Physicians in Texas now have online access to the Texas Prescription Program (TPP). This program gives physicians the real-time ability to query the prescription database and find out which controlled substances their patients have been prescribed by other practitioners. Texas physicians can register and begin using the database by visiting https://www.texaspatx.com

“The importance of this new program cannot be overstated with respect to the protections it offers practitioners from Texas Medical Board complaints based upon the prescription of controlled substances to patients who are already receiving those drugs from other providers,” says Austin attorney Dan Ballard.

Access to TPP information is statutorily restricted, and is available to practitioners and pharmacists who are inquiring about their patients, and to various regulatory and law enforcement personnel.

Monitoring of controlled substance prescriptions is not new to Texas. The Texas Legislature created the TPP in 1982 to monitor Schedule II controlled substance prescriptions. The TPP program has since been expanded to including monitoring of Schedule III through Schedule V controlled substance prescriptions.

Federal authorities monitor the substances from manufacture through distribution to retail facilities; however, most pharmaceutical drug diversion occurs at the retail/consumer level. The TPP seeks to control misuse by following controlled substances to the point of ultimate use.

The need for a prescription monitoring program has increased dramatically in recent years due to what is being dubbed “generation Rx.” According to the Drug Enforcement Administration, nearly 1 in 10 high school seniors admits to abusing powerful prescription painkillers. A shocking 40 percent of

*continued on next page*
Background

Until recently, practitioners and pharmacists who wished to access TPP information had to complete a form on the DPS website (http://www.txdps.state.tx.us/InternetForms/Forms/TP-11.pdf) and send it via fax or mail. The DPS then verified the request, pulled the data, and returned the information via mail.

In 2009, legislation was passed to strengthen the TPP, including the creation of a secure website “to allow practitioners and other authorized users easy and quick access to the data in the prescription monitoring system so that:

- prescribers and pharmacies can make better decisions when prescribing and dispensing controlled substances; and
- regulatory agencies and law enforcement can identify licensees and individuals who are attempting to prescribe, dispense, or obtain controlled substances for illegal use.”

The improvements also included:

“(B) To make the data more useful and up to date, pharmacies should be required to submit prescription data to the program at least every seven days rather than the current requirement to submit no more than the 15th day after the end of the month in which the prescription was dispensed or up to 45-days after the prescription was dispensed so that the data is more up to date and useful to all who access the system.

(C) The Texas PMP should adopt those requirements in the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) that will allow the Texas PMP to share data with other states that operate a prescription monitoring program.

(D) The portion of the Texas Controlled Substances Act that deals with the PMP should be amended based on certain agreed upon provisions of the Prescription Monitoring Program Model Act developed by the Alliance of States with Prescription Monitoring Programs.

(E) The current requirement for a practitioner’s DPS and DEA controlled substance registration numbers to be on all prescriptions for controlled substances in Texas should be modified to require only the DEA controlled substance registration number.

(F) All licensing boards for health care professionals allowed to prescribe controlled substances should be allowed to access data collected by the PMP.”

Online access

Physicians will now have easier access to the monitoring program through the Prescription Access in Texas II (PAT II) website, https://www.texaspatx.com/Login.aspx. The TPP receives between 40 and 45 million records per year, and potentially more than 150,000 users will query the system. Due to the number of users and the volume of information, and to ensure security and software compliance, PAT II is being rolled out in stages. At the time of publication, the anticipated rollout schedule for the online PAT II program is as follows:

- June 30 — existing pilot users (doctors and pharmacists) and existing vetted law enforcement users.
- July 31 — medical board investigators and physicians.
- July 31 — nursing board investigators, new law enforcement, and mid-level practitioners.
- Aug. 15 — pharmacy board investigators and pharmacists.
- Aug. 31 — board investigators for podiatry, dental and veterinary; and podiatrists, dentists and veterinarians; out-of-state practitioners.

All registrants who would like to use PAT II will need to have a current medical license, a current DPS number, and a current DEA number. The PAT II site features tutorials and FAQs that explain how the program works.

Risk management considerations

By Dan Ballard, JD

As the PAT II web site is now available, physicians and practices should consider how to best manage their access. Once registered, providers may not share their log-in information with anyone. According to the PAT II web site, the Texas Health and Safety Code, Chapter 481 does not allow delegation of authority to access the PAT II web site. This means that practitioners may not delegate a staff member to research the data on their behalf.

Consequently, there is an additional prohibition on access to non-patient records. Physicians and practices may consider developing written policies that clarify:

- Prohibitions on sharing log-in information; access to the data is not delegable.
- Rules regarding access; persons accessing the database should access only their own patients. Accessing other information is prohibited and would constitute a HIPAA violation.

In the last several years, state licensing boards in Texas have conducted a number of investigations against providers based in part upon the provider prescribing controlled substances to a patient while that patient was obtaining similar prescriptions from other providers.

Providers should be aware that licensing boards will very likely begin expecting physicians to query the new database on any patient who is suspected of doctor shopping to obtain controlled substances. In the past, the defense against these kinds of allegations has been “But how would I know my patient is already getting drugs from another physician?” With the new database in place, this defense will be difficult to assert.
Many physicians have asked “Can’t I just trust what my patient tells me and take their word at face value?” The answer given by state licensing boards is “No, absolutely not.” Providers should take reasonable measures to detect fraud and abuse when it comes to prescribing controlled substances. Using this new database will be viewed as one of those reasonable measures.

One practice tip that should be considered — after you ask the patient if he or she is receiving controlled substances from another physician, tell the patient that you are going to query the prescription database to “assure that nothing gets missed.” Letting the patient know this in advance gives them the opportunity to tell the truth and will help you maintain good rapport with the patient.

If the patient expresses dissatisfaction at being “policed” by the physician, it may be helpful to offer the explanation that “This is just part of the new process we need to go through in prescribing controlled substances.”

While there is a recently enacted law that makes it a felony for patients to falsely deny that they have a prescription for a controlled substance issued for the same time period by another practitioner, there is currently no law requiring the physician to take the further step of turning that patient in to law enforcement authorities.

Currently, one prescribing practice receiving attention in Texas is writing for the “unholy trinity” of hydrocodone, lorazepam, and carisoprodol. If the patient is obtaining one or two components of this cocktail from another physician, and you then prescribe the third component, then you may unwittingly participate in a very undesirable prescribing practice. Querying the new database may prevent this from occurring and may protect you from licensing board scrutiny on this issue.

Practitioners should also be aware that they may access the database to inquire about their own prescribing activity regarding controlled substances (not just for a specific patient). One instance in which this could be useful is if a physician suspects that controlled substance prescriptions are being written or called in fraudulently under the physician’s name.

Using the new online database will help protect your patients, the public, and you from the many problems associated with prescribing controlled substances. Properly used, this new database can be a powerful tool in protecting everyone from the hazards of prescription drug diversion.

Source

Resources
PAT II Site
https://www.texaspatx.com

DEA Information on Prescription Monitoring Programs
http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#4

Texas DPS Information on Prescription Monitoring Program
http://www.txdps.state.tx.us/RegulatoryServices/narcotics/narccsr.htm

Texas Medical Board Pain Clinic Registration
http://www.tmb.state.tx.us/professionals/physicians/licensed/painManagementClinicRegistration.php

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TMLT announces 15% dividend

The Board of Governors has approved a 15% dividend for TMLT policyholders who renew in 2013. The dividend will save physicians approximately $20 million in 2013 premium.

This is the eighth time TMLT has declared a dividend, saving policyholders approximately $226 million since 2005. Policyholders will receive detailed information about the dividend before their policy renews.
Closing the loop: tracking test results and referrals

Objectives
At the conclusion of this educational activity, the physician should be able to:

1. describe several issues to consider when developing a test result management system;
2. define the four basic steps of a tracking system; and
3. discuss the issues involved with result management in an electronic medical record (EMR).

Course author
Michele Luckie is a senior risk management specialist with Texas Medical Liability Trust.

Disclosure
Michele Luckie has no commercial affiliations/interests to disclose related to this activity.

Target audience
This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement
Under AMA guidelines, physicians are required to complete and pass a test following a CME activity in order to earn CME credit. A passing score of 70% or better earns the physician 1 CME credit. Physicians will be allowed two attempts to pass the test.

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. TMLT designates this enduring material for a maximum of 1 AMA PRA Category 1 Credit ™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Pricing
Reporter CME content is available at no cost. The following fee will be assessed when CME credit is applied for.

Policyholders: free
Non-policyholders: $75

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

Instructions
You have two options to obtain CME credit from this activity.

Option 1 – online
Complete Reporter CME test and evaluation forms online. After reading the article, go to www.tmlt.org/reporterCME. Click on “Earn CME” under “Closing the loop” (2012 Volume 4). Follow the instructions to complete the test and evaluation forms. Your CME certificate will be emailed to you. Please allow up to 4 weeks for delivery of your certificate.

Option 2 – on paper
Please read the entire article and answer the CME test questions on the paper test forms on page 9. To receive credit, submit the completed test and evaluation forms to TMLT. All test questions must be completed. Please print your name and address clearly. Allow 4 to 6 weeks from receipt of test and evaluation form for delivery of the certificate.

Questions? Please call the TMLT Risk Management Department at 800-580-8658, ext. 5919.

Estimated time to complete activity
It should take approximately 1 hour to read this article and complete the questions.
A 59-year-old man came to the emergency department (ED) with complaints of respiratory problems. His medical history included chronic obstructive pulmonary disease, sleep apnea, chronic bronchitis, emphysema, obesity, and he reported that he had smoked cigarettes for more than 40 years. A chest x-ray revealed a “possible 1 cm pulmonary nodule superimposed over the anterior end of the left 5th rib,” which was not present on a chest x-ray taken seven months earlier. The radiologist recommended a left rib series, which was not done because the patient left the ED against medical advice. This report was faxed to the patient’s internal medicine physician, the defendant in this case.

**Physician action**

The defendant’s partner had his nurse call the patient to inform him of the abnormal chest x-ray and to have him return to the clinic in the near future. This call was not documented in the record, and the practice did not schedule an appointment for the patient. Two months later, the patient came to the ED, and was hospitalized after a serious episode of respiratory distress. A chest x-ray indicated “a nodular density over the left anterior 5th rib measuring 2.7 cm.” This x-ray report notes the defendant as the ordering physician and was in the patient’s office chart. There was no indication this report was reviewed, and the defendant testified that he did not see the report.

The patient came to the clinic the next month, and was treated for bronchitis by the defendant. Two months later, the patient was re-admitted to the hospital by the defendant’s partner. Differential diagnosis was pneumonia or empyema. A chest x-ray noted “a mass-like infiltrate” measuring 5 cm in diameter, and a repeat film two days later noted “the previously described nodule or mass was totally obscured by pleural effusion.” A CT scan of the chest was ordered.

The radiologist noted no discreet mass, and he suspected that the mass-like density adjacent to the heart border on earlier films represented some focal lung consolidation or loculated fluid. An empyema of the left chest was drained three days later. X-rays were done twice to confirm chest tube placement. At discharge, the radiologists noted, “moderate opacification remained in the left lung base” but was slightly improved since the previous study.

One month after his hospitalization, the defendant saw the patient for respiratory distress. The physician ordered a chest x-ray to rule out pneumonia. That report described an apparent mass-like infiltrate, again seen in the frontal view. According to the radiologist, the lack of change of that focal infiltrate raised the possibility of neoplasm. He recommended a CT scan. Seven days later, the CT scan revealed a “4.5 x 3 cm mixed density mass seen inferior laterally in the inferior lingular segment of the left upper lobe abutting the pleural surface.” The radiologist noted that malignant neoplasm along with some associated loculated effusion remained a definite consideration.

The patient was referred to a pulmonologist. A biopsy of the lung tissue indicated squamous cell carcinoma. This diagnosis was made approximately seven months after the patient’s first visit to the ED. At last report, he had received multiple courses of chemotherapy.
The process for good patient follow up begins with an educated physician. Effective tracking and follow up on test results and failure to take action to confirm or rule out a diagnosis of cancer was acknowledged as a significant weakness in the care given by the defendant physician.

Disposition
Due to concerns regarding liability and potential significant damages, this case was settled on behalf of the internal medicine physician.

Risk management considerations
- Routinely follow up with other physician consultants regarding test results. Consider the use of a follow-up tracking system to facilitate this process. Timely review and appropriately following up on all patient reports (lab, imaging, other diagnostic tests, or reports from consultants) is a prudent practice protocol. The ordering/referring physician has this responsibility and allowing reports to be filed in the patient's record without review is difficult to defend. Physicians are encouraged to write their initials, the date of review, and orders for follow up on the reports to verify their actions. Review non-urgent test findings with patients at their next scheduled appointment, and document this discussion in the medical record.

- To reduce risk, physicians may need to make an extra effort to document a patient's noncompliance or failure to follow up.

- Losing track of a patient who requires continuity of care, particularly in response to any abnormal report, places a physician at risk. Rather than advising the patient to "return to the clinic in the near future," give the patient a scheduled appointment. That patient is then on the schedule and if the appointment is not kept, he/she can be contacted and this action documented in the medical record.

Effective tracking and follow up
The process for good patient follow up begins with an educated patient. Physicians and their staff should explain the need for any test, referral, or follow-up to the patient and document the discussion in the medical record. Clear information and concise instructions will help patients participate in their care and understand the importance of their physician's recommendations.

Many methods exist to assist physicians in monitoring and reporting test results to patients. The following are some general issues that should be considered before implementing any particular system.

1. Develop a written policy that outlines what information will be tracked; specific actions to be taken; who is responsible for the implementation and oversight of the process; and a separate policy regarding confidentiality of results. All employees involved should have a clear understanding of their responsibilities.

2. If you are implementing an EMR, be willing to start from scratch. The current system may need to be completely redesigned in order to remain effective.

3. Keep it as simple as possible. The fewer steps involved and the least number of handoffs required, the less opportunity there will be to misroute information.

4. Use available technology when possible. Electronic medical records can be helpful by alerting when a test result is due or when a patient should return for follow-up care. Practices without EMRs can still use basic word-processing, spreadsheet, and database software to manage portions of their tracking system.

5. Clinically significant results need special attention. Laboratories and radiologic facilities conducting tests for the practice should be instructed to communicate significant results to the practice by phone instead of assuming a dictated report is received. The ideal tracking system will vary from practice to practice based on needs and resources. However, the four basic steps for managing patients' test results remain the same: tracking tests until the results have been received; notifying patients of the results; documenting that the notification occurred; and making sure that patients with abnormal results receive the recommended follow-up care. Error-reduction theories suggest that any good system should include the following elements.

1) Determine data to be tracked. When tests are ordered on a patient there is specific information that should be tracked from the beginning of the process to the end. This data might include:

- name of the ordering physician;
- patient name or identifier;
- type of test;
- date test is scheduled;
- lab or facility where the test is done;
- date results are received;
- results reviewed by; and patient notification date
2) Standardization. Adopting a standard process to carry out a complex task reduces dependence on memory and helps new employees understand the process and use it correctly. A problem in many practices is that there is no clearly defined, uniform system to manage test results. When each physician uses a different tracking method it becomes confusing to the staff and prevents effective communication of medical information.

3) Use of technology. Paper tracking systems can be effective but also labor-intensive. Most electronic medical record software packages include a test-tracking component. These components vary by vendor, but some allow physicians to order all their tests via the EMR and receive the results in electronic review queues. Practices using EMRs should request training on how to make efficient use of this feature. Practices not currently using an EMR can develop electronic spreadsheets and reminders in Excel and Microsoft Word.

4) Involve your patients. Notifying every patient of every result may be costly and time consuming, but notifying only those with abnormal results can prove problematic. Test results can be sent to the wrong office, misplaced once received, or accidentally filed without physician review. Adopting a “no news is good news” policy regarding test result notification does not protect patients from harm caused by failure to follow up. Patients should be encouraged to call the practice if they have not received their test results within a set time frame. Keep in mind that while it is beneficial to get patients involved in the follow-up process, doing so does not relieve physicians of their duty to follow up.

5) Document, document, document. Whatever system is implemented to track test results, it is very important that every step in the process is documented. If the patient refuses to have the recommended testing, note this in the patient’s chart along with his or her reasoning. Physicians should explain the consequences of not undergoing the ordered tests and document the patient’s understanding.

Failure to report test results

The following case study involves the death of a patient and includes criticism from the plaintiffs about the lack of a process to ensure patients receive test results.

Presentation

A 42-year-old man came to the emergency department (ED) with complaints of chest pain. A full work-up in the ED did not reveal any cardiac problems. The patient was told to follow up with his primary care physician. The patient’s internal medicine physician referred him to a cardiologist because the patient had a significant history of cardiac disease (his father and uncle both died from myocardial infarctions).

Physician action

The patient went to the cardiologist a few days after the ED visit. A stress test and myocardial perfusion test were ordered. The stress test was performed that day and the myocardial perfusion test was performed two days later. The consult, stress test report, and perfusion report involved three different specialists in this cardiology group practice.

The patient’s wife called for the test results on Tuesday, three days later. She was advised that they were unavailable and told to call again Friday morning. Calling again on Friday, the patient’s wife told the receptionist that her husband had continued chest complaints. She was told a nurse would call her back. Hearing nothing, the patient’s wife called again at noon and was told the results were unavailable. She was told a nurse would call her that afternoon.

The patient came home that afternoon at 5 p.m. with increased chest pain. He reported feeling ill. The patient’s wife called the cardiologist’s office and reached the answering service. At 5:08 p.m., a nurse called from the practice. The nurse told the patient’s wife that she would try to determine the results of the studies, but said in general if they were “positive,” the cardiologist would have had the patient come in for further evaluation. The nurse advised that the patient should continue to take his nitroglycerin if he was having chest pains. If the patient had no relief from the nitroglycerin, he should go immediately to the ED. The patient’s wife disputes that the nurse told them to go to the ED if the chest pain continued.

On Saturday morning, the patient went to his son’s sporting event, but felt ill and returned home. He contacted his internal medicine physician. He told her the test results were not yet available, and that he was continuing to have back and chest pain. The patient also told his physician that the nurse told him that if the results were positive, he would already have been called. After hearing the patient’s complaints, the internal medicine physician felt he was suffering from GERD or possible gallbladder or appendix irritation. She called in a prescription for stomach medication and said she would personally follow up on the tests Monday morning.

That afternoon, the patient’s son found the patient at home in full cardiac arrest. EMS was called and paramedics attempted to resuscitate the patient, but he died on the way to the hospital. An autopsy found that the patient had a 100% occlusion in one vessel and 80% stenosis in the LAD vessel. The cause of death was listed as arteriosclerotic cardiovascular disease; hypertension.

The results of the tests performed by the cardiologist were not transcribed until two days after the patient’s death (11 days after the stress test and 9 days after the myocardial perfusion test). Both tests were read as “normal.”

Allegations

A lawsuit was filed against the cardiologist and his group. The plaintiffs alleged negligence in evaluating the stress and myocardial perfusion tests; delay in reporting test results to the patient; and failure to immediately refer the patient to the ED. The plaintiffs were also critical of the practice for failing to have...
procedures that would have assured quicker reporting of test results. The allegations also included wrongful death.

**Legal implications**

Three board certified cardiologists reviewed this case for the defense. They believed the stress test was read appropriately, especially since the patient completed the entire treadmill test without chest pain or significant EKG changes. A nuclear imaging expert also reviewed the images from the myocardial perfusion test. Initially, he read them as “normal.” However, retrospectively, there was some evidence of decreased perfusion in the area of the heart where the occlusions were found on autopsy. The expert said he would have to testify that retrospectively, the study was “abnormal.”

All the experts who reviewed this case believed there was some delay in interpreting the nuclear imaging portion of the stress test. Additionally, there was some criticism of the nurse’s inappropriate advice to the patient regarding test results as she informed his spouse, if they were positive, the patient would have been contacted.

Finally, all the experts agreed that if the patient’s condition had been diagnosed and treated appropriately he would have survived and led a fairly normal life. His life expectancy probably would have been reduced by 10 years and his work life expectancy would have been reduced by 2 to 3 years.

**Disposition**

This case was settled on behalf of the cardiologist and the professional association.

**Risk management considerations**

All physicians need to develop and implement strict protocols for timely dictation and transcription of findings, patient follow up, and recommendations pursuant to their patient encounters. With such a significant family history, would a cardiologist consider this patient to be high risk? Does the index of concern and suspicion increase? Do pending tests for a patient like this justify timely interpretation, transcription, and further action?

Another issue in this claim involved the difference in recall between the nurse and the patient’s spouse. Clear guidelines regarding staff responsibilities when talking to patients or family members in person or by phone/e-mail are relevant for all practices. Each of these encounters should be documented in the medical record as part of the chronological diary reflecting patient care. Thus, one can avoid a debate about whose memory is correct.

**EMR-based result management**

As we have discussed, test result management is an essential part of quality clinical care and a vital part of ambulatory medicine workflow. While electronic health records show promise for improving the reliability of managing test results, there are complexities involved that still leave room for improvement.

Thomas Yackel and Peter Embi conducted a study at an academic hospital with affiliated clinics that produced 600,000 ambulatory visits a year. The organization’s 2166 physicians had implemented an EMR with results-management capabilities. At the time of the study, about 54,000 test results per month were being forwarded to their electronic in-boxes. Over a two-year period, hundreds of thousands of results were electronically communicated. A vast majority were correctly routed with the delivery, receipt, and follow-up actions recorded and electronically auditable.

The advantages of instantaneous delivery and comprehensive tracking are significant. However, some unexpected errors occurred while using an electronic result communication system. The reasons for the errors were diverse and included problems with routing logic, provider records, system settings, and maintenance. A lack of understanding of the complex interplay between systems, lack of adequate testing, failure to follow procedures, and human error contributed to the mistakes. In the instances where errors occurred, there was inadequate redundancy built into the process to tolerate faults, and manual testing had a limited ability to find configuration and data integrity issues before they occurred.

Most of the errors were discovered by end users and reported after the error had occurred multiple times. This suggests that the sensitivity to monitor for errors in current electronic systems is low and mechanisms to identify such issues are lacking.

The study recommended the following steps to improve the safety of electronic result management.

1. “Develop fault-tolerant systems that automatically report delivery failures. Safe patient care depends on timely and accurate delivery of results to providers. This is especially true in the ambulatory setting where test ordering and resulting are often asynchronous occurrences separated by weeks or months. A “best efforts” approach to reporting results does not meet the current need. Result management systems should be designed to tolerate multiple faults and still correctly deliver results. In the case where the system cannot deliver, results should go to an error queue — much like an interface error queue — to be analyzed and delivered manually. In order to design fault-tolerant systems that anticipate failure points, we must have access to data on past events. Systematic reporting of actual errors should be encouraged for users and implementers of results management systems.

2. Use robust testing to find rare errors that occur both within and between systems. Current standards for testing result management systems do not exist. Testing for fault tolerance requires specifically designed testing scripts that anticipate the failure points and seek to verify system adequacy. As types of errors are categorized and recorded, specific testing designed to exploit those problems should be built.

*continued on page 14*
CME test questions

Instructions: Using black ink, read each question, select the answer, and then clearly mark your selection. Under newly revised AMA guidelines, physicians are now required to complete and pass a test following a CME activity, in order to earn CME credit. A passing score of 70% or better earns the physician 1 CME credit. Physicians will be allowed two attempts to pass the test.

Please fax the completed test and evaluation forms to the Risk Management Department, attention Stephanie Downing 512-425-5996. You can also mail the test and evaluation forms to the TMLT Risk Management Department, attention Stephanie Downing, P.O. Box 160140, Austin, Texas 78716-0140. A certificate of completion will be mailed to the address you provide on the CME evaluation form.

Effective January 2012, new pricing will take effect for Reporter CME courses.
Policyholder: to remain free Non-policyholder: $75

Reporter CME content will continue to be available at no cost. This fee is assessed when CME credit is applied for.

This form can also be completed online at www.tmit.org/reportercme

1. What percentage of physicians are satisfied with their test result management system?
   ○ a. more than one-half
   ○ b. less than one-half
   ○ c. more than one-third
   ○ d. less than one-third

2. Financial loss is one of the adverse clinical consequences of missing test results.
   ○ a. true
   ○ b. false

3. Which of the following is not a component of a good tracking system?
   ○ a. use of technology as much as possible
   ○ b. documenting every step in the process in the patient's medical record
   ○ c. involving the patient as little as possible in the process
   ○ d. adopting a standard protocol for the practice

4. All electronic medical record (EMR) systems provide fail-safe capabilities to track test results.
   ○ a. true
   ○ b. false

5. In Yackel's study, the majority of the errors reported resulted from implementation decisions.
   ○ a. true
   ○ b. false

Statement of completion

I attest to having spent ______________ hours in this CME activity.

Physician signature __________________________ Date ______________

Volume 4 2012
CME evaluation form
Please complete the following regarding the article, "Closing the loop: tracking test results and referrals."
Please fax the completed evaluation with the CME test questions.

1. The objectives for this CME were met.  ○ Yes  ○ No

2. The material will be useful in my practice.  ○ Yes  ○ No

3. Did you perceive any evidence of bias for or against any commercial products? If yes, please explain.
   ○ Yes  ○ No

4. How long did it take you to complete this learning activity?
   ○ .5 hr  ○ .75 hr  ○ 1 hr  ○ 1.25 hrs  ○ 1.5 hrs

5. On a scale of 1 to 5, with 5 being the highest, how do you rank the effectiveness of this activity as it pertains to your practice?
   ○ 1  ○ 2  ○ 3  ○ 4  ○ 5

6. What will you do differently in your medical practice after reading this article?

7. Suggestions for course improvement are:

8. Suggestions for future topics include:

Contact information

Name

Address

Phone

TMLT policyholder?  ○ Yes  ○ No (If no, please provide payment information)

Pay by check made payable to TMLT. Please complete the above contact information and mail to:
TMLT, Attn: Stephanie Downing, PO Box 160140, Austin, TX 78716

Pay by credit card. Please complete the contact information above and credit card detail below.
We accept Visa, MasterCard and American Express

Name of Cardholder

Credit Card #

Expiration Date  CVV#
(3 digits located on the back of Visa or MasterCard and 4 digits located on the front of American Express)

Email address (to have your certificate emailed). Please print legibly. We cannot email your certificate if we cannot read your email address. To ensure your certificate is received in your email inbox, please add TMLT to your address book or safe sender list. Otherwise, your certificate may be flagged by your e-mail provider as unsolicited mail or "spam."

Volume 4 2012
TMLT’s fall risk management seminar “HIE, HB 300, HIPAA, HITECH and Cyber Liability — What does all this mean to me?” will be offered in five Texas cities in October and November.

The seminar will discuss how health information exchanges (HIEs) will affect physician practice and liability; review the changing privacy and security requirements under HIPAA, HITECH, and House Bill 300; and help physicians identify areas of cyber liability exposure.

**CME and discount information**

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide CME for physicians. TMLT designates this educational activity for a maximum of 2.5 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

TMLT has designated this course for 1 hour of education in medical ethics and/or professional responsibility.

TMLT policyholders who complete this program will earn a 3 percent discount (maximum $1,000) that will be applied to their next eligible policy period.

**About the Speakers**

The seminar is presented by attorneys Pegi S. Block and Debra Sales Elmore.

**Pegi S Block, JD** is a partner with Block & Elmore, PLLC, in Houston. Ms. Block has been representing physicians and clinics for the past 20 years in numerous medical malpractice and drug and device lawsuits. She also represents physicians in medical board proceedings and privacy law matters. A graduate of the University of Houston Law Center, Ms. Block is a certified mediator and past president of the Northeast Harris County Bar Association. She is also a member of the Health Law Sections of the State Bar of Texas and Houston Bar Association, and a member of the Health Care Compliance Association.

**Debra Sales Elmore, RPh, JD** is a partner with Block & Elmore, PLLC in Houston. Ms. Elmore graduated from The University of Texas with a degree in pharmacy and earned her law degree from the South Texas School of Law. Her primary practice areas are medical malpractice defense, drug and device litigation, and health care law. She is a member of the Health Law sections of the American Bar Association, Texas Bar Association, and Houston Bar Association, and a member of the Health Care Compliance Association.

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**CME and discount information**

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide CME for physicians. TMLT designates this educational activity for a maximum of 2.5 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

TMLT has designated this course for 1 hour of education in medical ethics and/or professional responsibility.

TMLT policyholders who complete this program will earn a 3 percent discount (maximum $1,000) that will be applied to their next eligible policy period.

**About the Speakers**

The seminar is presented by attorneys Pegi S. Block and Debra Sales Elmore.

**Pegi S Block, JD** is a partner with Block & Elmore, PLLC, in Houston. Ms. Block has been representing physicians and clinics for the past 20 years in numerous medical malpractice and drug and device lawsuits. She also represents physicians in medical board proceedings and privacy law matters. A graduate of the University of Houston Law Center, Ms. Block is a certified mediator and past president of the Northeast Harris County Bar Association. She is also a member of the Health Law Sections of the State Bar of Texas and Houston Bar Association, and a member of the Health Care Compliance Association.

**Debra Sales Elmore, RPh, JD** is a partner with Block & Elmore, PLLC in Houston. Ms. Elmore graduated from The University of Texas with a degree in pharmacy and earned her law degree from the South Texas School of Law. Her primary practice areas are medical malpractice defense, drug and device litigation, and health care law. She is a member of the Health Law sections of the American Bar Association, Texas Bar Association, and Houston Bar Association, and a member of the Health Care Compliance Association.

TMLT's fall risk management seminar “HIE, HB 300, HIPAA, HITECH and Cyber Liability — What does all this mean to me?” will be offered in five Texas cities in October and November.

The seminar will discuss how health information exchanges (HIEs) will affect physician practice and liability; review the changing privacy and security requirements under HIPAA, HITECH, and House Bill 300; and help physicians identify areas of cyber liability exposure.

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Failure to timely treat internal bleeding

by Louise Walling and Laura Hale Brockway, ELS

Presentation
A 25-year-old woman came to her ob-gyn for prenatal care. This was the patient’s first pregnancy. She informed her physician early in her pregnancy that she was a Jehovah’s Witness, and that she would not accept a transfusion of whole blood or red blood cells under any circumstance.

The patient’s pregnancy progressed without complication. At 6:50 p.m. on August 26, the patient came to the hospital for induction of labor.

Physician action
The patient’s labor failed to progress, so the ob-gyn performed a cesarean delivery. A 10-pound girl was delivered at 10:49 p.m. Her APGAR scores were 9/9. According to the medical records, the patient lost approximately 600 cc of blood during the delivery.

The patient was moved to the PACU at 11:25 p.m. Based on the medical records, nursing staff only monitored the patient’s vital signs from 11:25 p.m. to 12:25 a.m. There is no documentation of the patient’s blood pressure from 12:25 a.m. until she was transferred to the floor at 1:20 a.m. At that time, her blood pressure was found to be 98/52 mm Hg and her pulse was elevated at 100 bpm.

The patient’s blood pressure was recorded as 75/50 mm Hg at 2:05 and 2:10 a.m. The ob-gyn was called at 2:20 a.m., when the nurse noted that the patient’s blood pressure had dropped to 80/48 mm Hg and her pulse dropped to 86 bpm.

The ob-gyn ordered a stat CBC that revealed a hemoglobin level of 8.7. The patient was transferred back to labor and delivery for observation. The ob-gyn arrived at the hospital at 2:52 a.m. He noted the patient’s blood pressure was 58/38 and that she was experiencing tachycardia. The patient was given ephedrine and neosynephrine at 2:55 a.m. and 2:59 a.m. At 3:06 a.m., the ob-gyn was at the patient’s bedside, planning for an exploratory laparotomy.

The ob-gyn — along with other members of the hospital staff — had previously spent time trying to persuade the patient, her husband, and their pastor (who came to the hospital after being called by the patient’s husband) that a blood transfusion was needed. It was explained to the patient (while she was still fully cognizant) and the others that she was too unstable for surgery and a blood transfusion was needed to stabilize her. The patient and the others continued to refuse a transfusion. The discussions with the family about the receipt of blood were thoroughly documented.

The ob-gyn called in a general surgeon to assist, and the patient was taken to the operating room at 4:05 a.m. Surgery started at 4:23 a.m. The ob-gyn documented approximately four liters of hemoperitoneum bleeding in the left lower uterine segment. The segment was sutured and no active bleeding was noted. The procedure was completed at 5:03 a.m., and the patient was transferred to the ICU.

The patient continued having difficulty maintaining her blood pressure despite the use of volume expanders. Efforts were once again made to convince the patient’s husband and their pastor that a blood transfusion was needed or the patient would die. They continued to refuse the transfusion. The patient coded and despite 55 minutes of CPR, she died at 6:22 a.m.

An autopsy was performed and the cause of death was listed as “exsanguination status post primary C-section.”

Allegations
A lawsuit was filed against the ob-gyn and the hospital. The allegations included failure to promptly diagnose and treat the patient’s internal bleeding.

Legal implications
The plaintiff’s expert testified that the ob-gyn should have considered taking the patient to surgery immediately upon arrival at the hospital. He stated that the ob-gyn wasted too much time assessing the patient, calling for general surgery assistance, and trying to convince the patient to accept the transfusion. It was argued that the ob-gyn knew the patient was bleeding and the earlier the bleeding was stopped, the better chance for survival.

As to the hospital, it was alleged that the nurses failed to timely communicate the patient’s deteriorating vital signs to the ob-gyn.

The defense argued that bleeding following a cesarean delivery is a known and accepted complication, and it was reasonable for the ob-gyn to examine the patient and assess her condition before taking her to surgery. It was appropriate for the ob-gyn to try and stabilize the patient before surgery with the administration of fluids and drugs. Two hours passed from the time the ob-gyn was called to the beginning of the surgery. The defense ob-gyn expert indicated this was a reasonable time frame given all the factors involved.

The ob-gyn testified that the patient was too unstable for surgery and a blood transfusion was the only treatment that would save

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Wrong procedure performed

by Louise Walling and Laura Hale Brockway, ELS

Presentation and physician action

A 40-year-old woman began treatment at a family physician’s cosmetic clinic. The patient was seen multiple times for eyebrow treatments and liposuction. On April 9, the patient underwent a bilateral mastopexy performed by the family physician under local anesthesia. The operation time was from 11:10 a.m. to 3 p.m.

The patient was seen for follow up over the next week, and it was noted that her sutures were intact. On April 22, she reported discharge from one of the wounds. The patient denied pain, redness, and fever. The family physician noted a “very small amount of normal looking discharge on the patient’s pad, most likely after the scab was accidentally pulled.” It was noted that the sutures were intact and there was no redness, warmth, or tenderness. The patient was told there was no evidence of wound infection.

The patient returned on May 12 and reported that the sutures were oozing pus. She did not have fever. The family physician placed steri-strips around the area.

Over the next two months, the patient either called or was seen by the family physician for complaints that the incisions were bleeding or that tissue was coming off. The patient was told to apply silver sulfadiazene cream.

On August 5, the patient returned to the office and reported that she felt the incisions were getting worse. The family physician re-sutured the wounds. There was no sign of infection and the patient was given silver sulfadiazene cream. Returning for a suture check on August 11, the patient was told the sutures would probably “give” before the incision healed. The right sutures appeared to be “giving,” while the left sutures appeared to be holding well.

On August 28, the patient reported she had been in pain for two days, mainly on the left side. The incision on the left breast seemed to be healing nicely and two sutures were removed. The incision on the right breast appeared to be getting better, but was still “open.” The patient was told it would take a long time to heal. She was seen five times in September for dressing changes.

The patient went to a plastic surgeon on October 1. She documented a breakdown of the mastopexy incisions with stretching of the areola causing overly large areola and surrounding scarring. The plastic surgeon recommended removal of the sutures to allow the wounds to heal. She did not recommend liposuction of the breasts because of the open wounds and the potential for spreading bacteria to the remainder of the breast tissue. She indicated that the patient might need surgery to address the “plate size” areola.

The patient advised the family physician that she had seen a plastic surgeon and was advised to remove the sutures due to the risk of infection. The family physician told the patient that liposuction was an option to remove the volume out of each breast and then stage the closure part of the procedure. She advised the patient to get a third opinion.

On October 5, the patient saw another plastic surgeon. His assessment was status post bilateral periareolar surgery with unknown technique and poor outcomes. He noted the patient had multiple visible sutures with excess length clearly exposed in the wound. The plastic surgeon recommended removal of the sutures and discussed possible options for corrective surgery. These included debridement and closure along with subsequent breast reduction/mastopexy.

Two days later, the patient underwent debridement of open wounds on both breasts. The plastic surgeon indicated that the patient had widely open wounds on the medial aspect of each breast with visible absorbable sutures within the tissues. A culture was taken and she had light growth of *staph aureus* on the right side. The patient continues to be treated by a plastic surgeon and will need additional surgeries to repair the scarring.

Allegations

A lawsuit was filed against the family physician, alleging the bilateral mastopexy was the wrong procedure due to the size and volume of the patient’s breasts. The damages involved bilateral breast disfigurement from scarring and shape distortion.

Legal implications

The plaintiff’s expert was critical of the family physician’s choice of procedure. The bilateral mastopexy required adding 350 to 500 cc of anesthetic solution to the breasts, which further enlarged the volume and size of the breasts so that any ring excision would be difficult to close without adding to the tension and incision lines. The plaintiffs were also critical that the family physician did not produce an operative report and it took her an excessive amount of time (four hours) to perform a relatively minor procedure. This was the first time the family physician had performed this surgery and the plaintiffs alleged she should have referred the patient to a more experienced surgeon.

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Physicians who reviewed this case for the defense did not support the family physician’s actions. The procedure she performed had a significant likelihood of failure because of the size of the patient’s breasts. The patient should have undergone breast reduction surgery instead of mastopexy. Additionally, reviewers were critical of the anesthesia used, the lack of an operative report, and for failing to refer the patient to a plastic surgeon for wound care.

**Risk management considerations**

Selecting the right procedure for the right patient in an elective surgery is the first way to achieve optimal results and to mitigate a physician’s risk.

Lack of an operative report hindered the physician’s defense. Timely, thorough documentation will strengthen a physician’s defense.

The post-procedure wound care complications continued for weeks and then months. It is important to know when to refer to a wound care specialist or to another specialist for a second opinion and/or treatment. Referring to a specialist may promote the process of wound healing and diminish further complications.

**Disposition**

This case was settled on behalf of the family physician.

Louise Walling can be reached at louise-walling@tmlt.org. Laura Hale Brockway can be reached at laura-brockway@tmlt.org.

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3. Implement tracking mechanisms for critical tests, such as cancer screening and diagnostics. Proactive tracking for critical tests has often been a component of paper-based routing systems. For example, a paper log of Papanicolaou tests sent out by a clinical practice, with a regular check on results received, serves to verify proper result management. Electronic systems should offer similar capabilities that allow local practices to monitor those tests they deem crucial. Automatic and manual ticklers for less crucial tests would also help identify errors more quickly and prevent patient harm.

4. Deliver results directly to patients. There is no one who has a stake greater in the proper management of test results than the patient. With the advent of personal health records, direct notification to patients is feasible and provides an additional layer of safety in the result delivery system. Established practice, medical culture, and some laws prevent or limit such disclosures; however these practices are not in sync with patient-directed healthcare and reduce overall system safety.”

Most of the errors mentioned above are not attributable to a particular EMR or even Health IT in general. The majority of the errors resulted from local configuration and implementation decisions rather than the technologies themselves. The main lesson derived from this information is that care must be taken by those responsible for implementing health information systems to remain aware of and monitor for unexpected consequences.

There are many advantages to using an EMR to manage test results. Electronic systems can improve the speed of delivery and make results available anywhere a physician can access their EMR. Patients can have direct access to their test results via portals and follow-up actions can be automatically captured. However, electronic systems do not eliminate result delivery failures and can in fact create a new set of errors. EMR and other health information designers along with those responsible for the implementation and management of EMR systems need to be aware of the types of errors described above and take them into account as they move forward.

**Conclusion**

Test results are being managed within a complex health care system and physicians cannot control every variable in the process. Ultimately, an informed and involved patient, a well-designed tracking system, and physicians and staff who feel safe to discuss system failures will render safer patient care and improve outcomes. ¹

**Sources**


Michele Luckie can be reached at michele-luckie@tmlt.org.
August 2012

To all TMLT policyholders
Re: TMLT Trustee nominations and elections for the 2013 board year

As a TMLT policyholder, you have the right to nominate candidates and vote in the annual election for Successor TMLT Trustees. This is your chance to exercise your voice in governance of the Trust, and I strongly encourage you to participate.

Nine trustees govern TMLT. The terms of the Trustees are three years, but no Trustee can serve more than nine consecutive years. The terms are staggered and three places are up for election each year. The three positions up for election in 2012 for the 2013 Board year are Places 7, 8, and 9. The current Trustees holding Place 8 and Place 9 are incumbents eligible for re-election.

As required by the Trust Instrument and Bylaws, the Trustees have nominated three physicians for these positions. These have been submitted to and approved by the TMA House of Delegates. They are:

1. Place 7 — Ray Callas, MD, Anesthesiologist from Beaumont, Texas
2. Place 8 — Arthur Evans, MD, Neurosurgeon from Lindale, Texas
3. Place 9 — Donald Butts, MD, Colon and Rectal Surgeon from Houston, Texas

The Trust Instrument and Bylaws further provide that any eligible policyholder may be nominated as follows:

• Any nomination for the Board by an eligible policyholder must be in writing and supported in writing with the signatures of at least four other eligible policyholders. All nominees must be qualified to serve under the Trust Instrument and Bylaws.

• Nominations MUST be made for a specific Place and designated as a nomination for Places 7, 8, or 9.

• Nominations must be submitted to the Secretary of the Board of Trustees, TMLT, P. O. Box 160140, Austin, Texas 78716-0140. They must be received by TMLT in Austin, Texas, no later than September 20, 2012.

After all nominees have been determined, ballots and candidate bios will be mailed to eligible policyholders. A deadline for return will be indicated on the ballots. A candidate for any Place up for election must receive a majority of the vote of those participating in the election for such Place.

I urge each of you to participate in this year’s Board election. Let your voice be heard.

Sincerely,

Charles R. Ott, Jr.
President and Chief Executive Officer
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her life. When it became clear that consent for transfusion would not be forthcoming, the ob-gyn proceeded with the surgery.

**Risk management considerations**

When accepting a patient who expresses a refusal to accept blood products, physicians may benefit from having a documented discussion that includes the benefits of a blood transfusion in certain circumstances and possible hazards of refusing blood products as a treatment. If the patient continues to verbalize refusal, this too should be documented in the clinical record. The discussion could be embodied in a written informed refusal form that is witnessed by someone other than the physician and signed by all parties. This form could then be placed in the medical record.

**Disposition**

This case was taken to trial and the jury returned a verdict in favor of the ob-gyn. The case against the hospital was settled before trial.

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