

# **Patient Safety Curriculum**

## **Module III**

### **Improving a Critical Dimension of Quality in Health Care**

#### ***Case Studies and Root Cause Analysis of Adverse Events***

#### **Workshop Leaders Guide**

**NOTE TO INSTRUCTOR:**

This module is designed to support a lecture presentation and group discussion. It contains 25 PowerPoint slides, a transcript for presenting the cases, and complete instructions for conducting a root cause analysis for the adverse events in cases presented. Be sure to read the presentation guidelines on pages 3.5 and 3.6 before the session. Be prepared to use a flipchart to make note of participants' comments on the cases and root cause analysis.

**Learning Objectives**

Upon completion of this module, participants should be able to

1. Recognize the steps for performing a root cause analysis of an adverse event.
2. Identify the following systemic factors that contribute to medical errors in the cases presented:
  - human resource issues
  - information management issues
  - environmental issues
  - leadership and organizational culture
  - communication issues

**Presentation Outline**

<b>Topic</b>	<b>Slide #</b>
1. Introduction and Definitions .....	1 – 4
2. Case #1 .....	5 – 12
3. Case #2 .....	13 – 18
4. Case #3 .....	19 – 25

**Guidelines for Presentation and Discussion**

This module is designed to support three case study presentations and root causes analyses of the adverse events in those cases.

Make sure that the following resources are available and in working order for this session:

- the CD-ROM containing the PowerPoint slide presentation of Module III
- hardware necessary for displaying the slides
- a flipchart and markers for noting comments during your question and answer sessions
- handouts for each participant (*be sure to bring enough copies of the forms*)
  - an attitude survey (*distribute before the session*)
  - a presentation evaluation form (*distribute after the session*)

**Evaluation Forms**

On the next two pages are forms for the participants to complete when they attend the curriculum and want to obtain CME credit (1.0 hour for Module III).

***Attitude Survey***

This anonymous survey is meant to assess the participants' attitudes toward issues in patient safety improvement. Participants should complete this survey before the session. If you have the opportunity to review the completed surveys before the session, you can tailor your presentation to address key issues revealed in the surveys. Keep in mind that patient safety improvement and medical errors are sensitive subjects some participants may be reluctant to discuss. Remind participants that the purpose of this curriculum is not to complain or point fingers, but to explore opportunities and global strategies for the improvement of patient safety.

***Presentation Evaluation Form***

This anonymous evaluation form gives participants an instrument to rate the presentation with regard to its ability to provide new knowledge and skills, its relevance to clinical practice, and its overall educational value. It also includes queries regarding participants' suggestions for improvement and other comments.

**Attitude Survey**

(Each participant should complete this survey before the session, after the session if necessary.)

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
1. Root cause analysis is for safety officers, nurses, and pharmacists, not physicians.	1	2	3	4	5	6
2. Root cause analysis uncovers problems that cannot be solved because they relate to human errors.	1	2	3	4	5	6
3. Root cause analysis in the facility(ies) where I have privileges will help to reduce medical errors.	1	2	3	4	5	6
4. Root cause analysis may be helpful in hospital settings, but not in ambulatory care.	1	2	3	4	5	6
5. Root cause analysis is too expensive and time consuming to be practical.	1	2	3	4	5	6
6. Practice of evidence-based medicine can improve patient safety.	1	2	3	4	5	6
7. Voluntary error reporting and analysis is a good way to begin improving patient safety.	1	2	3	4	5	6
8. The benefits of computer-based systems (for medical records, etc.) outweigh the barriers to their adoption.	1	2	3	4	5	6

**Presentation Evaluation Form**  
(to be completed after the session)

**Please rate this presentation in terms of its ability to provide you with the following:**

Scale: 1 = needs a lot of improvement 2 = Needs some improvement 3 = Okay 4 = Good 5 = Very good 6 = Exceptional

	1	2	3	4	5	6
<b>A. Knowledge of...</b>						
root cause analysis	1	2	3	4	5	6
relationships of system processes to clinical practice	1	2	3	4	5	6
issues relating to the use of IT systems	1	2	3	4	5	6
practices for error reporting and analysis in local facilities	1	2	3	4	5	6
<b>B. Clinical relevance...</b>						
raised issues that I have seen in practice	1	2	3	4	5	6
focused on important topics likely to affect my practice	1	2	3	4	5	6
provided me with new knowledge or skills	1	2	3	4	5	6
provided practical suggestions I can apply in my practice	1	2	3	4	5	6

**How would you rate the overall value of this session? (circle one)**

Poor                  Fair                  Okay                  Good                  Very Good                  Excellent

**Comments and suggestions for improvement:**

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## Module III Overview and Implementation Guidelines

**NOTE TO FACILITATOR:**

Use slides 1 through 4 to introduce this module to the participants. The remaining slides (5-25) pertain specifically to the case studies and related exercises.

This module of the curriculum presents three cases that describe adverse events and medical errors. The cases were selected to represent a variety of common and challenging problems in patient safety.

- Case #1 presents a non-English-speaking surgical inpatient whose chest pain is undiagnosed and untreated while he awaits a chest x-ray.
- Case #2 describes an adverse drug event in a medical inpatient.
- Case #3 reports a missed diagnosis of ectopic pregnancy in a primary care practice.

The cases are based on actual events, although facts were altered to protect patients' confidentiality and for didactic purposes. The cases illustrate how to conduct a root cause analysis — an important tool for understanding and addressing adverse events in health care.

### Guidelines for Case Study Presentation and Discussion

1. Using the *transcript* provided, a participant or the facilitator should read each case aloud. The cases are abbreviated in order to illustrate the value of an investigation of root causes (including interviews with the people involved).
  - *Teaching notes* follow the transcript of each case to highlight the major teaching points in that case. The facilitator should read these before presenting the case to the class.
2. The facilitator should invite the audience to reconstruct the event after reading the case.
  - A *sample flowchart* outlines the sequence of events in the case. This is a helpful approach for analyzing adverse events and can be elicited from the participants in a discussion.
  - A set of *interviews* with key players will help to flesh out the details of the case and allow learners to revise their reconstruction as additional information is made available.
3. A *sample root cause analysis* flags some of the immediate (proximate) causes and contributing factors (or latent causes) of each adverse event. Use pages 3.10, 3.14, and 3.18 for your own reference to complete your own flipchart pages during your root cause analysis activity. These pages can also be used as handouts for your participants.

## Guidelines for Root Cause Analysis

You may find the following guidelines helpful for developing root cause analyses of the case studies in this module. They are based on the root cause analysis template for sentinel events developed by the Joint Commission on Accreditation of Healthcare Organizations.

### 1) *Describe the event.*

Using the medical record and interviewing the important participants in the patient's care, describe in detail the event and activities leading up to it. When did the event occur? (Was it on a weekend, or during off-hours?) What service areas were affected? Specify the injury or potential injury to the patient.

### 2) *Identify the proximate cause(s) that led to the event.*

The proximate cause explains why the event occurred. For example, assume that an adverse drug reaction (the event) occurred because the doctor wrote an order for a tenfold overdose of antibiotic (proximate cause), which the pharmacy dispensed (proximate cause) and the nurse administered (proximate cause). These proximate causes of the adverse event are deficiencies in the processes of care and hence, errors. It may be helpful to construct a diagram of the event, showing the steps in the current process of care and steps where the process failed.

### 3) *Identify the contributing factors (or latent errors) that led to the proximate cause.*

Contributing factors permit errors to occur. For example, a nurse who forgot to administer a dose of medication may have been required to do a double shift. Fatigue and staff shortages would be contributing factors to this medication error. Many contributing factors fit into the following categories:

- *Human resource issues:* Was staff adequately trained and skilled? Was staffing adequate? Was there appropriate supervision?
- *Information management issues:* Was necessary information available, accurate, and complete?
- *Environmental issues:* Did the physical environment contribute to the event? Are safeguards in place to minimize and address environmental risks?
- *Leadership and culture:* Did the organizational culture impair safe care?
- *Communication:* Was communication among staff adequate?

### 4) *Create an action plan.*

This is the most important step of the analysis. The goal is to develop improvements that can be implemented and tested. How could one prevent this problem from happening again? Although education and training are important, improvements that rely on exhortation, education, and reliance on memory are unreliable. The best action plans change the process of care itself.

**NOTE TO FACILITATOR:**

Show slides 5 through 9 while reading the transcript. (The transcript is duplicated on the Notes pages of the PowerPoint file for Module III.)

**Transcript of Case #1: Post-surgical Chest Pain**

A 65-year-old Haitian man was admitted to the hospital for elective cholecystectomy. On the morning of the first postoperative day, he reported an episode of chest discomfort. The patient did not speak English, so his daughter served as interpreter. She related a ten-minute episode of sharp, left-sided chest pain at rest with mild shortness of breath.

The surgeon noted a low-grade temperature, rales at the right base on lung exam, and sinus tachycardia on the electrocardiogram (EKG). She paged the medical consultant, but the call was not returned promptly. The surgeon was called to the Operating Room (OR) for her first case. Before going to the OR, she ordered a chest radiograph to rule out postoperative pneumonia.

The patient was taken to the Radiology Department. Two hours later, the patient's daughter asked a nurse to find out what had become of her father. The nurse telephoned the Radiology Department. A technician there said that the patient would return to the floor shortly. When the patient arrived at his room thirty minutes later, his daughter reported that he had been experiencing chest pain and increasing shortness of breath for the past hour.

The surgeon was then paged in the OR. An OR nurse returned the page and — after conferring with the surgeon — requested a repeat EKG. It was completed and faxed to the surgeon. The surgeon also asked a staff radiologist to review the chest film, but the film could not be located.

Meanwhile, the patient's condition worsened. He had become diaphoretic, hypotensive, and tachypneic. His oximetry on 2 liters/hour of oxygen was 75%. A code was called, and the patient emergently intubated. A computed tomography (CT) angiogram of the chest subsequently revealed a saddle pulmonary embolus.

The chest film ordered four hours earlier was never completed.

## Teaching Notes for Case #1: Post-surgical Chest Pain

Chest pain is a common complaint in health care and one with a broad differential diagnosis. In this case, a surgeon considered several possible diagnoses, then ordered and reviewed the appropriate diagnostic tests. In this case, she incorrectly judged that the patient had an early pneumonia. Perhaps a more astute or experienced clinician would have noted the early signs of pulmonary embolus and anticoagulated the patient. The surgeon in this case sought advice from a colleague, but the colleague was not available and the surgeon was needed in the OR.

A major feature of this case is the problem of adequate monitoring for patients who require diagnostic tests and procedures. Here, the patient was abandoned in the Radiology Department until the daughter called his absence to the attention of his health care providers. There were many process-of-care deficiencies, including failure of the floor nurse to communicate the patient's status to the nurse who received the patient in Radiology; failure of the transporter to leave the patient in a safe and supervised setting; and failure of the Radiology staff to find out what the patient was doing in their department and to monitor his condition. Few hospitals have well-developed mechanisms to insure smooth transition to and from sites where patients undergo diagnostic testing. As a result, patients find themselves in limbo without a responsible caregiver.

Inadequate supervision of patients is compounded by limited staff resources and unpredictable demands for their skills. In this case, the radiology nurse was pulled into a procedure room. Hospitals cannot rely on staff members without clinical training (like transporters and technicians) to assess the clinical status of patients. The surgeon found herself in a difficult position as well, with no one to manage the patient while she was in surgery. She tried to handle the case remotely, but this was ultimately an unsuccessful strategy.

The patient's language and culture presented additional obstacles to high-quality care. The patient and his daughter were rather passive characters in the case, unable to assert themselves effectively. The patient did not appreciate the significance of recurrent chest pain and dyspnea, and he was reluctant to or incapable of obtaining help.

### *Questions for Participants*

- What processes of care should be improved in order to prevent this type of event? (Learners may suggest solutions that rely on education and training, but these approaches are not robust and are rarely sustainable.)
- What should clinicians tell the patient and his family about the day's events?
- (optional question) Are any of the characters in the case likely to be punished as a result of the incident?

**Interviews Following Case #1: Post-surgical Chest Pain (use Slide 10)*****The surgeon***

“Patients have lots of complaints postoperatively, and it’s hard to sort them out. We often see post-op atelectasis and low-grade fever after abdominal surgery. When I heard about the patient’s chest pain, I thought about angina, but the EKG looked normal to me. I wondered about pulmonary embolus, too, but his breathing seemed OK at the time. I called a medical consultant to discuss the case, but I was paged to the OR before he called back. I tried to manage the patient’s case from the OR, but it was tough to do. As the patient’s attending physician, I take full responsibility for his care. I wish I had served him better at the bedside. A reality of modern medicine is that it is hard to be in two places at once.”

***The medical consultant***

“The man was *in extremis* when I met him at the code. The suspicion was high for pulmonary embolus, so we started heparin and transferred him to the ICU. His first EKG showed the characteristic signs of a PE. It’s too bad that I wasn’t involved when he first developed symptoms. I was paged to the patient’s floor earlier in the day, but no one answered the phone when I called. I didn’t realize until later that this patient needed my help.”

***The transporter***

“I brought the patient downstairs to the Radiology Department. I didn’t see anyone there, so I waited with the patient for a while. I was paged to the Emergency Room to bring a critical patient to the ICU, so I had to go. One of the procedure rooms had a big light that said ‘XRAY IN USE – DO NOT ENTER.’ I was surprised that the patient was still in Radiology when they called me two and a half hours later. There was no one around, so I assumed the test was done. He didn’t look well when I took him upstairs.”

***The radiology nurse***

“It was a very busy day. I was involved in several complicated procedures. When I came out of the fluoroscopy suite, there was a man sleeping in our holding area. He was not my patient, so I assumed the other nurse was following him. In the half-hour I spent in the holding area, she did not come to check on him. The patient tried to tell me something when he woke up, but I couldn’t understand him. They needed my help in the procedure room with a bleeding vessel, so I was not able to find his nurse. When I came out, the patient was gone.”

***The radiology technician***

“I just answer the phone. I got a call at the start of my shift from a nurse on the surgical floor about the patient. He was in the holding area. I called transport to take him upstairs. He said something I did not understand and looked upset and uncomfortable.”

***The patient (translated by daughter)***

“They put me in the stretcher and took me to a big room. My daughter told me they were going to take a picture of my heart, and so I waited. I fell asleep for a while, but the pain in my chest woke me up. I had pain with every breath. A nurse was there, I told her about the pain, but she didn’t understand and walked away. I tried to tell a doctor about it, but they took me upstairs. At first I thought the pain would go away, but then it got worse. I tried to sit up, so I could breathe better. It took a long time for a doctor to see me, and by then I was very sick.”

**Sample Root Cause Analysis for Case #1: Post-surgical Chest Pain**

<i>What Happened? Proximate Cause</i>	<i>Why did this happen? Contributing Factors</i>	<i>Risk Reduction Strategy Action Plan</i>
Surgeon delayed diagnosis of pulmonary embolus	1. Lack of adequate experience to recognize complication	<ul style="list-style-type: none"> <li>• CME training on complications of care</li> <li>• Develop postoperative chest pain guidelines</li> </ul>
	2. Limited access to and slow response of a medical consultant	<ul style="list-style-type: none"> <li>• Use text pagers or create voice mail to leave message if unable to return pages quickly</li> </ul>
	3. No clinical back-up available when patient became ill on the floor and while attending surgeon was operating	<ul style="list-style-type: none"> <li>• Create system of clinical back-up on floor using a second surgeon, physician assistant, or nurse practitioner</li> </ul>
Transporter left patient in Radiology without notifying a responsible party	4. Overworked staff	<ul style="list-style-type: none"> <li>• Training of transporters</li> </ul>
	5. Poorly designed process for handing off care in diagnostic testing	<ul style="list-style-type: none"> <li>• Require that hand-offs be made in person</li> <li>• Develop communication card that stays with patient, outlining clinical issues</li> </ul>
	6. Environment not conducive to communication with staff in procedure rooms	<ul style="list-style-type: none"> <li>• Require nurse-to-nurse sign out for tests and procedures</li> </ul>
Radiology nurse did not monitor the patient or complete task of finding the responsible nurse	7. Party responsible for the patient was not well specified	<ul style="list-style-type: none"> <li>• Increase staffing</li> <li>• Clearly outline duties of nurse in holding area</li> </ul>
	8. Nurse was distracted by competing clinical responsibilities	<ul style="list-style-type: none"> <li>• Redesign workflow to facilitate communication between floor nurses and Radiology staff</li> </ul>
Neither technician nor nurse recognized that patient was in distress	9. No interpreter available 10. Patient not assertive	<ul style="list-style-type: none"> <li>• Improve access to interpreters; allow daughter to accompany patient to diagnostic testing</li> <li>• Require routine assessment, including vital signs, for patients at diagnostic testing for more than one hour</li> </ul>

**NOTE TO FACILITATOR:**

Show slides 13 through 15 while reading the transcript. (The transcript is duplicated on the Notes pages of the PowerPoint file for Module III.)

**Transcript of Case #2: Adverse Drug Event**

An 88-year-old woman with dementia, a history of hypertension, and coronary artery disease (post coronary artery bypass graft) was sent from her nursing home to the Emergency Department for worsening confusion. She had been admitted to the hospital six weeks earlier and treated for urosepsis, at which time an allergy to levofloxacin was noted.

Initial evaluation revealed leukocytosis and pyuria, but no fever or flank pain. The Emergency Department physician concluded that a urinary tract infection was the most likely cause of the patient's altered mental status and elected to treat her with levofloxacin.

The first dose was administered on the medical floor shortly after the patient arrived.

Over the next six hours, the patient became increasingly agitated and required sedation and restraint. She developed a diffuse erythematous rash across the chest and back, swollen lips and tongue, and audible wheezes. Concern was raised of an anaphylactic reaction. She was transferred to the Intensive Care Unit (ICU) where she was treated with intravenous corticosteroids, an antihistamine, and inhaled beta agonists. The levofloxacin was changed to an intravenous cephalosporin.

After the event, the patient's paper chart was brought to the ICU from the Medical Records Department. The discharge summary from her previous admission reported an allergic reaction to levofloxacin. The patient's daughter, on arrival to the hospital later that evening, was exasperated to learn of her mother's condition. She said, "You're supposed to help her get better, not worse!"

## Teaching Notes for Case #2: Adverse Drug Event

Adverse drug events (ADEs) are common in medical care. In two Boston teaching hospitals, Bates and colleagues reported that ADEs affected 6.5 percent of medical and surgical inpatients. Twenty-eight percent were judged preventable. Preventable ADEs occurred most often during prescribing (56 percent) and administration (34 percent). (Source: Bates et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. ADE Prevention Study Group. *JAMA* 1995; 274:29-34.)

In a companion study, Leape analyzed the underlying problems in the medication prescription, dispensing, and delivery system. Many major systems problems were identified, including problems with dissemination of drug knowledge, inadequate availability of patient information, and deficiencies in the “allergy defense.” (Source: Leape et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995; 274:35-43.)

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In this case, the patient experienced a serious preventable adverse drug event. The case is tragic in that information about the patient’s allergy was available from several sources, including the patient’s family, the medical record, and perhaps the medical director of the nursing home. Unfortunately, responsible clinicians did not have the right information at the right time to prevent an anaphylactic reaction.

The ED physician reviewed the records available to him and made a reasonable choice of medication to treat her condition. He did not probe deeply because he did not suspect a problem and because he needed to address an incoming trauma case. Like the ED physician, the floor nurse felt pressured to administer the drug. She was motivated by a desire to treat the patient promptly and by workload demands.

The pharmacist bemoaned the fact that the hospital’s sophisticated electronic pharmacy information system identifies drug allergies only when key data is entered in the system. How do we insure that physicians and nurses communicate critical clinical information to the pharmacy?

### *Questions for Participants*

- Should the nursing home physician confer with the Emergency Department physician at the time of ED evaluation?
- Should a demented patient wear a medical alert wristband?
- Is there a trade-off between clinicians’ attempts to provide timely care — such as rapid administration of antibiotics and other treatments — and safety?

**Interviews Following Case #2: Adverse Drug Event (Use Slide 16)*****The Emergency Department Physician***

“I saw the patient and requested her records. I thought about treating her UTI with a cephalosporin, but the nurse told me the patient had very thin veins and tenuous IV access. I thought a quinolone made sense because you can take it orally. I reviewed the transfer sheets from the nursing home record and saw no note of an allergy. Unfortunately the patient was too sick to tell me about her allergies. I wish I’d waited for the chart to come up from Medical Records, but there was a trauma case coming in and we needed the bed.”

***The floor nurse***

“It was a busy day. We had four admissions all at once. I settled the patient and went on to help the other nurses. I administered all my patients’ medications, but I didn’t get a chance to sit down and do my paperwork until the end of the shift. I then remembered hearing about the patient’s last admission and recalled there was an allergic reaction to levofloxacin. But by that time, she was already wheezing and swollen. We all rely on the doctors and pharmacists too much to get the order right.”

***The pharmacist***

“What a catastrophe! I remember receiving the order for levofloxacin. The pharmacy computer showed that the patient had no known drug allergies. We dispensed the drug and sent it up to the floor. Although the pharmacy computer keeps a record of every drug allergy that is brought to our attention, there is no consistent way that the information gets to us. If it is written in an admission note or discharge summary but not on the physician order sheet, there is no way we would learn of the allergy. We do the best we can, but we need some help from the clinicians.”

***The daughter***

“I am beyond exasperated. I know that things are busy and that the doctors and nurses here try to do the right thing, but they ought to know better than to give my mother a medicine she’s allergic to. If you can’t get a simple thing like that right, how can patients expect that you’ll get it right when you do something complicated? What’s so hard about saving allergy information in a single place so everyone can find it? I know all about my mother’s allergies and medications. Why couldn’t somebody give me a call?”

**Sample Root Cause Analysis for Case #2: Adverse Drug Event**

<i>What Happened? Proximate Cause</i>	<i>Why did this happen? Contributing Factors</i>	<i>Risk Reduction Strategy Action Plan</i>
ED physician prescribed drug to which patient was allergic	1. Medical record did not arrive in timely way 2. Nursing home data was incomplete	<ul style="list-style-type: none"> <li>• Pharmacy reviews discharge summaries for allergy information</li> </ul>
	3. Workload and trauma case distracted MD’s attention	<ul style="list-style-type: none"> <li>• Increase staff resources in the Emergency Dept.</li> </ul>
	4. MD assumed pharmacy would double-check order 5. MD failed to call nursing home MD or family to confirm allergies	<ul style="list-style-type: none"> <li>• Secure urgent access to medical records for patients in the ED</li> </ul>
	6. Patient unable to answer questions about medical history	<ul style="list-style-type: none"> <li>• Provide patients with allergy information wrist bands</li> </ul>
Pharmacy dispensed medication to which patient was allergic	7. Allergy not documented in the pharmacy computer during previous admission	<ul style="list-style-type: none"> <li>• Educate staff</li> <li>• Centralize and integrate a single electronic medical record</li> </ul>
Nurse administered drug to which patient was allergic	8. Nurse unable to check records until late in day because of workload	<ul style="list-style-type: none"> <li>• Address staffing and workload issues</li> </ul>

**NOTE TO FACILITATOR:**

Show slides 19 through 22 while reading the transcript. (The transcript is duplicated on the Notes pages of the PowerPoint file for Module III.)

**Transcript of Case #3: Missed Ectopic Pregnancy**

A 35-year-old woman presented to her physician's office complaining of three weeks of painless vaginal bleeding. She called her primary care physician's office for an appointment, but he was away. The patient met with an associate instead. The covering physician obtained the following history:

The patient's last menstrual period began three weeks prior to the visit, on time but scant. Other than uterine fibroids, she had no significant past medical history. She took no medications or herbal remedies. Her general physical examination was unremarkable. She was afebrile, and there was no evidence of orthostasis or pallor. On pelvic examination, there was blood at the cervical os and a nongravid uterus with several small masses consistent with myomas. There was no cervical motion tenderness.

The covering physician thought that a bleeding due to a fibroid was the most likely diagnosis but could not rule out annovulation, incomplete abortion or uterine polyp from the differential diagnosis. He obtained cultures for chlamydia and gonorrhea. He ordered a CBC and a blood pregnancy test.

He instructed the patient to call the next day for laboratory results and prescribed a five-day course of medroxyprogesterone acetate.

When the patient called the office for test results, a nurse told her that her physician would get back to her by the end of the day. The patient called the office again the next day, but received no return call.

She continued to bleed. With no instruction from her primary care doctor and increased fatigue, she arrived at the hospital Emergency Department with orthostasis, tachycardia, and tachypnea. The hematocrit (HCT) was 14%. Pelvic ultrasound showed a ruptured ectopic pregnancy. She had emergency laparoscopic surgery that required a salpingectomy. The hospital course was complicated by hypotension and sepsis.

## Teaching Notes for Case #3: Missed Ectopic Pregnancy

Diagnostic errors are common in health care, accounting for 22 percent of adverse events in one large study of hospitalized patients. We know relatively little about the prevalence of medical errors among outpatients, but it may be substantial. Missed diagnoses account for a large share of malpractice claims.

This case features a cascade of errors, beginning with the missed diagnosis of ectopic pregnancy. The “miss” reflects the atypical presentation of a potentially catastrophic condition. Because of its myriad presentations and potentially serious consequences, many physicians assume pregnancy in women of reproductive age with pelvic symptoms until proven otherwise.

The covering physician ordered a blood pregnancy test to rule out an incomplete abortion. His failure to follow up on the test is a professional lapse that makes him vulnerable to malpractice claims and administrative sanction. Legally and professionally, a clinician is responsible for a patient’s care until the work-up is complete or another clinician takes over. The problem with this narrow view of physician error is that it does not take into account the defective processes of care that permit errors to occur.

This case demonstrates several flawed processes of care. The nurse, for example, followed standard operating procedures by asking the primary care doctor to report a positive test result. Certain test results merit urgent attention and can not wait for a routine call-back. A positive pregnancy test in the right clinical setting is of equivalent urgency to a patient who calls in with chest pain or suicidal intent.

The process is also problematic because it relies on timely and accurate exchange of clinical information among care providers, the laboratory, and the patient. Neither the covering physician nor the nurse communicated directly with the primary care doctor. There was no note available in the medical record. The laboratory report did not make it to the attention of the primary care physician. No one elicited from the patient the clinical information necessary to assess the significance of her test results. The primary MD did not return her messages in a timely fashion.

This case would turn out differently if providers changed the process of care. For example, providers could implement point-of-service pregnancy testing, so relevant laboratory data would be available immediately. Practitioners need to standardize the messaging system in the practice. A clinician could review all pregnancy tests each day to follow up on positive results. Alternatively, nurses should be allowed to report pregnancy test results, guided by an algorithm that prompts patients about pain and fever.

### ***Question for Participants:***

***What current practices would you consider to be “best practices” in...***

- *Communications among PCPs, their practice associates, and specialists on referral*
- *Communications between providers and ordered services (e.g., lab, pharmacy)?*

**Interviews Following Case #3: Missed Ectopic Pregnancy (Use Slide 23)*****Patient***

“They tell me that I will recovery fully, but I worry about my fertility. I want to have a baby, but now there’s only one ovary and maybe some scarring on the tubes. I could get another ectopic pregnancy. I’m angry with myself for not being more assertive with the nurse at my doctor’s office. I should have insisted that she give me my test results and explain what they meant. I don’t understand why the doctor never called me back.”

***Covering Physician***

“I feel horrible about this case. She was a healthy young woman with painless vaginal bleeding. If only I’d followed up the lab tests myself before going out of town. I was in a hurry and didn’t have time ... and she seemed like a very responsible person. I thought that ectopic pregnancy was very unlikely without fever or pain and with symptoms that had gone on for almost a month.”

***Nurse***

“I haven’t slept well since this poor woman was admitted to the hospital. It feels like it was my fault. We have an office policy that physicians give patients their positive test results. I thought that the positive pregnancy test was good news and wanted to let the doctor tell her patient about it. I looked in the chart to see if there was something unusual going on in the case, but the covering physician’s dictated note was not back yet. The patient didn’t say anything that made me worry about a serious problem.”

***Primary Care Physician***

“This case was a comedy of errors. I was away when the patient came in initially. My associate saw her but didn’t sign out the case to me because he did not expect any life threatening problems. The laboratory report of the pregnancy went to his desk as the ordering physician, not mine. I received a message to call the patient late in the day on Friday, but I didn’t get to it because I was still catching up on work and messages from earlier in the week. I wonder if we will be sued?”

**Sample Root Cause Analysis for Case #3: Missed Ectopic Pregnancy**

<i>What Happened? Proximate Cause</i>	<i>Why did this happen? Contributing Factors</i>	<i>Risk Reduction Strategy Action Plan</i>
Covering MD missed diagnosis of ectopic pregnancy	1. Atypical presentation	• Provider education
	2. Failure to check laboratory tests	• Point-of-service pregnancy testing
	3. Failure to consult specialist	• Expedited referral process; improved instructions to patient about what to do if symptoms persist
RN did not disclose laboratory results to patient	4. Dictated progress note not yet in chart	• Require brief written note on urgent-case visits
	5. Important clinical information not elicited from patient	• Revise and update protocol for disclosing laboratory information to patient
Primary MD did not call patient back in timely fashion	6. Covering MD did not sign out case	• Create expectation for formal written sign out
	7. Message from nurse was not sufficiently detailed	• Page provider directly  • Update office messaging system and expectations regarding returned calls
	8. No clear office standard for return calls	• Provide patients with e-mail access to primary care MD

When you have finished the root cause analysis and conclusions (slide 25) for this case, you have completed Module III.