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A Clinical Appraisal of Medication Injury for the Podiatric Physician

Medical errors can be costly to both you and patients.

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Learning Objectives

1) Recognize published clinical base evidence related to the paradigm shift associated with risk factors for medication injury and potential drug misadventure.

2) Recognize problematic drug misadventures and drug injury as reported as medication injury litigation and settlements as they appear in both the medical and legal literature.

3) Appreciate mitigating strategies to assist clinicians to avoid medication injury.

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*Following this article, an answer sheet and full set of instructions are provided (pg. 112).—**Editor***

Introduction

Literature accounts have noted that healthcare institutions are responsible for medication errors accounting for twenty percent occurrence. The most common error is giving the medicine at the wrong time or omitting a dose.[1-3] Medical errors cause an estimated 250,000 deaths in the United States annually. It is estimated that 7,000 to 9,000 patients die every year from medication errors.[4] Medication errors can cause death, permanent injury, or a full range of serious health issues.

It is estimated that 250,000 deaths are caused by medical errors in the United States annually.

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare

Continued on page 106

Medication Injury (from page 105)

professional, patient, or consumer.[4] Riaz, et al. asserts that medication errors occur every day causing injury to the patients and even deaths.[5] Further, these healthcare professionals are not fully aware of the damages done by medication errors in terms of patients' discomfort and economic burden.[5] It has been established that it costs over $40 billion per year to care for and treat patients who were victims of medication errors.[4]

Podiatric physicians must acknowledge that medication errors can happen to anyone and at any place, for example, the patient's or the provider's home, the provider's office, hospitals, pharmacies, and even a senior living facility. One common etiology of medication errors is poor communication. It is an accepted concept that physicians, nurses, hospitals, pharmacies, and others who make and distribute drugs could commit a variety of medication errors, including prescribing or giving the incorrect drug or wrong dosage, failing to give the medication at the right time, failing to monitor how the patient reacts to the drug, failing to check the patient's medical history, not considering possible interactions with other drugs the patient takes, failing to inform about the side-effects, not giving proper instructions on when and how to take the medication, not writing a readable prescription, or not labelling a medication correctly.

Literature has declared that a medical error has several potential sources and given how The United States healthcare system is complicated, an observer, realizing the complexity of identifying both medical errors and medication errors present, without a formal classification system, may overlook these errors.[6-8] The United States has positioned itself as the most advanced country in the world. However, it is difficult to reconcile these two notions without acknowledging that perhaps our institutions are not being proactive enough in combating the unsettling pattern of medical and medication errors.[6-8] While the issue is multi-faceted and involves several stakeholders, mitigating both medical errors and medication errors requires a closer look by the podiatric physician at the behavioral drivers involved.

Podiatric physicians have become aware that clinical errors and malpractice claims are increasing and that they are an important aspect of medical practice. As pointed out in previously cited literature, it is widely accepted that medication errors are the most common and preventable cause of patient injury. Further, both medical and clinical observations, as well as legal citations, have alerted providers that prescription errors associated with both drug errors and adverse drug effects have been documented as frequent occurrences in practically all healthcare settings. Given this reason, the purpose of this review is to present the central theme of prevention of medication error and injury by presenting data to recognize published clinical base evidence related to the paradigm shift associated with medication injury.

The FDA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare provider, patient, or consumer.

First, the definition for the risk factors resulting in potential drug injury, potential drug misadventure, as well as recognizing the problems in establishing causality for medication or drug injury will be presented. Second, data and tools to recognize the problematic drug misadventures and drug injury as reported in case studies, litigation, settlements, and clinical coping will be presented as mitigating strategies as they appear in both the medical and legal literature. Finally, mitigating strategies to assist in avoiding medication error and medication injury grounded in clinical base literature will be introduced.

Continued on page 107

TABLE 1

Examples of Medication Errors

Prescribing	Prescription Errors	Dispensing Drug Products	Administration	Monitoring
Irrational	Manufacturing the Formulation	Wrong Drug	Wrong Dose	Fail to Monitor
Inappropriate	Wrong Strength	Wrong Formation	Wrong Route	Failing to Alter Therapy When Needed
Ineffective Prescribing	Contaminants or Adulterants	Wrong Label	Wrong Duration	Erroneous Alterations
Underprescribing	Wrong or Misleading Packaging		Wrong Frequency	Adverse Effects
Over prescribing				

TABLE 2

Why Providers Fail to Report Adverse Drug Reactions and Their Rationale for Their Actions

Complacency—only safe drugs are allowed on the market
Fear—of involvement in litigation or of an investigation
Guilty feelings about the damage physicians may have caused their patients
A desire to collect and publish a personal series of cases
Ignorance about what should be reported or the process
Difference in reporting mere suspicions
Indifferences to the responsibility that an individual doctor has contributed to the general body of knowledge about the effects of drug treatment

Medication Injury *(from page 106)*

Medication Errors-Drug Injury

Medication errors refer to mistakes in prescribing, dispensing, and giving medications. The Food and Drug Administration (FDA) defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare provider, patient, or consumer.[9] The FDA declares that this definition is based on the one stated by the National Coordinating Council for Medication Error Reporting and Prevention.[10]

The deliberate or intentional use of abuse, misuse, or off-label use of a drug product in a manner that is inconsistent with FDA-required labelling is not generally considered a medication error. A "preventable event" refers to events that are due to errors that could be avoided. As an example, they say that a patient receiving a wrong drug because of look-alike container labels is a preventable event. On the other hand, a patient with no previous history of allergies who experiences anaphylaxis after taking a sulfa drug is *not* considered preventable.[9]

Finally, the agency states a medication error may or may not result in an adverse event.[9] Table 1 presents examples of medication errors.

An adverse event is a definable injury caused at least partly by medical management; the injury must have prolonged the hospital stay or caused disability at the time of discharge or both. An adverse drug event or adverse effect results from medical intervention related to a drug prescribed and administered. A negligent adverse event is defined as an injury caused by the failure to meet standards expected of an average physician or institution.

A drug-related problem is an event or circumstance involving a patient's drug treatment that actually or potentially interferes with the optimal achievement of an optimal outcome. An inappropriate drug is defined as the use of a drug despite new data showing problems with its use. An incorrect drug dose is defined as the use of an extended-release product with the wrong frequency.

An example of contraindicated therapy occurs when a patient's allergy is ignored. An inappropriate drug combination is when a drug is used when its use is unsupported by standard medical literature. Finally, the designation of an inappropriate indication is defined as the use of a drug for an indication with an unfavorable risk or unknown benefit, or is unapproved by health authorities.

Professional Negligence

Edersheim and Stern describe potential liability for physicians when prescribing medications by offering a series of vignettes.[11] They further offer that liability for unintentional harm is governed by tort law; and for medical professionals, the subset of tort law is known as professional negligence law.[11,12] The Four D's of malpractice include (a) Duty—He or she must have undertaken this patient's treatment; (b) Derelict—The person must prove that the provider was derelict in this duty or in some way acted below the standard of care that was expected; (c) Directly—This dereliction of duty must directly cause damage to the patient or third parties. Injury must bear a causable relationship to the physician's actions and cannot be caused by intervening actors or conditions; and (d) Damages—The dereliction of duty must have directly caused "damages" or compensable harm to the patient.[11,12]

Das, et al. report that medication errors that occur most often centered around the practice prescribing medications account for 29-56%.

On the other hand, Mello and Hemenway assert the argument that the notion that the tort liability system deters negligence in healthcare has been invoked to make the "business case for patient safety".[11] However, they delineate that existing data on the relationship between hospital adverse events and malpractice claims typically are interpreted as evidence that the tort system does not deter negligence because of the poor fit between those who are negligently injured and those who sue.[13]

Bhatt presents that errors occur most often in prescribing (39–56%) and result in malpractice claims in 13–25% of cases in India.[14] Bhatt also emphasizes that rational prescribing

Continued on page 108

Medication Injury (from page 107)

and improved therapeutic knowledge through re-training and effective use of computers in prescribing could prevent errors and reduce economic consequences for patients, doctors, and hospitals.[14]

Das, et al. report the incidence data of different aspects of iatrogenic problems due to drugs in adverse events (3.7%), adverse drug events (2.4–6.5%), and adverse drug reactions (6.7%).[15] Negligence in serious adverse drug effects and death accounted for 34% and 51% respectively,[15] preventable adverse effect reactions were 25–50%.[15] Medication errors occur most often centered around the practice prescribing medications (29–56%).[15] The most common cause of medication errors was determined as a lack of knowledge about the drug (29%) and the patient (18%).[15] Medication errors result in malpractice claims in 13–25% of cases that occur due to mistakes and slips of action and lapses of memory.[15]

Dukes and Swartz report that major drug contraindications have been described in the literature and have been overlooked by providers.

Is it feasible for a physician or provider to learn and remember sufficiently about the drugs they use, and thus, use them properly? The area of drug therapy is a large one and the prescriber cannot be expected to be familiar with more than a small fraction of it, but it is necessary and possible for them to know a small part of it which they need to do their daily work—for example, 200–300 medications and replacing older medications with newer medications as they become available in the market. Dukes and Swartz report that there is no doubt that some physicians make little effort to keep abreast of events of adverse effects.[16]

Dukes and Swartz report that major drug contraindications have been described in the literature, and that they have often been overlooked by providers.[16] These authors suggest that physicians have ready knowledge of all the significant risks associated with the drugs that they use daily, including adverse drug reactions, drug-drug interactions, and drug contraindications, because there are readily available sources.[16]

Fitzgerald determined that drugs can mask clinical signs.

Pollock, et al. outlines the systematic approach advocated by the World Health Organization that can help minimize poor-quality and erroneous prescribing.[17] This six-step approach to prescribing suggests that the physician should (1) evaluate and dearly define the patient's problem; (2) specify the therapeutic objective; (3) select the appropriate drug therapy; (4) initiate therapy with appropriate details and consider non-pharmacologic therapies; (5) give information, instructions, and warnings; and (6) evaluate therapy regularly (e.g., monitor treatment results, consider discontinuation of the drug).

The authors add two additional steps: (7) consider drug cost when prescribing; and (8) use computers and other tools to reduce prescribing errors.[17] These eight steps, along with ongoing self-directed learning, form a systematic approach to prescribing that is efficient and practical for any physician.[17] Using prescribing software and having access to electronic drug references on a desktop or handheld computer can also improve the legibility and accuracy of prescriptions and help physicians avoid errors.[17] Table 2 summarizes why providers fail to report adverse drug reactions.

Vignettes and Clinical Coping

Given that vignettes are important instructional design tools to allow participants to demonstrate clinical reasoning and competence, four case vignettes have been selected to allow the participant or reader to develop an understanding that medication-adverse events can be interpreted as drug injury. The premise of these four vignettes is grounded in history as well as relative, scientific, clinical, legal literature and citations.[18–21] For contextual fluidity, the presentation of each case has been truncated so that pointed relative information is presented.

Case 1

A 52-year-old male taking warfarin daily for prevention of stroke with atrial fibrillation develops a lower extremity skin infection and visits a local urgent care facility on a weekend for evaluation and treatment. The patient receives a diagnosis of cellulitis of the lower extremity and a prescription for trimethoprim/sulfamethoxazole double strength to be taken one tablet twice daily for fourteen days. The drug is dispensed by the urgent care facility, not the patient's usual pharmacy. Several days later, the patient was admitted to the hospital with an acute bleed and an elevated international normalized ratio (INR) of 12.

Case 1—Clinical Coping

A medication was prescribed which was known to affect the metabolism of warfarin. Studies have shown that through inhibition of Cytochrome P450 enzymes, trimethoprim/sulfamethoxazole double strength as well as other antibiotics and medications may significantly increase warfarin levels and the patient's INR, thereby placing the patient at increased risk for bleeding. Although the risk of a significant drug-drug interaction may be minimized or avoided by choosing an antibiotic less likely to affect warfarin levels, in some cases, doing so

Continued on page 109

Medication Injury *(from page 108)*

may not be possible and the only option may be increased monitoring and warfarin dosage adjustment. Regardless, it is important that podiatric physicians be aware of the large number of drug-drug interactions with warfarin and the associated monitoring that is required. This case highlights the importance of medication reconciliation and patient communication throughout the patient encounter process.

Case 2

A female patient went to the hospital with a toe infection because she did not respond to multiple courses of antibiotics. She reported high fever and multiple allergies. She told the defendant physician that she was allergic to Keflex® (cephalosporin), but she was vague in giving more specific details about her alleged potential reaction to the drug. The doctor prescribed Ancef®, another cephalosporin. The next day, after three or four doses, the patient had an acute respiratory attack. She claimed the symptoms were an anaphylactic reaction to the medication, which never should have been prescribed for her. Defendants presented that the event was not an anaphylaxis, but flash pulmonary edema, which was related to her many years of smoking. The patient had received both Ancef® and Keflex® without event at other times. The jury returned a defense verdict in favor of the physician.

The precipitating event in case 1 was a drug-drug interaction between Warfarin and Trimethoprim/sulfamethoxazole double strength.

Case 2—Clinical Coping

Medication histories are important in preventing prescription errors and consequent risks to patients. Fitzgerald determined four reasons for taking an accurate medication history:[20]

1) A knowledge of the drugs a patient has taken in the past or is currently taking and the responses to those drugs to help in planning future treatment.

2) Drug effects should always be on the list of differential diagnoses, since drugs can cause illness or disease, either directly or because of an interaction.

3) Drugs can mask clinical signs. For example, beta-blockers can prevent tachycardia in a patient with hemorrhage.

4) Drugs can alter the results of labs. For example, amiodarone alters thyroid function tests.

Podiatric physicians should take the opportunity to educate patients about their medications.

An inaccurate history on admission to the hospital may lead to unwanted duplication of drugs, drug interactions, discontinuation of long-term medications, and failure to detect drug-related problems like drug allergies.

Case 3

A 59-year-old male patient with diabetic mellitus Type 2 and a history of foot infection with osteomyelitis was admitted by the attending with an order for the pharmacy to dose vancomycin and Zosyn® based on renal status. The pharmacist calculated that the patient should receive vancomycin 1.25 grams IV q12hrs and Zosyn® 3.375 grams IV q6 hours. The attending provider also ordered a consult for infectious disease to manage anti-infective agents. The patient received two doses of vancomycin 1.25 grams at 1200 and 0000. An order for 2000 mg vancomycin loading dose was ordered and given over night at 0300 within the first 24 hours of admission.

The patient received another 1.25 gm as scheduled, as well as Zosyn® for a total 13.5 grams in 24 hours. The first vancomycin trough level reported prior to the fourth dose was determined as 60 mcg/mL and serum creatinine base line was determined to be 1.2 mg/dL and rose to 5 mg/dL within 24 hours, and creatinine clearance was calculated to be 70 mL/min and decreased to 30 mL/min after 24 hours and over two weeks, the creatinine clearance was decreased to 12 ml/min. The nephrologist diagnosed the patient with vancomycin nephritis, and over six weeks, the creatinine clearance remained below 17mL/min.

In Case 3, the drug injury was caused by drug-induced nephrotoxicity.

Case 3—Clinical Coping

Knowledge of drugs that are nephrotoxic is essential to avoid medication-induced injury. The podiatric physician is encouraged to obtain a medication guide to dose medication based on a patient's renal status and also be aware that these medications are nephrotoxic. Both prescription and over-the-counter medications are filtered by the kidneys. A podiatric physician can determine the level of kidney function with a blood test for serum creatinine to calculate an estimated Glomerular Filtration Rate measurement (eGFR). Further, podiatric physicians are encouraged to obtain consultations from nephrology, infection disease, and pharmacist drug review for renal dosing for at-risk patients.

Case 4

A 38-year-old woman who suffered liver failure secondary to acetaminophen toxicity died on November 19, 1999. She had taken two Vicodin ES® (Hydrocodone/acetaminophen) tablets every four hours after

Continued on page 110

Medication Injury (from page 109)

undergoing an outpatient bunionectomy on November 12, 1999.

The prescription provided by the defendant surgeon directed her to "take one to two tablets every 4 to 6 hours as needed for pain", which led to the patient ingesting a lethal dose of acetaminophen. The pharmacist testified that she relied on the physician and did not usually consider the toxic effect of therapeutic doses of acetaminophen. The pharmacist was dismissed by the court early in the litigation. The Cook County, IL court reached a settlement for the plaintiff in the amount of $2,700,000.

In case 4, the Cook County, IL court reached a settlement for the plaintiff in the amount of $2.700.000.

Case 4—Clinical Coping

A podiatric physician is encouraged to be familiar with the following FDA recommendation for acetaminophen. The FDA recommended on January 2014 that clinicians stop prescribing and dispensing combination drugs that contain more than 325 mg of acetaminophen per dosage unit. The FDA also urged pharmacists who receive prescriptions for higher than over the counter doses to perform a drug review, educate, and communicate with the patients to avoid acetaminophen. The FDA asked manufacturers to limit the amount of acetaminophen in prescription combination drugs to 325 mg by January 2014.

Data from the U.S. Acute Liver Failure Study Group point to acetaminophen poisoning as the culprit behind half of the nation's cases of acute liver failure. Unintentional overdoses account for 48% of acetaminophen-related acute liver failure. In that population, 38% of patients were simultaneously taking more than one acetaminophen-containing drug and 62% were taking an opioid-acetaminophen combination.

Mitigating Strategies for Avoiding Medication Injury

A podiatric physician must realize that as the population ages, attention must be directed toward providing quality trauma care for older patients. Lester, et al. states that polypharmacy is a known risk factor for hospital admission and injury in older adults and is a potential target for improvement in trauma outcomes.[22] Podiatric physicians should familiarize themselves with the Beers Criteria because it can serve as both a clinical tool and a measure of quality and can be used as an admission screening tool in all older patients.[22]

Further, the podiatric providers can study both the STOPP (Screening Tool of Older Persons' Prescriptions) and START (Screening Tool to Alert to Right Treatment), which are explicit criteria that facilitate medication review in multi-morbid older people in most clinical settings.[23] Finally, lower extremity providers can apply the WHO eight steps described by Pollock et al., along with ongoing self-directed learning and compose a systematic approach to prescribing that is efficient and practical, which can help minimize poor-quality and erroneous prescribing.[17]

Conclusions

The purpose of this review was to present the central theme of prevention of medication error and injury by showing the data recognized in published clinical base evidence related to the paradigm shift associated with medication injury. First, the definition for the risk factors for potential drug injury and potential drug misadventure were offered.Second, tools to recognize problematic drug misadventures and drug injury as reported in medication injury litigation and settlements were presented. Finally, mitigating strategies to assist in avoiding potential harmful effects of medications that could be responsible for medication injury grounded in clinical base literature was offered. **PM**

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Continued on page 111

Medication Injury (from page 110)

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CME EXAMINATION

SEE ANSWER SHEET ON PAGE 113.

1) Identify the tool(s) that may be used to mitigate medication harm and drug injury:

- **A) Beers Criteria**
- **B) STOPP (Screening Tool of Older Persons' Prescriptions)**
- **C) START (Screening Tool to Alert to Right Treatment)**
- **D) All are tools that may be used to mitigate medication harm and injury**

2) According to this review, how many estimated deaths are caused by medical errors in the United States annually?

- **A) 150,000**
- **B) 250,000**
- **C) 350,000**
- **D) 500,000**

3) In case 4, the Cook County, IL court reached a settlement for the plaintiff in the amount of _____.

- **A) $1,200,000**
- **B) $3,700,000**
- **C) $2,400,000**
- **D) $2,700.000**

4) According to this review, the precipitating event in case 1 was a drug-drug interaction between Warfarin and _____

- **A) Ampicillin**
- **B) Fentanyl**
- **C) Trimethoprim/sulfamethoxazole double strength**
- **D) Morphine**

5) According to this review, what type of drug injury was described in case 3?

- **A) Drug-induced allergy**
- **B) Drug-induced ototoxicity**
- **C) Drug-induced hepatotoxicity**
- **D) Drug-induced nephrotoxicity**

6) Identify one of Fitzgerald's four reasons for taking an accurate medication history:

- **A) Drugs can cost too much**
- **B) Drugs can mask clinical signs**
- **C) Drugs cannot alter laboratory tests**
- **D) Drugs are available as generic**

Continued on page 112

Continuing Medical Education

CME EXAMINATION

7) Food Drug Administration (FDA) defines a medication error as any _____ that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare provider, patient, or consumer.

A) Unescapable event
B) Required event
C) Unavoidable event
D) Preventable event

8) According to this review, the four D's of malpractice include all but which one?

A) Disheveled
B) Duty
C) Derelict
D) Damages

9) According to this review, Das, et al. report that medication errors that occur most often centered around the practice prescribing medications account for _____%.

A) 10–21
B) 54–86
C) 29–56
D) 41–98

10) According to this review, Dukes and Swartz report that _____ have been described in the literature and have been overlooked by providers.

A) major drug discoveries
B) major drug costs
C) major drug recalls
D) major drug contraindications

SEE ANSWER SHEET ON PAGE 113.

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There is **no charge** for the mail-in service if you have already enrolled in the annual exam CME program, and we receive this exam during your current enrollment period. If you are not enrolled, please send $33.00 per exam, or $279 to cover all 10 exams (thus saving $51 over the cost of 10 individual exam fees).

Facsimile Grading

To receive your CME certificate, complete all information and fax 24 hours a day to 1631-532-1964. Your CME certificate will be dated and mailed within 48 hours. This service is available for $2.95 per exam if you are currently enrolled in the annual 10-exam CME program (and this exam falls within your enrollment period), and can be charged to your Visa, MasterCard, or American Express.

If you are *not* enrolled in the annual 10-exam CME program, the fee is $33 per exam.

Phone-In Grading

You may also complete your exam by using the toll-free service. Call 1-800-232-4422 from 10 a.m. to 5 p.m. EST, Monday through Friday. Your CME certificate will be dated the same day you call and mailed within 48 hours. There is a $2.95 charge for this service if you are currently enrolled in the annual 10-exam CME program (and this exam falls within your enrollment period), and this fee can be charged to your Visa, Mastercard, American Express, or Discover. If you are not currently enrolled, the fee is $33 per exam. When you call, please have ready:

1. Program number (Month and Year)
2. The answers to the test
3. Credit card information

In the event you require additional CME information, please contact PMS, Inc., at **1-800-232-4422**.

ENROLLMENT FORM & ANSWER SHEET

Please print clearly...Certificate will be issued from information below.

Name _____ Email Address _____
Please Print: FIRST MI LAST

Address _____

City _____ State _____ Zip _____

Charge to: _____Visa _____ MasterCard _____ American Express

Card # _____ Exp. Date _____ Zip for credit card _____

Note: Credit card is the only method of payment. Checks are no longer accepted.

Signature _____ Email Address _____ Daytime Phone _____

State License(s) _____ Is this a new address? Yes _____ No _____

Check one:

_____ I am currently enrolled. (If faxing or phoning in your answer form please note that $2.95 will be charged to your credit card.)

_____ I am not enrolled. Enclosed is my credit card information. Please charge my credit card $33.00 for each exam submitted. (plus $2.95 for each exam if submitting by fax or phone).

_____ I am not enrolled and I wish to enroll for 10 courses at $279.00 (thus saving me $51 over the cost of 10 individual exam fees). I understand there will be an additional fee of $2.95 for any exam I wish to submit via fax or phone.

Over, please

ENROLLMENT FORM & ANSWER SHEET *(continued)*

EXAM #1/22
A Clinical Appraisal of Medication Injury for the Podiatric Physician
(Smith)

Circle:

1.	A	B	C	D	6.	A	B	C	D
2.	A	B	C	D	7.	A	B	C	D
3.	A	B	C	D	8.	A	B	C	D
4.	A	B	C	D	9.	A	B	C	D
5.	A	B	C	D	10.	A	B	C	D

Medical Education Lesson Evaluation

Strongly agree [5]	Agree [4]	Neutral [3]	Disagree [2]	Strongly disagree [1]

1) This CME lesson was helpful to my practice ____

2) The educational objectives were accomplished ____

3) I will apply the knowledge I learned from this lesson ____

4) I will makes changes in my practice behavior based on this lesson ____

5) This lesson presented quality information with adequate current references ____

6) What overall grade would you assign this lesson?

A B C D

7) This activity was balanced and free of commercial bias.

Yes _____ No _____

8) What overall grade would you assign to the overall management of this activity?

A B C D

How long did it take you to complete this lesson?

_____hour _____minutes

What topics would you like to see in future CME lessons ? Please list :

_____

_____

_____

_____

_____