Medical Device and Laboratory Product Problem Reporting from Physicians' Offices

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The Medical Device and Laboratory Product Problem Reporting Program (PRP) is a system through which health care professionals (physicians, nurses, laboratory technologists, therapists) and others can report medical device problems occurring in physicians' offices and can be assured that industry and government will be made aware of their concerns.

Organized in 1973, the PRP is modeled after a successful system used by pharmacists since 1971. The program works simply and efficiently and is designed to evaluate complaints about any medical or laboratory device.

The program's objective is to improve product quality by communicating device-related health risks to health care professionals, industry, and government.

The PRP is coordinated by the United States Pharmacopeial (USP) Convention, Inc, an independent, nonprofit organization responsible for establishing drug standards, and is funded by the Food and Drug Administration (FDA). More than 40 professional organizations, including the American Academy of Family Physicians, are co-sponsors.

Examples of Problem Reporting

The following examples illustrate how well the PRP has worked.

- A surgeon reported to USP that handles from an overhead operating room light had fallen off during surgery, injuring the operating team and contaminating the surgical field. After discussing the problem with the FDA, the manufacturing firm issued an urgent warning to hospitals and clinics using its equipment and sent representatives to each site with new parts to correct the problem.
- A nurse anesthetist reported to the USP that the bag assembly delivered with a nonconductive anesthesia breathing circuit had come apart while in use on four separate occasions. As a result of the complaint, the manufacturer redesigned the bushing in the bag assembly so that it fit more tightly to the neck of the anesthesia bag. Mylar tape replaced the retaining band around the bag neck to prevent separation of the bag from the neck inset.
- Blood glucose meters, important to the quality of diabetes self-care, have been the subject of nearly 2800 reports received since 1984. Complaints were mainly about erroneously high and low test results. Investigations revealed that nearly three quarters of the problems could be traced to users' failure to maintain meters properly and to follow correct techniques and instructions for meter use. As a result of these findings and those from the FDA-funded Human Factors Analysis of Blood Glucose Monitoring study, projects are under way to improve written instructions and to upgrade training programs in the proper use of the meters.

Guidelines for Problem Reporting

Health professionals should report any deficiency in or problem with a medical or laboratory device that results in a death or injury, or creates a condition that may be unsafe or hazardous, or otherwise presents a public health concern.

The PRP is designed to process efficiently reports about device problems that relate to performance malfunctions and failures, design defects, defective components, improper packaging, questionable sterility, inadequate labeling, and erroneous instructions. Suggestions for correcting problems and improving product performance or quality are also accepted.

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When to Report

Problems with medical and laboratory devices should be reported when any of the following is true:

- Performance problems with a device resulted in a decision to discontinue its use
- Repeated repairs did not solve the problem
- Design or repair changes to the product adversely affected its performance
- Poor quality control by the manufacturer is indicated
- Incompatibility between devices exists
- The malfunction of a device resulted in prolonged hospitalization of or repeated surgical procedures on a patient
- User error is the cause

When Not to Report

Concerns about medical and laboratory devices probably should not be reported when:

- Desired changes in a product are only cosmetic
- Personal preference is at issue rather than device performance
- Normal wear of a device is encountered

What to Include in a Report

Product defects should be thoroughly investigated and documented by the health care professional before being reported. When a product fails to perform as expected, the package insert should be checked carefully to make sure the directions were followed properly. The device should be used at least once under controlled conditions to try to repeat the problem. The defective device should be kept, as well as any other material evidence that could be used if an investigation of the product is made.

Reporters should supply as much information as possible about the device and the circumstances surrounding the complaint, including:

- Identification numbers (lot, model, serial)
- Complete name of the device and of the manufacturing firm
- Whether the device was being reused, if it was disposable
- Whether directions for use were properly followed
- The location where the device was being used when the event occurred
- The title(s), practice specialty(ies), degree(s) or other qualifications of the person using the device
- A complete description of the problem along with actual or potential adverse effects on the patient or others involved
- An analysis of the role the device played in the event

How to Report a Problem

If a problem is encountered while using a medical device, the USP may be called toll-free at 1-800-638-6725 (in Maryland, call collect 301-881-0256); alternatively, a self-mailing report form can be completed and returned to:

The United States Pharmacopeia
Product Problem Reporting
12601 Twinbrook Parkway
Rockville, MD 20852

Reports may be submitted to the PRP in confidence. Confidentiality is never compromised; patient names, however, should not appear on any report. The USP acts as an intermediary, providing the manufacturer and the FDA with a copy of each report.

Reporters may remain anonymous by requesting that the USP delete the names of individuals and institutions from reports forwarded to the FDA. For persons submitting written reports, an area is provided on the form to indicate whether they wish to disclose their identities. This disclosure area is important to complete in order for the USP to process reports according to the reporter's wishes.

What Happens to a Report

When notified of a problem, the USP acknowledges receipt of the complaint, if the reporter's name and address are available, and forwards copies of the complaint to the FDA's Center for Devices and Radiological Health. The manufacturer also receives a copy of the report.

All device problem reports are entered into a database called the Device Experience Network (DEN). Problems that present an immediate risk to the public health receive prompt FDA attention and follow-up. The FDA can take steps to ensure that the manufacturer of a hazardous device resolves the problem by means of recall, safety alert, relabeling, or other suitable mechanism.

Of course, not all reports involve problems that require immediate resolution. The FDA continually reviews data in the DEN to detect problems and the potential for hazards. FDA analysts usually begin their

review of each report received with an evaluation of past problems with the device and manufacturing firm. In addition, with the use of a computer, DEN data are routinely reviewed for trends.

If a repeated problem with the same device or firm is detected, FDA staff are usually involved in resolving the problem. For example, if the problem can be resolved through labeling (ie, instructions), FDA personnel will review the proposed language to ensure that the change is the most effective method of solving the problem.

Obtaining Information About Product Problems

For device users who wish to keep up to date on problems that have been reported, the National Technical Information Service (NTIS) publishes the monthly "Problem Reporting Program (PRP) Reports from the Device Experience Network (DEN)." The publication summarizes each complaint received for the previous month and includes, when available, the FDA's final assessment. A subscription may be ordered at a cost of about $150 from:

NTIS
Subscriptions Department
Springfield, VA 22161

A subscription order may also be placed by calling the NTIS at (703) 487-4630.

Information from the DEN is also available through provisions of the Freedom of Information Act by writing to:

Food and Drug Administration
Freedom of Information Staff–HFI 35
5600 Fishers Lane, Rockville, MD 20857

In those rare instances when it is critical to find out about problems with a particular device, a health professional may call the USP at 1-800-638-6725. Most of the time USP staff will be able to answer questions regarding reported device problems. If they cannot, they will direct the call to appropriate FDA personnel. The USP will not always have the information at hand to respond directly to an inquiry.

The USP (and the FDA) have limited resources and can take only emergency calls. For prepurchase and general information about problems with devices, contact the NTIS or FDA's Freedom of Information Staff.

Recently Legislated Device Problem Reporting Requirements

The Safe Medical Devices Act of 1990, which amends existing laws covering medical devices, was passed by Congress and was signed into law by the President on November 28, 1990. The Act grew out of Congressional concern about the safety and effectiveness of medical devices.

One of the goals of the Safe Medical Devices Act is to help ensure that the FDA quickly learns about serious device problems so that the agency can quickly take steps to correct them.

The Act will affect a variety of health care facilities (excluding physicians' offices) and users of medical devices. Congress wants facilities where users of devices work to report serious problems associated with medical devices to the FDA.

A section of the Act states that beginning November 28, 1991, certain health care facilities—such as hospitals, nursing homes, ambulatory, surgical and emergency care units, but *not* physicians' offices—must report device-related deaths, serious illnesses, or serious injuries.

Health care workers should be aware that no health care facility is required to report anything until November 28, 1991. The FDA plans to propose regulations that will implement the report-by-facilities part of the Act in the summer of 1991. Final regulations should be issued several months later. The new reporting requirements for health care facilities will become part of a regulation that also spells out the reporting requirements for manufacturers, distributors, and importers.

The FDA is soliciting comments from professional societies and organizations to help develop a regulation that meets Congressional intent, takes into account the unique nature of health care facilities, and imposes minimum costs on all parties. The FDA held a conference in late April to discuss the impact of the proposed requirements.

In addition, comments can be made when the proposal appears in the *Federal Register*. You may receive a copy of the proposed and final regulations by writing USP at the address cited on page 635.

In the interim, the FDA encourages the health care community to continue submitting reports to the USP.