SEARCHING FOR THE SOURCE ER

Administering drugs to hospital patients is a complex process with many opportunities for mistakes—some deadly. Knowing how the system works and why missteps happen is crucial.

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OF MEDICATION RXRS

Hospitals are obligated to provide the correct medicine to the right patient, in the proper dose, for the right reason. Nonetheless, medication errors in hospitals are ubiquitous—a patient will likely endure, on average, at least one medication error every day.[1] At least 1.5 million medication errors occur every year in hospitals, long-term care facilities, and outpatient clinics,[2] and each day as many as 120 patients die in hospitals as a result.[3] If you are handling a medication error case, you first need to know how hospital medication systems work and why mistakes occur.

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 of the health care professional, patient, or consumer."[4] These errors happen for various reasons, but almost all are the result of systemic failures in the medical facility. When adverse events occur, hospitals use a root cause analysis to identify a problem's origin. You should follow a similar process in a medication error case.

Assume a patient on blood thinners is given an overdose of heparin at an emergency room (ER) and dies. The sole cause appears to be a nurse's dose miscalculation. Take a step back and begin your case by "backchaining": Rather than focus on the end result, work back through the chain of events, link by link, to identify the cause of the error and prove why your client's injuries should have been prevented.[5]

What were the systemic failures? In this example, does the hospital have built-in safety mechanisms to prevent double-dosing? When the patient was admitted, did the pharmacy have immediate access to the list of all the patient's medications, including those that were administered in an outpatient setting, such as a cardiac catheterization lab? Do these preadmission medications trigger pharmacy system alerts for duplicate therapy and drug interactions? Does the pharmacy have computer procedures to warn practitioners about overdoses and underdoses of high-alert medications? Was bar coding used in the ER to document the heparin administration?

Two types of errors lead to adverse events: active failures and latent conditions.[6] Active failures are human errors, such as misidentification of a medication, confusion over names and packaging that look or sound alike, and failure to administer a dose. Latent conditions are generally due to high-level managerial decisions related to equipment, technology, maintenance, staff, or communication. They include faulty designs or dormant weaknesses that exist in the medication system long before the event occurs—the accident waiting to happen.

The Medication Delivery System

A single dose of medicine is delivered at the end of a complicated 30- to 40-step process, and each step presents an opportunity for error.[7] It is not uncommon for a 300-bed hospital to dispense 2,400 to 4,000 doses of medication daily.[8] Safe medication delivery requires synchronization among multiple medical personnel and disciplines—prescribers, pharmacists, nurses, and other care staff. No other interdepartmental relationship within a hospital requires this level of coordination or is as crucial to preventing errors.

In most hospitals, the medication system has five main components: prescribing, transcribing, dispensing, administering, and monitoring. The methods to accomplish these tasks are complex, and they vary widely among hospitals. Many hospitals have a patchwork of electronic data systems supplied by different vendors, and the systems do not always work together.[9]

Prescribing. Before the first dose of medicine is ordered, the patient's medication history must be obtained at admission, including the dosage, route, indication, frequency, and the time the

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last dose was taken before admission.[10] Transitions—whether from home to the ER or between points within the hospital—are particularly fraught with risks for error. The prescriber must reconcile the patient's medication history with the drugs administered at the hospital and resolve any conflicts, known as the medication reconciliation process. This process ensures continuity of care, avoids duplicate dosing or drug omissions, and prevents drug reactions.

The medication order is guided in part by the hospital's drug policy system, which includes a drug formulary, clinical practice guidelines, and staff education on medication use. A physician is not limited to prescribing from the formulary, but off-formulary use may be restricted to certain medical specialties or maximum dosages. With the order, the prescriber must submit the patient's full name and location, patient data (age, allergies, and weight), medication name (generic and brand), drug strength (in metric units), dosage, route of administration, frequency of administration, and the purpose of the medication.[11] He or she also must adhere to hospital policy regarding "do not use" medical abbreviations in order entries.[12]

Transcribing. In this step, the prescriber submits an order to the hospital pharmacy, which transcribes it into a paper or electronic medication administration record (MAR or eMAR).[13] Hospitals are responsible for establishing policies that dictate the form and elements of a medication order, the types of orders that are acceptable, and what to do when orders are incomplete, illegible, or unclear.[14]

Although most hospitals use electronic medical records, the adoption of electronic medication ordering systems has lagged. Despite consistent evidence that a computerized prescriber order entry (CPOE) system cuts prescribing errors by 50 percent, a 2013 American Society of Health-System Pharmacists (ASHP) national survey found that only 65 percent of hospitals use this program; other orders are handwritten, oral, digital image capture, or faxed.[15] CPOE's advantage is that the prescriber has real-time access to patient medication information, dosing information, drug-to-drug alerts, and lethal medication error reminders.[16] But CPOEs are not risk free. Selection of the wrong product from a drop-down menu or inappropriate use of a default dose can cause problems. And when the pharmacy computer system is outdated or the CPOE is a stand-alone program, an important safety backup is missing.

Dispensing. Pharmacies are responsible for dispensing the correct medications. Hospitals must meet the Joint Commission's (formerly the Joint Commission for the Accreditation of Hospitals) medication management standards for accreditation. One standard requires pharmacists to review and approve the "appropriateness of all medication orders for medications to be dispensed in the hospital."[17] However, a 2011 ASHP survey found that only 70.6 percent of hospital pharmacists complied with this standard before administering the first dose of medicine.[18]

A pharmacist's concerns about anything from dosage to potential or existing medication interactions should be clarified with the individual prescriber before dispensing. Courts have recognized that pharmacists have special knowledge and a duty to consult with the prescribing physician when they have concerns about dosage or contraindications.[19] If there is an ambiguity or poor handwriting, a pharmacist may not guess or assume what the prescriber meant.[20]

Once a pharmacist approves a medication order, it is entered into a MAR or eMAR. Handwritten MARs can contribute to errors if they are illegible or transcribed with inconsistent information, including error-prone abbreviations and confusing generic or brand names. On the other hand, eMARs help prevent errors by documenting new, changed, or discontinued orders contemporaneously.

DESPITE CONSISTENT EVIDENCE THAT A COMPUTERIZED PRESCRIBER ORDER ENTRY SYSTEM CUTS PRESCRIBING ERRORS BY 50 PERCENT, A 2013 AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS NATIONAL SURVEY FOUND THAT ONLY 65 PERCENT OF HOSPITALS USE THIS PROGRAM.

The hospital determines how the drug is dispensed, but hospitals, particularly larger ones, are increasingly moving from a centralized drug distribution center with one location—which maintains inventory and prepares and distributes drugs—to a decentralized system with pharmacy satellites staffed by a pharmacist and technicians where drugs are stored and dispensed to patients. Many use automated dispensing cabinets (ADCs), which are placed on patient floors, prefilled by a pharmacy technician. They are linked to the pharmacy computer program to ensure that nurses and other staff have access to only a specific patient's medication orders.

Central to the successful use of these systems is "unit dose" drug distribution. Recognized by the Joint Commission as the standard of practice for medication

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administration in inpatient settings, a unit dose is a single dose dispensed from the pharmacy that is ready to administer to a patient, without any further dosage calculation or manipulation required. However, many medications arrive in bulk and require repackaging or compounding for unit dose distribution, and this creates another step where errors can occur.

With the swipe of a patient's wristband and a medication label, bar codes confirm the correct match between the patient and the drugs administered and create a chronology of drug dispensation, which is tracked in the patient's eMAR. Although bar coding can prevent deadly errors, not all hospitals use it.[21] One safety expert noted that supermarkets keep better track of groceries than many hospitals do of medications.[22]

Administering. It is at this critical point that errors are least likely to be detected, intercepted, and prevented. Proper identification and careful use are essential, particularly with "high-alert" medications—drugs that carry a greater risk of causing injury or death if misused.[23] The Institute for Safe Medication Practices periodically issues a list of high-alert medications and hospitals are required to maintain a process for managing them.[24] Drug categories most often identified as high-alert are blood coagulation modifiers, opioid analgesics, and insulin.[25]

Many high-alert medications are administered by IV, which can be particularly dangerous because of the rapid onset of adverse effects and the difficulty in reversing those effects. Errors can be reduced through "smart" infusion pumps, which contain an electronic library of drugs with dosing units, usual concentrations, and dose limits, and prevent delivery of an overdose or a drug that is contraindicated. But orders that are manually entered can override the pumps and eliminate their systemic alerts.

Monitoring. Assessing the patient's drug response, documenting the results, and detecting adverse reactions, particularly when high-alert drugs are used, are components of monitoring. Certain medications require closer observation than others, and medical staff should evaluate the patient to determine if the medication is effective for its intended purpose, such as an anti-arrhythmic drug. Staff must also watch out for side effects, adverse or allergic reactions,

and be apprised of necessary monitoring during shift changes.

Case Strategy

Resist the temptation to focus the case on the caregiver at the time when the negligence was identified. The defense will likely argue that accidents happen and no one meant to cause harm. Evidence of a hospital's repeated failure to integrate safety protocols in the medication delivery process is harder to defend. Shining a light on a hospital's pattern of errors can provoke fear and anger in a jury instead of a passive acceptance that "stuff happens."[26]

To backchain a case, you need to find the rules, identify the systems, and demonstrate the hospital's pattern of errors, going as far back as possible. Many rules govern hospital pharmacies: the Joint Commission's medication management standards, the hospital's own protocols, and the Agency for Healthcare Research and Quality's recommendations. Other resources also discuss drug safety in hospitals: the authoritative text *Medication Errors*, the Institute for Safe Medication Practices, and the American Association for Justice's Medication Errors Litigation Packet and Pharmacy and Pharmacist Liability Litigation Packet.[27]

In one of my firm's wrongful death cases, a young man was admitted to a hospital with intractable back pain and prescribed the high-alert opioid Dilaudid. He was given an overdose and died. We backchained and found errors in the prescribing, administration, and monitoring stages. We deposed the prescribing pain specialist, who ignored the patient's morbid obesity and history of sleep apnea as a contraindication to Dilaudid, a known respiratory depressant. The prescriber expected the pharmacist to catch the potential risks. Nursing staff, who administered the drug, had not been adequately trained to program the pump, and the patient received four doses in the first hour. Monitoring orders to check for drowsiness every two hours and take vital signs were disregarded. In discovery, we learned that the hospital did not have protocols to address or prevent these problems.

Evaluate the hospital's medication delivery system. Does the hospital use computer systems and technology, and if so, is there a single provider or multiple computer programs? Do the technology systems work together seamlessly, or does a user need to toggle between programs to access information? Find out whether the system is standardized and what alerts are built in, and evaluate the system's usability and whether it can be manually overridden.

In another case, the pharmacy technician stocked an ADC with 100 mg tablets of chlorpromazine (an antipsychotic) instead of chlorpropamide (an antidiabetic). Four patients received the wrong drug, one with fatal results. If you are confronted with these types of facts, find out what safety strategies the hospital used to differentiate similar looking and sounding drugs: Did the hospital use reminders and attach "name alert" stickers to look-alike products? Did it change the appearance of look-alike names on the storage shelf, the product labels, and the computer screens by using color, bold type, or all caps to avoid confusion, such as chlorproMAZINE and chlorproPAMIDE? Take the time to uncover this information.

Examine the deficiencies and find out how long the hospital knew about safety gaps. By amassing evidence of known risks and ineffectual management decisions to improve or eliminate the risks, you can demonstrate the hospital and its pharmacy were negligent. By focusing on problems with facilities' medication delivery and safety systems, these lawsuits are the impetus to improve patients' health and hospital safety.

MORE ON MEDICATION ERRORS

Visit the Web pages below for additional information.

AAJ SECTION

Professional Negligence
www.justice.org/sections

AAJ LITIGATION GROUP

Pharmacy and Pharmacist Liability
www.justice.org/litgroups

LITIGATION PACKETS

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Notes

1. *See* Inst. of Med., *Preventing Medication Errors: Quality Chasm Series* 1–2 (Philip Aspden et al. eds., Natl. Acads. Press 2007), http://books.nap.edu/catalog.php?record_id=11623.
2. *Id.* at 5.
3. Inst. of Med., *To Err is Human: Building a Safer Health System* 1 (Linda T. Kohn et al. eds., Natl. Acads. Press 1999), www.iom.edu/Reports/1999/to-err-is-human-building-a-safer-health-system.aspx; *see also* Evelyn M. Tenenbaum, *Using Informed Consent to Reduce Preventable Medical Errors*, 21 Annals of Health L. 11 (2012).
4. *See* Natl. Coordinating Council for Medication Error Reporting & Prevention, *About Medication Errors: What Is a Medication Error?* (2014), www.nccmerp.org/aboutMedErrors.
5. *See* Rodney Jew, *Advocacy Track: Rethinking Your Litigation Strategy Before It's Too Late—Exploring Critical Thinking and Problem Solving*, AAJ Annual Conv. (2012), also available at www.PlaybackAAJ.com.
6. James Reason, *Human Error: Models and Management*, 320 Brit. Med. J. 768, 769 (2000).
7. Lucian L. Leape, *Systems Analysis and Redesign: The Foundation of Medical Error Prevention,* in *Medication Errors* 3 (Michael R. Cohen ed., 2d ed., Am. Pharmacists Assn. 2007).

8. James Baker et al., *Analysis of the Medication Management System in Seven Hospitals* 2 (CareFusion Corp. 2010), www.carefusion.com/pdf/Medication_Management/DI2097_medBPM_Whitepaper.pdf.
9. Leape, *supra* n.7, at 9.
10. *See* Joint Commn., *Accreditation Program: Hospital, Natl. Patient Safety Goals* Goal No. 8, NPSG.08.01.01, at 16 (2010) (Hospitals should "accurately and completely reconcile medications across the continuum of care.").
11. *See ASHP Guidelines on Preventing Medication Errors in Hospitals*, 50 Am. J. Hosp. Pharm. 305 (1993).
12. *See* Joint Commn., NPSG.02.02.01 (2008); *see also* Joint Commn., *Facts About the Official "Do Not Use" List*, www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf.
13. *See* Craig A. Pedersen et al., *ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration—2011*, 69 Am. J. Health-Sys. Pharm. 768, 777, 783 (2012).
14 *See* Joint Commn. E-dition, *Medication Management*, Stand. MM 04.01.01, at 7–9 (2012), www.uhnj.org/mdstfweb/The_Joint_Commission/Medication%20Management.pdf.
15. *See* Craig A. Pedersen et al., *ASHP National Survey of Pharmacy Practice in Hospital Settings: Prescribing and Transcribing—2013*, 71 Am. J. Health-Sys. Pharm. 924 (2014).
16. Eric G. Poon et al., *Effect of Bar-Code Technology on the Safety of Medication Administration*, 362 New Eng. J. Med. 1698 (2010).
17. *See* Joint Commn., *supra* n. 14, Stand. MM 05.01.01, at 9–10 ("A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital."). The exceptions to this rule are ER medication orders, radiology services using contrast, and urgent situations when a delay could lead to harm.
18. *See* Pedersen, *supra* n. 13, at 775–76. In hospitals with 600 or more staffed beds, it is 98.4 percent, but only 44.2 percent in hospitals with less than 50 staffed beds.
19. *See e.g. Horner v. Spalitto*, 1 S.W.3d 519 (Mo. App. W. Dist. 1999); *see also* Dov Apfel, *Hospital Liability for Misuse of Obstetrical Drugs*, Trial 32 (Dec. 2013); Frank M. McClellan, *Reading the Rx Right Is Not Enough*, Trial 26 (May 2002).
20. *See* Michael R. Cohen & Judy L. Smetzer, *Preventing Dispensing Errors* in *Medication Errors*, *supra* n. 7, ch. 10, at 205, 213.
21. *See* Pedersen, *supra* n. 15.
22. *See* Leape, *supra* n. 7, at 9.
23. Inst. for Safe Medication Practices, *ISMP's List of* High-Alert *Medications* (2012), www.ismp.org/Tools/highalertmedications.pdf; *see also* Michael R. Cohen et al., *High-Alert Medications: Safeguarding Against Errors* in *Medication Errors*, *supra* n. 7, ch. 14, at 317–411.
24. *See* Joint Commn., *supra* n. 14, Stand. MM.01.01.03, at 3–4 (eff. July 1, 2014).
25 *See* ISMP, *supra* n. 23.
26. For example, an investigation of a fatal medical error resulting in the death of an infant found more than 50 hospital system failures. Judy L. Smetzer et al., *Lesson From the Denver Medication Error/Criminal Negligence Case: Look Beyond Blaming Individuals*, 33 Hosp. Pharm. 640 (1998).
27. For more information on AAJ's litigation packets, visit www.justice.org/litigation packets.