Human Factors Engineering and Patient Safety: A Worksystem Framework for "Protection Through Prevention"

Part 1: Introduction, Overview & Methodology

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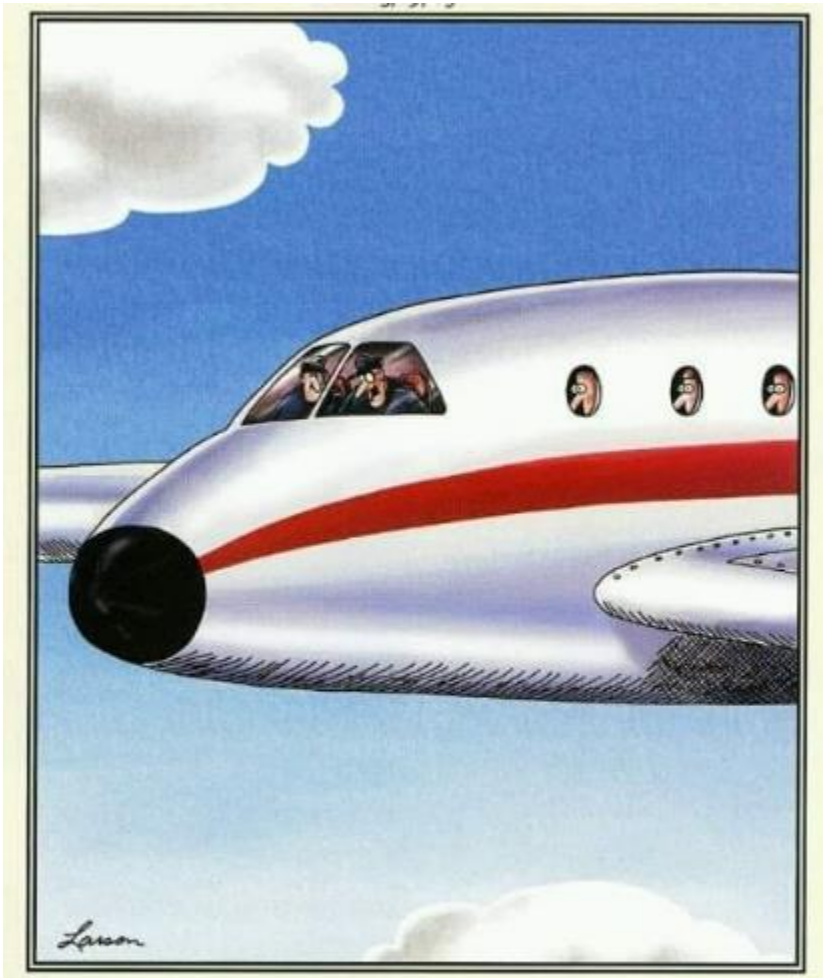
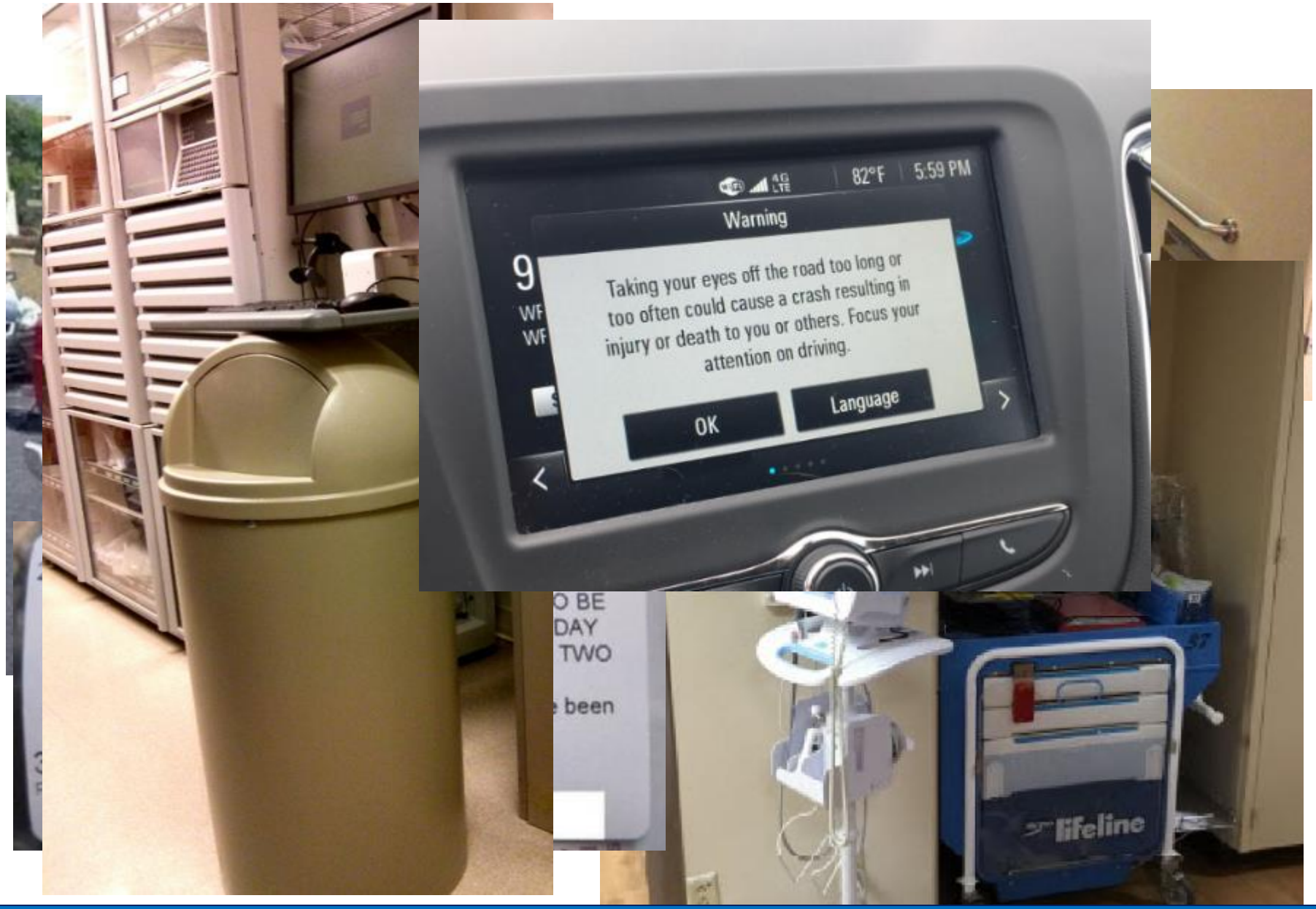
Human Factors:
Engineering a Better
Clinical Worksystem

Human Factors Engineering



"The fuel light's on, Frank! We're all going to die! ... Wait, wait. ... Oh, my mistake—that's the intercom light."

Do We Need Human Factors?



https://www.youtube.com/watch?v=1KEse_x1Sko

What is Human Factors?

Human Factors is a science to improve safety and efficiency by improving the clinical "**worksystem**"

- **Worksystem**: the physical, cognitive, and psychosocial aspects of the work environment that supports and impedes human performance
- Think of tools, layout, training, & staffing

Observing how tasks are actually performed often can identify opportunities for improvement. (*Baby name handwritten on warming cup.*)

What challenges do you encounter daily that make your job harder than needed?

How do you identify these challenges?

Isn’t Human Factors Just Common Sense?

BS&WH Human Factors Framework for Nursing Worksystem Improvement

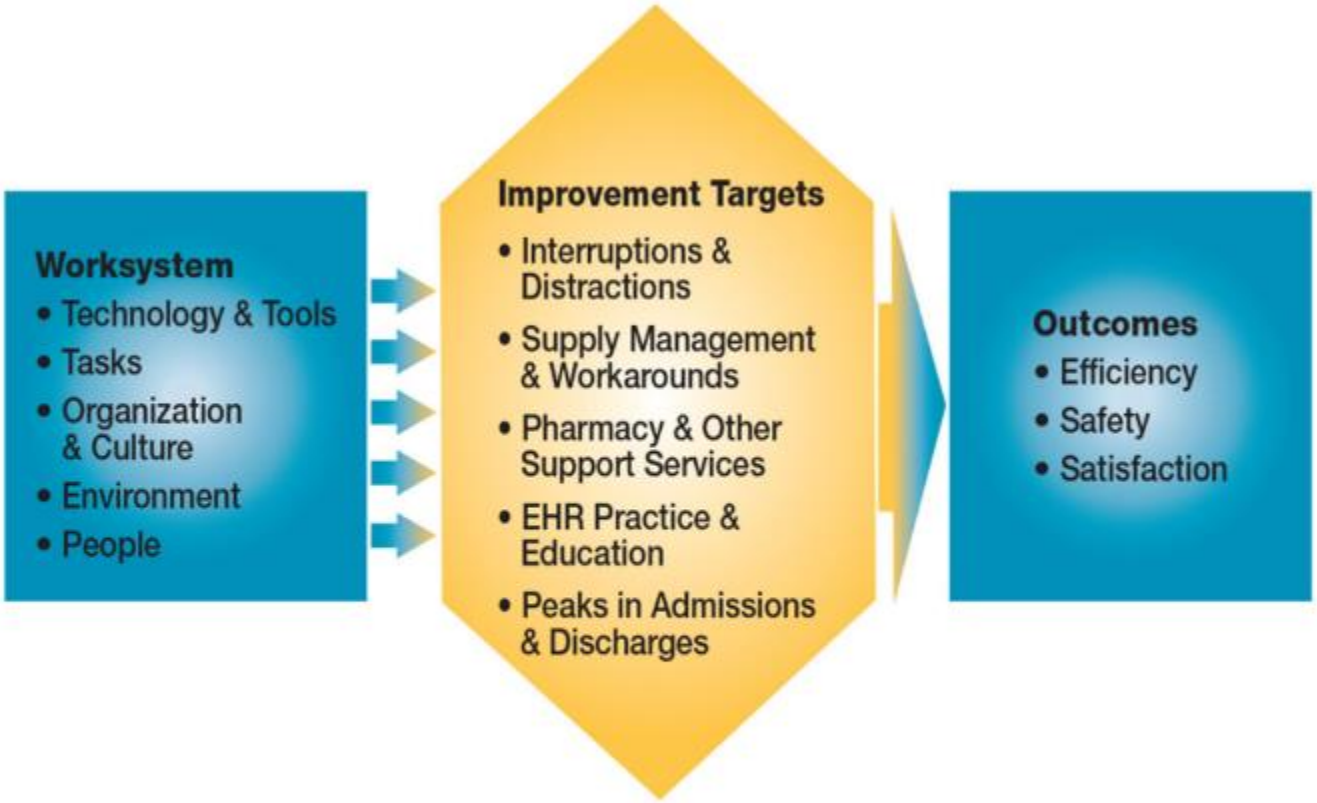


Figure 1: Baylor Scott&White Health Human Factors Framework for Nursing Worksystem Improvement ©, based on the SEIPS model (2). From left to right: the 5 components of SEIPS, the specific worksystem intervention targets and the desired outcomes.

Probst, C.A., Carter, M., Cadigan, C., Dalcour, C., Cassity, C., Quinn, P., Williams, T., Montgomery, D.C, Wilder, C., & Xiao, Y. Utilizing a human factors nursing worksystem improvement framework to increase nurses' time at the bedside and enhance safety. J Nurse Adm 2017; 47(2): 94-100.
-- PMID: 28067682

Why Learn About Human Factors?

To gain new perspectives on human errors and safety hazards

To generate fresh ideas for improvement

To empower frontline staff to identify barriers and build solutions

"Human factors" are often cited as causes of incidents. But our behaviors reflect our work environment

What issues do you encounter that make errors more likely? (e.g., interruptions)

What are Human Factors?

Perceptual factors

- Can she see? Hear? Feel?

Cognitive factors

- Can he comprehend? Remember?

Physical factors

- Can she reach?

Systems factors

- Can he work as part of a team?

Device factors

- Does she have the right tool for the job?

Emotional factors

- Is he mad, stressed?

A Brief History of Human Factors

Early 1900s:

- Gilbreths began work in motion study and shop management
  - Studied design of workstations and equipment (e.g., brick laying)
  - Hospital surgical teams & surgery procedures (e.g., surgeon reach for an instrument)

World War II

- Need to mobilize vast numbers of troops made it impractical to select individuals for specific jobs
- Focus shifted to designing for people's capabilities, while minimizing limitations
- Technology outpaced people's ability to adapt to poor design
  - Ex: crashes by highly-trained pilots

1945 – 1960

- USAF establishes engineering psychology labs
- First civilian company formed to do engineering psychology contract work

1960 – 1980

- Expanded beyond military and space applications
  - Pharmaceuticals
  - Computers
  - Automobiles
  - Consumer products

A Brief History of Human Factors

1980 – 1990

- Computer revolution propelled HF into the limelight
  - Ergonomically designed computer equipment & user-friendly software
- Computer technology presented new challenges for HF profession
  - Control devices, information presented via screens, impact of technology

1990 – 2000s

- Human Factors explodes into a myriad of areas
  - NASA (e.g. space station, control devices, instrument design)
  - Computers
  - Aviation
  - Website & Video game design / usability
  - Driving & transportation safety
  - **Healthcare & Medical devices**

Present

- Grown beyond issues of productivity and safety to embrace more intangible criteria such as user experience and user satisfaction

Theme: we learn about error through tragedy...by 'bodies and blood'

To Error Is Human

Human errors are inevitable & often made worse with a suboptimal work-systems:

- Confusing messages on a screen, unclear expectations, shortage of time
- Fatigued, stressed, with hazardous attitudes

Breast milk fridge in NICU

Our worksystem sometimes sets us up for errors. *(Breast milk for different babies in a fridge)*

What is an example of memory slips that you can anticipate? (e.g., forgetting to plug in a device)

Human Errors: Do you know?

According to a review, we make

- 3 errors per 100 in simple arithmetic tasks
- 3 errors per 1000 in reading labels
- 1 error per 100 to remember a step in a task

Look-alike meds

Under time stress, we often make more errors.

Can you think of an error that is predictable? (e.g., entering a wrong number)

Park, K.(1997). *Human error*. Handbook of human factors and ergonomics,

User error vs Use Error

Defibrillator "ON" button design

3 EMS Reports in 12 months:

→ VF cardiac arrest

→ RN charges unit…

→ Clears patient…

→ Presses "on" button

→ Machine powers down

- 2 minute delay in shock

→ PATIENT DIES

"ON" button does not shock

Could it be because of lack of user experience? Design?

Power Down: Common Error?

- Simulation study (Denmark): Occurred in 5 of 192 shock attempts by 72 experienced MDs

- How do we prevent?
  - Blaming, retraining
  - Policy, memo

- Considering human factors…
  - Recognize this predictable human error will recur
  - Redesign the device or process to either:
    1. Prevent error from occurring
    2. Facilitate recovery from error once occurs
    3. Stop unrecovered errors from hurting patient

*Hoyer, Christensen, et al. (2008). "Adverse design of defibrillators: turning off the machine when trying to shock." Annals of Emergency Medicine **52**(5): 512-514.

Don't Blame the Users

1000X Heparin Dosing Errors

- –3 babies killed in Indiana…
- –Babies killed in Texas, Montana
- –Dennis Quaid's children injured…

Look at the ampules. What problems do you see?

Two Heparin bottles
- 10 *vs* 10,000 units/mL
- Hep-Lock *vs* injection
- Look similar, especially not comparing side by side

Shifting the focus from

The user: blaming, retraining

Use: redesigning to

Prevent error

Facilitate error **recovery**

Stop unrecovered errors from harming

Recent Example of Human Factors & Error: Asiana Airlines #214 (July 6, 2013)

Pilot error caused the crash, no mechanical malfunctions discovered

NTSB Areas of Interest:

- Crew Communication
  - Crew Resource Management (how the crew worked together)
    - Captain noted plane was too low, told pilot to raise nose seconds before crash
    - Clash of personalities led to lack of acknowledgment
    - Conflicting communication styles
    - Failure to utilize and follow checklist protocols

Pilot Training:

- 3 pilots were all veterans of big jets
  - Had little experience in their new roles
    - Pilot flying still qualifying on Boeing 777
    - Training captain was on his first flight as trainer
    - Crew should not have been paired together

Recent Example of Human Factors & Error: Asiana Airlines #214

NTSB Areas of Interest cont'd:

- Automation Bias / Dependence
  - Pilots rely on automation to reduce workload, especially on transoceanic flights
    - Skills erode as automation is relied upon
    - The autothrottle was armed
    - Several autopilot modes were set and used incorrectly
    - The glide slope was not functioning (had not for weeks) & caused crew confusion; caused pilot to lose awareness of the plane's position
    - Pilots were unable to function without it
  - Pilots were unable to correct / account for automation when needed
    - Did not keep pilots 'in the loop'

Vanderbilt Medication Error (Dec 26, 2017)

Vanderbilt ex-nurse indicted on reckless homicide charge after deadly medication swap

Nurse at Vanderbilt Medical Center confuses two medications whose names start with the same two letters.

Brett Kelman, Nashville Tennessean | Published 4:40 p.m. CT Feb. 4, 2019 | Updated 12:37 p.m. CT April 10, 2019

- Patient admitted for subdural hematoma & vision loss to VUMC
- Patient claustrophobic & prescribed **Versed** in order to undergo PET scan
- Nurse retrieved **Vecuronium** (neuromuscular blocking med that causes paralysis) from electronic dispensing cabinet
  - Unable to find Versed, nurse triggered an Override from cabinet (unlocking additional medications)
  - Nurse entered 'Ve' into search field and selected 'First medication from list', Vecuronium
- Nurse administered Vecuronium, patient became unresponsive (suffered cardiac arrest & partial brain death)
  - Patient not monitored post administration
  - Estimated patient was in scan ~30min before staff noticed something was amiss
- Patient expires 3 days later after removal from ventilator & nurse terminated

https://www.documentcloud.org/documents/5346023-CMS-Report.html?fbclid=IwAR2xQsxlfKxis4mecgrCSt-6XvKnSmKDeN7Sb_20is2oBbFICt_9xUDkyvQ#document/p6

Vanderbilt Medication Error

HEALTH INC.

When A Nurse Is Prosecuted For A Fatal
dical Mistake, Does It Make Medicine

At Vanderbilt, a ~~nurse's error~~ killed a patient and threw Medicare into jeopardy

Brett Kelman, Nashville Tennessean

Published 11:00 a.m. CT Nov. 29, 2018 | Updated 7:25 p.m. CT Nov. 29, 2018

medication administration process that allowed a nurse to give a muscle relaxant rather than a sedative, then threw nurse under a bus

RaDonda Vaught appears at a court hearing with her attorney, Peter Strianse, in February. Vaught, a former nurse at Vanderbilt University Medical Center, was charged with reckless homicide after a medication error killed a patient.

Mark Humphrey/AP

https://www.npr.org/sections/health-shots/2019/04/10/709971677/when-a-nurse-is-prosecuted-for-a-fatal-medical-mistake-does-it-make-medicine-saf

Vanderbilt Medication Error: Human Factors Issues

- No 'auto-push' from EHR order to cabinet (i.e. no automation)
  - Forces nurse to perform search in cabinet
- Override reason / two-person override process unclear
- Alphabetical sorting of medications from override list
  - Is alpha-sort appropriate? What about most common on top?
- Medication selection confirmation process gaps
- Medication retrieval from cabinet via override process gaps
- Medication administration via BCMA not performed
  - Does your facility/system have BCMA in procedural areas? How do we make this workflow operational?
- Lack of patient monitoring following sedative
- Fair & Consistent (or 'Just') Culture violated & criminal charges leveled
  - How can we expect staff to identify safety gaps if errors are punished?

Is this Use or Use**R** error?

Human Factors & Approaches to Safety

Human Factors	• Fatigue • Circadian rhythm • Lighting • Noise • Alarm fatigue	• Memory • Calculation • Reading • Sustained attention • Multitasking	• Culture • Inter-professional communication
Approaches	• Schedules • Layout & visibility • Work environment • Alarm reduction	• Forcing functions • Visual aids • Simplification • Standardization • Checklists • Independent checks • Interruption management	• Learning from defects • Shared perspectives • Structured communication • Read-back

- Axiom 1: Human errors are inevitable
- Axiom 2: Patient harms from human errors can be prevented

Human Factors Engineering: Design human-technical systems to reduce risks of harm

Human Factors Methods

Understand work and context	**Design** for effectiveness and sustainability	**Test** solutions
Observe, not assume, how work is done	Reduce reliance on vigilance	Assess requirement on users
Look for • All tasks, equipment • Short-cuts, workarounds, batching • Time-pressure • Distraction & interruptions • Variability • Informal job aids • Reach, travel distance • Visibility • Time & motion	• Think ○ Forcing functions ○ Simplification ○ Automation ○ Standardization • Use judiciously ○ Protocols ○ Independent doublechecks • Avoid reliance on ○ Rules and policies ○ Education	• Identify needs for ○ Calculation ○ Memorization ○ Detailed reading • Include non-experts • Include expected extreme conditions • Respect users

BSWH Strategy to Diffuse Human Factors

Developing 1% awareness in 100% of workforce

- Vs. < 1% of workforce being 100% aware

Now the fun part!!

(depending on your definition of fun)

Human Factors Principle of Short Term Memory

A short demonstration of memory...

Try to remember the following 8 letters

Human Factors Principle of Short Term Memory

FB IJF KTV

Human Factors Principle of Short Term Memory

Can you recall the eight letters?

...now try

Human Factors Principle of Short Term Memory

FBI JFK TV

Human Factors Principle of Short Term Memory

Now can you recall the eight letters?

FB IJF KTV

Vs

FBI JFK TV

Human Factors Principle of Short Term Memory

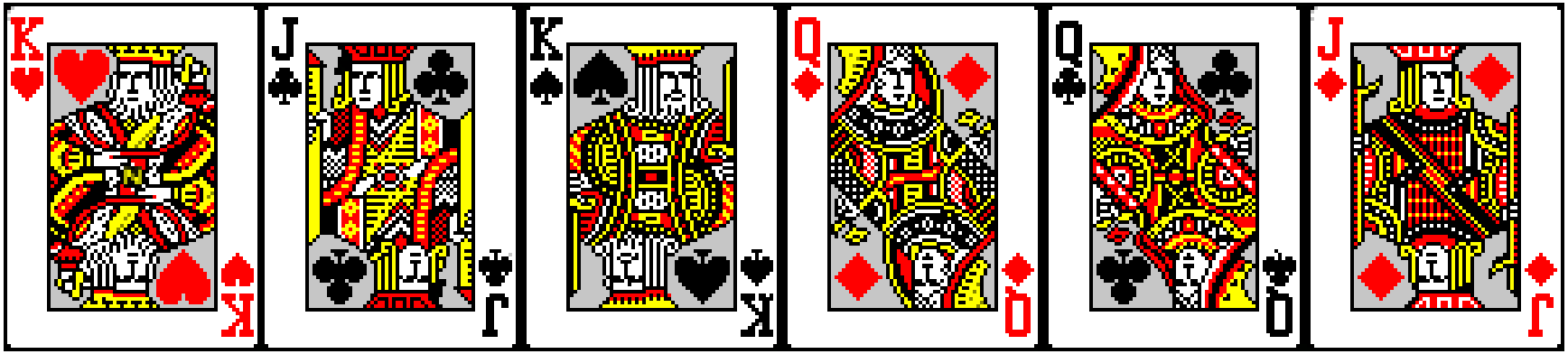
Take Home Message?

Our memory is unreliable, but strategies can help
(e.g., chunking, visual aids, checklists)

We place high trust in unaided memory despite
interruptions and distractions that cause us to forget specific information

Human Factors Principle of Encoding

Pick a card and remember it...



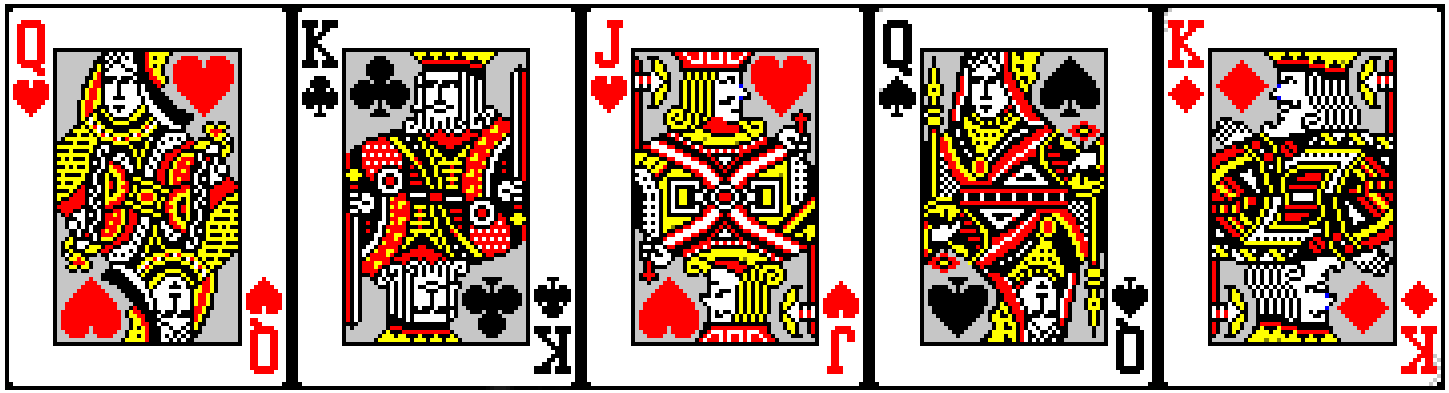
Human Factors Principle of Encoding

Remember your card!

Now I will take away one card, the very one you picked....

Human Factors Principle of Encoding

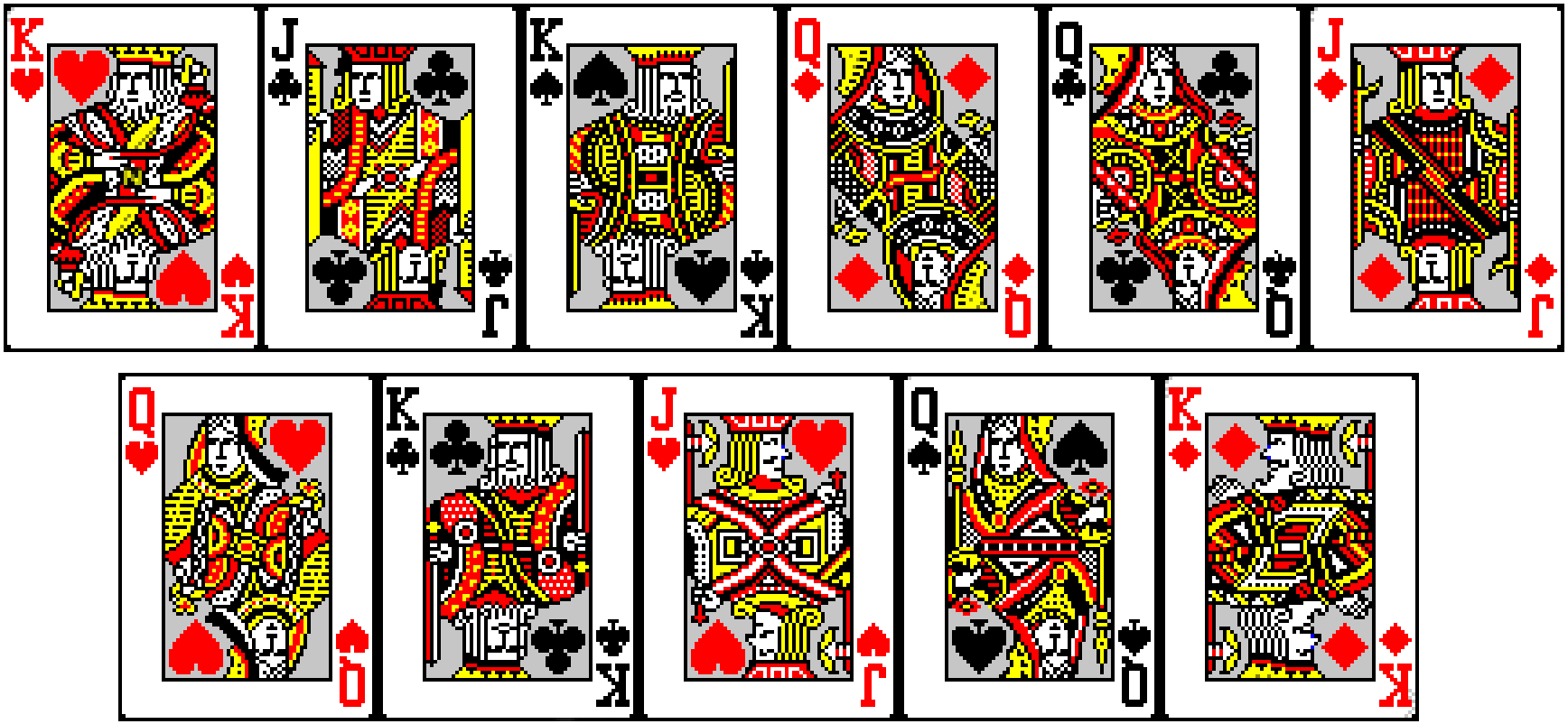
Your card is now removed! Am I magic?



Human Factors Principle of Short Term Memory

Take Home Message?

Encoding errors are to be expected and lead to biases.



Human Factors Principle of Visual Search

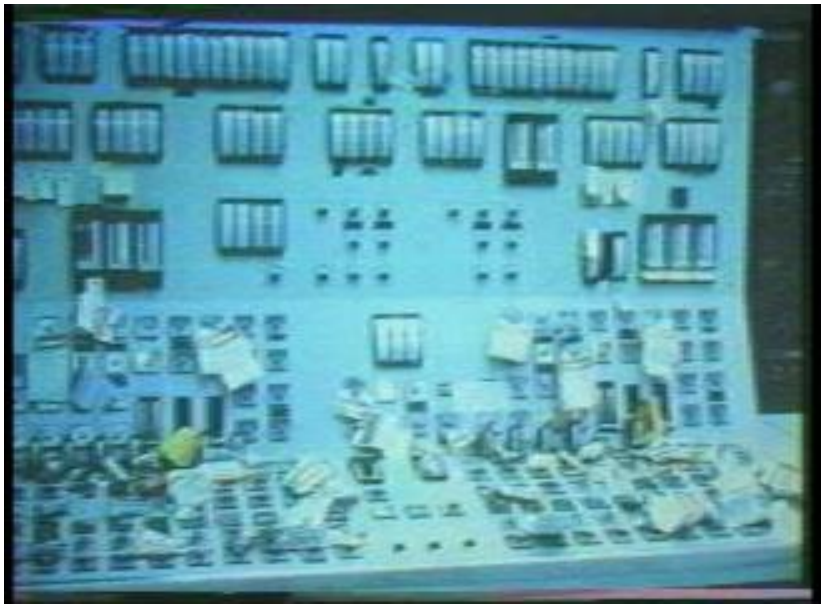
- Non-systematic & non-exhaustive
- May not see things under time-stress

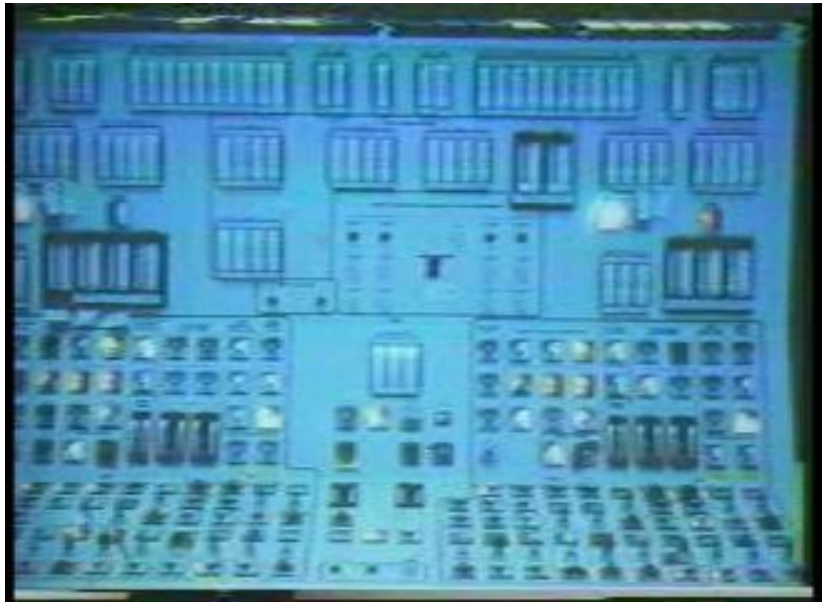
Human Factors Principles:

- Cluttered displays increase the chances of missing something
- Cluttered displays increase time to locate a target
- Buried information takes longer to find

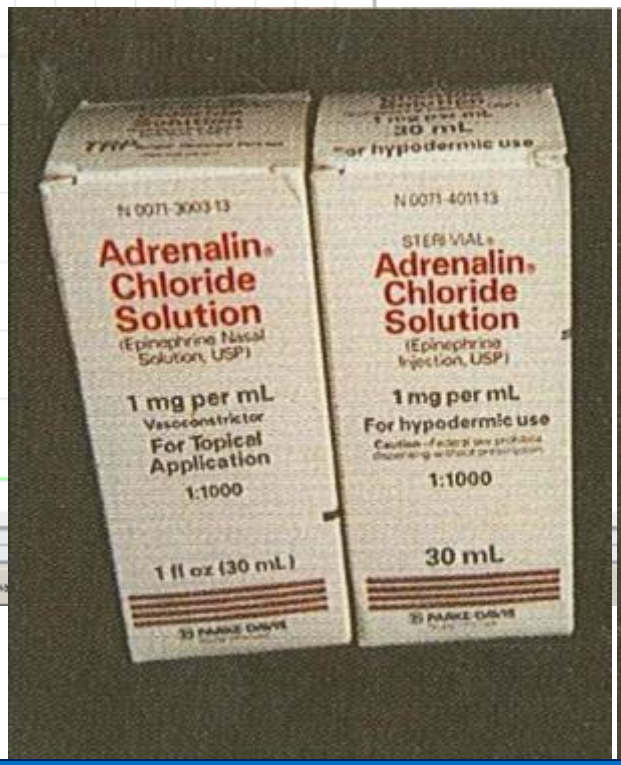
Human Factors Principle of Visual Search

A quick example from a nuclear power plant...





Human Factors Principle of Visual Search

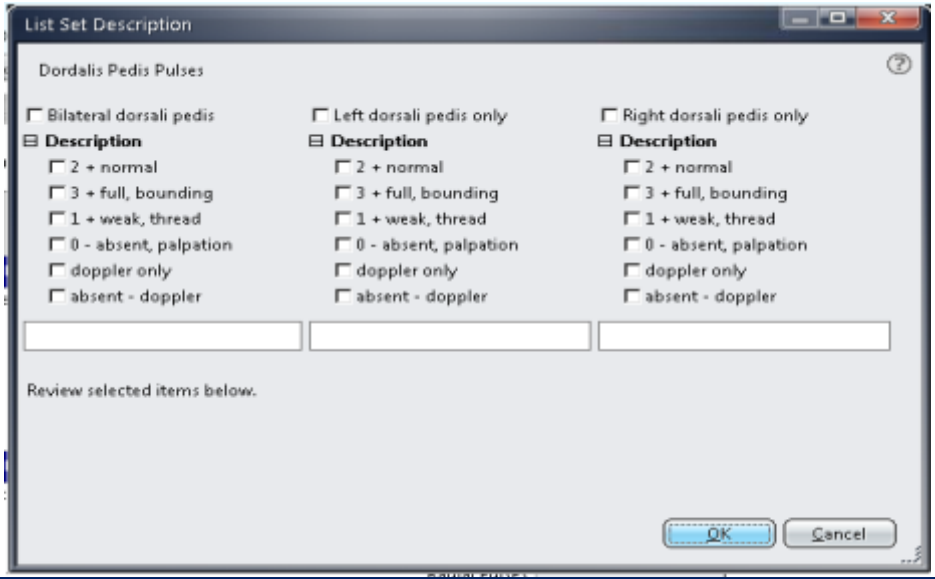


Human Factors Principle of Visual Search

Take home message?

We don't utilize a systematic approach to search tasks; cluttered displays increase search time and chance of error

- Chunking is effective
- Visual organization & grouping can help



Human Factors Principle of Reading

An Illustration on How We Read...

I cdnuolt blveiee that I cluod aulaclty uesdnatnrd what I was rdanieg. The phaonmneal pweor of the hmuan mnid! Aoccdrnig to rsareech at Cmabgirde Uinervtisy, it dneos't mtetar in what oredr the lttrees in a word are, the olny iprmoatnt tinhg is that the frsit and lsat letetr be in the rhgit pcale. This is bcuseae the huamn mnid deosnot raed ervey lteter by istlef, but the word as a wlohe.

Human Factors Principle of Reading

Take home message?

We don’t read word for word, we...

Seek out and acquire specific items of information for a task

Scan to locate relevant instruction or words relevant to a task

Develop routines to rapidly locate information and to ignore rarely used information

Read to confirm, not to identify discrepancies

Take Home Messages

- Focusing on the “User” tends to limit solutions to blaming and questioning commitment.

- Human errors usually reflect defects in the worksystem. Fix these defects to achieve robust improvement.
  - Relying on short-term memory, manual calculation
  - Supplies and controls difficult to reach
  - Devices difficult to learn
  - Noise, distractions, fatigue
  - Interruption, time-stress, multi-tasking

Human Factors & Safety

Most patient harms are preventable. Human Factors science encourages us to:

- Simplify & standardize
- Decrease reliance on vigilance and memory
- Build error-proofing defenses

If you take anything away from today…

- We operate inside of a complex **worksystem**
- We do not spend enough time in healthcare **observing** the worksystem
- Human factors provides a skillset / methodology to fill these gaps in safety

Safety features do not work until staff routinely use them (such as the drug library in smart pumps).

Is there a recent safety improvement that does NOT just rely on "being more careful"?

Human Factors & Approaches to Safety

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Q & A

Thank You!

End of Part 1. Stick around for Part 2, “Application”!

C. Adam Probst, PhD, MS, CPPS (Adam.Probst@bswhealth.org)

Human Factors Engineering and Patient Safety: A Worksystem Framework for "Protection Through Prevention"

Part 2: Case Studies, Group Interaction & Application

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Let’s walk through a couple of examples…

WARNING:
These Really Happened!

Case 1: Sterile Processing

How did they miss the signs?

A near miss in sterile processing

– What aspects of the worksystem led to a near miss of selecting a non-sterile kit?

Human Factors observation

– How easy is it to segregate ‘clean’ instruments from ‘sterile’?

– What is the actual workflow for moving ‘clean’ instruments into the sterile core?

– What is the actual process for storing ‘clean’ instruments until they can be sterilized?

– Do staff know which racks hold ‘clean’ instruments and which ‘sterile’?

Transition Rack: where ‘clean’, but not sterile, instruments are stored before going to the autoclave for sterilization

Observation & Improvement Cycle

Observation identified difficulties for staff to distinguish the transition rack from sterile racks

- Sterile storage racks on wheels; often pressed against the transition rack
- Signage was rarely acknowledged
- Staff had not previously reported such difficulties

Improvements were targeted to separate clean from sterile racks

Risk of Unprocessed Trays in OR

Use of unprocessed instrument were reported in OR Manager

Do you know the risk in <u>your</u> facility?

Checklist for risk assessment in Sterile Core (DSP):

- ❑ Walk-throughs to identify separation of sterilized and unsterilized trays and peel packs at <u>all points</u>, especially transition areas before and after sterilization
- ❑ Locations designated with signage and floor markings for dirty, cleaned, loading, cooling areas, and sterilized areas
- ❑ Procedures for Non-DSP staff to retrieve trays from DSP
- ❑ Competency check offs for all sterilization indicators; New staff check offs
- ❑ Education board to show sterilization indicators in use
- ❑ Structured handoffs; Methods for managing and minimizing distractions
- ❑ Audit tools to monthly assess compliance with procedures

Checklist for risk assessment in ORs:

- ❑ Sterility confirmation procedures during setup & timeout (e.g., collection of all indicators)
- ❑ Competency check offs for all sterilization indicators; New staff orientation
- ❑ Audit tools to periodically assess compliance with procedures

Checklist for safety culture at DSP

- ❑ Huddle questions (e.g., quarterly) : how an unprocessed tray may get into OR, and how to prevent?
- ❑ Recognition of reporting (incidents, good catches, deviations of standard work, defects in trays)

Case 2: Blood pressure cuff connection

How do you hook that up wrong?

Error Proofing via Forcing Functions

<u>Near Miss:</u>

<u>Automatic BP cuff connected to IV port</u>

- Dad-to-be unplugged the automatic BP cuff to take Pt to rest room
- Upon return to bed, he attempted to reconnect Pt to monitors
- **Automatic BP cuff fit perfectly into IV port**
- Nurse discovered misconnection moments before the automatic BP cuff pushed air into Pt's IV (potentially causing a fatal event)

Relation of BP cuff to IV port

Human Factors Provides Robust Ways to Prevent Error

Short term fix

Place a warning label on the end of BP cuff

Sticker on warns staff about potential errors

Is there a better solution?

Yes! Utilize a "forcing function" to prevent connection to IV ports via tubing that requires turning to connect


Old BP tubing fit perfectly into IV port

Vs.

Make misconnection IMPOSSIBLE ("Forcing Function")


New BP tubing needs ¼ turn; does not fit

Case 3: Expressed Breast Milk in a NICU

How do you mix up the milk?

Case Study: EBM Labeling Safety Gaps

- Multiple steps, people & equipment involved
- Infrastructure
- Confirming accuracy
- Warming process
- Storage Practices
- Labels stored at bedside, often right next to each other
- No reminder to bring labels/No label access while in nutrition room
- Patient transfers

Comments from NICU RNs – Contributors to Accurate EBM Labeling

- Equipment
- Space
- Workload
- Practices
- Technology
- Education

EBM Bag Storage Practices

Lack of freezer space makes it difficult to maintain separation consistently across multiple shifts & users

EBM Bag Storage

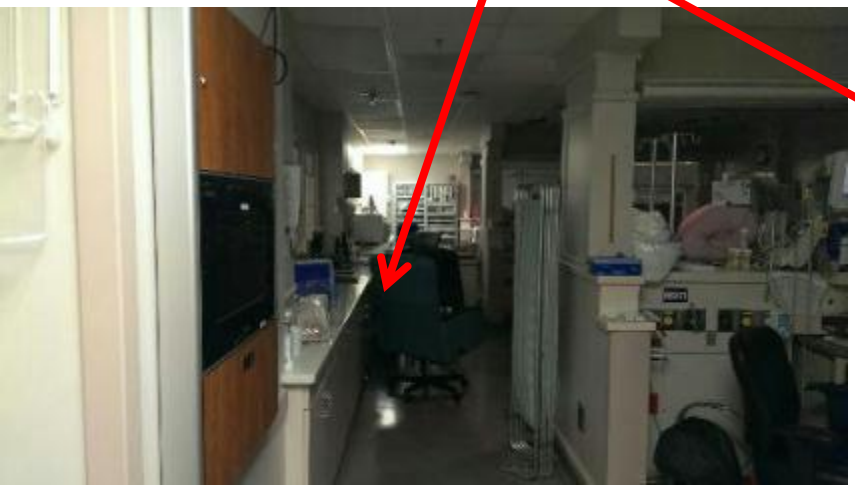
Labels on baskets are easier to read than hand-writing on plastic bags

Hand-writing on plastic bags, in good position, is much easier to read than container labels

Pod Layout

Freezer is at far end, behind chairs and supply cart

Distance and barriers create disincentives for only getting a single baby's feed at a time



Distance from furthest Pt to pod refrigerator

. . . .

Close-up view; behind obstacles

Infrastructure

Lack of space leads to disparate placement of warming cups

Distance between pods and nutrition rooms incentivizes RNs to batch

Distance from South nutrition room to furthest pod is excessive

- Nutrition room lacks counter space for multiple RNs to mix simultaneously
- Results in staff waiting on each other & rushing through the process

Warming Practices

Unlabeled warming cup

Warming cup with unlabeled feeding bottle

- Lack of warming equipment forces staff to utilize Styrofoam cups filled with warm water
- Cups are placed in disparate locations & not always labeled

Nutrition Room Practices

- Nutrition rooms have a dedicated area for mixing (supplies & sterility)

- Bringing entire bags reduces the chance of placing mixed feeds back into wrong bags…

…but mixing in nutrition rooms mean being away from the bedside

- Batching tasks for multiple babies is an attractive shortcut to reduce the number of trips & save time

There are no patient labels, should syringes be drawn up here?

Pod Storage & Pt Care Activities

Preparing all syringes at the start of a shift may reduce the number of steps required

- Feeding is often required in conjunction with multiple tasks (e.g. lab draws)
- Staff are pressured to quickly transition from one task to the next

Nutrition Room Equipment Storage

Storing excess equipment in nutrition rooms prevents additional freezer utilization

EBM: Human Factors Recommendations

- Evaluate utilizing a single staff member to complete all EBM mixing
  - Ex: nutritional staff, staff nurses that rotate responsibility, etc
- Focus effort to increase number of RNs who can mix protein
  - Reduce omission of mixes due to no one being assigned, improve productivity/efficiency and improve assignment activities
- Par level optimization & maintenance
  - To reduce the amount EBM accumulated & stored by NICU
    - Difficult to ascertain since bottles contain variable amount
    - Due to economic situation, some moms must store all EBM in NICU
- Label design
  - Using large labels for bags & basket (e.g. only baby name in 72 point font)
- Physical separation of bags in storage
  - Inside fridges/freezers, nursery countertop space, nutrition room mixing countertop space
- Staff engagement
  - Discussion & awareness about how frequent EBM errors occur & how they happen

Case 4: Bypass Machine

How do you misconnect those tubes?

Cardiopulmonary Bypass Machine Human Factors Inspection: Motivation for Change

- Tubing misconnections are a persistent, common issue:
  - Numerous types of tubes are misconnected in a variety of situations (The Joint Commission, Issue 36)
  - The most common recommendation for misconnection instances is a redesign of connectors/tubes (Simmons et al., 2011)
  - Labeling of tubes was found to be a proactive deterrence to misconnections (Kimchi-Woods & Shultz, 2006)

- CPB tubing is not immune to misconnections:
  - Venous and Arterial lines were switched leading to the oxygenator (MAUDE Report # 8010762-2011-00006)
  - A gas line was mistakenly connected to the outlet port instead of inlet port (MAUDE Report # 1212122-2012-00016)

Simmons, D., Symes, L., & Graves, K. (2011). Tubing misconnections: normalization in deviance. *Nutrition in Clinical Practice*, *26*(*3*), 286-293.
Kimchi-Woods, J. & Shultz, J.P. (2006). Using HFMEA to assess potential for patient harm from tubing misconnections. *Journal on Quality and Patient Safety*, *32*(*7*), 373-381.

Cardiopulmonary Bypass Machine Human Factors Inspection: Potential for Harm

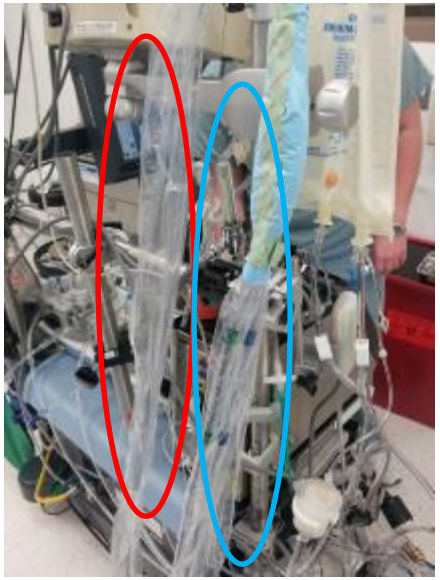
Terumo CPB Machine:

- Arterial and Venous lines are identical in appearance and diameter leading to potential error; by being incorrectly attached (i.e. switched)

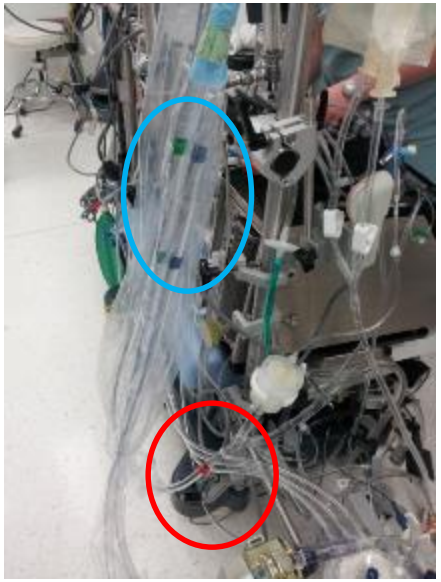
- Excess line length can lead to removal of identifying colored tape when shortening the lines
  - Red: Arterial
  - Blue & Green: Venous

- Difficult, lengthy troubleshooting process with little guidance
  - When errors are discovered, minutes are required to identify the source of error and correct it

Cardiopulmonary Bypass Machine Hookup: Specific Risks

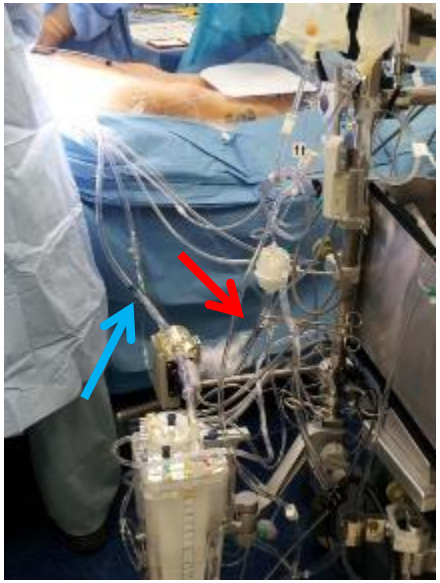


Arterial and **Venous** lines identical in appearance & diameter

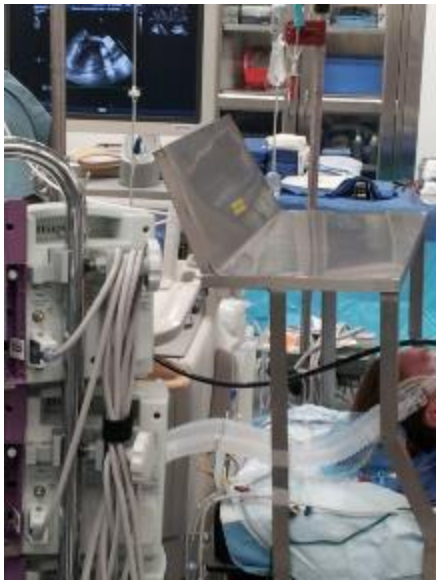


Few markers to distinguish lines from each other (colored tape)

Lines not distinguishable when in the manifold



Long lines jumble



Draped

'CV Monster' blocks anesthesia's view of the field

Cardiopulmonary Bypass Machine Hookup: Recommendation Types

1. Provide visual cues on equipment to promote proper use
2. Recommend design changes to manufacturers
3. Develop policies and procedures that encourage proper use, such as tracing lines
4. Educate staff on avoidable risks and appropriate behaviors
5. Employ proposed solutions (next slide)

Cardiopulmonary Bypass Machine Hookup: Proposed Solutions

Identified Risks	Proposed Solutions
Arterial and Venous lines identical in appearance & diameter Few markers to distinguish lines from each other (colored tape) Lines not distinguishable when in the manifold	1. Place colored tape every 6” along lines Red: Arterial Blue/Green: Venous 2. Evaluate manufacture’s opportunities - Spiral color strips along tubing - Connectors: making misconnection impossible
Long lines jumble	1. Standardize the set up of all cases that utilize CPB machines 2. Policy to trace lines at every connection 3. Do not disconnect > 1 line at a time
‘CV Monster’ blocks anesthesia’s view of the field	Explore other vender options (Ex: the Head Butler)
No guidance for troubleshooting	Create a guide so surgical teams can quickly identify & fix errors

Group Exercise:
Walkthrough of Two Safety Events

Case A: Heparin Infusion *or….*
Case B: Temazepam Workaround

- Some common human factors:
  - mental workload
  - fatigue
  - distractions
  - physical environment
  - physical demands
  - device/product design
  - teamwork
  - process design
  - medical device design

- <u>Applying what you've learned:</u>
  - What are some human factors principles involved?
  - How could Human Factors Engineering been applied to these scenarios to reduce risk?

Q & A

Thank You!

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Extra Cases

(if needed)

Case: Retained Surgical Items

Why don’t they follow count procedures?

Cima 2008 Study (*JACS*)

- Mayo Clinics (98 ORs), post-op hi-res **film survey every case**
- 2003-2006, 191 168 cases
- 34 retained foreign object cases
  - (1 in 5 622 cases)
  - 20 found on post-op film survey, all with correct count (59%)
  - 6 false negative in intra-op film (taken in 18 cases, 33% failure)
  - 23 were with sponges

Sentinel Event Alert (Issue 51, 10/17/2013)

- 2005-2012, 772 incidents (16 deaths) of retained surgical items, mostly sponges, reported to TJC
  - The absence of policies and procedures
  - Failure to comply with existing policies and procedures
  - Problems with hierarchy and intimidation
  - Failure in communication with physicians
  - Failure of staff to communicate relevant patient information
  - Inadequate or incomplete education of staff

Human Factors of Retained Surgical Items (RSIs)

- Over-confidence: *It won't happen to me*
  - RSIs are rare: 1 event per 5000-7000 cases (every 12-18 years if 400 cases a year)
- Crying wolf: *counting must be wrong*
  - Discrepant counts are often: 1 in 8-145 cases (weekly/monthly)
  - Discrepant counts are almost always false-positive: ~98%
- Counting fatigue: *too much time spent on counting*
  - Time-consuming: 6-15% of operative time, many episodes
  - Frustrating: > 10 minutes to resolve discrepant counts
- Confirmation bias: don't see/feel what is not expected to find
- Handoffs, Disruptions, distractions, competing tasks
- ➔ **Normalization of deviance**

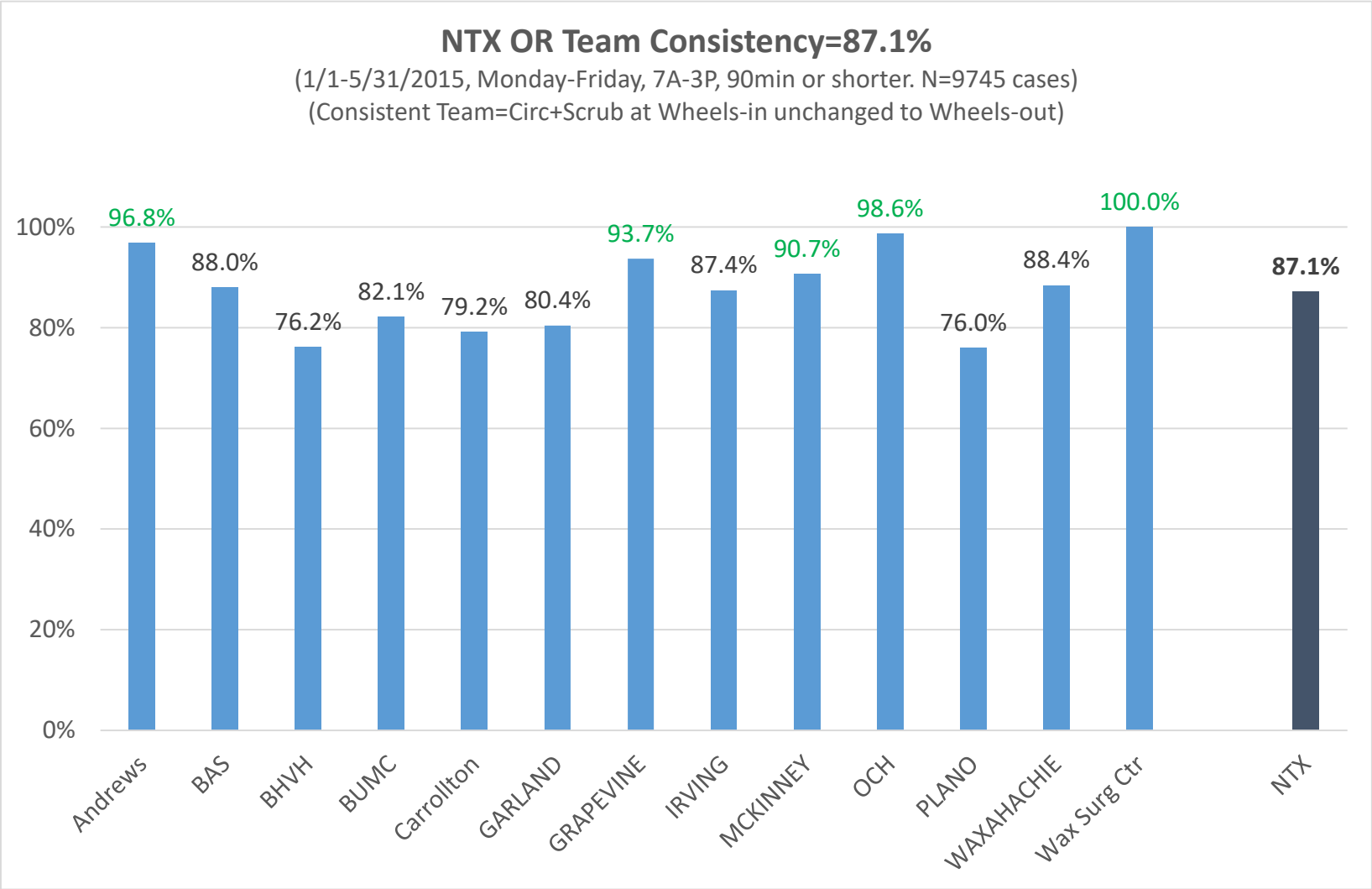
Preventing Retained Surgical Items: The Basics

- Reduce risk factors to safety culture in OR
  - Positive enforcement of speaking up and encouraging to speak up
  - Expect engaged teams and surgeons; team responsibility for safety
  - Manage of disruptions, distraction, competing tasks on counting
  - *Minimize negative impact of hand-offs and unfamiliar staff*
  - Minimize dismissive attitude
  - Build a just culture; understand and follow policies
  - Build a learning culture: track miscounts and team problem-solving
- Standardize and simplify counting
  - Minimize number of sites of used sponges
  - Standardized locations (ideally one location) for holding used sponges
  - Same procedure for counting
  - Reduce barriers for efficient counting procedures

Team Consistency Goal Setting
A Pilot Analysis

- Why: OR staff changes disrupt surgical flows, increase risks to patients, increase case durations; these changes in short cases (≤90 min) and associated impacts are potentially avoidable.
- Method: 5 month CPM data (Jan 1-May 31, 2015)*
  - Consistent team: the circulator and scrub at wheels-in remain unchanged to the end of the case (wheels-out)
  - Case durations (wheels-in to wheels-out) 90 min or less
  - Cases included: Monday-Friday, 7AM-3PM
- Overall team consistency (NTX): 87.1%

1. <85%: BHVH, BUMC, Carrollton, Garland, Plano
2. 85-90%: BAS, Irving, Wax
3. 90-95%: McKinney, Grapevine
4. 95-98%: Andrews
5. >98%: OCH, Wax Surg Ctr



- Staff changes in 1,259 cases (12.9%)
  - 30.7% of the 11-1PM cases with staff changes
  - 2.3%, 10.3%, & 19.8% for 0-30, 31-60 & 61-90 min cases, respectively
  - 8.8% with circulator changes, 5.7% with scrub changes

Case: Crash Cart Design

Why are they searching so long?

This drawer has everything.

How to make it easier to use in a code?

Human Factors *of* Code-cart Drawers

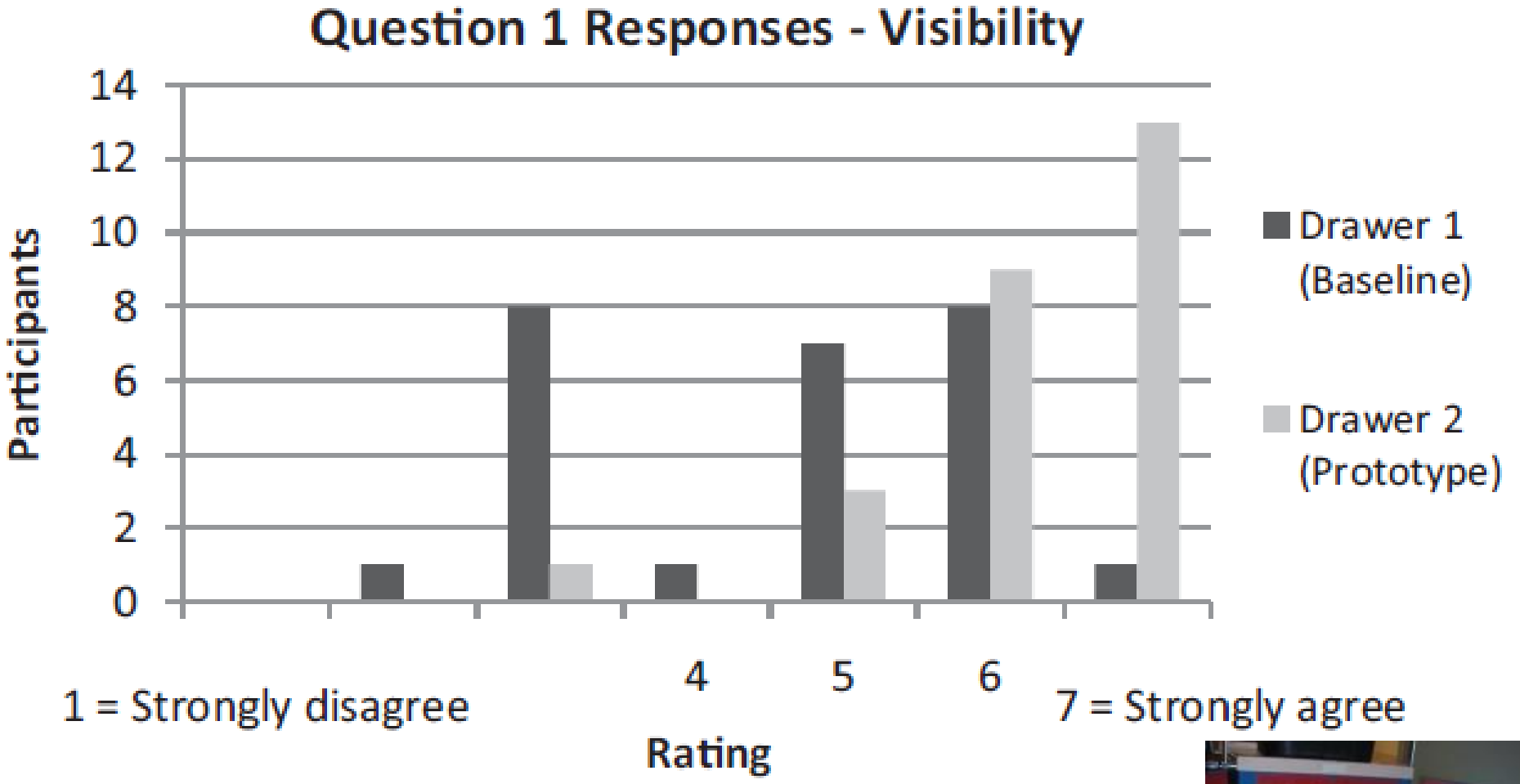
- *Visibility*
- *Organization*

Improvement goals:
- To reduce time to retrieve items
- To reduce wasted motions

Rousek & Hallbeck, *Human Factors*, 2011

Baseline

Prototype



Prototype: 10 *sec* faster (54.6*s*±6.4 vs 63.8*s*±6.9)
with 3 fewer wasted motions (0.6±0.8 vs 3.2±1.1)

Case: OSI Surgical Table

How do you miss that T pin?

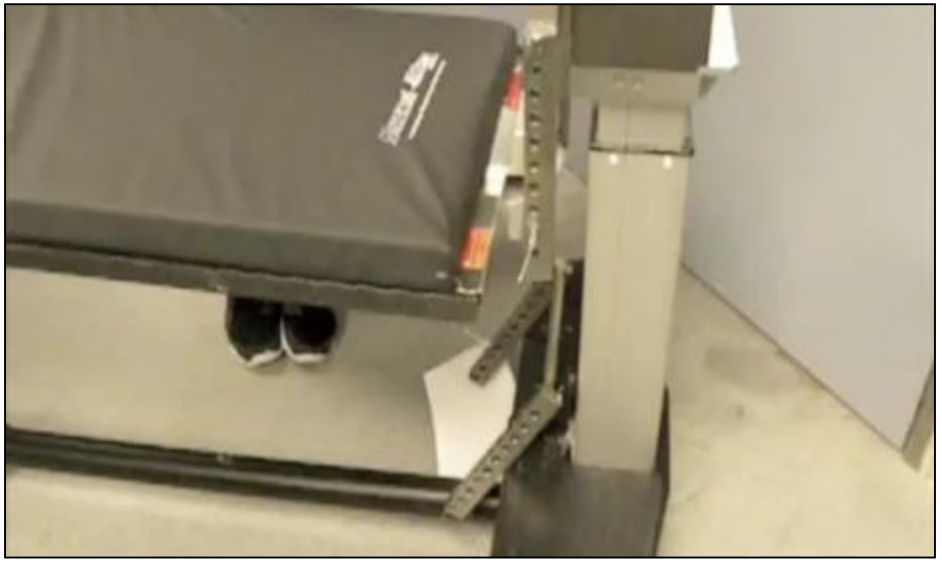
Human Factors Field Inspection

- In OR, with OR technician and surgeon
- Q1: how does one miss a T-pin?
- Q2: how does the table become instable?
  - Risk 1: T-Pins
    - Inadvertent removal
    - Unrecognized missing pin
  - Risk 2: Rotation locks
    - Unanticipated tilting
    - Instability of the bed

FDA CLASS I RECALL (July 29, 2011 from Mizuho OSI)

"...staff had neglected to install a T-Pin..."

"Many of these incidents could have been easily prevented with proper user training and proper operation of the device."



Did you notice the missing T-Pin?

Design flaw:
Binding dowels stop unsecured bed top from falling

Temporary fix:
Color coded handles remind staff to count T-pins