

A DOSE OF INSIGHT

A data-driven review of
**the state of
medication-related
errors & liability in
American healthcare**

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TABLE OF CONTENTS

- Introduction..... 01**

- A Fresh Approach to Claims Data 01**

- Medication Error at a Glance 02**

- Process Vulnerabilities 04**
 - Ordering Risks..... 04
 - Administration Risks 05
 - Monitoring and Management Risks 05

- The Dangerous Duo: Opioids and Anticoagulants**
 - Medication Error and Opioids..... 06
 - Medication Error and Anticoagulants 07

- Managing Risk..... 07**

- Technology Innovations & Other Best Practices 08**

- Staying on Top of New Developments 09**

- Conclusion 10**



“Medication-related events are the fourth most common root cause of medical professional liability claims.”

INTRODUCTION

The medication episode of care in America—the process of ordering, dispensing, administering, monitoring, and managing medications—has been revolutionized in recent years by new technologies and new practices. Despite these advances, medication-related events are the fourth most common root cause of medical professional liability claims. To help reduce medication errors and improve patient safety, physicians and healthcare providers need fresh perspectives, data-driven insights, and new ways of thinking about the everyday activities of choosing medications for patients.

This special publication provides insight into the root causes of medication-related claims based on an analysis of over 10,000 closed medical professional liability claims at Coverys across a five-year period (2012–2016).^{*} We offer statistics, insights, and recommendations in the hopes that when presented with this information, healthcare professionals will be inspired to investigate and implement new processes and systems to safely improve patient health through the use of medications.

^{}Unless otherwise indicated, statistics and other information in this publication were derived from this proprietary data.*

A FRESH APPROACH TO CLAIMS DATA

Medical professional liability claims are often an unmined source of rich information about the measures individuals and organizations can take to improve patient safety. Typically, a fully investigated liability claim will contain valuable information, such as:

- Allegations of primary and secondary causes of the claim (e.g., medication-related, diagnostic, surgical/procedural)
- Patient health and demographic information
- Injury severity
- Physician specialty
- Risk management issues (e.g., clinical systems, clinical judgment, documentation)
- Location of the alleged error (e.g., office/clinic, room/bed, surgery, ED/urgent care)
- The human and financial costs

At Coverys, we view medical professional liability claims data trends as signals—warning us about potential patient harm, claims, and looming lawsuits. These signals can be critical in identifying and mitigating risks to patients before they happen. They also present an opportunity to assist physicians and hospitals in avoiding potential lawsuits.

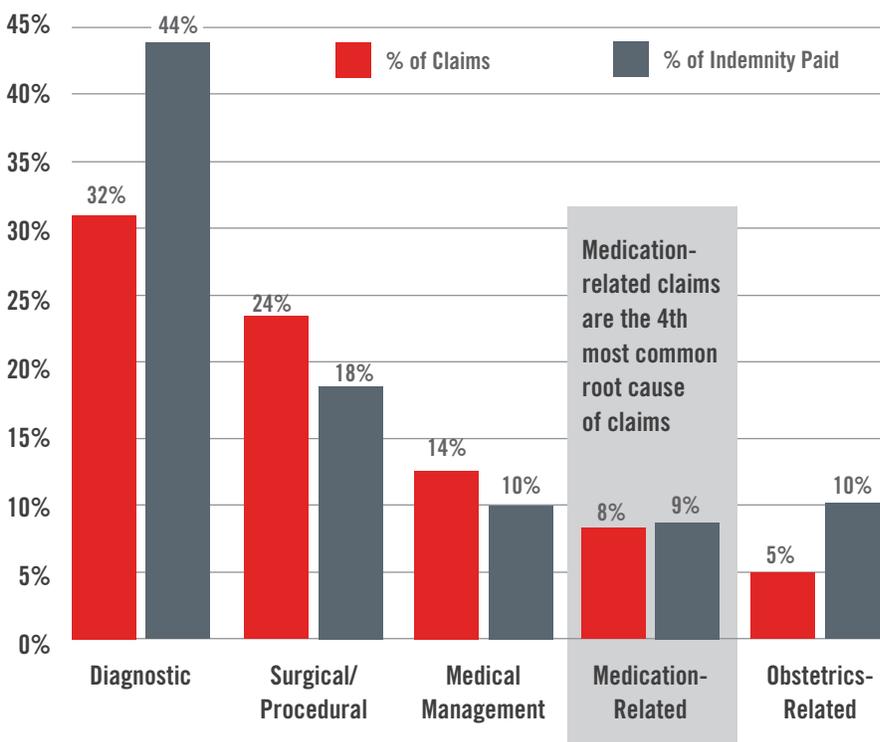
42% of medication errors occur in an office or clinic setting

31% of medication errors are related to inadequate monitoring of a patient's medication regimen

38% of medication error cases ultimately involve a patient death

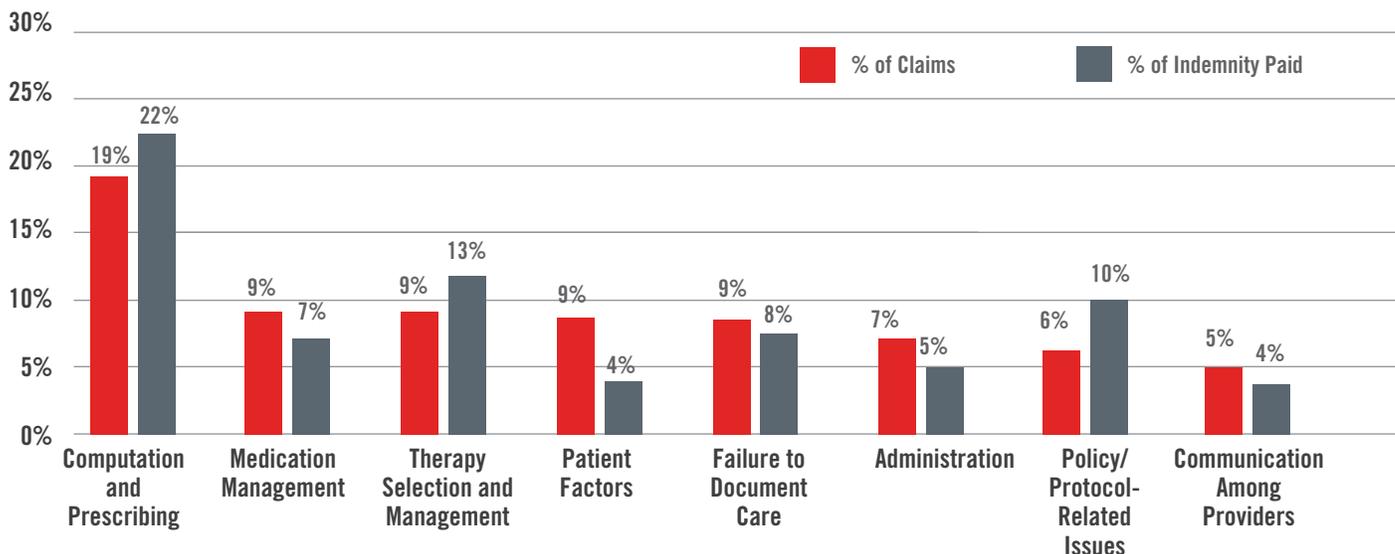
LEADING CAUSES OF CLAIMS

Medication-related errors and liability are cited as the fourth most common root cause of claims, after diagnostic, surgical/procedural, and medical management issues, and ahead of obstetrics-related issues.



Source: Coverys Claims Data, Closed Claims 2012-2016

TOP RISKS THAT TRIGGERED MEDICATION-RELATED CLAIMS

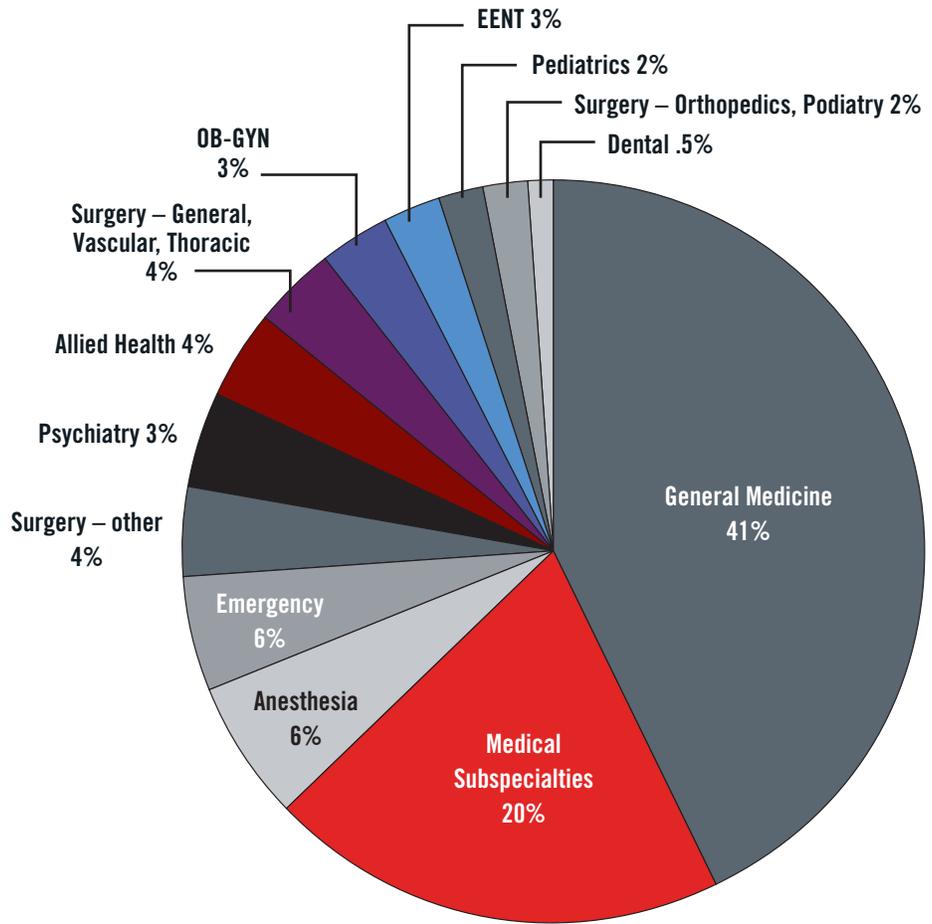


Source: Coverys Claims Data, Closed Claims 2012-2016

CLAIMS BY SPECIALTY

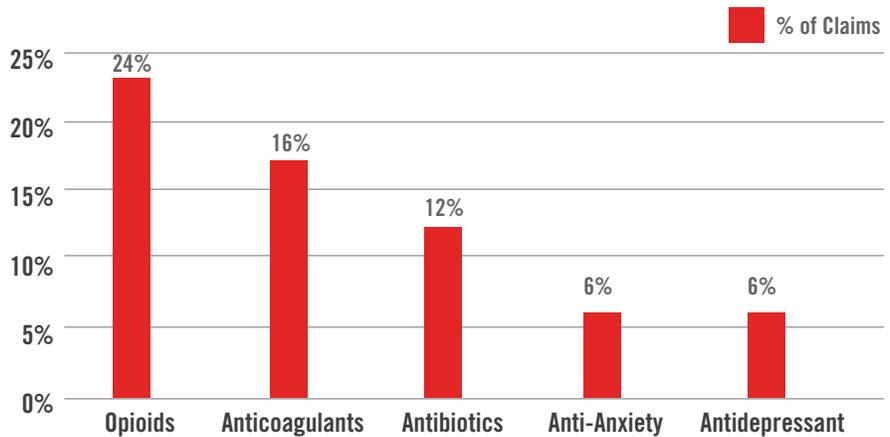
The majority of medication-related claims stem from general medicine (internal, family, etc.) followed by medical subspecialties (e.g. dermatology, pulmonology, gastroenterology, cardiology, neurology, and infectious diseases).

Source: Coverys Claims Data, Closed Claims 2012-2016



TOP MEDICATIONS INVOLVED IN CLAIMS

Events involving opioids and anticoagulation drugs represent the highest percentage of medication-related claims, followed by antibiotics.

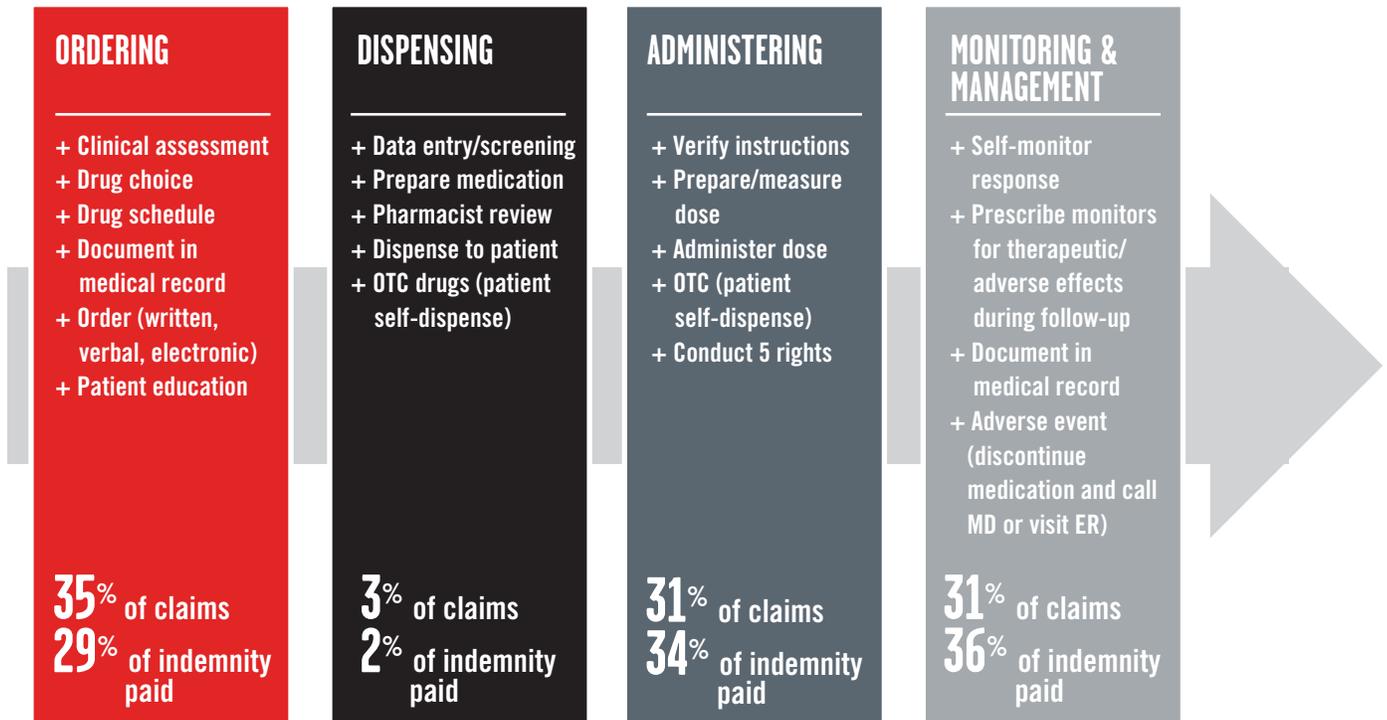


Source: Coverys Claims Data, Closed Claims 2012-2016

PROCESS VULNERABILITIES

Introducing medication to the treatment plan of a patient is no small matter. There are many distinct decisions and steps along the way that can potentially result in an adverse event. The following process diagram illustrates key steps in the medication episode of care.

Every step in the medication episode of care matters and can be vulnerable to patient safety risks. The costs—human and financial—are highest during the first and final steps.



ORDERING RISKS

According to our data, **there is no riskier step in the medication episode of care than the initial ordering of medication.**

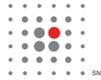
- 35 percent of medication-related claims focused on ordering as the root cause.
- 29 percent of claims with ordering as the root cause resulted in indemnity payments.

Ordering medication can include such issues as:

- A medication considered unsafe for children under the age of six prescribed to a four-year-old child.
- A patient is given a dosing schedule that is too frequent to be safe.
- The clinical assessment of the patient is incomplete and a prescribed medication contains an ingredient to which the patient is allergic.

While this initial step in the process should be a strong focus for physicians, other clinical providers, and pharmacists, the good news is that allegations related to the ordering of medication are on the decline, perhaps an indication that technologies and processes are making ordering safer.

It's notable that the second step in the process—dispensing—only triggered 3 percent of claims and 2 percent of indemnity paid. We believe that dispensing risk has been reduced because of the implementation of well-designed technologies that reduce historic vulnerabilities.



ADMINISTRATION RISKS

Claims involving alleged issues with administration of medications represent 31 percent of all medication-related claims and are the third highest process issue for providers. When verifying instructions, preparing or measuring a dose, or physically administering a dose of medication to a patient (or when patients take the medications themselves), much can go wrong.

Our data shows a slight rise in the incidence of these issues—28 percent of such cases resulted in indemnity paid.

Practitioners should never lose sight of properly managing the “5 Rights” during medication administration: right patient, right drug, right dose, right route, and right time.

MONITORING AND MANAGEMENT RISKS

According to our data, monitoring and managing a patient’s medications is the second riskiest step in the medication episode of care, resulting in more than 31 percent of medication-related claims. Evidence indicates that a lack of vigilance in medication reconciliation can contribute to an adverse event. While technologies have significantly improved the selection, dispensing, and administration of medications, the work of medication reconciliation is an ongoing challenge.

Medication monitoring and reconciliation—ensuring that the full collection of various medications any given patient is taking are still safe, necessary, and appropriately dosed—requires impeccable processes and clear communication as patients move across the continuum of care and ongoing medication adjustments are made.

Ten years ago, work was done in the healthcare industry to focus on the importance of medication reconciliation. For instance, healthcare providers are often required to ask at every patient encounter, “What medications (prescription and over-the-counter) are you taking? What supplements are you taking?” However, with many patients seeing many doctors in different systems and with multiple medications, it can be hard to keep up. Sometimes patients are not well aware of all the medications that have been prescribed to them and go on new ones at each physician visit.

At the monitoring and management stage, communication is key. It’s important to discuss how a medication is working, whether the patient is having any side effects or adverse reactions, and—over the long term—to reassess whether the medication is still the right choice taking into consideration other medications the patient is taking and/or new symptoms or conditions. We suggest the slightest mention of a side effect be documented in the patient’s medical record and that providers find reliable ways to get patients to comply with medication reconciliation processes. There are dozens of mobile apps patients can use to keep track of their medications, or they can use paper “medication cards” that are regularly updated.

BE ON ALERT!

Adverse drug events can happen with any medication, though there are several types of drugs that pose a high risk for creating patient harm. The Institute for Safe Medication Practices (ISMP) identified top **high-alert medications based on practice setting**.¹ Following are the top five (for a complete list, visit <https://www.ismp.org/Tools/highAlertMedicationLists.asp>).

Acute Care Setting

- EPINEPHrine, subcutaneous
- Epoprostenol (Folan), IV
- Insulin subcutaneous and IV
- Magnesium sulfate injection
- Methotrexate, oral, non-oncology use

Clinical & Ambulatory Setting

- CarBAMazepine
- Chloral hydrate liquid, for sedation of children
- Heparin, including unfractionated and low molecular weight heparin
- MetFORMIN
- Methotrexate, non-oncology use

Long Term Care Setting

- Digoxin
- Parenteral and oral EPINEPHrine,
- Parenteral iron dextran
- Parenteral methotrexate, oral, non-oncology use
- Concentrated morphine solution, oral

Other high-alert medications include:

- Chemotherapeutic agents
- Sedatives

THE DANGEROUS DUO: OPIOIDS AND ANTICOAGULANTS

America is in the midst of an opioid epidemic. Nearly half of all U.S. opioid overdose deaths involve a prescription opioid.² When harm befalls a patient as a result of the use or misuse of a prescribed medication, the first questions are often: “Was this a preventable outcome?” and “Is the patient’s medical provider accountable in any way?”

In examining our claims data, we found **opioids accounted for the highest percentage of medication-related claims**—more than 14 percent—and **anticoagulation drugs were a close second** at 9 percent. With an unfettered rise in thromboembolic disorders among Americans, it’s no surprise that the use of anticoagulants has increased. It has been estimated that more than six million Americans currently take anticoagulants as part of the acute and long-term prevention and treatment of such disorders.³ And thinning the blood, while an effective therapy in countless cases, can sometimes be dangerous.

MEDICATION ERROR AND OPIOIDS

- More than 46 percent of claims related to opioids had primary care prescribers, whereas only a small percentage of claims involved medical subspecialties, surgery, or pediatrics. General practitioners must know when pain management is outside their scope of practice and should feel comfortable seeking guidance and/or referring patients to other experts to treat unresolved pain.
- Fifteen percent of opioid claims involved an allegation that the physician behaved in an inappropriate way with a drug-seeking patient.
- Emergency departments and operating rooms are having fewer issues related to adverse outcomes with opioids (22 percent of opioid claims combined), while offices/clinics and hospital rooms—where interactions between patient and practitioner are often short and relationships limited—are the locations where risk has been growing (resulting in 78 percent of opioid-related claims).
- Long-term medication monitoring and management is a significant area of vulnerability; 35 percent of opioid-related claims cited the monitoring/management phase as the step in which risk/error occurred.

MEDICATION ERROR AND ANTICOAGULANTS

- The majority of anticoagulation claims allege medication-related issues (49 percent) or lapses in clinical judgment (19 percent).
- More than 40 percent of claims related to anticoagulants involved general medicine prescribers, whereas only a small percentage of claims involved medical subspecialties, surgery, orthopedics, or emergency medicine.
- The issuance and management of anticoagulation drugs accounts for 28 percent of all anticoagulation claims in the office/clinic setting and 43 percent of such claims in the hospital setting.
- With anticoagulation medications, dosing is vital. Among risk management subcategories in anticoagulation claims, computation and prescribing error were involved in the highest number (32 percent) of cases.
- Anticoagulation claims were steady across our five-year review. Nearly all allegations involved the beginning and the end of the episode of care with 44 percent of anticoagulation claims stemming from the initial ordering of the medication and 44 percent of all such claims relating to the monitoring and management of the patient over time.

“Problems are most likely to arise in the first and last steps of the medication episode of care: ordering and monitoring/management.”

WHO CAUSES OR PREVENTS MEDICATION ERROR?

While perhaps the heaviest burden for ensuring patient safety falls to physicians, the medication episode of care requires the coordinated and competent oversight of many professionals.

- Physicians
- Dentists
- Advanced Practice Providers (nurse practitioners, physician assistants, etc.)
- Nurses
- Medical Assistants
- Pharmacists and Pharmacy Technicians

MANAGING RISK

Our data analysis revealed five key findings critical to better managing most medication-related challenges.

1. **Problems are most likely to arise in the first and last steps of the medication episode of care: ordering and monitoring/management.** Common themes include computational and prescribing errors and medication reconciliation.
2. **Different patients face different risks.** Our littlest, largest, youngest, and oldest patients are at highest risk of medication errors. For example: A small patient may require doses to be titrated upward slowly to ensure they can tolerate it; an obese patient’s dosing guidelines are dependent upon other health issues they may face; patients with advanced age often take multiple medications which makes reconciliation of all their medications important; and, when treating children, it’s important to check labeling guidelines, which often include special instructions for pediatric patients.

“Who’s at risk of medication-related harm? Our littlest, our largest, our youngest, and our oldest patients.”

- 3. The implementation of appropriate safety measures, systems, technologies, and training saves lives.** Practitioners need support if they are to make vast reductions in the incidence and severity of medication-related errors. That support comes from nearly every place in the organization, including IT and HR.
- 4. Different settings create different opportunities and challenges.** Forty-two percent of medication errors occur in the office or clinic setting, but operating rooms, emergency departments, and inpatient settings pose their own risks.
- 5. Opioids and anticoagulants are unlike any other types of medication.** These drugs perform vital functions, yet carry grave risks. As the use of opioids and anticoagulants continues to be increasingly common in the U.S., so too are the injuries and deaths that result from vulnerabilities in the ordering, dispensing, administration, and management and monitoring of these drugs.

INDUSTRY STRENGTHS

There are many places within the healthcare industry where improvements in practices relating to medications are being applied successfully. Following are key findings based on our research.

- The incidence of giving “unnecessary medication” is quite low.
- The fewest medication-related claims are from the patients of dental procedures and orthopedic and podiatric surgeries. Combined, these three areas triggered less than 3 percent of the claims in our data set and just 2 percent of indemnity paid.
- Things like barcoding on wristbands and medications, single-use medication vials, and smart pumps for opioids have become commonplace and are best practices to be emulated.

TECHNOLOGY INNOVATIONS & OTHER BEST PRACTICES

There is much to be done to improve the overall safety of the medication episode of care in America. Many organizations and providers have implemented novel technologies and proven processes worth emulating. IT health innovations (such as computerized physical order entry, electronic medication administration records, and clinical decision support tools) have been widely adopted and are helping to keep patients safer.

Following is a list of what we believe are the top six improvements in medication safety in recent years:

- 1. Barcoding.** Hospitals and healthcare facilities have utilized patient identification wristbands for years. Many organizations have added barcodes to wristbands that are used to access medication and other information. Healthcare providers are required to scan barcodes prior to administering drugs. Moreover, recent advances in printing, such as the use of direct thermal wristband printers, have allowed healthcare facilities to produce more durable and reliable barcodes. This includes water- and heat-resistant barcodes capable of holding up to a week’s worth of wear.

“The FDA makes 400-500 clinically relevant changes to previously approved drug labels each year.”⁶

- 2. The Five Rights.** Training healthcare workers in following proper protocol when administering medication should include a double-check of: 1. “Right Patient,” 2. “Right Medication,” 3. “Right Dose,” 4. “Right Route,” and 5. “Right Time” to help prevent adverse events.
- 3. Antibiotic Stewardship.** The Centers for Disease Control and Prevention (CDC) estimates 20%-50% of all antibiotics prescribed in U.S. acute care hospitals are either unnecessary or inappropriate.⁴ Effective antibiotic stewardship programs require the coordinated involvement of physicians, pharmacists, infection preventionists, laboratory professionals, nurses, and information technology teams. To reduce adverse events associated with antibiotic use, the CDC recommends hospitals adopt the core elements of an antibiotic stewardship program⁵—a proactive step in improving patient safety.
- 4. Smart Pumps for IV Opioids.** In a hospital or inpatient clinic setting where patients are often given patient-controlled analgesia (PCA) to control pain, “smart pumps” are doing appreciable work in preventing life-threatening overdoses.
- 5. O₂ Monitoring with IV Opioids.** At many healthcare facilities, continuous respiratory monitoring of patients on IV opioids is allowing clinicians to prevent opioid-induced sedation and respiration depression—a sometimes fatal event.
- 6. Self-assessments.** For high-alert medications like opioids and anticoagulants, practitioners are benefitting from assessment tools that gauge an organization’s practices on evaluating patients. This includes patients selected for therapy, protocols for dosing, guidelines for administering and monitoring patients receiving drug therapy, and policies that address managing the discontinuation of said medications and their proper disposal. Coverys’ insureds can access self-assessment tools we adapted with permission from those developed by the Pennsylvania Patient Safety Authority (PPSA), which includes a checklist for healthcare facilities to measure their practices. You can access PPSA assessments at <http://patientsafety.pa.gov/pst/Documents/Opioids/organization.pdf> and <http://patientsafety.pa.gov/pst/Documents/Opioids/assessment.pdf>

STAYING ON TOP OF NEW DEVELOPMENTS

The U.S. Food and Drug Administration makes 400-500 clinically relevant changes to previously approved drug labels each year.⁶ To keep on top of these changes, sign up for the PDR Alert Network at www.PDR.net. You will receive email alerts when substantive changes are made to medication labeling—such as warnings not to prescribe a specific drug to certain patients or information about drug interactions. You can also earn CME credit by taking short quizzes to demonstrate your knowledge of information shared in the alerts.

CONCLUSION

When it comes to making patients safer, conversations between provider and patient and the routine activities surrounding medication are paramount. It's these “everyday” or “routine” decisions, interactions, and processes surrounding the medication episode of care that can and must be handled better. Physicians and healthcare providers must ask:

- What technologies could prevent medication error?
- What new practices and attitudes can we adopt in this regard?
- Where are we most vulnerable when it comes to making medication-related errors, and how can we start plugging those holes immediately?

Today, 70 percent of Americans will take a medication with assistance or through self-administration.⁷ And tomorrow, they'll do it again. Until we're confident as a healthcare industry that we're doing everything reasonable in our power to keep patients safe, we should give pause to every IV bag hung, every injection pushed, every transdermal patch placed, and every pill or liquid medication swallowed.

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Unless otherwise noted, statistics and information in this publication were derived from an analysis of over 10,000 closed medical professional liability claims at Coverys across a five-year period (2012–2016).

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