Medication Errors and Medical Malpractice:

Reducing the Risk of Claims and Board Complaints

MICA®
RISK TEAM

Mitigating the Risk of Prescribing Errors in Ambulatory Care

Prescribing failures in the ambulatory setting contribute to a significant percentage of medication-related malpractice lawsuits. In a study of 30,000 closed claims alleging medication errors, prescribing errors ranked second, behind medication management errors, as the most frequent cause of these lawsuits. In the study, 63% of outpatient prescribing error cases involved primary care, followed by cardiology (39%), orthopedics (38%), and ob/gyn (35%).

Researchers analyzing these closed medical malpractice cases concluded that prescribing mistakes are frequently a combination of human error and systems shortcomings. While automated systems have reduced errors in prescribing mechanics such as order entry and processing, prescribers are human and remain prone to cognitive breakdowns, clinical judgment errors, and data gathering failures. Cognitive errors are sometimes difficult to spot and correct before patient harm occurs. They also are hard to explain to jurors, making it risky to take these cases to trial.

Some of the most common prescribing-related errors traceable to cognitive error include:

- Ordering the wrong medication for the patient's condition;
- Ordering a medication contraindicated by a patient's known allergy;
- Ordering a medication contraindicated by a patient's current medications;
- Ordering a medication contraindicated by a patient's underlying comorbidity; and
- Failure to adequately obtain and document informed consent.

Avoiding cognitive errors is not easy, but physicians and advanced health care professionals can implement processes aimed at decreasing the risk of such errors or increasing the odds of correcting an error before it causes patient harm. At the end of this article, the MICA Risk Team suggests several such processes your practice could implement.

Before we get there, we'll take you on a lessons-learned journey by summarizing two MICA closed claims and an Arizona Medical Board published decision. All three cases involve allegations of prescribing-related errors. We use the facts of each case to demonstrate how the processes we suggest can reduce the risk of certain cognitive errors.

Case #1

Facts

Plaintiff/patient (P) was in her 60s with a history of breast cancer and complaints of arthritic pain and swelling in her hands, knees, ankles, and feet. Defendant (Dr. D) was P's family medicine physician.

Beginning in 2012, P periodically complained of aches, pain, tenderness, and stiffness in her hands, ankles, knees, and feet. Dr. D diagnosed osteoarthritis involving multiple sites. Sometimes Dr. D would refer P to her orthopedist, but he also recommended 80 mg Kenalog injections that he administered intramuscularly (IM). On multiple occasions between 2012 and 2014, he administered 240 mg of Kenalog IM over a period of 7-10 days.

In 2014, Dr. D administered Kenalog 80 mg IM on May 6 and again on May 12 for P's complaints of pain, swelling, and tenderness in her ankles. One month after these injections, Dr. D diagnosed P with bronchitis and prescribed Levaquin 500 mg once daily.

A week later, P saw her oncologist and mentioned difficulty walking due to sore Achilles tendons. The oncologist noted P had recently received Kenalog injections and was taking Levaquin. The oncologist called P's orthopedic surgeon to discuss concerns that Levaquin was "perhaps" causing the tendinitis and could lead to spontaneous tendon rupture. After this call, the oncologist instructed P to stop Levaquin and follow up with the orthopedic physician.

When P followed up with her orthopedist, she reported her right tendon felt better since she saw the oncologist a week earlier, but the left remained sore and tender. The orthopedist documented that this was probably Achilles tendinosis caused by Levaquin and recommended gentle stretching, elevation, ice and heat, and Aleve or Tylenol as needed.

In July, three weeks after the orthopedist appointment, P returned to see Dr. D. Dr. D documented that P had less pain and tenderness in her ankles and was moving better, but he also noted a chief complaint of "reaction to Levaquin and tendinitis." He documented that P's oncologist told her Levaquin caused the tendinitis. Dr. D administered three 80 mg Kenalog IM injections over the next seven days.

The next month, P consulted with two different orthopedic surgeons for continued complaints of Achilles tendinitis and bilateral ankle edema. Both surgeons noted a potential connection between the tendinitis, Kenalog injections, and Levaquin. MRI showed a retracted complete tear of both Achilles tendons. P underwent tendon reconstruction surgery, but some deficits remained.

Allegations

P sued Dr. D alleging negligent prescribing of Levaquin and administration of Kenalog, resulting in bilateral Achilles tendon ruptures.

Evidence

P's standard of care expert witness, a family medicine physician, testified:

- Levaquin is associated with increased risks of tendinitis and tendon failure.
- In patients older than 60, these risks are even higher.
- Combining Levaquin with corticosteroids such as Kenalog further increases these risks.
- The FDA issued a black box warning for Levaquin specific to these risks, and Levaquin's prescribing information describes these risks.
- Dr. D fell below the standard of care by prescribing Levaquin to P because of her age and after she received Kenalog a month before.
- Dr. D also violated the standard of care by administering Kenalog a month after P took Levaquin.
- Dr. D failed to follow the FDA's guidance to inform patients of the potential side effects and discontinue Levaquin if any symptoms or rupture occur.
- Dr. D administered excessive doses of Kenalog.
- P likely would not have suffered tendon ruptures if Dr. D had not followed Levaquin with additional Kenalog injections.

Case Disposition

P and Dr. D agreed to settle the case. The terms of the settlement are confidential.

Case # 2

Facts

Defendant (Dr. D), an orthopedic surgeon, performed a left total hip replacement on a patient (P) in his late 60s. P had a history of hypertension, hyperlipidemia, diabetes, sleep apnea, gout, and mild to moderate atherosclerotic coronary artery disease. In addition to other regular medications, he was taking Warfarin for atrial fibrillation.

A month after surgery, P developed a postoperative infection and was hospitalized. Treatment included the placement of drains, a wound vacuum device, and IV antibiotics.
Two months postoperatively, Dr. D noted there was no hematoma or drainage, and P should continue activity as tolerated with follow up in 3 months.

A month later, however, Dr. D saw P for mild groin pain radiating down his thigh. Dr. D prescribed Meloxicam 7.5 mg twice a day as needed with 6 refills and a Medrol dose pack with 2 refills.

Three weeks after prescribing Medrol and Meloxicam, Dr. D obtained CT results and aspirated P's hip. He diagnosed a hematoma and ordered an EMG to evaluate the femoral nerve.

A few days later, P was unconscious in his home and could not be resuscitated.

Two days before P's death, his health insurance plan sent a Meloxicam-Warfarin drug interaction warning to Dr. D's practice. The warning said that taking Warfarin with an NSAID can potentiate the risk of gastrointestinal bleeds, concurrent prescribing requires caution, and "prescribers should monitor patients taking both for signs and symptoms of bleeding". A nurse practitioner read and initialed the warning and inserted it into the medical record.

During deposition in this case, the nurse practitioner conceded it was below the standard of care not to either call the patient or notify Dr. D of the alert.

Pharmacy records showed that the pharmacist overrode the electronic contraindication alert that appeared when P refilled his Warfarin. The pharmacist did not document counseling P about combining these drugs.

Allegations

P's surviving family members sued Dr. D, the nurse practitioner, the pharmacist, and the pharmacy, alleging negligent prescribing and dispensing of Meloxicam with Warfarin resulting in gastrointestinal bleeding and death.

Evidence

Plaintiff's expert witness, a board-certified orthopedic physician, provided the following opinions about Dr. D's care and treatment:

- The standard of care requires an orthopedic surgeon to diagnose the cause of a patient's pain before prescribing medication to treat the pain. Dr. D should have waited for the CT results before prescribing NSAIDs. Other than mild pain, the patient did not have signs and symptoms of inflammation. Meloxicam and Medrol Dosepak were not indicated based on the exam findings and CT results.

- Medrol is a potent anti-inflammatory requiring caution in patients at risk for infection and should not be prescribed with refills. If Medrol is prescribed for a patient at risk for gastrointestinal bleeding, the standard of care requires the

physician to also order a proton pump inhibitor to reduce the risk of erosion to the stomach lining.

- It is never reasonable to prescribe Meloxicam for a patient on Warfarin.
- Assuming for the sake of argument that jurors decide a reasonable and prudent physician might prescribe Meloxicam and Warfarin together, the standard of care also requires the prescribing physician to:
  - Call the patient's cardiologist and PCP for their agreement to prescribing them together;
  - Use a different drug if recommended by the cardiologist or PCP;
  - With the cardiologist's and PCP's agreement, prescribe the lowest effective dose (Meloxicam 7.5mg once daily) for the shortest period of time (approximately 1 week);
  - Engage the patient in a thorough informed consent discussion about the risks and benefits of taking medications with a major drug-drug interaction; and
  - Document the consent discussion.
- It was below the standard of care to prescribe the maximum daily dose of Meloxicam with 6 refills and a Medrol Dosepak with 2 refills, especially without warning the patient not to take these two medications concurrently.
- When Dr. D's practice received the health plan alert, Dr. D or the nurse practitioner should have notified the patient, asked if he was experiencing any problems or side effects, and asked if the medication was helping the pain. Had this been done, the patient would have reported he was still in pain and Dr. D likely would have discontinued Meloxicam before the patient died.

Case Disposition

Dr. D settled this case with the Plaintiff before trial. The settlement details are confidential.

Case # 3

The Arizona Medical Board investigated a patient's complaint about an ob-gyn who prescribed testosterone injections at the patient's first and only appointment. The patient complained that the physician did not check lab work before prescribing testosterone and did not teach the patient how to inject it. The patient then saw a different physician who said the prescribed testosterone dose was four times higher than normal.

During the investigation, the Board's ob-gyn expert determined the physician fell below the standard of care as follows:

- The ob-gyn documented an inaccurate patient history.
- The ob-gyn did not perform a complete physical exam.
- The ob-gyn did not document a discussion with the patient about the use of testosterone and the associated risks.

During a formal interview with the Board, the ob-gyn explained the following:

- The ob-gyn does not usually conduct a physical exam during an initial visit.
- The ob-gyn prescribed testosterone without an exam because the patient appeared desperate for relief of symptoms. The Board's decision and meeting minutes do not specify the symptoms.
- The ob-gyn informed the patient of the risks and benefits of testosterone but did not document the discussion because she closed the medical record to speak face-to-face with the patient.

The Board issued a Non-Disciplinary Letter of Concern based on the ob-gyn's failure to:

- Document when a completed gynecological examination was to occur;
- Order labs to obtain baseline levels prior to prescribing injectable hormones;
- Document the medication instructions discussion; and
- Document the patient's mental health history.

Improving Your Prescribing

To minimize the risk of common prescribing errors that lead to lawsuits and board investigations like those summarized in this article, consider integrating the following into your workflows and processes.

Obtain And Document Informed Consent

Informed consent isn't just for surgeons. Following a standardized informed consent process is essential when you prescribe a new medication for your patient. As a prescriber, you should allow time during the appointment to engage your patient in a discussion about:

- Risks/contraindications;
- Benefits;
- Alternatives;
- How to use the medication;
- Potential side effects; and
- Anything the patient should watch for when taking the medication.

Tips for an effective informed consent conversation include:

- ✓ Talk in terms the patient can understand;
- ✓ If there is any hint of a language gap, use an interpreter;
- ✓ If there is any concern about cognitive issues with the patient, involve family or caregivers if appropriate;
- ✓ Encourage and allow time for patient questions;
- ✓ Thoroughly document the discussion and note any questions asked by the patient/family;
- ✓ In addition to the chart note, consider using a consent form for frequently prescribed medications. Ask patients to sign to confirm their understanding of the discussion and the medication education information. Give the patient a copy. The form may also contain medication instructions that patients can refer to at home in case they forget what you said.

Document Your Prescribing Thought Process

In a lawsuit alleging prescribing errors, the plaintiff's attorney will ask why you selected a particular medication or dose or whether your decision was reasonable despite known contraindications. Thoroughly documenting your thought process in the medical record at the time of prescribing can help you answer these questions and strengthen your defense of any lawsuit or board investigation. Many lawsuits are filed nearly two years after the care you provided, meaning you likely won't remember the details of the patient's visit or your exact thought process. In this situation, you will find a written record of your thought process invaluable.

In addition, the process of documenting your rationale may serve as a safeguard against cognitive prescribing errors. Documenting gives you another opportunity to identify weaknesses in your analysis, enabling you to avoid or correct errors before patient harm occurs.

Gather Adequate Information About The Patient

Prescribing without gathering and documenting all the necessary information was an issue in two of the cases discussed above. Board investigators in Case #3 concluded the physician should have obtained labs and documented the patient's mental health history prior to prescribing. In Case #2, Plaintiff's expert testified the defendant physician should have determined the cause of the patient's pain prior to prescribing.

Standardizing your information gathering process is one strategy that can help you avoid a similar situation. Consider developing written guidelines for medications you frequently prescribe. In the guidelines, list types of clinical data to gather and document in the record prior to prescribing. Your EHR vendor may be able to build alerts into your system to remind you if you omit required data.

Develop A Process For Addressing Payor, Pharmacy, And EHR Drug Alerts

Drug alerts help prevent cognitive prescribing errors but, as Case #2 demonstrates, alerts are useless if ignored or overlooked. Develop written procedures to address different types of drug alerts your practice receives. Educate clinicians and staff on their roles in implementing these procedures, and audit to ensure compliance.

Maintain Up-To-Date References/Literature/Guidelines For Medications You Prescribe

When developing medication-specific guidelines, incorporate literature, guidelines, and warnings from pharmaceutical companies, professional organizations, government agencies like the FDA, and other authoritative sources. Support prescribers in your practice my making these reference materials easy to access.

Improving Medication Management in Ambulatory Care

Although patient safety experts have focused for years on reducing the frequency of medication errors, the proportion of malpractice cases triggered by these errors remains relatively unchanged. One thing that is changing is the care setting where these errors occur.

An analysis of closed malpractice cases dating back to 2003 reveals that while medication-related claims involving inpatient care are decreasing, medication errors in physician practices and other outpatient settings are increasing. The study of nearly 30,000 closed claims suggests that 1 in 9 malpractice cases involves a medication issue. Half of these occurred in the ambulatory setting and often involved family or internal medicine practitioners.

The same study found that 56% of medication-related cases involved errors in medication management. Of these, 35% closed with payment to the Plaintiff. Top medication categories involved in medication management cases were analgesics (17%) and anticoagulants (14%).

Among all medication-related cases involving anticoagulants:

- 50% involved Warfarin;
- 35% involved family or internal medicine physicians;
- 67% occurred in the management phase of the medication process;
- 43% occurred during the prescribing phase; and
- The average indemnity payment per case was $598,000.

In this article, we take a closer look at two closed MICA claims involving alleged Warfarin management errors. In both cases, the defendants were primary care physicians. Find out how each case was resolved and what the Plaintiffs' medical experts said the standard of care required.

Following these case summaries, we suggest some risk management strategies aimed at improving your medication management process and minimizing your risk of facing similar claims.

Case # 1

Facts

The patient (P) was in his 70s with a history of atrial fibrillation, hyperlipidemia, hypertension, knee pain, idiopathic neurologic balance problems in his lower extremities, and mitral valve stenosis.

Dr. D, board-certified in internal medicine, managed P's Warfarin therapy, including periodic INR results, for several years. P had been on one 4 mg Warfarin pill twice daily (8 mg total) for a few years.

Dr. D referred P to an orthopedist for complaints of left knee pain. P did not return to Dr. D's office for 3 months, after a total knee replacement, hospital inpatient admission, and rehabilitation facility admission. During that time, the hospital and rehabilitation facility sent discharge summaries to Dr. D showing that P resumed taking a total of 8 mg of Warfarin per day after the surgery.

When P resumed his regular INR checks at Dr. D's practice, he did not see Dr. D. Anticoagulant patients who came to the practice for an INR check appointment would see only a medical assistant or a nurse. After reviewing lab results, Dr. D would adjust anticoagulant doses as needed, enter prescription orders, and direct staff to call patients with instructions.

At the patient's first visit to Dr. D's practice since his surgery, the medical assistant documented that P was taking a total of 2 mg of Warfarin a day. P's INR was 4.2 (therapeutic range 2-3) and a staff member called P that day to confirm the 2 mg total daily dose.

A week later, P called the office and asked if he should be taking more than 2 mg per day. Dr. D and the staff did not follow up on P's question or review P's medication history.

P returned to the practice for multiple INR checks over the next few months. His INR results were consistently out of range. Dr. D made dosage adjustments based on lab results, but these adjustments were based on a mistaken belief that P was taking 2 mg daily after surgery.

When P saw Dr. D for a physical exam, Dr. D realized P was taking considerably less Warfarin than in years prior. At that visit, Dr. D changed P's dose back to 8 mg Warfarin per day.

Three days later, however, P suffered an embolic stroke.

Allegations

P sued Dr. D for failing to meet the appropriate standard of care when he negligently prescribed and managed Warfarin. P alleged that Dr. D's negligent care caused or contributed to the stroke, resulting in persistent residual physical and mental deficits.

Evidence

P's standard of care expert witness, a board-certified internist, testified to the following points during a deposition before the scheduled trial.

- The standard of care requires a physician to know the correct dosage of Warfarin a patient is taking.
- Dr. D's dose adjustments were inadequate, in part, because they were based on a misunderstanding of the dose P was taking.
- Dr. D should have recognized that P's INR remained significantly subtherapeutic for months placing P at significant risk for stroke.
- Dr. D should have increased the Warfarin dose upon learning of the dose error.

Dr. D's attorney retained medical experts to rebut these criticisms and testify that Dr. D's care was reasonable.

Case Disposition

P and Dr. D settled the case before the trial date. The details of the settlement are confidential.

Case # 2

Facts

The Defendant (Dr. D), board-certified in internal medicine, had been treating the patient (P) for about 4 years. P was in his 60s and had a history of stroke with residual weakness and foot drop, atrial fibrillation, hepatitis C, tachycardia-bradycardia syndrome, heart valve replacement surgery, and a permanent pacemaker. P was unsteady and fell at home many times requiring emergency treatment.

Dr. D usually prescribed Warfarin using the American College of Cardiology's guideline for maintaining the INR between 2.5 to 3.5 for patients with artificial heart valves. In P's case, Dr. D agreed to adjust the target INR to accommodate P's concerns about falling and bleeding. Dr. D documented that the target range for P's INR would be 2.5 to 3.1. Over four years, Dr. D documented 16 INRs between 1.5 and 3.6.

P then experienced a stroke and died. The hospital lab's INR was 1.8. Several physicians involved in P's hospital care documented that P suffered an embolic stroke likely due to inadequate anticoagulation and a subtherapeutic INR.

Allegations

P's surviving adult children sued Dr. D, alleging that he failed to meet the required standard of care in his prescribing and monitoring of Warfarin. They alleged that this negligent care caused P's stroke and subsequent death.

Evidence

Plaintiff's expert witness, board-certified in internal medicine, testified during a deposition about the required standard of care and how Dr. D's negligence resulted in P's death. His opinions included:

- The standard of care for a physician managing a patient with two mechanical heart valves is to maintain an INR between 2.5 and 3.5.
- Patients with two mechanical heart valves are at higher risk of stroke if the INR is not kept in this range.
- The medical records show that Dr. D consistently failed to reasonably adjust P's Warfarin doses when the INR was sub- or supratherapeutic.
- There is no documentation of Dr. D communicating with P about the INR falling outside of the appropriate range.
- There are certain rare circumstances in which modifying the target INR is acceptable. If a physician agrees to modify the INR target, the physician must discuss the increased stoke risk with the patient and obtain the patient's consent to the increased risk. There is no documentation that Dr. D obtained P's informed consent to the change in the INR target.
- A reasonable prudent internist in the same or similar circumstances would not have agreed to an INR below 2.5 for a patient with two mechanical heart valves.
- If the upper limit of a patient's target INR is reduced to 3.1, the standard of care requires the physician to closely monitor the patient and adjust dosages to consistently keep the INR in the narrower 2.5 to 3.1 range. Dr. D failed to increase INR monitoring and adjustment causing subtherapeutic INRs resulting in stroke and death.

Dr. D testified in deposition that INRs between 2 and 2.4 were not greatly concerning since P was worried about a bleed. The expert witness who testified in support of Dr. D said that Dr. D acted reasonably by considering P's concerns and modifying the INR target range accordingly.

Case Disposition

P's children and Dr. D settled the lawsuit before trial. The details of the settlement are confidential.

Lessons Learned – Strategies to Reduce the Risk of Medication Management Claims

Although cognitive errors trigger many medication-related malpractice lawsuits, others result from gaps in the medication management process. Closing these gaps, and reducing your risk of lawsuits and board complaints, involves careful assessment of your medication management process to determine where errors and breakdowns may occur. The cases summarized in this article provide an excellent starting point for such an assessment because they illustrate process weaknesses commonly seen in medication management lawsuits involving Warfarin and other drugs.

When reviewing your medication management process, look closely at the following areas of the medication management process where communication breakdowns and errors commonly occur:

Medication Reconciliation

Accurate medication reconciliation during each outpatient encounter is essential but doesn't always happen. Electronic health records may auto-populate the medication list, but prescribers and practice staff rushing to stay on schedule may forget to verify its accuracy. Patients or caregivers that don't know or can't remember the correct medication information may contribute to the problem.

In Case #1, involving the dosage mistake, it's possible the physician could have prevented the adverse event that led to litigation with careful medication reconciliation. Had the physician or staff reviewed documentation in the patient's medical record, they might have discovered the error months earlier.

Performing medication reconciliation each time you see your patient can decrease the risk of medication errors and adverse events. If your medication reconciliation is sporadic or your process is error-prone, consider implementing these strategies:

- ✓ Require patients to bring their prescription and non-prescription medications to each visit (sometimes called the "brown bag" method) so you can accurately document the medication, dosage, and reason for use. The physician in Case #1 testified in deposition that the practice has since revamped its medication reconciliation process to include this approach.

- ✓ Develop written medication reconciliation procedures and incorporate reconciliation into workflows. Define team member responsibilities by specifying who (MA, RN, MD/DO, APRN/PA) will perform what task and when.

- ✓ Develop specific procedures for medication reconciliation after surgeries and medical procedures, hospital discharges, and other care transitions. Medication errors and adverse drug events frequently occur during care transitions and many are associated with communication breakdowns. In Case #1, the physician assumed that other providers would change the patient's Warfarin dosage before, during, and after the surgery. Yet the discharge summaries showed the patient remained on his usual dose when he returned home. This information was in the physician's records but, without proper medication reconciliation, was overlooked.

- ✓ Provide initial education and regular refreshers on the importance of medication reconciliation and office procedures.

- ✓ Monitor compliance with medication reconciliation protocols.

Communication, Medication-Specific Patient Education, and Consent

Improving communication with patients may help you and your practice staff avoid mix-ups and misunderstandings that lead to medication management errors. Communication includes written and oral communication between patients, physicians, and staff as well as medical record documentation. Consider these strategies:

- ✓ Develop a procedure for ensuring that someone responds to and documents all phone and electronic communications from patients. In Case #1, the patient called and questioned his Warfarin dose. This was an opportunity to discover the dosage mix-up sooner, but there was no evidence that anyone from the practice investigated the patient's concerns.

- ✓ If your practice manages Warfarin, other anticoagulant therapies, and medications that require frequent or regular monitoring, develop a procedure for communicating INRs, other lab results, and dosage changes to patients. Documentation of these communications in the medical record is equally important and will help you defend a medical malpractice lawsuit or board complaint.

- ✓ At each visit, ask patients if they have questions about the medications they are taking and allow time for a question-answer session.

- ✓ Prescribers should engage patients in medication informed consent discussions, by providing patients with information about the risks and benefits of, alternatives to, and reasons for a particular medication. Case #2 serves as a reminder that education and consent discussions should continue throughout medication management. The defense of Case #2 might have been stronger had the physician documented frequent discussions about the potential consequences of the patient's request to deviate from the INR target range.

- ✓ Consider developing Warfarin treatment agreements. These forms should incorporate information provided during the education and consent discussion. They should also highlight patient responsibilities such as keeping INR check appointments and taking the medication as prescribed. Following a thorough education and consent discussion, ask patients to sign the form to confirm understanding and agreement. The physician in Case #1 testified in deposition that the practice now follows this procedure.

Policies, Processes, Guidelines

- ✓ In Case #1, where the patient saw only a medical assistant or nurse during INR checks, the physician testified the practice changed its process. Patients now also see a physician during each INR check.

- ✓ Maintain readily available, up-to-date references and authoritative literature on medications you prescribe.

Process Improvements to Reduce Age-Related Vaccine Administration Errors

Vaccine administration errors are common. Studies suggest that errors occur in as many as one-third of all vaccines administered. The World Health Organization reports that such errors cause more adverse events than vaccines themselves.

Age-related vaccine errors, including wrong dose, age, or vaccine, rank at the top of the list of common vaccine errors. In 2022, the Institute for Safe Medication Practices (ISMP) analyzed over 1400 vaccination-related adverse events reported to its National Vaccine Errors Reporting Program (VERP) between June 2020 and December 2021. The ISMP VERP was created in 2012 and is the only national vaccine error reporting program in the United States. After excluding COVID-19 vaccine errors, ISMP found that age-related errors (wrong dose, age, or vaccine) were the most frequent types of errors, occurring in nearly **half** of all reported events. Compared to a similar study ISMP published in 2016, there has been little improvement in the frequency of age-related vaccine errors over the past decade.

The 2022 ISMP study found:

24% of reported events involved wrong vaccine

13% of reported events involved wrong age

9% of reported events involved wrong dose

42% of reported events involved nurse practitioners or RNs

34% of reported events involved medical assistants

14% of reported events involved other clinicians such as physicians or physician assistants

While many vaccine errors don't cause personal injury, they lessen patient trust in vaccines, clinicians, and the U.S. health care system. Errors can result in inadequate immunological protection and/or increased costs (due to overvaccination or re-vaccination). They may also prompt patients (or pediatric patients' parents) to file board complaints or write negative online reviews.

Common Causes of Errors

Many age-related vaccine administration errors are preventable simply by identifying and correcting error-prone processes. Common causes of errors include:

- Look-alike/sound-alike names, labels, packaging, design, and wording;
- Interruptions, hurrying, or distractions during vaccine preparation/administration;
- Preparing and administering vaccines for more than one patient at a time; and
- Administering vaccines prepared by a different staff member.

Error Examples

The following errors reported to ISMP VERP may ring a bell if you've experienced a similar situation in your own practice:

Errors Due to Packaging Similarities

GSK manufactures adult and pediatric formulas of HepA and HepB vaccines. The adult and pediatric formulas are packaged in similar cartons - both say GSK Havrix or GSK Engerix-B. Age range indications appear in small font on the carton only; syringes are not labeled. The packaging similarities and lack of syringe labeling likely contributed to the following errors:

- MA mistakenly administered the adult formulation of Havrix HepA to a pediatric patient. Notably, a different staff member prepared the syringe.
- Nurse accidentally gave Engerix-B pediatric formula to an adult patient. Due to a stocking error, pediatric doses were in the adult bin. The nurse didn't check the carton label before pulling out a syringe.

Errors Due to Package Design and Hurried Personnel

Merck manufactures the VAQTA HepA vaccine with pediatric and adult formulas. Although labeling on the cartons and syringes identifies the different dosages and age range indications, the information is easy to overlook because it appears below the vaccine name in similar font. Errors result when hurried staff members stop reading after seeing the vaccine name.

DTaP vs Tdap

After a prescriber ordered DTaP for an infant, the nurse accidentally pulled and administered Tdap. DTaP is indicated for ages 6 weeks to 6 years, while Tdap is meant for ages 10 to 64. Their similar proper names and abbreviations make them easy to confuse, especially since they also have similar packaging. ISMP says mix-ups involving DTaP and Tdap are frequently reported.

Process Improvements to Minimize or Eliminate Errors

Gaps in vaccination preparation and administration processes lead to errors. To avoid age-related and other vaccine errors, assess your processes for weaknesses and make changes accordingly. To help you, we've put together a list of strategies you can implement now.

RISK-REDUCTION STRATEGIES

- ✓ **Store adult and pediatric vaccines separately from each other, in different refrigerators/freezers.**
- ✓ **Circle important information on packaging to emphasize differences in indications and dosages.**
- ✓ **Separate vaccines into bins or other containers based on type and formulation.**
- ✓ **Use color-coded identification labels on vaccine storage containers.**
- ✓ **Don't list vaccines with look-alike names sequentially on order forms, computer screens, or medical records.**
- ✓ **Use "name alert" or "look-alike" warning labels on vaccine packaging and storage bins.**
- ✓ **If look-alike packaging is a risk, consider purchasing products from different manufacturers when possible.**
- ✓ **Establish no-interruption areas where vaccines are prepared.**
- ✓ **Educate staff about why it's essential to avoid distractions/interruptions during vaccine preparation and administration.**

RISK-REDUCTION STRATEGIES

- ✓ **Check the packaging and vial labels three times before preparing the syringe.**
- ✓ **Label vaccine syringes immediately after preparation.**
- ✓ **Prepare vaccines for one patient at a time.**
- ✓ **Do not administer vaccines prepared by someone else.**
- ✓ **Triple-check work before administering a vaccine and ask another staff member to confirm.**
- ✓ **Before administering, verify the patient's identify using two unique identifiers (e.g., name and birth date). ISMP says that failure to verify the patient's age contributes to about 1 in 5 age-related vaccine errors.**
- ✓ **Vaccinate one patient at a time. If several people in the same family need vaccinations on the same day (i.e., multiple siblings or parent and child), place patients in different rooms if possible. If patients must remain together, bring only one patient's vaccines into the treatment area at a time, each labeled with the names of the patient and the vaccine.**

In addition to implementing the strategies outlined in this article, consider developing a process to regularly track and analyze vaccine errors that occur in your practice. Taking a closer look at errors makes it easier to identify gaps, so you can make changes to eliminate repeat errors and improve patient safety and trust.

About MICA's Risk Team

The Risk Team at MICA offers a collaborative approach to preventing medical malpractice claims and strengthening your defense against them. Our Risk Consultants integrate their legal, nursing, practice administration, and quality management experience into responses and resources that address your pain points. The Risk Team is standing by to answer your calls and emails about regulatory requirements, documentation, managing conflict, policies and processes, and other types of risk. With the support of MICA's Risk Team, you can put your energy into your patients' care. Call or email our Risk Consultants directly at **800-705-0538** or rm_info@mica-insurance.com.

Services Highlights

- Unlimited access to our Risk Consultants by phone or email. You can rely on MICA's Risk Team for action planning, resources, ideas, information, and guidance.
- Virtual or in-person comprehensive or focused risk assessments of your organization's policies, procedures, and medical record documentation.
- Monthly e-newsletter with links to new resources, samples, templates, and guides. Online risk management and specialty-specific CME courses available on demand at no additional cost.

About MICA

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