Medical Product Safety

CHAPTER 17

Lead Agency
Food and Drug Administration

Contents

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

The objectives in this chapter track the use of electronic medical records and prescription services, patient receipt of counseling about prescriptions, and availability of surveillance systems to monitor adverse drug reactions.

All Healthy People tracking data quoted in this chapter, along with technical information and Operational Definitions for each objective, can be found in the Healthy People 2010 database, DATA2010, available from http://wonder.cdc.gov/data1010/.

More information about this Focus Area can be found in the following publications:

- *Healthy People 2010: Understanding and Improving Health*, available from http://www.healthypeople.gov/2010/Document/tableofcontents.htm#under.
- *Healthy People 2010 Midcourse Review*, available from http://www.healthypeople.gov/2010/data/midcourse/html/default.htm#FocusAreas.

Highlights

- Some progress was achieved in objectives for this Focus Area during the past decade [1]. Five of the eight Medical Product Safety objectives with data to measure progress (objectives 17-2a through 17-2d, and 17-5a) moved toward or achieved their Healthy People 2010 targets (Figure 17-1).
- The use of electronic medical records by health care providers in health care organizations (objective 17-2a) increased 166.7% between 2000 and 2007, from 12% to 32%, exceeding the 2010 target of 18%.
- The use of computerized prescriber order entry in general and children's hospitals (objective 17-2c) increased 533.3% between 2003 and 2010, from 3% to 19%, exceeding the 2010 target of 4%. Similarly, the use of computerized prescriber order entry in urban acute care facilities (objective 17-2d) increased 76.9% between 2007 and 2009, from 13% to 23%, exceeding the 2010 target of 20%.
- The monitoring of adverse events associated with medical practice (objective 17-1a) declined 25.6% between 1999 and 2009, from 82% to 61%, moving away from the 2010 target of 90%.
- Blood donations among adults aged 18 and over (objective 17-6) remained stable. Six percent (age adjusted) of the U.S. population donated blood in 2008, showing no change from 1998. This objective did not meet the 2010 target of 8%.

Summary of Progress

- Figure 17-1 presents a quantitative assessment of progress in achieving the Healthy People 2010 objectives for Medical Product Safety [1]. Data to measure progress toward target attainment were available for eight objectives. Of these:
  - Three objectives (17-2a, c, and d) met or exceeded their Healthy People 2010 targets.
  - Two objectives (17-2b and 17-5a) moved toward their targets, but data to test the significance of the difference between the baseline and final data points were unavailable.
  - One objective (17-6) showed no change.
  - Two objectives (17-1a and 17-5b) moved away from their targets, but data to test the significance of the difference between the baseline and final data points were unavailable.
- One objective (17-4) had no follow-up data available to measure progress, and two objectives (17-1b and 17-3) were deleted at the Midcourse Review.

- Figure 17-2 displays health disparities in Medical Product Safety from the best group rate for each characteristic at the most recent data point [2]. It also displays changes in disparities from baseline to the most recent data point [3].
  - Disparity data were available for only one objective (17-6, blood donations). This objective showed no health disparities of 10% or more by race and ethnicity, sex, education level, or disability status.

Transition to Healthy People 2020

The range of objectives covered in the Medical Product Safety chapter for Healthy People 2020 has been narrowed in comparison with the objectives presented in Healthy People 2010. The Healthy People 2010 Focus Area covered topics including electronic medical record use, blood donation, oral counseling on prescription medications and adverse medical events. In contrast, the Healthy People 2020 Topic Area focuses on overall improvement of patient treatment and appropriate use of medical products including drugs, biological products, and medical devices. The Healthy People 2020 objectives reflect strong scientific support for safe use of medical products, which promotes better health among Americans. See HealthyPeople.gov for a complete list of Healthy People 2020 topics and objectives.

Objectives in the Healthy People 2020 Medical Product Safety Topic Area fall into two major categories:

- Monitoring of adverse medical events
- Safe and effective treatment of pain.

The differences between the Healthy People 2010 objectives and those included in Healthy People 2020 objectives are summarized below:

- The Healthy People 2020 Medical Product Safety Topic Area has a total of 11 objectives, 5 of which are developmental [4]. The Healthy People 2010 Medical Product Safety Focus Area also had 11 objectives.
- Two Healthy People 2010 objectives were retained "as is" [5]. Monitoring and analyzing adverse medical events within health care organizations and blood donations (objective 17-1a) was retained. The blood donation objective (objective 17-6) was also retained, but was moved to the Blood Safety Topic Area.
- Two Healthy People 2010 objectives were deleted at the Midcourse Review due to a lack of tracking data. These objectives include: adverse medical events associated with medical devices (objective 17-1b) and provider review of medications taken by patients and those with chronic conditions (objective 17-3).
- Seven Healthy People 2010 objectives were archived [6].
  - Three objectives addressing the receipt of oral counseling and useful information regarding prescription medications were archived due to a lack of national data in the future (objectives 17-4, 17-5a, and 17-5b).
  - Four objectives that refer to electronic medical record use (objectives 17-2a through 17-2d) in Healthy People 2010 were also archived, as the Medical Product Safety Topic Area is no longer focusing on that issue.
- Although the Healthy People 2010 objectives on electronic medical record use have all been archived, there is a new objective on monitoring the proportion of medical practices that use electronic health records in the Healthy People 2020 Health Communication and Health Information Technology Topic Area.
- Nine new objectives were added to the Healthy People 2020 Medical Product Safety Topic Area:
  - Four objectives that track the safe and effective treatment of pain have been added. These objectives track patients suffering from untreated pain due to a lack of access to pain treatment, the number of non-FDA approved pain medication on the market, and serious injuries and death from pain medications.
  - Another new objective tracks the use of safe and effective medical products associated with predictive biomarkers.
  - Four objectives were added to measure the number of emergency department visits for common, preventable adverse events from medication.

Appendix D, "A Crosswalk Between Objectives From Healthy People 2010 to Healthy People 2020," summarizes the changes between the two decades of objectives, reflecting new knowledge and direction for this area.

Data Considerations

In general, data on educational attainment are presented for persons aged 25 and over, consistent with guidance given by the Census Bureau. However, because of the requirements of the different data systems, the age groups used to calculate educational attainment for any specific objective may differ from the age groups used to report the data for other Healthy People 2010 objectives, as well as from select populations within the same objective. Therefore, the reader is urged to

exercise caution in interpreting the data by educational attainment shown in the Health Disparities Table. See *Healthy People 2010: General Data Issues*, referenced below.

Additional information on data issues is available from the following sources:

- All Healthy People 2010 tracking data can be found in the Healthy People 2010 database, DATA2010, available from http://wonder.cdc.gov/data2010/.
- Detailed information about the data and data sources used to support these objectives can be found in the Operational Definitions on the DATA 2010 website, available from http://wonder.cdc.gov/data2010/focusod.htm.
- More information on statistical issues related to Healthy People tracking and measurement can be found in the Technical Appendix and in *Healthy People 2010: General Data Issues*, which is available in the General Data Issues section of the NCHS Healthy People website under Healthy People 2010; see http://www.cdc.gov/nchs/healthy_people/hp2010/hp2010_data_issues.htm.

Notes

1. Displayed in the Progress Chart (Figure 17-1), the percent of targeted change achieved expresses the difference between the baseline and the final value relative to the initial difference between the baseline and the Healthy People 2010 target. As such, it is a relative measure of progress toward attaining the Healthy People 2010 target. See the Reader's Guide for more information. When standard errors were available, the difference between the baseline and the final value was tested at the 0.05 level of significance. See the Figure 17-1 footnotes, as well as the Technical Appendix, for more detail.

2. Information about disparities among select populations is shown in the Health Disparities Table (Figure 17-2). 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, racial and ethnic health disparities are measured as the percent difference between the best racial and ethnic group rate and each of the other racial and ethnic group rates. Similarly, disparities by sex are measured as the percent difference between the better group rate (e.g., female) and the rate for the other group (e.g., male). Some objectives are expressed in terms of favorable events or conditions that are to be increased, while others are expressed in terms of adverse events or conditions that are to be reduced. To facilitate comparison of health disparities across different objectives, disparity is measured only in terms of adverse events or conditions. For comparability across objectives, objectives that are expressed in terms of favorable events or conditions are re-expressed using the adverse event or condition for the purpose of computing disparity, but they are not otherwise restated or changed. For example, objective 1-1, to increase the proportion of persons with health insurance (e.g., 72% of the American Indian or Alaska Native population under age 65 had some form of health insurance in 2008), is expressed in terms of the percentage of persons without health insurance (e.g., 100% – 72% = 28% of the American Indian or Alaska Native population under age 65 did not have any form of health insurance in 2008) when the disparity from the best group rate is calculated. See the Reader's Guide for more information. When standard errors were available, the difference between the best group rate and each of the other group rates was tested at the 0.05 level of significance. See the Figure 17-2 footnotes, as well as the Technical Appendix, for more detail.

3. The change in disparity is estimated by subtracting the disparity at baseline from the disparity at the most recent data point and, therefore, is expressed in percentage points. See the Reader's Guide for more information. When standard errors were available, the change in disparity was tested at the 0.05 level of significance. See the Figure 17-2 footnotes, as well as the Technical Appendix, for more detail.

4. To be included in Healthy People 2010, an objective must have a national data source that provides a baseline and at least one additional data point for tracking progress. Some objectives lacked baseline data at the time of their development but had a potential data source and were considered of sufficient national importance to be included in Healthy People. These are called "developmental" objectives. When data become available, a developmental objective is moved to measurable status and a Healthy People target can be set.

5. As of the Healthy People 2020 launch, Healthy People 2020 objectives that were retained "as is" from Healthy People 2010 had no change in the numerator or denominator definitions, the data source(s), or the data collection methodology. These include objectives that were developmental in Healthy People 2010 and are developmental in Healthy People 2020, and for which no numerator information is available.

6. Archived objectives had at least one data point in Healthy People 2010 but were not carried forward into Healthy People 2020.

Comprehensive Summary of Objectives: Medical Product Safety

Objective	Description	Data Source or Objective Status
17-1a	Monitoring and analyzing adverse events associated with medical therapies	National Survey of Pharmacy Practice in Acute Care Settings, American Society of Health Systems Pharmacists.
17-1b	Monitoring of adverse medical events associated with medical devices	Deleted at the Midcourse Review.
17-2a	Electronic medical record use by health care providers in health care organizations	Annual Health Care Information and Management Systems Society Leadership Survey, Healthcare Information and Management Systems Society.
17-2b	Electronic medical record use by pharmacists in managed care and integrated health systems	National Survey of Ambulatory Care Responsibilities of Pharmacists in Managed Care and Integrated Health Systems, American Society of Health Systems Pharmacists.
17-2c	Computerized prescriber order entry use by general and children's hospitals	National Survey of Pharmacy Practice in Hospital Settings, American Society of Health Systems Pharmacists.
17-2d	Computerized prescriber order entry use by urban acute care facilities	The Leapfrog Group Hospital Patient Safety Survey.
17-3	Provider review of medications taken by older patients and those with chronic conditions	Deleted at the Midcourse Review.
17-4	Receipt of useful information about prescriptions from pharmacies	Evaluation of Written Prescription Information Provided in Community Pharmacies, Food and Drug Administration.
17-5a	Oral counseling about medications from prescribers	National Survey of Prescription Medicine Information Received by Consumers, FDA.
17-5b	Oral counseling about medications from pharmacists	National Survey of Prescription Medicine Information Received by Consumers, FDA.
17-6	Blood donations (age adjusted, 18+ years)	National Health Interview Survey (NHIS), CDC, NCHS.

Figure 17-1. Progress Toward Target Attainment for Focus Area 17: Medical Product Safety

LEGEND — Moved away from target[1] | Moved toward target | Met or exceeded target

	Objective	Percent of targeted change achieved[2] (0 25 50 75 100)	2010 Target	Baseline (Year)	Final (Year)	Baseline vs. Final: Difference[3]	Baseline vs. Final: Statistically Significant[4]	Baseline vs. Final: Percent Change[5]
17-1a.	Monitoring and analyzing adverse events associated with medical therapies		90%	82% (1998)	61% (2009)	-21	Not tested	-25.6%
17-2.	Electronic medical record use by							
	a. Health care providers in health care organizations	333.3%	18%	12% (2000)	32% (2007)	20	Not tested	166.7%
	b. Pharmacists in managed care and integrated health systems	13.3%	46%	31% (1999)	33% (2001)	2	Not tested	6.5%
	Computerized prescriber order entry use by							
	c. General and children's hospitals	1,600.0%	4%	3% (2003)	19% (2010)	16	Not tested	533.3%
	d. Urban acute care facilities	142.9%	20%	13% (2007)	23% (2009)	10	Not tested	76.9%
17-5.	Oral counseling about medications from							
	a. Prescribers	2.8%	95%	24% (1998)	26% (2004)	2	Not tested	8.3%
	b. Pharmacists		95%	14% (1998)	6% (2004)	-8	Not tested	-57.1%
17-6.	Blood donations (age adjusted, 18+ years)	0.0%	8%	6% (1998)	6% (2008)	0	No	0.0%

NOTES

See the Reader's Guide for more information on how to read this figure. See DATA2010 at http://wonder.cdc.gov/data2010 for all HealthyPeople 2010 tracking data. Tracking data are not available for objective 17-4. Objectives 17-1b and 17-3 were deleted at the Midcourse Review.

FOOTNOTES

[1] Movement away from target is not quantified using the percent of targeted change achieved. See Technical Appendix for more information.

[2] Percent of targeted change achieved = $\frac{\text{Final value} - \text{Baseline value}}{\text{Healthy People 2010 target} - \text{Baseline value}} \times 100$.

[3] Difference = Final value – Baseline value. Differences between percents (%) are measured in percentage points.

[4] When estimates of variability are available, the statistical significance of the difference between the final value and the baseline value is assessed at the 0.05 level. See Technical Appendix for more information.

[5] Percent change = $\frac{\text{Final value} - \text{Baseline value}}{\text{Baseline value}} \times 100$.

DATA SOURCES

17-1a. National Survey of Pharmacy Practice in Acute Care Settings, American Society of Health Systems Pharmacists.
17-2a. Annual Health Care Information and Management Systems Society Leadership Survey, Healthcare Information and Management Systems Society.
17-2b. National Survey of Ambulatory Care Responsibilities of Pharmacists in Managed Care and Integrated Health Systems, American Society of Health Systems Pharmacists.
17-2c. National Survey of Pharmacy Practice in Hospital Settings, American Society of Health Systems Pharmacists.
17-2d. The Leapfrog Group Hospital Patient Safety Survey.
17-5a–b. National Survey of Prescription Medicine Information Received by Consumers, FDA.
17-6. National Health Interview Survey (NHIS), CDC, NCHS.

Figure 17-2. Health 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 objective	Race and Ethnicity: American Indian or Alaska Native	Asian	Native Hawaiian or Other Pacific Islander	Two or more races	Hispanic or Latino	Black, not Hispanic	White, not Hispanic	Summary index	Sex: 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 (age adjusted, 18+ years) (1998, 2008)[1]				B[i]			B			B			B		B[i]	B

NOTES

See DATA2010 at http://wonder.cdc.gov/data2010 for all Healthy People 2010 tracking data. Disparity data are either unavailable or not applicable for objectives 17-1a, 17-2a through d, 17-4, and 17-5a and b. Objectives 17-1b and 17-3 were deleted at Midcourse Review.

Years in parentheses represent the baseline and most recent data years (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 (e.g., 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.

Measures of variability were available for the objective in this table. Thus, the variability of best group rates was assessed, and statistical significance was tested. Disparities of 10% or more are displayed when the differences from the best group rate are statistically significant at the 0.05 level. Changes in disparities over time are indicated by arrows when the changes are greater than or equal to 10 percentage points and are statistically significant at the 0.05 level. See Technical Appendix.

LEGEND

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.

Reliability criterion for best group rate not met, or data available for only one group.

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

Percent difference from the best group rate

Less than 10%, or difference not statistically significant (when estimates of variability are available).

10%–49%

50%–99%

100% or more

Changes in disparity over time are shown when: (a) disparities data are available at both baseline and most recent time points; (b) data are not for the group(s) indicated by "B" or "b" at either time point; and (c) 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. See Technical Appendix.

Increase in disparity (percentage points)

↑ 10–49 points

↑↑ 50–99 points

↑↑↑ 100 points or more

Decrease in disparity (percentage points)

↓ 10–49 points

↓↓ 50–99 points

↓↓↓ 100 points or more

Availability of Data

Data not available.

Characteristic not selected for this objective.

FOOTNOTE

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

[i] The group with the best rate at the most recent data point is different from the group with the best rate at baseline. Both rates met the reliability criterion. See Technical Appendix.

DATA SOURCE

17-6. National Health Interview Survey (NHIS), CDC, NCHS.