Human Factors Engineering and Infection Prevention

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Objectives

1. Describe Human Factors Engineering (HFE) and the Hierarchy of Controls
2. Describe the challenges to compliance with Infection Control Precautions
3. Provide three examples of how HFE can improve infection prevention and controls

No conflicts to declare

Illustrating HFE

HFE in :

1. **Work processes and flow**: Cleaning and Disinfection
2. **User-Centred Design:** Bedpan Decontaminators
3. **The Procurement Process:** BPD and UVC machines

Human Factors Engineering

- AKA ergonomics
- Optimizes the relationship between technology or the “system” and humans
- Designs the system to match human abilities
- Different methods to analyze the situation. Most adapted from Nielsen, 1992

Not just for technological issues!!!

Challenge for Infection Control

- Delayed Feedback
- Lack of Connection with Positive Results
- System Complexity
- Time Pressures
- High Cognitive Workload
- Few Visible Infection Control Cues
- Inconsistent Ergonomic Design
- Need for Problem Solving

Anderson J Using human factors engineering to improve the effectiveness of infection prevention and control Crit Care Med 2010;38:S269-S281

Two types of Errors

- **ACTIVE:** committed by the user

- **LATENT:** inherent to the design or at the organizational level

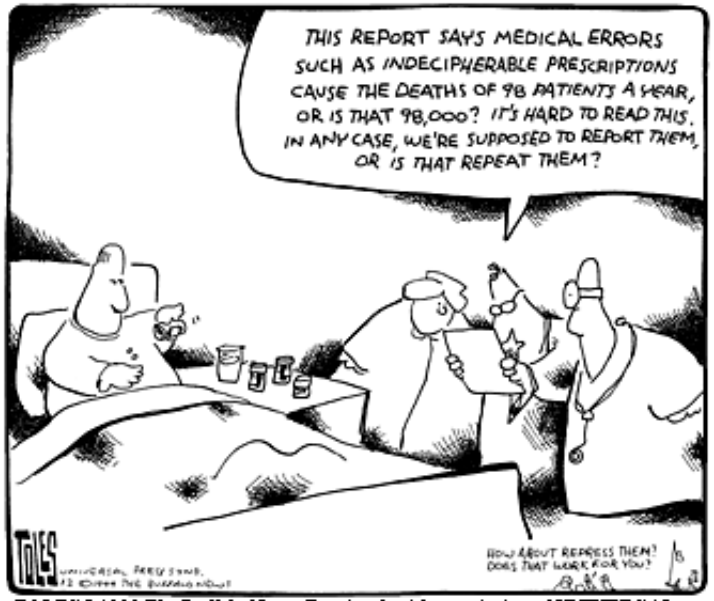
Latent errors may predispose to Active Errors

E.g. Cleaner uses wrong solution because of similar names
Precept/ Percept Virex/Virox

Reason J Understanding Adverse Events: Human Factors. Quality in Health Care 1995;4:80-89.

Human factors ≠ Humans at Fault

- "No blame culture"
- An error that occurs by the user is attributable to the design of the system
- The goal is to design systems that elicit rather than force desired behaviour



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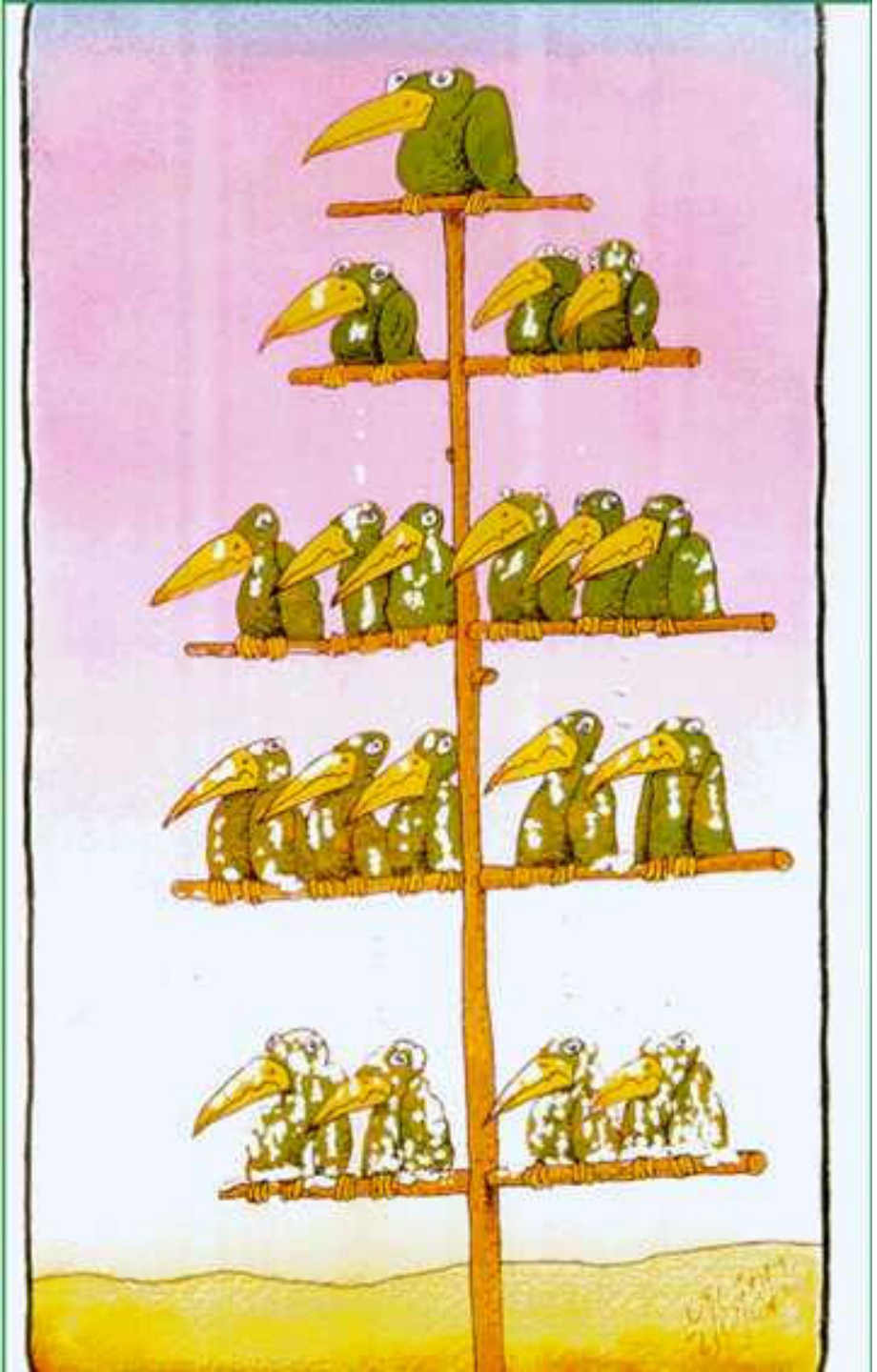
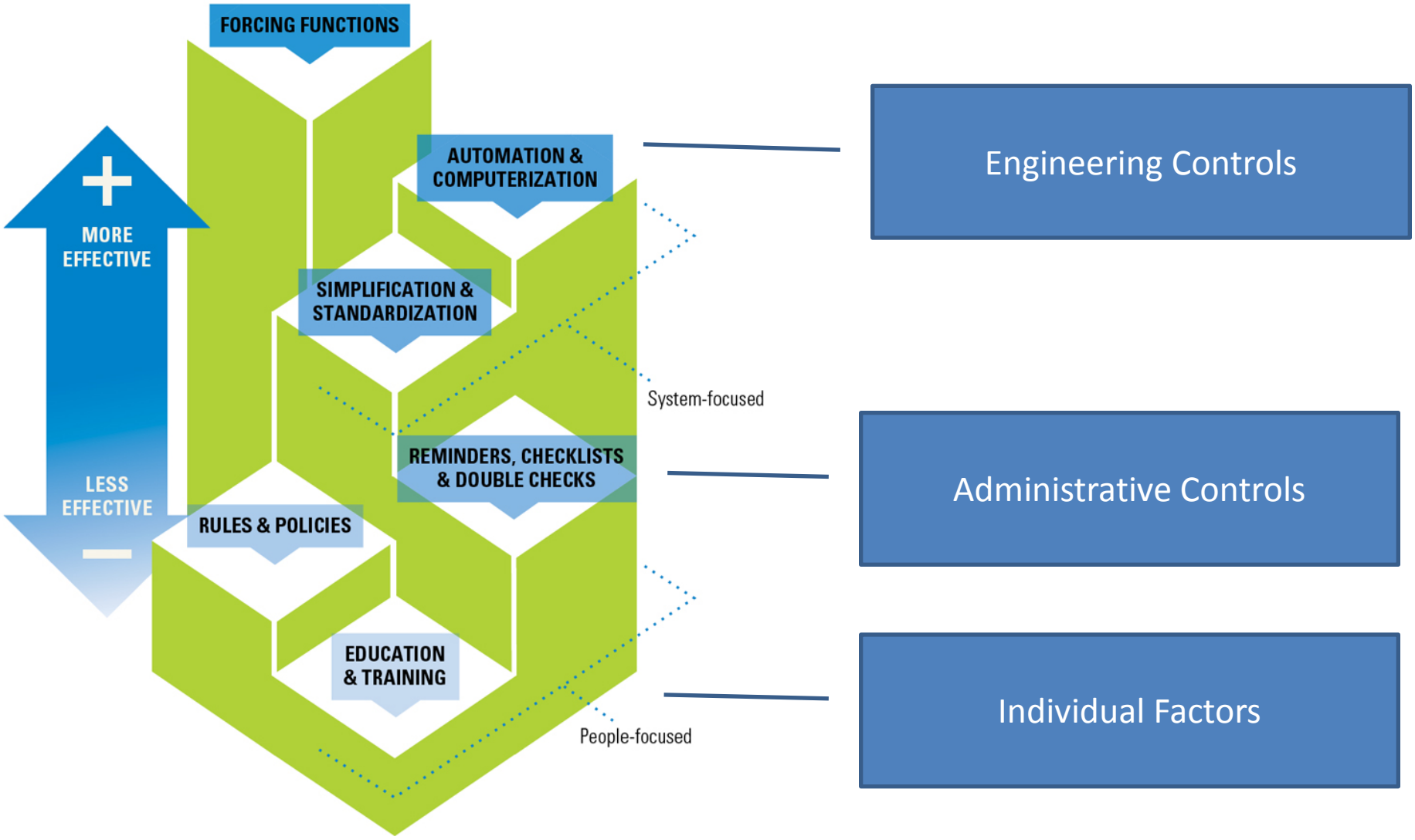


‘hierarchy’ *ερός*-hieros, sacred, and *ρχω*-arkho, rule

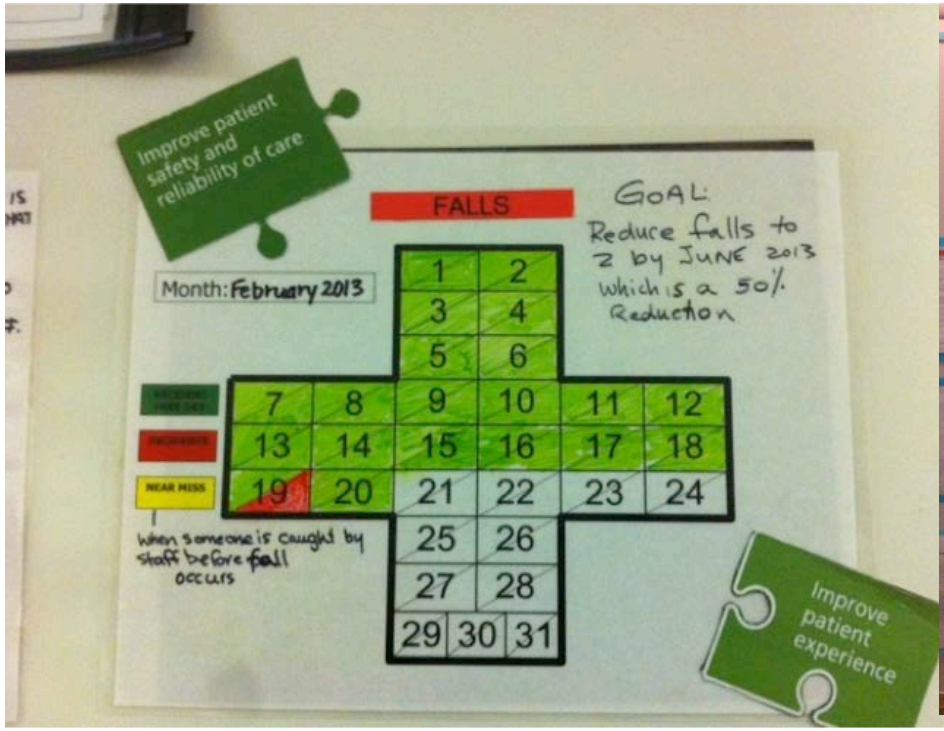
a *system of* ***ranking*** *and organizing things or people, where each element of the system (except for the top element) is subordinate to a single other element.*

FIGURE 2.
The Hierarchy of Intervention Effectiveness



Cafazzo JA and St-Cyr O. From discovery to design: the evolution of human factors in healthcare. Healthcare Quarterly 2012;15:24-29

Whatever you do Make it Relevant

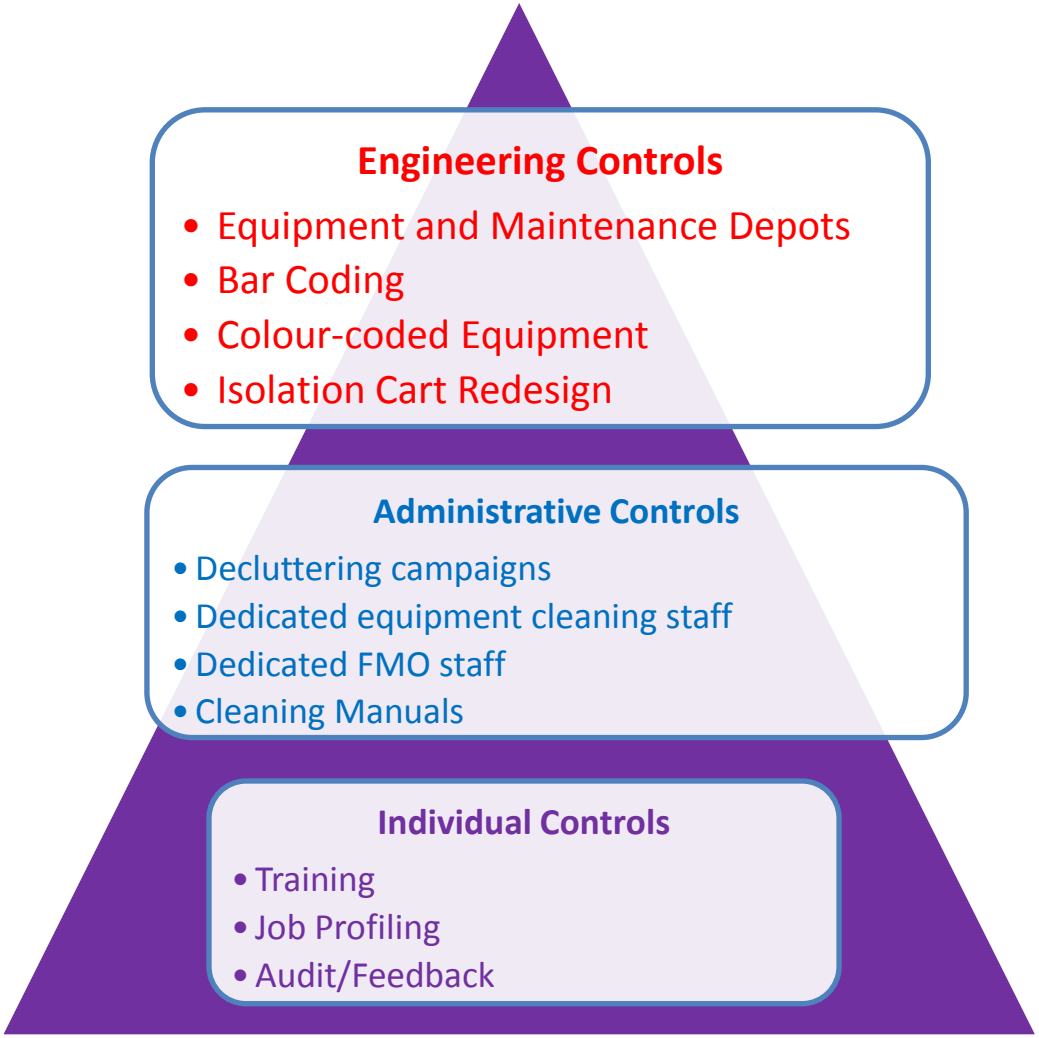


Example 1: Cleaning and Disinfection and Equipment Maintenance

The Issue: inconsistent cleaning of surfaces and equipment

Solving a human-system interaction.

Using a hierarchical approach

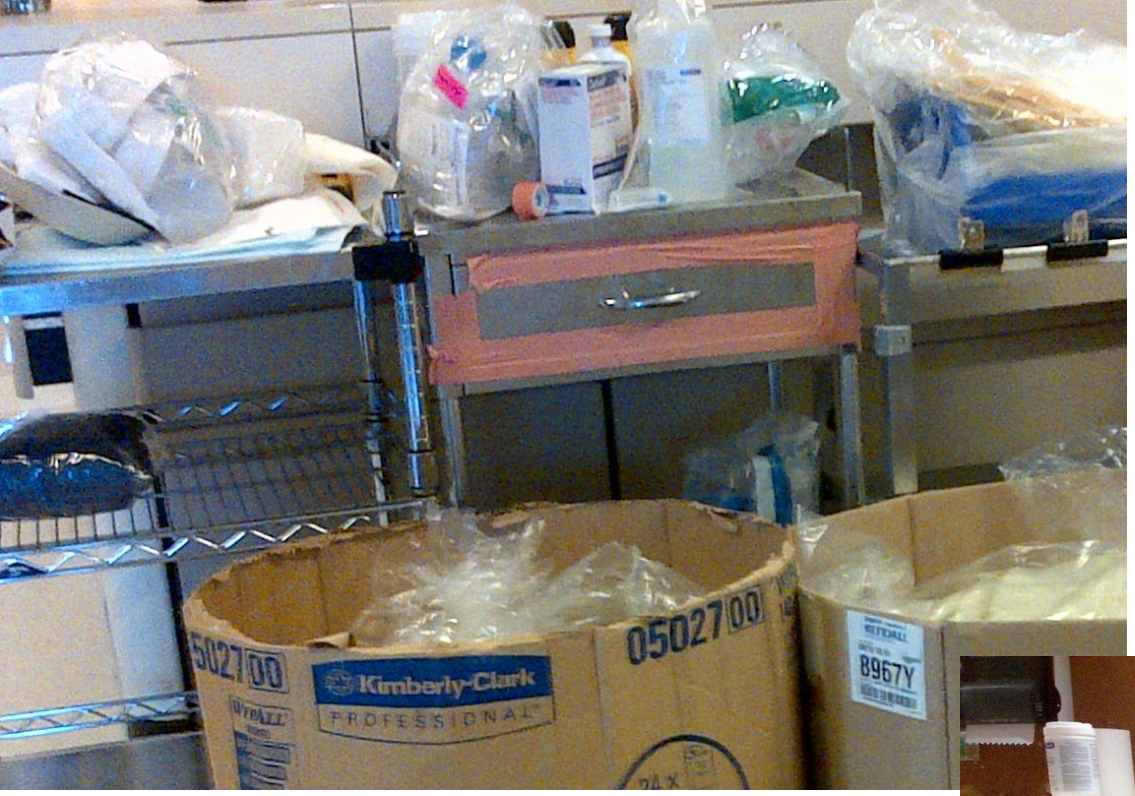



Standardizing and
Forced Function of
The Process/Task

Forced Function Differentiation (Visible Cues)
The Process/Task

Procedures/Policies
Instructional Aids

Piece of Equipment	Location of Cleaning	Department Responsible for Cleaning	Hospital grade surface cleaner/ disinfectant
4. Bladder scanners *(various models)* 	Point of use	Nursing staff, physicians, **ALL USERS**	Hospital grade disinfectant Clean probe, probe cable and all touch points on the scanner.
5. Calf compressor *(SCD)* 	Point of use	Nursing staff - remove sleeves, give precursory wipe and place in soiled utility room	Hospital grade disinfectant
	Soiled utility room	Equipment Depot staff (attach "CLEAN" sticker)	
	Equipment Depot	Equipment Depot staff - after 30 days (attach "CLEAN" sticker)	
6. Canes, single point and quad canes *(includes bariatric)* 	Nursing unit storage area	OT/PT staff between patient use	Hospital grade disinfectant

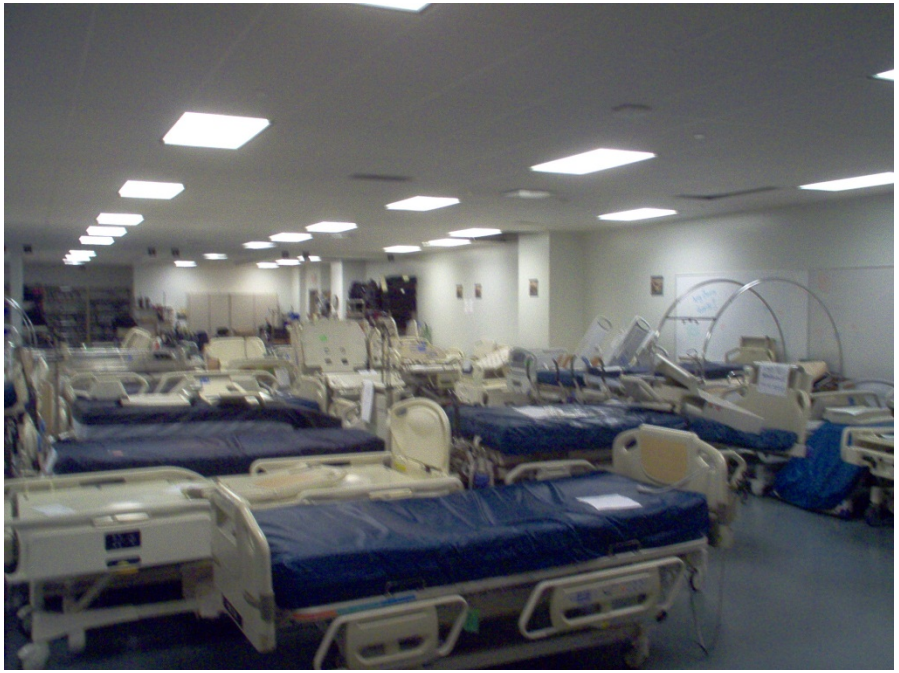


Decluttering and new Carts

Simplify
Minimal Mental Effort Required


Remove
Redundacy

The New Equipment Depot at VGH



Centralized Bed /Stretcher Service Bays

Visible cues

Simplify mental and physical effort


Standardize and Automate
Every piece of equipment has a barcode:
Visible Cues
CLEAN
Date FEB 18
Initials AS
IVAC - SINGLE
PAR: 3
T11150 CER
PRI
SEC
OPTIONS
Clear
Enter

"I'll be happy to give you innovative thinking. What are the guidelines?"

Example 2: User Centred Design

The bedpan disinfector saga

The issue

Bedpan washer disinfectors: An in-use evaluation of cleaning and disinfection

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British Columbia, Canada

Background: As part of a comprehensive approach to decreasing *Clostridium difficile* in our health authority, an evaluation of the in-use performance of 2 brands of bedpan decontaminators (BPDs) in 2 acute care facilities was performed.
Methods: A continuous quality improvement approach consisting of 5 BPD audits and 4 intervention phases was used over a 16-month evaluation period. Visible fecal soil on processed items was used as the progress indicator, and infection preventionists performed audits.
Results: A total of 1,982 observations was recorded. Percent failures rates ranged from 7.6% to 33% dependent on the intervention phase. Polypropylene materials had fewer failures compared with stainless steel. The addition of rinse agent significantly improved results particularly in polypropylene items (1% failure rate). A number of human factors issues and equipment design features compromised the BPD's ability to function adequately.
Conclusion: Users should thoroughly evaluate the in-use efficacy of BPDs and use a step-wise approach to identify and correct both human and equipment deficiencies. Forced function and compliance features for correct loading of machines, detergent and rinse agent dispensing, and ability to operate the machine only when detergent is present should be integral to the BPD design.
Key Words: Disinfection; bedpan decontaminators; *Clostridium difficile*; environmental cleaning.

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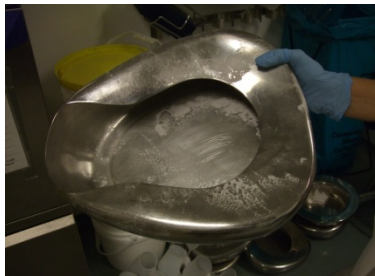
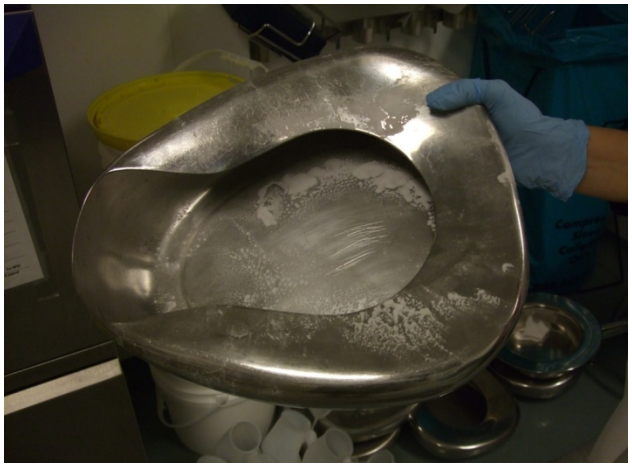


Methodology

- Processed bedpans audited over a twelve month period for visible fecal soilage
- A total of five audits and four phases of interventions done. A total of 1,982 inspections completed.



Hospital-wide audit → Process Review → Phase 1 Interventions → Re-audit → Phase 2 Interventions → FOCUS on two floors

Mechanical and educational interventions → Audit 3 → Audit 4 → **No Success** → New Device Required

HFE and User Centered Design

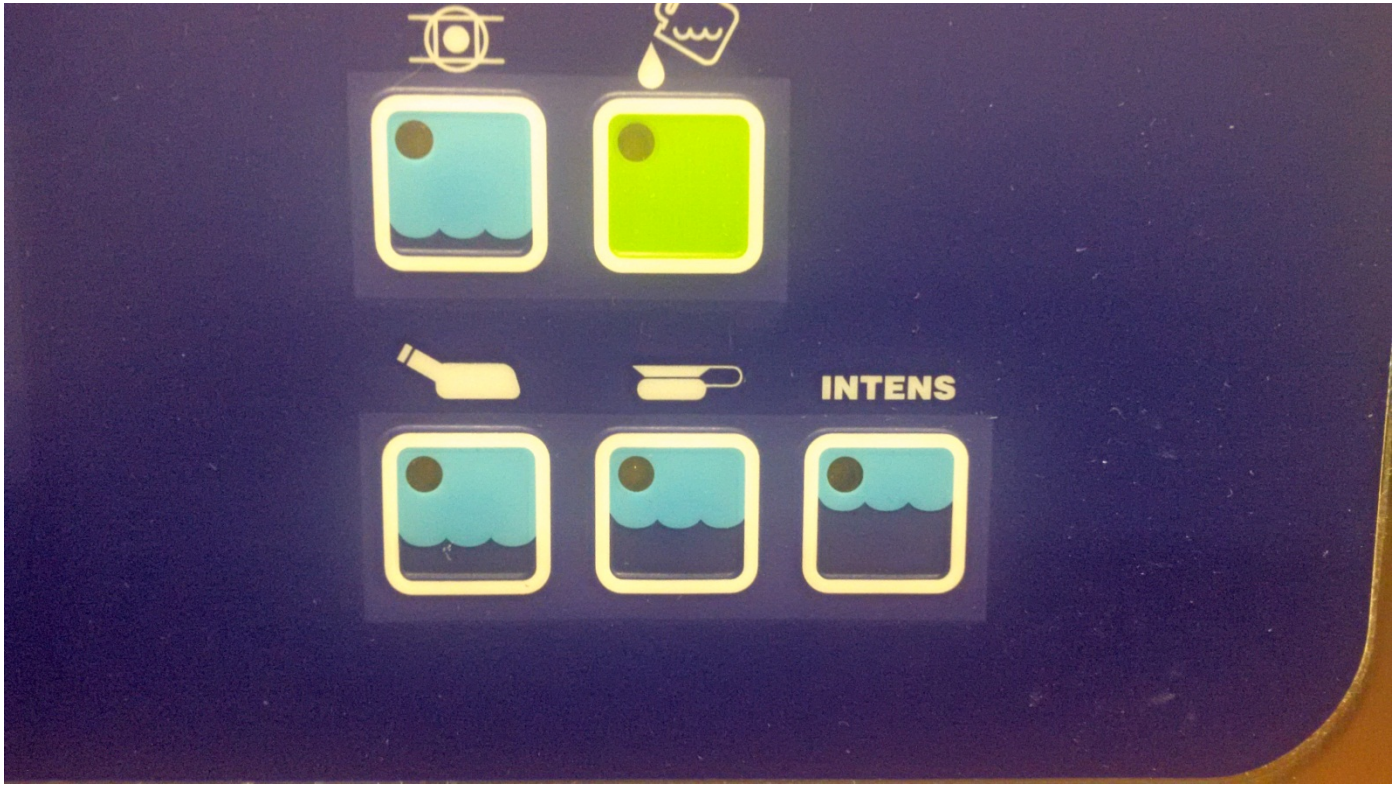
IDEAL

- An **iterative** process
- Concepts and prototypes developed
- User testing informs and optimizes the design of the system

ALTERNATIVELY

- Once design flaws are identified by users, they participate in the design change

Multiple options



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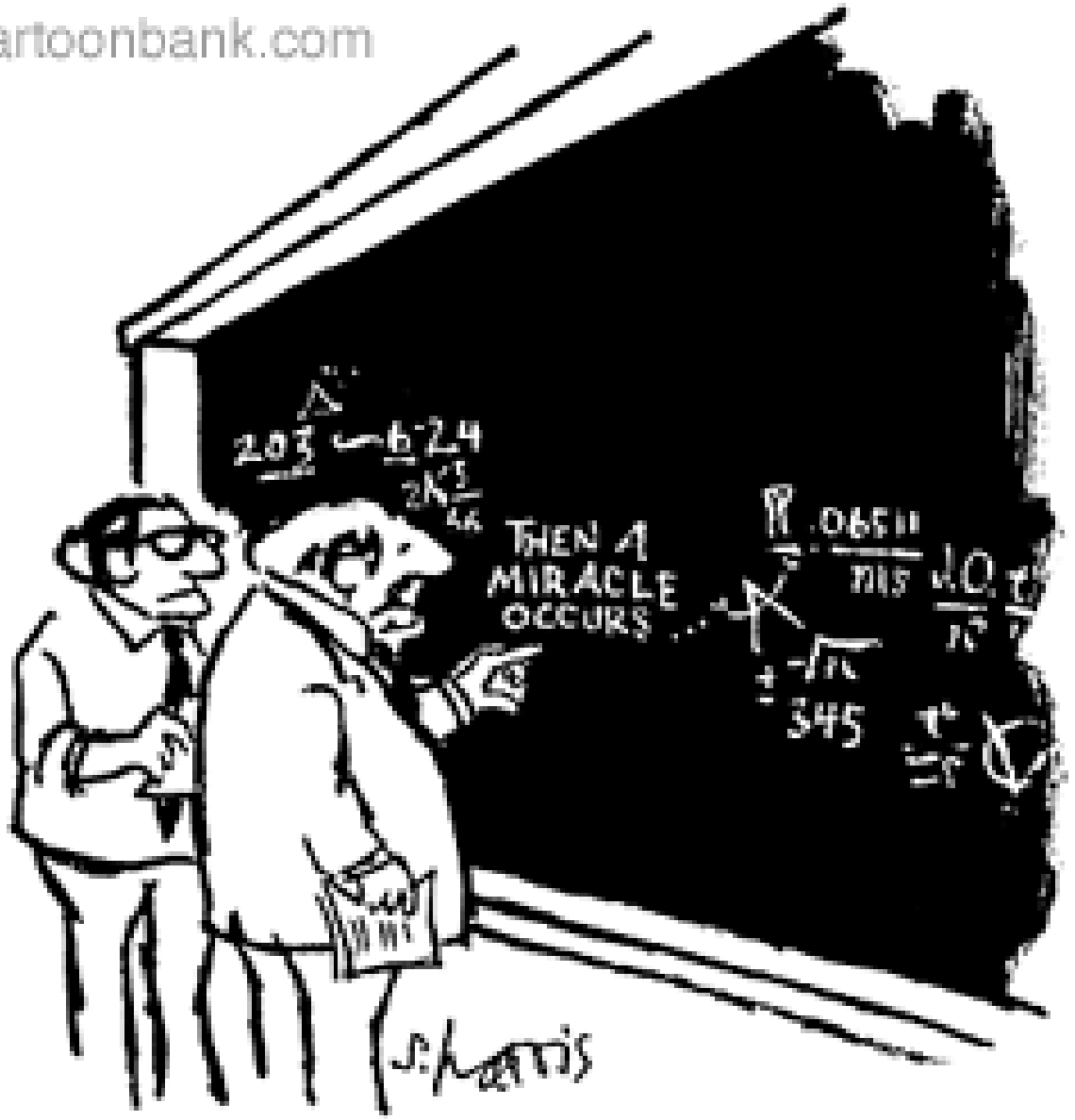
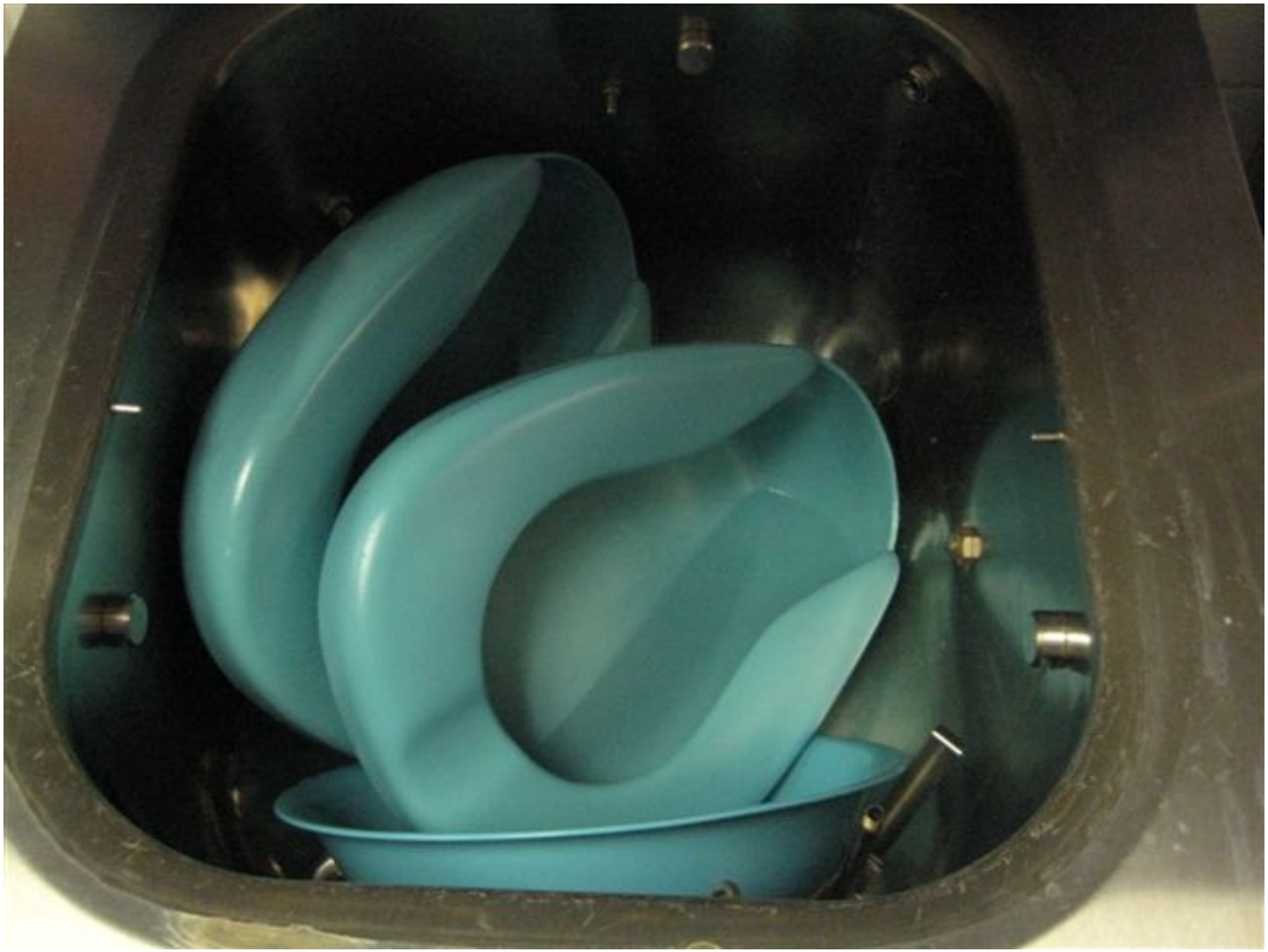


"I think you should be more explicit here in step two."

Encrypted error codes



No forced Function for loading

Labeling

Fill connections inserted into detergent and rinse bottles were not clearly identified.

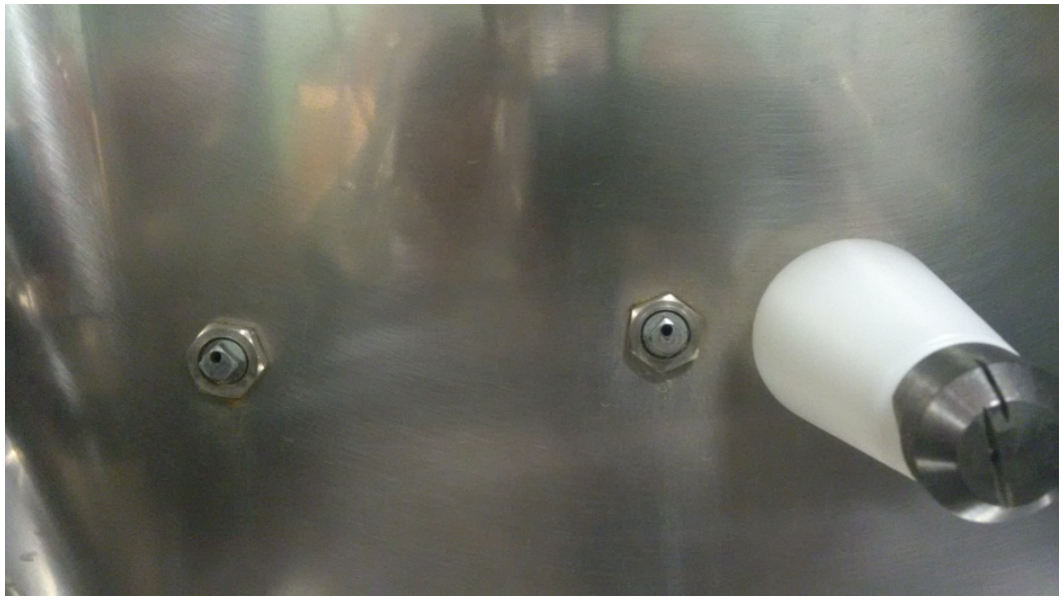
Detergent and rinse product connections were found often to be inserted into the wrong product.

Poor visual cues

Detergent and rinse product packaging very similar.

Inefficient Design

Nozzles clogged with fecal matter, metal filings, gasket materials.



So what happened next?

- Multidisciplinary team met to define parameters for a new BPD
- Business case to SET accepted
- RFP process completed
- NEW BPDs installed

An example of Substitution on a grand scale

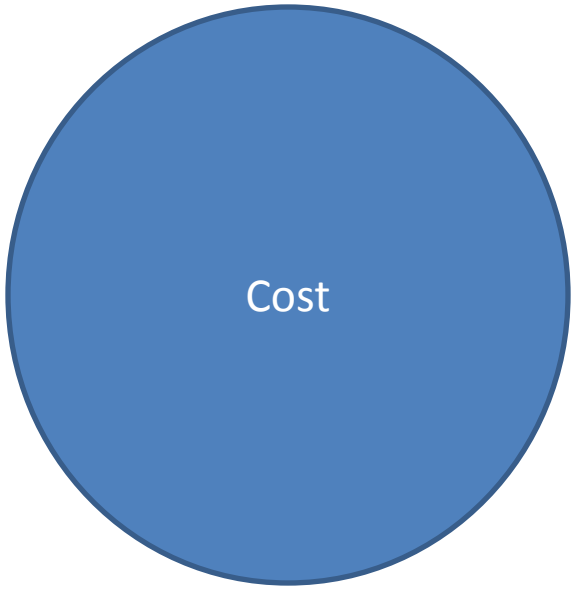
Example 3: Human Factors and the Procurement (RFP) Process

Human Factors Evaluation Methods for Procurement

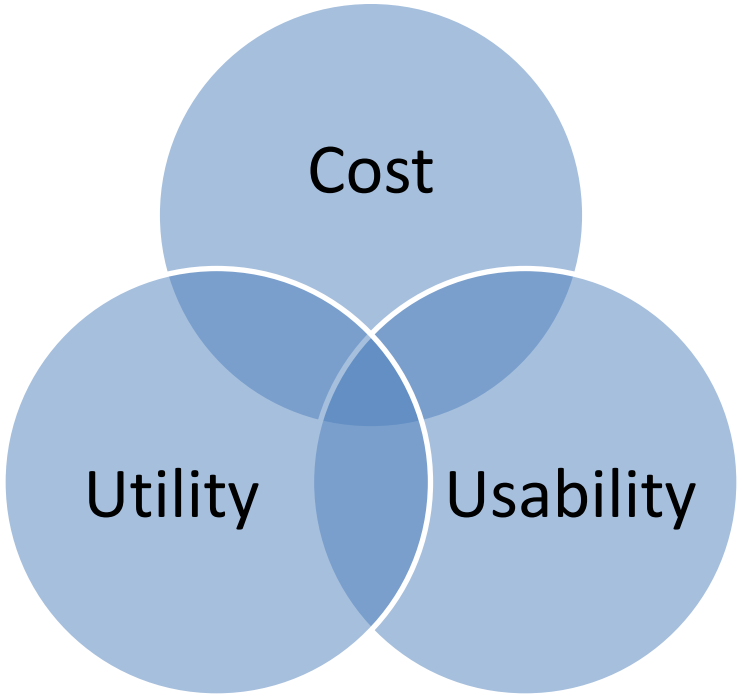
Namshirin, P; Ibey, A; Lamsdale, A. (2011). Applying a multi-disciplinary approach to the selection, evaluation, and acquisition of smart infusion pumps. *Journal of Medical and Biological Engineering,* 31(2): 93-98

Request for Proposal (RFP) Process

Previous Process



Current Process (Double Envelope)



The ‘New’ Procurement Process

- Does it require HFE or IPAC involvement?
- Who need to be involved?
- Have you conducted an environmental assessment
- Have you assessed the Resources, Capacity, Needs Assessment

Planning

Requirements Design

- What are the questions that require answers about the product(s)

- Validate and assess the responses
- RFP Assessment
- Clinical / Usability Assessment
- Operational Impact
- Short and long term costs

Evaluations

Defining Requirements

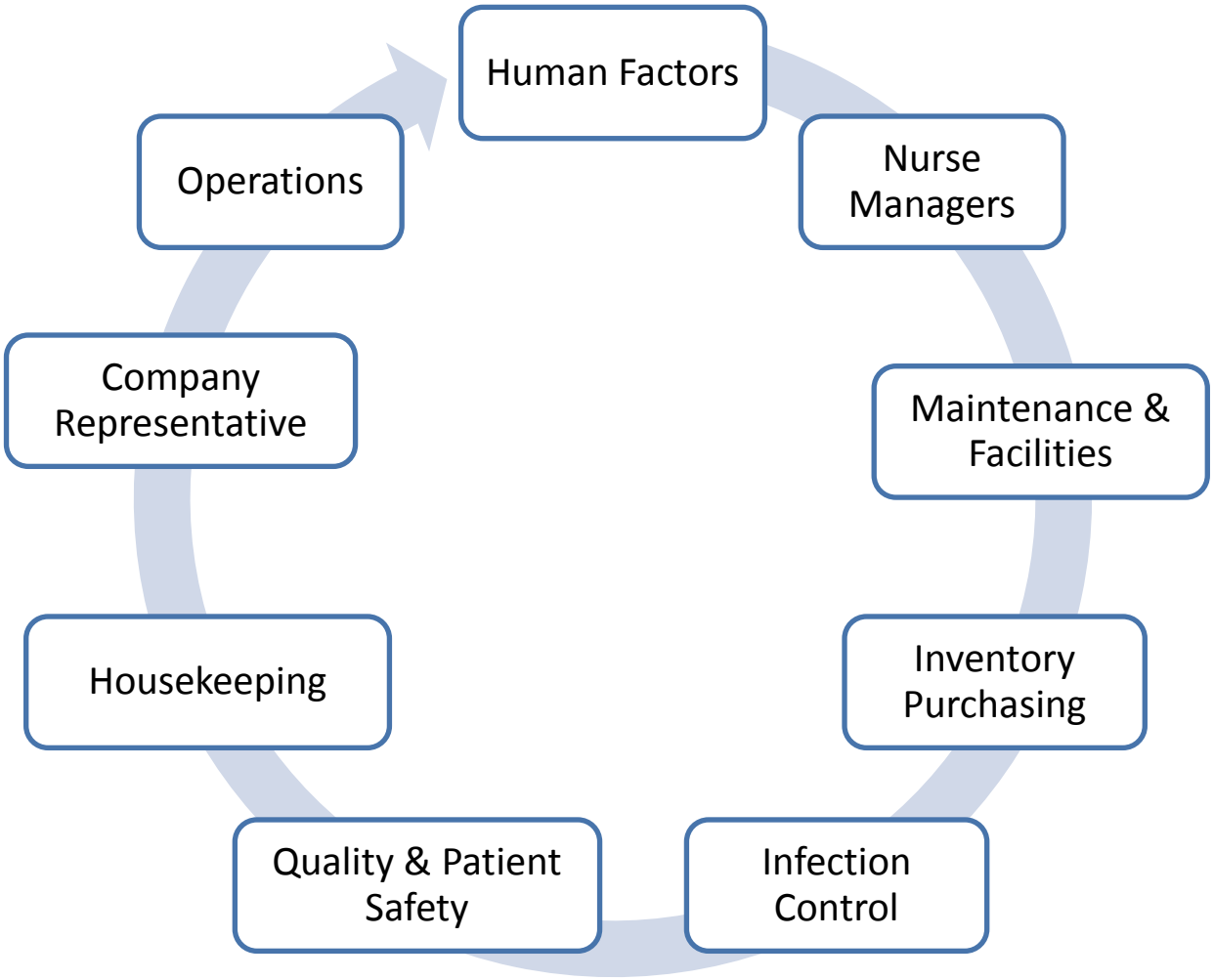
- Determine whether or not the manufacturer conducted human factors/usability testing of the device in question **during** product development
  - ANSI/AAMI HE75-2009 (Human Factors Engineering - Design of Medical Devices)
  - ISO IEC 62366: 2007 (Medical Devices – Application of Usability Engineering To Medical Devices)

Prioritization

- **Severity:**
  What is the potential for, and magnitude of, harm to the patient and/or user associated with device use?
- **Probability:**
  How many devices will be purchased, and what is the risk of multiplying errors as a result of increased device use?
- **History:**
  Are there known issues or potential problems with the device that can cause harm to the patient or user based on past use or reported incidents?
- **Complexity:**
  What are the physical and cognitive demands placed on a user while interacting with the device, giving consideration to the primary use environments and user tasks.

Courtesy of Alberta Health Services Document: Incorporating Human Factors into the Procurement Process, July 30, 2013

Stakeholder Assessment



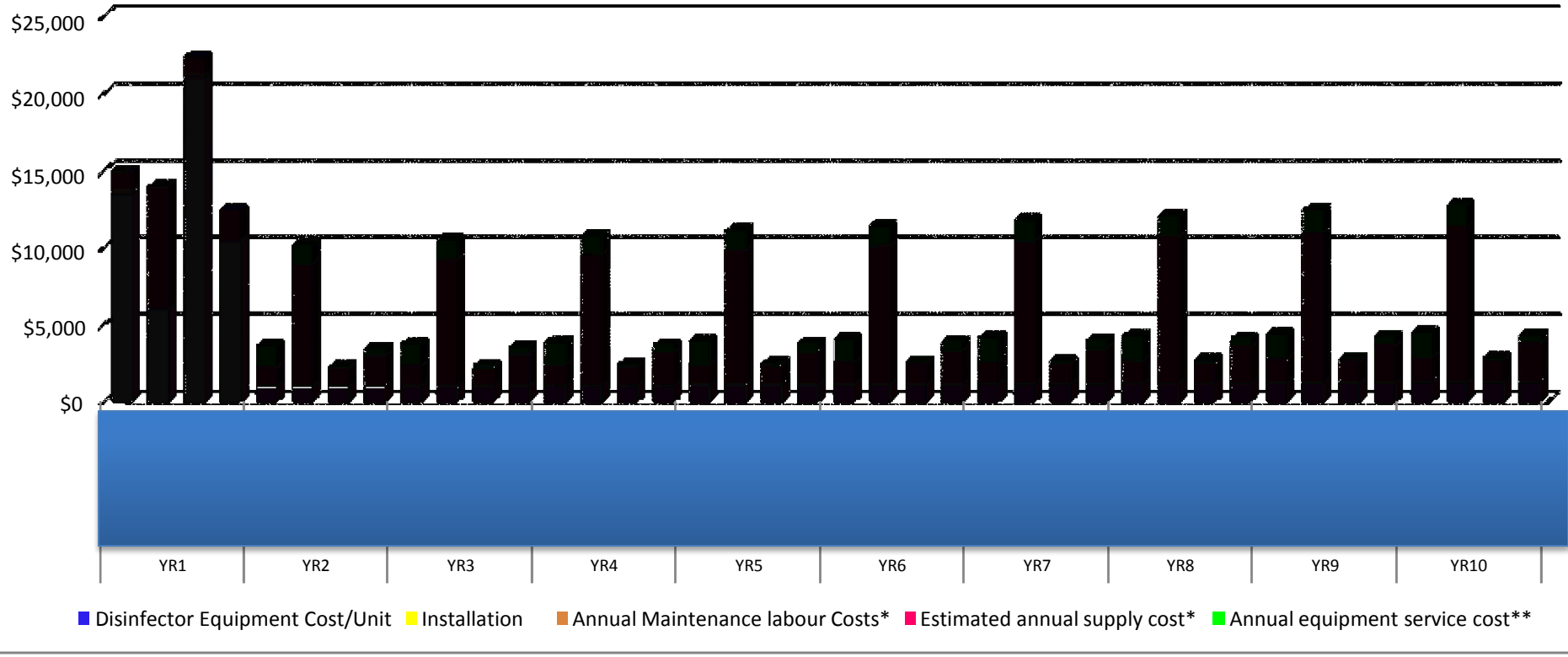
Ensuring you have the right people at the table through the entire procurement process

Scoring Weightings

Technical Evaluation	15%	50%
Clinical & Human Factors	15%	
Infection Control	20%	
Product & Services /Quality	10%	
Total Cost	30%	
Value Adds	5%	
RFP Terms/Conditions	5%	

Bedpan Disinfector Total Cost/Unit: Capital and Operating

A = $51,499 score - 26.5/30
B = $116,997 score - 11.6/30
C= $45,411 score 30/30
D = $47,579 score = 28.6/30



Using HFE Principles in Facility Procurement should

- Be efficient of time
- Enhance team dynamics
- Advocate for manufacturers to perform HFE design trials before marketing
- Allowed for onboard language to assist others as whenever one is going through a RFP


The Wave of
the Future

C. Human Factors in Developing Reprocessing Instructions

You should consider the following recommendations regarding human factors in developing your reprocessing instructions:

1. We recommend that you develop consistent reprocessing instructions across each of your product lines. Labeling that provides consistent methods and terminology, and utilizes the same document layout for all devices of a type, may help improve the user's comprehension and adherence to the instructions.
2. You should address any known post-market human factors issues known to exist for reprocessing your device or similar devices. Examples of human factors issues include, but are not limited to, actions requiring substantial dexterity or strength, good visual acuity, or familiarity with uncommon practices. Information on post-market issues may be found by reviewing your internal user complaint files, the published literature, the FDA's Medical Device Reporting (MDR) system, and FDA Safety Alerts and Public Health Notifications. We recommend that you refer to the following sources for additional information on human factors:
   a. FDA's guidance "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094461.pdf).
   b. FDA's guidance, "Human Factors Principles For Medical Device Labeling" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095300.pdf).
   c. The current FDA-recognized version of IEC Standard 62366, "Medical Devices – Application of usability engineering to medical devices."
   d. The current FDA-recognized version of ANSI/AAMI HE75, "Human Factors Engineering – Design of Medical Devices."
3. For devices that are subject to design controls under 21 CFR 820.30, you should validate your reprocessing instructions to ensure that users will be able to successfully understand and follow them. FDA recommends considering the following:

From FDA: Reprocessing medical Devices in Health Care Settings: Validation methods and Labeling Guidance for Industry and Food and Drug Administration Staff.

a. Your validation study participants should be representative of the professional staff that would perform these actual reprocessing procedures. If users would be wearing personal protective equipment (PPE), such as goggles, full-length face shields, heavy-duty utility gloves or liquid-resistant covering with sleeves, then the validation study participants should wear them as well.
b. Participants may use the instructions to perform an actual or simulated reprocessing procedure or verbally describe what they would do as they read the instructions.
c. If attributes of the use environment might affect use of the instructions and reprocessing of the device, they should be represented in the study.
d. Observing and documenting participant behavior during testing will allow you to assess the participants' adherence to the instructions and to identify and understand the nature of any errors or problems that occur.
e. After using the instructions independently, you should ask the participants if they had difficulty in performing the reprocessing, and allow them to describe their experience. You should ask specifically about any errors, problems or hesitations that were observed. The participants should provide subjective feedback regarding any wording in the instructions that they found confusing, misleading, or incomplete. The participants' responses and comments should be documented. If you make significant changes to the instructions after testing them, you should validate the success of the changes at eliminating or reducing the problems previously identified.

Conclusion

- Never underestimate the culture of "enablement" that HFE brings
- Humans are not the problem!
- Increasing emphasis to build HFE principles into much of what we do
- HCWs are finding their "voice" in this field

Human Factors

Literature

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2. From discovery to design: the evolution of human factors in healthcare. Cafazzo Healthcare Quarterly 2012;15:24-29
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4. Integrating human factors with infection prevention and control Storr J. The Health Foundation Thought paper May 2013 www.health.org.uk