

CACCN Ottawa

**Human Factors:
From Theory to Critical Care
Bedside**

Carol Dueck RN BScN MCE (C)

Dan Perri BScPhm, MD, FRCPC

Overview

- Medical Error - The problem
- ICU medication errors
- A brief introduction to Human Factors
- ISMP and Human Factors

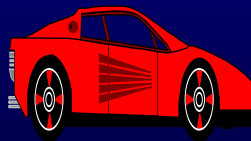
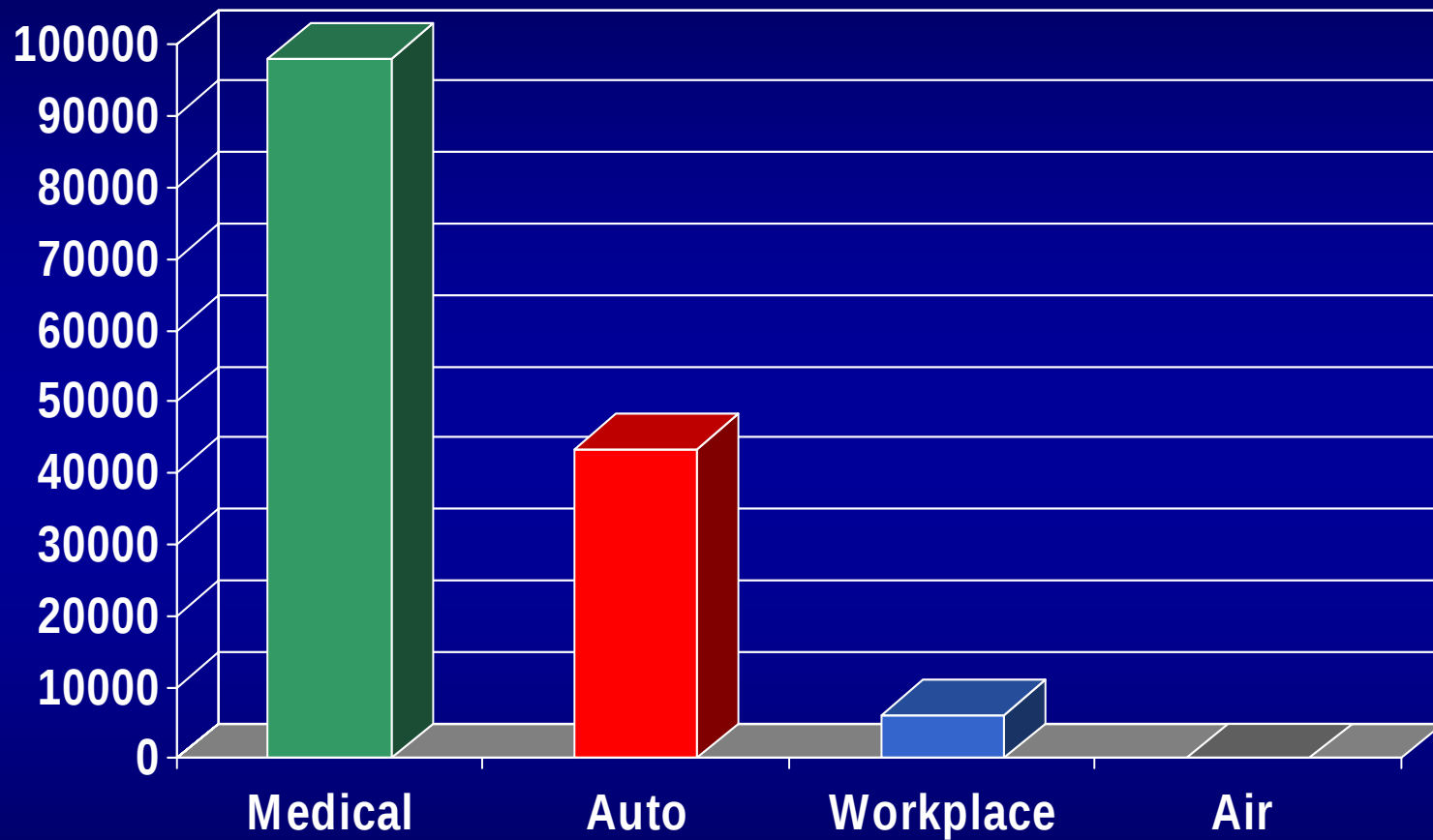
Medical Error – Did you know...

- Estimated number of deaths per year in the US hospital system attributable to medical error: 98,000
- Number of jumbo jet crashes required per day for equivalent death rate: 1.5
- Rank of medical errors among leading causes of death in the US: 5th
- Percentage of anesthesiologists who, when surveyed anonymously, admitted to committing a fatal error: 24

Medical Error – Did you know...

- Percentage of Americans who are "very concerned" that an error will lead to harm when flying in a commercial aircraft: 32
- Percentage of Americans who are "very concerned" that an error will lead to harm when going to a hospital for care: 47
- Percentage of Americans who believe they have experienced a medical error: 42
- Estimated annual cost of medical error to the US healthcare system: \$24B

Annual Accidental Deaths (U.S.)



Canadian Adverse Event Study: Scope of the Problem

- The rate of adverse events in patients admitted to Canadian hospitals is **7.5%**
- As many as 9250 to 23750 people die in Canadian hospitals every year as a result of ***preventable*** medical errors
- **24%** of the errors were due to **medications/fluids**
- 37% of adverse events were determined to be preventable

Incidence of Medication Error

- 1977 – California Medical Association: 5%
- 1984 – New York (Harvard Study): 4%
- 2004 – Canadian Adverse Events: 2%*

* Likely an underestimation based on study design

Adverse Drug Events (ADEs)

- There are 6 adverse drug events & 5 potential ADEs per 100 hospital admissions
- 1 in 100 medication errors cause an ADE
- Estimates of ICU medication errors range from 5% to 44%* (timing error)
- Most studies suggest a higher rate of ADEs in ICUs than general medical or surgical wards

Adverse Events in the ICU

25% of ICU ADEs are life-threatening:

- Polypharmacy
- Patient Morbidity
- Drugs with narrow therapeutic index
- Rapid treatment decisions
- Decentralized drug preparation
- Delayed diagnosis
 - Patients unable to report symptoms

Putting the Data Together

- 1 in 20 ICU patients experiences an ADE
- 25% of these ADEs are potentially fatal
- 1 in 100 ICU patients has a life-threatening adverse drug event!
- Half of these are preventable
- In 30 years of medication error research, the error rate has remained unchanged
- *Have we been going about it all wrong?*

Medication Errors in the ICU

Factors associated with patient harm are:

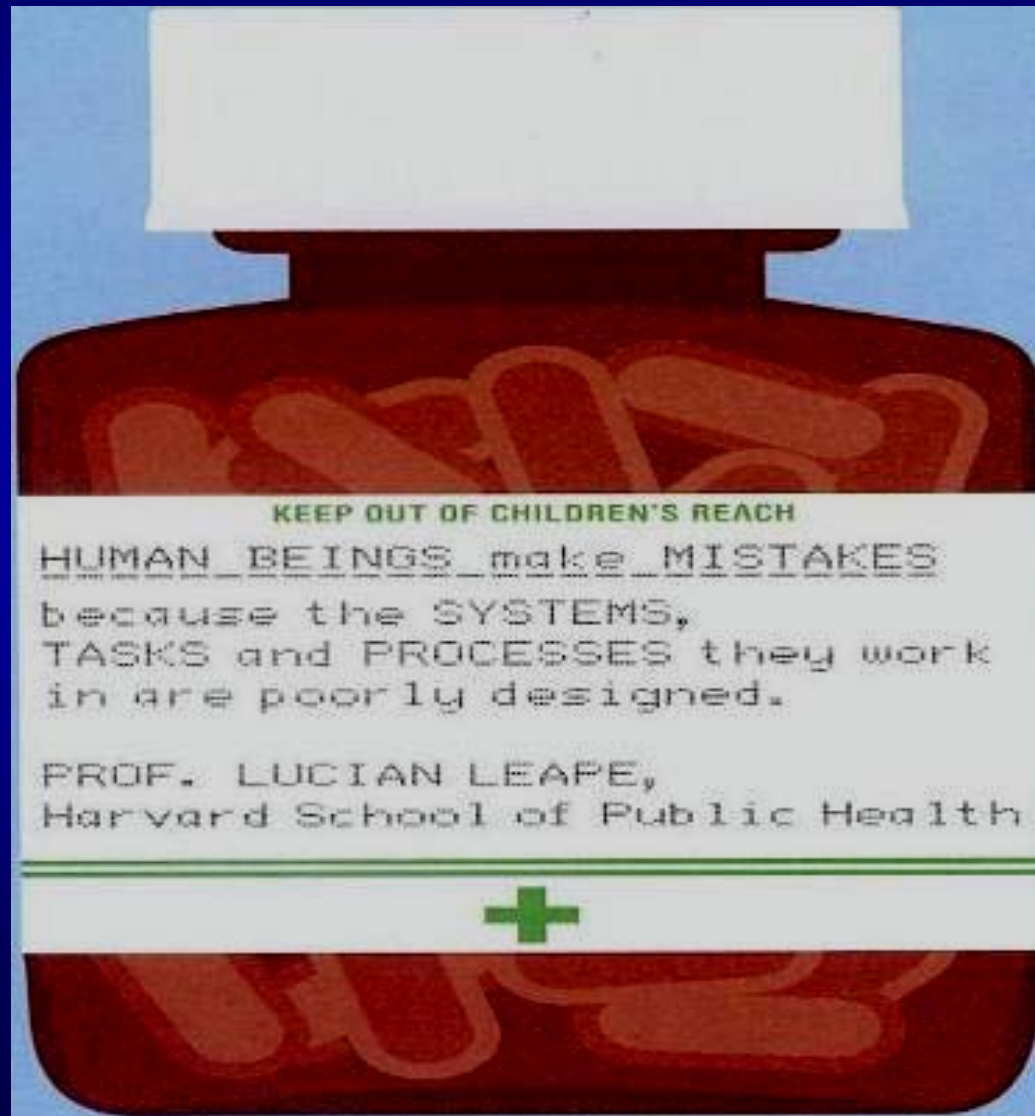
- Communication Failures
- Distractions/Interruptions
- Inexperienced Staff
- Insufficient Staffing
- Shift Change
- Drug Order Entry Problem
- Inadequate Supervision
- Noisy Work Environment
- Equipment Failures
- Lack of 24 Hour pharmacy
- Bed Availability Problems
- System of patient coverage
- Emergency Situation
- Patient Understanding

How many of these depend on one individual?

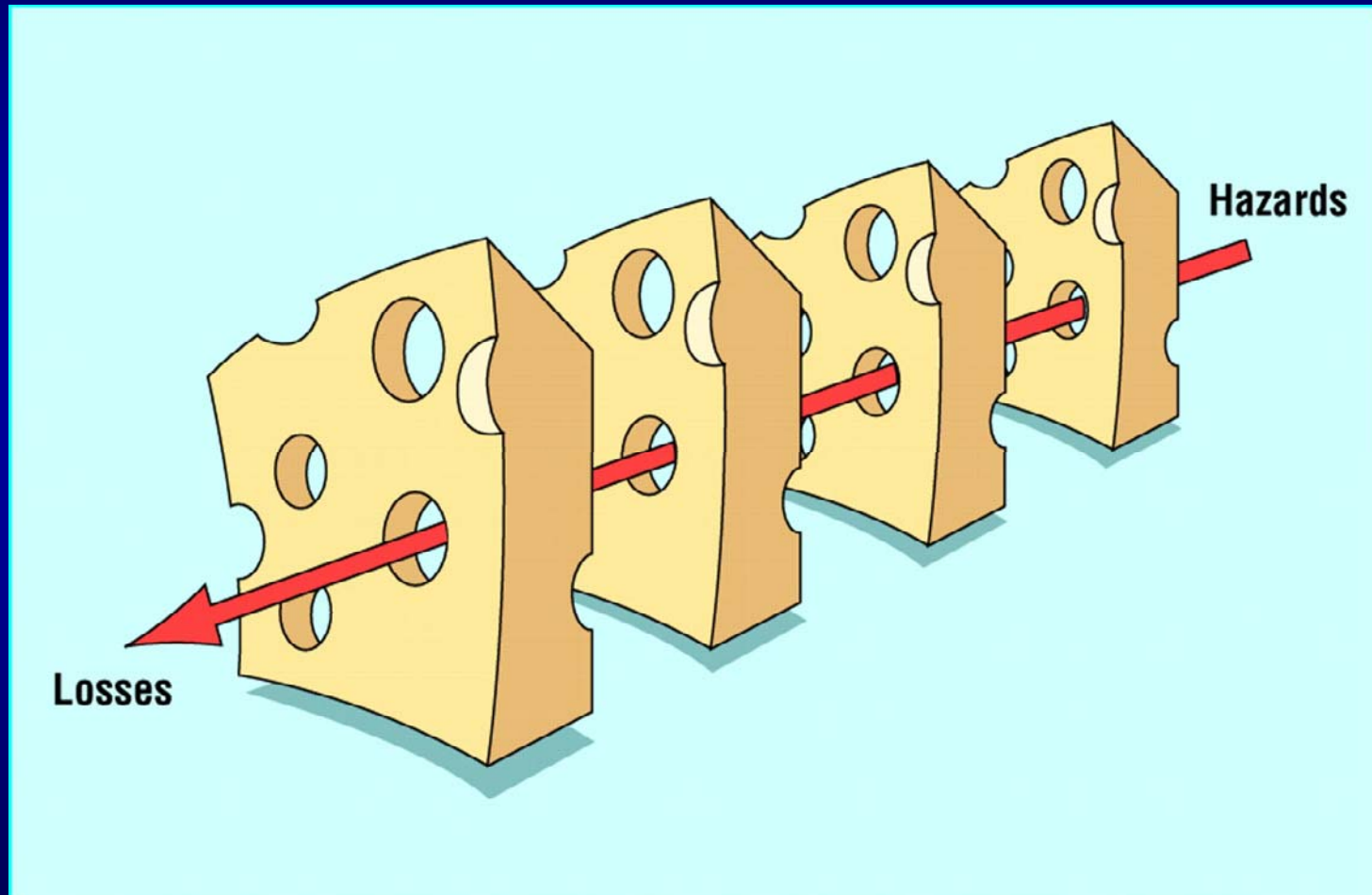
Top 10 Causes of ICU Medication Errors

1. Communication Failure	16%
2. Distractions / Interruptions	12%
3. Training / Supervision Problems	8%
4. Inexperienced Staff	6%
5. Shift Change	2-4%
6. Increased Workload	2-4%
7. Order Entry Problem	2-4%
8. Limited Access to Patient Information	2%
9. No 24 Hour access to pharmacy	2%
10. Insufficient Staffing	1%

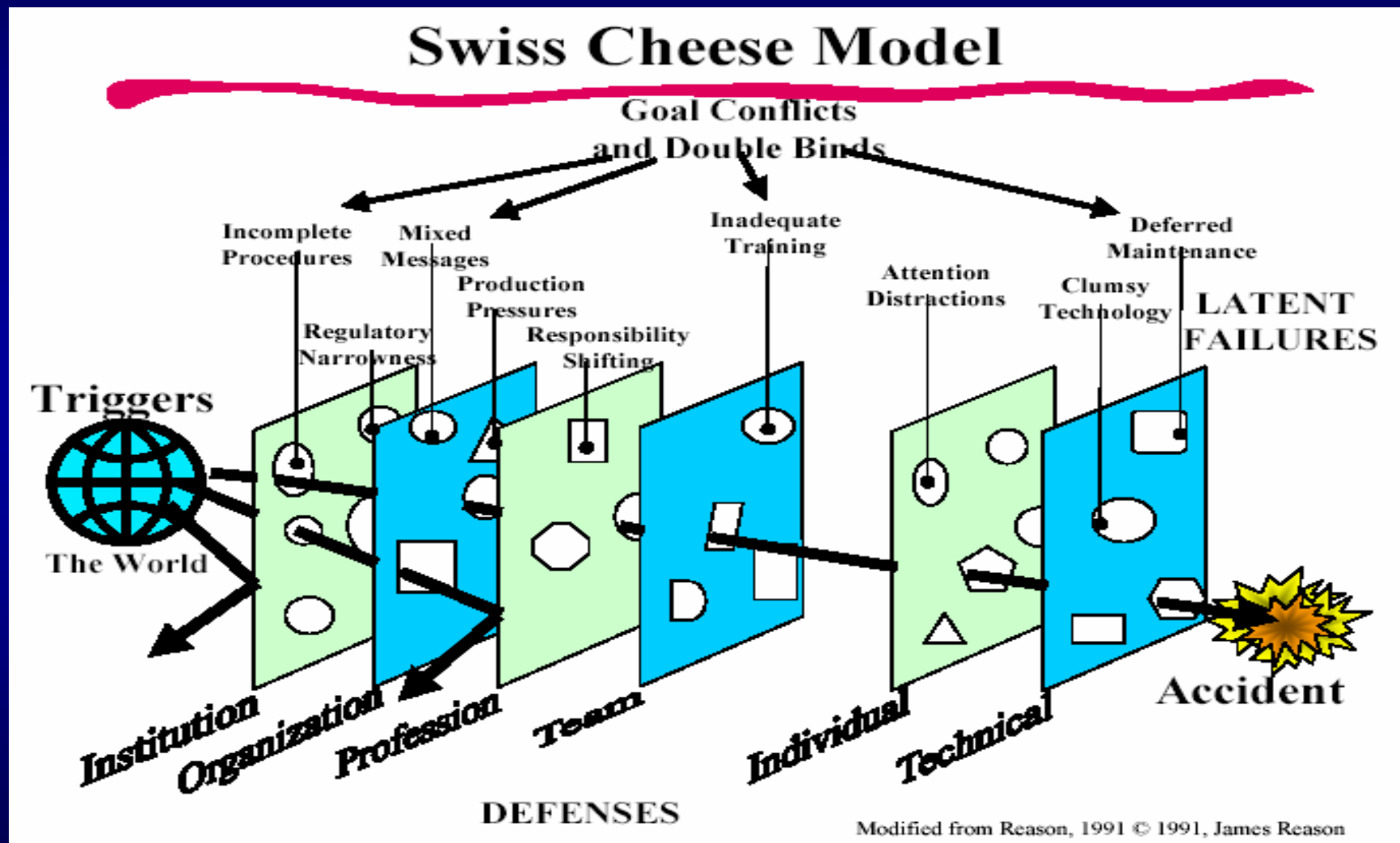
So, why are mistakes made?



Reason's Swiss Cheese Model



Reason's Model in the Real World



The “Old” Model for Safety

- Health workers are supposed to be perfect.
- Bad things happen only when people make mistakes.
- People / organizations that fail are bad.
- Blame & punishment sufficiently motivate carefulness.
- If we just work harder, things will be better.

The “New” Model for Safety

- Risk of failure is inherent in complex systems.
- Risk is always emerging.
- Not all risk is foreseeable.
- People are fallible ...no matter how hard they try not to be.
- Systems are fallible.
- The focus should be on changing the system and not the individual.

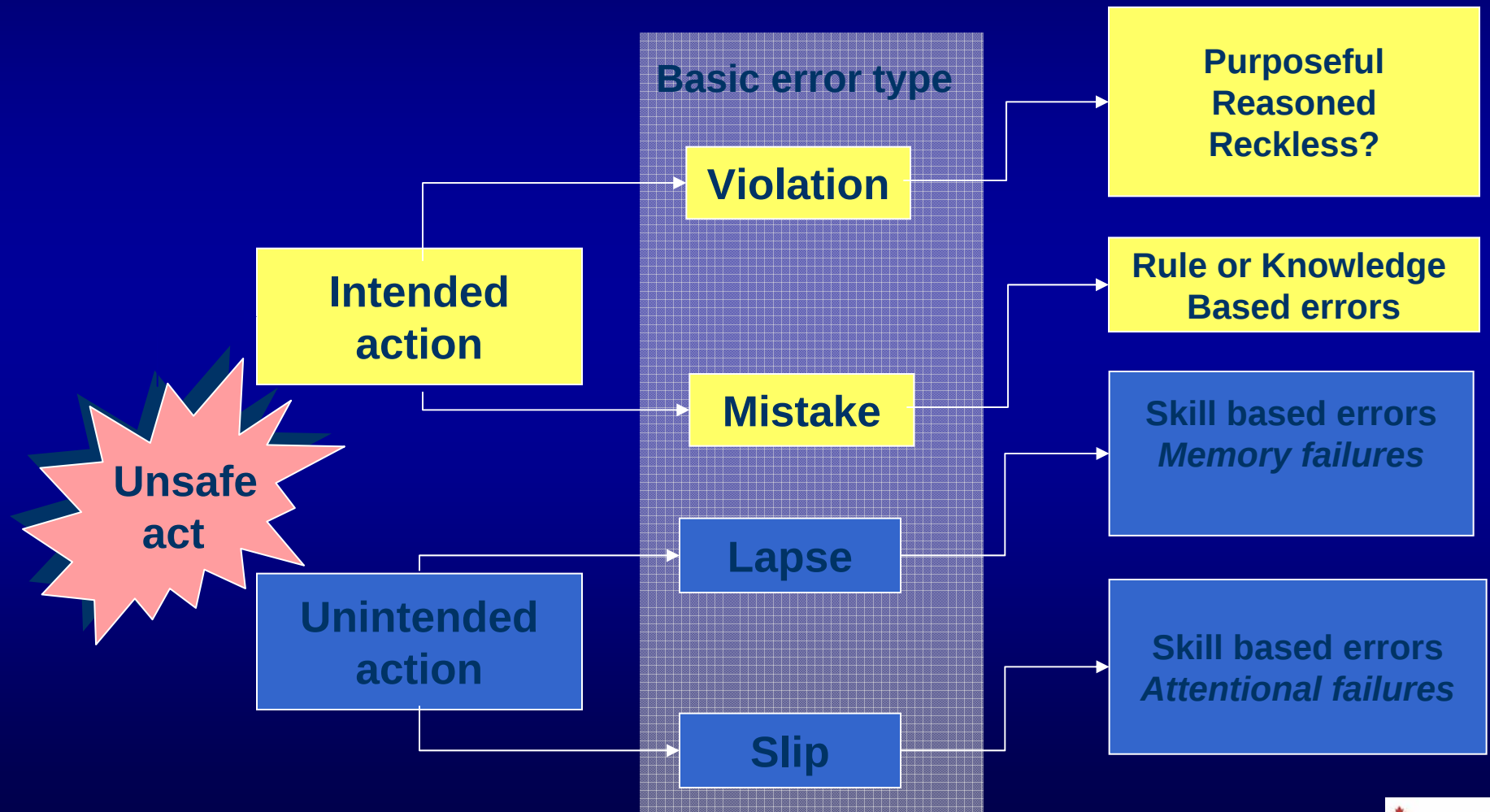
Human? Technology? System?



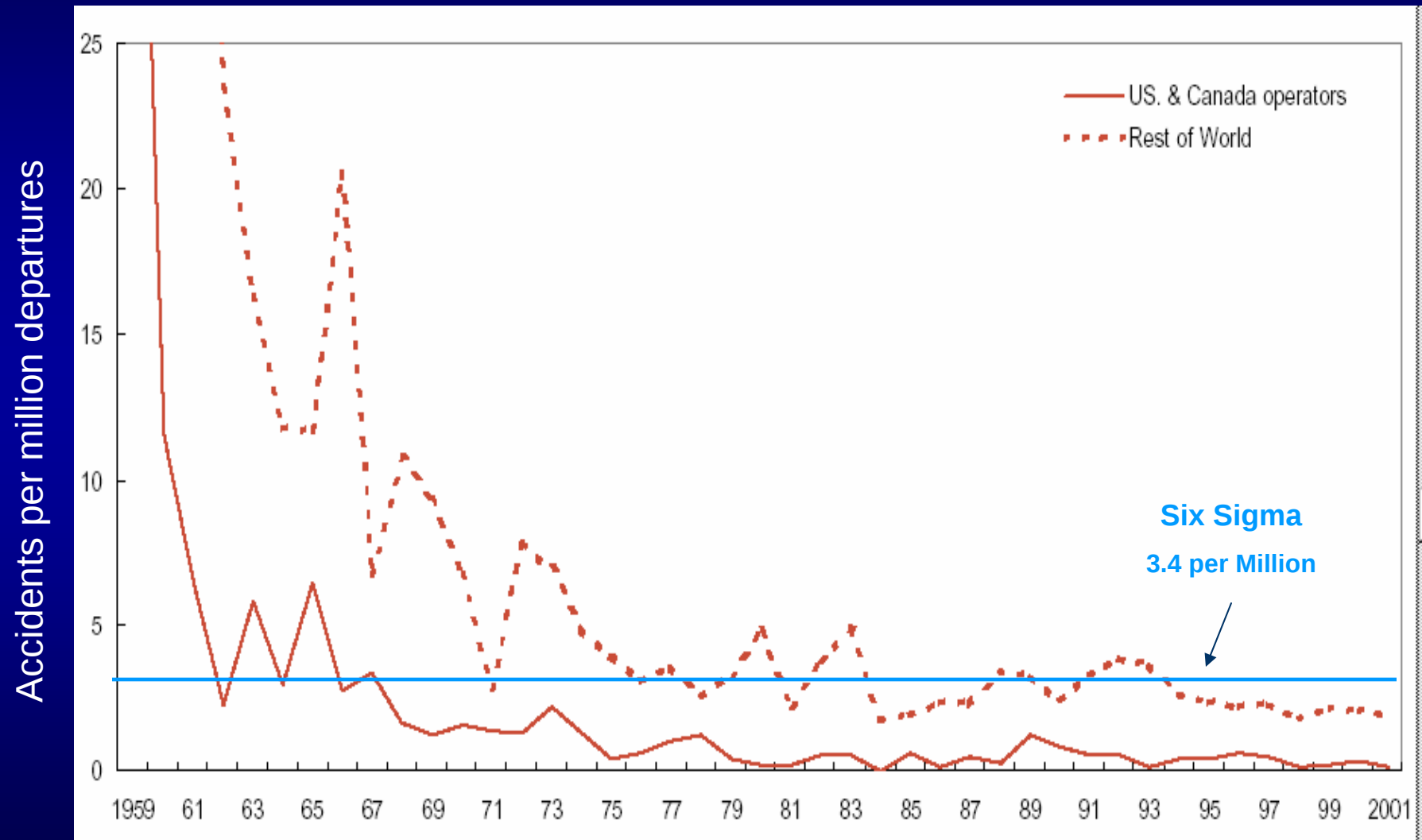
Human? Technology? System?



Reason's Error Types



Aviation Error Reduction Over Time



How did aviation get to Six-Sigma*?

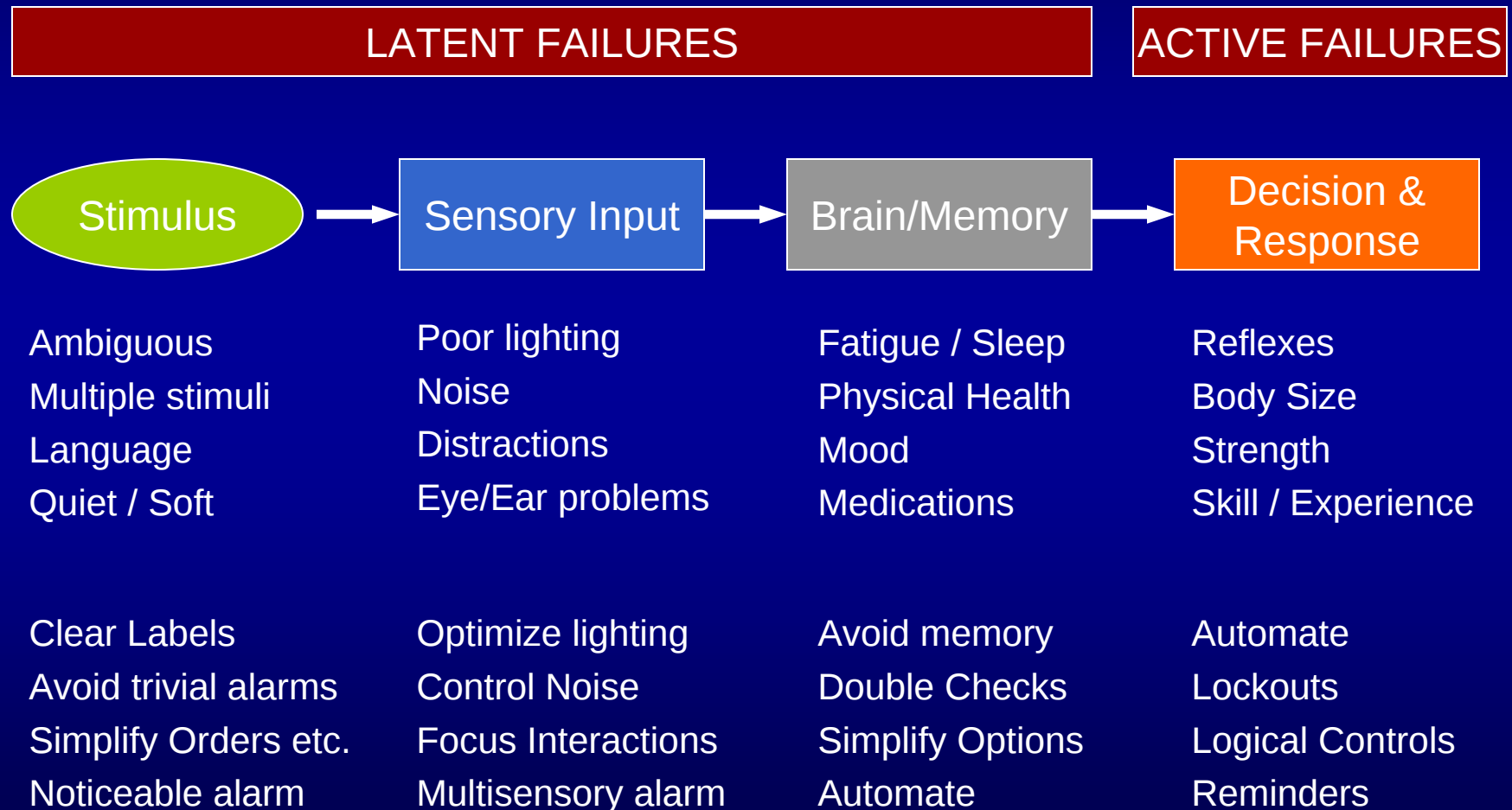
1. Equipment reliability & redundancy
2. Human performance predictability
3. Hire for attitude, train for proficiency
4. Train and credential as a team
5. Collect safety data and monitor performance continuously
6. Strong leadership at multiple levels
7. Emphasis on Human Factors to manage threats and errors

*Six Sigma = 3.4 errors per million opportunities (99.99966% accuracy)

Human Factors

- Human factors account for the interrelationships between us, the tools we use, and the environment in which we live and work
- It is human nature to overestimate our abilities and underestimate our limitations
- The emerging discipline of human factors combines psychology with engineering

Basics of Human Factors



Human Factors Engineering Principles

- Simplify key processes
- Standardize work processes
- Improve verbal communication
- Create a learning environment
- Promote effective team functioning
- Anticipate that humans make errors

HFE Principles cont'd

- Design systems to fit user's capabilities and limitations
- Avoid over-reliance on memory and problem solving
- Use “affordances” and “natural mapping”
- Use “constraints” and “forcing functions”
- Avoid reliance on vigilance and sustained attention

HFE Tools

1) Heuristic Evaluation

- Checklist approach done by HF expert
- Devices, communication, environment, feedback

2) Root Cause Analysis

- An event is reviewed for latent and active failures

3) Failure Mode Effect (and Criticality) Analysis

- Prospective RCA (event has not occurred)

4) Usability Testing

- Piloting a new tool or device

“We should not all have to
learn the same lessons by
making the same errors”

Society of Academic Emergency Medicine Patient Safety Task Force

ISMP Canada Vision

- Independent nonprofit Canadian organization
- Established for:
 - collection and analysis of medication error reports
 - development and education of recommendations for the enhancement of patient safety.
- Serves as a national resource for promoting safe medication practices throughout the health care community in Canada.

No place in health care

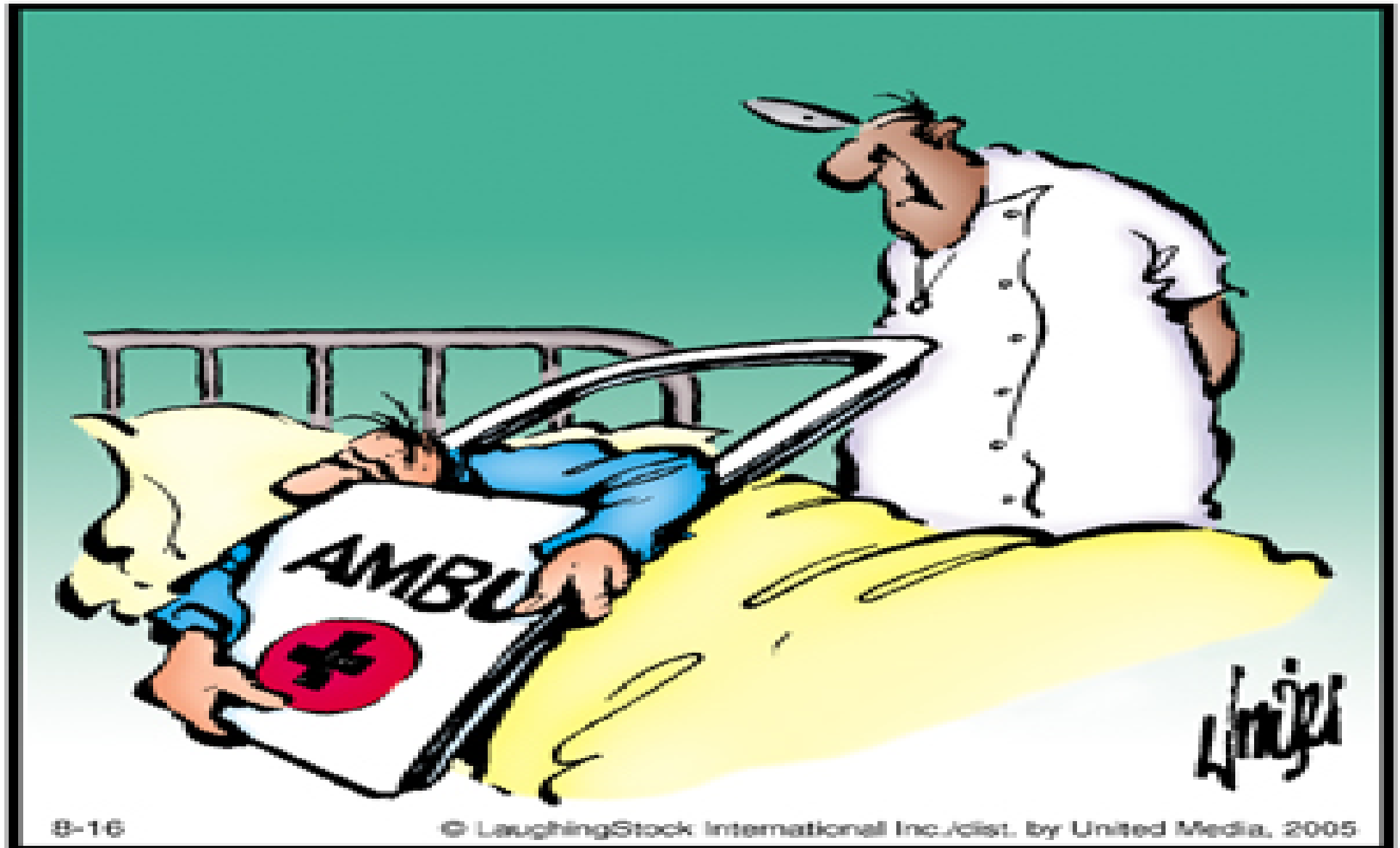
Some mistakes

are too much

fun to make only

once!



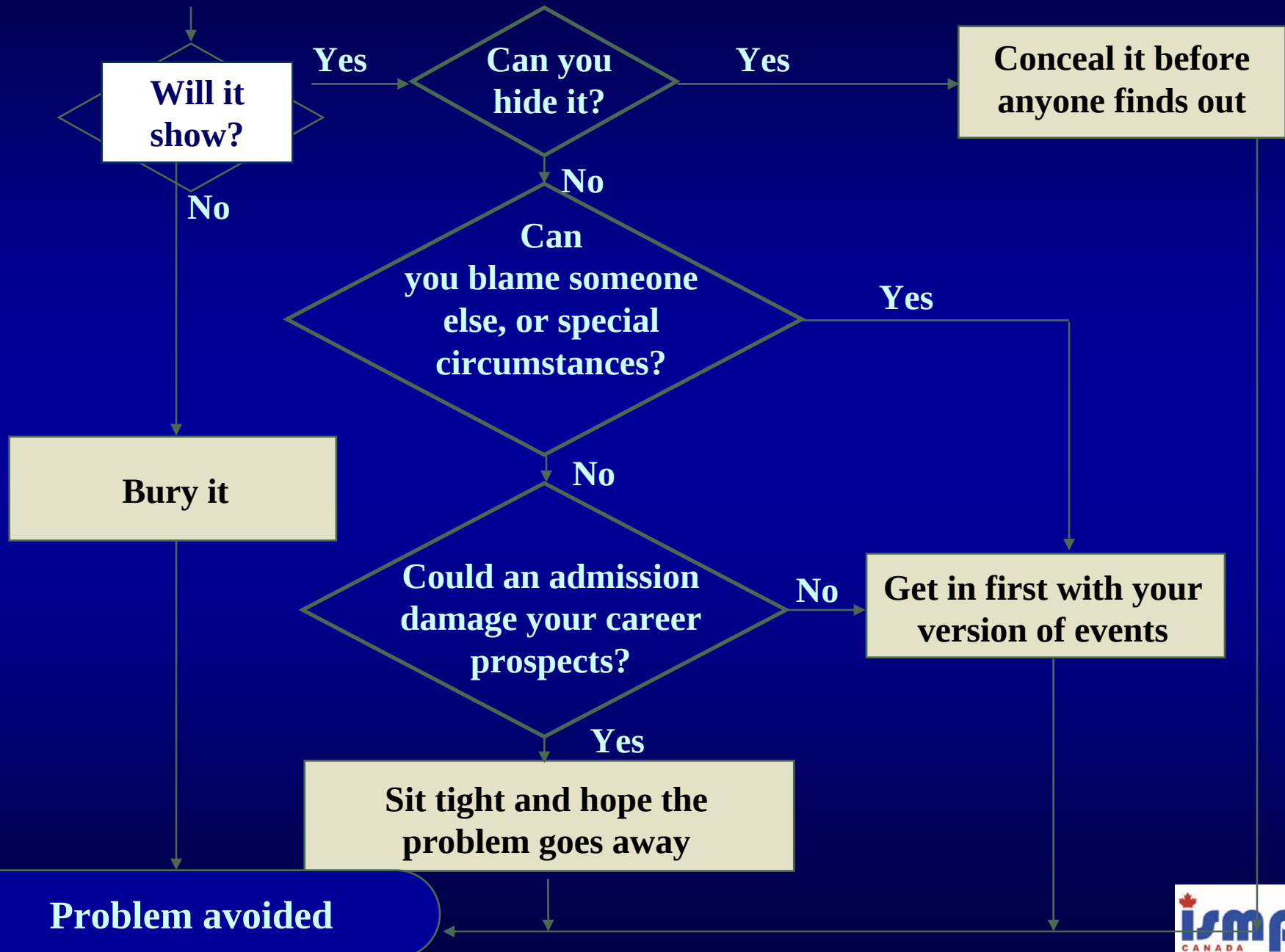


8-16

© LaughingStock International Inc./dist. by United Media, 2005

“Now, now. ... What’s all this I hear about you not wanting to come into my nice hospital.”

You've made a mistake



What is Failure Mode and Effects Analysis (FMEA)?

- FMEA is a team-based systematic and proactive approach for identifying the ways that a process or design can fail, why it might fail, the effects of that failure and how it can be made safer.
- FMEA focuses on how and when a system will fail, not IF it will fail.

FMEA Origins

- FMEA in use more than 40 years beginning in aerospace in the 1960s
- 1970s and 1980s used in other fields such as nuclear power, aviation, chemical, electronics and food processing fields
- High Reliability Organizations
- Automotive industry requires it from suppliers, reducing the after-the-fact corrective actions

Gaining Insight

Engineering

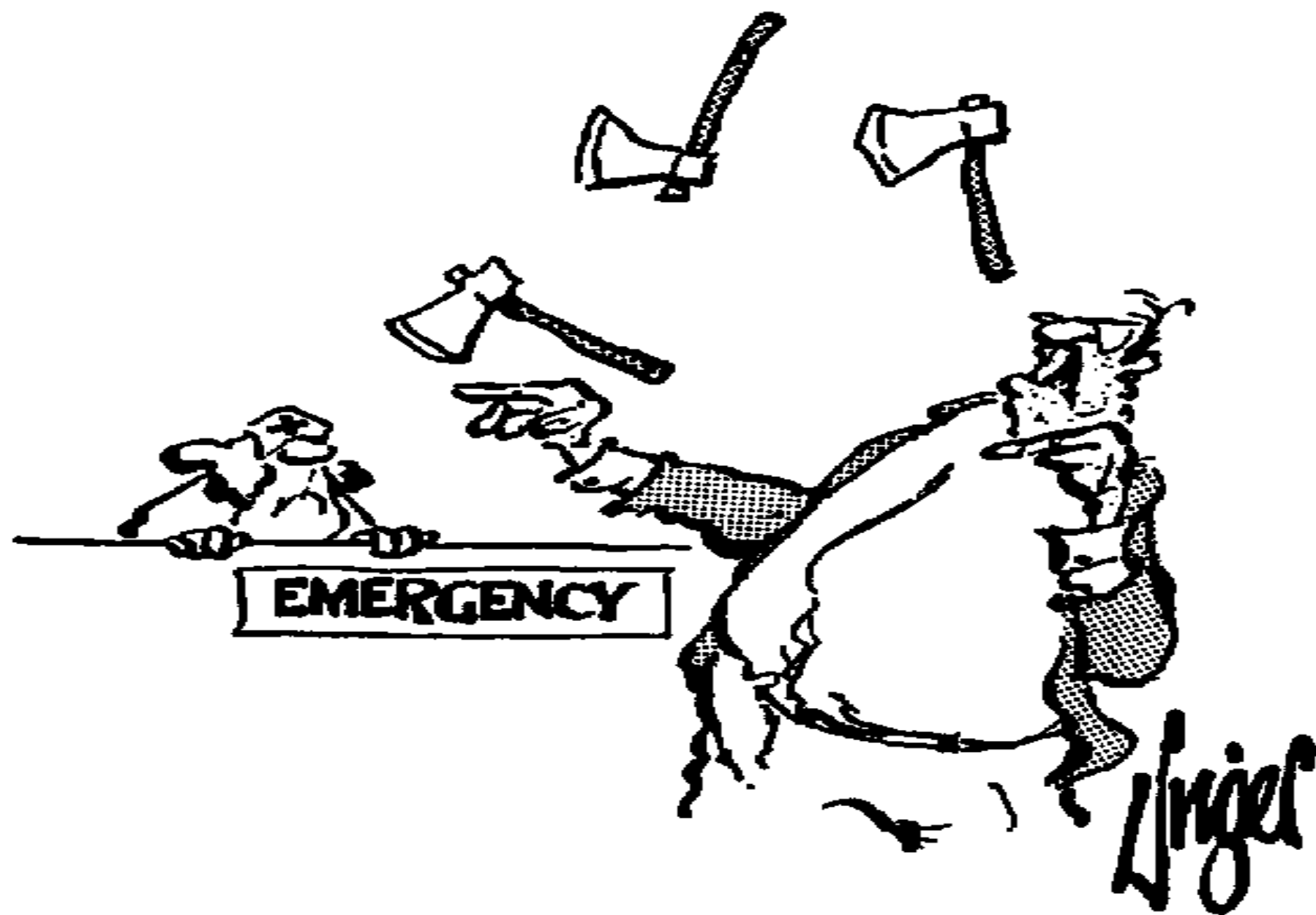
- Begin with premise that anything can and will go wrong
- Don't expect humans to perform perfectly or without variation
- Design systems accordingly and are proactive

Health Care

- Errors are the result of human failures
- Humans generally perform flawlessly
- Perfect performance is the expectation
- Use re-training, and punishment to root out bad apples

Why FMEA?

- Is a proactive approach for quality and safety
- Initiates system fixes before a patient dies or is injured
- Makes systems more “robust” and enhances performance
- Makes systems more “fault tolerant”
- Focuses on systems, not individuals



"I can't stop."

JCAHO: 2003 National Patient Safety Goal #5

As of Jan. 2003- all accredited US hospitals surveyed for implementation of

“5. Improve the safety of using infusion pumps.

- Ensure free-flow protection on all general-use and PCA (patient controlled analgesia) intravenous infusion pumps used in the organization. “

CCHSA Patient Safety Goals 2005

- Improve the effectiveness of communication among care/service providers and with the recipients of care/service.
 - Implement verification processes and other checking systems for high risk care/service activities such as: ordering or receiving the results of critical tests; administering surgical or other invasive procedures; diagnostic testing; and medication use.

When to Use FMEA?

- Proactive look at designing a new system or process
- When processes are changed
- Review of High Risk or Complex processes
- Interdisciplinary processes with hand offs and interdependent steps *

Typical FMEA topics in Health Care

- Blood administration
- Admission / discharge / transfer processes (ADT)
- Patient Identification
- Chemotherapy
- Allergy Information Processing
- Specimen Collection
- New equipment purchase

Sample FMEA Critical Care

Failure Mode

- Wide variety of sliding scale orders (RPN 168)
 - Use of unapproved abbreviations (RPN 34)
 - **Causes**
 - Each physician has own method of writing sliding scale orders
 - Use of “u” instead of word “units” in written order
 - **Effects**
 - Possible order enter errors
 - Misinterpret “u” as zero
 - **Actions**
 - Develop standardized sliding scale order sheet to reduce number of different sliding scales and eliminate use of unapproved “u” abbreviation
- (Source – IHI website 2005)

Medication Safety Self Assessment Tool



HOSPITAL MEDICATION SAFETY SELF-ASSESSMENT™



- Acute care – under revision
- Community Pharmacy – in development
- Long-term Care – in development
- Available at no charge in Ontario on request
- 195 standard statements



Recommendations from Canadian Adverse Events Study:

- Improved reporting and monitoring of adverse events
- Improved communication and coordination among caregivers
- Application of relevant new technologies

Baker GR, Norton PG et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ 2004; 170(11):1678

ERROR TRACKING PROGRAM

Non-punitive, Non-blame, systems approach

The logo for the Analyze-ERR program. It features a large, stylized blue letter 'A' on the left. To its right, the word 'ANALYZE-ERR' is written in a bold, sans-serif font. 'ANALYZE' is in blue, and 'ERR' is in red. A registered trademark symbol (®) is located to the upper right of the word 'ERR'.

VERSION 1.3

Now Version 3.0



The permission to use the Taxonomy of Medication Errors copyrighted by the National Coordinating Council for Medication Error Reporting and Prevention in this program is gratefully acknowledged.

Copyright 2002,2003 ISMP Canada. All rights reserved.

Culture of Safety

Support a shift to:

- Voluntary reporting of errors and “good catches” (near misses) is the norm
- Seeing errors as a system fault
- Non-punitive environment

Analyze- ERR® Participation

- Support MoH – offered without charge to Ontario Hospitals
- Current usage:
 - 60 + acute care sites
 - 5 LTC
 - EMS
- Submit to build Ontario database (over 10,000 reported events) source for educational bulletins and interventions

HFT

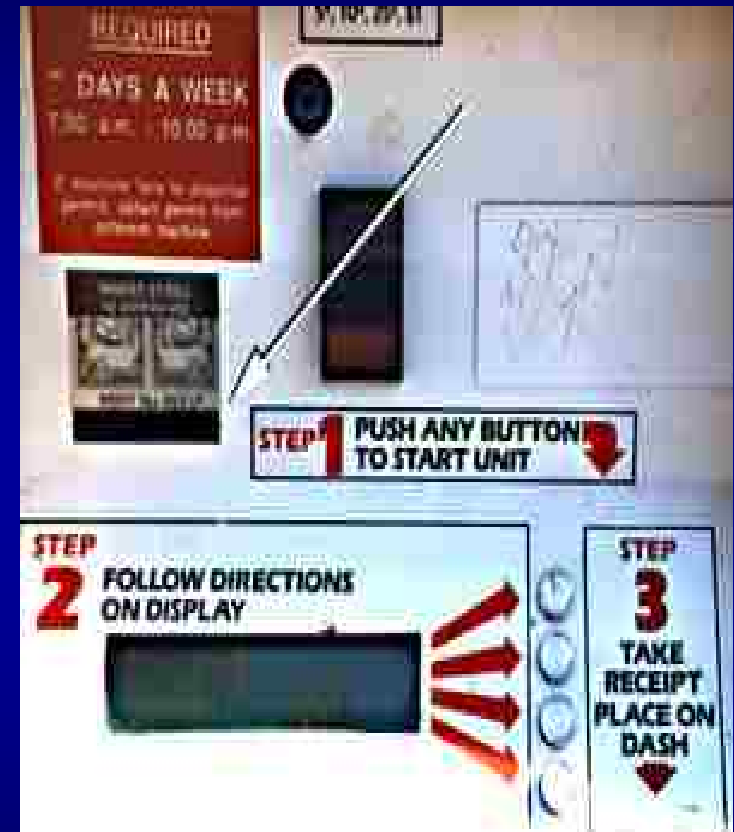
Human Factors Theory

- A new discipline about which all healthcare personnel should be aware / underpin orientation programs
- A guiding principle to perform RCA and FMEA
- Provides triggers to ask relevant questions in event analysis
- Helps understand how humans interact with devices and systems

Human Factors Engineering Guidelines

- Application Human Factors Theory
- Feedback and visibility of system status
- Consistent model
- Functions of controls are clear / consistent
- Displayed messages are clear / understandable
- Minimizing user memory load
- Readable and understandable labels and warnings
- Recognition and recovery from errors

Reduce Memory OVERLOAD



Decision Making

- Driving factors for decisions of purchasing equipment in Critical Care:
 - Budget ?
 - Congruence with current equipment and practices ?
 - Easy to learn ?
 - Who else is using it ?
 - FMEA complete?
 - HFT?

Apply HFT

- **Communication**
- **Education / training**
- **Fatigue / scheduling environment**
- **Equipment**
- **Rules / Policies / Procedures**
- **Barriers**

Source - VA Hospitals

Human Factors - Guiding Principle

Fit the task or tool to the human, not
the other way around

Confirmation Bias

It leads one to “see” information that confirms our expectation rather than to see information that contradicts our expectation.

HINT: “Alphabet”

B

Hint: “NUMBER”

B

Confirmation Bias
can lead to
Substitution Errors

The power of the human mind

According to a research at Cambridge University, it doesn't matter in what order the letters in a word are. The only important thing is that the first and last letter be at the right place. The rest can be a total mess and you can still read it without problem. This is because the human mind does not read every letter by itself, but the word as a whole.

Amazing huh?

Look-a-like / Sound-a-like

- Lamictal / Lamisil drug error
 - Use TALL MAN lettering to distinguish

lamiCTAL / lamiSIL

- In ICU – Morphine / Hydromorphone
Sufentanil / Fentanyl
 - Segregate or separate storage

Project example

- Telemetry unit in Toronto area
- Participant in Opioid (Narcotic) Project ISMP Canada in “Storage and Standardization” section
- Address potential errors and time consumed with narcotic count and administration

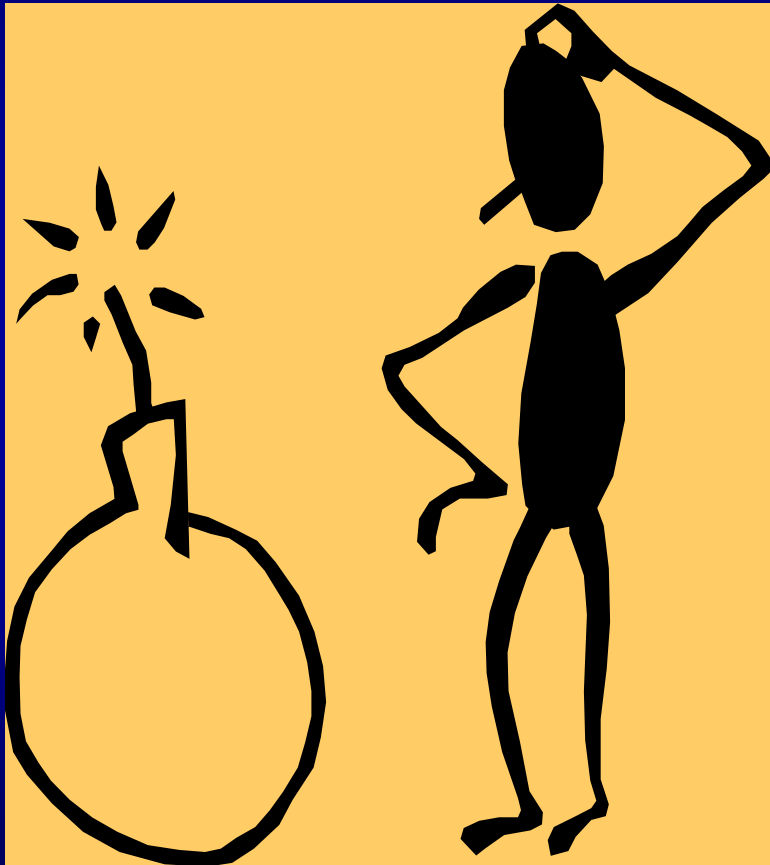


Important Observations

- Too full
- Unused products
- Look alike products
- Labels torn off long acting preparations



Errors?



- Nurses, pharmacists and physicians are not perfect creatures
- Working in an imperfect system
- Examine just one task that happens repeatedly everyday in ICU.....

Adverse Events

#1

Surgical = 34.2%

#2

**Medication and
fluid-related =
23.6%**

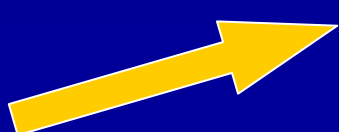


Table 5: Procedures or events to which AEs were related, by service most responsible for delivery of care at time of AE

Type of procedure or event*	Most responsible service; no. of AEs			Total
	Medicine	Surgery	Other†	
Surgical	6	115	2	123
Drug- or fluid-related event	69	15	1	85
Other clinical management	30	11	2	43
Diagnostic	26	11	1	38
Medical	16	9	1	26
Other‡	9	8	1	18
System event§	3	4	4	11
Fracture	2	5	1	8
Anesthesia-related event	1	6	0	7
Obstetric	0	1	0	1
Total	162	185	13	360

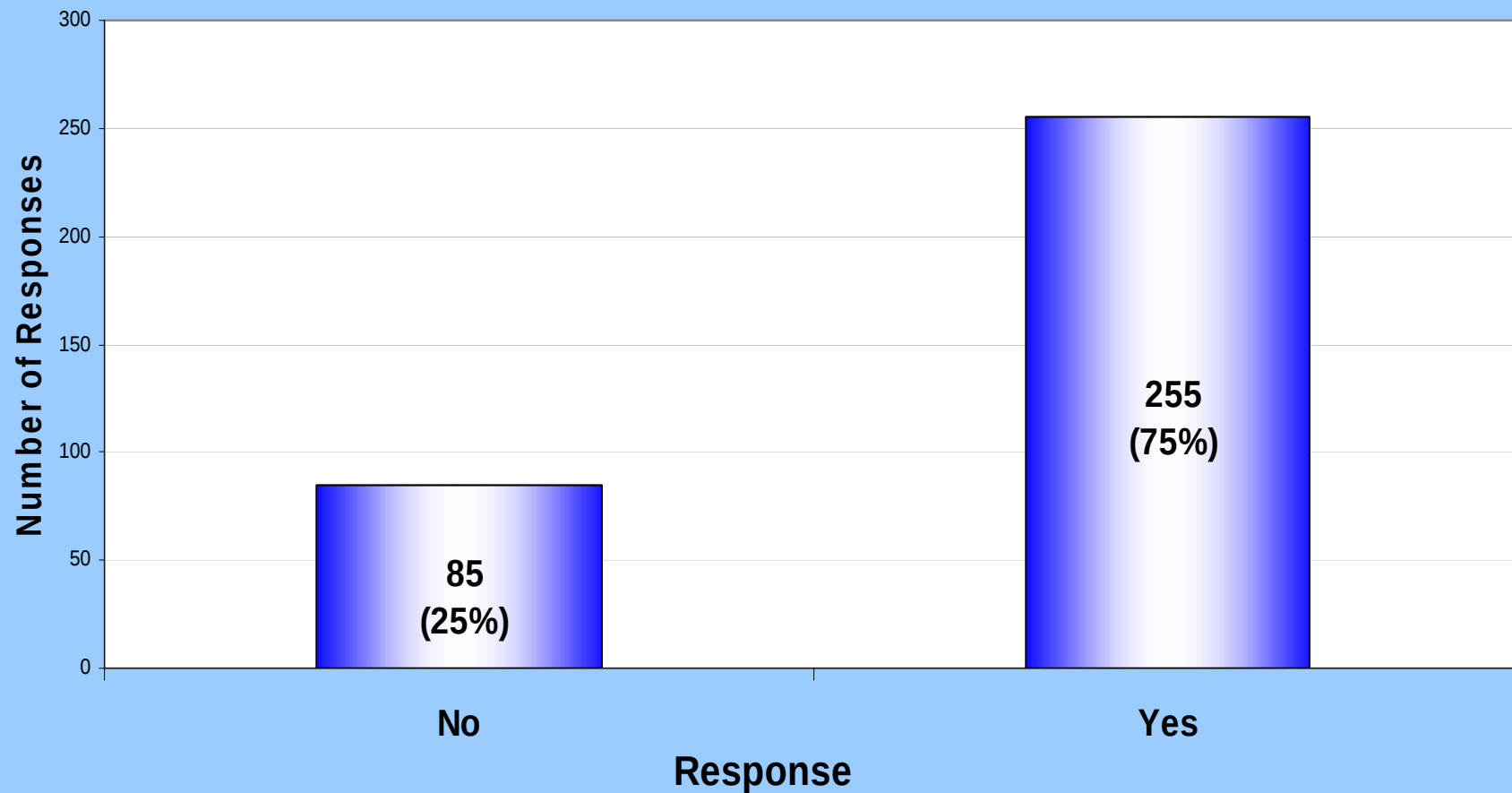
*Physician reviewers could attribute events to more than 1 type of procedure.

†Includes dentistry and oral surgery, nursing, osteopathy, pharmacy, physiotherapy and podiatry.

‡AEs not covered in previous categories (e.g., burns, falls).

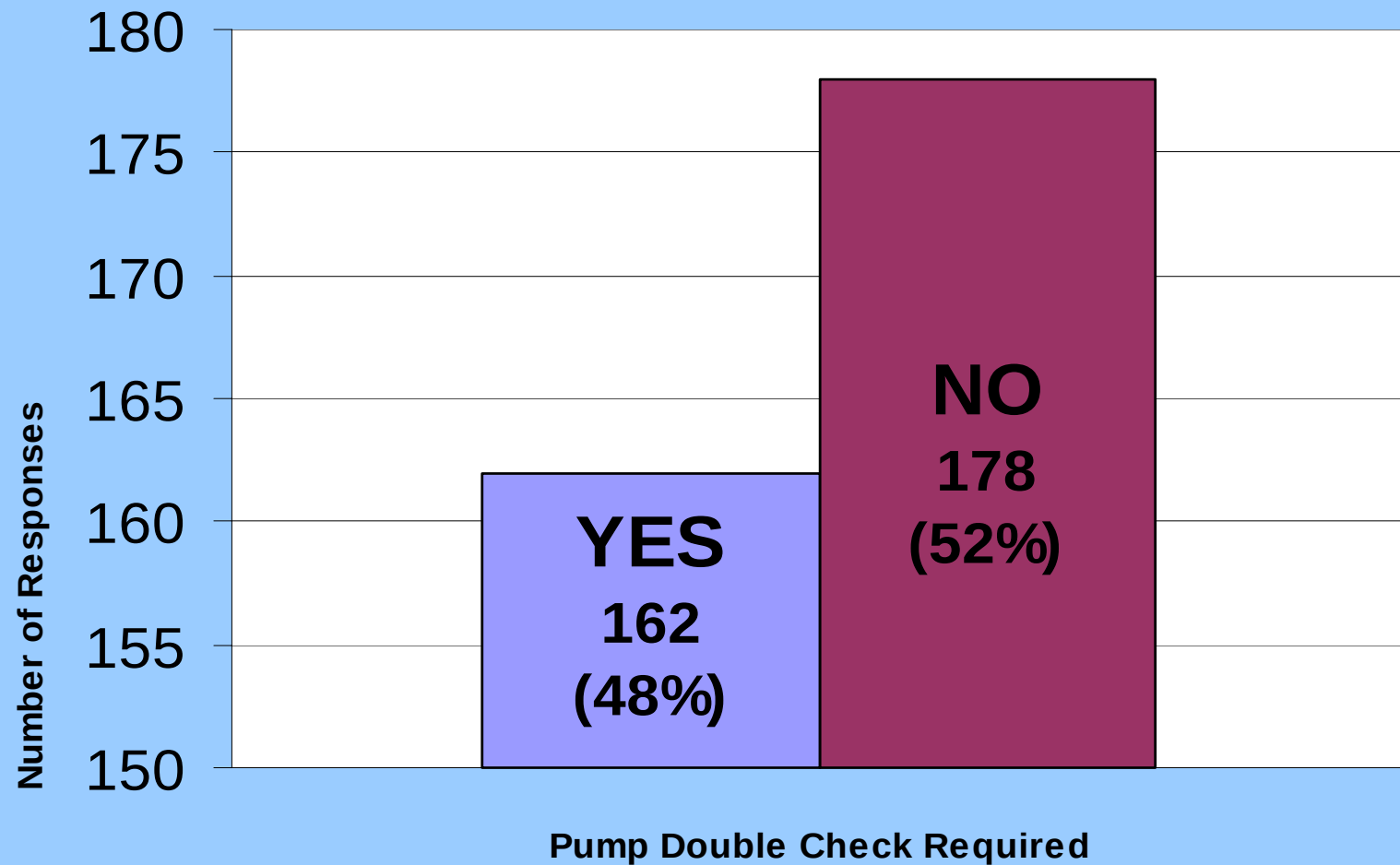
§System events include AEs that cannot be attributed to an individual or specific source (e.g., communication, reporting, lack of equipment).

ISMP Canada Infusion Pump Safety Project
Pump Problems Encountered (n=340)

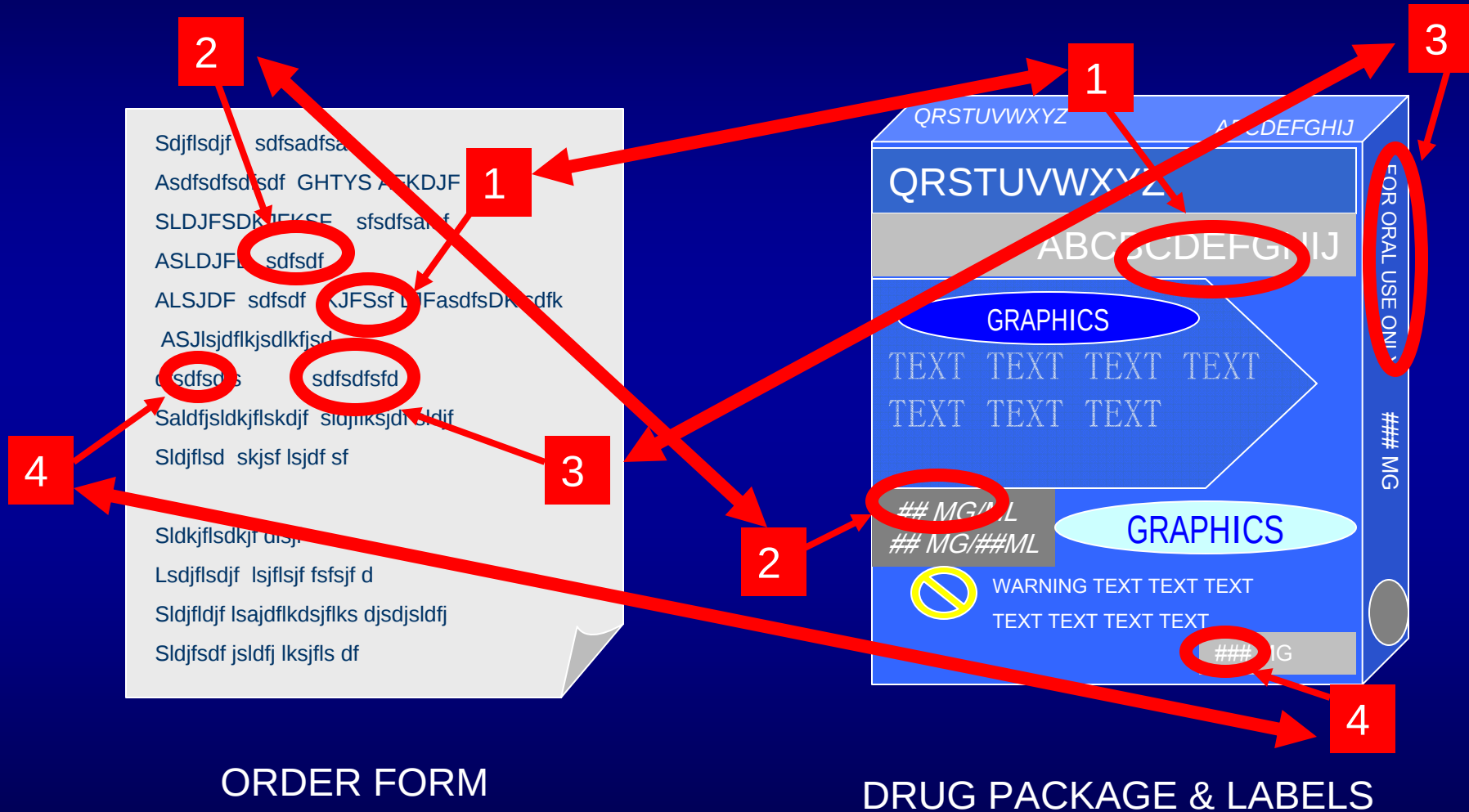


ISMP Canada Infusion Pump Safety Project

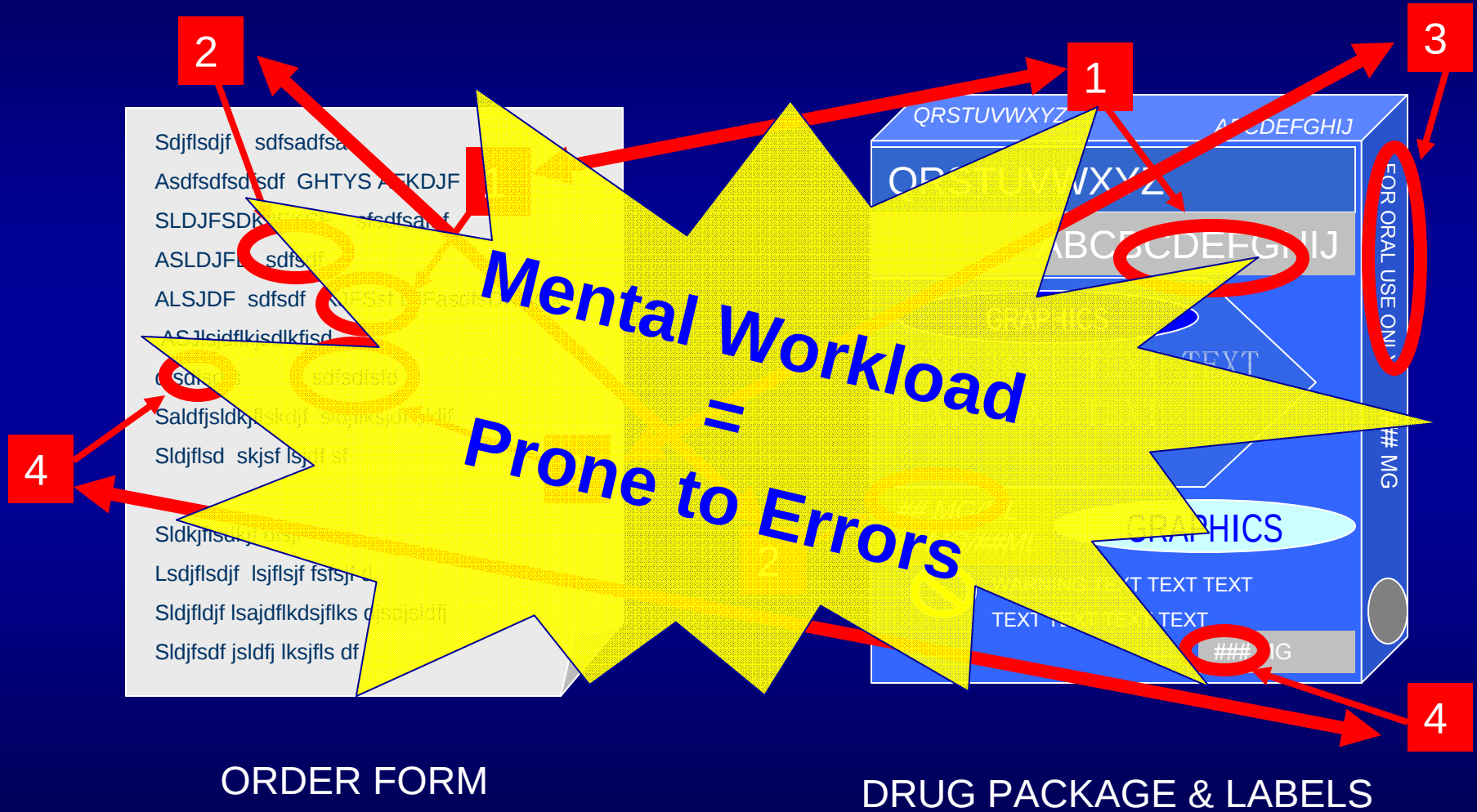
Double Check Policy (n=340)



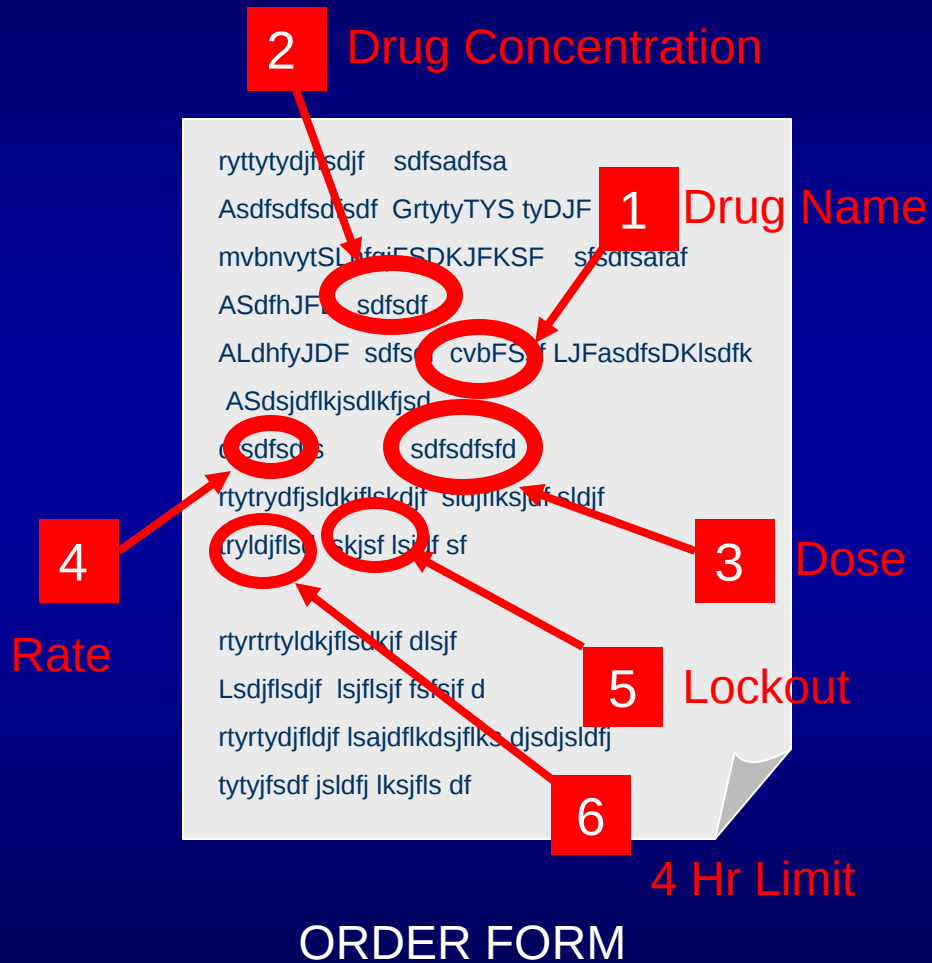
The Physical and Cognitive World



Drug Packages & Labels



Keyhole Effect



What Did ISMP Do?

- Worked with a human factors engineer to develop a process
- Tested the process on one PCA pump
- Tested a redesign of the process
- Developed a tool that works!

First Usability Test

Compared:

- Flow sheet method – nurse uses flow sheet (monitoring form) to record settings from pump
- Verbal read back method – nurse conducting check reads pump settings for first nurse to check against order form

Review of Existing Forms for Congruity, Consistency, Predictability

Order Form

PCA Order Form

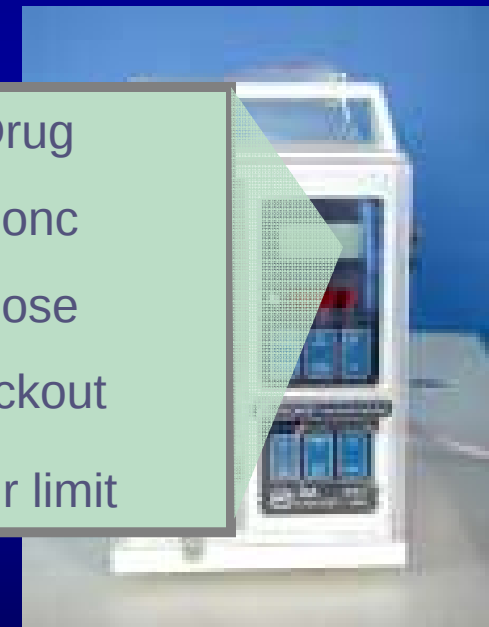
Drug
Conc
Dose
Lock-out time
4 hr limit

Flow Sheet (Double Check Tool)

Flow Sheet

Drug
Conc
Dose
Lock-out time
4 hr limit

Pump



Tools – Design Forms and Labels to Match

Doctor's Order Sheet
Anesthesia/Acute Pain Service
Patient Controlled Analgesia (PCA) Orders

PLEASE USE BLOCK OR BLUE BALLPOINT PEN, PRESS HARD

ALLERGIES:
NO KNOWN ALLERGIES
KNOWN ALLERGIES: (Specify)

PHYSICIAN'S ORDER AND SIGNATURE

While on PCA device, the patient is to receive no further supplemental Narcotics or other CNS depressants unless approved by the Anesthesia/Acute Pain Service.

Only the patient should press the PCA delivery pendant unless otherwise directed by the APS.

(Check ☒ appropriate box(es) and complete orders as required)

1. PCA DRUG:
☐ Morphine 2 mg/mL
☐ Hydromorphone 0.4 mg/mL
☐ Other: _____

2. PUMP SETTINGS:
Dose _____ mg to _____ mg
Initial Lockout Interval _____ minute(s)
Four hour limit _____ mg

3. MONITORING:
i) a) Two RN's will check and verify the initial PCA settings and document on PCA Flow Sheet.
b) RN will check and verify PCA setting every shift and document on PCA Flow Sheet.
c) Respiratory Rate and Sedation Score q 2 h x 24 hours, then q 4 h. Record on PCA Flow Sheet.
ii) **Call Acute Pain Service (APS) if:**
a) Respiratory Rate less than 10/minute.
b) Blood Pressure Systolic less than 90 mm Hg.
c) Pulse less than 50 beats per minute.
d) Sedation Score of 3 (somnolent, difficult to rouse) or if patient confused.
e) Inadequate pain control (eg: Pain score greater than 4 out of 10).
f) If four hour limit of drug dose is reached before 4 hours has elapsed.
iii) If side effects of slow respiratory rate, hypotension or somnolence occur, **STOP** PCA Pump immediately and inform attending service as well as Acute Pain Service.

Independent Double Check CHECKLIST

☐ Patient Name?
☐ Syringe Drug?
☐ Syringe Conc?
☐ Programmed Conc?
☐ Micro- or Milligram?
☐ Four hour limit?
x _____
signature



Checklist Tool

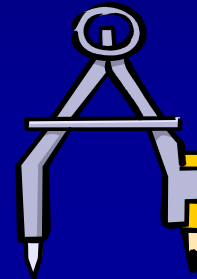
The tool is a checklist embedded onto a PCA order form

- reminds and guides nurses through an independent double check



Goals of Tool Design

- Simple, concise, natural language & familiar terms
- Logical layout of info
- Located close to where task is carried out
(minimize working memory)
- Easily identifiable as reference
- (should not require reading)
- Provides enough info and detail for new user
- Provides “quick” shortcuts for familiar users



Develop Tools (cont'd) – Incorporate a Checklist

This is an example of an existing PCA order form. This order form was NOT evaluated. Only the *Independent Double Check CHECKLIST* was evaluated in the usability test.

Doctor's Order Sheet

Anesthesia/Acute Pain Service
Patient Controlled Analgesia (PCA) Orders

PLEASE USE BLACK OR BLUE BALLPOINT PEN. PRESS FIRMLY.

ALLERGIES:
NO KNOWN ALLERGIES
KNOWN ALLERGIES: (Specify) _____

PHYSICIAN'S ORDER AND SIGNATURE

While on PCA device, the patient is to receive No further supplemental Narcotics or other CNS depressants unless approved by the Anaesthesia/Acute Pain Service.

Only the patient should press the PCA delivery pendant unless otherwise directed by the APS.

(Check ☒ appropriate box(es) and complete orders as required)

1. **PCA DRUG:**
☐ Morphine 2 mg/mL.
☐ Hydromorphone 0.4 mg/mL.
☐ Other: _____

2. **PUMP SETTINGS:**
Dose _____ mg to _____ mg.
Initial Lockout Interval _____ minute(s).
Four hour limit _____ mg.

3. **MONITORING:**
i) a) Two RN's will check and verify the initial PCA settings and document on PCA Flow sheet.
b) RN will check and verify PCA setting every shift and document on PCA Flowsheet.
c) Respiratory Rate and Sedation Score q 2 h x 24 hours, then q 4 h. Record on PCA Flow Sheet.
ii) **Call Acute Pain Service (APS) if:**
a) Respiratory Rate less than 10/minute.
b) Blood Pressure Systolic less than 90 mm Hg.
c) Pulse less than 50 beats per minute.
d) Sedation Score of 3 (somnolent, difficult to rouse) or if patient confused.
e) Inadequate pain control (eg: Pain score greater than 4 out of 10).
f) If four hour limit of drug dose is reached before 4 hours has elapsed.
iii) If side effects of slow respiratory rate, hypotension or somnolence occur, **STOP** PCA Pump immediately and inform attending service as well as Acute Pain Service.

Independent Double Check CHECKLIST

☐ Patient Name?
☐ Syringe Drug?
☐ Syringe Conc?
☐ Programmed Conc?
☐ Micro- or Milligram?
☐ Dose?
☐ Lockout?
☐ Four hour limit?
X _____
signature _____

2128

Focus of
usability
test

Independent Double Check

CHECKLIST

☐	Patient Name?
☐	Syringe Drug?
☐	Syringe Conc?
☐	Programmed Conc?
☐	<i>Micro or Milligram?</i>
☐	Dose?
☐	Lockout?
☐	Four hour limit?
x	_____
	signature

Independent Double Check Tool

Key Results

- Feedback indicated that the checklist:
 - Provided an effective **visual reminder**
 - Provided a **visual reference alleviating burden on memory**
 - Provided the **right prompts to check specific things that might be easily missed**
 - **Was intuitive**
 - Needs to be **tailored** to specific settings

Recommendation

Implement a policy of
independent double checks
for PCA infusions

Why Do Independent Double Checks?

- Not about competence
- Reduces probability of error
- Acknowledges that errors happen
- Acknowledges human factors issues with equipment

WHY IDC?

- We have unreasonable expectations of staff
- Selective independent double checks are an additional barrier until our systems have improved

CULTURE AND COMMUNICATION

1. Educate staff regarding the system-based causes of medication error.
2. Educate staff about the hierarchy of effectiveness of error reduction strategies.
3. Include the patient/family in the narcotic medication-use process.

STORAGE AND STANDARDIZATION



1. Remove the following stock items from patient care areas:

- Hydromorphone ampoules or vials with concentration greater than 2 mg/mL (exceptions may include palliative care).
- Morphine ampoules or vials with concentration greater than 15 mg/mL.
- Morphine ampoules or vials greater than 2 mg/mL in paediatric patient care areas.
- Sufentanil (exceptions may include Operating Room and Labour and Delivery).

2. Assess risk associated with narcotic stock in patient care areas.
3. Restrict as much as possible the admixing of narcotic solutions outside of pharmacy.
4. Standardize infusion concentrations of parenteral narcotic medications and selection of medications for pain management.

INDEPENDENT DOUBLE CHECK



1. Implement a policy of Independent Double Checks for PCA infusions.

The policy should include a clear process for an independent double check and documentation when the following occur:

- o Initial pump programming
- o Changes in pump programming
- o Solution changes
- o Patient transfers

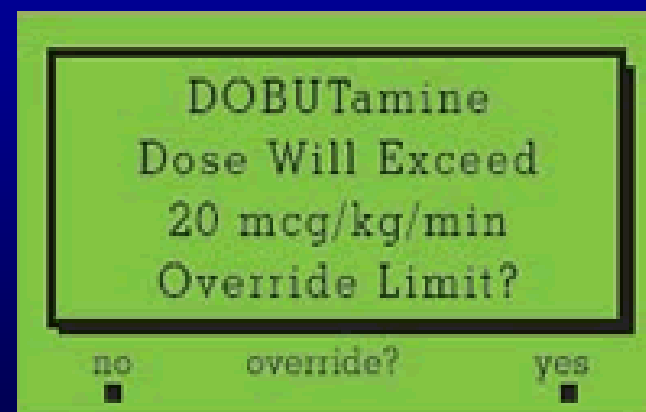
2. Consider a policy of Independent Double Checks for:
 - a. All opioid infusions (continuous or intermittent)
 - b. Epidural infusions

PCA AND EPIDURAL

1. For PCA, develop and follow patient selection criteria (inclusion and exclusion).
2. For epidural, identify and implement multiple error prevention strategies to enhance differentiation of epidural infusions from other infusions.

Smart Pumps

- Comprehensive drug libraries to accommodate hundreds of drugs
- Specific for care areas
- Detects and warns out-of-range dose
- Maximum and Minimum dose and infusion rate
- Intervention Log
- CQI Report



Defibrillators

Definition?

- Multifunction device with end users in a hectic, noisy, dynamic environment
- Must be usability tested and validated
 - Clear, easily read controls and displays
 - Pacemaker pads and wires connection is obvious without causing more entanglement!

Source: Using Human Factors Engineering to Improved Patient Safety. J Gosbee, JCR Inc. 2005

SBAR

HFT tool for communication

- Bedside report as team response to STAT call
- Paper tool for phone consults

S = Situation

B = Background

A = Assessment

R = Recommendation / Request

“Technically the biggest ‘safety system’ in healthcare is the minds and hearts of the workers who keep intercepting the flaws in the system and prevent patients from being hurt. They are the safety net, not the cause of injury”.

Don Berwick