Midcourse Review

HEALTHY PEOPLE 2010

Medical Product Safety 17

Lead Agency:

Food and Drug Administration

Contents

Goal: Ensure the safe and effective use of medical products.

Introduction*

The safe use of medical products can benefit all Americans by helping them live longer and healthier lives. Medical product safety can be increased by decreasing the number of adverse events associated with the products, increasing consumer understanding of how to use drugs and medical devices safely and effectively, and ensuring that the Nation has an adequate supply of safe blood for transfusions.

The objectives of the Medical Product Safety focus area contribute to the Healthy People 2010 overarching goals to increase quality and years of healthy life and eliminate health disparities. The objective for monitoring adverse events associated with therapies showed progress toward its target. Increased surveillance and reporting of defective equipment and medications and unexpected side effects of therapies enhance quality of life by reducing the number of persons exposed to inadvertent harm. Such monitoring keeps quality products on the market while minimizing the threat of injury from products intended to heal.

Another objective addresses the need to increase the use of information technology within health care organizations. Three of the related subobjectives concerning electronic medical records and computerized order entry use made progress toward their targets. These subobjectives reduce health disparities by improving continuity and standardization of care. Having ready access to accurate and up-to-date medical information about a person can help prevent diagnostic and treatment errors by physicians unfamiliar with the patient's history. When adverse events are avoided, individual health is improved.

Three objectives address better product safety through ensuring the delivery of accurate health information. Education about appropriate product use is central to improving quality and length of life, especially in persons requiring chronic medical therapies, by allowing for maximum benefit to be derived from medical products. Further, communicating the product information needed for appropriate use so it is understandable, even to audiences with limited health literacy, can help to eliminate health disparities across the Nation. These objectives seek to improve provider and pharmacy communication with patients about medicines to maximize patients' understanding of their medicines and therapy.

Having a blood supply that is both safe and adequate to meet ongoing and emergency needs can directly contribute to the quality and length of life of all Americans in need of transfusions. An adequate blood supply assures the continued survival of, for example, patients with bleeding disorders and people needing transfusions to address life-threatening blood loss due to acute injuries. However, blood availability is restricted by, among other factors, the number of donors who qualify to give blood. One objective seeks to increase the pool of qualifying donors so that all persons will have access to blood when needed.

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* Unless otherwise noted, data referenced in this focus area come from Healthy People 2010 and can be located at http://wonder.cdc.gov/data2010. See the section on DATA2010 in the Technical Appendix for more information.

Modifications to Objectives and Subobjectives

The following discussion highlights the modifications, including changes, additions, and deletions, to this focus area's objectives and subobjectives as a result of the midcourse review.

Three of the six medical product safety objectives were modified. The objective for monitoring adverse events (17-1a) was reworded to better reflect the identified data source. Linked, automated information systems (17-2) was reworded for a similar reason and divided into four subobjectives for clarity:

- Health care providers in health care organizations using electronic medical records (17-2a).
- Pharmacists in managed care and integrated health systems using electronic medical records (17-2b).
- General and children's hospitals using computerized prescriber order entry (17-2c).
- Urban acute care facilities using computerized prescriber order entry (17-2d).

This objective regarding the use of information technology (17-2) and its four subobjectives (17-2a through d) became measurable as nationally representative data sources were identified. Given the importance of moving toward linked, automated systems to facilitate better health care, the targets were set to a 50 percent increase over the baseline for each subobjective.

One objective to increase the receipt of useful information about prescriptions from pharmacies (17-4) remained developmental, while the data obtained from a national study are being reanalyzed to provide a valid baseline measure.

As stated in *Healthy People 2010*: "Most developmental objectives have a potential data source with a reasonable expectation of data points by the year 2004 to facilitate setting 2010 targets in the mid-decade review. Developmental objectives with no baseline at the midcourse will be dropped." Accordingly, at the midcourse review, both the developmental subobjective for monitoring and analyzing adverse events associated with medical devices (17-1b) and the objective for provider review of medications taken by patients (17-3) were deleted due to lack of nationally representative data sources. However, the U.S. Department of Health and Human Services (HHS) and the agencies that serve as the leads for the Healthy People 2010 initiative will consider ways to ensure that these public health issues retain prominence despite their current lack of data.

Progress Toward Healthy People 2010 Targets

The following discussion highlights objectives that met or exceeded their 2010 targets; moved toward the targets, demonstrated no change, or moved away from the targets; and those that lacked data to assess progress. Progress is illustrated in the Progress Quotient bar chart (see Figure 17-1), which displays the percent of targeted change achieved for objectives and subobjectives with sufficient data to assess progress.

Progress was made in the Medical Product Safety focus area. Two subobjectives met or exceeded their targets (17-2a and c). Two subobjectives made progress toward their targets (17-1a and 17-2b). One objective and one subobjective showed no movement toward or away from their targets (17-6 and 17-5a), and one subobjective moved away from its target (17-5b). Trends could not be assessed for one objective and one subobjective at the time of the midcourse review (17-4 and 17-2d).

Objectives that met or exceeded their targets. Two subobjectives met their 2010 targets. The proportion of providers in health care organizations using electronic medical records (17-2a) increased from 12 percent in 2000 to 19 percent in 2004, surpassing its target. The proportion of general and children's hospitals using computerized prescriber order entry (17-2c) increased from 4 percent in 2001 to 6 percent in 2003, achieving the target.

Achieving and moving beyond these targets involves the entire health care system. Practices such as using electronic medical records and computerized prescriber order entry, if adopted, can enhance the quality of care by reducing potential errors.[1, 2] Information technology use in health care organizations is linked to financial resources. Accordingly, influencing organizations to allocate resources to implement information technology is a challenge. Large organizations, however, are beginning to implement electronic medical records and computerized prescriber order entry systems. For example, the U.S. Department of Veterans Affairs intends to have all of its acute care facilities equipped with bar-coding technology. However, financial and other incentives are probably needed to address smaller organizations, ambulatory settings, and physician offices.

The Food and Drug Administration (FDA) is encouraging health care providers to adopt information technologies and is working with the National Library of Medicine to establish a publicly accessible electronic repository of current prescription drug labeling. This repository can be used by decision support systems throughout the health care community to inform prescribing decisions.

Other activities encompass collaboration among organizations to establish standards for electronic recording, submission, and dissemination of approved product labeling to improve use by providers and patients.[1] In addition, standard vocabularies and taxonomies to facilitate the seamless exchange of electronic data submissions between different operating systems are being developed by FDA, the National Cancer Institute, the U.S. Pharmacopeial Convention, and others. These collaborations offer opportunities for outside groups to contribute to developing the information technology standards necessary for more universal data exchange.

Objectives that moved toward their targets. One objective and one subobjective moved toward their targets. Pharmacists using electronic medical records (17-2b) achieved 13 percent of the targeted change between 1999 and 2001 (see earlier discussion). The proportion of health care organizations monitoring and analyzing adverse events associated with their medical therapies (17-1a) increased between 1998 and 2003, achieving 25 percent of the targeted change.

FDA's approval process includes a rigorous review of science-based clinical trials to identify clinically important safety issues in the population studied. However, the more rarely occurring safety issues may only become evident with wider use. To identify early signals of patient harm, FDA relies on required reporting by product manufacturers and on health care providers' voluntarily reporting suspected serious adverse events. To move the subobjective for monitoring and analyzing adverse events (17-1a) toward its target, FDA, the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality are collaborating to broaden the ability

to capture adverse event and medication information. Collaborations such as Connecting for Health[3] have been founded to facilitate automated data collection by devising tools for health information networks and by partnering to support development of health information exchange between different localities.

FDA also has programs to improve the safe use of regulated products by facilitating reporting of serious adverse events related to the use of these products to FDA. MedWatch,[4] FDA's Safety Information and Adverse Event Reporting Program, is one such program. MedWatch also disseminates updated drug safety information to inform providers of the most recent safety information. Furthermore, FDA's Medical Device Safety Network (MedSun) program is intended to improve the safe use of medical devices by the following actions:

- Reducing barriers to reporting medical device-related adverse events by device-user facilities (such as hospitals and outpatient clinics).
- Training device-user facilities to recognize and report adverse events.
- Sharing information between device-user facilities about the identification, understanding, and resolution of device problems.

Other opportunities for meeting the target include taking advantage of adverse event recording and reporting systems that are linked between organizations, including FDA.

Preventing adverse events before they occur is the ideal solution. Accordingly, FDA is working on several projects to help identify the potential for an adverse event before it happens to a patient. For example, FDA continues to implement postmarketing risk management programs with active surveillance and is furthering its efforts to reduce medication errors by implementing a universal bar-coding system for prescription medicines and blood products.

Objectives that demonstrated no change. One objective and one subobjective remained static. No change was noted for the receipt of oral counseling about medications from prescribers (17-5a). Between 1998 and 2000, 24 percent of patients received counseling about their new prescription medicines.

National organizations are encouraging prescriber counseling with consumer-focused campaigns. Examples are the Partnership for Clear Health Communication's "Ask Me 3"[5] and the National Council on Patient Information and Education's "Talk About Prescriptions."[6] FDA participates in forums designed to influence health care professionals' behavior and emphasize the importance of counseling. FDA has finalized changes to prescription drug labeling for health care professionals. These revisions are expected to facilitate oral counseling by making clearer what information FDA and product manufacturers believe patients should be told.

Blood donations (17-6) also showed no change relative to the target. Between 1998 and 2003, the overall proportion of people in the United States who donated blood each year remained static at 6 percent.

Donor recruitment and retention are two major challenges in meeting the target. In the past, recruitment has not fulfilled demands. Blood and blood components have a limited shelf life and must be continually replenished. Further transfusion-transmitted diseases and various exclusionary behaviors have decreased the pool of eligible donors.

Through FDA, HHS is working to support industry efforts to recruit and retain new blood donors. The HHS Advisory Committee on Blood Safety and Availability works to ensure an adequate blood supply.

FDA provides guidance on donor incentives and participates in workshops[7, 8, 9] on donor incentives, donor suitability, and best practices in donor recruitment. In addition, FDA has actively worked with the blood community to improve the donation process by developing improved, tested donor-screening materials and computer-assisted donor interviews.

Objectives that moved away from their targets. One subobjective, receipt of oral counseling about medications by pharmacists (17-5b), moved away from its target. In 2000, 12 percent of patients received oral counseling about their prescription medicines from their pharmacists, compared with 14 percent who received such counseling during the baseline year of 1998.

Remaining challenges include the limited time and incentives for pharmacists to counsel patients. FDA has identified several opportunities for advancing this subobjective. These include collaborating with CMS in its oversight role for the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), as well as working with State pharmacy boards to encourage oral counseling.

Objectives that could not be assessed. As discussed previously, provider review of medications taken by patients (17-3) was deleted due to lack of an identifiable data source. Receipt of useful information about prescriptions (17-4) remained developmental. Although FDA sponsored the collection of national data in 2001 to measure the usefulness of written information about prescription drugs, a single valid baseline measure could not be established. Furthermore, overall usefulness varied depending on what medication information was being assessed.

According to Public Law 104-180, FDA will not require the distribution of written medication information uniform in content and format as long as, by 2006, 95 percent of patients getting new prescriptions also get useful written information about the dispensed medicine. The specific requirements defining useful written information are detailed in a long-range action plan agreed on by a consortium of stakeholders and accepted by the Secretary of HHS.[10] FDA is working with various private-sector stakeholders to meet this target, including recent guidance to the publishers of medication information.[11]

The use of computerized prescriber order entry by urban acute care facilities (17-2d) became measurable on the basis of data acquired from the Leapfrog Group. The baseline data from 2003 showed that 5 percent of urban acute care facilities used computerized prescriber order entry. The second evaluation occurred in 2005, and data analysis is under way.

Progress Toward Elimination of Health Disparities

The following discussion highlights progress toward the elimination of health disparities. The disparities are illustrated in the Disparities Table (see Figure 17-2), which displays information about disparities among select populations for which data were available for assessment.

In this focus area, only the blood donations objective (17-6) had population-based data available for assessing progress toward the elimination of health disparities. As the Disparities Table shows, no significant disparities existed within any of the characteristics examined (race and ethnicity, gender, education level, or disability status). Studies of donor behavior and motivation[12, 13] suggest that education about donation, access to donation facilities, and targeted recruitment practices all influence donation likelihood.

Opportunities and Challenges

Medicines, vaccines, medical devices, and blood products are central to the quality of health care delivery and account for an increasing portion of every medical dollar spent.[14, 15] Efforts to ensure the safe use of these products are an important component in improving the overall quality of health care. Several medical product safety objectives focus on the development and use of technologies in the health care system to enhance patient safety. Meeting these objectives and continued progress in this area will require additional investments in the private sector and strengthened private-public partnerships.[3]

Three Institute of Medicine reports focusing on the role of health care informatics and information infrastructure in preventing medication errors and adverse events have been issued over the past decade: *To Err Is Human—Building a Safer Health System,*[16] *Crossing the Quality Chasm: A New Health System for the 21st Century,*[17] and *Preventing Medication Errors.*[2] The reports highlight the need to improve the communication of essential information to health care providers and consumers. Having health care informatic systems in place can facilitate the delivery of quality health care and improve patient awareness.[16] Developing common data standards and investing in the development, testing, and implementation of the infrastructure needed to support electronic medical records and computerized order entry will continue to present both challenges and opportunities.

However, the contributions of electronic systems to product safety are limited. Effective interactions and communication between health care providers and patients remain essential to the safe and effective use of medical products. Environments that encourage and sustain personal interactions between health care providers and patients are critical to continued improvements in medical product safety.

Emerging Issues

The expanded use of health information technology is an important focus for improving medical product safety. HHS is coordinating across the Federal executive branch the development of a nationwide interoperable national health information technology infrastructure that would include electronic medical records, digital prescribing programs, and electronic decision-support programs.[14] The system is intended to improve health care quality and patient safety by the following:

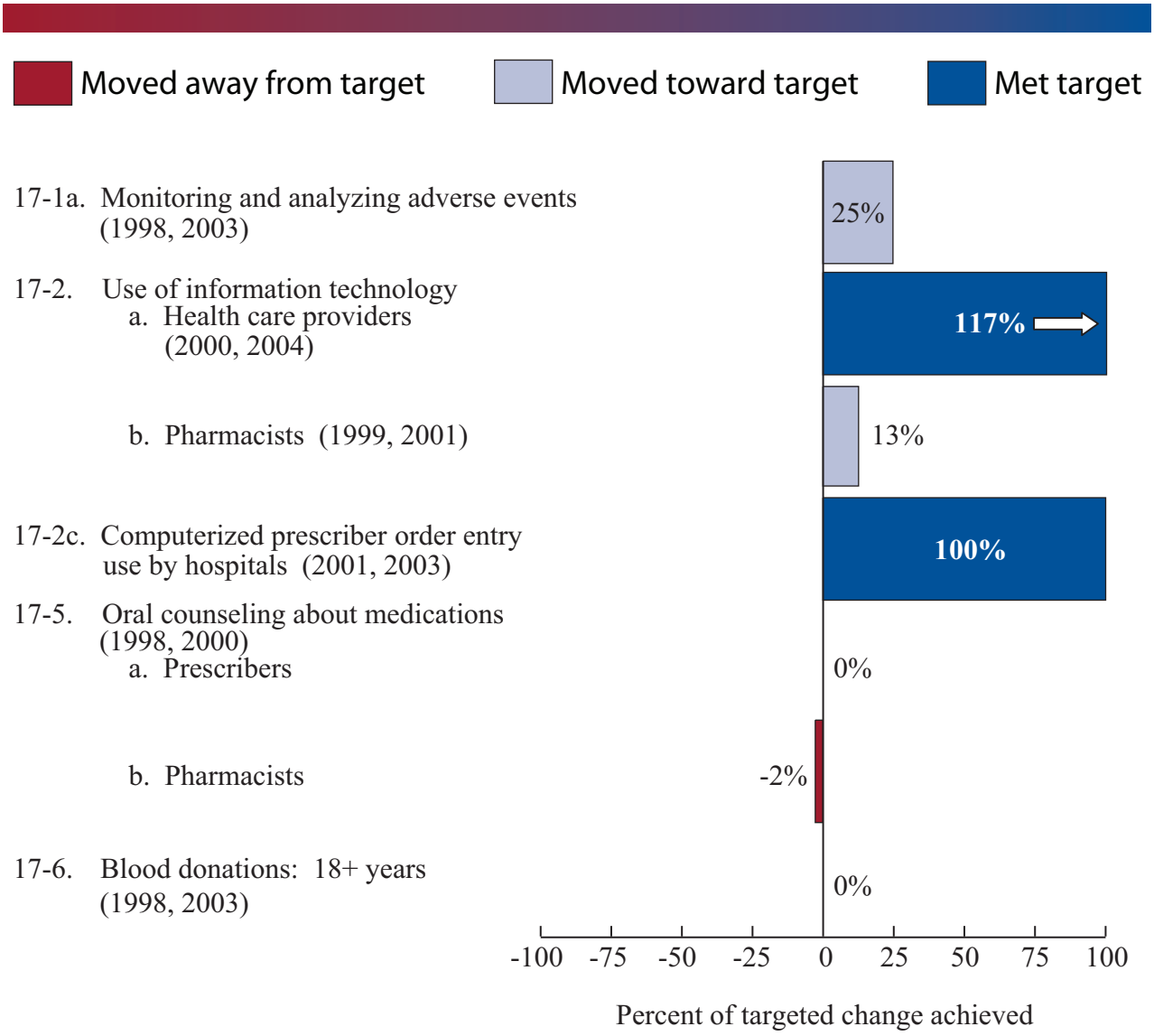
- Reducing medical errors.
- Improving communication to better inform and empower consumers.
- Enhancing the capacity of postmarket surveillance to expeditiously detect previously unknown problems with medical products.

Within the realm of blood transfusions, FDA has established protective measures to reduce the risk of transfusion-transmitted infections. However, these measures also have the effect of reducing the number of eligible donors. FDA's Blood Product Advisory Committee assesses the possible impact on the blood supply of all new interventions implemented in response to emerging blood safety threats. A number of emerging risks have recently resulted in actions that may affect blood donations. These actions include measures to reduce the risks of infection with the bloodborne variant of Creutzfeldt-Jakob disease (vCJD), the human form of "Mad Cow Disease"; severe acute respiratory syndrome (SARS); and West Nile virus. In particular, FDA's recommendation to defer potential donors because of specific dietary practices related to vCJD risk has resulted in an estimated 7 percent loss of otherwise eligible donors since 1999.[18]

However, FDA also regularly reviews new scientific information that would support reentering donors who had previously been deferred because of a potential infectious disease risk. As a result, persons who tested falsely positive and have shown no signs or symptoms of infection with HIV or hepatitis C have been readmitted into the pool of approved donors.

In summary, although progress has been made toward implementing linked, automated information systems, continuing efforts are necessary to reach the targets of the objectives and subobjectives in the medical product safety focus area. The analyses of the data concerning patients' receipt of useful written information from pharmacies must be completed so that a single baseline measure is available to assess progress. Continued and expanded collaborative efforts to encourage blood donation and expanded patient counseling about prescription medicines are needed.

Figure 17-1. Progress Quotient Chart for Focus Area 17: Medical Product Safety



Notes: Tracking data for objectives 17-2d and 17-4 are unavailable. Objectives 17-1b and 17-3 were deleted at the midcourse.

Years in parentheses represent the baseline data year and the most recent data year used to compute the percent of the Healthy People 2010 target achieved.

$$\text{Percent of targeted change achieved} = \left(\frac{\text{Most recent value} - \text{baseline value}}{\text{Year 2010 target} - \text{baseline value}}\right) \times 100$$

Figure 17-2. Disparities Table for Focus Area 17: Medical Product Safety

Disparities from the best group rate for each characteristic at the most recent data point and changes in disparity from the baseline to the most recent data point.

Population-based objectives	Characteristics: Race and ethnicity: American Indian or Alaska Native	Asian	Native Hawaiian or other Pacific Islander	Two or more races	Hispanic or Latino	Black non-Hispanic	White non-Hispanic	**Summary index**	Gender: Female	Male	Education: Less than high school	High school graduate	At least some college	**Summary index**	Disability: Persons with disabilities	Persons without disabilities
17-6. Blood donations: 18+ years (1998, 2003) *[1]							B			B			B			B

Notes: Data for objectives 17-1a, 17-2a through d, 17-4, and 17-5a and b are unavailable or not applicable. Objectives 17-1b and 17-3 were deleted at the midcourse.

Years in parentheses represent the baseline data year and the most recent data year (if available).

Disparity from the best group rate is defined as the percent difference between the best group rate and each of the other group rates for a characteristic (for example, race and ethnicity). The summary index is the average of these percent differences for a characteristic. Change in disparity is estimated by subtracting the disparity at baseline from the disparity at the most recent data point. Change in the summary index is estimated by subtracting the summary index at baseline from the summary index at the most recent data point. See Technical Appendix for more information.

The **best group rate** at the most recent data point.

- B — The group with the best rate for specified characteristic.
- b — Most favorable group rate for specified characteristic, but reliability criterion not met.
- Best group rate reliability criterion not met.

Disparity from the best group rate at the most recent data point.

Percent difference from the best group rate

- Less than 10 percent or not statistically significant
- 10-49 percent
- 50-99 percent
- 100 percent or more

Changes in disparity over time are shown when the change is greater than or equal to 10 percentage points and statistically significant, or when the change is greater than or equal to 10 percentage points and estimates of variability were not available.

Increase in disparity (percentage points)

- ↑ 10-49
- ↑↑ 50-99
- ↑ ↑↑ 100 or more

Decrease in disparity (percentage points)

- ↓ 10-49
- ↓↓ 50-99
- ↓↓ ↓ 100 or more

Availability of data.

- Data not available.
- Characteristic not selected for this objective.

* The variability of best group rates was assessed, and disparities of ≥ 10% are statistically significant at the 0.05 level. Changes in disparity over time, noted with arrows, are statistically significant at the 0.05 level. See Technical Appendix.

[1] Baseline data by race and ethnicity are for 1999.

Objectives and Subobjectives for Focus Area 17: Medical Product Safety

Goal: Ensure the safe and effective use of medical products.

As a result of the Healthy People 2010 Midcourse Review, changes were made to the Healthy People 2010 objectives and subobjectives. These changes are specific to the following situations:

- Changes in the wording of an objective to more accurately describe what is being measured.
- Changes to reflect a different data source or new science.
- Changes resulting from the establishment of a baseline and a target (that is, when a formerly developmental objective or subobjective became measurable).
- Deletion of an objective or subobjective that lacked a data source.
- Correction of errors and omissions in *Healthy People 2010.*

Revised baselines and targets for measurable objectives and subobjectives do not fall into any of the above categories and, thus, are not considered a midcourse review change.[1]

When changes were made to an objective, three sections are displayed:

1. In the Original Objective section, the objective as published in *Healthy People 2010* in 2000 is shown.
2. In the Objective With Revisions section, strikethrough indicates text deleted, and underlining is used to show new text.
3. In the Revised Objective section, the objective appears as revised as a result of the midcourse review.

Details of the objectives and subobjectives in this focus area, including any changes made at the midcourse, appear on the following pages.

[1] See Technical Appendix for more information on baseline and target revisions.

ORIGINAL OBJECTIVE

17-1. (Developmental) Increase the proportion of health care organizations that are linked in an integrated system that monitors and reports adverse events.

17-1a. Health care organizations that are linked in an integrated system that monitors and reports adverse events associated with medical therapies.

17-1b. Health care organizations that are linked in an integrated system that monitors and reports adverse events associated with medical devices.

Potential data sources: Office of Postmarketing Drug Risk Assessment (OPDRA), MEDWATCH, and Manufacturer and User Device Experience (MAUDE) Database, FDA.

OBJECTIVE WITH REVISIONS (Including subobjective deleted)

17-1. ~~(Developmental)~~ Increase the proportion of health care organizations that ~~are linked in an integrated system that monitors and reports adverse events~~ are monitoring and analyzing adverse events associated with medical therapies within their systems.

17-1a.* Health care organizations that are ~~linked in an integrated system that monitors and reports~~ monitoring and analyzing adverse events associated with medical therapies within their systems.

~~**17-1b.**~~ *(Subobjective deleted due to lack of data source)* ~~Health care organizations that are linked in an integrated system that monitors and reports adverse events associated with medical devices.~~

Target: 90 percent.

Baseline: 82 percent of health care organizations were monitoring and analyzing adverse events associated with medical therapies within their systems in 1998.

Target setting method: 10 percent improvement.

~~**Potential d**~~**Data sources:** National Survey of Pharmacy Practice in Acute Care Settings, ~~Office of Postmarketing Drug Risk Assessment (OPDRA), MedWatch, and Manufacturer and User Device Experience (MAUDE) Database, FDA~~American Society of Health System Pharmacists (ASHP).

* For data control purposes, subobjectives are not renumbered.

REVISED OBJECTIVE

17-1. Increase the proportion of health care organizations that are monitoring and analyzing adverse events associated with medical therapies within their systems.

REVISED OBJECTIVE *(continued)*

17-1a.* Health care organizations that are monitoring and analyzing adverse events associated with medical therapies within their systems.

Target: 90 percent.

Baseline: 82 percent of health care organizations were monitoring and analyzing adverse events associated with medical therapies within their systems in 1998.

Target setting method: 10 percent improvement.

Data source: National Survey of Pharmacy Practice in Acute Care Settings, American Society of Health System Pharmacists (ASHP).

* For data control purposes, subobjectives are not renumbered.

ORIGINAL OBJECTIVE

17-2. (Developmental) Increase the use of linked, automated systems to share information.

17-2a. By health care professionals in hospitals and comprehensive, integrated health care systems.

17-2b. By pharmacists and other dispensers.

Potential data sources: National Survey of Pharmacy Practice in Acute Care Settings and Survey of Managed Care and Ambulatory Care Pharmacy Practice in Integrated Health Systems, American Society of Hospital Pharmacists (ASHP).

OBJECTIVE WITH REVISIONS

17-2. ~~(Developmental)~~ Increase the proportion of health care providers and organizations that are using~~use of linked, automated systems to share~~ information technology.

~~**17-2a.** By health care professionals in hospitals and comprehensive, integrated health care systems.~~

~~**17-2b.** By pharmacists and other dispensers.~~

Target and baseline:

Objective	Increase in Health Care Providers and Organizations Using Information Technology	2000 Baseline (unless noted)	2010 Target

OBJECTIVE WITH REVISIONS *(continued)*

		Percent	
17-2a.	Health care providers in health care organizations using electronic medical records	12	18
17-2b.	Pharmacists in managed care and integrated health systems using electronic medical records	31 (1999)	46
17-2c.	General and children's hospitals using computerized prescriber order entry	4.3 (2001)	6.0
17-2d.	Urban acute care facilities using computerized prescriber order entry	5.0 (2003)	7.0

Target setting method: 50 percent improvement.

~~Potential d~~Data sources: Healthcare Information and Management Systems Society (HIMSS); American Society of Health System Pharmacists (ASHP); The Leapfrog Group.~~National Survey of Pharmacy Practice in Acute Care Settings and Survey of Managed Care and Ambulatory Care Pharmacy Practice in Integrated Health Systems, American Society of Hospital Pharmacists (ASHP).~~

REVISED OBJECTIVE

17-2. Increase the proportion of health care providers and organizations that are using information technology.

Target and baseline:

Objective	Increase in Health Care Providers and Organizations Using Information Technology	2000 Baseline (unless noted)	2010 Target
		Percent	
17-2a.	Health care providers in health care organizations using electronic medical records	12	18
17-2b.	Pharmacists in managed care and integrated health systems using electronic medical records	31 (1999)	46
17-2c.	General and children's hospitals using computerized prescriber order entry	4.3 (2001)	6.0
17-2d.	Urban acute care facilities using computerized prescriber order entry	5.0 (2003)	7.0

Target setting method: 50 percent improvement.

REVISED OBJECTIVE *(continued)*

Data sources: Healthcare Information and Management Systems Society (HIMSS); American Society of Health System Pharmacists (ASHP); The Leapfrog Group.

OBJECTIVE DELETED

17-3. ***(Objective deleted due to lack of data source)*** **(Developmental) Increase the proportion of primary care providers, pharmacists, and other health care professionals who routinely review with their patients aged 65 years and older and patients with chronic illnesses or disabilities all new prescribed and over-the-counter medicines.**

NO CHANGE IN OBJECTIVE

17-4. (Developmental) Increase the proportion of patients receiving information that meets guidelines for usefulness when their new prescriptions are dispensed.

Potential data source: Patient/Consumer Medication Information Survey, FDA.

NO CHANGE IN OBJECTIVE

17-5. Increase the proportion of patients who receive verbal counseling from prescribers and pharmacists on the appropriate use and potential risks of medications.

Target and baseline:

Objective	Increase in Patients Receiving Oral Counseling From	1998 Baseline	2010 Target
		Percent	
17-5a.	Prescribers	24	95
17-5b.	Pharmacists	14	95

Target setting method: 296 percent improvement for prescribers and 579 percent improvement for pharmacists. (Better than the best will be used when data are available.)

Data source: National Survey of Prescription Drug Information Received by Consumers, FDA.

NO CHANGE IN OBJECTIVE
(Data updated and footnoted)

17-6. Increase the proportion of persons who donate blood, and in so doing ensure an adequate supply of safe blood.

Target: 8 percent.

Baseline: 6[1] percent of the total population aged 18 years and older donated blood in 1998.[1]

Target setting method: Better than the best.[2]

Data source: National Health Interview Survey (NHIS), CDC, NCHS.*

* The data source changed from the American Association of Blood Banks.
[1] Baseline and baseline year revised from 5 and 1994 after November 2000 publication.
[2] Target setting method revised from 60 percent improvement after November 2000 publication with the availability of population-level data.

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[6] National Council on Patient Information and Education. *Talk About Prescriptions*. More information available at www.talkaboutrx.org; accessed October 31, 2006.

[7] FDA Workshop. "Streamlining the Blood Donor History Questionnaire." October 2000. More information available at www.fda.gov/cber/minutes/bldqstn101600.htm; accessed October 31, 2006.

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[15] Agency for Healthcare Research and Quality. More information available at www.ahrq.gov/QUAL/rxtherapies/rxria.htm; accessed October 31, 2006.

[16] IOM. *To Err Is Human: Building a Safer Health System.* 2000. More information available at http://books.nap.edu/catalog/9728.html; accessed October 31, 2006.

[17] IOM. *Crossing the Quality Chasm: A New Health System for the 21st Century.* 2001. More information available at http://books.nap.edu/catalog/10027.html; accessed October 31, 2006.

[18] FDA. *Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products*. More information available at www.fda.gov/cber/gdlns/cjdvcjd.htm; accessed October 31, 2006.

Related Objectives From Other Focus Areas

1. Access to Quality Health Care
1-3. Counseling about health behaviors

3. Cancer
3-10. Provider counseling about cancer prevention
3-12. Colorectal cancer screening

4. Chronic Kidney Disease
4-8. Medical evaluation and treatment for persons with diabetes and chronic kidney disease

5. Diabetes
5-17. Self-blood-glucose-monitoring

7. Educational and Community-Based Programs
7-11. Culturally appropriate and linguistically competent community health promotion programs

9. Family Planning
9-3. Contraceptive use
9-4. Contraceptive failure
9-5. Emergency contraception

11. Health Communication
11-1. Households with Internet access
11-2. Health literacy
11-3. Research and evaluation of communication programs
11-4. Quality of Internet health information sources
11-5. Centers for excellence
11-6. Satisfaction with health care providers' communication skills

12. Heart Disease and Stroke
12-10. High blood pressure control
12-12. Blood pressure monitoring

13. HIV
13-6. Condom use

15. Injury and Violence Prevention
15-10. Emergency department surveillance systems
15-13. Deaths from unintentional injuries

23. Public Health Infrastructure

23-2. Public access to information and surveillance data
23-13. Use of geocoding in health data systems
23-14. Access to epidemiology services

24. Respiratory Diseases

24-6. Patient education