Medical Product Safety

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

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PROGRESS REVIEW

In the 14th session in the second series of assessments of *Healthy People 2010,* Anand Parekh, Acting Deputy Assistant Secretary for Health (Science and Medicine), chaired a focus area Progress Review on Medical Product Safety. He was assisted by staff of the lead agency for this *Healthy People 2010* focus area, the Food and Drug Administration (FDA). Also participating in the review were representatives from other U.S. Department of Health and Human Services (HHS) offices and agencies.

The complete November 2000 text for the Medical Product Safety focus area of *Healthy People 2010* is available online at **www.healthypeople.gov/document/html/volume2/17medical.htm**. Revisions to the focus area chapter that were made after the January 2005 Midcourse Review are available at **www.healthypeople.gov/data/midcourse/html/focusareas/fa17toc.htm**. Additional data used in the Progress Review for this focus area's objectives and their detailed definitions can be accessed at **wonder.cdc.gov/data2010**. For comparison with the current state of the focus area, the report on the first-round Progress Review (held on November 5, 2003) is archived at **www.healthypeople.gov/data/2010prog/focus17/2003fa17.htm**. The meeting agenda, tabulated data for all focus area objectives, charts, and other materials used in the Progress Review can be found at a companion site maintained by the Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS): **www.cdc.gov/nchs/about/otheract/hpdata2010/focusareas/fa17-mps2.htm**.

Data Trends

In his overview of data for the focus area, Richard Klein of NCHS addressed in particular the societal burden of adverse medical events (AMEs), defined as injuries due to medical management. In the United States, AMEs impose an average cost of $58,766 per event, or $113,280 per event if negligence is involved. Annually, AMEs result in 10.9 million ambulatory care visits, including 1.8 million visits to hospital emergency departments (EDs). Also, at least 1.5 million preventable adverse drug events (ADEs) occur annually in the United States. The total annual cost of in-hospital ADEs is at least $3.5 billion, which includes an average of $8,750 per patient stay. Among persons aged 65 years and older, ED visits for AMEs have been increasing. In 1992, ED visits occurred at a rate of 5 per 1,000 population among that age group. In 2005, the rate increased to more than 14 per 1,000. Those ED visits associated with medical or surgical complications increased fourfold between 1992 and 2005. In a 2004 report by the HHS Agency for Healthcare Research and Quality (AHRQ), the agency stated that persons aged 65 and older represented 34 percent of AHRQ's Nationwide Inpatient Sample but made up 56 percent of the sample that suffered an adverse drug-related event (an unexpected or negative

effect of a drug properly administered in therapeutic or prophylactic dosage). This age group made up 25 percent of the population that were affected by misadministration of a drug or an accidental drug overdose; 35 percent were in the age group 18 to 44 years, who accounted for 27 percent of the sample patient population. Of the nine focus area objectives and subobjectives that were retained after the 2005 Midcourse Review, two are improving, three have met or exceeded their targets, three show little or no change from the baseline, and one lacks data for tracking purposes. Mr. Klein then examined in greater detail the objectives highlighted during the Progress Review.

(Obj. 17-1a): In 2003, 84 percent of healthcare organizations were monitoring and analyzing adverse events associated with medical therapies within their systems, compared with 82 percent in 1998. The target is 90 percent.

(Obj. 17-2a): In 2000, 12 percent of healthcare providers in healthcare organizations were using electronic medical records, a proportion that increased to 32 percent in 2007, thus surpassing the target of 18 percent.

(Obj. 17-2c): In 2001, 4 percent of general and children's hospitals were using computerized prescriber order entry (CPOE), a proportion that increased to 9 percent in 2006, surpassing the target of 6 percent. In general, the proportion of general and children's hospitals that use CPOE increases with the size of the hospital as measured by number of patient beds. In 2006, about 6 percent of general and children's hospitals with fewer than 50 staffed beds were using CPOE, compared with almost 23 percent of those with more than 400 beds.

(Obj. 17-2d): In 2003, 5 percent of urban acute care facilities were using CPOE, a proportion that increased to 9.0 percent in 2006, surpassing the target of 7 percent.

(Objs. 17-5a, -5b): In 1998, 24 percent of patients received verbal counseling about medications from prescribers, compared with 26 percent in 2004. The target is 95 percent. In 1998, 14 percent of patients received verbal counseling about medications from pharmacists, a proportion that decreased to 6 percent in 2004. The target is 95 percent.

(Obj. 17-6): In 2006, approximately 6 percent of the age-adjusted population aged 18 years and older donated blood, the same as in 1998. The target is 8 percent. In 2006, almost 9 percent of persons in the age range 18 to 24 years donated blood, compared with just over 2 percent of persons aged 65 years and older. Six percent of males were blood donors in 2006, compared with 5 percent of females. Among racial and ethnic groups for which reliable data are available, the proportions of blood donors in 2006 were as follows: Hispanic, 3 percent; non-Hispanic black, 3 percent; Asian, 4 percent; and non-Hispanic white, 7 percent. By level of education, the donor proportions among persons aged 25 years and older in 2006 were as follows: less than high school completion, 2 percent; high school graduate, 4 percent; and at least some college education, 7 percent. Three percent of persons with disabilities donated blood in 2006, compared with 6 percent of persons without disabilities.

Key Challenges and Current Strategies

In presentations that followed the data overview, the principal themes were introduced by Randall Lutter, FDA's Deputy Commissioner for Policy; Jay Epstein, Director, Office of Blood Research and Review in FDA's Center for Biologics Evaluation and Research; and Gerald DalPan, Director, Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research. Their statements and Progress Review briefing materials identified a number of barriers to achieving the objectives, as well as activities underway to meet these challenges, including the following:

Barriers

- Data from the HHS Centers for Medicare & Medicaid Services (CMS) showed that, on average, 25 percent of persons older than 65 were taking seven or more prescription drugs daily.
- The total number of reported AMEs has increased. However, it cannot be determined to what extent this increase may be due, in part, to a larger number of systems and venues facilitating an increase in reporting or to other factors, including the aging of the population and the increasing use of multiple drugs to treat chronic diseases among the elderly.
- Widespread adoption of integrated electronic technologies for reporting AMEs has been slowed by cost factors and the lack of uniform standards for collection, monitoring, and analysis of data.
- Improvements in health care employing transfusion-based therapy, such as transplantation and cancer chemotherapy, have increased the demand for blood. Although increased use of apheresis (separation and collection of specific blood components) has allowed for multicomponent collections from a single donor, this procedure can go only so far toward meeting blood supply demands.
- Protective measures to identify high-risk blood donors and prevent transfusion-transmitted infections, such as donor referrals for risk of malaria and variant Creutzfeldt Jacob disease, have had the side effect of reducing both the number of eligible donors and the number of available units for transfusion from among those collected.

Activities and Outcomes

- FDA's Medical Device Surveillance Network (MedSUN) pilot program to collect data on medical device adverse events has expanded to about 350 hospitals. Since the inception of the program, an average of 40 to 60 reports on adverse events have been collected per week. MedSUN is continuing to expand by creating a number of subnetworks targeted to specific devices or practice settings, including HeartNet (electrophysiology laboratories), KidNet (neonatal and pediatric intensive care units), and LabNet (hospital clinical laboratories).
- Through the Sentinel Initiative, FDA has engaged the private sector and academia in a national dialogue directed toward developing the data collection, risk identification, and analysis components of an integrated network for information on medical product safety. Pursuant to the October 2007 FDA Amendments Act, FDA is currently developing plans to adapt the information gathered in large, electronic, population-based data sets by these non-Federal organizations for use in post-marketing safety assessments.
- FDA has published a Final Guidance document for developing useful patient information and a rule that went into effect in June 2006 that changes the content and format of prescription drug labeling for physicians. The rule adds a requirement for

inclusion of a section called "Patient Counseling Information." A proposal to address issues related to the use of prescription drugs in pregnant women is also under discussion.

- FDA has signed Memoranda of Understanding with the Department of Veterans Affairs and the Department of Defense that provide for the sharing of data concerning AMEs and medical product safety in general.
- As of April 26, 2006, a unique bar code is now required on the labels for most prescription drugs, biologics, and non-prescription products used in hospital settings, as well as for blood and blood components intended for transfusion. FDA estimates that this regulatory action will help prevent approximately 500,000 adverse events from medication and transfusion errors over the 20-year period following imposition of this rule.
- MedWatch, FDA's Safety Information and Adverse Event Reporting System, continues to extend its outreach, with more than 62,000 enrollees now receiving alerts through its listserv and other outlets. In 2007, MedWatch began an initiative to expand the number of healthcare partners and to encourage them to submit reports of adverse events, medication errors, and product problems and to assist FDA by furthering the public dissemination of FDA safety messages.
- Recent developments in the transfusion medicine field (for example, the rapid growth in the collection of double red blood cell units by apheresis) have led to improvements in the management of available blood inventories and increased the value of higher frequency donation by current donors.
- Over the past few years, FDA has approved new or improved tests to detect the presence of the infectious agents for West Nile virus, SARS, HIV, hepatitis B and C, and Chagas disease in prospective blood donors.
- FDA's TRANS-Net is a Web-based monitoring system that, when fully operational, will have the capability of identifying seasonal and emergency-related local and regional blood supply shortages.

Approaches for Consideration

Participants in the Progress Review made the following suggestions for public health professionals and policymakers to consider as steps to enable further progress toward achievement of the objectives for Medical Product Safety:

- Explore options for providing financial incentives for pharmacists to counsel their customers about the medications they have been prescribed.
- To help decrease medication errors, make written information about medications more readily accessible to patients.
- Increase efforts to expand the reach of public information activities about proper use of medications, especially among non-English speakers and less than fully health literate English speakers.
- Enhance public outreach activities concerned with use of medications by making greater use of prior testing to determine the effectiveness of particular activities among targeted population groups.
- Aim to put in place a monitoring system that would permit daily reporting on blood supplies nationwide.
- Explore alternative strategies for increasing blood supplies, such as encouraging more frequent donations by suitable donors.
- Seek ways to mitigate the factors that adversely affect the storage and viability of blood supplies.

- Expand collaboration between FDA and other HHS agencies, particularly CMS, AHRQ, and the Indian Health Service, to ensure that the most advanced information technology is applied for the benefit of programs concerned with medical product safety.
- Give greater attention to the special difficulties and needs experienced by smaller businesses in attempting to meet industry-wide quality standards pertaining to medical product safety.
- Consult with manufacturers of medical products in seeking ways to mitigate the burden of Federal regulatory activities.

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[Signed January 2, 2008]

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