Thinking Like an Engineer: Utilizing Human Factor Methodologies to Improve IV Medication Safety in the Peri-operative Setting

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DISCLOSURE

- The speaker has no conflicts of interest to disclose in relation to this presentation

Learning Objectives for Pharmacists and Pharmacy Technicians

1. Describe the medication use process during the administration of anesthesia.
2. Identify the differences between the system vulnerabilities for preparing medications from a manufacturers drug vial vs. a pharmacy prepared prefilled syringe.
3. Discuss the severity of the system vulnerabilities for preparing medications from a manufacturers drug vial vs. a pharmacy prepared prefilled syringe.
4. Explain strategies to improve medication safety during the course of administering an anesthetic for surgery.
5. State the basic elements involved when considering prefilled syringe adoption in the O.R.

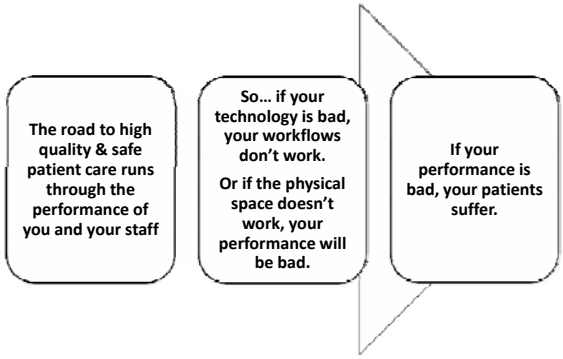
A Call from the Institute of Medicine

- IOM report *To Err is Human: Building a Safer Health System* released in 2000
- Led to many human factors engineering efforts designed to reduce:
  - Error rates in hospitals
  - Consequences of errors
- Much of the focus has been on nursing work, ICUs, surgery

Take Away Messages...

This is what we know:	
• Quality and safety emerge from the interaction between people and the system in which they work. • **Human factors engineering** helps us to understand that interaction so that we can better design systems to improve quality and safety.	**Learn about it!**
• We have tools, standards, guidelines, and principles for improving human performance, safety, and productivity.	**Use & apply them!**
• Human factors engineering improves performance and safety…	**…when used and implemented appropriately**

Main Take-Away Message



Common Healthcare Thinking

- Errors are personal failings
  - When something bad happens, someone must be at fault
- Policies create safety
- And recently…
  - ***Technology will save us!***

What Is Human Factors Engineering?

Science

- Discovers and applies information about human behavior, abilities, limitations, and other characteristics to…
- … the design of tools, machines, systems, tasks, jobs, and environments…
- … for productive, safe, comfortable, and effective human use

Practice

- Designing the fit between people and:
  - Products
  - Equipment
  - Facilities
  - Procedures
  - Environments

HFE Topics of Study

- Usability
- Organizational changes
- Workflow
- Handoffs
- Mental workload
- Situation awareness
- Human-automation interaction
- Training
- Teamwork and team training
- Information processing
- Naturalistic decision making
- Interruptions/distractions
- Violations
- Human error
- Safety
- Resilience
- Alerts
- Lifting

Who *Requires* Human Factors Engineering In Their Designs?

- US Federal Aviation Administration
- Department of Defense
- Department of Transportation
- Nuclear Regulatory Commission
- Department of Energy
- National Aviation and Space Administration
- FDA – Medical Device Testing

What Are the Objectives?

- **Reduce** errors, fatigue, stress and injuries at work, while at the same time…
- **Improve** productivity, ease of use, safety, comfort, acceptance, job satisfaction, and quality of life

Or simply –
improve safety, quality, efficiency, and productivity
all at the same time

Too good to be true?

Raise your hand when you know
HOW MANY results are out of range!!!

Ready…?

Species : Adult Canine
Patient : SYDNEY
Client : SUE B

Test		Results	Reference Range
ALKP	=	85 U/L	23 - 212
ALT	=	23 U/L	10 - 100
BUN	=	16.6 mg/dl	7.0 - 27.0
CREA	=	0.77 mg/dl	0.50 - 1.80
GLU	=	130.6 mg/dl	77.0 - 125.0
TP	=	6.21 g/dl	5.20 - 8.20
Na	=	148.9 mmol/l	144.0 - 160.0
K	=	4.44 mmol/l	3.50 - 5.80
Cl	=	116.9 mmol/l	109.0 - 122.0

Okay, try again.

Raise your hand when you know
HOW MANY results are out of range!!!

Ready…?

Test	Results	Reference Range	Indicator (LOW / NORMAL / HIGH)
ALKP	= 85 U/L	23 - 212	
ALT	= 23 U/L	10 - 100	
BUN	= 16.6 mg/dl	7.0 - 27.0	
CREA	= 0.77 mg/dl	0.50 - 1.80	
GLU	= 130.6 mg/dl	77.0 - 125.0	
TP	= 6.21 g/dl	5.20 - 8.20	
Na	= 149.9 mmol/l	144.0 - 160.0	
K	= 4.44 mmol/l	3.50 - 5.80	
Cl	= 116.9 mmol/l	109.0 - 122.0	

What Was the Difference?

The first data presentation:	The second data presentation:	Both presentations:
• Was cognitively challenging because you needed to mentally find the lab value, and then interpret whether or not the value was in range • Each comparison was an opportunity for error	• Provided what we call a **direct perception** display to answer the cognitive challenge I posed to you	• Are typical of types of displays you might encounter every day • Affected accuracy (quality/safety) and response time (productivity) • Only one was good

Can HFE Really Do All That?

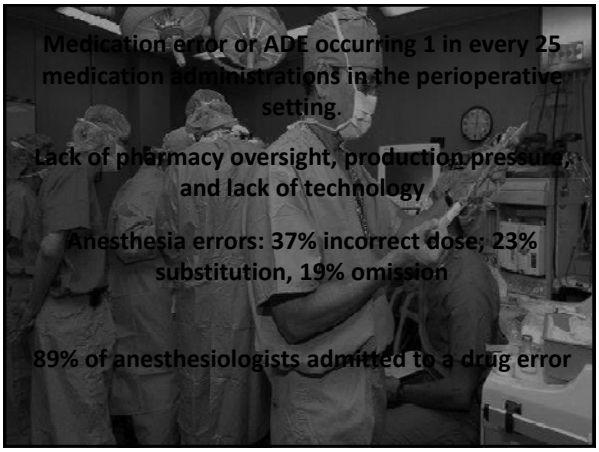
- Yes, because we focus on designing systems to support human performance
- It's about human performance **in context** or **in the system**

What Does HFE Focus on to Meet the Objectives?

- **Identification** of performance: what are people actually doing?
- **Analysis** of the interaction between human performance and work systems
- **Design** of work systems to support/extend performance & eliminate/reduce performance obstacles

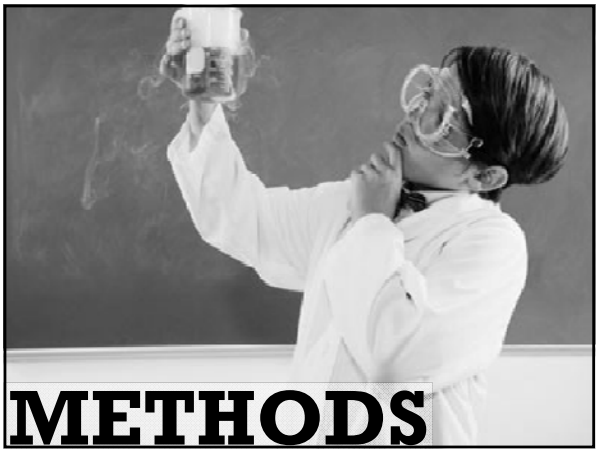
Use "HFE Thinking"

- Systems (e.g., machines or hospitals) need to be designed for people, and to work with people
- Systems must be designed to accommodate the range of users
- How systems are designed will influence human behavior and therefore system performance
- Design needs to be evidence-based, not "common sense" or designer driven
- All design must take into account the system of use



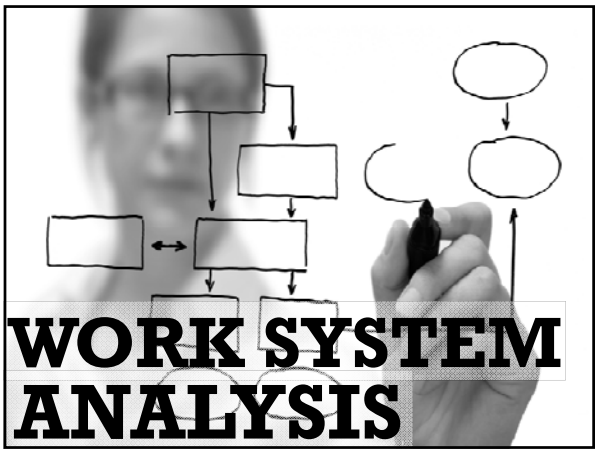
Medical Univ. of South Carolina

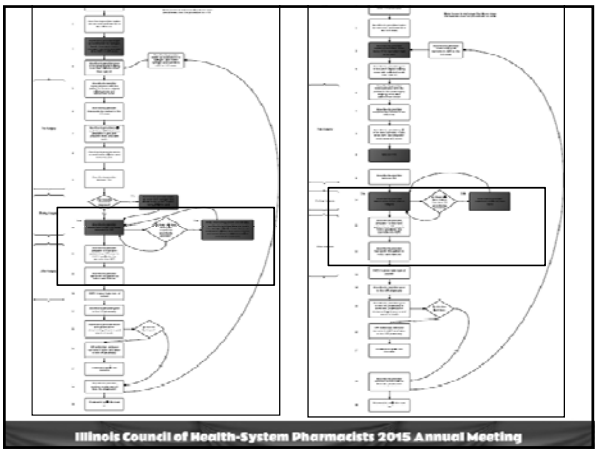
- **Located in Charleston, SC**
- **709-bed academic medical center**
- **Level 1 Trauma Center**
- **Operating Room Suites**
  - Medical University Hospital Main OR
  - Ashley River Tower OR
  - Rutledge Tower Ambulatory OR
- **23,550 cases/year**
- **3 OR Pharmacies**
  - 6 FTE pharmacists
  - 3.2 FTE pharmacy technicians
  - 0.4 FTE pharmacy students



Methods

- **Work system analysis observing general surgery cases**
  - Self-filled syringes
  - Pre-filled syringes
- **Identify system vulnerabilities/process map**
- **Anesthesia clinician proactive risk assessment**
  - Occurrence
  - Severity
  - Disruptiveness to workflow





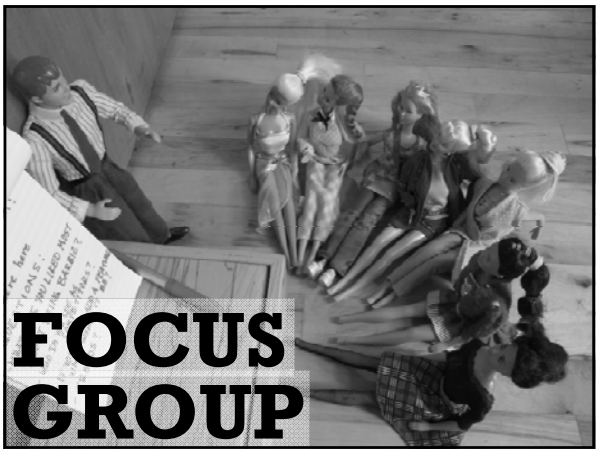
What are "system vulnerabilities"?

An activity or event that has the potential to reduce safety, efficiency, and/or provider workflow

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

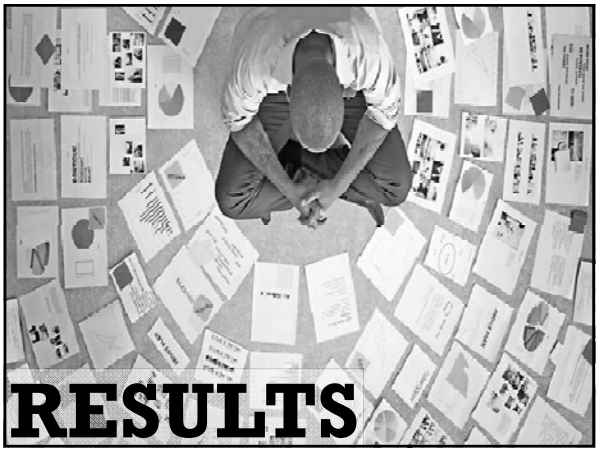
SV#	Steps in WFA	SV Description	Possible Effects	Additional Notes	Occurrence	Severity on Patient	Disruptiveness to Workflow	Discussion
1	3(E) 2(F) 2(G); 10a (D); (E) Anesthesia provider draws up medication, places sticker on syringes and labels syringes	Anesthesia provider completes the process in an incorrect sequence: placing medication sticker first, then drawing-up medication, and finally labeling self filled syringes.	This SV could lead to the potential for **incorrect labeling** of medication, and **incorrect medication administration**, especially if completed in distracting environment.	As required by the Joint Commission, medications should be drawn-up first, and then a sticker should be placed and a label created. This SV violates the TJC standard.				
2	3 (G); 10a (F) Anesthesia provider labels the syringe by signing initials, date and time of the draw-up, and the concentration of the med.	Anesthesia provider forgets to label, or purposely does not label, or inappropriately labels post-immediate administered medication.	This SV could lead to the potential for **incorrect medication administration**.	The Joint Commission requires that self-prepared medications must be appropriately labeled with the drug name, strength, amount, expiration date, MD/CRNA initials, and date and time of when it was drawn up. This SV is a violation of the TJC standard.				
3	3 (H) Anesthesia provider prepares syringes in a pink, bin in the top drawer of ADC and then goes to the pre-surgery holding room	When preparation is complete, anesthesia provider leaves syringes on the ADC counter surface, instead of storing them in the drawer of ADC.	Leaving syringes on counter, increases the exposure time to air, causing **sterility problems**. Also, it increases the risk that these medications can be tampered with or taken by inappropriate personnel.	N/A				

SV#	Steps in WFA	SV Description	Possible Effects	Additional Notes	Occurrence	Severity on Patient	Disruptiveness to Workflow	Discussion
1	1 Anesthesia provider organizes needed medications and stores PPS cassette/ narc kit in ADC	Anesthesia provider stores cassette / narc kit in ADC directly without working on necessary preparation and organization for current case.	Not organizing PPS prior to the case could create **workflow delays** when patient arrives to the OR.	N/A				
2	3 (A); 4; 5 10a (B) Anesthesia provider organizes medications by quickly looking at medication name and dose	Although Tall-Man lettering (e.g., Succ vs. Vec) is used, similarly colored packaging is used for completely different medications.	This similar packaging creates the opportunity for **an incorrect medication** to be selected and then administered to patient.	The potential impact of this SV is magnified during hectic situations when extra medications are needed.				
3	2; 7; 10a Anesthesia provider pulls medication in the ADC top drawer and prepares work area by placing PPS on ADC counter surface.	Each anesthesia provider organizes syringes on ADC surface based on personal preferences, such as grouping similar types of syringes together (e.g., emergency, induction, muscle relaxation, etc.).	This SV could increase the opportunity for a **medication administration error**, especially when other providers take over shifts because the new provider may not be familiar with the previous provider's method of organization.	There is no national best practice for this process standardization.				
4	9; 10a Anesthesia provider prepares and administers medication	Multiple teaching methods by attending anesthesiologists result in different medication delivery styles and administration quality by residents	This SV could impact the **quality of medication administration** of anesthesia medications.	The teaching process should be standardized.				



Focus Group

Ratings	Occurrence	Severity on Patient	Disruptiveness to Workflow
1	This SV **rarely** occurs (e.g. 0-3 times per year)	This SV results in **no injury** to the patient.	This SV has **no influence** on provider's workflow
2	This SV **sometimes** occurs (e.g. roughly 1-2 times per month)	This SV results in **moderate injury** to the patient	This SV results in a **slight but recoverable disruption** to provider's workflow
3	This SV **often** occurs (e.g. daily/weekly)	This SV results in **major but recoverable injury** to the patient	This SV results in a **moderate but recoverable disruption** to provider's workflow
4	This SV **always** occurs (e.g. 1-3 times per case)	This SV results in **permanent loss of function or catastrophic death** of the patient	This SV results in an **severe and unrecoverable disruption** providers' workflow



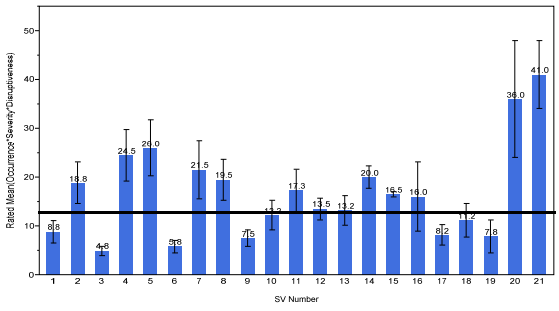
Results

	SELF-FILLED SYRINGES	PRE-FILLED SYRINGES
Number of cases	8	9
Process steps	21	19
System vulnerabilities	21	8
Medications administered per case	9.6	10.3

System Vulnerabilities - SFS

- **Complexity of the preparation and administration process**
- **Variability of task risks to sterility**
- **Lack of standardization of labeling**
- **Usability concerns of packaging**
- **Significant waste after administration**

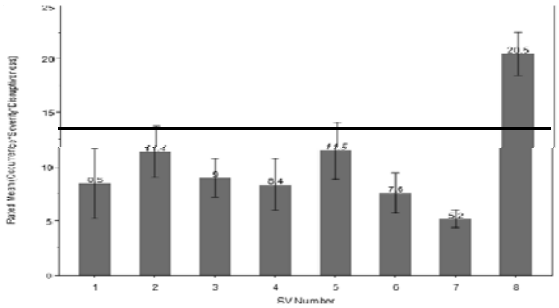
System Vulnerabilities - SFS



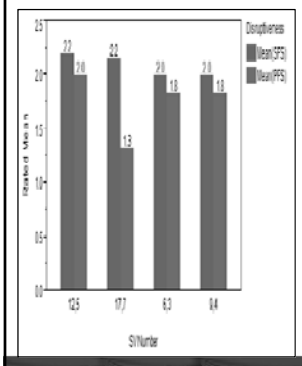
System Vulnerabilities - PFS

- **Variability of task completion**
- **Usability concerns of packaging**
- **Amount of wasted medications**

System Vulnerabilities - PFS

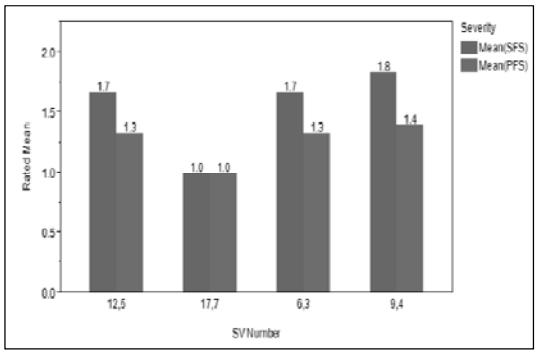


Disruptiveness



- **Obtaining syringes**
- **Syringe organization**
- **Variable delivery styles**
- **Product waste**

Severity



Severity - SFS

- **11 SV had severity score above 16**
  - Pharmacists management product vial changes (drug shortages)
  - Difficulties to ensure the correct medication name on the vial packaging
  - Complex medication preparation process during surgery

Study Conclusions

- **Reduced risk with use of PFS**
- **Highest severity SV for SFS are completely removed with the use of PFS**
- **Most of SV for PFS can be reduced through training and user-centered re-design**
  - Working with anesthesia clinicians on 8 system vulnerabilities
  - Consider the addition of barcode scanning in the OR
- **Make anesthesia providers aware of USP 797 immediate use regulations**

Drug Waste

61%

TOTAL WASTE REDUCTION WITH THE USE OF PFS

Waste Reduction Summary

	Phase I (baseline)	Phase II (PFS)
Days	10	10
Cases	154	171
Case w/ waste	110 (71%)	66 (38%)
Drug waste (mL)	3284.2 mL	1266.3 mL
Avg. waste per case	21.3 mL	7.4 mL

Clinician Satisfaction Survey

% of Respondents (n=24)	Survey Question
79.3 %	Clinicians felt that less drug was wasted when they used PFS
91%	Clinicians felt that using PFS saved them time in preparing syringe for procedure
74%	Clinicians felt that using PFS increased their confidence in integrity of the preparations

* 24 respondents including attending anesthesiologists, resident/fellow anesthesiologists, CRNA, and anesthesia technicians

Clinician Satisfaction Survey

Time saved with the use of PFS	
Estimated time saved	**% of respondents (n=24)**
5 to 6 minutes	42%
3 to 4 minutes	29%
7 to 9 minutes	8%
1 to 2 minutes	4%

* 4 clinicians did not respond to this survey question

Clinician Satisfaction Survey

Most beneficial features of PFS
1. Labeling
2. Reduced risk of contamination
3. No need for reconstitution
4. Tamper evident
5. Diluted
6. Expiration based upon real-time stability
7. Sterility testing

Conclusion

- **System Vulnerabilities can be identified**
- **More system vulnerabilities identified with self-filled vs prefilled syringes**
  - Prefilled syringes have the potential to improve medication safety through enhanced labeling, standardization, and extended beyond use dating.
  - Use of prefilled syringes show a decrease in drug waste vs self-filled syringes

Thinking Like an Engineer

POST-TEST QUESTIONS - FORTIER

1. The Institute of Medicine is against Human Factors Engineering as a way to improve systems and performance.
    a. True
    b. False

2. Human Factors Engineering helps to improve
    a. Quality
    b. Satisfaction
    c. Efficiency
    d. Comfort
    e. All of the Above

3. Which of the following are human factors engineering principles were utilize in this study?
    a. Proactive risk assessment
    b. Work system analysis
    c. Identify system vulnerabilities
    d. All of the Above

4. The proactive risk assessment determined the severity of the following system vulnerabilities, except?
    a. Disruptiveness
    b. Provider error
    c. Occurrence
    d. Severity to patient

5. The implementation of pre-filled medications syringes improved human factors medication safety in the OR by:
    a. Reducing the number of workflow steps around the administration of medications in the OR
    b. Increasing the number of workflow steps around the administration of medications in the OR
    c. Significantly reducing the severity of system vulnerabilities within the medication use process in the OR
    d. A and C
    e. None of the above