

DiPiro's Pharmacotherapy: A Pathophysiologic Approach, 12th Edition >

## Chapter e4: Medication Safety

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### UPDATE SUMMARY

#### Update Summary

March 20, 2023

The following sections, tables, and figures were updated:

- Added self-assessment questions and answers

### KEY CONCEPTS

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- 1 Medication errors (MEs) are defined as any mistake at any stage of the medication-use process; adverse drug events (ADEs) are MEs that result in injury.
- 2 All MEs are preventable, while ADEs can be categorized as preventable and potential.
- 3 MEs occur at an alarmingly high rate, with some ADEs having fatal outcomes for patients.
- 4 MEs can occur at any step of the medication-use process: selection and procurement, storage, ordering and transcribing, preparing and dispensing, administration, or monitoring.
- 5 Determining the actual and potential root causes of MEs helps to correct future errors in the medication-use system.
- 6 Quality improvement methods that prevent MEs and thereby minimize ADEs include identifying the ME and/or ADE, understanding the reasons for the ME and/or ADE, designing and implementing changes to prevent an ADE or ME, and checking the outcome of that change.
- 7 Healthcare organizations have implemented various measures to reduce the incidence of MEs and ADEs, such as computerized physician order entry (CPOE), automated drug distribution systems, bar-code scanning, and “smart” infusion pumps with decision support and where information is passed in a bidirectional manner between the pump and the patient’s electronic medical record (EMR).
- 8 Medication reconciliation or comparing a patient’s current medication orders to all of the medications that the patient had been taking before any care transition (hospital admission, transfer, or discharge) is a vital process in preventing MEs and ADEs.
- 9 Promoting a “just culture” of medication safety cultivates trust in the workplace that makes personnel feel comfortable sharing safety information (eg, unsafe situations) and assuming personal responsibility and accountability for complying with safe medication practices.

## BEYOND THE BOOK

### BEYOND THE BOOK

1. Watch the <https://tinyurl.com/tqh8n3k> video entitled “CUSP: Understand Just Culture,” sponsored by the Agency for Healthcare Research and Quality. This 5.5-minute video describes the fundamental tenets of a “just culture” environment with examples that clarify the concept.
2. Use the above video to think about a patient care situation where a medication error occurred—and how it was managed and resolved. Write down two to four ways the “just culture” concepts were used—or not used—in that situation.

## INTRODUCTION

Medical errors are not a new phenomenon. Medical errors causing harm may lead to devastating effects on patients. In 1991, the Harvard Medical Practice Study showed that a significant number of people are victims of medical errors, and a subset experienced MEs. This landmark study reviewed the incidence of adverse events and negligence in hospitalized patients in the state of New York showing that almost 4% of patients experienced an iatrogenic injury (one caused by healthcare practices or procedures), prolonging their hospital stays.<sup>1</sup> Importantly, nearly 14% of those mistakes were fatal. Examples of mistakes noted in the Harvard study included renal failure from angiographic dye and a missed diagnosis of colon cancer. Drug complications were the most common type of outcome attributed to negligence, accounting for 19% of these preventable adverse events.<sup>1</sup>

The goal of medication therapy is achieving defined therapeutic goals to improve a patient’s quality of life while minimizing harm.<sup>2</sup> Known and unknown risks are associated with the therapeutic use of prescription and nonprescription drugs and drug administration devices.<sup>3</sup> Mishaps related to medication therapy include both ADEs and MEs.<sup>4</sup>

MEs negatively affect patients’ confidence in the healthcare system and increase healthcare costs. Research conducted by the American Society of Health-System Pharmacists (ASHP) showed that 61% of patients surveyed reported that they were “very concerned” about being given the wrong medicine during a hospital stay.<sup>5</sup> MEs are also very costly—to healthcare systems, patients and their families, and healthcare workers. The emotional cost of an ME is also significant, including the burden on the family for grieving loss or stress for the healthcare worker (often referred to as the “second victim”) involved in an ME that caused harm.

Many MEs are not detected by standard reporting systems and often do not cause patient harm. According to the “Fourth Annual Report on Medication Errors in US Hospitals” by the United States Pharmacopeia (USP), 49% of MEs never reach the patient.<sup>6</sup> Many MEs have little to no clinical importance or have minimal impact on patient care. According to the 2002 USP study of the anonymous Web-based reporting system MEDMARx, 98% of reported MEs ( $n = \sim 190,000$ ) resulted in no harm to the patient. Tragically, however, MEs do sometimes result in serious patient morbidity and mortality.<sup>7</sup> In fact, preliminary data from the Centers for Disease Control and Prevention (CDC) list accidents (of which MEs are included) as the fifth leading cause of death in the United States in 2010.<sup>8</sup>

The 1999 report “To Err Is Human” by the Institute of Medicine (IOM), a preeminent source, irrevocably changed the way MEs were viewed in health systems. In many ways, this was the first comprehensive report that quantified the problem of medical errors in health systems. The report stated that medical mistakes kill 44,000 to 98,000 patients annually in the United States, causing more deaths than breast cancer, motor vehicle accidents, and infections of human immunodeficiency virus.<sup>9</sup> In the years since this landmark publication, medication safety has become a priority across the country. Another IOM report in 2007, “Preventing Medication Errors,” described system changes that are necessary to improve safety to include computerized physician order entry (CPOE), barcode-assisted medication administration (BCMA), multidisciplinary communication, and the active involvement of patients in their treatment.<sup>10</sup>

As mentioned previously, medication safety has attracted the attention of government and regulatory agencies, including The Joint Commission (TJC) and the Centers for Medicare & Medicaid Services (CMS). Both of these organizations have revised their standards to emphasize a systematic approach to identifying and preventing MEs and ADEs. Healthcare professionals are obligated to ensure that medications are used safely and errors are

prevented. Web addresses for those and other organizations and government agencies involved in medication safety are listed in [Table e4-1](#).

TABLE e4-1

Medication Safety Information Resources

National Patient Safety Foundation	<a href="http://www.npsf.org">www.npsf.org</a>
Institute for Safe Medication Practices	<a href="http://www.ismp.org">www.ismp.org</a>
Agency for Healthcare Research and Quality	<a href="http://www.ahrq.gov">www.ahrq.gov</a>
Centers for Medicare & Medicaid Services	<a href="http://www.cms.gov">www.cms.gov</a>
The Joint Commission	<a href="http://www.jointcommission.org">www.jointcommission.org</a>
Just Culture of Patient Safety	<a href="https://www.ahrq.gov/hai/cusp/videos/07a-just-culture/index.html">https://www.ahrq.gov/hai/cusp/videos/07a-just-culture/index.html</a>
National Coordinating Council for Medication Error Reporting and Prevention	<a href="http://www.nccmerp.org">www.nccmerp.org</a>
Institute of Medicine of the National Academies	<a href="http://www.iom.edu">www.iom.edu</a>

This chapter provides the healthcare professional with fundamental background information on the principles and practices of medication safety and reviews definitions, prevalence, causes, and methods for preventing MEs and ADEs. As more is known about identifying and preventing MEs and ADEs, the healthcare system will become a safer environment.

DEFINING MEDICATION ERRORS AND ADVERSE DRUG EVENTS

**1** Health professionals should use a standard definition of MEs and ADEs to foster a shared vision to reducing their prevalence. Doing so helps to ensure MEs and ADEs are viewed similarly among various disciplines and regions. It also helps to ensure continuity in their reporting based on published guidelines.

The IOM defines an ADE as an injury resulting from medical intervention related to a drug, which can be attributable to preventable and non-preventable causes.<sup>11</sup> The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) defines an ME as follows: “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.”<sup>11</sup> This NCCMERP definition of MEs has recently been implemented in other agencies guidelines most notably CMS and TJC.<sup>12,13</sup>

Patients can experience an ADE even if the correct medication was prescribed and administered because an ADE refers to the effect the drug had on the patient, not necessarily that an error occurred in the medication process. This is in direct contrast to MEs, which involve any mistake in the medication process, regardless of patient outcome. Not all MEs lead to serious consequences; however, preventing MEs at any point in the medication-use process has the potential to reduce harm (eg, ADEs). Although an ME in one patient may not cause harm, that same ME in another patient could prove to be fatal.

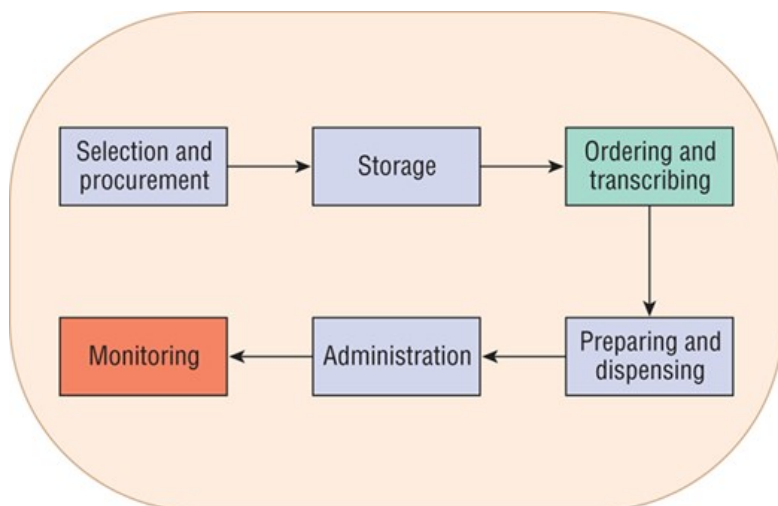
It is important to understand the difference between MEs and ADEs. Broadly speaking, MEs describe process errors and ADEs describe MEs causing negative clinical outcomes. The following example illustrates the differences between MEs and ADEs. Consider the case of two patients (patient A and patient B) who each received a dose of digoxin that was too high for their respective compromised renal function. An ME in prescribing occurred in patient A and patient B because the incorrect dose was prescribed for each patient. However, harm from this prescribing error (digoxin toxicity) occurred only in patient A. This event would be documented as an ME and ADE in patient A and an ME in patient B.

2 Put another way, all ADEs cause patient harm, but are not necessarily preventable. All MEs are preventable, but do not necessarily cause patient harm. ADEs can be categorized as preventable, non-preventable, or, if they have not actually occurred, potential.

MEs can be categorized by the node of the medication-use process in which the error occurred. For the purpose of safe medication management, TJC divides the medication-use process into the six critical processes shown in Fig. e4-1. Although MEs can occur at any stage in the medication-use process, upward of 80% of errors reported are in either the ordering and transcribing or administration processes.<sup>14</sup>

FIGURE e4-1

Medication-use process. (Data from ASHP guidelines on preventing medication errors in hospitals. *Am J Hosp Pharm*, 1993;50:305–314. © 1993, American Society of Health-System Pharmacists, Inc.)



Source: Joseph T. DiPiro, Gary C. Yee, Stuart T. Haines, Thomas D. Nolin, Vicki L. Ellingrod, L. Michael Posey: *DiPiro's Pharmacotherapy: A Pathophysiologic Approach*, 12e Copyright © McGraw Hill. All rights reserved.

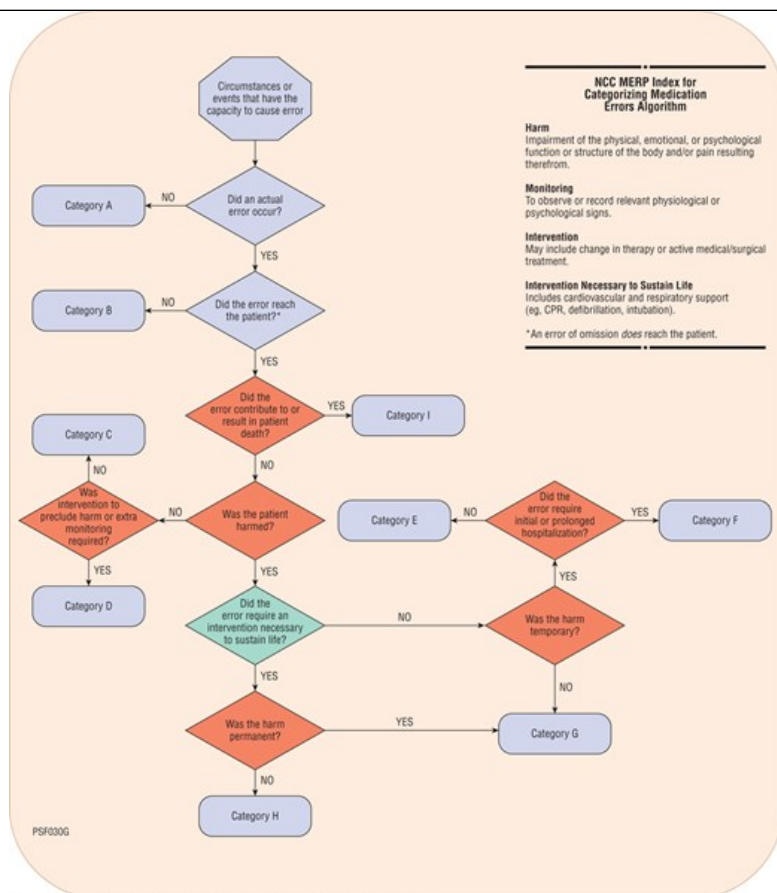
Another common method to categorize MEs is the NCCMERP Index for Categorizing Medication Errors Algorithm shown in Fig. e4-2. This algorithm categorizes MEs according to the severity of the outcome.<sup>15</sup> The algorithm provides the user an easy method to categorize an ME that occurred. To fully understand and use this algorithm, it is necessary to understand the following terms:

1. Harm: impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom
2. Monitoring: to observe or record relevant physiologic or psychological signs
3. Intervention: changes in therapy, active medical and/or surgical treatments, or other responses of health professionals or the patient
4. Intervention Necessary to Sustain Life: cardiovascular and respiratory support or other measures that maintain basic physiologic functioning

FIGURE e4-2

National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) Index for Categorizing Medication Errors Algorithm.

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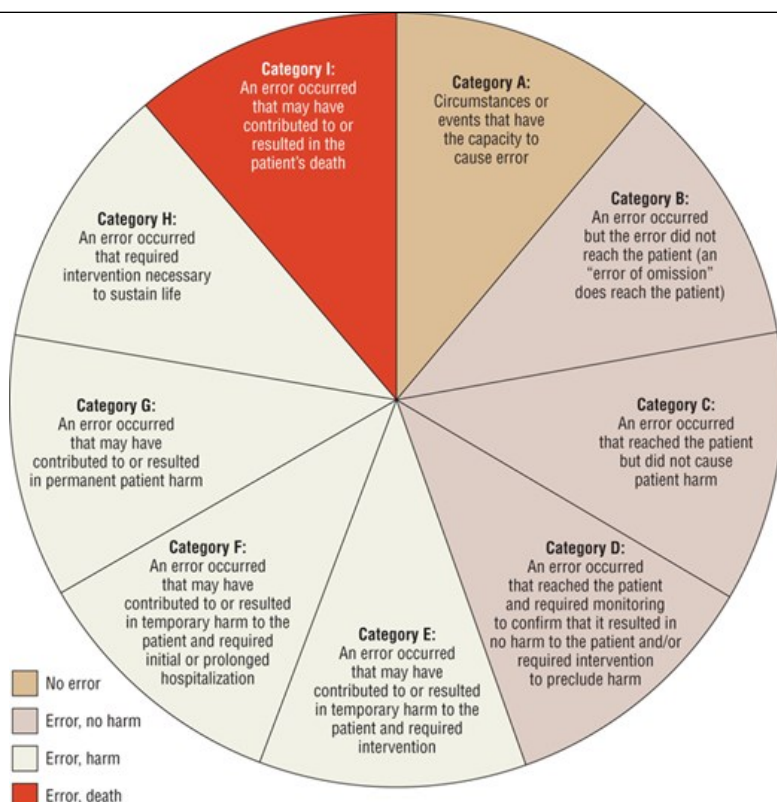


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By and large, the classification system developed by NCCMERP has gained widespread acceptance (Fig. e4-3). This system allows for comparison of numbers and types of MEs across health systems. It takes into account whether or not the patient received the medication, what if any treatment or monitoring was required, and lastly, the outcome. Note that the same ME could occur in two patients, but if they had different outcomes, the error categories would be different. For example, if patient A received a 10-fold overdose of an opioid-containing medication and required naloxone to treat respiratory depression, this would be a category E error. However, if patient B received the same inappropriate dose of the same opioid-containing medication and was also treated with naloxone, but in this case the patient had to stay an extra night in the hospital, this would be a category F error. The NCCMERP Index for Categorizing Medication Errors, shown in Fig. e4-3, is a more concise diagram consisting of all the different categories.

FIGURE e4-3

National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) Index for Categorizing Medication Errors. (Reprinted with permission from the National Coordinating Council for Medication Error Reporting and Prevention. Copyright © 2001. All rights reserved.)



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It should be noted other approaches to categorization are sometimes used. One method is to simply judge whether or not MEs were clinically significant.<sup>15</sup> In addition, Hartwig, Denger, and Schneider developed a more elaborate, severity-indexed classification program.<sup>16,17</sup>

## PREVALENCE

**3** Each year in the US hospitals, 6.7% of all patients admitted will experience a medical error. Of these errors, 3.1% will cause harm, and 13% will have fatal outcomes. Surprisingly, a large percentage of medical errors occur frequently, and are both predictable and preventable. MEs and ADEs are both included in the broad category of medical errors. Preventable ADEs occur in 2% of hospitalized patients, and MEs resulting in harm contribute to approximately 7,000 deaths annually in the United States.<sup>11</sup>

Beyond their human toll, MEs and ADEs are economically costly as well. These errors can prolong treatment courses and hospital stays as well as require therapeutic and pharmacologic intervention. The IOM report noted that the hospital cost of an ADE averaged \$4,700.<sup>11</sup> Putting this figure in perspective is important for understanding the costs associated with ADEs. Using published data to extrapolate the incidence of ADEs in a given hospital (6.7% of hospital admissions), an organization with 15,000 admissions per year (~40/day) could expect approximately 1,100 ADEs yearly at a cost of \$5.2 million annually. Most strikingly, cost projections compiled in 2000 at the University of Arizona showed that the morbidity and mortality costs for MEs were in the range of \$177 billion among the US ambulatory population alone.<sup>17,18</sup> The types of mistakes examined in that analysis include incorrect medications, wrong-site surgeries, hospital- or treatment-acquired infections, and mistaken identities.

With the involvement of the IOM and significant impact of MEs, accrediting bodies have added detailed error prevention standards. TJC, a standard-setting organization for hospitals and other healthcare organizations, implemented yearly goals for patient safety that weigh significantly in the organization's accreditation review of a hospital.<sup>18</sup> CMS requires certain conditions of participation for healthcare institutions to receive federal funding for Medicare patients. An example includes prevention of hospital-acquired complications during or after procedures such as surgery and catheterization. This requirement is heavily weighed during reviews in an effort to ensure that hospitals have adequate processes and practices in place to prevent medical errors.<sup>19</sup>



## PRIMUM NON NOCERE

From the Oath of Hippocrates, this means “First, Do No Harm” and reiterates the role of healthcare workers in preventing ADEs. Most MEs do not result in patient harm. If harm occurs, it can range from an extra day of monitoring in the hospital to permanent bodily damage or even death.

MEs that are most likely to cause harm to the patient include incorrect administration of medication (such as inappropriately crushing tablets), delivering drugs through the wrong route (such as IV vs intramuscular), and dispensing wrong medications. Insulin, morphine, and heparin are cited as being the agents most frequently involved in errors that result in harm to patients.<sup>20,21</sup>

### Causes of Medication Errors

**4** As shown in Fig. e4-1, medication selection and procurement is the first step in the medication process. MEs in this step include failing to order adequate stock of a medication to meet patient needs, ordering expired or adulterated medication, confusion with substitutions during product shortages and recalls, and ordering the incorrect product, strength, or dilution.

The second step is storage. An ME occurs when any medication that has been stored improperly is subsequently given to a patient. This could include failing to refrigerate a medication or failing to protect a medication from light.

The third step is ordering and transcribing. MEs in ordering occur when the drug selected and/or its dose, frequency, or dosing duration is not appropriate for the patient’s disease or physiologic condition. MEs in the transcribing phase include failure to correctly interpret the medication order.

During preparing and dispensing, health professionals must obtain and package the correct drug, dose, or dilution of a product. Medication dispensing errors are defined as any discrepancy between the medication dispensed and the original prescriber’s order.

Likewise, an ME in administration is any discrepancy between how the medication is given to the patient and the administration directions from the physician or hospital guidelines.

MEs involved in monitoring and evaluating the effects of medication are defined as not ensuring proper follow-up of the therapeutic effect of a medication or failing to recognize an adverse effect of a medication.

One analysis showed that the most common errors involved prescriptions in which a medication was incorrectly prescribed (18.5%), dosage or quantity was incorrectly interpreted during dispensing (25.5%), and omission (25.6%), in which the prescribed medication was not administered.<sup>21</sup> Other studies have slightly different descriptions of the medication ordering process. 49% of MEs occur during the ordering phase, 11% during the transcribing phase, 14% during the processing (preparing and dispensing) phase, and 26% in the administration phase.<sup>22</sup> A majority of errors in the ordering phase are wrong dose or frequency, known drug allergy, and drug-drug interactions.<sup>23</sup> Many errors occur in the administration phase, such as wrong dose or incorrect drug administration technique.<sup>23</sup>

MEs are preventable. ADEs are preventable if they result from an error. In one analysis, two-thirds of ADEs are preventable with an incidence of error caused by provider negligence at around 40%.<sup>24</sup> This same study categorizes errors as diagnostic, treatment, preventive, or other. The key is in finding the appropriate system or process at the correct step in medication distribution in an attempt to completely alleviate the risk of error.

MEs occur for a number of reasons, including the following:

1. Ambiguous strength designation on labels or in packaging
2. Drug product nomenclature (look-alike or sound-alike names, use of lettered or numbered prefixes and suffixes in drug names)
3. Equipment failure or malfunction
4. Improper use of electronic order entry systems
5. Inaccurate dosage calculation

6. Inadequately trained personnel
7. Inappropriate abbreviations used in prescribing
8. Labeling errors
9. Excessive workload
10. Lapses in individual performance
11. Medication unavailable

## Preventing Medication Errors

It is important to understand that it is human nature to make mistakes. Furthermore, medication-use systems are extremely complex. Therefore, it is vital to create systems with built-in safeguards in order to reduce risk and promote safe use of medications. Systems for ordering, dispensing, and administering medications should be designed to minimize or prevent error.

5 Errors can occur at any step in the medication-use process. For each type of error, it is important to determine the root cause, or main reason, for the error. After researching the error and determining its root cause, a tracking system for MEs should be created. Multiple examples of tracking systems are available; errors may be grouped by the type of error or the extent of patient harm.

6 To design safer medication delivery systems, data must be collected, analyzed, and trended. MEs can be classified by the type of technical error that occurred. The ASHP Guidelines on Preventing Medication Errors in Hospitals classifies errors as shown in **Table e4-2**. System failures teach health professionals a tremendous amount about the weaknesses inherent in today's complex medical delivery processes. Once tracking systems are in place for MEs and ADEs, processes and systems can be put in place to prevent errors. This may require an upgrade to the current computer program, an upgrade to that software, or an entirely new system. It may mean separating look-alike, sound-alike medications. It may mean creating preprinted orders based on guidelines to prevent inappropriate drug, dose, or monitoring. Training of staff may be required, and monitoring and follow-up are often needed.

TABLE e4-2

### Types of Medication Errors



Type of Error <sup>a</sup>	Examples
Prescribing error	Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy, or other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors that reach the patient
Omission error <sup>b</sup>	Failure to administer an ordered dose to a patient before the next scheduled dose
Wrong time error	Administration of medication outside a predefined time interval from its scheduled administration time (this interval should be established by each individual healthcare facility)
Unauthorized drug error <sup>c</sup>	Administration of medication not authorized by a legitimate prescriber for the patient
Improper dose error <sup>d</sup>	Administration of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the patient (ie, one or more dosage units in addition to those that were ordered)
Wrong dosage-form error <sup>e</sup>	Administration of a drug product in a different dosage form than ordered by the prescriber
Wrong drug-preparation error <sup>f</sup>	Drug product incorrectly formulated or manipulated before administration
Wrong administration-technique error <sup>g</sup>	Inappropriate procedure or improper technique in the administration of a drug
Deteriorated drug error <sup>h</sup>	Administration of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised
Monitoring error	Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy
Adherence error	Inappropriate patient behavior regarding adherence to a prescribed medication regimen
Other ME	Any ME that does not fall into one of above redefined categories

<sup>a</sup>The categories may not be mutually exclusive because of the multidisciplinary and multifactorial nature of MEs.

<sup>b</sup>Assumes no prescribing error. Excluded would be (1) a patient's refusal to take the medication or (2) a decision not to administer the dose because of recognized contraindications. If an explanation for the omission is apparent (eg, patient was away from nursing unit for tests or medication was not available) that reason should be documented in the appropriate records.

<sup>c</sup>This would include, for example, a wrong drug, a dose given to the wrong patient, unordered drugs, and doses given outside a stated set of clinical guidelines or protocols.

<sup>d</sup>Excluded would be (1) allowable deviations based on preset ranges established by individual healthcare organizations in consideration of measuring devices routinely provided to those who administer drugs to patients (eg, not administering a dose based on a patient's measured temperature or blood glucose level) or other factors such as conversion of doses expressed in the apothecary system to the metric system and (2) topical dosage forms for which medication orders are not expressed quantitatively.

<sup>e</sup>Excluded would be accepted protocols (established by the pharmacy and therapeutics committee or its equivalent) that authorize pharmacists to dispense alternate dosage forms for patients with special needs (eg, liquid formulations for patients with nasogastric tubes or those who have difficulty swallowing), as allowed by state regulations.

<sup>f</sup>This would include, for example, incorrect dilution or reconstitution, mixing drugs that are physically or chemically incompatible, and inadequate product packaging.

<sup>g</sup>This would include doses administered (1) via the wrong route (different from the route prescribed), (2) via the correct route but at the wrong site (eg, left eye instead of right), and (3) at the wrong rate of administration.

<sup>h</sup>This would include, for example, administration of expired drugs and improperly stored drugs.

Data from Reference 4.

## 7 Implementation strategies to reduce MEs:

1. Computerized provider order entry (CPOE)
2. Automated drug-distribution cabinets enabled with bar-code scanning
3. Robotic drug dispensing systems (intravenous and oral products)
4. Barcode-assisted medication administration (BCMA)
5. Smart IV infusion pumps with a two-way interface to an electronic medical record (EMR)

Studies have shown many MEs and ADEs are preventable. Numerous studies have shown roughly 25% of all MEs and ADEs would never have occurred if various strategies had been implemented. CPOE reduces preventable ADEs by 17% and decreases nonintercepted serious MEs by 50%.<sup>25</sup>

Other strategies, such as automated drug-distribution cabinets enabled with bar-code scanning, help to decrease storage and dispensing errors. This strategy, however, is not without its own potential for error as pharmacy technicians and others, such as nurses and pharmacists, must use the bar-code scanner when filling the cabinets and removing medications to assure for the safety double check.

The use of BCMA is growing in popularity with many health systems already implementing this technology. When used appropriately, BCMA can decrease MEs by 65% to 86%.<sup>26,27</sup> BCMA prevents medication administration errors in outpatient areas—most notably the emergency department where BCMA is not routinely used.<sup>28</sup> The BCMA process involves using medications dispensed by the pharmacy with a barcode on the medication. This barcode is on all medications regardless of route including IV medications. If the incorrect medication is scanned, a warning will appear. As with other strategies, there is potential for error with bar-code administration as well. Examples would include nurses who override the warnings or who administer the medication before scanning the barcode. Both of these instances could lead to either an ME or ADE or both.

Most IV products are delivered to patients using “smart pumps.” These pumps allow the organization to program the pump with standard concentrations and standard infusion ranges, preventing the nurse from administering it outside specified limits for each drug. These pumps are also set up with soft and hard stops whereby if a nurse sets the pump outside specified ranges, the pump could alarm with a soft stop in which case the nurse could override it, or a hard stop in which case the nurse would be unable to override the alarm. The Institute for Safe Medication Practices cautions that while this technology can reduce MEs and ADEs, “smart pumps aren’t smart by themselves.” The information on most smart pumps

cannot be viewed on the EMR as pump software is not owned by most EMR vendors. The next step to “close the loop” in preventing intravenous infusion errors is to integrate smart pumps with the EMR so that data are sent bidirectionally between the two technologies.

A new approach to preventing MEs is to use computer simulation technology to educate and train healthcare workers in preventing errors. Organizations have been using simulation to establish competency in a variety of areas, such as airway management, surgical procedures, and basic life support. A recent review of the literature noted a growing interest in establishing programs that simulate potential for MEs.<sup>29</sup> When properly designed, simulations may assist providers in preventing serious and fatal MEs by providing “real life” experience.

It is important to remember the significance of MEs and ADEs on patients and the healthcare system. The cost of improving systems and training is negligible compared with the value of lives saved. In addition, the introduction of technology brings on new errors; the hope is that these errors will cause less harm than historical dispensing errors. Healthcare workers must always be diligent in predicting new sources of error from any robotic or automated system.

## MEDICATION RECONCILIATION

**8** Medication reconciliation is one of the most important safety practices to reduce MEs during care transitions. It involves comparing and reconciling hospital admission and discharge medication orders with patients’ home medications, or comparing medications when patients are moved among different areas in a hospital (eg, from intensive care unit to a regular care unit). Many health systems are using the emergency department as the point to perform admission medication reconciliation since 30% to 40% of those patients are being admitted. This task can be performed by the pharmacist, pharmacy intern, or pharmacy technician depending on state rules and regulations.

Inadequate reconciliation accounts for 46% of all MEs and up to 20% of all ADEs among hospitalized patients.<sup>30,31</sup> Furthermore, MEs can be reduced by more than 76% when medication reconciliation is implemented at hospital admission, transfer between units in the hospital, and hospital discharge.<sup>32</sup>

Medication reconciliation involves the following steps: determining a current list of medications; developing a list of medications to be prescribed; comparing the two lists; making clinical decisions based on the two lists, as well as finalizing the list of medications and communicating it to the patient and other clinicians. Medication reconciliation at discharge is extremely important to not only ensure patients know how they should take their medications and any side effects that may occur, but alert them to any new additions or deletions to their medication list.

## “JUST CULTURE” OF PATIENT SAFETY

**9** An accepted idea in patient safety is the “just culture” concept. Introduced by the attorney David Marx in 2001, it focused on the sequence of events that led to the error, rather than the person who made the error.<sup>32</sup> This concept encourages internal risk transparency, coaching and counseling of employees, avoiding negative retribution for errors, and gathering and then using information to prevent recurrence of the error.

Before “just culture,” there were two main philosophies regarding errors in healthcare. These were the *punitive culture* and the *blame-free culture*. In the punitive culture, those who made an error were held personally responsible, regardless of the root cause. This was thought to discourage reporting of errors. The blame-free culture encouraged reporting of errors as there was no risk of punishment, regardless of the cause of the error. However, the lack of blame did not provide incentive against risky or even reckless behaviors.

The key distinguishing characteristic of “just culture” is that the focus is on the cause of the error, and therefore errors caused by system failures are not punished. However, reckless or negligent behaviors that lead to errors are punished. Therefore “just culture” has an inherent accountability not seen in a pure blame-free culture.

“Just culture” does not negate previous information provided in researching MEs. The “just culture” approach to MEs improves internal communication and reporting processes, resulting in an effective, successful error-reporting process.

The introduction of “just culture” of patient safety has afforded a great opportunity to prevent MEs and ADEs. Employees are encouraged to help design systems to reduce human error and risky behaviors. It is a proactive approach in which risks are reviewed and outcomes of events are evaluated. The approach allows the staff to be a stakeholder in the process of risk reduction, encouraging health workers to discuss and review errors without fear of retribution. A 2009 publication by TJC describes “just culture” as “an environment where employees hunger for knowledge and eagerly

seek to understand risk.”<sup>31</sup> The main focus in “just culture” is on systems and improving system designs.

CONCLUSION

MEs are a public health problem. They affect a large number of patients with the risk of causing severe patient harm. Errors can occur at any step in the medication-use process, from ordering to post-administration and monitoring.

Within a facility or health system, a set of clear definitions and guidelines of MEs and ADEs is needed. Once these definitions are set, a tracking process can be designed. The “just culture” approach encourages all employees to be stakeholders in the prevention of MEs and ADEs. The staff can design, follow, and review results of their own ME tracking process, all with this old adage in mind: “An ounce of prevention is worth a pound of cure.”

ABBREVIATIONS

ADEs	adverse drug events
ASHP	American Society of Health-System Pharmacists
BCMA	barcode-assisted medication administration
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CPOE	computerized physician order entry
EMR	electronic medical record
IOM	Institute of Medicine
ME	medication error
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention
TJC	The Joint Commission
USP	United States Pharmacopeia

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## SELF-ASSESSMENT QUESTIONS

1. What term best describes the stress or trauma experienced by a healthcare worker involved in a medication error that caused harm?
  - A. just culture
  - B. compassion fatigue
  - C. second victim
  - D. worker worry
2. Which of the following organizations is the most appropriate resource for medication safety information?
  - A. Institute of Medicine of the National Academies
  - B. National Quality Forum
  - C. American Medical Association
  - D. Utilization Review Accreditation Commission
3. “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer” is the definition for which term?
  - A. Adverse drug event
  - B. Nonpreventable harm

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- C. Medication error
- D. Adverse drug reaction
4. Patient PM received a dose of insulin that was too high, resulting in a hypoglycemia event that led to the patient becoming unconscious and requiring aggressive correction. Which of the following best describes this error type(s)?
- A. Medication error only
- B. Adverse drug event only
- C. Neither medication error nor adverse drug event
- D. Both medication error and adverse drug event
5. At which node of the medication use process is a medication error most likely to occur?
- A. Administration
- B. Preparation/Dispensing
- C. Storage
- D. Monitoring
6. Which of the following lists the nodes in the medication use process in the correct order?
- A. Administration, Monitoring, Storage, Ordering and Transcribing, Preparing and Dispensing, and Selection and Procurement
- B. Selection and Procurement, Monitoring, Storage, Administration, Ordering and Transcribing, and Preparing and Dispensing
- C. Ordering and Transcribing, Selection and Procurement, Preparing and Dispensing, Monitoring, Administration, and Storage
- D. Selection and Procurement, Storage, Ordering and Transcribing, Preparing and Dispensing, Administration, and Monitoring
7. Which of the following is included in the NCC MERP Index for Categorizing Medication Errors Algorithm?
- A. Patient Type
- B. Harm
- C. Process
- D. Second Victim
8. Which of the following NCC MERP categories is defined as an error that occurred and may have contributed to or resulted in temporary harm to the patient and required intervention?
- A. Category E
- B. Category B
- C. Category A
- D. Category D
9. NCC MERP categories B, C, and D can best be classified under which of the following types?



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- A. Errors that resulted in death
- B. Errors that resulted in harm
- C. Errors that resulted in no harm
- D. No errors resulted
10. Which organization requires certain conditions of participation for healthcare institutions to receive federal funding for Medicare patients?
- A. TJC
- B. NCC MERP
- C. IOM
- D. CMS
11. Which of the following medications is most frequently involved in errors that lead to patient harm?
- A. Heparin
- B. Fluoxetine
- C. Metformin
- D. Acetaminophen
12. Which of the following is a reason medication errors occur?
- A. Appropriate abbreviations used in prescribing
- B. Proper use of electronic order entry systems
- C. Accurate dosage calculation
- D. Inadequately trained personnel
13. Which of the following is an implementation strategy that can be used to reduce medication errors?
- A. Using paper health records
- B. Robotic drug dispensing systems
- C. Smart infusion pumps with mono-directional interface
- D. Manual drug-distribution cabinets
14. Medication reconciliation is a process to prevent medication errors and includes which of the following steps?
- A. Providing the admission medication list to patients at discharge
- B. Determining the past list of medications
- C. Making clinical decisions only on the past list
- D. Finalizing and communicating the reconciled list to the patient and clinicians
15. Which of the following terms is defined as holding individuals personally responsible, regardless of the root cause of a medication error?
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- A. Just culture
- B. Punitive culture
- C. Blame-free culture
- D. Risk culture

## ANSWERS

1. **B.** Second victim refers to the stress experienced by a healthcare worker involved in a medication error that caused harm.
2. **A.** The Institute of Medicine of the National Academies is the most appropriate resource. All other organizations listed are healthcare organizations that provide other resources, not medication safety. Refer to [Table e4-1](#).
3. **C.** NCC-MERP defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.
4. **D.** Both medication error and adverse drug event occurred as there was an administration error (dose too high) and harm resulted (severe hypoglycemia).
5. **A.** 80% of errors reported are in the ordering/transcribing or administrative processes. See [reference 14](#).
6. **D.** The Joint Commission divides the medication use process into six critical processes as listed in response D and depicted in [Figure e4-1](#).
7. **B.** The NCC MERP index includes harm. See [Figure e4-2](#).
8. **A.** Category E is defined as an error that may have contributed to or resulted in temporary harm to the patient and required intervention. See [Figure e4-2](#).
9. **C.** NCC MERP Categories B, C, and D can best be classified as errors that resulted in no harm. See [Figure e4-3](#).
10. **D.** CMS requires certain conditions of participation for healthcare institutions to receive federal funding for Medicare patients.
11. **A.** Heparin is most frequently involved in errors that lead to patient harm and is on the ISMP list of high-alert medications. See [reference 21](#) for more information.
12. **D.** Inadequately trained personnel is a reason that medication errors may occur. All other answer options provided lower the risk for medication errors.
13. **B.** Robotic drug dispensing systems are implementation strategies to reduce medication errors. All other options represent manual options that are at risk for lapses in individual performance or poor transfer of data that can lead to medication error.
14. **D.** Finalizing and communicating the reconciled medication list to the patient and clinicians is an important step in the medication reconciliation process. Providing the admission medication list to patients at discharge does not help patients understand the medications they need to take going forward. Past medication lists do not reflect the medications that the patient is currently taking. Making clinical decisions only on the past list and not on a current list/clinical needs is inappropriate for medication reconciliation.
15. **B.** Punitive culture is defined as holding individuals personally responsible, regardless of the root cause of the medication error.