert force during an activity. The key to making muscles stronger is working them against resistance, whether that from weights or gravity. Individuals who are interested in gaining muscle strength should try exercises such as lifting weights or rapidly taking a flight of stairs. Exercises or activities of this type are anaerobic and do not utilize oxygen to produce energy, unlike cardiovascular endurance activities.

Next, **Muscular Endurance** is the ability of the muscle to continue to perform without fatigue. To improve muscle endurance, try aerobic activities such as walking, jogging, cycling or dancing.

**Flexibility** is also an important component of fitness. This refers to the range of motion around a joint. Good flexibility in the joints can help prevent injuries through all stages of life. An individual can improve flexibility by participating in activities that lengthen the muscles such as swimming or a basic stretching program. It is important to note that flexibility is joint specific.

Finally, **Body Composition** refers to the relative amount of muscle, fat, bone, and other vital parts of the body. A person’s total body weight (what you see on the bathroom scale) may not change over time, but the ratio of fat to lean mass (muscle, bone, tendons, and ligaments) can change. Body composition is important to consider for health and managing your weight.

Remember that the key to optimal physical fitness is to incorporate activities that address all five of the physical fitness components. Also, keep in mind that activities need not be planned and structured to improve health; in fact, an increase in daily routines such as walking up a flight of stairs, gardening, raking leaves, moving furniture, or dancing also offer health benefits.

**References**


Angelica Haro, MS,
Physical Activity and Cardiovascular Health Program
Los Angeles County Department of Public Health
Physician Registry

Become a Member of the Health Alert Network
The Los Angeles County Department of Public Health urges all local physicians to register with the Health Alert Network (HAN). By joining, you will receive periodic email updates alerting you to the latest significant local public health information including emerging threats such as pandemic influenza. Membership is free. All physician information remains private and will not be distributed or used for commercial purposes.

Registration can be completed online at www.lahealthalert.org or by calling (323) 890-8377.
Be aware of public health emergencies! Enroll now!

THE PUBLIC’S HEALTH
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Los Angeles, CA 90012

This Issue...
Ensuring Vaccine Safety. ..................1
inSPOTLA Website Updated and Expanded ....1
International Health Regulations. ............3
Coccidioidomycosis or Valley Fever. .........5
Components of Fitness. ........................7

Selected Reportable Diseases (Cases)¹ — AUG/SEPT 2007

<table>
<thead>
<tr>
<th>Disease</th>
<th>THIS PERIOD OCT 2007</th>
<th>SAME PERIOD LAST YEAR OCT 2006</th>
<th>YEAR TO DATE – OCT</th>
<th>YEAR END TOTALS</th>
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<td>98</td>
<td>1,236</td>
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<td>Meningococcal Infect.</td>
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<td>Mumps</td>
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<td>NGU</td>
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<td>Pertussis</td>
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1. Case totals are provisional and may vary following periodic updates of the database.