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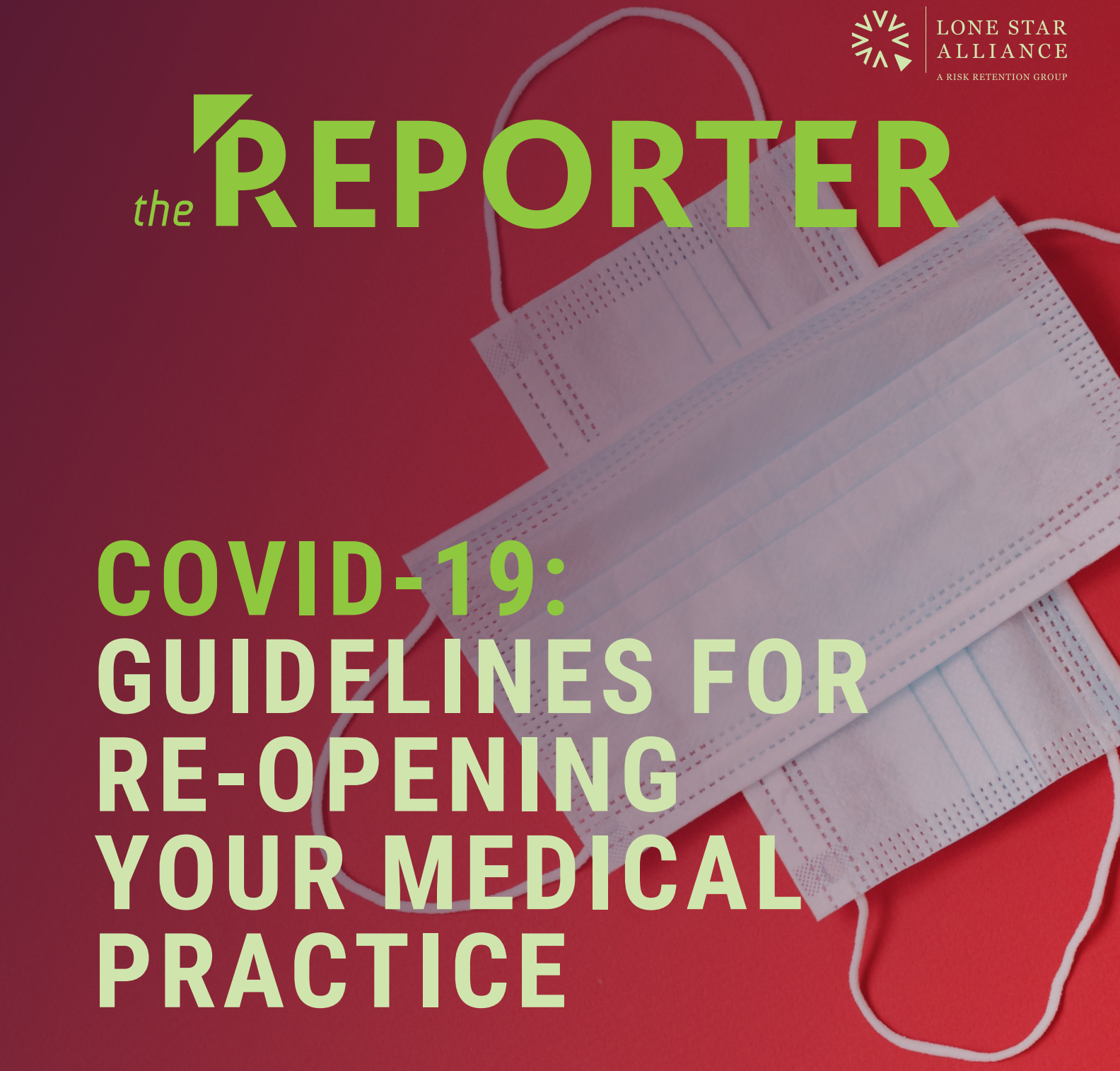

COVID-19: GUIDELINES FOR RE-OPENING YOUR MEDICAL PRACTICE

Also in this issue:

- **CME:** Medication and prescribing safety
- **Closed claim:** Failure to diagnose and treat infection in a timely manner
- **Closed claim:** Failure to respond to test results

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COVID-19: GUIDELINES FOR RE-OPENING YOUR MEDICAL PRACTICE

by Wayne Wenske, Senior Marketing Coordinator

As COVID-19 shelter in place orders relax and practices re-open for in-person visits, physicians must now work under new safety standards and guidelines. To help you practice in this "new normal," please consider these risk management guidelines.

AMA GUIDELINES

The American Medical Association (AMA), has published a checklist for physicians to ensure medical practices are ready to re-open safely. The checklist comprises the following 12 guidelines.[1]

1. Comply with governmental guidance.
The federal government and several state governments have published guidance and recommendations for reopening businesses. Federal guidelines, entitled "Opening up America again," are available online (see "Additional Resources" and "Sources" on pages 6 and 7).[2]

The AMA has created a state-by-state fact sheet that provides directives for the "resumption of elective or non-urgent procedures." [3] This document includes guidance from the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention (CDC), and the American College of Surgeons. It is also available online.[3]

In Texas, the Texas Medical Board (TMB) has created a new rule (emergency rule 190.8(2)(U)) specific to COVID-19 that outlines the "required minimum standards for safe practice." [4] The emergency rule establishes minimum standards for safe practice for all physicians providing patient care or engaging in in-person patient encounters and requires the following.

- A mask must be worn by both the patient and physician or the physician's delegate when there is less than a 6-foot distance between the patient and the physician or the physician's delegate.
- Providers must follow the policies put in place by the physician, medical and health care practice, or facility regarding COVID-19 screening and testing and/or screening patients.
- Before an appointment, patients must be either screened for potential symptoms of COVID-19 or verified as previously screened within the last 20 days.
- Before any medical procedure or surgery on the mucous membranes, including the respiratory tract, with a high risk of aerosol transmission, the minimum safety equipment used by a physician or physician's delegate should include N95 masks, or an equivalent, and face shields.
- All medical and health care practices, offices, and facilities, other than hospitals as defined under Chapter 241 of the Texas Health & Safety Code, shall post a notice describing these minimum standards for practice in all public and private areas and treatment rooms.[4, 5]

If you practice outside of Texas, consult with your state medical board for guidance. Additional TMB standards can be accessed online.[6]

2. Make a plan.
Take the time and steps needed to prepare your practice for a successful reopening. Start by taking inventory of your personal protective equipment (PPE) and assess what your needs will become as you reopen. Place orders for what you need and try to have deliveries in advance of reopening.

Keep track of the appointments that were cancelled before closing. Identify which patients are more vulnerable, and prioritize those patients as appointments are rescheduled. [7]

Take a look at your office, exam rooms, waiting areas, and administrative areas. Where can changes be made to minimize infection? Consider removing magazines, children's toys, or other clutter from the waiting area that could be harboring germs. Consider installing protective shields or barriers at desks where patients check in, pay their bills, or make appointments.[7]

Revisit your policies and procedures. Consider whether or not cancellation policies and payment policies are sensitive to what your patients may be experiencing due to COVID-19, such as financial difficulties, child care scheduling issues, or unemployment.[7]

Create an internal policy or rule about how to handle staffing and cleaning work areas if a patient, employee, or visitor is diagnosed with COVID-19 after being in the clinic. Establish when and how long employees who interacted with a diagnosed patient or visitor will be out of the clinic.[1]

3. Open incrementally.
At first, you may want to identify what patient visits can be made via telemedicine and continue to perform those visits remotely. Consider reopening your office gradually for in-person visits. For example, you may want to assign one-third of your time to in-person visits and keep two-thirds as telehealth visits. This will allow you to assess how things are going and address any challenges that arise before opening more broadly.[8]

Administrative staff who do not need to be physically present in the office should be directed to work remotely. Consider bringing employees back in phases or on alternating days to reduce contact.

Clearly communicate your office hours. Publish this information widely and often – through email to patients, on social media, and on your website.[7]

4. Institute safety measures for patients.
To ensure that patients are not coming into close contact with one another, adopt a modified schedule to avoid

high volume or density. Designate separate waiting areas for "well" and "sick" patients. You might even consider scheduling well visits in the morning and sick visits in the afternoon, or vice versa. If possible, designate "entrance only" and "exit only" doors for your patients.[7]

Consider a flexible schedule for the practice, with perhaps a longer workday with more time in between visits to avoid backups. Limit patient companions to those whose participation is necessary based on the patient's circumstances. For example, a parent for a minor; a spouse; or caregiver for a disabled patient are acceptable.

Consistent with CDC guidance, practices should require all individuals who visit the office to wear a cloth face covering or mask. This expectation should be explained to patients and visitors before they arrive.

To facilitate compliance, provide resources to help patients make a cloth face covering or mask, such as the CDC webpage. There are also several YouTube videos to share on how to make a mask. Visitors and patients who arrive to the practice without a cloth face covering or mask should be provided with one by your practice, if supplies are available.[1]

In addition to the AMA guidelines, here are some additional recommendations.[8]

- Communicate clearly to patients when the practice will reopen, how visits will be different, and what is expected of them. Assure them that you and your staff are taking all recommended precautions to protect their health and safety.
- New expectations will include maintaining physical distancing while in the office. Staff and patients must stay at least six feet apart unless patient care requires closer contact. Patients should also be informed of screening procedures before their appointment. (See section 7 on the next page.)
- Some practices may adopt procedures for escorting patients directly to an exam room upon arrival. Other practices might instruct patients to send a text message to the office when they arrive and to wait in their cars until they are called in for their appointment.

5. Ensure workplace safety for clinicians and staff.
Clearly communicate to staff and colleagues that they cannot come to work if they are experiencing any symptoms of COVID-19, or if they have recently come into contact with someone who has tested positive for COVID-19.

All employees should be screened daily for fever and other symptoms before they begin work. This may be done by employees before they report to work. Maintain records of employee screening efforts and results in a confidential file, separate from personnel files.

Clinical staff should wear face masks, gowns, eye protection, and gloves when caring for patients suspected of COVID-19 infection. Masks and gloves should also be worn when seeing other patients due to the possibility of patients being asymptomatic for COVID-19 infection.[8]

Minimize person-to-person contact as much as possible, including during the employee screening process. Consider reconfiguring workspaces to increase social distancing between workers.

Establish open communication with the facilities department of your building regarding the cleaning schedules and protocols for shared building spaces, such as lobbies, kitchens, bathrooms, elevators, stairwells, doors, and other common areas. You may also want to maintain this contact to stay informed of any workers in the building who test positive for COVID-19.[1]

Additional recommendations include the following.

- Ensure that handwashing and sanitizing supplies are available to patients and staff. "Staff should perform hand hygiene before and after each patient contact, after contact with potentially infectious material, and before putting on and after removing PPE, including gloves." [8]
- "If possible, divide staff up into shifts or teams. If one team gets exposed, the other team will be protected." [8]
- Clean and disinfect exam rooms after each patient encounter, per guidelines from the CDC. These guidelines are found online on the CDC website. [9]
- Frequent disinfection of surfaces and objects touched by multiple people is important. Disinfect light switches and door handles daily. [8]
- Using automatic door openers or propping certain doors open will help cut down on the need and/or frequency for disinfecting these surfaces. [8]
- Display prominent signs with instructions on hand washing, cough etiquette ("cover your cough"), and respiratory hygiene ("use a tissue to cover your mouth and nose when coughing or sneezing").[7]
- "Consider recording a video of your practice showing all the precautions you have undertaken for your patients' and staff's safety. Show staff wearing masks and gloves or in full PPE gear. Capture them in action disinfecting door handles, light switches, work surfaces, and so on. Upload the video to your practice website and share it across social media platforms." [7]

6. Implement a tele-triage program.
When scheduling patients for appointments, consider

using a tele-triage program to assess the need for face-to-face appointments. When a patient calls the practice, use the program to discuss symptoms and the patient's current status. Based on the information gathered, the patient may be scheduled for an appointment or re-directed to the practice's HIPAA-compliant telemedicine platform, a COVID-19 testing site, or to a hospital.

If your practice was already using a tele-triage service pre-COVID for after-hours calls, contact your service to determine how the service could be expanded to tele-triage daytime calls. Consider reassigning practice personnel to operate this service during office hours.

Visits that can be conducted via telemedicine should be. It is also important to verify that those patients scheduled for telemedicine visits have the necessary technology and understand the technical instructions for accessing the visit.

Additional recommendations when scheduling patients include:

- ask patients to complete intake paperwork and registration forms online before their appointments;
- ensure your website is updated with new business hours, registration forms, and instructions for patients regarding COVID-19 safety guidelines, including screenings, face masks, physical distancing, and procedures for entering the practice;
- evaluate your telemedicine tools for ease of use and long-term viability; and
- review your options for the best HIPAA-compliant telemedicine platform for you and your patients. The TMA has posted a comprehensive guide for telemedicine vendor options online.[10]

7. Screen patients before in-person visits.
Before an in-person appointment, confirm to the best of your ability that the patient does not have symptoms of COVID-19. Establish a system for staff to call the patient within 24 hours of the appointment to 1) review the logistics of the reopening practice protocol, including what to expect when they arrive for their appointment, and 2) screen the patient for COVID-19 symptoms.

Use a script of questions for your staff to follow when conducting these calls. Include questions such as the following. A full script template is available at the AMA website.[1]

- "Have you or a member of your household had any of the following symptoms in the last 21 days: sore throat, cough, chills, body aches for unknown reasons, shortness of breath for unknown reasons, loss of smell, loss of taste, fever, temperature at or greater than 100 degrees Fahrenheit? (If yes, obtain information about who had the symptoms, what the symptoms were, when the symptoms started, when

the symptoms stopped.)"
- "Have you or a member of your household visited or received treatment in a hospital, nursing home, long-term care, or other health care facility in the past 30 days? (If yes, obtain the facility name, location, reason for visit/treatment and dates.)"
- "Have you or a member of your household traveled outside the U.S. in the past 30 days? (If yes, obtain the city, country and dates.)"
- "Have you or a member of your household traveled elsewhere in the U.S. in the past 21 days? (If yes, obtain the city, state and dates.)"
- "To the best of your knowledge have you been in close proximity to anyone who tested positive for COVID-19? (If yes, obtain information about when the contact occurred, what the contact was, how long the people were in contact, and when the diagnosis occurred.)" [1]

When the patient arrives at your office, he or she should also be screened before entering. Some practices may deploy staff in a designated area of the parking lot or in an anteroom to screen patients before they enter. Other practices may use text messaging or other electronic means to do such screening, subject to patient consent and relevant federal and state regulations.

Again, strictly limit individuals accompanying patients to those who are necessary. These individuals should be screened in the same manner as a patient.

8. Coordinate testing with local hospitals and clinics.
Contact your county medical society or state medical board for information on available COVID-19 testing sites. Identify several testing sites in your area and contact them to ensure that tests are available. Also, determine the turnaround time on testing results.

"Provide clear and up-to-date information to patients regarding where they can be tested and how the process works. Some health systems have instituted the practice of testing all patients who are being scheduled for elective or high-intensity procedures (such as outpatient surgeries or services requiring close contact). Depending on the nature of your practice, you may consider doing the same." [1]

9. Limit non-patient visitors.
Minimize contact between your patients and any non-patient visitors to your practice, such as a vendor, supplier, or maintenance worker. Establish a protocol for rerouting these visits to phone calls or video conferences. The AMA suggests that a physician may want to hold "office hours" to speak with suppliers, vendors or salespeople by phone or video conference.[1]

Clearly post your new policy for non-patient visitors outside the practice door and on your website. For visitors who must physically enter the practice (to do repair work, for example), you may want to designate specific times outside of office hours for these individuals.

10. Contact your medical malpractice insurance carrier.
Contact your medical liability insurance carrier to discuss your current coverage and whether any additional coverage may be warranted during the COVID-19 pandemic. Legislation may be forthcoming in some states to expand protections to physicians treating COVID-19 patients. It's important to be in close contact with your insurer to confirm your status and level of coverage.

11. Establish confidentiality/privacy.
Before reopening, the AMA recommends establishing or updating your confidentiality, privacy, and data security protocols, policies, and procedures. Require all employees to review all new and/or updated materials and sign them to acknowledge their review and understanding of them.

Again, results of any screenings of employees should be kept in employment records only (but separate from the personnel file). HIPAA authorizations are still necessary for sharing information about patients for employment purposes. Co-workers and patients may be informed that they came into contact with an employee who tested positive for COVID-19, but the identity of the employee and details about his or her symptoms cannot be shared with patients or co-workers without consent.

While certain HIPAA requirements related to telemedicine have not been enforced during COVID-19, generally HIPAA's privacy, security, and breach notification requirements must continue to be followed.[1]

12. Consider legal implications.
The AMA states, "New legal issues and obligations may arise as the practice reopens. For example, some practices may not have had to make decisions about paid sick leave (per the 'Families First Coronavirus Response Act') because they were on furlough; as the practice reopens, these sorts of employment obligations should be considered and decisions about opting out or procedures for requesting these leaves communicated to employees…Lastly, coordinate with your local health department as provided for by law; provide them with the minimum necessary information regarding COVID-19 cases reported in your practice, and stay informed of local developments." [1]

ADDITIONAL RESOURCES

- CDC website: Information for Healthcare Professionals about Coronavirus (COVID-19). This site includes clinical care guidance, including a telephone response guide, guidance by patient type, infection control, optimizing PPE supplies, and FAQs. https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html

- Texas Medical Association: COVID-19 Resources. This site includes links to state mandates for new COVID-19 Safety Rules; TMA guides, and FAQs. https://www.texmed.org/CoronaVirus/

- Texas Health and Human Services: Coronavirus Disease 2019 (COVID-19) website. https://dshs.texas.gov/coronavirus/

- The Institute for Health Metrics and Evaluation (IHME) COVID-19 projections. https://covid19.healthdata.org/united-states-of-america

- Johns Hopkins University of Medicine: Coronavirus Resource Center. https://coronavirus.jhu.edu/

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CME - MEDICATION AND PRESCRIBING SAFETY

by Roxanna Maiberger, MPAff, Risk Management Representative

OBJECTIVES

Upon completion of this course, the physician will be able to:

1. discuss medication error prevention strategies;
2. describe how to reduce risks associated with compounding medications;
3. define complementary and alternative medications; and
4. discuss the importance of medication safety protocols.

COURSE AUTHOR

Roxanna Maiberger is a Risk Management Representative at Texas Medical Liability Trust (TMLT).

DISCLOSURE

Roxanna Maiberger has no commercial affiliations/interests to disclose related to this activity. TMLT staff, planners, and reviewers have no commercial affiliations/interests to disclose related to this activity.

TARGET AUDIENCE

This 1-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for medical liability.

CME CREDIT STATEMENT

The Texas Medical Liability Trust is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Texas Medical Liability Trust designates this enduring material for a maximum of 1 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

PRICING

A fee of $75 will be charged when accessing this CME course online at http://lonestara.inreachce.com.

ETHICS CREDIT STATEMENT

This course has been designated by TMLT for 1 credit in medical ethics and/or professional responsibility.

TEST

To receive CME credit, physicians should complete the test questions that follow the activity. A passing score of 70% or better earns the physician 1 CME credit.

INSTRUCTIONS

the Reporter CME test and evaluation forms must be completed online. After reading the article, go to http://lonestara.inreachce.com. Follow the online instructions to complete the forms and download your certificate.

Questions about the CME course? Please call TMLT Risk Management at 800-580-8658.

ESTIMATED TIME TO COMPLETE ACTIVITY

It should take approximately 1 hour to read this article and complete the questions and evaluation form.

RELEASE/REVIEW DATE

This activity is released on June 15, 2020 and will expire on June 15, 2023.

Please note that this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

INTRODUCTION

Medication safety is a critical risk management topic, as errors may occur at multiple junctures during a patient's course of treatment. Recent studies show that medication errors can be attributed to 7,000 to 9,000 deaths in the United States per year.[1] These numbers may be underreported, because adverse medication outcomes may not be properly accounted for at the time of an individual's death. In addition, an individual may not attribute concerns or symptoms to the medications he or she is prescribed.

Medication errors can involve all participants in the health care system, including practitioners, pharmacists, and patients. However, medication errors most commonly occur during the ordering and/or prescribing stages.[1] Examples of errors generally include:

- improper prescribing;
- incorrect route or dose of medication; and
- incorrect frequency of medication.[1]

In conducting research for this article, data from TMLT policyholder phone inquiries and TMLT practice-based loss control services were reviewed, in addition to such resources as the National Center for Biotechnology Information. Within this data, several issues regarding medication safety and its relation to patient safety became apparent.

This article is designed to increase awareness and provide health care providers with ways to prevent medication errors, promote patient safety, and implement effective risk management practices regarding medication and patient safety.

Additionally, a brief overview on complementary and alternative treatments and compounded medications is provided. While these topics do not inherently increase the incidence of medication errors, it is important to review them because of the unique risks, benefits, and regulations that often accompany these types of treatments.

This article also serves as a reminder about the importance of following safety guidelines, assessing practices for various risk exposures, and implementing a plan to mitigate these potential risk exposures.

The following areas of discussion are included:

- medication errors and risk reduction;
- complementary and alternative treatment;
- compounding medications; and
- the importance of policies and procedures.

Discussion of medication safety can encourage maintenance of best practices and result in increased patient safety. While focus is often placed on the actions of physicians and health care professionals, this is not meant to imply that health care providers alone can reduce medication errors. It requires the participation of physicians, health care professionals, medical practice staff members, pharmacists, governing entities, and patients.

MEDICATION ERRORS AND RISK REDUCTION

In an article published in the *British Journal of Pharmacology,* medication errors are defined as "a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient." [2] It further explains that the "treatment process" involves various elements of the health care system and its members. Understanding the role of each health care team member can allow proper risk reduction techniques to be implemented. Additionally, knowing where the failure occurred in relation to the treatment process allows for proper re-evaluation.

Some members of the care team are listed below, along with a brief overview of the role they play. This information can inform effective updates to policies and procedures related to medication and patient safety, described later in this article.

While additional responsibilities are associated with the roles below, they are included here specifically within the context of medication errors. Thus, it is not a comprehensive list, but rather, some common areas of consideration.

Treatment process members and roles: [2, 3]

- **Health care practitioners** (physicians, advanced practice registered nurses, physician assistants) have the responsibility to properly prescribe the right treatment for the patient, which includes prescription of the correct medications (e.g. route, dosage, and frequency). Educating the patient on proper use of medications is also important, including a risk and benefit discussion. Health care practitioners also have a responsibility to remain aware of certain drug recalls as they pertain to the practice, and to follow reporting guidelines for adverse drug reactions.
- **Health care staff** have a responsibility to adhere to the appropriate policies and procedures in which they are employed. Health care staff include, but are not limited to, front office staff and medical assistants.
- **Pharmacists** are responsible for filling prescriptions; double-checking the prescriptions for contraindications per individual patient; counseling patients on medication; and following proper reporting requirements as it pertains to their profession and state regulations.
- **Pharmaceutical companies** are required to follow drug recall notification laws when they are triggered, as well as comply with strict Food & Drug Administration (FDA) testing guidelines.
- **Patients** have a responsibility to be transparent and honest with their health care practitioner and to provide the most accurate medical history possible. Patients also have a responsibility to inform their physician or health care provider of any side effects they may be experiencing with medications.[3]

Risk management considerations

Understanding these roles throughout the treatment process helps physicians make informed decisions to reduce medication errors. Several risk management considerations are outlined below.

Setting patient-physician relationship expectations from the beginning

When feasible (e.g. for new patients), it is prudent and recommended to help patients understand that they play a crucial role in the care provided. Communicate to patients that they have a responsibility to be transparent with health care practitioners in order for them to receive safe and effective treatment.

Establishing a protocol to educate patients about their role at the beginning of the patient-physician relationship can be done in a few ways:

- conduct an educational discussion during the first visit;
- instruct patients to sign and acknowledge information regarding their role and responsibility to provide accurate information in the new patient packet;
- incorporate this language into the practice's policies and procedures, or other verbiage that informs staff members of the practice's culture and patient communication guidelines.

These steps may help the patient feel more engaged in the treatment process and highlight the importance of transparency between the patient and health care provider.

Document these efforts, as they clearly present what occurs (or is intended to occur) during a patient encounter.

From the outset of care, patients should be encouraged to communicate any unexpected medication reactions or side effects, and staff should be trained to take these complaints seriously.

Requiring patients to bring all medications to the first visit or annually
Human error is often unintentional, but it can result in important information being omitted. When it comes to medications, omissions can have serious negative implications. By asking patients to bring their medications to their first visit, the potential omission of important medication history may be reduced.

Patient education
Patients often forget or disregard critical elements to their prescribed treatment plan, including instructions for taking medications or recommendations for lifestyle changes. Therefore, it is important to check in and make sure the patient understands the information provided during the visit.

From a risk management standpoint, it is important to encourage patients to adopt the education and advice provided. One way of doing this is to ask patients to repeat what they have just learned and leave ample opportunity for questions.[4]

If possible, provide an educational document the patient can refer to after the visit, such as a fact sheet or worksheet listing their specific prescription; how to take the medication; any side effects to look for; and contact information for your office in case the patient has any questions. Many electronic health record systems offer tools to quickly generate and provide this information to patients. Instruct the patient to call 911 in case of an emergency.

Document the specific types of education or materials provided in the patient record. For example, if a patient is asked to consult the patient education section on the practice's website and given a handout on how to take a specific medication, this should all be documented.

Communication among the health care team
Conducting regular check-ins provides opportunities to re-evaluate established protocols among your health care team members. This can be an important step towards improving patient safety and preventing medication errors and adverse reactions.

For example, establishing biannual or monthly meetings aimed at addressing established protocols among the health care team could be useful. Additional meetings can be set if a situation arises that needs immediate attention. During these meetings, it is important to set the standard that honest feedback and recommendations are welcomed from staff members.

Medication safety discussion topics could include:

- review of medication prescribing modules in the electronic health record, and accurate entry;
- process, including frequency, for reviewing and updating patient allergies and current medications;
- management of prescription refills, including delegation protocols if applicable;
- discussion of tasks that may only be managed by a physician or non-physician practitioner;
- management of sample medications, including receiving, storing, and distributing medications to patients;
- documentation standards for prescriptions, refills, and samples.

Document efforts made to re-evaluate practice systems during a check-in. Designate one individual and a back-up individual to oversee and accomplish these tasks to ensure these efforts are updated correctly and documented in a timely manner.

Understanding the role of each health care team member; conducting periodic re-evaluation and improvements; and maintaining contemporaneous, complete documentation serve together as a foundation for promoting patient safety.

This applies throughout the remainder of discussions on complementary and alternative treatment, compounded medications, and the importance of practice-based policies and procedures.

COMPLEMENTARY AND ALTERNATIVE TREATMENT

Many patients in the United States, especially those with chronic conditions, use complementary and alternative treatments.[5] The use of complementary and alternative medicine (CAM) in treating patients by health care professionals may be defined and regulated by state laws and guidelines. This section includes a brief overview of CAM regulations in Texas. However, if you practice outside of Texas, it is recommended to check your state medical board rules to ensure compliance.

General definitions
According to the National Center for Complementary and Integrative Health, complementary and alternative medicine are defined separately.

- Complementary Medicine: "A non-mainstream practice being used together with conventional medicine."

- Alternative Medicine: "A non-mainstream practice being used in place of conventional medicine." [6]

In Texas, these terms are defined in one definition found in Chapter 200 of the Texas Medical Board Rules on Standards for Physicians Practicing Complementary and Alternative Medicine:

> "Complementary and Alternative Medicine — Those health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods." [7]

The statute further defines "Reasonable Potential for Therapeutic Gain" as "an expected beneficial outcome resulting from the application of a health care method containing medicinal or healing properties that is supported by scientific evidence and does not solely rely on placebo effect." [7]

It is important to know and follow state regulations for these types of treatments. If there are questions related to the specific interpretation of state rules, consult a licensed attorney. In general, the use of non-FDA approved medications and/or treatments is not recommended.

In Texas, these CAM practice guidelines require an assessment of the patient that, "should include, but is not limited to conventional methods of diagnosis." These rules further specify that physicians must disclose the following to the patient:

> "(A) the objectives, expected outcomes, or goals of the proposed treatment, such as functional improvement, pain relief, or expected psychosocial benefit;
> (B) the risks and benefits of the proposed treatment;
> (C) the extent the proposed treatment could interfere with any ongoing or recommended medical care;
> (D) a description of the underlying therapeutic basis or mechanism of action of the proposed treatment purporting to have a reasonable potential for therapeutic gain that is written in a manner understandable to the patient; and
> (E) if applicable, whether a drug, supplement, or remedy employed in the treatment is:
> (i) approved for human use by the U.S. Food and Drug Administration (FDA);
> (ii) exempt from FDA preapproval under the Dietary Supplement and Health Education Act (DSHEA); or
> (iii) a pharmaceutical compound not commercially available and, therefore, is also an investigation article subject to clinical investigation standards as discussed in paragraph (7) of this section." [8]

These rules also mandate a documented treatment plan, periodic review of treatment, adequate medical records, and therapeutic validity of the treatment.[8]

Related to CAM is the recent passage of House Bill 1325 during the 86th Texas Legislature, which legalized the sale of "hemp and hemp-derived extracts like CBD [cannabidiol] oil as long as they contain no more than 0.3% THC [tetrahydrocannabinol]." Under this law, marijuana is still illegal in Texas.[9, 10]

The passage of House Bill 1325 should not be confused with the Texas Compassionate Use Act, passed in the 84th Texas Legislature. This law allows qualifying patients with intractable epilepsy to be prescribed and treated with "low-THC cannabis."[11] This low-THC cannabis differs in that it can contain higher levels of THC and CBD.

The intricacies of the Texas Compassionate Use Act are numerous and outside the scope of this CME article. For additional information on the Texas Compassionate Use Act, please contact your medical liability carrier or health care attorney.

Risk management considerations

Considering where the CAM treatment lands within the scope of practice is important. Scope of practice is constantly evolving, and if you have questions about it, consult your attorney, state medical society, and/or specialty society.

Before starting a new type of treatment, document the training completed by any practitioner or staff member rendering these treatments or services in your practice. Training documentation may be required in your state and by your practice. It also promotes the expertise and credibility of the practitioner and practice offering the treatment.

It is critical to consult with your medical liability carrier regarding any change in treatments offered by your practice. Coverage can change based on the types of medical services provided. It is important to be transparent with your medical liability carrier to ensure that you have adequate coverage.

For example, with the passage of House Bill 1325, Texas physicians and other health care providers often have questions associated with the sale of CBD oil. Generally, the sale of products (including but not limited to CBD oil) by physicians is not recommended.

The American Medical Association (AMA) and Texas Medical Association (TMA) offer the following opinion on the sale of health-related products.

AMA Code of Medical Ethics Opinion 9.6.4:

> *"The for-profit sale of health-related products by a physician can create a conflict of interest for the physician. The conflict of interest exists because the physician has a financial interest in selling the products. Concern about the conflict of interest is heightened because of the unique nature of the patient-physician relationship. The basis of the patient-physician relationship is trust. The for-profit sale of health-related products risks demeaning the relationship and the professional practice of medicine."*[12]

The TMA Board of Councilors Current Opinion, "Sale of Health Related Products from Physicians' Offices,"[13] includes identical language.

Additionally, sale of any products by physicians and the liability associated with these sales may not be covered by your liability insurance carrier. So, it is important to be diligent in these decisions to sell products. Review and compliance with Stark Law is also important, and it is recommended to consult a health care attorney before considering selling any health-related products at your practice.

Informed consent is another important component in the patient education process. Fully informed patient consent is required before rendering CAM treatment to a patient. Patients should be well educated about the risks, benefits, or unknowns regarding the treatment. This discussion also helps to establish reasonable expectations with the patient. Proper documentation of these efforts to inform and educate the patient is critical to a complete, defensible medical record. This documentation may also be required depending on treatment type and state regulations.

COMPOUNDED MEDICATIONS

In some instances, compounded medications can fill a gap in a patient's treatment plan and benefit them when other standard therapies are unavailable.[14] Physicians should perform due diligence to ensure the compounding pharmacies they use are in good standing with state pharmacy boards and have a good patient safety record.

In addition, it is important to remember a few key risk management considerations before prescribing a compounded medication to a patient.

Non-FDA approved medications/treatments

Compounded medications are not FDA approved; they have not gone through the same testing processes for quality and efficacy as those approved by the FDA.[15] This can present an increased potential for adverse reactions in patients.

Informed risk/benefit discussion

Because compounded medications are not FDA approved and the specific compounded formula is determined by the health care practitioner, it is critical to inform the patient of the risks and benefits associated with the use of compounded medications. Obtaining patient

consent and documenting the education provided is also recommended.

As with any new prescription, emphasize that patients must promptly communicate any unexpected or negative side effects back to their health care practitioner. If the patient does not communicate what they are experiencing, this can result in a significant breakdown among the health care team and may delay important treatment decisions. The patient's role in the treatment process is a necessary component to an effective health care team.

Reporting adverse reactions

If or when you become aware of an adverse outcome occurring with a medication, it is important to first ensure that the patient's health is stable. Once you have confirmed that the patient is getting the care they need, consider reporting the adverse outcome to the FDA's MedWatch Voluntary Reporting program online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1.

If the patient's experience is not an isolated incident, reporting this information could provide the FDA with important data that could potentially result in a risk alert for the medication. Without reporting, general patient safety could be at risk.

Additionally, proactively contacting your medical liability insurance carrier's claims department may be appropriate. Should a claim or lawsuit occur, reporting at the onset of the patient's adverse event could result in producing more accurate documentation of what transpired rather than trying to recall it months later.

POLICIES AND PROCEDURES

Effective risk management requires attention to detail, re-evaluation, and strong written policies and procedures that are followed by each member of the health care practice. Often, policies and procedures are created, and quickly become outdated due to the natural evolution of the practice. However, when regularly reassessed and treated with intention, they can be powerful, helpful resources to improve patient safety.

The need for written policies and procedures is simple: there is a need for standardized processes to be documented and available for reference by staff. Additionally, these types of policies can prevent inappropriate medical decision-making by an unlicensed individual.

When policies are updated, document your individual staff members' acknowledgement of these updates.

Some important policies related to promoting medication safety, preventing adverse reactions, and improving patient safety include the following.

Office-Based Emergency Policy — This policy assigns team members to their required roles in the event of a patient emergency in the office (e.g. heart attack, adverse reaction to a medication administered at the practice). If the practice is located near a hospital, it is not safe to assume the hospital will assist during an office-based emergency with their own emergency personnel or equipment. If medications are regularly administered in the practice, providers should be familiar with potential adverse reactions. Emergency protocols should address staff response, the location and maintenance of any

emergency equipment or medication, contacting 911 if needed, and treatment protocols. If and when an unplanned patient emergency occurs, taking these steps could increase patient safety and practice defensibility.

Sample Medication Policy — This policy outlines a method for maintaining, tracking, and documenting sample medications given to patients. Maintaining a medication sample log or other reliable tracking method of which patients receive specific sample medications is a good risk management practice. If using a sample log, include the medication sample's lot number and expiration date in the log and patient record.

In Texas, prescribers are required to document sample medications in the patient's medical record. If practicing outside of Texas, please check with your state medical board for guidelines on sample medication documentation.

Practice policies should address how samples should be documented in the medical record. Including this information in the patient's medical record may save time and energy by helping the practice in contacting patients in the event of a medication recall. For example, if a sample birth control is recalled due to efficacy concerns, it would be necessary to contact those patients who received the samples specified in the recall notice.

Medication Refill Policy — Often these protocols outline requirements for patients to be seen within certain time frames before medications are refilled. They may also outline certain medications office staff may refill, provided the appropriate delegation by the health care practitioner.

Having a standardized medication refill policy is necessary for any physician who prescribes controlled substances. Beginning March 1, 2020, physicians in Texas must query the prescription monitoring program (PMP) database before prescribing opioids, benzodiazepines, barbiturates, or carisoprodol.[16]

In February 2020, the Texas Medical Board provided additional guidance that explained the mandatory PMP query rule does not apply to inpatient care.[17]

Protocols for outpatient practice should include references to any state requirements regarding prescribing or refilling controlled substances.

Visit the Texas State Board of Pharmacy's website at https://www.pharmacy.texas.gov/PMP/ for more information on setting up a PMP account. Again, if you are practicing outside of Texas, it is important to check your state medical and pharmacy board rules to ensure compliance.

Staff members can be delegated the task of querying the PMP database, but it is important to provide training guidelines and rules for them to follow. Provide these instructions in the refill policy for querying the PMP. Additionally, when assigning a delegate, the staff member should have his or her own login credentials to ensure clarity of who is performing the query. Staff members should review pharmacy board education on appropriate use of the PMP database.

Injection Safety Policy — Injectable medications can include both FDA-approved medications and compounded medications (which are non-FDA approved). Establish a written policy based on the specific needs and workflows of your health care practice for these types of medications and treatments.

Following the CDC infection control guidelines and annually reviewing them for any potential updates should be part of an effective risk management plan. For example, the CDC recommends that multi-use vials be assigned to one patient when feasible. From a risk management perspective, once a multi-use vial is punctured, writing the puncture date on the vial is recommended to facilitate compliance with manufacturers' efficacy guidelines for the specific medication.[18] Providers should be familiar with appropriate storage guidelines for any medications to be administered or distributed by the practice.

CONCLUSION

Preventing medication errors, among other daily practice responsibilities, is a priority that requires effort from everyone involved in the treatment process. The system is only as strong as its weakest link.

Implementing effective risk management protocols can help reduce patient safety hazards. Regarding compounded medications and CAM, it is important to adhere to state and federal regulations and monitor potential changes. Taking the time to proactively consider and adopt some of these measures and protocols can elicit a more effective response if adverse events occur. An effective risk management plan takes time and effort. But if the plan can reduce preventable patient safety issues, it is worth the investment.

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FAILURE TO DIAGNOSE AND TREAT INFECTION IN A TIMELY MANNER

by Wayne Wenske, Senior Marketing Coordinator

PRESENTATION

On June 3, a gastroenterologist performed a hemorrhoidal banding procedure on a 35-year-old man. After the procedure, the patient was instructed to follow up in two weeks with the gastroenterologist.

On June 8, the patient returned to the gastroenterologist's office reporting increased rectal pressure and discomfort. He reported taking sitz baths and ibuprofen with no relief. He also reported a low-grade fever.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. This study has been modified to protect the privacy of the physicians and the patient.

PHYSICIAN ACTION

On rectal exam, the gastroenterologist noted ulceration with mild inflammatory changes. The patient's temperature was not recorded. The patient was prescribed tramadol 50 mg for pain, to be taken orally every four hours, and topical nifedipine and lidocaine. The patient was instructed to follow up in two weeks.

On June 11, the patient returned to the gastroenterologist with reports of worsening rectal pain and discomfort, low-grade fever, mild diaphoresis, and nausea and vomiting. He also reported that the tramadol and ibuprofen did not relieve his discomfort. Again, the patient's temperature was not taken.

The gastroenterologist noted that the patient's progressive symptoms were concerning for developing perianal abscess. He advised the patient to go to the emergency department (ED) for evaluation.

At 5:03 p.m., the patient went to the ED at a local hospital. Laboratory work was obtained and showed white blood cell (WBC) count at 34,200. Vital signs showed a pulse of 107 and a temperature of 102.9 degrees. A CT scan with IV contrast of the abdomen and pelvis revealed inflammatory/infectious process in the left pelvis, most notably within the left obturator internus and left anorectal junction. The patient reported his pain level as a 10 out of 10.

At 9:55 p.m., the ED physician discussed the patient's condition with Hospitalist A, who accepted and admitted the patient.

At 10:54 p.m., the ED physician noted that he had spoken with a colorectal surgeon about the patient's condition, including vital signs, CT findings, labs, and course for admission. The colorectal surgeon agreed to see the patient.

At 11:55 p.m., the ED physician noted that he informed the on-call hospitalist, Hospitalist B, about the patient.

On June 12 at 12:04 a.m., the patient's pulse rate was 115. At 2:30 a.m., Hospitalist B signed the patient's admission form and admitted the patient with a diagnosis of sepsis, proctitis, metabolic acidosis, and ketonuria due to volume depletion. Hospitalist A initiated intravenous antibiotics, fluid infusion, and deep venous thrombosis (DVT) prophylaxis treatment for the patient. For pain, the patient was given IV morphine, hydrocodone-acetaminophen, and acetaminophen.

At 4:28 a.m., his WBC count indicated an increase to 59,900, and his lactic acidosis worsened to 5.0 mmol/L. The patient's next pulse rate, taken at 7:30 a.m., was 143.

At 9:20 a.m., the colorectal surgeon saw the patient; was informed of the patient's latest lab results and vitals; and took him to surgery for immediate debridement. The surgery was completed at approximately 10:55 a.m. The patient was extubated and taken to the recovery room in stable condition. He was still tachycardic, with a heart rate of 150.

While in transport from recovery to the intensive care unit, the patient's heart stopped. Resuscitation was unsuccessful. The patient was pronounced dead at 3:56 p.m. An autopsy report noted the cause of death to be sepsis secondary to ulcerative proctitis.

ALLEGATIONS

A lawsuit was filed against the gastroenterologist, Hospitalist B, the colorectal surgeon, and the hospital. Allegations included:

- failure to detect and diagnose infection in a timely manner, including failure to take the patient's temperature during his June 8 and June 11 appointments with the gastroenterologist;
- failure to respond to worsening vital signs and WBC counts in a timely manner (Hospitalist B and colorectal surgeon);
- failure to examine the patient in a timely manner (colorectal surgeon); and
- failure to take the patient to surgery in a timely manner (colorectal surgeon).

LEGAL IMPLICATIONS

Consultant reviews of this case varied widely. A clinical, anatomic, and forensic pathology physician reviewed the case, including the autopsy. She concluded that the patient's cause of death was due to complications resulting from *Clostridium sordellii,* an extremely rare, aggressive bacteria. She stated that most of these infections are fatal, despite appropriate antibiotic treatment. The pathologist also stated there was no evidence of extensive necrosis in the autopsy photographs; instead, she believed this was a soft tissue infection due to pelvic sepsis.

Two gastroenterologists reviewed the case for the defense and were mostly supportive of the gastroenterologist. They stated that complications from a banding procedure are very rare but do include perianal abscess or peritoneal sepsis. They agreed that the gastroenterologist was correct in sending the patient to the ED on June 11 when symptoms became elevated.

However, one of the consultants felt the gastroenterologist could have initiated antibiotics or referred the patient to the ED on June 8, when the patient first returned to the gastroenterologist with pain and fever. Neither consultant believed earlier treatment would have necessarily averted

the outcome. Both were critical of the gastroenterologist for not taking the patient's temperature.

Two surgical consultants for TMLT agreed that the colorectal surgeon should not have waited 12 hours to see the patient after being informed of his deteriorating status. While the outcome may not have been avoidable due to the aggressive nature of the sepsis, they believed waiting that long was detrimental.

Additional consultants agreed that the care provided in the ED was appropriate and did not contribute to the patient's death.

A gastroenterologist reviewing this case for the plaintiff found that the defendant gastroenterologist violated the standard of care by failing to consider, recognize, and manage a complication after hemorrhoid banding, especially when the patient reported worsening symptoms and fever that did not resolve. The defendant was also criticized for failing to expedite diagnostic testing; imaging of the abdomen and pelvis; and aggressive treatment of the patient's condition.

Another consultant felt that the patient's sepsis would not have developed and progressed had IV antibiotic treatment started on June 8. Because the patient was healthy and young, earlier intervention may have prevented the patient's death.

A surgeon reviewing the case for the plaintiff stated that the colorectal surgeon fell below the standard of care for allowing 12 hours to pass before taking the patient to surgery when there was evidence of pelvic and systemic infection. He felt the patient's presentation required immediate surgical intervention.

Another consultant felt that by the time the patient came to the ED, his symptoms were suggestive of necrotizing infection and required both broad spectrum antibiotics and surgical debridement. This consultant felt that had debridement surgery been performed earlier, the patient's age and general good health would have helped him to survive.

DISPOSITION

The case was settled on behalf of the gastroenterologist, colorectal surgeon, Hospitalist B, and the hospital.

RISK MANAGEMENT CONSIDERATIONS

The plaintiffs alleged that certain actions by the defendants led to diagnostic errors. Two actions they point to are failing to take the patient's temperature during office visits and not taking the patient to surgery in a timely manner. Had the physicians documented the reasons behind their actions, this case may have been easier to defend.

It is also worth noting that the patient was young and healthy. His symptoms may not have initially presented as severely as they may have in an older patient. This may have led the gastroenterologist to be less alarmed about the patient's symptoms.

The Association of American Medical Colleges suggests the following four steps to help reduce diagnostic errors.[1]

1. Take a complete patient history and examination with a broad differential diagnosis in mind.
2. Recognize you may have a bias or a stereotype and put it aside.
3. Look for findings that do not align with the illness script of your provisional diagnosis.
4. Rule out life-threatening or worst-case scenario illnesses.

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FAILURE TO RESPOND TO TEST RESULTS

by Gracie Awalt, Marketing Associate, and Wayne Wenske, Senior Marketing Coordinator

PRESENTATION

On June 9, a 60-year-old woman came to her primary care physician's office with reports of abdominal pain and fullness, diarrhea, nausea, and vomiting for 10 days. She also reported watery and bloody stool.

The patient's medical history included coronary artery disease, dyslipidemia, hypertension, pre-diabetes, obstructive sleep apnea, attention deficit disorder, and postoperative right leg deep vein thrombosis. The patient's medications were atorvastatin, venlafaxine, losartan, mirtazapine, lisdexamfetamine, and aspirin.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. This study has been modified to protect the privacy of the physicians and the patient.

PHYSICIAN ACTION

A physician assistant (PA) saw the patient and documented that she had normal conjunctivae and white sclerae, a non-tender abdomen with normal tone and no masses present, no hepatomegaly, and a non-tender spleen or liver.

The patient's lab work showed the following abnormal liver test results: total bilirubin 12.9 (normal < 1.2), alkaline phosphatase 191 (normal 46-118), ALT 1779 (normal 5-50), and AST 1476 (normal 9-50). The patient's creatinine was normal at 0.98.

After discussing options, the primary care physician and PA decided to obtain a viral hepatitis panel and CT scan of the patient's abdomen without contrast. However, the CT scan was performed with contrast and revealed a "mildly distended gall bladder wall, no acute process, malignancy, obstruction noted." The hepatitis panel was negative for acute hepatitis A and B. The patient was diagnosed with gastroenteritis and prescribed ciprofloxacin for 10 days.

On June 16, the patient returned with worsening symptoms. She was seen again by the PA, who noted the patient said she felt like her body was "shutting down" and was in "obvious distress." The patient's conjunctivae were yellowish, her sclerae was white, and the PA noted jaundice and abdominal tenderness and protuberance. After noting elevated liver enzymes and biliary obstruction, the patient was referred to a local emergency department (ED) with a triage report to the on-call ED physician.

The ED physician performed an initial exam and noted icteric sclerae and right upper quadrant abdominal tenderness. Additional lab work showed worsening liver test results; the test showed 1.5 creatinine (normal 0.6-1.3) and hyponatremia with a serum sodium of 129 (normal 136-145).

An abdominal ultrasound showed heterogenous liver parenchyma and non-specific gallbladder wall thickening. The primary impression was acute new onset biliary obstruction. The ED physician requested a gastroenterology consult.

An intake hospitalist noted the possibility of non-viral hepatitis and ordered workup for autoimmune hepatitis; acute hepatitis B and hepatitis C; and acetaminophen/alcohol levels, after consulting with a gastroenterologist. Once the reports were returned, the hospitalist documented the absence of acetaminophen use, and her recommendation that if the patient's liver function worsened, a liver transplant center should be contacted.

On June 17, the patient had worsening coagulopathy, increased creatinine at 3.88, and encephalopathy. The gastroenterologist contacted a liver transplant center. While awaiting transfer, a work up was done including magnetic resonance cholangiopancreatography, hepatitis B and C PCR, and acetaminophen levels. Anti-nuclear and anti-mitochondrial antibodies returned negative.

On June 18 at 2:30 p.m., the patient was transferred to receive a liver transplant. The delay was due to bed availability issues. After she was admitted, the plan was to consult the liver transplant center and continue supportive care, but no documentation of the consultation exists.

On June 19, the patient died from cardiac arrest. According to the pathology report, the cause of death was sub-massive hepatic necrosis resulting in clinical hepatic failure.

ALLEGATIONS

A lawsuit was filed against the primary care physician and physician assistant. Allegations included:

- failure to quickly respond to abnormal lab values; and
- failure to refer the patient to a liver specialist.

LEGAL IMPLICATIONS

Consultants who reviewed the case for the defense were mostly negative in their assessment of the care provided to the patient. The consultants expressed that when the patient first came to the physician on June 9, the patient's high bilirubin values would have caused her to look jaundiced. After the abnormal lab results came in, the patient should have immediately been referred to an acute care hospital. Instead, a limited evaluation was conducted with a viral serology and CT scan, and the patient was sent home.

However, these consultants believed that even if the patient had been admitted to an acute care hospital on June 9, there was no guarantee that a liver transplant could be achieved quickly enough to save the patient. The treating gastroenterologist at the transplant center said the patient was very ill when she arrived; there were 13,000 people on the transplant list; and no way to quickly determine when the patient could be prioritized for surgery.

The gastroenterologist thought the week the patient spent at home eliminated the patient's chance of survival and agreed with the consultants that the patient would have benefitted from being admitted on June 9 to an acute care hospital for specialist care.

Consultants for the plaintiff addressed the possibility of drug toxicity. One consultant believed that discontinuing the patient's meds would have saved the patient, but another consultant stated the autopsy report did not provide the cause of liver failure, so drug toxicity could not be determined. This consultant believed a liver transplant was required due to the patient's advanced liver failure.

One consultant criticized the care provided by the hospital for not acting on test results quickly enough. The consultant believed that since the results showed worsening conditions, diagnosis was delayed; medication should have stopped, and the patient should have seen the gastroenterologist immediately instead of the following day.

A gastroenterologist plaintiff's consultant was critical of the care provided in this case. He believed a non-medical professional would have noticed jaundice in the patient with a bilirubin level of 12 on June 9. He felt the primary care physician and the PA both failed to comprehend the serious nature of the illness, and the lab results clearly indicated one of the following: autoimmune hepatitis, ischemic hepatitis, or acute or reactivation viral hepatitis.

The consultant believed all medications should have been discontinued (specifically atorvastatin); follow-up care could have improved; and the patient should have immediately been referred to a specialist. He thought the patient died of drug-induced liver failure, although he admitted that the autopsy report made his conclusion difficult to prove.

Consultants for the defense had mixed opinions. Those who were not supportive believed the patient's unusual presentation on June 9 should have prompted more immediate care. They also believed a liver transplant would have preserved the patient's life.

Those who supported the care thought the patient had an underlying condition, like fatty liver disease, that exacerbated the liver failure and the patient's death. One consultant felt the patient probably stopped taking atorvastatin or was not absorbing it due to illness, while another expressed that atorvastatin should have been discontinued, but does not believe this was the cause of death. These consultants thought the primary care physician and PA performed appropriate follow up and referral, and they were unsure if earlier hospitalization would have saved the patient.

DISPOSITION

The lawsuit was settled on behalf of the primary care physician and physician assistant.

RISK MANAGEMENT CONSIDERATIONS

In this case, the primary care physician and the PA both failed to either read or note the patient's abnormal test results on June 9. The reasoning behind the diagnosis of gastroenteritis was not documented in the patient record.

Poor documentation was a factor in this case. Keeping accurate, contemporaneous, complete, and legible patient records can be a physician's best defense in defending a claim. Had the physician or PA documented the reasoning for the diagnosis, their actions may have been easier to defend.

Also, when employing an advanced practice provider, such as a PA, it is important to have written protocols regarding responsibilities, scope of practice, and standing delegation orders. The patient's record did not reflect that the physician ever saw or evaluated the patient himself during these appointments. According to the documentation, the patient only saw the PA during her appointments on June 9 and June 16. Due to the patient's condition, abnormal test results, and long history of medical issues, it would have been prudent for the physician to examine the patient himself.

Physicians who delegate duties are vicariously liable for the activities performed by advanced practice providers or staff members. To reduce the risk of errors, explicitly state in your practice's policies and procedures when the physician needs to be contacted, such as when receiving abnormal test results.

In addition, protocols for handling test results should also be clearly stated in the policies and procedures. It is important that staff members have a clear understanding and knowledge of lab report standards and what constitutes an abnormal result. If the staff member does not understand a lab report or recognize a test value, he or she should be instructed in the policies and procedures to request clarification from the physician, lab, or hospital. Staff members should be required to regularly review the policies and procedures and acknowledge their understanding of the materials in writing.

There was also concern about the delays experienced by the patient after admission to the hospital. Physicians ordering diagnostic testing or treatments in a hospital are responsible for following up on the test results. The physician should provide clear orders about urgency (routine, stat, etc.) to ensure lab or test results are received and reviewed in a timely manner.

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