



Prevention of Medical Errors and Patient Safety

Background:

The Duval County Medical Society (DCMS) is proud to provide its members with free continuing medical education (CME) opportunities in subject areas mandated and suggested by the State of Florida Board of Medicine to obtain and retain medical licensure. The DCMS would like to thank the St. Vincent's Healthcare Committee on CME for reviewing and accrediting this activity in compliance with the Accreditation Council on Continuing Medical Education (ACCME).

This issue of *Northeast Florida Medicine* includes an article, "Prevention of Medical Errors and Patient Safety" authored by Linda Edwards, MD, Francys Calle Martin, Esq., and Kari Aasheim, JD, which has been approved for 2 AMA PRA Category 1 credits.TM For a full description of CME requirements for Florida physicians, please visit www.dcmsonline.org.

Faculty/Credentials:

Linda Edwards, MD is the Senior Associate Dean for Educational Affairs, University of Florida College of Medicine, Jacksonville, FL. Francys Calle Martin, Esq. is the Senior Loss Prevention Attorney and Vice President of Florida Academic Healthcare Patient Safety Organization. Kari Aasheim, JD is the Deputy Administrator for the University of Florida J. Hillis Miller Health Center Self Insurance Program.

Objectives:

1. Define medical error and discuss the multiple factors propelling medical error prevention and patient safety efforts.
2. Review The Joint Commission and state agency standards, regulations relating to sentinel and adverse events, and the process of root cause analysis.
3. Review the Board of Medicine's most misdiagnosed conditions and provide examples of each and the consequences for both the patient and the healthcare provider.

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Date Credit Expires: March 1, 2019

Estimated Completion Time: 2 hours

How to Earn this CME Credit:

1. Read the "Prevention of Medical Errors and Patient Safety" article.
2. Complete the posttest. Scan and email your test to Kristy Williford at kristy@dcmsonline.org.
3. You can also go to www.dcmsonline.org/NEFMCME to read the article and take the CME test online.
4. All non-members must submit payment for their CME before their test can be graded.

CME Credit Eligibility:

A minimum passing grade of 70% must be achieved. Only one re-take opportunity will be granted. If you take your test online, a certificate of credit/completion will be automatically downloaded to your DCMS member profile. If you submit your test by mail, a certificate of credit/completion will be emailed within four weeks of submission. If you have any questions, please contact Kristy Williford at 904.355.6561 or kristy@dcmsonline.org.

Faculty Disclosure:

Linda Edwards, MD, Francys Calle Martin, Esq., and Kari Aasheim, JD report no significant relations to disclose, financial or otherwise with any commercial supporter or product manufacturer associated with this activity.

Disclosure of Conflicts of Interest:

St. Vincent's Healthcare (SVHC) requires speakers, faculty, CME Committee and other individuals who are in a position to control the content of this education activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly evaluated by SVHC for fair balance, scientific objectivity of studies mentioned in the presentation and educational materials used as basis for content, and appropriateness of patient care recommendations.

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St. Vincent's Healthcare designates this educational activity for a maximum of 2 AMA PRA Category 1 credits.TM

Physicians should only claim credit commensurate with the extent of their participation in the activity.

Prevention of Medical Errors and Patient Safety

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Abstract: *Following a number of studies on the high incidence of medical errors and increasing efforts to improve patient safety, the prevention and reduction of medical errors has become a priority for federal and state regulatory agencies and healthcare providers across the nation. It is important for physicians to understand how federal, state, and independent regulatory agencies have shaped the patient safety movement and have provided an organized structure for identifying the causes of medical errors and the manner in which they can best be prevented. Based on national reports of patient safety events and malpractice data, federal, state, and independent regulatory agencies have established patient safety goals for the prevention of medical errors.*

Introduction

The Health and Medicine Division, formerly known as the Institute of Medicine (IOM), is a division of the National Academies of Sciences, Engineering, and Medicine focused on improving health and healthcare in our nation and throughout the world. This team issues recommendations and reports to foster discussion and critical thinking, such as the oft-cited 1999 report *To Err Is Human*, in which a medical error is defined as, “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”¹ The IOM estimates as many as 98,000 people die every year as a result of preventable medical errors. A recently released study published by Johns Hopkins University researchers in the *British Medical Journal* claims that 251,000 lives are lost every year as a result of medical errors. If correct, this statistic places medical error third among leading causes of death in the United States, behind heart disease and cancer.² Medical error prevention is, therefore, an urgent public health concern requiring close examination of contributing factors and prompt identification of appropriate strategies to reduce risks to patients.

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Error Reduction and Prevention

To control increasing government costs resulting from pervasive medical error in the United States, Congress passed the Deficit Reduction Act (DRA) in 2006, which required the Centers for Medicare and Medicaid Services (CMS) to compile a list of conditions that, in part, result in high costs and can reasonably be prevented. CMS developed a list of Hospital Acquired Conditions (HACs) and implemented policies denying or limiting payment by CMS for treatment made necessary by HACs. The current list of HACs is lengthy, but some notable examples include falls, catheter-associated urinary tract infections, unplanned retained foreign objects after surgery, and significant pressure ulcers. While these HACs may not be the result of an error or negligent care, the reimbursement consequences have raised the stakes significantly in medical error prevention.

At the state level, the Florida Board of Medicine has prescribed a range of disciplinary actions for a variety of medical errors, such as wrong site surgery, unplanned retained foreign objects, practicing beyond the scope permitted, and gross or repeated malpractice.³ In addition, Florida's statutes require hospitals, ambulatory surgical centers, nursing homes, and physician offices to report certain adverse events to the Florida Agency for Health Care Administration (AHCA) and risk management, as governed by 395.0197, Florida Statutes. Under Florida law, an adverse event is defined as, “an event over which healthcare personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred,” and results in one of a number of injuries including death, brain damage, additional medical or surgical intervention, or transfer to a higher level of care.⁴ Each facility must submit an annual report of these occurrences to AHCA. A subset of adverse incidents that meet the foregoing criteria and result in one of the injuries listed, must be reported to AHCA within 15 days of the occurrence, hence the name “Code 15” report.⁴ This report includes a description of the circumstances surrounding the event, as well as analysis and interventions taken to correct and prevent recurrence.⁵ License numbers of personnel who were directly involved in, or witnessed, an adverse event are also required on Code 15 reports.

Physician providers are also required to report certain adverse incidents occurring in their office to the Florida Department of Health (DOH), rather than AHCA. Adverse events that are required to be reported by physician offices are similar to those reported by hospitals to AHCA.⁶ AHCA routinely forwards Code 15 reports to DOH to determine whether they should initiate a practitioner investigation. AHCA also maintains an annual report of malpractice claims reported statewide.

Root Cause Analysis (RCA)

The Joint Commission (TJC) is an independent, not-for-profit organization that accredits and certifies over 21,000 healthcare organizations across the nation and has become a symbol of patient safety given its commitment to the highest quality performance standards. TJC defines a sentinel event as a patient safety event that reaches a patient and results in death, permanent harm, or severe temporary harm and intervention required to sustain life.⁷ When a sentinel event occurs, TJC requires a RCA be completed within 45 days, though many facilities complete them sooner while the details of the event are fresh in everyone's minds. While in Florida AHCA's definition of an adverse event is not necessarily synonymous with TJC's Sentinel Event, most adverse events undergo a RCA. They are called "sentinel" because they signal the need for immediate investigation and response.

The first step involved in a RCA is gathering the information and circumstances surrounding the event by using a multidisciplinary team that includes leadership and all those involved in the event. The causal factors identified drive the corrective action plan, and specific individuals and departments are identified as responsible for the corrective actions. Once solutions to the patient safety event are identified and implemented, it is important to close the loop by following up in a timely fashion to ensure that actions taken were effective.

Not all sentinel events occur because of a medical error, and not all medical errors result in a sentinel event. Hospital reporting of sentinel events to TJC is voluntary. Therefore, the most reported RCA events per year represent only a small proportion of actual events occurring between 2005 and 2016. Presently, the top ten sentinel events reported to TJC are wrong patient/site/procedure, unintended retention of a foreign body, delay in treatment, suicide, operative or post-operative complications, falls, other unanticipated event, medication error, criminal event, and perinatal death/injury.⁸ Of the sentinel events reported to TJC through RCA, human factors, leadership, and communication continue to be the top three root causes for the past several years. Since 1998, TJC has published "Sentinel Event Alerts" which

address root causes and risk reduction strategies of sentinel events. Many of the strategies and recommendations have since become TJC hospital standards of accreditation.

The proactive counterpart to RCAs, Failure Mode and Effect Analysis (FMEA), is a method for evaluating processes before an adverse event occurs by identifying where and how failures might occur. A FMEA team, comprised of individuals involved in the process, reviews the steps in the process to identify and evaluate those parts of the process most in need of change. Prioritizing is important to ensure systems and processes with the highest likelihood of patient or staff harm are addressed first.

In 2015, the National Patient Safety Foundation (NPSF), an independent, not-for-profit organization, published "RCA²: Improving Root Cause Analyses and Actions to Prevent Harm."⁹ Recognizing the value of the RCA process, but noting its inconsistent success, RCA² sought to create methods and techniques to identify how and why the patient safety event occurred, but then also take positive action to prevent its recurrence. "The most important step in the RCA² process is the identification of actions to eliminate or control system hazards or vulnerabilities identified in the causal statements." Once identified, the focus turns to the development of strong action plans with support of facility leadership. Numerous patient safety organizations, including TJC, have endorsed the use of RCA².

Patient Safety

In 2005, Congress passed the Patient Safety and Quality Improvement Act (PSQIA) which established federal privileges and confidentiality for patient safety work product reported to a Patient Safety Organization (PSO).^{10,11} As of January 2017, there are 52 listed PSOs serving Florida.¹² The legal protections of the PSQIA have significantly enhanced provider willingness to share patient safety and performance improvement information to facilitate development and dissemination of preventive measures and best practices.

In 2002, TJC established its National Patient Safety Goals program to help accredited organizations focus on specific areas of patient safety concern. For 2017, TJC has identified the following National Patient Safety Goals:¹³

1. Identify patients correctly
2. Improve staff communication
3. Use medicines safely
4. Use alarms safely
5. Prevent infection
6. Identify patient safety risks
7. Prevent mistakes in surgery

The first goal addresses the issue of reliably identifying the patient for whom service or treatment is intended and matches the service or treatment to that patient using acceptable identifiers. Acceptable patient identifiers include their name, identification number, or telephone number. Two identifiers must be used when administering medications or blood products.

The second goal is to improve the effectiveness of communication among caregivers. The rationale is to ensure that critical test results are promptly communicated to the appropriate caregiver so that indicated treatment can be started immediately. TJC proposes the development and implementation of written procedures for managing the results of critical tests and diagnostic procedures.

The third National Patient Safety Goal promotes reducing or eliminating errors involving medication administration. Since 2005, there have been more than 460 sentinel events related to medication error.⁸

The fourth goal is the safe use of critical alarms which addresses issues such as overuse of alarms. Overuse of alarms may confuse or desensitize staff to critical alerts. The Joint Commission requires hospitals to establish alarms as an organizational priority and identify the most important alarms to manage, based on their own internal situations.

The fifth goal is to reduce infections in healthcare facilities, including post-operative infections, central line infections, and urinary tract infections from the use of catheters. Prevention and control strategies must be tailored to the specific needs of each hospital, based on their own risk assessment.

The sixth goal is to identify patient safety risks, including patient assessments for suicide risk, which is a frequently reported sentinel event. Between 2005 and 2016, there were 972 sentinel events reported to TJC involving suicide.⁸ Identification of individuals at risk for suicide while under the care of, or following discharge from, a healthcare organization is an important step in protecting at-risk individuals.

The seventh National Patient Safety Goal is the prevention of mistakes during surgery. There were 1,225 wrong patient, wrong site, or wrong procedure surgeries voluntarily reported to TJC from 2005 through the second quarter of 2016.⁸ This is the leading reported sentinel event and the figure nearly doubled from 2014, when there were 73 sentinel events reported, to 2015 with 121 reported. Having a pre-procedure verification process and performing a time-out with the operating room team before anesthesia is administered to ensure the correct procedure, for

the correct patient, at the correct site, is a recognized standard of practice. Marking the location of the surgery is also recommended.

Patient safety is also a Florida statutory requirement. Under Florida Statute 395.1012,¹⁴ each licensed facility is required to adopt a patient safety plan implementing the requirements of the Conditions of Participation for hospitals receiving reimbursement from CMS.¹⁵ This statute further requires that all licensed facilities appoint a patient safety officer and a patient safety committee, which will include at least one person who is neither employed by nor practicing in the facility,¹⁴ to promote the health and safety of patients by evaluating patient safety measures of the facility and implementing the patient safety plan.¹⁴

Diagnostic Errors

Diagnosis is the foundation upon which all healthcare services and treatment rest. It is through correct diagnosis that subsequent healthcare decisions are made. Building upon *To Err Is Human*, IOM published *Improving Diagnosis in Healthcare* in 2015, revealing the occurrence of diagnostic errors had been largely underestimated and that most patients would suffer at least one diagnostic error in their lifetime.

Noting numerous conflicting definitions of diagnostic error in the healthcare industry, IOM endorses a patient-centered definition: “failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.”¹⁶ Taking some inspiration from TJC National Patient Safety Goals, the IOM outlined eight goals to reduce diagnostic error and improve diagnosis.¹⁶

- Facilitate more effective teamwork in the diagnostic process among healthcare professionals, patients, and their families.
- Enhance healthcare professional education and training in the diagnostic process.
- Ensure that health information technologies support patients and healthcare professionals in the diagnostic process.
- Develop approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance.
- Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses.

- Design a payment and care delivery environment that supports the diagnostic process.
- Provide dedicated funding for research on the diagnostic process and diagnostic errors.

According to that IOM study, diagnostic errors cause harm by preventing or delaying the appropriate treatment or providing unnecessary or harmful treatment. In the outpatient setting, it is estimated that each year five percent of adults will experience a diagnostic error. In the hospital setting, diagnostic errors are estimated to account for 6 to 17 percent of adverse incidents each year.¹⁶

Diagnostic errors are also the leading type of paid medical malpractice claims and are twice as likely to have caused the patient's death. In a recent study analyzing 25 years of data submitted to the National Practitioner Data Bank,¹⁷ diagnostic errors were the highest claim type at 28.6 percent and accounted for 35.2 percent of total payments, which was also the highest proportion. Diagnostic errors were the leading cause of claims-associated death and disability. After adjusting for inflation, diagnosis-related payments totaled \$38.8 billion.¹⁶

Misdiagnosed Conditions

The timely and accurate diagnosis of medical conditions is of significant importance to the Florida Board of Medicine, so much so that continuing education requirements include mandatory discussion of the five most misdiagnosed conditions.¹⁸ As of the date of this publication, those conditions include cancer related issues, neurological/spine related issues, cardiac/stroke related issues, infectious/communicable diseases, and pulmonary related issues.¹⁸ It is important to look at each condition and actual Board of Medicine case scenarios.

Cancer Related Issues

In 2016, the American Cancer Society estimated 1,685,210 new cancer cases were diagnosed, and 595,690 deaths were attributed to cancer in the United States.¹⁹ Florida had one of the highest state diagnosis rates at 121,240. The top three most diagnosed cancers in Florida were lung and bronchus, female breast, and prostate cancer.¹⁹

Misdiagnosis of cancer, includes missed diagnosis, wrong diagnosis, and delayed diagnosis. In one case presented to the Board of Medicine, the patient underwent an x-ray of the chest that revealed a focal area of increased density in her lung. The physician documented the findings, as well as the patient's re-

luctance to undergo a CT scan citing lack of insurance. Six years later, new diagnostic studies revealed a small infiltrate of her lung and radiographic follow-up was recommended. The physician documented a plan to follow up, but failed to do so, and failed to order additional studies. Over a year later, the patient presented to another physician who ordered a CT of the chest which revealed a malignant appearing mass in the right lung, and a biopsy later revealed adenocarcinoma.

The Board of Medicine found that the physician failed to practice medicine with that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by a reasonably prudent similar health-care provider. The physician was also cited for keeping illegible records, not documenting tests ordered, radiographic follow up, or crucial conversations with the patient, as well as not maintaining a concise ongoing problem list.

Neurological/Spine Related Issues

A retrospective study of diagnostic errors in neurological emergencies found that these incidents can be classified into three categories: knowledge gaps, cognitive errors, and systems-based errors.²⁰ Misdiagnosis of cerebellar lesions and erroneous radiology resident interpretations of neuroimaging were the most common mistakes nationwide.

In a related incident before the Board of Medicine, a patient presented with complaints of severe headaches, confusion, and dizziness and a history of previous shunt insertion for hydrocephalus. A CT scan revealed hydrocephalus with shunt catheter in place and no signs of acute intracranial hemorrhage. The patient was diagnosed with a malfunctioning shunt and was taken to the operating room where the old shunt was removed and a new shunt placed. A left frontal burr hole was also made. The physician documented in the operative report that he had evacuated blood from the patient's head and informed the patient of it. Post-operatively, the patient was found to be obtunded and having seizures, requiring ventilator-assistance. The investigation revealed the physician performed an unnecessary procedure by drilling a burr hole that was not indicated and deceptively documented that a hematoma was evacuated.

Cardiac/Stroke Related Issues

There has been much publicity recently regarding the failure to diagnose heart disease, particularly in women, and the historical and cultural reasons for this disparity.²¹ According to the Centers for Disease Control, heart disease is the leading cause of death

for women in the United States.²² Almost 64 percent of women who die suddenly from heart disease have no previous symptoms, making it more difficult to diagnose.²³

The Board of Medicine reviewed an incident of a patient who presented to the emergency room with unstable vital signs and complaints of left arm, side, and knee pain subsequent to a fall. Her history was positive for myocardial infarction, coronary artery bypass grafts, hypertension, and myelofibrosis. The emergency department physician incorrectly interpreted the chest x-ray, despite the radiology report indicating pleural effusion and left lower lobe atelectasis and an abnormal electrocardiogram showing tachycardia. The only treatment rendered was a 500mL bolus of normal saline. Without further evaluation or timely intervention, the patient continued to deteriorate, coded, and expired.

The Board of Medicine determined that the physician failed to meet the standard of care by failing to properly diagnose and treat the patient, failing to correctly interpret the chest x-ray, failing to address the abnormal electrocardiogram, and failing to recognize a hemothorax in a patient with left sided chest trauma with hypotension and tachycardia.

Infectious/Communicable Diseases

The misdiagnosis of infectious or communicable diseases is concerning not only for the patient involved, who will likely have a delay in the initiation of care, but for other patients and healthcare workers who may also be exposed. In this next scenario, the patient arrived in the emergency room with a temperature of 102°F and altered mental state and was diagnosed with transient ischemic attack. A consulting neurologist diagnosed encephalitis and recommended a lumbar puncture, but this recommendation was not acted upon. A CT scan of the head did not show hemorrhagic or thrombotic infarct, and the presence of fever suggested a differential diagnosis of herpes or toxoplasma infection. Accordingly, an infectious disease consultation was requested. The infectious disease physician was found to have failed to meet the standard of care by having his P.A. perform the exam, failing to reference herpes simplex encephalitis in the differential, failing to order a spinal tap, failing to order an MRI, and failing to immediately start the patient on acyclovir antiviral therapy. The patient suffered seizures, further deterioration, and was placed on a ventilator. Ultimately, the failure resulted in severe irreversible brain injury caused by untreated herpes encephalitis and the patient remained in a state of total dependency.

Pulmonary Related Issues

In one retrospective study of pulmonary embolism, over 30 percent of patients presenting to the emergency department had a delayed diagnosis.²⁴ Patients were often sent home or admitted to the hospital with an incorrect diagnosis depending on their clinical presentation or other chronic, coexisting medical conditions.

The Board of Medicine reviewed the treatment of a patient who arrived to the emergency room from her physician's office with shortness of breath and chest pain and to be ruled out for pulmonary embolism. The emergency room physician utilized a shortness of breath template and recorded no new vital signs. After ordering essentially non-diagnostic studies, the ER physician ordered antibiotics and potassium chloride to treat the diagnosis of cough and hypokalemia and discharged the patient. One week later, the patient died from a saddle pulmonary embolism. The physician was found to have practiced below the standard of care by failing to perform a proper history and physical, failing to order appropriate diagnostic studies, and failing to rule out pulmonary embolism.

Medical Error Reduction: In Conclusion

Medical errors will never be completely eliminated, but by utilizing available patient safety data, adhering to National Patient Safety Goals, and utilizing tools such as RCA to identify those areas of greatest patient safety concern, medical errors can be reduced. As the preceding examples have illustrated, commonly encountered challenges with the stages of the diagnostic process can be minimized by consistently performing a thorough history and physical, promptly following up on diagnostic tests, and communicating findings to the patient. Medical record documentation is also extremely important to the practice of medicine and the communication between multiple services and healthcare providers involved in a patient's care. Failure to keep appropriate written records is also a frequent cause of Board of Medicine disciplinary action and a hindrance to the provision of appropriate care. As more and more healthcare organizations transition to the electronic health record, the benefits of this technology, such as diagnostic decision support, clinical reminders, and system alerts, will help avert the risk of diagnostic missteps. ❖

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Prevention of Medical Errors & Patient Safety Quiz

CME Questions & Answers (circle one answer)/Free to DCMS Members/\$55.00 charge non-members*

(Return by March 1, 2019 BY EMAIL: kristy@dcmsonline.org)

1. *To Err is Human*, the 1999 study by the Institute of Medicine, estimated that as many as 98,000 patients die in hospitals every year as a result of preventable medical errors.
 - a. True
 - b. False
2. The federal Patient Safety and Quality Improvement Act (PSQIA):
 - a. Establishes federal privilege and confidentiality protections for patient safety information.
 - b. Seeks to improve patient safety standards.
 - c. Allows healthcare providers to identify and learn from errors through voluntary reporting systems.
 - d. All of the above.
3. Most patient safety events are not the result of individual carelessness, but system failures.
 - a. True
 - b. False
4. What are factors propelling medical error prevention?
 - a. Malpractice suits
 - b. Media coverage of error, reimbursement denials for preventable hospital acquired conditions, state, federal and professional licensure requirements
 - c. Computerized medical records
 - d. Mortality rate
5. Per The Joint Commission, when must a root cause analysis be completed for a Sentinel Event?
 - a. Within 45 days
 - b. As soon as possible
 - c. Within 15 days
 - d. When you can get a team together
6. What is the current number one sentinel event reported to The Joint Commission?
 - a. Medical errors
 - b. Equipment defects
 - c. Wrong patient surgery, wrong site surgery, wrong procedure surgery
 - d. Infection
7. Human factors, leadership, and communication continue to be the top 3 root causes of The Joint Commission reported events.
 - a. True
 - b. False
8. What is the primary focus of the RCA team?
 - a. Meet the Joint Commission requirements
 - b. Identify weaknesses and failures in systems and processes and take effective action that will result in sustained improvement
 - c. Terminate those involved in the event
 - d. Report the event to the Department of Health
9. Certain adverse events have to be reported to Florida's Agency for Health Care Administration (AHCA) within 15 days.
 - a. True
 - b. False
10. What are the Florida Board of Medicine's most misdiagnosed conditions this biennium?
 - a. Sepsis, cardiovascular disease, urologic disease, cancer, fetal distress
 - b. Meningitis, Zika, Tuberculosis, neurological conditions
 - c. Cancer, neurological, cardiac, infectious disease, and pulmonary
 - d. Brain injury, fractures, surgical complications, appendicitis, blood dysplasia, Leukemia

1. What will you do differently as a result of this information? _____
2. How will you apply what you learned to your practice? _____

Evaluation questions & CME Credit Information

(Please evaluate this article. Circle one number using this scale: 1= Strongly Agree to 5= Strongly Disagree)

The articles met the stated objectives:	1	2	3	4	5
The articles were appropriate to my practice:	1	2	3	4	5
The topics were current and well presented:	1	2	3	4	5

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