



**World Health
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Patient Safety
A World Alliance for Safer Health Care

**Patient Safety
Research Introductory
Course
Session 1**

What Is Patient Safety?

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Aim

To describe the fundamental concepts of the science of patient safety, in their specific social, cultural and economic context



Overview

- 1) Introduction
- 2) Theory
- 3) Examples
- 4) Interactive
- 5) Conclusions



Questions for Lecture 1

1. **Descriptive research is always better than inferential research.**
 - a. True
 - b. False

2. **When is doing qualitative research especially helpful?**
 - a. When you want to understand the reasons behind a safety issue
 - b. When you do not have enough resources to do a large, prospective, quantitative study
 - c. both a and b
 - d. neither a nor b

3. **When does it make most sense to do an observational research study?**
 - a. When the human subjects committee requires it
 - b. When the magnitude of a problem isn't known
 - c. When you want to find out whether or not a solution worked
 - d. When you have tested a solution and found that it didn't work well
4. **What is the strongest research design type?**
 - a. Cross-sectional
 - b. Survey
 - c. Retrospective
 - d. Prospective



Common Types of Error

- A nurse gives a patient a 4 X overdose of methotrexate; the patient dies
- A physician removes the wrong kidney
- A patient receives a 10 X overdose of insulin, goes into shock, is resuscitated, but has persistent brain damage.



Case

- 64 year old woman is admitted to hospital with fevers. Presumed diagnosis of pneumonia, treated for that with penicillin. On day 2, she develops a severe rash, felt to be caused by her infection. Involves entire body. Service is very busy. No senior doctor available. Penicillin continued. Rash progresses. On day 4 she is confused, gets out of bed at night, floor is wet, and she slips and falls, fracturing hip. Dies on day 7.
- What happened?



Causation

- Individuals made errors
 - *Junior doctor didn't know what was causing rash*
 - *Senior doctor wasn't available*
 - *Nurse wasn't there when patient got out of bed*
- However, the system also allowed errors to slip through
 - *No good approach for dealing with very busy period*
 - *Insufficient nurse staffing at night*
 - *Operating room was too full and no surgeon available*



The Burden of Unsafe Care

- Adverse events due to medical devices & medications:
 - Good data from developed nations
 - Very little data from developing / transitional nations
- Surgical errors, health-care associated infections
 - Common sources of harm in all nations
 - Preliminary data from developing / transitional nations
- Unsafe blood products
 - Likely major cause of harm in some developing nations
 - Reasonably good data from select nations (WHO)
- Patients safety among pregnant women and newborns
 - Better data needed from developing / transitional nations



The Burden of Unsafe Care: Developing Countries

Mothers and newborns

Maternal mortality rates:	
North America:	1 in 3700
Asia (some countries):	1 in 65
Africa (some countries):	1 in 16



% deliveries in developing countries attended by health professional: 53%



The Burden of Unsafe Care: Unsafe Injections

- 16 billion injections a year in developing countries
- 39.6% with syringes and needles reused non sterilized (70% in some countries)
- Unsafe disposal can lead to re-sale of used equipment on the black market.



The extent of harm caused by unsafe injections is unknown



Unsafe Blood, Counterfeit Drugs

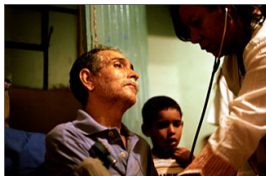
- 5–15% of HIV infections in developing countries are due to unsafe blood
- Unsafe blood risks transmission of: hepatitis B & C syphilis, malaria, Chagas disease and West Nile fever
- Counterfeit drugs account for up to 30% of medicines consumed in developing countries

The extent of harm caused by unsafe blood and medications are unknown



Deficit of Qualified Health-care Providers

- The deficit in 57 countries is estimated to be 2.4 million doctors, nurses and midwives
- Fatigue, production pressures cause high risk of mistakes





Theory--Definitions

- Error
 - *The failure of a planned action to be completed as intended or use of a wrong inappropriate, or incorrect plan to achieve an aim.*
- Adverse event
 - An injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalization or disability at the time of discharge from medical care, or both



Theory—Definitions (II)

- Near miss
 - An event that almost happened or an event that did happen but no one knows about. If the person involved in the near miss does not come forward, no one may ever know it occurred.
- Patient safety
 - The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include “errors,” “deviations,” and “accidents.” Safety emerges from the interaction of the components of the system; it does not reside in a person, device, or department. Improving safety depends on learning how safety emerges from the interactions of the components. Patient safety is a subset of health care quality.



Theory—Definitions (III)

- Safety culture

A culture that exhibits the following five high-level attributes that health care professionals strive to operationalize through the implementation of strong safety management systems.

(1) *A culture where all workers (including front-line staff, physicians, and administrators) accept responsibility for the safety of themselves, their coworkers, patients, and visitors.*

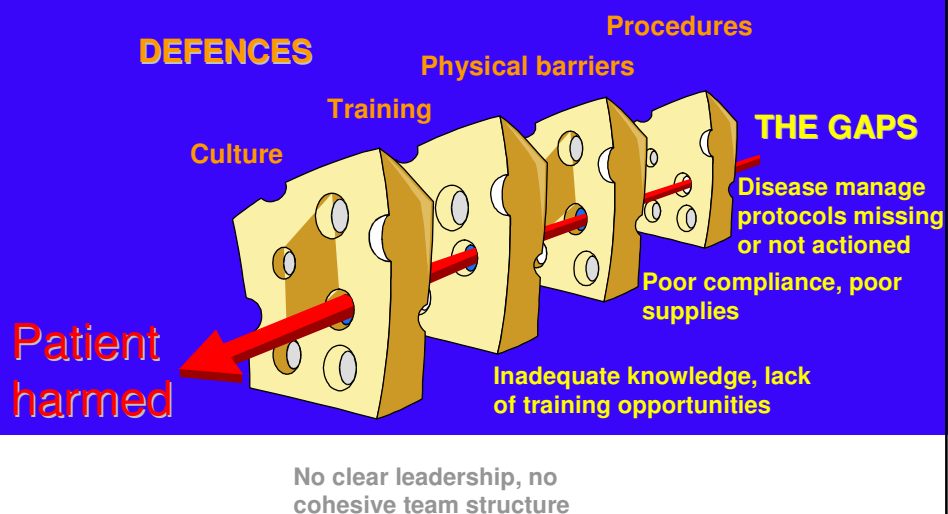
(2) *[A culture that] prioritizes safety above financial and operational goals.*

(3) *[A culture that] encourages and rewards the identification, communication, and resolution of safety issues.*

(4) *[A culture that] provides for organizational learning from accidents.*

(5) *[A culture that] provides appropriate resources, structure, and accountability to maintain effective safety systems.*

A Systemic Problem that Harms Patients





Vincent Framework for Risk Analysis

Factors that Influence Clinical Practice

- Institutional context
- Organizational and management factors
- Work environment
- Team factors
- Individual (staff) factors
- Task factors
- Patient characteristics

Team Factors and Their Components

- Verbal communication
- Written communication
- Supervision and seeking help
- Structure of team

Vincent, BMJ, 1998



History of the Patient Safety Movement

- **1995** Harvard Medical Practice Study results published
- **1998** To Err Is Human, Institute of Medicine
- **2000** An Organization with a Memory
- **2002:** 55th World Health Assembly Resolution
- **2004:** Launch of the World Alliance for Patient Safety
- **2005:** Launch of the first Global Patient Safety Challenge



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Examples

- Hand hygiene and healthcare associated infections
- Unsafe surgery and anesthesia
- Medication errors
- Patient for Patient Safety



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Hand Hygiene and Healthcare Associated Infections



Unsafe Surgery and Anesthesia

- Estimated 234 million major surgical procedures done each year worldwide
- These procedures can cause deaths and complications
- Multiple interventions possible but checklist has been effective

Checklist Data

	Before	After
Death rate	1.5%	0.8%
Complication rate	11%	7%



Medication Errors

- Leading cause of harm in hospitals in developed countries
- About one patient in 10 is harmed
 - About a third are preventable
- One medication error per patient per day
 - Most don't result in harm



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Patients for Patient Safety



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A Transforming Concept

Corollary # 1:

It makes no sense to punish people for making errors

Corollary # 2:

You can decrease errors by improving systems



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Human Factors Principles

1. Avoid reliance on memory
2. Simplify
3. Standardize
4. Use constraints and forcing functions
5. Use protocols & checklists wisely
6. Improve information access
7. Reduce handoffs
8. Increase feedback



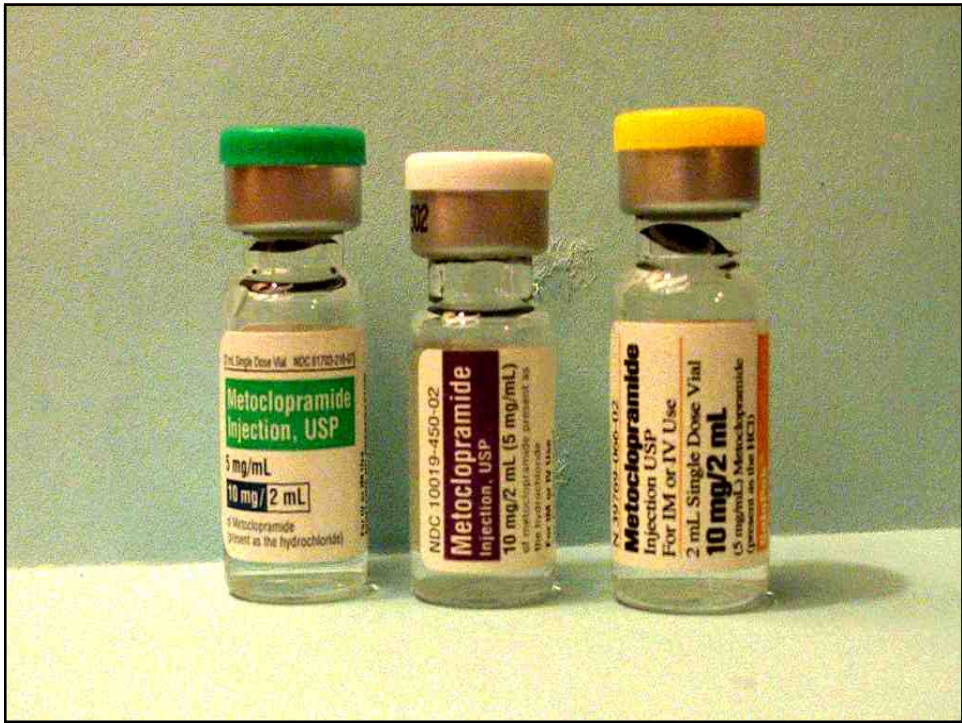
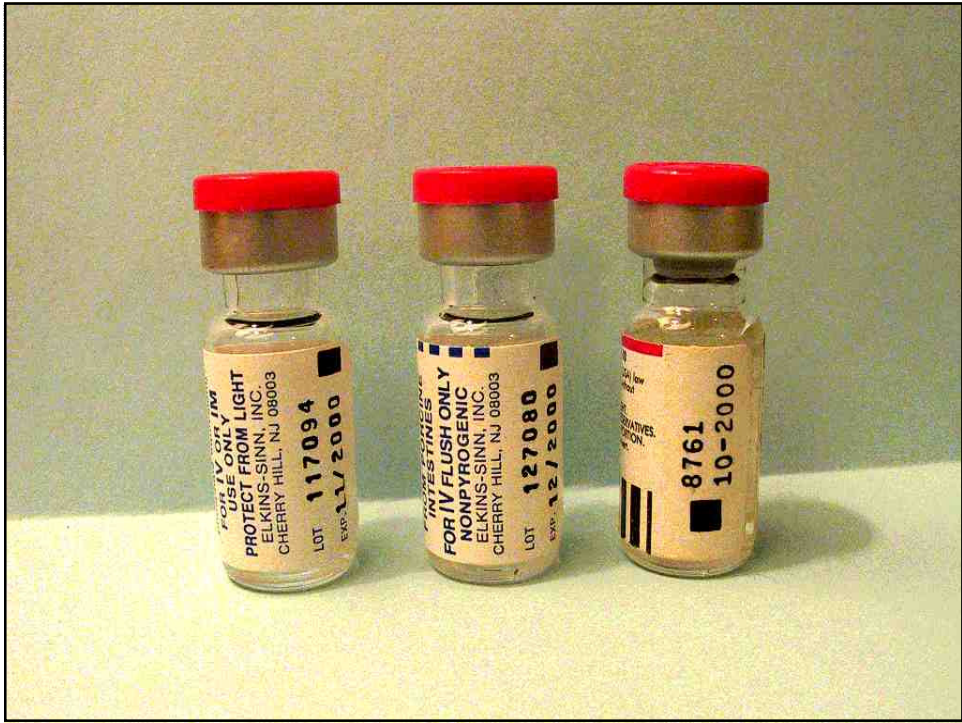
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Human Factors Violations

- Reliance on memory
- Excessive number of handoffs
- Non-standard processes
- Long work hours
- Excessive work loads
- Spotty feedback
- Variable information availability





A nurse gives a patient a 4 X overdose of methotrexate

- Rate of errors when nurses calculate doses and measure out medications from multidose vials 11%
- Rate of errors when nurses calculate doses and add medications to intravenous solutions 21%



A nurse gives a patient a 4 X overdose of methotrexate

Systems Changes:

- Eliminate multidose vials on nursing units
- Eliminate nursing calculation and preparation of medication doses
- All calculations done by pharmacist
- All medications mixed by pharmacist
- All medications provided in unit of use dose
- Bar-coding checking system



A physician removes the wrong kidney

- Percentage of all operations performed on the wrong site ? 0.01%
 - Reported to Regulatory Authority: 1/31,000
- Percentage of hand surgeons who admit to operating on the wrong site at least once 21%



A physician removes the wrong kidney

Systems Changes: Team with Checklist

- Physician marks the operative site with the patient before anesthesia or sedation
- Use a verification checklist that includes all documents and medical records referencing the intended procedure and site
- “Time out” briefing and oral verification of the correct site by all members of the team before starting every procedure
- Ensure verification procedures are followed



A patient receives a 10 X overdose of insulin

Physician wrote the order for insulin:

NPH insulin, 10U q AM



A patient receives a 10 X overdose of insulin

Known causes of prescribing errors:

- Use of letter “u” for “unit”
- Use of 0 after decimal (10.0)
- Forgetting medication allergy
- Dose calculations

Rate of prescribing errors by physicians
when writing prescriptions by hand: 8%



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A patient receives a 10 X overdose of insulin

Systems Changes:

- Computerized medication ordering
- Pharmacy checking
- Bar coding administration
- Patient participation



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Interactive

- Who has an example of human performance limitation in your setting?
- Who has an example of a human factors problem?
- Communication problem?
- Latent error in your setting?



Additional References

- Executive Summary: In Institute of Medicine (US): To err is human: building a safer health system. Washington, National Academy Press 2000
- Reason J. Human error: models and management. BMJ 2000; 320:786-790.
- Leape LL. Error in medicine. JAMA 1994; 272:851-1857.



Conclusions (I)

- Patient safety appears to be a problem in all nations
- Definitions are important so we can count the same things
- Frameworks such as the Reason framework and Vincent framework can be helpful for understanding why an accident happened
- Common themes include issues with human performance, human factors, and communications



Conclusions (II)

- Aviation has achieved very high levels of safety through standardization
 - Many lessons for medicine, though not all applicable
- Need more information about the frequency of adverse events, errors by country and setting
- Research needed to:
 - Identify and describe safety issues
 - Develop and test safety solutions



Answer: Questions for Lecture 1

- 1.(b)
- 2.(b)
- 3.(d)
- 4.(d)



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Thank You