PRÁTICAS SEGURAS NO USO DE MEDICAMENTOS: ÊNFASE EM MEDICAMENTOS POTENCIALMENTE PERIGOSOS

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SecondStory™

Syllabus

Science of Safety

Planning for Safety

Measuring Errors and Measuring Safety

High Alert Medicines

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Syllabus

Course Format

Lecture

Case Studies

Team Discussions

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Science of Safety

Complex systems

Human error and “human factors”

Taxonomy of safety

Recognizing bias

Methods for risk reduction

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Science of Safety

adaptive

Complex^ systems

- A coherent and unified way of viewing, interpreting and of organizing our thoughts about the world.
- A collection of elements whose operation is interdependent.
- Systems obey rules that cannot be understood by breaking them into parts
- Systems stop functioning (or malfunction) when an element is removed or altered significantly.

- Jim Bagian

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adaptive

Complex^ systems: Healthcare Examples

- Hospital admissions and discharges
- Medication prescribing, dispensing, administration
- Medication delivery
- Dietary and food delivery
- Patient transfers
- Prescriber order entry
- Pharmacist order entry

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Complex adaptive systems

Why do we say “adaptive” ?

Systems are adaptive because of the variable we call the “person”

YOU (the person) are interacting in a unique way with the system – producing different results.

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Issues that impact human performance and increase risk for error include:

- Factors present before action takes place. These are predisposing mental and physiological states, such as fatigue, stress, dehydration, hunger, and boredom
- Factors that directly enable decision making, such as perception, attention, memory, reasoning, and judgment
- Factors that directly enable decision execution, such as communication and being able to carry out the intended action

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Which of the following are examples of a human factor that contributed to a medication error?

A nurse, working for 12 hours without a rest break, administers the wrong dose of an infant.

A busy oncologist, against hospital policy, tells the senior intern to calculate the chemotherapy dose for a new patient.

A pharmacist receives a verbal order to urgently dispense fosphenytoin but instead prepares a syringe of phenytoin.

None of the above are “human factors” !

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Human errors

- Cognitive
  - slips and lapses (thinking, memory and judgment)
- Performance errors
  - technical and operational
- Other
  - disability or impairment (poor vision, psychological)

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The term “human factors” is INCORRECTLY used to refer to the factors that cause humans to make errors—like fatigue, emotions, habit, and assumptions.

These are factors, and they do affect humans, and that’s why people refer to them—mistakenly—as “human factors.”

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"Human factors is an established science that uses many disciplines …to understand how people perform under different circumstances.

We define human factors as: *the study of all the factors that make it easier to do the work in the right way."*

WHO definition

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Which of the following are based on Human Factor design?

Training and Education

Newsletters and Warning Posters

Punishment and Discipline

Policy and Procedure changes

Medication safety courses – like this one

NONE ARE BASED ON HUMAN FACTOR DESIGN !!

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Which of the following are based on Human Factor design?

Dose-range limits for prescribing software

Dose-range limits for infusion control devices

Removing concentrated KCL from patient care areas

No needle syringes

Stocking a single concentration of heparin

ALL ARE BASED ON HUMAN FACTOR DESIGN !!

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The term “human factors” is better described as

discipline of human factors engineering

that deals with the interface of people, equipment, and the environment in which they work.

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Taxonomy - Definitions

Quality – The extent to which a service or product produces desired outcomes

Safety – Prevention or moderation of hazard induced harm

Hazard – A circumstance that can lead to harm, damage, or loss

Risk – The chance a specific event will occur – along with its consequences and likelihood

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Taxonomy – Classifications of System Failures

- Knowledge transfer
- Allergy defense
- Inter-service and intra-service communication
- Conflict resolution
- Workflow
- Labeling and documentation
- Computerization/automation/informatics
- Standardization

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System Failure: Unsafe labeling practices

- Look-alike and sound-alike drug names and packaging
- Unsafe abbreviations and nomenclature
- Lack of written instructions for patients
- Lack of understandable directions for use

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System Failure: Knowledge transfer

- Failure to provide drug information at the point-of-care
- Ineffective documentation and retrieval systems for medical information
- Assure clinical competency in the use of high-alert drugs
- Decrease the reliance on human memory for high risk tasks

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System Failure: Lack of standardization

- failure to use standardized concentrations
- use of non-standardized equipment
- failure to use pre-printed orders, including use of joint drug-lab orders

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Classification of Corrective Actions

- Actions taken to immediately correct the safety problem
  - Remove immediate hazards
  - Clinical recovery and actions
- Actions taken to change systems and other factors
  - Systems-based
  - Non systems based

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Classification of Corrective Actions

Clinical Interventions and Recovery

Policy & Procedure

Education and Training

Personnel

Technology / Equipment / Automation

Formulary or Drug Product

Product Analysis

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Science of Safety

Classification of Corrective Actions

Clinical Interventions and Recovery

Policy & Procedure

Technology / Equipment / Automation

Formulary or Drug Product

Education and Training

Personnel

Product Analysis

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Classification of Corrective Actions

Education and Training

Review with staff

Counseling - individual

Inservice - work team

Multidisciplinary review

Competency assessed training

Orientation plan

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Classification of Corrective Actions

Personnel and Staffing

Determine / assign responsibility

Staffing pattern change

Skill mix change

Discipline and Punitive actions

NOT recommended Except within a Just Culture System

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Classification of Corrective Actions

Product Analysis

Drug product analysis

Microbiologic analysis

Device analysis

Software analysis

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Recognizing the Effect of Bias

- Confirmation bias (during the event)
  - The tendency to selectively search for, consider and accept information that confirms one's beliefs.
  - Example: Selecting a drug based on it location, shape, color, past experience.
  - Example: Approving an order based on trust in the persons you work with.
  - Example: Entering a series of keystrokes based on past patterns

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Recognizing the Effect of Bias

Confirmation bias: Case Study - PCA order set

Concentration

Initial Bolus

Clinician Bolus

PCA lockout

PCA dose

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Science of Safety

Recognizing the Effect of Bias

Confirmation bias: Case Study - PCA order set

Concentration
Initial Bolus
Clinician Bolus
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Concentration
Clinician Bolus
Initial Bolus
PCA dose
PCA lockout

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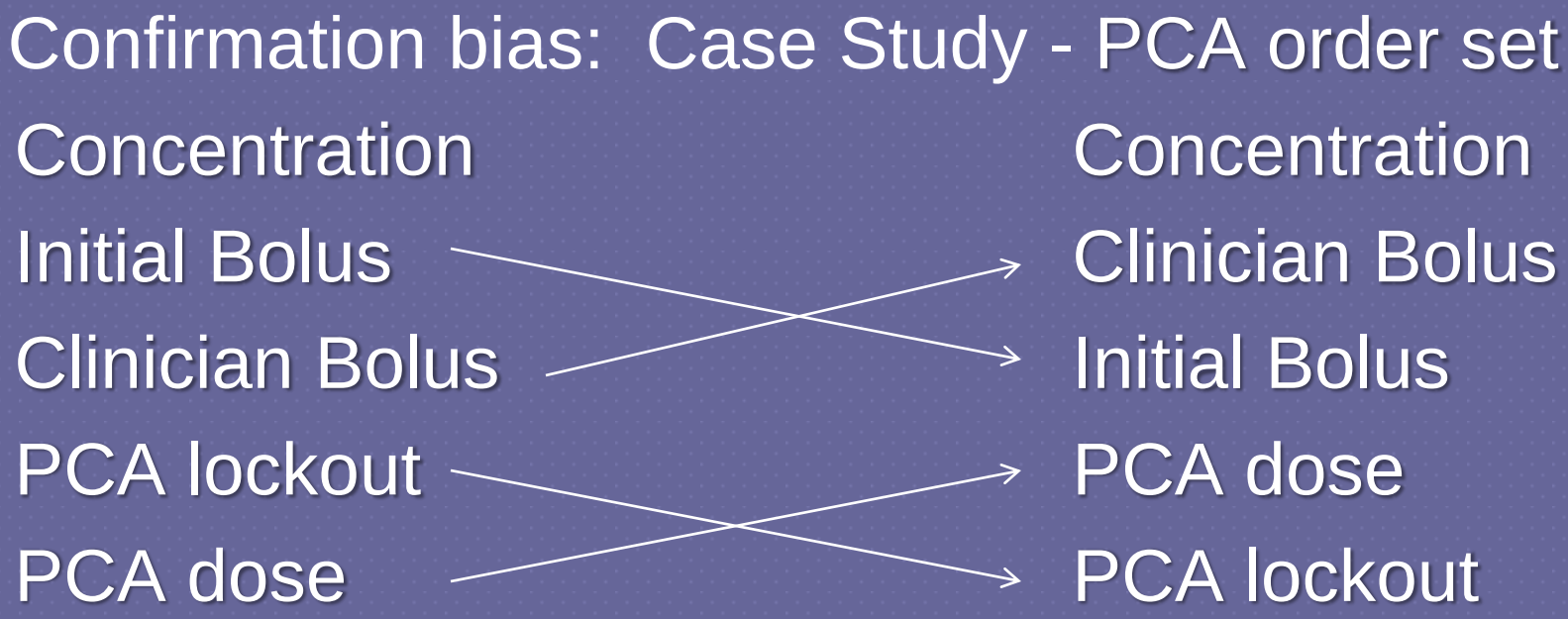
Recognizing the Effect of Bias



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Recognizing the Effect of Bias

- Hindsight bias (looking in the past)
  - Investigation of event
  - Affects the conclusions
  - Contaminates root cause analysis
  - Leads to inappropriate corrective actions

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- Hindsight bias
  - Knowing the outcome alters judgment of preventability
  - Evidence establishing a causal link seems more obvious, leading investigators to conclude it was foreseeable and therefore preventable
  - User is generally unaware of the magnitude of the effect on judgment
  - Highly common when one is intentionally searching for the cause
  - Leading to the conclusion: human error is the cause

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Following a adverse event or error, the person(s) investigating will focus on the most practical variables that can be changed.

Other factors, incentives, economics, organization and technology, may be important
but are perceived as unchangeable…therefore, not part of the problem faced by the investigator.

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Hindsight bias: Case Study

- The first 5 subjects enrolled in a multi-center cancer trial, experience blood counts that are significantly lower than expected, resulting in delays in subsequent cycles.
- The doctor contacts colleagues at several other centers. No other clinical center has experienced this adverse event.
- Because no other center has experienced the problem, the doctor and sponsor do not propose changes to the research plan.
- The doctor also reports the event to hospital's adverse event reporting system, in accordance with policy on medication safety.

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Hindsight bias: Case Study

- The medication safety pharmacist conducts a thorough independent investigation into the 5 events.
- To everyone's surprise, they discover that the locally-developed dosing charts for mixing the chemotherapy contain a calculation error.
- Enrollment is immediately suspended
- Immediate recall of all dosing charts in use
- Study coordinator distributes a new dosing chart

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Hindsight bias: Case Study

How did hindsight biases affect this case?

(Take 2 minutes to discuss with the persons sitting beside you)

- Multi-center cancer trial – highly controlled situation
- Lowered blood counts are common in oncology
- Clinical staff used the dosing charts without questioning the accuracy
- No other center has experienced the problem
- Corrective action plan – does not address the root cause

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Strategies for prevention and problem solving

- Layers of protection – there is no one solution
  - Design and usability testing
  - Competencies: Individual and Team
  - Communication effectiveness
  - Systems awareness
  - Situational awareness
  - Recovery from error

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Strategies for prevention and problem solving

- Culture of Learning – an optimal problem solving strategy
  - Understand the real system-behavior (not the policy)
  - Credible root cause analysis
  - Detect and analyze “quase acidentes”
  - Anticipate risks and hazards (failure mode and effects analysis)
  - Knowledge transfer
  - Learning from other hospitals

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Strategies for prevention and problem solving

In the next 10 minutes…..

- List 2 prevention strategies that work well in your hospital. What would you do to make them better?
- List 2 problem solving strategies that could be improved in your hospital. What is the most important improvement needed?

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Case Study

What's a drug like you, doing in a patient like this?

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Case Study: A Safety Event?

- J.M. is an adult female admitted to orthopedics for traumatic dislocated shoulder
- Meds - fluticasone inhaler, albuterol inhaler
- Allergies - ibuprofen

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Case Study: A Safety Event?

- Morphine IV for pain
- Operative sedation- midazolam and fentanyl
- Orthopedic reduction of shoulder successful
- Orthopedic post-op: ketorolac 30mg IM x 1 now

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Case Study: A Safety Event?

- While waiting for the pharmacy to deliver, nurse borrows ketorolac from another patient's supply
- Later Pharmacy calls nurse to hold the dose because of a drug allergy
- Pharmacy reports the event to the safety program
- Medication safety officer investigates the event and talks with all staff

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Case Study: A Safety Event?

- "First" stories of the account:
  - **Physician prescribed cross-reactive drug**
  - **Nurse administered cross-reactive drug**
  - **Nurse "borrowed" drug from another patient**
  - **Pharmacist submitted an incident report**

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Case Study: A Safety Event?

- "Second" stories from the providers:
  - **nursing history noted allergy to ibuprofen and no prior history with ketorolac**
  - **nurse previously received conflicting data on ketorolac-ibuprofen cross-allergies from Pharmacy**
  - **nurse had given ketorolac without allergy in past**
  - **nurse reported ketorolac insert did not warn**
  - **nurse reported patient in pain and did not want to wait for pharmacy to deliver meds…"they're always slow"**
  - **nurse and physician did not discuss orders**

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Case Study: A Safety Event?

- "Second" stories from the providers:
  - **preprinted care map listed ketorolac for pain**
  - **resident unaware of the cross reactivity**
  - **resident assumed "allergy" was GI upset**
  - **intern's pocket drug guide did not list allergy**

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Case Study: A Safety Event?

- "Second" stories from the providers:
  - **pharmacist received order 1 hour later**
  - **pharmacist called nurse to hold order because of allergy alert on medication profile**
  - **"nurses borrow drugs all the time"**
  - **not enough staff to review all orders prior to use**
  - **"they could have taken it from floor stock if they wanted to"**

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What happened to the patient?

- Patient's pain controlled with ketorolac without complications or harm.
- Since there was no harm, how should the hospital respond?

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For the next 10 minutes, talk with the person beside you to…

List the possible barriers and solutions to good problem solving in this case.

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Science of Safety

Possible barriers and solutions to problem solving

Barrier	Solution
Isolated incident (maybe not)?	Analyze “quase acidentes”, interview staff for more stories
No harm	Focus on systems and learning, not outcomes and luck
Root problem is deep within normal workflow systems and drug delivery	Review shared expectations and timeliness of drug delivery system
Lack of professional trust	Improve communication skills

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Team Discussion– Science of Safety

List the

SYSTEM FAILURES

identified in this case

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Case Study: Team Discussion

Medication safety problems identified in this report:

- Allergy defense systems
- Knowledge deficits
- Rule violations….but justified?
- Inadequate review of orders prior to administration
- Delays in providing pharmacy services
- Inter-service communications
- Patient information availability

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Planning for Safety

Organizational resources – people

Who are members of your Patient Safety Team?

Medication Safety Officer ?

Patient Safety Officer ?

Drug Information Specialist ?

Safety Committee Members ?

Director of Quality ?

Pharmacists – Nurses – Physicians - Technicians ?

TODOS AS PESSOAS !

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Planning for Safety

Organizational resources – information

- Evidence-based resource center
- Safety journals and safety alerts
- Database of organizational actions
- Communication tools to spread the knowledge
- Tools for root cause and failure mode analysis
- Database of safety problems
- Simulation laboratory – Usability testing

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Planning for Safety

Organizational resources – time and money

Measure and trend the…..

- Time budgeted to safety planning and learning
- Money spent for safety improvements
- Time-to-Event analysis: shorten time & costs
- Frequency and costs of extra hospital days
- Days without a serious preventable medical injury
- Time to collect, investigate and analyze safety reports
- Time to provide feedback and share lessons learned

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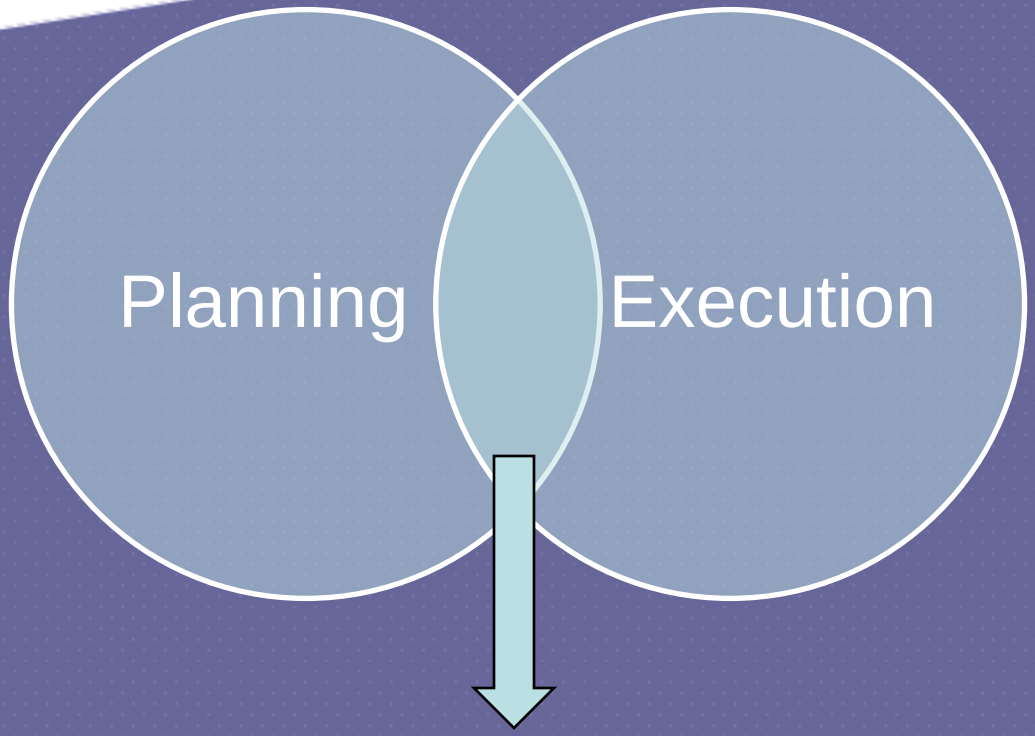

Medication Safety

Safety by Design….Not by Random Chance !

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Planning for Safety

Risk Reduction Strategies

- Simplification
- Reduction
- Forcing functions
- Constraining functions
- Automation, computerization, and technology
- Standardization and protocols
- Staffing and competency
- Policies, rules, and expectations
- Checklists & double-checks
- Risk assessment and communication errors
- Education and information
- Personal initiative – vigilance and situational awareness

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Case Study – Planning for Safety

- JM is a 1.7 kg infant in critical care unit
- IV fat emulsion – 100 ml dispensed in the original bottle
- Nurse infuses at 0.5 ml per hour by pump
- After 30 minutes, infant not breathing – does not survive
- IV infusion container is empty
- Lab analyses shows high lipid concentration – no blood
- Infusion pump examined – no defect found
- Conclusion: overdose of fat emulsion from unknown causes or failures

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Team Discussion – Planning for Safety

- What are the barriers and solutions to good problem solving in this case?
- List 2 specific actions to prevent future problems of this type?

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Measuring Errors and Measuring Safety

- Using a Structure-Process-Outcome approach to measuring safety
- Defining safety events and REPORTABLE safety events
- Close-call and near miss reporting
- De-identified compared to anonymous internal reporting of events
- Safety scorecards and reports (departmental, inter departmental, administrative)

SecondStory™

Measuring Errors and Measuring Safety

Review of traditional error detection methods

- Voluntary reporting: errors and “quase acidentes”
- Chart Review
- Triggers – electronic and manual
- Discharge Diagnosis
- Counting other events - returned/missed doses

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Measuring Errors and Measuring Safety

Review of Non-traditional methods

- Direct Observation (Barker et al)
- Pharmacist interventions and clinical notes
- Drug information questions
- Poison center events
- Hospitals admissions / re-admissions

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Measuring Errors and Measuring Safety

Common measures used to report “safety”

Adverse event rates

Adverse event reporting rates

Adverse event trend curves

Number of doses missed

Most common types of drugs, errors, system failures

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Measuring Errors and Measuring Safety

BUT WAIT !!!

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Measuring Errors and Measuring Safety

Common measures used to report “safety”

Hospitals often state they are measuring “safety” when in fact they are measuring errors.

Hospital leaders expect this type of measure

Historical use – “group think”

Perception (false) that it is easy to count

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Measuring Errors and Measuring Safety

Improving the measures used to report safety

RECOMMENDATIONS

Change the “conversation” toward safety

Develop safety metrics that show system improvements

Report valid error metrics AND safety metrics

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Case Study – Measuring Errors and Measuring Safety

O Hospital Belo

- Data from multiple types of reporting systems are analyzed by the medication safety team.
- Every month, the team receives reports of:
  - the most common types of medication events
  - the top most common drugs and drug categories
  - distribution of the practitioner-types involved in events
  - distribution of events by severity and preventability
  - report of events by location

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Case Study – Measuring Errors and Measuring Safety

O Hospital Belo

- Senior administrators are frustrated that, despite these active “safety” programs, medication events continue to trend the same, month after month.
- You are an expert consultant asked to improve the outcomes of their safety surveillance program.

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Case Study – Measuring Errors and Measuring Safety

For the next 10 minutes, talk with the colleagues near to you and….

List at least 3 areas that you will evaluate during your site-visit.

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Case Study – Measuring Errors and Measuring Safety

Areas to evaluate during your visit include:

- Analysis by system failure
- Analysis by type of corrective action (system-based?)
- Implementation of actions and follow-up on adherence
- Leadership support for improvements
- Layers of protection and prevention
- Culture of learning and use of external safety reports
- Culture of safety

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Measuring Errors and Measuring Safety

Common errors in the analysis of safety reports

- Use of Error rates vs. Reporting rates
- Failure to consider normal variation in trend curves
- Failure to consider event rates adjusted for volume
- Micro analysis (detail analysis of small data sets)
- Emphasis on human error as the cause
- Failure to interpret complex data for hospital leaders

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Measuring Errors and Measuring Safety

Common errors in the analysis of safety reports

- Bleeding due to Warfarin
  - Frequency data: 5 cases of bleeding due to warfarin toxicity
  - Trend data: 1 case last month and 4 cases this month.
  - Reporting rate data: 1 case/1000 patient days last month and 4 cases per 1000 patient days this month
  - Risk rate data: 1 case per 100 persons receiving warfarin, each month
- The alarming apparent 400% increases is not real.

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Team Discussion – Measuring Errors and Measuring Safety

Learning from Safety Programs

- Thinking about your hospital's safety program, list 2….
  - Medication safety lessons you learned this year.
  - Safety lessons your organization has communicated this year.
  - Actions your organization could take to improve learning.
  - Actions you will take in the next 2 months to improve how you learn from your safety program.

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High Alert Medicines

Defining and Identifying

- Medications that have a higher risk of causing significant patient harm when they are used in error (also high risk when used correctly).
- Global list – ISMP, the primary source.
- Local List – Risks vary, related to your practice.

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High Alert Medicines

Defining and Identifying

- Why is the risk of causing significant harm higher?
  - narrow therapeutic range
  - special monitoring to detect toxicity
  - rapid onset toxicity
  - insidious onset toxicity (symptoms lag toxicity onset)
  - difficult to reverse effects

- Errors are NOT necessarily more common

SecondStory™

High Alert Medicines

Defining and Identifying

Different professions perceive risk differently

and

may not agree or comply with your list.

The challenge - communicate the hazard.

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High Alert Medicines

Defining and Identifying

In addition to the well known examples…..

- adrenergic agonists and antagonists
- anesthetic agents
- antiarrhythmics
- chemotherapeutic agents
- epidural or intrathecal medications
- liposomal forms of drugs
- parenteral nutrition preparations

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High Alert Medicines

Layers of defense

- Product Design (engineering factors)
- Physics of safety
  - Time: increase time onset of error and patient
  - Time: decrease time to detect error and toxicity
  - Space: distance, barriers, portals
  - Energy: make it easy to do the right thing
- Usability test, assure it works in your practice
- Situational awareness

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High Alert Medicines

Common Safety Methods

- Red Flags
- Red Rules
- Checklists
- Overwraps
- Pre-printed orders
- Protocols and Standard orders
- Coupled orders (drug + lab)
- Standardized nomenclature
- Separate storage
- Lock boxes

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High Alert Medicines

Common Safety Methods

- Camel spelling
- Special Colors
- Special Shapes
- Bar coding
- Dose range checks
- Infusion range checks
- Age/Weight checks
- Double-checks and independent double checks
- Engineering and design matching
- Communication standards (shift changes, critical communications)
- Restricted uses, locations, prescribers

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High Alert Medicines

- Defining and identifying
- “Layers of defense”
- Common methods to reduce risk

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Case Study – High Alert Medicines

(and High Risk Patient)

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Case Study

- TM is a 50 year old female on a medicine floor at this 300 bed community hospital
- Problem list:
  - Uncontrolled hyperglycemia
  - Upper gastrointestinal bleed
  - Alcohol and Tobacco abuse
  - Hypertension for 10 years
  - Pancreatitis

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- Procedures: Endoscopy
- Medications:
  - Insulin infusion at 3 units/hour, adjusted per sliding scale
  - Cimetidine infusion 20 mg/hour
  - Diazepam 2.5 mg at bedtime
  - Endoscopy - midazolam 6 mg total
  - Endoscopy - fentanyl 150 mcg total

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History of Significant Events:

- After the change of nursing shifts at approximately 0700 hours, the patient was transported to the Endoscopy unit for further evaluation of GI bleed.

- The patient's blood glucose was noted to be 80 mg% (4.4mmol/L) at 0900 hours.

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Q1. Correct management of the patient at this time includes:

A. Administer flumazenil reversal

B. Administer naloxone reversal

C. Increase rate of intravenous fluids

D. Increase neurochecks to every 20 min.

E. None of the above

SecondStory™

Q1. Correct management of the patient at this time includes:

A. Administer flumazenil reversal

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E. None of the above

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- Following return to the floor, the patient was drowsy with a Ramsay sedation score of 3.
- Repeat blood glucose was noted to be 50 mg% (2.8 mmol/L) and the insulin infusion pump was turned off.
- Approximately 2 hours later, the patient was still drowsy.

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Q2. Immediate actions include:

A. Stop all intravenous fluids
B. STAT blood glucose
C. STAT Consult Neurology
D. STAT Consult Anesthesiology

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Q2. Immediate actions include:

A. Stop all intravenous fluids

B. STAT blood glucose

C. STAT Consult Neurology

D. STAT Consult Anesthesiology

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- STAT blood glucose alert value = 25 mg% (1.4mmol/L)
- The nurse administered dextrose 50% injection

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Q3. What is this patient's problem?

A. Encephalopathic cirrhosis
B. Cimetidine-induced encephalopathy
C. Hypoglycemia due to insulin
D. None of the above

SecondStory™

Q3. What is this patient's problem?

A. Encephalopathic cirrhosis
B. Cimetidine-induced encephalopathy
C. Hypoglycemia due to insulin
D. None of the above

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- After the patient was stabilized, the cimetidine bag was repositioned on the top rack of the IV pole with the intent of restarting the infusion
- At that time the bag thought to be cimetidine actually contained insulin
- The physician was immediately notified

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The Adverse Drug Event

- Hypoglycemia secondary to acute insulin overdose

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- What are the contributing factors for this adverse event?

A. Human error
B. Human factors design flaw
C. Prescribing error
D. Process deficiency
E. All the above

SecondStory™

- What are the contributing factors for this adverse event?

A. Human error
B. Human factors design flaw
C. Prescribing error
D. Process deficiency
E. All the above

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- Human error
  - Failure to check dose and identity of medication properly
  - Failure to administer intravenous medication properly
- Prescribing error
  - Failure to write orders to monitor drug effect at clinically appropriate intervals

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- Process deficiency
  - No policy/standard on checking meds connected to the proper IV line and infusion device
- Controllable environmental factors
  - Dimmed or low lighting

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- Other factors
  - Patient sedated (for medical reasons) during insulin infusion and unable to report or display typical symptoms of hypoglycemia

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If you were “in charge”, you would:

A. Study root causes.

B. Discipline physician and nurse

C. Require double check for insulin drips

D. Educate all staff about insulin

E. All the above

SecondStory™

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Case Study – High Alert Medicines
(and high risk patients)

Could a similar event happen at your hospital?

How would your hospital respond after an event like this?

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Team Discussion – High Alert Medicines

- Are there human factors (design flaws) that contributed to this error?
- What safety actions can be taken to minimize this risk in the future?

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Team Discussion – High Alert Medicines

- Human factors that contributed to this error
  - Insulin infused without automated monitoring of blood sugar
  - Device lacked design to confirm insulin was not infusing
  - Infusion device for insulin same as device for other drugs
  - Other design flaws?

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Team Discussion – High Alert Medicines

What safety actions can be taken to minimize this risk in the future?

- Device redesign (not in local control)
- Coupled insulin-lab order set
- Coupled insulin-nurse monitoring order set
- Reduce use of insulin infusions
- Special process controls for high risk patients

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SUMMARY

Themes of the Annenberg Conference series

(Tools → Beliefs → Practices → Goals)

- Establish visibility to error and set a national agenda for change
- Change the thinking/culture about error/put a face to error
- Systems errors vs. individual blame
- Use error identification and reduction strategies proven effective in other industries (e.g. airlines)

-Annenberg Patient Safety Conferences 1996-2001

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SUMMARY

Themes of the Annenberg Conference series

(Tools → Beliefs → Practices → Goals)

- Change focus of reporting/analysis to emphasize systems errors/root causes
- Increase emphasis on patterns of errors/trends
- Increase emphasis on high alert medications
- Apply cognitive psychology and human factors engineering

-Annenberg Patient Safety Conferences 1996-2001

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Action Plan

Design a personal action plan to use today's information to improve the safety program at your hospital.

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Obrigado a todos pela atenção e estou pronto para

perguntas e debates