

First, Do No Harm

Part 1: A Case Study of Systems Failure



Facilitator's Guide

p4ps

Partnership for Patient Safety



Drawn from closed malpractice claims files of the Risk Management Foundation of the Harvard Medical Institutions

RISK MANAGEMENT FOUNDATION
HARVARD MEDICAL INSTITUTIONS



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Modern health care presents the most complex safety challenge of any activity on earth. However, we have failed to design our systems for safety, relying instead on requiring individual error-free performance enforced by punishment, a strategy abandoned long ago by safer industries such as aviation and nuclear power.

Leape, et al. Journal of the American Medical Association. October 28, 1999.

Introduction

First, do no harm is a 17-minute composite of three real (CRICO) closed malpractice cases. Although the patient is an expectant mother, the video is intended to stimulate discussion about system issues associated with a broad spectrum of care delivery and patient safety issues, not just obstetrical care.

The nature of systems is that they will produce the results they've been "designed" to produce. The goal of this educational opportunity is to help providers assess their current systems and design new ones. Improved systems will produce fewer errors, enable efficient adjustments when errors do occur, and help create a data base so that specific errors are not repeated.

Overall Objectives of an Educational Session Based on *First, do no harm*

- Provide examples of system problems that stimulate discussion of opportunities for improvement.
- Address organization and corporate culture issues that may contribute to medical error and patient injury.
- Increase knowledge of the types of errors, their consequences, and deeper causes.
- Heighten clinicians' awareness of their role in complex systems to facilitate identification of significant breakdowns or "gaps" in the care continuum.
- Stimulate discussion of characteristics of organization and systems that could prevent patient injury.
- Raise awareness of the emotional and physical toll on patients and providers when medical errors are made.
- Highlight strategies for reducing risk of malpractice litigation (especially in obstetrics).

Participants viewing and discussing the video should be able to identify actual and potential system failures that contributed to suboptimal care. Subsequently, they'll have a better understanding for creating action plans to prevent similar occurrences in their own practice settings.



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Planning a session for viewing *First, do no harm*.

1. Meet or talk with the planner or organizer of the session if possible.
2. Discuss any specific objectives they may have for the session.
3. Determine the likely composition of the audience:
 - Multi-specialty;
 - One specialty (which one);
 - Clinicians only;
 - Clinicians and administration;
 - Mixed clinical professions (nurses, NPs, PAs, CNMs, etc.);
 - All participants from one institution (or from several).
4. Decide whether to contact or prepare any audience member or segment in advance.
5. Determine the length of time allowed for the session.
6. Determine whether the space for the session can accommodate a VCR and whether the equipment available is compatible with space and the size of the audience.
7. View the video several times with above information in mind.
8. Develop appropriate opening questions.



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Presenting the Session

1. Introduce the video (suggested script):

This video was created using facts from three closed medical malpractice cases from the CRICO files. They were selected because they illustrate common and systemic causes of conditions that often result in patient harm. Although the cases presented in the video focuses on obstetrical care, the events can be generalized to other care delivery settings. For instance, the prenatal clinic scenario could be any physician's office or any clinic setting. The operating room scenes could be played out in ambulatory and other inpatient surgeries. As you view the video think systems issues rather than individual performance—all caregivers portrayed are doing their best. Our goal in creating, showing, and discussing this video is to assist you in making complex systems in your delivery system better for you as you care for patients and safer for the patients you care for.

NOTE: Audiences react differently based on their professional and personal experience and background. You may want to tell the audience that although the content is not medically graphic, it contains very emotional scenes.

2. Take notes while the audience is watching the video, writing down any reactions from participants that may help frame the opening question
3. After the final scene ends, let the silence sit for 8-10 seconds, either while you let the credits roll or after you've turned off the VCR after the last scene.
4. Lead with the question you chose or acknowledge someone who appears ready to speak.
5. Examples of opening questions:
 - What scene was the most compelling for you and why?
 - Name a communication breakdown that you have personally experienced and tell us what happened as a result.
 - Name one problem that you saw that you could personally do something about in your practice setting.
 - What were some of the systems issues that you identified?
 - Do you think any of this could happen in your institution/practice?
 - Choose a scene and tell us how you would handle whatever the person was confronted with.
 - Put yourself in _____'s place and tell us what you would do next.
 - Do you have a policy or procedure that could help create any of the problems we saw?
 - Is there one situation that you have encountered and you fixed something so that an error was avoided?
6. If you and your audience prefer to explore specific segments of the video, scene summaries are provided on the following pages.



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Scene 1: Initial OB Appointment & Scheduling of Follow-up

IN CUE: "This is all strictly routine."

OUT CUE: "We will see you then."

Description

The Romanovs' doctor escorts them out of her office, reiterating plans for next visit; the couple attempts to make next appointment consistent with what they understand to be their doctor's orders.

Theme

The physician relies on the system to help her care for the patient in the way she determined was optimal. In their attempt to comply with the physician's plan, the patient and her husband encounter administrative difficulties they are unprepared to handle.

Learning Objectives

- Recognize the role that support staff can play in the care continuum
- Identify clinicians' role for monitoring the effectiveness of administrative systems
- Determine how the Romanovs could have been supported through their task of making a follow-up appointment.
- State one piece of advice you would give the Romanovs at this point.

Discussion Points

- Do you have a policy that could help to create this particular set of circumstances in your office (or in your institution)?
- How would you handle the situation that confronted this support person?
- What would have been an ideal scenario?
- What responsibilities do each of the players have in this actual scenario? What is the responsibility of the institution?, the physician?, the scheduling staff member?
- What effect do cultural issues have on the difficulty the Romanovs are experiencing?

Contributing Factors

Accident prone procedure
Clinician/patient-family communication

Clutter

Distractions

Fatigue

Fear

Frustration

Handoffs

Human Factors

Language Barrier

MD/MD Communication

Noise

Nurse/MD communication

Nurse/nurse communication

Provider hierarchy

Scheduling system

Stress

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Technology

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Scene 2: Patient in Pain at OB Triage Area

IN CUE: "So, you got something for me?"

OUT CUE: "It shouldn't be very long."

Description

The Romanovs arrive at the OB triage area with Mrs. Romanov in distress. They are confronted with procedures (and language, oral and written) that they do not understand and are told to wait in an area that is remote and invisible to the staff.

Theme

Patient encounters potentially hostile conditions at times when she is vulnerable (e.g., in pain, frightened, confused). The staff is distracted and the physical space is complicated to navigate.

Learning Objectives

- Recognize the role that the support staff can play in the care continuum.
- List the issues that may have contributed to the confusion surrounding the Romanovs visit to triage.
- Describe how the Romanovs could have been treated differently that may have altered the outcome of the case.
- State one piece of advice you would give the Romanovs at this point.

Discussion Points

- What are the human factors that may have contributed to the Romanov's experience at this stage?
- What could the support person have done differently? What policy/procedures was she following ?
- What cultural issues may have contributed to their experience?
- What advice would you give to the Romanovs at this point?
- Are there systems in your institution that could lead to similar problems?

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Scene 3: Triage Exam Room

IN CUE: "When it rains, it pours."

OUT CUE: "I know, I know."

Description

Mrs. Romanov has been moved to a triage exam room after spending more than two hours in pain in a remote waiting room. Seemingly, no one communicated with them during that time and the Romanovs seem to be unfamiliar with either the routine of the institution or what is happening to Mrs. Romanov at this point.

Theme

Patient is confused about what should be happening next, including why a physician has not seen them yet, what questions to ask and how to secure the attention they need. The providers are confused about the patient's history and about the presenting symptoms. Other patient needs supercede. The nurse introduces an unknown and frightening terms and does not explain them.

Learning Objectives

- List the communication issues that are affecting the patient's care at this time.
- Discuss how the environment may affect the nurses' ability to focus on the Romanovs needs at this point.

Discussion Points

- How are language/cultural difficulties becoming more important at this stage in Mrs. Romanov's care?
- What information does the nurse have about Mrs. Romanov at this point and where/how has she obtained it?
- How can the nurse get more information to pass on to labor and delivery?

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Scene 4: *Handoff to Labor and Delivery*

IN CUE: I'm so hungry I can't think straight."

OUT CUE: "I'm going to try to get the IV started for you, okay?"

Description

Mrs. Romanov is transferred to labor and delivery where she encounters new providers who seem equally unclear about her history.

Theme

The patient now encounter new providers and counts on them to have enough information to care for her and tell her what to expect next. The providers are not communicating very well with one another and certainly not with the patient or her husband. The atmosphere is rushed, and the handoffs appear hurried and inefficient.

Learning Objectives

- Discuss the human factors that contributed to the issues in this care.
- Discuss how multiple handoffs increase the opportunity for error.
- List some of the issues you identified in this scene that are common in your practice setting.

Discussion Points

- What are some human factors that may contribute to the difficulties with Mrs. Romanovs care? (See an example of a tool to use with human factors following these discussion questions.)
- What role are cultural issues playing in the care of this patient?
- What information about fetal monitoring results are being shared at this point among the caregivers? What is being shared with the patient?
- In what ways should communication among the care team be altered when there is a new member of the team?

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Scene 5: Resident interaction/Medical Student/ Patient to OR

IN CUE: "We have the asthma under control."

OUT CUE: "Can somebody call peds?"

Description

The OB resident interacts with nurses; a medical student is assigned to see Mrs. Romanov and surmises, via the EFM, that something is wrong. The resident is called and Mrs. Romanov is rushed to the C-section room.

Theme

The patient observes that the atmosphere is tense and providers are confused. Everyone is anxious about the outcome. Communication between caregivers is inadequate and exacerbates the confusion.

Learning Objectives

- Examine how communication between Jones and the resident may have affected Mrs. Romanov's care.
- Discuss how the unit may need to change staffing procedures when the level of activity increases.
- List pieces of information that should have been conveyed to the resident
- List the human factors that may have contributed to delay in getting Mrs. Romanov to a C-section

Discussion Points

- How could Nurse Jones' request to the resident to see Mrs. Romanov been phrased differently?
- Should a "chain of command" decision have been made by Nurse Jones when resident chose to send a medical student to see the patient? What would have been the implications of such a decision?
- What information should have been conveyed to the Romanovs before Mrs. Romanov was taken to the OR?
- What information should have been conveyed to Mr. Romanov after his wife was rushed away?

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Scene 6: OR Interaction

IN CUE: "Another rush section..."

OUT CUE: "We need an emergency trach..."

Description

The anesthesiologist is having trouble administering an epidural to Mrs. Romanov. The surgeons are anxious to deliver a healthy baby and decide to proceed after general anesthesia is given, even though an airway has not been established.

Theme

Competing patient interests (mother vs. baby), emergency situations, pre-existing hierarchical methods of communication all impact the caregivers performance and the patients' safety. Communication with the patient diminishes during the crisis.

Learning Objectives

- Discuss how real or perceived hierarchy affects communication
- List three changes in this OR that could improve communications.
- Discuss how stress contributes to errors

Discussion Points

- What information should the care team have been exchanging about Mrs. Romanov that may have lead to a more positive outcome?
- How can unfamiliarity with the physical plant contribute to an emergency situation?
- How could "corporate culture" have contributed to the lack of communication in the OR?

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Scene 7: Medication Error and Recovery

IN CUE: "Okay people, we have a baby boy."

OUT CUE: "...the toxicities."

Description

The Romanovs baby is delivered, successfully resuscitated, and given medication. A medication error is quickly discovered and disclosed, and immediate action is taken to mitigate possible adverse effects.

Theme

The design and arrangement of the physical space of the OR and the general commotion of a surgical emergency are demonstrated. Swift recognition and reporting of an error impacts the eventual outcome.

Learning Objectives

- Discuss how medication packaging and nomenclature can add to the opportunity for errors.
- Discuss how individuals in stressful situations are likely to resort to 'what they know,' or confirmation bias, when reading a label or picking a medication vial from a shelf.
- List three ways in which one can minimize the opportunity for errors associated with look-alike medication packages and names.
- Discuss the elements of a culture of safety as demonstrated by this scene.
- Discuss the impact of adverse events on clinicians, creating the "second victim."

Discussion Points

- Describe a culture of safety as it might relate to medication administration
- What are the human factors that may have contributed to this medication error?
- What are some steps that this institution could do to avoid such an error occurring again?

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Case Outcomes

Many participants want to know the outcomes of the cases used to create *First, do no harm*. Brief explanations are included below:

The first case includes the action from the beginning of the video up to the OR scene. The infant was born with Apgars scores of 0 and suffers from profound cerebral palsy with an approximate life expectancy of 10-12 years.

In the second case, which begins with the OR scene, the mother (who, in the real case, was admitted for an elective cesarean-section) suffered an anoxic brain injury due to a difficult intubation and died five weeks later in the ICU. Her baby was fine.

The third case (medication error) begins with the delivery of a healthy baby. After the medication mixup, the baby suffered some mild seizures but had no other clinical sequela. He remains in good health. The second victim in this third case was the nurse. Because she disclosed her mistake quickly and candidly, the providers were able to marshal the proper resources and perhaps prevent further harm to the infant. We believe, however, that she left nursing as a result of the emotional impact of this event.

System Improvement Measures (Now in Place)

As a result of these cases, several positive systems changes were implemented in the institutions in which the problem occurred:

- Improved procedures for change of shift reports
- More timely transfer of patients from triage to L&D, with overlapping staff
- Improvements in teamwork
- Clarification and standardization of policies
- Improved procedures concerning availability of code teams for all births in which there is a question of fetal distress
- Redesigning waiting areas so that patients are visible to the staff
- Redesign of work flow to accommodate high activity periods when necessary.

Recommended Change Concepts to Address Problems Demonstrated in *First, do no harm*.

Automate carefully

Differentiate/eliminate look-alike and sound-alike packaging and products

Drive out fear

Improve access to information

Improve direct communications

Increase immediate feedback

Obtain leadership commitment

Optimize the work environment for safety

Reduce handoffs

Reduce multiple entry

Reduce reliance on memory

Reduce reliance on vigilance

Simplify the process

Standardize

Train for teamwork

Use constraints and forcing functions

Use protocols and checklists wisely



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Additional Readings

- Bates DW, Gawande AA. Error in Medicine: What Have We Learned? *Annals of Internal Medicine*. 2000;132(9):763-67.
- Berwick DM, Leape LL. Reducing Errors in Medicine. *British Medical Journal*. 1999;319 (7203):136-37.
- Cook R, Woods D. Operating at the Sharp End: The Complexity of Human Error. IN Bogner MS Ed., *Human Error in Medicine*. Hillsdale, NJ. 1994.
- Cook R, Woods D, Miller C. Tale of Two Stories: Contrasting Views of Patient Safety (Report from a Workshop on Assembling the Scientific Basis for Progress on Patient Safety). Chicago, IL; National Patient Safety Foundation. 1998. (available as PDF from www.npsf.org).
- Keyes C. Responding to an adverse event. *Forum – Risk Management Foundation of the Harvard Medical Institutions, Inc.* 1997;18 (1):2-3.
- Leape LL, et al. Promoting patient safety by preventing medical error. *Journal of the American Medical Association*. 1998;280(16):1444-47.
- Quality Interagency Coordination Task Force (QuIC). Doing what counts for patients safety. Federal actions to reduce medical errors and their impact. (Report to the President). 2000. <http://quic.gov/report/indexframes.htm>.
- Reason J. *Managing the Risks of Organizational Accidents* Cambridge, England: Cambridge University Press. 1997.
- Reason J. *Human Error*. New York: Cambridge University Press. 1990.
- Stelovich S. (1997, April). Framework for handling adverse events. *Forum – Risk Management Foundation of the Harvard Medical Institutions, Inc.* 1997;18 (1):4-5.
- Weingart SN, et al. Epidemiology of Medical Error. *British Medical Journal*. 2000;320(7237):774-77.
- Woods, D., (1988). Coping with Complexity: The Psychology of Human Behavior in Complex Systems. In Goodstein L. Anderson H., Olsen S. ed.s, *Tasks, Errors and Mental Models*. New York: 1998.



Glossary of Contributing Factors

Accident prone procedure

Certain procedures (e.g., emergency C-sections) repeatedly incur problems and complications. Recognizing these high-risk procedures can help providers reduce the chance of error.

Clinician/patient-family communication

The more comfortable and trusting the relationship, the more likely patients are to pursue information they feel is lacking or unclear.

Clutter

A disorganized and/or overcrowded desk, office, or treatment area, at the very least, gives the impression of inefficiency and increases the risk for error.

Distractions

Multiple simultaneous demands being made on the clinical staff diminishes their ability to focus on any one point, including the patient's safety.

Fatigue

Physical tiredness and sleep deprivation are often facts of hospital life and, therefore, need to be recognized as potential risk factors.

Fear

Patients, or clinicians, who are intimidated by brusque or distracted caregivers may be reluctant to "bother" them with important questions or feedback.

Frustration

Time pressure, staffing constraints, unfair media attention, and systems that are difficult to use or often require "rework" can lead clinicians to think that quality patient care is impossible to deliver.

Handoffs

Clinicians who pass off, or receive, patients while distracted with other tasks risk the loss of important information about the patient's history, status, or short-term needs.

Human factors

Compensating for inconveniences we face while interacting with complex systems, our environment, and our colleagues can generate unexpected, and potentially risky downstream, consequences.

Language barrier

Misleading, or misunderstanding, patients or co-workers who do not share a common language is an increasing risk in the ever diversifying health care environment.

MD/MD communication

Even within the same specialty, a failure of physicians with a common patient to share, listen, and confirm comprehension can put patients at risk.

Noise

The cacophony and volume of ambient sounds can interfere with the ability to obtain and share important patient information.

Nurse/MD communication

A breakdown of physicians' and nurses' abilities to share, listen, and confirm comprehension can put patients at risk.

Nurse/nurse communication

A failure of nurses with a common patient to share, listen, and confirm comprehension can put patients at risk.

Provider hierarchy

Pertinent patient information must be communicated effectively among caregivers regardless of differences in "rank" if errors are to be minimized.

Scheduling system

Systems that do not allow for independent user judgment in exceptional circumstances can allow mistakes to happen.

Stress

Multiple simultaneous demands, emotionally charged atmosphere, and physically exhausting work can stretch providers' patience, allowing errors to occur.

Teamwork

Even the most competent individuals can deliver suboptimal care if they cannot work together.

Technology

Overreliance on "usually" reliable technology can result in a failure to recognize risks when the technology fails.

Unnatural workflow

If care happens outside a routine pattern, and the caregivers suffer from poor communication or teamwork skills, patients can be at risk.



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