Medical Product Safety

U.S. Department of Health & Human Services • Public Health Service

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PROGRESS REVIEW

In the 14th in a series of assessments of *Healthy People 2010*, Acting Assistant Secretary for Health Cristina Beato chaired a focus area Progress Review on Medical Product Safety. Dr. Beato noted the great benefits conferred on American society by medical products, as well as the attendant, sometimes life-threatening risks to health that can arise from a product's side effects or misapplication. The impact on society from these deleterious consequences in terms of death, disability, and expenditures on health resources raises medical product safety to a serious public health issue. In conducting the review, Dr. Beato was assisted by staff of the Food and Drug Administration (FDA), which is the lead agency for this *Healthy People 2010* focus area. Also participating were representatives of other offices and agencies within the U.S. Department of Health and Human Services.

Mark McClellan, then Commissioner of Food and Drugs, provided the context for FDA's actions to achieve the targets of the six objectives for Medical Product Safety, each of which is addressed by two of the five elements of FDA's Strategic Action Plan (SAP). Incorporated within the SAP, Dr. McClellan noted, are a number of strategies that will promote progress toward achievement of these objectives, including (1) enhancement of the ability to identify risks through partnerships with healthcare systems and Federal organizations, thereby permitting FDA to link medical records and public health monitoring systems to identify adverse therapeutic events; (2) integration of information technology as a strategic tool; (3) partnering with other agencies and the private sector to improve the quality of information given to patients about medications; (4) establishment of an agency-wide infrastructure to communicate information about risks; and (5) development of guidelines for industry on the content of information about medical products.

The complete text for the Medical Product Safety focus area of *Healthy People 2010* is available at **www.healthypeople.gov/document/html/volume2/17medical.htm**. The meeting agenda, data presentation (tables and charts), and other materials for the Progress Review can be found at **www.cdc.gov/nchs/about/otheract/hpdata2010/focusareas/fa17-mps.htm**.

Data Trends

In opening his presentation on the status of objectives in this *Healthy People 2010* focus area, Edward Sondik, Director of the National Center for Health Statistics, outlined the burden imposed on American society by the misuse of medical products and services. According to the 1999 Institute of Medicine report *To Err is Human: Building a Safer Health System*, adverse medical events (AMEs) cause an estimated 44,000 to 98,000 deaths annually at an estimated national cost of $36.7 to $50 billion. Of all AMEs, medication error accounts for an estimated 7,000 deaths annually, with 2 out of 100 admittees to healthcare facilities experiencing preventable adverse drug events (ADEs). The average increased hospital cost of preventable ADEs is about $4,700 per admission or $2 billion nationwide. The number of visits to hospital emergency departments because of AMEs increased from less than 800,000 in 1992 to more than 1.4 million in 2001.

Although complete tracking data are not yet available for developmental objectives 17-1, 17-2, 17-3, and 17-4, partial data suggest some trends. The proportion of children's and general medical surgical hospitals that were linked in integrated systems to monitor and report AMEs associated with medical therapies decreased from 81.6 percent in 1998 to 77.4 percent in 2001 (Obj. 17-1a). Electronic medical records were used by 19 percent of healthcare organizations in 2003, compared with 12 percent in 2000. In 2001, 33 percent of pharmacists in managed care and integrated health systems used such records, compared with 31 percent in 1999 (Obj. 17-2a). Linked, automated prescription systems were in use by pharmacists and other dispensers in 4.3 percent of children's and general medical surgical hospitals in 2001. The percentage varied by facility size from 1.1 percent of facilities having 50 to 99 beds to 20.4 percent of those with 400 or more beds (Obj. 17-2b). In 2001, 74 percent of patients received information from pharmacies that met guidelines for usefulness when their new prescriptions were dispensed, the same proportion as in 1998 (Obj. 17-4).

With respect to the measurable objectives in the focus area, 24 percent of patients in 2000 received oral counseling from prescribers on appropriate use and potential risks of medications, representing no change from 1998 (Obj. 17-5a). The proportion of patients receiving such counseling from pharmacists declined from 14 percent in 1998 to 12 percent in 2000 (Obj. 17-5b). The 2010 target is for 95 percent of patients to be in receipt of oral counseling from both prescribers and pharmacists. From 1998 to 2001, the proportion of persons 18 years of age and older who donated blood increased from 5.5 percent to 6.2 percent. Of four age groups, 18- to 24-year-olds gave blood in 2001 at a rate slightly exceeding the 2010 target of 8 percent of adults, compared with less than 2 percent of those aged 65 and older. Whites gave blood at a rate of 7 percent, which was at least twice the rates for blacks, Hispanics, and Asians. Years of education completed had a positive effect on blood donation rates: persons aged 25 years and older who had at least some college gave blood at a rate of 7.9 percent, compared with 1.8 percent of those who had not completed high school (Obj. 17-6).

Key Challenges and Current Strategies

Participants in the review identified a number of obstacles to achieving the objectives and discussed activities under way to meet these challenges, including the following:

- FDA has proposed a universal bar coding system for prescription medicines and blood products, which is expected to reduce the rate of medication errors.
- MedWatch, the FDA Safety Information and Adverse Event Reporting Program, serves both healthcare professionals and the public by providing timely clinical information about safety issues involving medical products. The MedWatch e-list disseminates safety alerts, recalls, withdrawals, and important labeling changes, some of which can be triggered by input to the program from practitioners and consumers who report serious problems they suspect are associated with medical products they prescribe, dispense, or use.
- The Electronic Common Technical Document (eCTD), now being adopted, will serve as an interface for industry to transfer information fulfilling regulatory requirements to FDA.
- In cooperation with the National Library of Medicine, FDA is setting up DailyMed, a computerized repository that stores up-to-date and comprehensive medication information.
- Currently operational in 180 hospitals, the Medical Product Surveillance Network (MedSUN) is an FDA pilot program to collect data on medical device adverse events.
- Available data have not established that oral counseling of patients about medications is more effective than written instructions. Indeed,

the advent of new avenues for acquisition of medications (e.g., by mail order or by purchase through the Internet) has highlighted the importance of accurate written information.

- Transfusion therapy associated with improvements in health care, such as transplantation and cancer chemotherapy, increases the demand for blood by about 3 to 4 percent a year. At the same time, the number of individuals who meet donor eligibility requirements tends to be reduced by protective measures to decrease the risk of known or potential transfusion-transmitted infections, such as HIV, hepatitis, SARS, West Nile virus, and dengue virus.
- Opportunities for blood drives in the workplace have been shrinking as the collection process has become more complex and as many downsized companies have become less willing to permit workers to be away from their jobs for the time required for donation. An additional cause of losses to the blood donor base is the aging of the donor population, because this affects repeat donors, who make up 80 percent of the donor pool and cannot easily be replaced.
- FDA has pilot-tested TRANS-Net, a Web-based monitoring system that, when fully operational, will have the capability for identifying local and regional shortages in the nationwide supply of blood and blood reagents, both in times of seasonal peak demands and in times of crisis.
- In 2003, virtually all prospective donors who carried the West Nile virus were screened out of blood donation programs after accelerated efforts had produced a diagnostic test in 8 months.

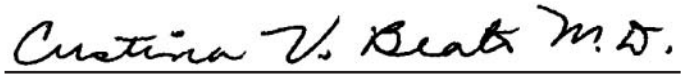
Approaches for Consideration

During the review, the following suggestions were made for steps to bring about further progress toward achievement of the objectives for medical product safety:

- Accelerate development of uniform nationwide standards for bar coding of prescriptions for medical products.
- Explore ways to lower the cost of computerization and electronic interchange of medical records, which constitutes a large impediment to greater deployment of electronic record-keeping.
- Expand outreach into the private sector as part of current partnering arrangements for electronically collecting data on adverse therapeutic events.
- Seek to establish and implement nationwide standards for capturing data on adverse medical events.
- Strengthen the infrastructure for preserving supplies of blood and blood products for longer periods of time.
- To stimulate greater public participation in blood drives, explore ways to increase donation by affinity groups, which accounts in part for the greater proportion of college students who regularly give blood.

Contacts for information about *Healthy People 2010* focus area 17—Medical Product Safety:

- Food and Drug Administration—Leslie Wheelock, wheelockl@cder.fda.gov
- Office of Disease Prevention and Health Promotion (coordinator of the Progress Reviews)—Nancy Stanisic (liaison to the focus area 17 workgroup), nstanisic@osophs.dhhs.gov



Cristina V. Beato, M.D.
Acting Assistant Secretary for Health