Chapter 7
Medication Error

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"All things are poison, and nothing is without poison. Only the dose makes a thing not poison."

Paracelsus

Introduction

Medications are the most common source of medical errors both in hospitals and in the ambulatory care setting, causing harm to at least 1.5 million people per year [1]. Medications account for approximately "1 out of every 131 outpatient deaths and 1 out of 854 inpatient deaths" [2], a total of 7,000 estimated potentially preventable deaths per year.

Adverse drug events (ADEs), in particular, related to ineffective patient education regarding medications and monitoring of drug therapies are accountable for up to 66 % of the adverse events after patients are discharged from the hospital [3]. Further, the use of high risk medications such as warfarin, insulin, and digoxin especially in elderly patients account for 33 % of the ADEs treated in emergency departments (EDs) and 41 % of ADEs leading to hospitalizations [4].

A medication error is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control

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of the health care professional, patient, or consumer. Such event may be related to professional practice, health care products, procedures, and systems [5]." An adverse drug event (ADE) is defined as an injury or harm to the patient that is caused by medication usage [6]. It is important to note that not all medication errors lead to ADEs and not all ADEs are medication errors.

According to the National Coordinating Council for Medication Error Reporting Program (NCC-MERP), medication errors are categorized into the following nine categories depending on the level of patient harm [5]:

Category A: Circumstances or events occur that have the capacity to cause error (no error).
Category B: An error occurred, but the error did not reach the patient (error, no harm).
Category C: An error occurred that reached the patient but did not cause patient harm (error, no harm).
Category D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm (error, no harm).
Category E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention (error, harm).
Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required an initial or prolonged hospital stay (error, harm).
Category G: An error occurred that may have contributed to or resulted in permanent patient harm (error, harm).
Category H: An error occurred that required intervention necessary to sustain life (error, harm).
Category I: An error occurred that may have contributed to or resulted in patient death (error, death).

Medication errors may occur at any of the five stages of the medication management process namely (1) ordering/prescribing, (2) transcribing and verifying, (3) dispensing and delivering, (4) administering, and (5) monitoring and reporting. It is estimated that 39 % of the errors occur during prescribing, 12 % during transcribing, 11 % during dispensing at the pharmacy, and 38 % during administering [7]. As illustrated in Fig. 7.1, most medication errors occur as a result of multiple vulnerabilities and failures in the continuum of the medication management process (the Swiss cheese concept) [8].

Similar to other adverse events, medication errors can arise from human errors and/or systems failures. Human errors include problems in practice (e.g., taking short cuts), training deficiencies, undue time pressure, distractions, and poor perception of risk. Systems failures can be related to products, procedures, or processes [2]. The most common medications associated with severe ADEs and mortality include central nervous system agents, anti-neoplastics, and cardiovascular drugs. The types of errors that contribute to patient death involve the wrong dose (40.9 %), the wrong drug (16 %), and the wrong route of administration (9.5 %) [9].

The American Hospital Association lists the following as the common types of medication errors [10]:

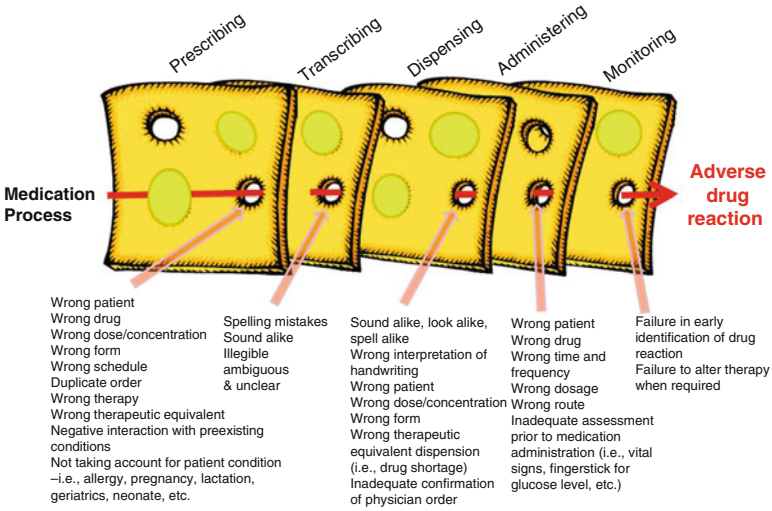

Fig. 7.1 Medication points of failures

- Incomplete patient information such as allergies, other medicines they are taking, previous diagnoses, and lab result
- Unavailable drug information such as a lack of up-to-date warnings from the Food and Drug Administration (FDA)
- Miscommunication of drug orders which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes or decimal points, confusion of metric and other dosing units, and inappropriate abbreviations
- Incorrect labeling as a drug is prepared and repackaged into smaller units
- Environmental factors such as heat, lighting, noise, and interruptions
- Failure to follow established facility policies and procedures

Case Studies

Case Study 1: Respiratory Depression Caused by Opioid Overdose

Clinical Summary

A 56-year-old patient with a history of metastatic esophageal cancer was admitted for progressive enlargement of a left neck mass leading to dysphagia and severe pain related to bone metastasis. He had been taking non-steroidal anti-inflammatory drugs (NSAIDs) at home with partial pain relief. In the ED, he was treated with intramuscular (IM) Ketorolac and was admitted for pain management and

hypercalcemia. Upon admission to the floor, the on-call resident ordered Fentanyl 50 mcg transdermal patch every 72 h because the patient had difficulty swallowing oral pain medications. The patient continued to complain of severe pain and additional morphine was administered subcutaneously (SQ) on as needed basis. Forty-eight hours after the admission, the patient was found to be comatose with pin-point pupils and slow, shallow breathing. Naloxone hydrochloride 0.4 mg/ml intravenous push (IVP) was administered to reverse the opioid effect and the patient subsequently developed generalized tonic–clonic seizures. The patient required intubation and mechanical ventilation and was observed in intensive care unit for 7 days. He was successfully extubated, transferred back to regular floor, and eventually discharged home. For the rest of the hospital stay, his pain was managed with short-acting morphine elixir 10 mg by mouth (PO) every 4 h with breakthrough coverage.

Analysis and Discussion

This case study illustrates a number of errors related to opioid prescribing for pain management. First, Fentanyl patch is a long-acting agent (the onset of action is up to 48 h); therefore it should not be used to treat acute pain especially in opioid-naïve patients. Second, the patient received a combination of SQ morphine along with Fentanyl leading to opioid overdose. Fifty micrograms of Fentanyl is equivalent to 135–224 mg of daily oral morphine equivalency. The prescribing physician should have been more aware and careful about the potential risks of prescribing opioids in high doses. At the same time, neither the pharmacist nor the nurses raised an alarm about the dose of pain medications being received by this patient. Finally, the rapid reversal of opioids may lead to seizures and other withdrawal symptoms. Hence, Naloxone should have been diluted and given in 0.04 mg/ml boluses, one-tenth of the IVP dose given to the patient.

Literature shows that opioid analgesics rank among the drugs most frequently associated with ADEs [11]. The most serious and sometimes fatal side effect is respiratory depression which is generally preceded by sedation. The reported incidence of respiratory depression in postoperative patients is about 0.5 % [11]. All patients receiving opioids must be adequately assessed and reassessed for pain and for previous history of opioid use/abuse to identify potential opioid tolerance or intolerance. There is commonly a lack of knowledge about potency differences among opioids, especially equivalence between short-acting and long-acting/sustained release opioid; therefore, sufficient time should be allowed to assess the patient's response to an initial dose before increasing the dosage or prescribing long-acting opioids. When converting from one opioid to another, or changing the route of administration from oral, IV, or transdermal, a pharmacist or pain management expert should be consulted if available or a conversion support system should be used to calculate correct doses [12]. When opioids are administered, the potential for opioid-induced respiratory depression should always be considered, especially in opioid-naive patients.

Fig. 7.2 Tall Man Lettering

Case Study 2: Wrong Drug Dispensing and Administration Due to Similar Sounding Names

Clinical Summary

On the oncology unit, Dr. Sure ordered Taxol (paclitaxel) 260 mg IV (175 mg/m² × 1.5 m² body surface area = 262.50 mg) for Ms. Jones for her advanced stage breast cancer. After a review of the order, the pharmacist mistakenly dispensed 260 mg of Taxotere (docetaxel). The nurse reviewed the order and thought what was sent up by pharmacy was the correct medication and administered Taxotere 260 mg. The usual adult dose for Taxotere is 60–100 mg/m² IV [13]. Due to this error the patient received the wrong medication at three times the usual dose and died 4 weeks later from neutropenic sepsis and hepatic failure.

Analysis and Discussion

Both Taxol and Taxotere are used for breast cancer, are from the same family of medications, the taxanes, but have different pharmacokinetics and side-effect profiles. There is an increased risk of serious (possibly fatal) reactions when receiving higher doses of Taxotere, such as severe neutropenia, neurosensory symptoms, asthenia, fluid retention, trouble breathing, chest pain or tightness, fast or irregular heartbeat, or abdominal swelling [13].

Since Taxol and Taxotere are look-alike, sound-alike, and spell-alike drugs, they need additional safeguards for differentiation. A simple and frequently used solution to improve safe use of such medications is to use Tall Man Lettering (Fig. 7.2) to highlight the dissimilar letters in two names [14]. The Institute for Safe Medication Practices (ISMP), FDA, the Joint Commission, and other safety organizations have promoted the use of tall man letters as a means of reducing confusion between similar drug names [15]. This methodology can be used throughout the medication process including on CPOE ordering screens, computer-generated pharmacy labels, pharmacy computer drug selection screens, shelf labels, automated dispensing

cabinet screens, computer-generated medication administration records, and even preprinted order sheets.

On the pharmacy dispensing side, the use of separate storage areas and different color containers could have helped to distinguish these two otherwise similar sounding medications. The nurse unfortunately also missed the opportunity to avert the error from reaching the patient. Had a bar-coded medication administration (BCMA) system to ensure the "five rights" of medication administration (right drug, dose, route, patient, and time) been in place at the bedside, the system would have detected that the medication being administered does not match the medication ordered thus averting this high-risk error [16]. Additionally, most institutions mandate verification by two nurses prior to administration of a high-alert medication such as a chemotherapeutic agent which had not been implemented at this hospital due to staffing constraints.

Discussion

There are five essential strategies in improving medication safety. These include:

1. Use of Information Technology
   IT applications such as electronic health records (EHRs) and computerized physician order entry (CPOE), especially when augmented by a point-of-care clinical decision support (CDS) system have been demonstrated to reduce medication errors and improve patient safety [17–19]. Advantages of CPOE include legibility, prompt pharmacy review, links to drug–drug interactions, decision algorithms, easier ADE identification, less risk for look-alike/sound-alike medication errors, and improved medication reconciliation. Another advantage of CPOE is the capacity to embed CDS tools in the form of order sets, guidelines, or protocols [17, 18]. In addition to the safety of medication ordering, IT tools also improve efficiency of the process through the automation of medication preparation and packaging via the use of robotic dispensers.

   Another technology that has been demonstrated to improve medication safety is the bed-side bar-coded medication administration (BCMA) system. In this system, the nurse scans the bar-coded bracelet on the patient's wrist band to ensure that the medication(s) will be administered to the right patient. The nurse also scans the unit dose of the medications. The system compares each medication with the physician's orders and alerts the nurse to any mismatch of patient identity or of the name, dose, or route of administration of the medication. BCMA systems have been shown to lead to a 54–87 % reduction in medication errors during the administration step [20, 21].

   It is important to note that technology is not a panacea and can have unintended and potentially adverse consequences on safety. A widely quoted 2005 study found that CPOE implementation in an academic tertiary care children's hospital during an 18-month period actually resulted in an unexpected *increase* in mortality rate [22]. A commercial CPOE program that was designed for adult general

medical–surgical usage was quickly implemented across this pediatric facility without appropriate customization, workflow configuration, and testing/user training. The study found an unexpected increase in mortality coincident with CPOE implementation and concluded that technology must not replace the critical thinking process necessary to make appropriate treatment choices. Other reports have also demonstrated that safe implementation of CPOE requires ongoing assessment of the system integration process with the human interface, as well constant monitoring and evaluation of medication error rates and mortality [23].

Other risks of CPOE include "alert fatigue" and an overreliance on the automated decision process sometimes substituting critical clinical thinking. "Alert fatigue" occurs when physicians receive too many alerts of questionable perceived value leading them to override the alerts. Therefore, the CPOE implementation should carefully consider the number and types of alerts that are turned on in a system [24, 25].

2. Addressing Health Literacy and Engaging Patients and Families
   Medication error prevention requires collaboration among different members of the healthcare team as well as with the patients and their families. The team should recognize the higher risk of medication error in patients with lower literacy levels as they may not have the skills necessary to effectively navigate the medication use process and are more likely to misinterpret the prescription label information and auxiliary labels [26, 27].
3. High Alert Medications
   High alert medications, such as anticoagulants, opioids, sedatives, insulin, chemotherapy, and electrolytes, can cause an immediate and life-threatening condition for the patient even when administered in usual doses. Due to high risk for patient harm, institutions should take additional steps to identify and mitigate risks to patient safety from such medications. Some steps include (1) standardize protocols and dosing; (2) establish order sets for the physicians with automated alerts; (3) dispense medications from pharmacy only and utilize auxiliary color-coded labels indicating high-alert medications; (4) establish monitoring parameters on assessing, reassessing, and documentation of patient responses to the medications; (5) train staff on early recognition of potential adverse events and how to rescue patients, including antidotes that are available; (6) employ redundancies such as automated or independent double checks, a procedure in which two clinicians separately check each component of prescribing, dispensing, and verifying the high-alert medication before administering it to the patient [28, 29].
4. Medication Reconciliation
   Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. It should be done at the points of transition in care where new medications are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner, or level of care. The medication reconciliation process comprises of the five steps below:

   (a) Develop a list of current medications, e.g., home medications
   (b) Develop a list of medications to be prescribed

(c) Compare the medications on the two lists
(d) Make clinical decisions based on the comparison
(e) Communicate the new list to appropriate caregivers and to the patient

Studies have shown that more than half the patients experience one or more unintended medication discrepancy at the time of a hospital admission and nearly 40 % of these have the potential for moderate to severe harm [30]. It is easy to overlook medications that may cause an adverse event, especially when combined with new medications or different dosages, so an effective medication reconciliation process across care setting can help prevent errors of omission, drug to drug interactions, drug–disease interactions, and other discrepancies [31].

5. Foster Pharmacy Collaboration
Pharmacists can advise physicians in prescribing medications and enhance both physicians' and patients' understanding of medications [32]. Pharmacist participation during rounds with the medical teams on a general medicine unit contributed to a 78 % reduction in preventable ADEs (from 26.5 to 5.6 per 1,000 hospital days) by providing support at the time when decisions about therapy are made [33]. In addition, increased collaboration with the team resulted in increase in interventions during rounding, such as dosing-related changes and recommendations to add or modify a drug therapy [33].

An Interdisciplinary Approach to Medication Error Prevention

In this section, we describe the role of various health team members in preventing medication errors and improving safety.

The Prescribers' Role

Prescribing is an early point at which medication errors can arise. For safer prescribing, ordering physicians should stay knowledgeable with current literature review, consult with pharmacists and other physicians, as well as participate in continuing professional education. It is critical that prescribers evaluate the patient's overall status and review all existing therapies before prescribing new or additional medications to ascertain possible antagonistic or complementary drug reaction(s). Medication orders should be complete, clear, and unambiguous and should include patient name, generic name, brand name (if a specific product is required), route and site of administration, dosage form, dose, strength, quantity, frequency of administration, prescriber's name, and indication. In some cases, a dilution rate and time of administration should be specified. The desired therapeutic outcome for each medication should be expressed when prescribed. It is important not to use inappropriate abbreviations such as "QD," "BID," etc. The prescriber should educate the patient/caregivers about the medication prescribed, special precautions or observations, and

potential anticipated side effects such as dry mouth or the first-dose hypotension. Finally, the prescriber should follow up and evaluate the need for continued therapy for individual patients on a regular basis [34].

The Pharmacists' Role

The pharmacist, in collaboration with other team members, should be involved in assessing therapeutic appropriateness, medication interactions, and pertinent clinical and laboratory data for all orders. Pharmacists need to be familiar with drug distribution policies and procedures to ensure safe distribution of all medications and related supplies. They also maintain orderliness and cleanliness in the work area where medications are prepared and should perform one procedure at a time with as few interruptions as possible. They should observe how medications are actually being used in patient care areas to ensure that dispensing and storage procedures are followed as recommended. A review of medications that are returned to pharmacy is important as such review processes may reveal system breakdowns or problems that resulted in medication errors (e.g., omitted doses and unauthorized drugs). Pharmacists also play a key role in counseling patients/caregivers and verifying that they understand why a medication was prescribed, its intended use, any special precautions that might be observed, and other needed information [34].

The Nurses' Role

Nurses play a key role in medication safety because they are the final check point in the medication process before the medication is actually administered to the patient [34]. Also, by virtue of their direct involvement in patient care activities, nurses are in the best position to detect and report medication errors. Nurses need to review medications with respect to desired outcomes, therapeutic duplications, and possible drug interactions. They must review and verify all orders before medication administration and ensure that the drug dispensed matches the order in all respects. It is the standard practice for a nurse to verify the "five rights"—the right patient, drug, time, dose, and route—at the bedside prior to administration. It is essential for a nurse to observe patients for medication responses and reactions, especially after the first dose. Nurses also play a key role in the education of patients and family to ascertain that they understand the use of their medications and any special precautions or observations that might be indicated [34].

The Patients' and Caregivers' Role

The most important role for the patient and the family is to keep an up-to-date list of all medications. They should learn to recognize their pills—what they look like in size, shape, and color, and the indication and potential side effects.

Teaching patients is not simply preparing a list of pills with days and times attached; it should also include information about their diseases and the indication for medications. Patients should be asked to repeat-back or demonstrate-back to make sure they understood that which was taught.

Conclusion

Medication errors are frequent, often harmful but with good systems and processes largely preventable. Equally important in medication safety is the role of organizational culture that promotes transparency in reporting and a non-punitive response to human errors. Only through an open and honest discussion of errors and systems failures, changes can be made to improve performance and prevent harm [35].

Lessons Learned

- Medication errors occur at all phases of the medication process.
- Even seemingly simple medication errors are multifactorial, frequently involving more than one process and more than one line of responsibility.
- Many medication errors occur due to poor communication. A collaborative approach and better communication and interaction among members of the healthcare team and the patient are essential.
- Information technology (IT) solutions such as CPOE and BCMA are critical elements of an overall organizational strategy to prevent errors.
- Developing an organizational culture of safety, so that leaders and staff are committed to safety and are preoccupied with potential errors, is a vitally important piece in improving medication safety. A safety culture embraces open communication and empowers staff to report concerns.
- Finally, we must always respect the power of medication and never underestimate its potential to cure but also to harm patients.

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