Monitoring medication effects includes observing, timely responding to, and documenting any adverse effects. The hospital has a policy that identifies all adverse effects that are to be recorded and those that must be reported. The hospital establishes a mechanism for reporting adverse events when required and the time frame for reporting.

Measurable Elements of MMU.07.00

1. Ⓓ The hospital follows a written process to monitor, respond to, and document actual or potential adverse drug events, and adverse drug reactions. (*See also* PCC.02.00, ME 3)
2. Ⓓ The hospital follows a written process addressing prescriber notification in the event of adverse drug events and adverse drug reactions.
3. The hospital complies with internal and external reporting requirements for actual or potential adverse drug events and adverse drug reactions.
4. The hospital uses a standardized process for reporting adverse drug events as part of the hospital quality and patient safety program.
5. Adverse drug events are reported as identified by the process in the time frame required.
6. The hospital conducts a root cause analysis of data when adverse drug event patterns or undesirable trends occur.
7. The hospital uses the analysis of adverse drug-related events to improve medication use processes.

Standard MMU.07.01

The hospital implements a process for identifying, reporting, managing, and tracking all medication errors and near miss events (or close calls).

Intent of MMU.07.01

JCI defines a *medication error* as "a preventable event that may cause or lead to inappropriate medication use or patient or resident harm while the medication is in the control of the health care professional, patient, resident, or consumer. Such events may be related to professional practice; health care products; procedures and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

Processes are developed and implemented for the purposes of identifying, tracking, trending, analyzing, and reporting errors and adverse events, near misses, and complications. In addition, to proactively learn where systems may be vulnerable to adverse events, the program collects data and information on "near miss" events and complications—a process variation that did not affect the outcome—and evaluates them to prevent the actual occurrence of adverse events. Routine measurement data, as well as data from intensive assessments, contribute to this understanding of where improvement should be planned and what priority should be given to the improvement.

The hospital is responsible for planning and implementing changes for improvement based on the analysis of errors or adverse events, near misses, and complications. The process includes defining a medication error and a near miss, using a standardized format for reporting, and educating staff on the process and importance of reporting. The hospital establishes a definition of a near miss and what types of events are to be reported, as well as potential complications related to the care, treatment, and services provided.

Health care organizations that foster a culture of safety focus on safe medication management practices, which include promoting the reporting of errors without fear of retribution. The documentation and reporting of errors are the first steps in learning from them and avoiding repeat occurrences. The information must be documented and reported, and the data must be analyzed to identify opportunities for improvement. Without implementing a process that includes utilization of the data for improving safety practices, hospitals face challenging barriers in their safety improvement efforts. For example, a survey in Europe showed the following results:

- Eight percent of hospitals do not record medication errors in a database, and only 13% of hospitals make medication errors data available to the public. However, 33% of hospitals do not have medication errors databases for sharing continual improvements.
- Fourteen percent of hospitals do not routinely track medication errors, and 71% of hospitals track medication errors centrally (with most using the error data monitoring as a root cause analysis to resolve incidents as well as being investigated at regular quality meetings). Nevertheless, 23% of hospitals do not use that system regularly.

The reporting process is part of the hospital's quality and patient safety program. The reports are directed to one or more individuals who are accountable to take action. The program focuses on preventing medication errors through understanding the types of errors that occur in the hospital and in other organizations and why near misses occur. Improvements in medication processes and staff training are used to prevent errors in the future. The pharmacy participates in such staff training. In addition, strategies to improve communication among the professionals involved in prescribing, validating, preparing, administering, and dispensing medication are key to reduce medication errors.

Measurable Elements of MMU.07.01

1. Ⓓ The hospital adopts definitions of a medication error and a near miss from established and updated guidelines.
2. Ⓓ The hospital establishes and implements written processes for the following:
   - Identifying medication errors and near misses
   - Timely reporting of medication errors and near misses
   - Managing medication errors and near misses, including investigating, developing an action plan(s), and following up on the actions over time as applicable
   - Tracking medication errors and near misses

   (*See also* IPSG.03.01, MEs 1 and 2; QPS.03.04, ME 3)
3. Those accountable for acting and following up on the reports are identified.
4. Ⓓ The hospital conducts a root cause analysis of the data when medication error and near miss patterns or undesirable trends occur.
5. The hospital uses the analysis of medication errors and near miss events to improve medication use processes.