CHAPTER 27

Medical Product Safety (MPS)

Lead Agency

Food and Drug Administration

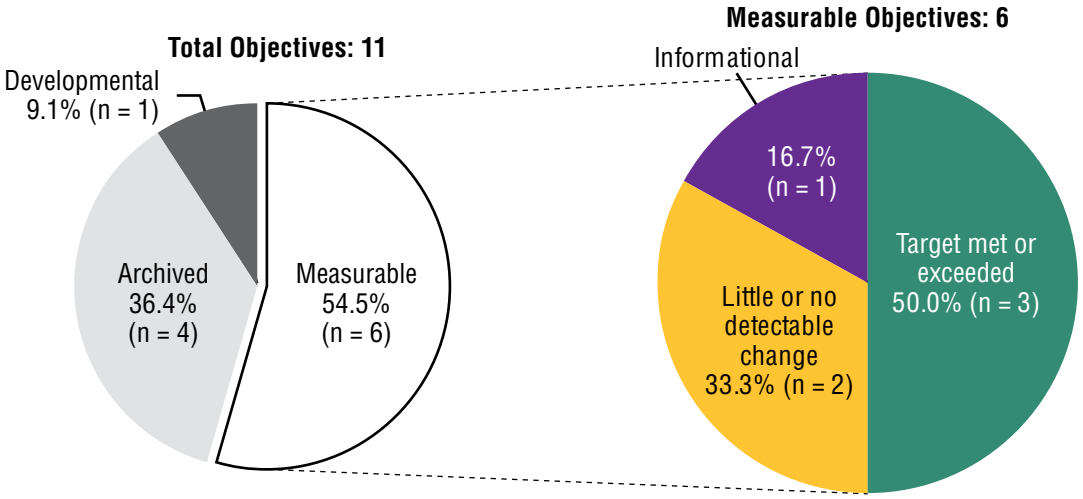
Contents

Goal: Ensure the safe use of medical products.

This chapter includes objectives that monitor the safe use of medical products and adverse drug events. The Reader's Guide provides a step-by-step explanation of the content of this chapter, including criteria for highlighting objectives in the Selected Findings.[1]

Status of Objectives

Figure 27–1. Midcourse Status of the Medical Product Safety Objectives



Of the 11 objectives in the Medical Product Safety Topic Area, 4 objectives were archived,[2] 1 objective remained developmental,[3] and 6 objectives were measurable[4] (Figure 27–1, Table 27–1). The midcourse status of the measurable objectives (Table 27–2) was as follows:

- 3 objectives met or exceeded their 2020 targets,[5]
- 2 objectives demonstrated little or no detectable change,[6] and
- 1 objective was informational.[7]

Selected Findings

- The proportion of **medical-surgical hospitals that reported adverse drug events** (MPS-1) increased from 60.7% in 2009 to 80.6% in 2012, exceeding the 2020 target (Table 27–2).
- There was little or no detectable change in **emergency department visits for overdoses from oral anticoagulants** (MPS-5.1) per 10,000 outpatient prescription visits (35.9 in 2006–2007 and 36.9 in 2008–2009) (Table 27–2).
  - » In 2008–2009, disparities by sex in rates of emergency department visits for overdoses from oral anticoagulants (MPS-5.1) were not statistically significant (Table 27–3).
- Between 2006–2007 and 2008–2009, **emergency department visits for overdoses from injectable antidiabetic agents** (MPS-5.2) decreased from 43.4 to 34.2 per 10,000 outpatient prescription visits, exceeding the 2020 target (Table 27–2).
  - » In 2008–2009, disparities by sex in rates of emergency department visits for overdoses from injectable antidiabetic agents (MPS-5.2) were not statistically significant (Table 27–3).
- Between 2006–2007 and 2008–2009, **emergency department visits for overdoses from narrow-therapeutic-index medications** (MPS-5.3) decreased from 8.9 to 7.6 per 10,000 outpatient prescription visits, exceeding their respective 2020 targets (Table 27–2).
  - » In 2008–2009, disparities by sex in rates of emergency department visits for overdoses from narrow-therapeutic-index medications (MPS-5.3) were not statistically significant (Table 27–3).

- There was little or no detectable change in **emergency department visits for medication overdoses in children less than 5 years of age** (MPS-5.4) per 10,000 population (32.7 in 2007–2008 and 34.3 in 2011–2012) (Table 27–2).
  - » In 2011–2012, disparities by sex in rates of emergency department visits for medication overdoses in children less than 5 years of age (MPS-5.4) were not statistically significant (Table 27–3).

More Information

Readers interested in more detailed information about the objectives in this topic area are invited to visit the HealthyPeople.gov website, where extensive substantive and technical information is available:

- For the background and importance of the topic area, see: https://www.healthypeople.gov/2020/topics-objectives/topic/medical-product-safety
- For data details for each objective, including definitions, numerators, denominators, calculations, and data limitations, see: https://www.healthypeople.gov/2020/topics-objectives/topic/medical-product-safety/objectives
  Select an objective, then click on the "Data Details" icon.
- For objective data by population group (e.g., sex, race and ethnicity, or family income) including rates, percentages, or counts for multiple years, see: https://www.healthypeople.gov/2020/topics-objectives/topic/medical-product-safety/objectives
  Select an objective, then click on the "Data2020" icon.

Data for the measurable objectives in this chapter were from the following data sources:

- Bridged-race Population Estimates: http://www.cdc.gov/nchs/nvss/bridged_race.htm
- Drugs@FDA: https://www.accessdata.fda.gov/scripts/cder/drugsatfda/
- List of Cleared or Approved Companion Diagnostic Devices: http://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/ucm301431.htm
- National Ambulatory Medical Care Survey: http://www.cdc.gov/nchs/ahcd.htm
- National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance Project: https://www.healthypeople.gov/2020/data-source/national-electronic-injury-surveillance-system-cooperative-adverse-drug-event
- National Hospital Ambulatory Medical Care Survey: http://www.cdc.gov/nchs/ahcd.htm
- National Survey of Pharmacy Practice in Hospital Care Settings: https://www.healthypeople.gov/2020/data-source/national-survey-pharmacy-practice-hospital-care-settings
- Releasable Pre-Market Approval Database: http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/default.htm

Footnotes

[1]The Technical Notes provide more information on Healthy People 2020 statistical methods and issues.

[2]**Archived** objectives are no longer being monitored due to lack of data source, changes in science, or replacement with other objectives.

[3]**Developmental** objectives did not have a national baseline value.

[4]**Measurable** objectives had a national baseline value.

[5]**Target met or exceeded**—One of the following, as specified in the Midcourse Progress Table:
- » At baseline the target was not met or exceeded and the midcourse value was equal to or exceeded the target. (The percentage of targeted change achieved was equal to or greater than 100%.)
- » The baseline and midcourse values were equal to or exceeded the target. (The percentage of targeted change achieved was not assessed.)

[6]**Little or no detectable change**—One of the following, as specified in the Midcourse Progress Table:
- » Movement was toward the target, standard errors were available, and the percentage of targeted change achieved was not statistically significant.
- » Movement was toward the target, standard errors were not available, and the objective had achieved less than 10% of the targeted change.
- » Movement was away from the baseline and target, standard errors were available, and the percentage change relative to the baseline was not statistically significant.
- » Movement was away from the baseline and target, standard errors were not available, and the objective had moved less than 10% relative to the baseline.
- » There was no change between the baseline and the midcourse data point.

[7]**Informational**—A target was not set for this objective, so progress toward target attainment could not be assessed.

Suggested Citation

National Center for Health Statistics. Chapter 27: Medical Product Safety. Healthy People 2020 Midcourse Review. Hyattsville, MD. 2016.

Table 27–1. Medical Product Safety Objectives

LEGEND

 Data for this objective are available in this chapter's Midcourse Progress Table.

 Disparities data for this objective are available, and this chapter includes a Midcourse Health Disparities Table.

 A state or county level map for this objective is available at the end of the chapter.

Not Applicable — Midcourse data availability is not applicable for developmental and archived objectives. **Developmental** objectives did not have a national baseline value. **Archived** objectives are no longer being monitored due to lack of data source, changes in science, or replacement with other objectives.

Objective Number	Objective Statement	Data Sources	Midcourse Data Availability
MPS-1	Increase the proportion of medical-surgical hospitals that report adverse drug events	National Survey of Pharmacy Practice in Hospital Care Settings, American Society of Health-System Pharmacists (ASHP)	
MPS-2.1	(Archived) Reduce the proportion of patients suffering from untreated pain due to a lack of access to pain treatment	(Potential) Medical Expenditure Panel Survey (MEPS), AHRQ	Not Applicable
MPS-2.2	(Archived) Reduce the number of non-FDA-approved pain medications	FDA Drug Registration and Listing Database, FDA; Electronic database of prescription sales in the US, Intercontinental Marketing Services (IMS)	Not Applicable
MPS-2.3	(Archived) Reduce serious injuries from the use of pain medicines	(Potential) Adverse Event Reporting System (AERS), FDA	Not Applicable
MPS-2.4	(Developmental) Reduce deaths from the use of pain medicines	(Potential) Adverse Event Reporting System (AERS), FDA	Not Applicable
MPS-3	(Archived) Reduce the number of adverse events from medical products	(Potential) National Electronic Injury Surveillance System (NEISS), CPSC	Not Applicable
MPS-4	Increase the number of safe and effective medical products—diagnostics, drugs and biologics—associated with predictive biomarkers	Drugs@FDA, FDA/CDER and FDA/CBER; List of Cleared and Approved Companion Diagnostic Devices (In Vivo and Imaging Tools), FDA/CDRH; Releasable Premarket Approval (PMA) Database, FDA/CDRH	
MPS-5.1	Reduce emergency department (ED) visits for overdoses from oral anticoagulants	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS	 
MPS-5.2	Reduce emergency department (ED) visits for overdoses from injectable antidiabetic agents	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS	 

Table 27–1. Medical Product Safety Objectives—Continued

LEGEND

 Data for this objective are available in this chapter's Midcourse Progress Table.

 Disparities data for this objective are available, and this chapter includes a Midcourse Health Disparities Table.

 A state or county level map for this objective is available at the end of the chapter.

Not Applicable — Midcourse data availability is not applicable for developmental and archived objectives. **Developmental** objectives did not have a national baseline value. **Archived** objectives are no longer being monitored due to lack of data source, changes in science, or replacement with other objectives.

Objective Number	Objective Statement	Data Sources	Midcourse Data Availability
MPS-5.3	Reduce emergency department (ED) visits for overdoses from narrow-therapeutic-index medications	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS	
MPS-5.4	Reduce emergency department (ED) visits for medication overdoses among children less than 5 years of age	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; Bridged-race Population Estimates, CDC/NCHS and Census	

Table 27–2. Midcourse Progress for Measurable[1] Medical Product Safety Objectives

LEGEND

✓ Target met or exceeded[2,3] | + Improving[4,5] | ○ Little or no detectable change[6–10] | − Getting worse[11,12] | Baseline only[13] | Informational[14]

Objective Description	Baseline Value (Year)	Midcourse Value (Year)	Target	Movement Toward Target[15]	Movement Away From Baseline[16]	Movement Statistically Significant[17]
✓[2] **MPS-1** Hospitals reporting adverse drug events (percent)	60.7% (2009)	80.6% (2012)	66.8%	326.2%		Yes
[14] **MPS-4** Safe and effective medical products associated with predictive biomarkers (number)	15 (2010)	35 (2014)				
○[8] **MPS-5.1** Emergency department visits for overdoses from oral anticoagulants (per 10,000 outpatient prescription visits)	35.9 (2006–2007)	36.9 (2008–2009)	32.3		2.8%	No
✓[2] **MPS-5.2** Emergency department visits for overdoses from injectable antidiabetic agents (per 10,000 outpatient prescription visits)	43.4 (2006–2007)	34.2 (2008–2009)	39.1	214.0%		No
✓[2] **MPS-5.3** Emergency department visits for overdoses from narrow-therapeutic-index medications (per 10,000 outpatient prescription visits)	8.9 (2006–2007)	7.6 (2008–2009)	8.0	144.4%		No
○[8] **MPS-5.4** Emergency department visits for medication overdoses in children (per 10,000 population, <5 years)	32.7 (2007–2008)	34.3 (2011–2012)	29.4		4.9%	No

NOTES

See HealthyPeople.gov for all Healthy People 2020 data. The Technical Notes provide more information on the measures of progress.

FOOTNOTES

[1]**Measurable** objectives had a national baseline value.

Target met or exceeded:

[2]At baseline the target was not met or exceeded and the midcourse value was equal to or exceeded the target. (The percentage of targeted change achieved was equal to or greater than 100%.)

[3]The baseline and midcourse values were equal to or exceeded the target. (The percentage of targeted change achieved was not assessed.)

Improving:

[4]Movement was toward the target, standard errors were available, and the percentage of targeted change achieved was statistically significant.

[5]Movement was toward the target, standard errors were not available, and the objective had achieved 10% or more of the targeted change.

Little or no detectable change:

[6]Movement was toward the target, standard errors were available, and the percentage of targeted change achieved was not statistically significant.

[7]Movement was toward the target, standard errors were not available, and the objective had achieved less than 10% of the targeted change.

[8]Movement was away from the baseline and target, standard errors were available, and the percentage change relative to the baseline was not statistically significant.

[9]Movement was away from the baseline and target, standard errors were not available, and the objective had moved less than 10% relative to the baseline.

[10]There was no change between the baseline and the midcourse data point.

FOOTNOTES—Continued

Getting worse:

[11]Movement was away from the baseline and target, standard errors were available, and the percentage change relative to the baseline was statistically significant.

[12]Movement was away from the baseline and target, standard errors were not available, and the objective had moved 10% or more relative to the baseline.

[13]**Baseline only:** The objective only had one data point, so progress toward target attainment could not be assessed.

[14]**Informational:** A target was not set for this objective, so progress toward target attainment could not be assessed.

[15]For objectives that **moved toward** their targets, movement toward the target was measured as the percentage of targeted change achieved (unless the target was already met or exceeded at baseline):

$$\text{Percentage of targeted change achieved} = \frac{\text{Midcourse value} - \text{Baseline value}}{\text{HP2020 target} - \text{Baseline value}} \times 100$$

[16]For objectives that **moved away** from their baselines and targets, movement away from the baseline was measured as the magnitude of the percentage change from baseline:

$$\text{Magnitude of percentage change from baseline} = \frac{|\,\text{Midcourse value} - \text{Baseline value}\,|}{\text{Baseline value}} \times 100$$

[17]Statistical significance was tested when the objective had a target and at least two data points, standard errors of the data were available, and a normal distribution could be assumed. Statistical significance of the percentage of targeted change achieved or the magnitude of the percentage change from baseline was assessed at the 0.05 level using a normal one-sided test.

Table 27–2. Midcourse Progress for Measurable[1] Medical Product Safety Objectives—Continued

DATA SOURCES

MPS-1	National Survey of Pharmacy Practice in Hospital Care Settings, American Society of Health-System Pharmacists (ASHP)
MPS-4	Drugs@FDA, FDA/CDER and FDA/CBER; List of Cleared and Approved Companion Diagnostic Devices (In Vivo and Imaging Tools), FDA/CDRH; Releasable Premarket Approval (PMA) Database, FDA/CDRH
MPS-5.1	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS
MPS-5.2	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS
MPS-5.3	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS
MPS-5.4	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; Bridged-race Population Estimates, CDC/NCHS and Census

Table 27–3. Midcourse Health Disparities[1] for Population-based Medical Product Safety Objectives

Most favorable (least adverse) and least favorable (most adverse) group rates and summary disparity ratios[2,3] for selected characteristics at the midcourse data point

LEGEND

At the midcourse data point	Group with the most favorable (least adverse) rate	Group with the least favorable (most adverse) rate	Data are available, but this group did not have the highest or lowest rate.	Data are not available for this group because the data were statistically unreliable, not collected, or not analyzed.

Population-based Objectives	Characteristics and Groups																																
	Sex			Race and Ethnicity								Education[4]							Family Income[5]						Disability			Location						
	Male	Female	**Summary Disparity Ratio[2]**	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 Disparity Ratio[3]**	Less than high school	High school graduate	At least some college	Associate's degree	4-year college degree	Advanced degree	**Summary Disparity Ratio[3]**	Poor	Near-poor	Middle	Near-high	High	**Summary Disparity Ratio[3]**	Persons with disabilities	Persons without disabilities	**Summary Disparity Ratio[2]**	Metropolitan	Nonmetropolitan	**Summary Disparity Ratio[2]**				
MPS-5.1 Emergency department visits for overdoses from oral anticoagulants (per 10,000 outpatient prescription visits) (2008–2009)			1.026																														
MPS-5.2 Emergency department visits for overdoses from injectable antidiabetic agents (per 10,000 outpatient prescription visits) (2008–2009)			1.207																														
MPS-5.3 Emergency department visits for overdoses from narrow-therapeutic-index medications (per 10,000 outpatient prescription visits) (2008–2009)			1.235																														
MPS-5.4 Emergency department visits for medication overdoses in children (per 10,000 population, <5 years) (2011–2012)			1.003																														

Table 27–3. Midcourse Health Disparities[1] for Population-Based Medical Product Safety Objectives—Continued

NOTES

See HealthyPeople.gov for all Healthy People 2020 data. The Technical Notes provide more information on the measures of disparities.

FOOTNOTES

[1]**Health disparities** were assessed among population groups within specified demographic characteristics (sex, race and ethnicity, educational attainment, etc.). This assessment did not include objectives that were not population-based, such as those based on states, worksites, or those monitoring the number of events.
[2]When there were only two groups (e.g., male and female), the **summary disparity ratio** was the ratio of the higher to the lower rate.
[3]When there were three or more groups (e.g., white non-Hispanic, black non-Hispanic, Hispanic) and the most favorable rate (R_b) was the highest rate, the **summary disparity ratio** was calculated as R_b / R_a, where R_a = the average of the rates for all other groups. When there were three or more groups and the most favorable rate was the lowest rate, the summary disparity ratio was calculated as R_a / R_b.
[4]Unless otherwise footnoted, data do not include persons under age 25 years.
[5]Unless otherwise footnoted, the poor, near-poor, middle, near-high, and high income groups are for persons whose family incomes were less than 100%, 100%–199%, 200%–399%, 400%–599%, and at or above 600% of the poverty threshold, respectively.

DATA SOURCES

MPS-5.1	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS
MPS-5.2	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS
MPS-5.3	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; National Ambulatory Medical Care Survey (NAMCS), CDC/NCHS; National Hospital Ambulatory Medical Care Survey (NHAMCS), CDC/NCHS
MPS-5.4	National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance Project (NEISS–CADES), CDC, CPSC, and FDA; Bridged-race Population Estimates, CDC/NCHS and Census