MEDICAL DEVICE REPORTING

User Facility Reporting

Issue No. 26 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Spring 1999

Medical Surveillance Network (MeDSuN)

by Susan Gardner, Ph.D.

Section 213 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 legislated a change to universal user reporting of device-related adverse events. The new law mandates that the current system be replaced by one that "limits user reporting to a subset of user facilities that constitutes a representative profile of user reports" for device-related deaths and serious injuries. This legislation gives FDA the opportunity to design and implement a national surveillance network to provide critically important data on medical devices.

In planning for the new system, the Food and Drug Administration (FDA) did research in three areas. The first effort was exploratory research in the form of focus groups and site visits with staff from various types of clinical facilities. The purpose of the exploratory research was to identify barriers to reporting. The most salient identified barriers were lack of feedback, concern for liability and data security, and reporting burden.

Using information gathered during the exploratory research, FDA implemented a second research initiative consisting of a one year pilot study named DeviceNet. It was designed to test the feasibility of overcoming some of the major barriers to reporting. For example, assurance of confidentiality was increased by having the pilot facilities report to a contractor (i.e., a neutral third party). After doing any needed follow-up, the contractor stripped the reports of identifying information before entering them into the pilot study database. Reporters from the pilot facilities were encouraged to call the contractor for any assistance needed to complete reports. This reduced the reporting burden on the facility. In addition, pilot facilities were sent bimonthly newsletters with articles about medical device issues and a list of all devices and problems reported in the pilot. The pilot results suggest that these measures were successful in increasing both the quality and the quantity of reporting.

Another important finding of the pilot was related to which adverse events are reportable. The hospitals and nursing homes participating in the pilot were asked to report all adverse events with the potential for harm, not just those required by the Safe Medical Devices Act (SMDA). Over one-half of the reported adverse events were not mandatory under SMDA (i.e., did not result in death or serious injury), but about one-third of the voluntary reports were considered at least "somewhat urgent" by FDA.

The final area of research consisted of conducting extensive interviews with experts in surveillance, medical error, and patient safety. Much of what is known about understanding accidents or misadventures in organizational systems is relevant and important in considering the design of a device surveillance network. For example, it is important to be informed of "close calls" and what steps were

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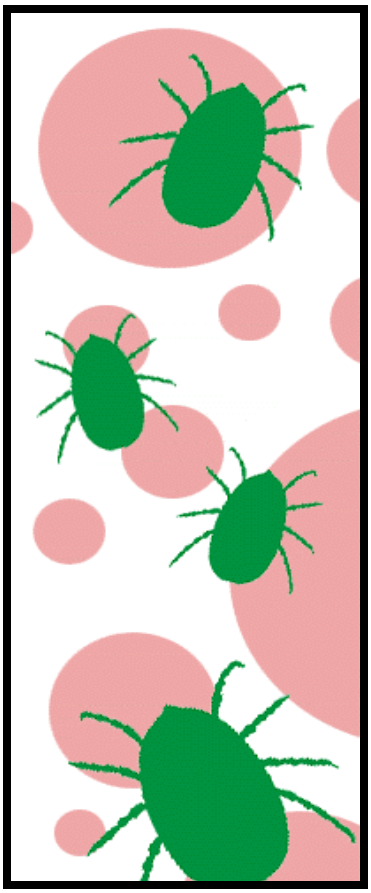
taken by a health care professional to prevent patient injury. By having such information, FDA will be able to identify the potential for error and be in a position to work with the healthcare community to prevent patient injury.

FDA was then faced with the challenge of merging a wealth of information from our research efforts into a system design (within the regulatory structure) that will meet our public health goals. The goals of the proposed Medical Device Surveillance Network (MeDSuN) are: (1) to improve the protection of patients and users by reducing the occurrence of device-related events; (2) to serve as an advanced warning system for the clinical community; and (3) to create a two-way communication channel between FDA and the user facility community. The system will allow for dissemination to healthcare professionals and the public of information regarding newly emerging device problems. It will also allow FDA to apply the knowledge gained from the reported data to its premarket device approval process and to prevention and control programs.

As a next step, FDA will initiate a significantly expanded Phase 2 pilot, incorporating all features proposed for the national MeDSuN system. Features of the proposed pilot include the selection of facilities by a probability-based sample design, beginning in two or three regions of the country. To the extent possible, barriers to reporting will be eliminated (for example, removing identification of reports by a third party before reports are sent to FDA). Facilities selected for the Phase 2 pilot will be given various incentives to participate such as timely and relevant feedback, training and educational support, and technical assistance. As with the first pilot, an important feature of the design is that facilities will be encouraged to report incidents having the potential for causing harm, not just deaths and serious injuries.

The extensive research of the past two years suggests that if the user community perceives the Network as another burden imposed by the Federal government, participation is likely to become perfunctory and unproductive. Although FDA currently cannot eliminate the mandatory aspect of the program, the proposed system will attempt to balance the mandatory aspect with incentives to improve patient safety through participation in the program.

Susan Gardner, Ph.D., is Deputy Director of the Office of Biometrics and Surveillance.



LYME DISEASE: DIFFICULT TO DIAGNOSE

Lyme disease is an infection caused by the bacterium *Borrelia burgdorferi* that is transmitted by a tick bite. The disease can be difficult to diagnose. It often starts with a large red rash at the site of the tick bite, followed by flu-like symptoms and fatigue. Early in the course of the disease, the symptoms often may go unnoticed or be mistaken for the flu, and not all persons develop the same symptoms. To further complicate matters, the symptoms of the disease mimic those of other diseases, so even persons who do complain of flu-like symptoms and fatigue can have any number of conditions other than Lyme disease.

There are blood tests to check for antibodies to the bacterium that causes Lyme disease. The tests, however, are not useful if done soon after a tick bite, because it takes 2 to 5 weeks after being bitten by an infected tick for antibodies to develop. Even when an **antibody** (blood) test is done later, the result **alone** does **not** reliably predict the presence or absence of Lyme **disease**. (See "How is Lyme disease diagnosed?" below.) The Food and Drug Administration (FDA), which regulates diagnostic tests for Lyme disease, has cleared for commercial sale and distribution only **blood tests** for antibodies that may be present in Lyme disease. Tests for Lyme disease that use **urine** or **other body fluids** have not been cleared by FDA.

How is Lyme disease spread?

Lyme disease is spread by the bites of *Ixodes* ticks (the deer tick, bear tick, western black-legged tick, or black-legged tick, depending on the region of the country). These ticks are much smaller than the common dog or cattle ticks. They can attach to any part of the body, often to moist or hairy areas such as the groin, armpits, and scalp.

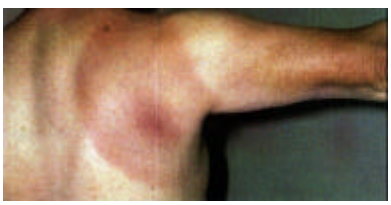
Campers, hikers, outdoor workers, and gardeners are at the greatest risk of exposure to infected ticks. Lyme disease is widely distributed in northern temperate regions of the world. In the United States, the highest incidence occurs in the Northeast, North Central states, and the West Coast (particularly in northern California).

What are the symptoms of Lyme disease?

The symptoms of **early Lyme disease** include:

- a characteristic skin rash (called erythema migrans),
- muscle and joint aches,
- headache,
- chills and fever,
- fatigue, and
- swollen lymph nodes.

Erythema migrans is a circular red patch that usually appears in 3 to 30 days after being bitten by an infected tick. The patch expands (to an average of 5 to 6 inches in diameter) and persists for 3 to 5 weeks. Sometimes many patches appear and vary in shape depending on their locations. The center of the patch may clear as the rash enlarges, giving a "bull's-eye" appearance. In some persons, the characteristic rash never forms or is not noticed, and not every rash that occurs at the site of a tick bite is due to Lyme disease. In some cases, the rash can be an allergic reaction to the tick saliva.



"The patch expands (to an average of 5 to 6 inches in diameter) and persists for 3 to 5 weeks."

In their larval and nymphal stages, Ixodes ticks are no bigger than a pin-head. Adult ticks are slightly larger.

The symptoms of late Lyme disease may not appear until weeks, months, or even years after a tick bite and include:

- arthritis (usually as pain and swelling in large joints, especially the knee);
- nervous system abnormalities such as numbness, pain, facial paralysis similar to Bell's palsy, and meningitis (fever, stiff neck, and severe headache); and
- irregularities of the heart rhythm.

How is Lyme disease diagnosed?

Lyme disease can be difficult to diagnose, because its symptoms mimic those of other diseases. For example, the fever, fatigue, and muscle aches can be mistaken for influenza or infectious mononucleosis. Joint pain can be mistaken for rheumatoid arthritis and neurologic signs for multiple sclerosis. Conversely, other types of arthritis or neurologic diseases can be misdiagnosed as Lyme disease.

To make a diagnosis of Lyme disease, the following should be considered:

- a history of possible tick bite, especially in areas of the country known to have Lyme disease;
- symptoms; and
- results of blood tests done at least 5 weeks after the tick bite to determine if antibodies to the bacterium *Borrelia burgdorferi* are present in the patient.

Blood tests are most useful in the later stages (greater than 1 year) of untreated Lyme disease, but even then results may be inaccurate. To improve the reliability of these tests, FDA supports the Centers for Disease Control and Prevention (CDC) recommendation for two-step testing and interpretation of results. This means that if the first test for antibodies to the Lyme disease bacterium is positive or equivocal (uncertain), a second test (called a "western blot") should be performed to verify the presence of specific antibodies to the bacterium. If the results of the first test are negative but symptoms persist, the doctor may want to retest at a later date.

Can Lyme disease be treated?

If there are definite symptoms of Lyme disease, the doctor may prescribe antibiotics which are usually given by mouth. Antibiotics should not be given only because a person was bitten by a tick. Patients who are diagnosed and treated with antibiotics in the early stages of Lyme disease usually recover quickly and completely. Most patients treated in the later stages of Lyme disease also

respond well to antibiotics. A few patients may have relapses and need additional antibiotic treatment. Permanent damage to the joints or the nervous system can develop in patients with chronic late Lyme disease. Usually these are patients not diagnosed in the early stages or their initial treatments were unsuccessful.

What precautions can be taken to reduce the chance of getting Lyme disease?

To decrease the chance of being bitten by a tick:

- avoid wooded, brushy, and grassy areas, especially in May, June, and July. (Contact the local health department or park/extension service for information on local distribution of ticks.)
- wear light-colored clothing, so that ticks can be seen more easily.
- wear long pants and long-sleeved shirts.
- wear shoes that cover the entire foot.
- tuck pant legs into socks or shoes and shirt into pants.
- wear a hat for extra protection.
- spray insect repellent containing DEET on clothes and exposed skin other than the face, or treat clothes with permethrin that kills ticks on contact.
- walk in the center of trails to avoid brush and grass.
- after being outdoors, remove clothing and wash and dry it at high temperatures.
- do a careful body check for ticks. To remove a tick, use tweezers and grasp the tick close to the skin. Pull straight back and avoid crushing the tick's body. Save the tick for possible identification by a doctor or the local health department.

Is there a vaccine for Lyme disease?

FDA recently licensed the first vaccine to aid in the prevention of Lyme disease. The new vaccine (trade-name Lymerix) is approved for use in persons 15 to 70 years of age who live or work in grassy or wooded areas where infected ticks are present. It is not currently available for persons under the age of 15 years.

Three doses of the vaccine, given over a period of 1 year, are needed. Although Lymerix may provide protection for a majority of people, it does not prevent all cases of Lyme disease. Studies by the manufacturer showed that after two doses of the vaccine in the first year, the protection rate against definite Lyme disease was 50 percent. In the second year after three doses, it was 78 percent. Since the vaccine is not 100 percent effective, continued preventive measures are still necessary for immunized individuals.

Need more information about Lyme disease?

For additional information about Lyme disease, talk with a doctor, healthcare professional, or local health department or contact:

Arthritis Foundation
P.O. Box 7669, Atlanta, GA 30357-0669
Telephone 1-800-283-7800
www.arthritis.org)

American Lyme Disease Foundation, Inc.
293 Route 100, Somers, NY 10589
Telephone 914-277-6970
www.aldf.com

or government agencies such as:

Centers for Disease Control and Prevention
National Center for Infectious Diseases
Atlanta, GA 30333
Telephone 404-332-4555
www.cdc.gov/ncidod/

and

Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857
Telephone 1-888-463-6332
www.fda.gov.

This article is based on information from the above sources.

Reporting Of Adverse Events To FDA

Clinicians are encouraged to report adverse events related to medical devices (including clinical laboratory assays) to MedWatch, FDA's voluntary reporting program. Pertinent adverse events could include test results that led to inappropriate treatment or a problem with quality control of an assay. Report these events by telephone to 1-800-FDA-1088, by FAX to 1-800-FDA-0178, or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857. For more information about Lyme disease test kits, contact Sharon L. Hansen, Ph.D., by FAX at 301-594-5940, or by mail at 2098 Gaither Road, HFZ-440, Rockville, MD 20850. ❀

HCFA to hold Conferences on YEAR 2000 (Y2K) Readiness Strategies

The Health Care Financing Administration (HCFA), with contract support from the Rx2000 Solutions Institute, is sponsoring a series of one-day conferences across the country to help Medicare and Medicaid providers met the challenge of the Year 2000 (Y2K) date changeover. The one-day conferences are offered **free of charge** to Medicare and Medicaid providers at the following locations:

June 22	Tampa/St. Petersburg, FL
June 29	Newark, NJ
July 13	Charlotte, NC
July 15	Memphis, TN
July 20	Houston, TX
July 22	Chicago, IL
July 28	San Francisco, CA
August 3	Detroit, MI
August 5	Pittsburgh, PA
August 9	Louisville, KY
August 11	Denver, CO

One of the most important goals of HCFA is to help Medicare and Medicaid providers to successfully address their Y2K risks. Information provided at the conferences will help providers maintain high quality patient care while ensuring uninterrupted processing of Medicare and Medicaid claims. A series of panel presentations will address:

- what steps need to be taken to ensure that Y2K changeover does not disrupt, slow, or temporarily stop process claims *internally*;
- what the pharmaceutical industry is doing to prepare for Y2K;
- how to successfully manage biomedical equipment and pharmaceutical Y2K risks; and
- how the Food and Drug Administration (FDA) views the Y2K impact on medical devices and the current status of FDA's information on biomedical equipment Year 2000 readiness.

Registration for any of the conferences is available on-line at http://www.rx2000.org or by calling De Carlos Bradley at (301) 270-0841, ext. 209. ❀

NEW MAMMOGRAM REQUIREMENTS EFFECTIVE APRIL 28

The Food and Drug Administration (FDA) further strengthened the nation's standards for mammography centers by requiring that all women receiving mammograms must be directly notified in writing about their results. The new requirements became effective on April 28, 1999, and are an addition to the final regulations that implemented the Mammography Quality Standards Act (MQSA) of 1992. They reflect improvements in the law made by the Mammography Quality Standards Reauthorization Act of 1998.

Although many mammography facilities already provide this service, the FDA rule ensures that written notification occurs promptly, is written in easy-to-understand language, and is provided by every mammography facility in the United States. More specifically, the mammography facility will:

- continue to report results directly to the patient's physician;
- send a separate, easy to understand summary report to the patient within 30 days;
- send each self-referred patient the summary report plus the report that would have been sent to the physician, if the patient had selected one;
- create a system to assure that self-referred patients receive referrals for clinical follow-up, if appropriate;
- send all reports with suspicious results or that suggest cancer diagnosis to patients within 5 working days;
- send all unclear or incomplete results to patients as soon as possible, so they can get follow-up care immediately; and
- collect follow-up data on patients with positive cancer results.

FDA added the new requirement after receiving anecdotal reports that the results of suspicious mammograms were often not reported and as a result, breast cancer was not detected until too late.

The final regulations also require mammography facilities to transfer original mammograms, not copies, to the patient's physician or to the patient on request. This will allow physicians to compare the new mammograms with the old ones.

Under MQSA, all mammography facilities in the United States must now:

- meet certain stringent standards for equipment, personnel, and image quality;
- be accredited by an FDA-approved accreditation body;
- be MQSA-certified; and
- be inspected annually.

Virtually all 10,000 mammography facilities in the United States have fully met the new standards and are certified to perform mammography. The names and locations of certified mammography facilities are available by calling the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or by visiting FDA's Web site at www.fda.gov/cdrh/faclist.html❀

RISKS WITH COLLAGEN HEMOSTASIS DEVICES*

By Beverly Albrecht Gallauresi, RN, BS, MPH

A 69-year-old-man underwent a diagnostic cardiac catheterization. Following the procedure, a collagen hemostasis device was inserted at the femoral arterial site to prevent bleeding. When continuous oozing was observed at the insertion site, the physician assessed the patient and diagnosed a retroperitoneal bleed. A large hematoma pressing on the urethra caused an obstruction and subsequent kidney damage. The patient is currently on hemodialysis.

What went wrong?

A retroperitoneal bleed may develop when a collagen sealant device fails to seal the vessel properly. Possible reasons for a poor seal include improper insertion technique, patient obesity, and hypertension.

What precautions can be taken?

Review your institution's policy and training requirements in the care of patients receiving a collagen hemostasis device. Discuss risks and possible complications with your patients. Depending on your institution's policy, the use of a consent form for a collagen device may also be appropriate.

Before the procedure

Thoroughly evaluate the patient before the procedure. Locate, assess, and mark pedal pulses and document the size and shape of abdominal girth.

After the procedure

- The patient should remain on bed rest at least 4 hours.
- Monitor the patient's vital signs and pedal pulses for changes.
- Frequently observe the patient's femoral arterial site for oozing, erythmia, tenderness, and swelling.
- Observe the patient's abdomen for any changes in size, shape, or tenderness. Instruct the patient to alert you of any changes or abdominal tenderness.
- Inform the physician immediately if the patient complains of abdominal tenderness or fullness or if you detect swelling or other changes from baseline. ❀

Beverly Albrecht Gallauresi, RN, BS, MPH, is a nurse consultant in CDRH's Office of Surveillance and Biometrics.

*Adapted from an article in the January issue of *Nursing '99*.

Watch for the Summer Issue by the end of August!

SUBJECT MATTER INDEX TO UFR BULLETIN, ISSUES 1-26

User Facility Reporting Bulletin

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997.

Editor: Nancy Lowe
Assistant Editor: Mary Ann Wollerton
Design: Edie Seligson

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health, HFZ-230
Rockville, MD 20857
FAX: (301) 594-0067
e-mail: nsl@cdrh.fda.gov