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Medical Product Safety

- 17-1 Monitoring of adverse medical events
 - 17-1a Medical therapies
 - 17-1b Medical devices
- 17-2 Linked, automated information systems
 - 17-2a Hospitals and comprehensive, integrated health care systems
 - 17-2b Pharmacists and other dispensers
- 17-3 Provider review of medications taken by patients
- 17-4 Receipt of useful information about prescriptions from pharmacies
- 17-5 Receipt of oral counseling about medications from prescribers and dispensers
 - 17-5a Prescribers
 - 17-5b Pharmacists
- 17-6 Blood donations

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. (Developmental) Health care organizations that are linked in an integrated system that monitors and reports adverse events associated with medical therapies.

Comments

An operational definition could not be specified at the time of publication.

Proposed national data sources are the Office of Postmarketing Drug Risk Assessment (OPDRA), MedWatch, and Manufacturer and User Device Experience (MAUDE) Database, FDA.

An adverse event is an undesirable result from use of a medical product. This includes terms such as adverse drug reaction (ADR), adverse experiment, and adverse effect.

See Appendix A for focus area contact information.



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

Comments

An operational definition could not be specified at the time of publication.

Proposed national data sources are the Office of Postmarketing Drug Risk Assessment (OPDRA), MedWatch, and Manufacturer and User Device Experience (MAUDE) Database, FDA.

An adverse event is an undesirable result from use of a medical product. This includes terms such as adverse drug reaction (ADR), adverse experiment, and adverse effect.

A medical device is an instrument, apparatus, implement, implant, machine, or other similar or related article intended in use for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

See Appendix A for focus area contact information.



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

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

Comments

An operational definition could not be specified at the time of publication.

Proposed national data sources are the National Survey of Pharmacy Practice in Acute Care and Survey of Managed Care and Ambulatory Care Pharmacy Practice in Integrated Health Systems, American Society of Hospital Pharmacists (ASHP).

See Appendix A for focus area contact information.



17-2b. (Developmental) By pharmacists and other dispensers.

Comments

An operational definition could not be specified at the time of publication.

Proposed national data sources are the National Survey of Pharmacy Practice in Acute Care and Survey of Managed Care and Ambulatory Care Pharmacy Practice in Integrated Health Systems, American Society of Hospital Pharmacists (ASHP).

See Appendix A for focus area contact information.



17-3. (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.

Comments

An operational definition could not be specified at the time of publication.

Proposed data sources are the Survey on Prescription Drug Issues and Usage, AARP; and the Physician Survey under the Medication Error Reduction Initiative.

This objective is adapted from a measure in Healthy People 2000 objective 12.6 (Food and Drug Safety), which tracked the proportion of primary care physicians who routinely review with their patients aged 65 years and older all prescriptions and over-the-counter medicines taken by their patients each time a new medication is prescribed.

This measure tracks the proportion of primary care physicians, pharmacists, and other health care professionals who routinely review with their patients aged 65 years and older, as well as patients with chronic illnesses or disabilities all new prescribed and over-the-counter medicines.

See Appendix A for focus area contact information.



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

Comments

An operational definition could not be specified at the time of publication.

A proposed national data source is the Patient/Consumer Medication Information Survey, FDA.

This objective is adapted from a measure in Healthy People 2000 objective 12.8 (Food and Drug Safety), which tracked the proportion of people who receive useful information verbally and in writing for new prescriptions from prescribers or dispensers. This measure tracks the proportion of patients receiving information that meets guidelines for usefulness when new prescriptions are dispensed.

See Appendix A for focus area contact information.



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

17-5a. Prescribers

Comments

A complete operational definition was not provided at the time of publication.

The national data source is the National Survey of Prescription Drug Information Provided to Patients, FDA.

This objective is adapted from a measure in Healthy People 2000 objective 12.8 (Food and Drug Safety), which tracked the proportion of people who receive useful information verbally and in writing for new prescriptions from prescribers or dispensers. This measure tracks the proportion of patients receiving verbal counseling from prescribers only on appropriate use and potential risk of medications.

See Appendix A for focus area contact information.



17-5b. Pharmacists

Comments

A complete operational definition was not provided at the time of publication.

The national data source is the National Pharmacy Consumer Survey, American Pharmaceutical Association.

This objective is adapted from a measure in Healthy People 2000 objective 12.8 (Food and Drug Safety), which tracked the proportion of people who receive useful information verbally and in writing for new prescriptions from prescribers or dispensers. This measure tracks the proportion of patients receiving verbal counseling from pharmacists only on appropriate use and potential risk of medications.

See Appendix A for focus area contact information.



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

Comments

A complete operational definition was not provided at the time of publication.

The national data source is the American Association of Blood Banks.

See Appendix A for focus area contact information.



