FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

USER Facility Reporting

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HIGHLIGHTS OF THE REPORT TO CONGRESS ON USER FACILITY REPORTING

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Background

The Safe Medical Devices Act of 1990 (SMDA, Public Law 101-629) requires hospitals; nursing homes; and ambulatory surgical, outpatient treatment, and diagnostic facilities to report device-related deaths to both the Food and Drug Administration (FDA) and the device manufacturer, if known. SMDA also requires that user facilities report device-related serious injuries and serious illnesses to the manufacturer, or to FDA if the manufacturer is not known. The medical device reporting (MDR) provisions for user facilities became effective on November 28, 1991.

Another provision of SMDA requires FDA to provide guidance to user facilities on how to comply with the reporting requirements. FDA is using a multifaceted approach that includes presentations and exhibits at professional meetings as well as publications. The *User Facility Reporting Bulletin* was established to provide a dialogue with the user facility community. A booklet entitled *Medical Device Reporting for User Facilities: Questions and Answers Based on the Tentative Final Rule* (HHS Publication FDA 92-4247) has been mailed to over 150,000 facilities and individuals since January 1992. The booklet also contains a reprint of the tentative final rule (*Federal Register* 56:60024). Until a final rule is published, the tentative final rule and booklet are intended as guidance.

SMDA also requires FDA to submit to Congress a report evaluating the effect of MDR on user facilities, i.e., costs, benefits, and degree of compliance. The Office of Management Services (OMS) within the Center for Devices and Radiological Health (CDRH) is presently completing the required report. Data gathered from the following sources were used in the evaluation:

- surveys by three state health departments;
- FDA field office inspections;
- MDR databases maintained within CDRH; and
- OMS reviews and studies.

The surveys were performed by the Colorado, Massachusetts, and Texas departments of health. Between November 1992 and June 1993, state investigators made 468 visits to randomly selected sites to collect information and review medical device occurrences, i.e., deaths, serious injuries, and serious illnesses.

The main objectives of the evaluation were to:

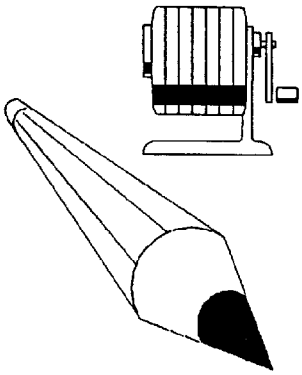
- determine the cost to both user facilities and FDA of implementing MDR;
- assess the public health benefits of MDR; and
- collect baseline data on compliance with MDR since it became effective for user facilities.

Implementing Medical Device Reporting

At the outset of the three-state study, investigators found awareness of user facility reporting requirements to be lower than expected. They noted whether facilities were aware of the reporting requirements and ultimately found that only 46 percent of the facilities had prior knowledge. Among the facility types, hospitals had the highest level of awareness (69 percent), followed by outpatient treatment facilities (45 percent), nursing homes (41 percent), ambulatory surgical facilities (40 percent), and outpatient diagnostic facilities (26 percent).

In the course of their surveys, state investigators requested a copy of each facility's written MDR procedures. CDRH reviewed 119 of the procedures (54 percent of the total sent to us) and found that only 9 percent covered the requirements of the tentative final rule, i.e., they contained definitions of event terminology and descriptions of training programs, internal systems and documentation, and record keeping practices. Twenty percent of the procedures simply mentioned user facility reporting or medical device adverse occurrences but failed to include any of the above specifics.

It is important to note that many of the facilities indicated they had not received information from FDA about medical device reporting. However, a separate CDRH review showed that over 71 percent of the sampled facilities were included in the CDRH database used for mailing this *Bulletin* and the booklet. Hospitals had the highest rate of coverage: 92 percent of the 125 surveyed hospitals were on the mailing list. Also, over 140 seminars, conferences, and exhibits have been held since 1990 to inform user facilities about MDR requirements.



Sharpen your pencils!
A reader questionnaire will appear in the next issue.

Facility Costs

State investigators collected cost information from each of the 468 facilities. Facilities that were unaware of the reporting requirements or had not kept accounting figures were asked to provide cost estimates. Based on the three-state study, the total start-up cost for the 45,300 user facilities nationwide is estimated to be about $27 million. Start-up cost includes time spent writing procedures and policies, developing or modifying internal systems, and developing a training program. Thereafter, the cost is estimated to be over $42 million annually. The estimated annual expenditures included the cost of investigating adverse occurrences, completing FDA test forms, developing and submitting semi-annual reports, maintaining internal computer systems, and conducting annual training programs.

FDA Costs

CDRH has pursued many activities relating to MDR since the enactment of SMDA. In March 1993, we started gathering data from CDRH employees who were involved with these activities. Data were collected for fiscal years 1990 through 1993. We categorized the activities into start-up costs and annual costs. In total, $5.1 million was spent for start-up costs. In fiscal 1993, the annual cost reached over one million dollars. The most costly start-up activities were software development and development of the implementing regulation. The most costly annual activities were data entry, analysis of incoming reports, and maintenance and enhancement of application software.

Since November 28, 1991, 4,526 reports have been sent directly to FDA by user facilities. In the same period, we received over 106,000 death and serious injury reports from manufacturers. An indeterminate number of these originated in user facilities.

Utilization and Benefit of MDR Data

State investigators took a two-pronged approach to acquire information on benefits to user facilities and to the public health resulting from the implementation of MDR requirements under SMDA. One approach was to ask the facility risk managers and administrators open-ended questions about the uses and public health benefits of MDR. The second approach was to ask specific questions about the effects that MDR has had on each facility.

Seventeen percent of risk managers believed that the reporting requirements will improve the quality and performance of medical devices. Twenty-eight percent had no plans to utilize MDR data or had no opinion. The remaining risk managers (55 percent) mentioned a variety of different uses, such as improving awareness of patient safety and assisting in device purchase decisions.

According to 37 percent of facilities, the promotion of quality patient care and safety was the primary public health benefit of MDR. In addition, facility representatives realized the program's potential to facilitate detection of situations that require device recalls.

Six additional questions were asked about the effects of reporting requirements on each facility. Responses were rated from "none" to "extensive." Although the open-ended questions elicited many positive responses from facility representatives concerning improved patient safety, replies to the other questions showed little or no perception of program effect on patient safety issues or prevention of serious injuries and illnesses. Most risk managers stated that SMDA does not help save lives. A question about the cost to facilities as a result of the MDR requirements generally received replies of "minimal" to "moderate."

Compliance Issues Revealed by the Three-State Study

As seen in the table on page 3, investigators found that only 52 of the 468 facilities had reportable occurrences — a total of 186 events. Of these, 161 were submitted to the manufacturer and/or FDA, an overall 87 percent reporting rate. Hospitals had the highest reporting rate at 90 percent. At the other end of the scale (except for outpatient diagnostic

Facilities		Facilities with Reportable Events		Reportable Events		
Type	Number in Survey	Number	Percent	Submitted by Facilities	Should Have Been Submitted	Reporting Rate (Percent)
HOS	125	35	28	90	100	90
NH	106	5	5	3	5	60
ASF	70	6	9	45	54	83
OTF	82	5	6	23	26	88
ODF	85	1	1	0	1	0
Total	468	52	11	161	186	87

Legend: HOS-hospital; NH-nursing home; ASF-ambulatory surgical facility; OTF-outpatient treatment facility; and ODF-outpatient diagnostic facility.

facilities, whose single reportable event went unreported) was the 60 percent reporting rate for nursing homes.

SMDA requires that user facilities report device-related deaths to both FDA and the device manufacturer, if known. Device-related serious injuries or illnesses are to be reported to the manufacturer, or to FDA if the manufacturer is not known. Of the 186 reportable occurrences in the surveys, investigators found 9 were deaths — all occurring in hospitals. Seven of these were correctly reported to both FDA and the manufacturer; the remaining 2 were submitted only to FDA.

The remaining 177 reportable occurrences involved serious injury or serious illness. State investigators found that 152 (86 percent) of these were actually reported. Ninety-four (62 percent) were correctly sent to the manufacturer, and 29 (19 percent) were "over reported" by being sent to both FDA and the manufacturer. Twenty-nine were sent to FDA only; of these, 7 were incorrectly sent to FDA and 22 were correctly submitted to FDA because the manufacturer was not known. Overall, 123 (76 percent) of the reportable events were submitted properly.

State investigators also found that sixty-three of serious injury and illness reports (36 percent) were misclassified as "malfunction" reports.

Compliance Issues Based on FDA Inspections

CDRH requested that each of the 21 FDA district offices visit 2 user facilities before the final rule is issued. To date, the district offices have visited 17 facilities. They found 12 reportable occurrences, all of which occurred at 4 hospitals. The district offices concluded that facilities needed additional education about the requirements.

Summary

The MDR requirements of SMDA have the potential to improve public health. However, the evidence so far indicates that the reporting program has yet to approach this potential. Many facilities are unaware of SMDA and would benefit from additional educational efforts. It might be possible to maximize benefits and minimize costs by narrowing the scope of the regulation and targeting it specifically to the most likely problem areas. Ultimately, the success of MDR will depend upon the extent to which CDRH, manufacturers, and user facilities communicate. ❖

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