A Human Factors Approach to Device Procurement

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Goals

1. Procurement
2. Human Factors and Procurement
3. Case Study
   Epidural Pump Evaluation

What is Human Factors?

designing for human use

a body of information about human abilities, human limitations, and other human characteristics that are relevant to design

Chapanis, A. (1995, p. 11). Human Factors in Systems Engineering. Toronto: John Wiley.

Human Factors Engineering

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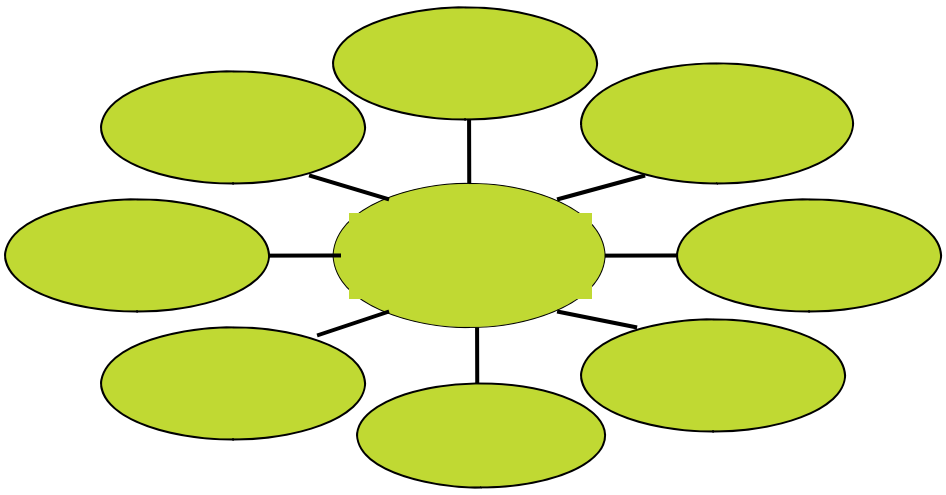
the application of human factors information to the design of tools, machines, systems, tasks, jobs, and environments for safe, comfortable and effective human use

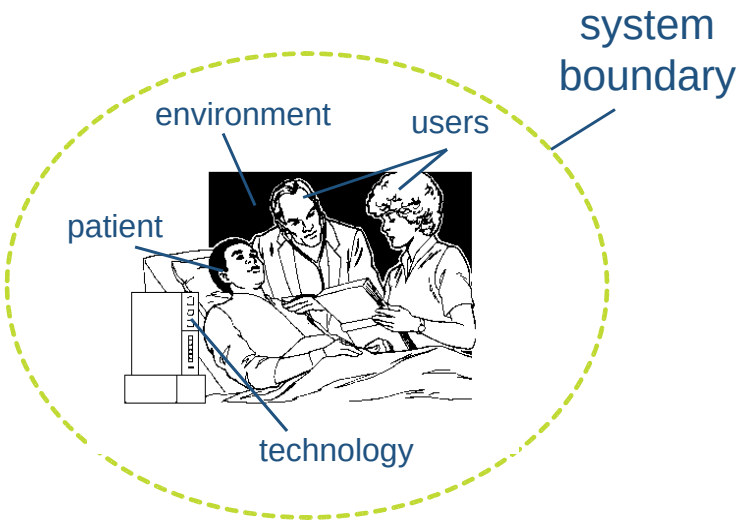
Chapanis, A. (1995, p. 11). Human Factors in Systems Engineering. Toronto: John Wiley.

Multidisciplinary



Chapanis, A (1995)

System Perspective



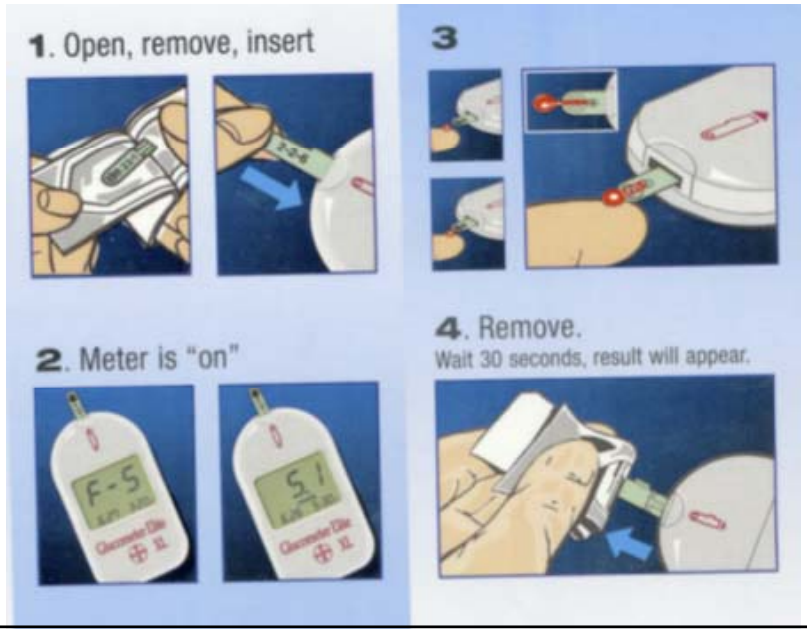
Procurement Decisions

- We make decisions with the information available to fit the anticipated need identified

  We don’t know what we don’t know

Examples

Blood Glucose Meter



Electrosurgical Unit

Electrosurgical unit

- Automated electrosurgical unit allows for instantaneous cutting
- Controls and functions are confusing
- Accidental activation during surgery
- Outcome – healthy tissue becomes unnecessarily charred

Cassano-Piche, A.L., et al., (2003)

Electrosurgical Unit Controls

Auto Cut	Auto Bipolar
1	2
2	1
3	0
4	Aus Off

Cassano-Piche, A.L., et al (2003)

Positive & Negative Pressure Caps for CVC and PICC lines

Positive Pressure

Negative Pressure

Positive Pressure NEW

Negative Pressure

Tracheostomy Tubes

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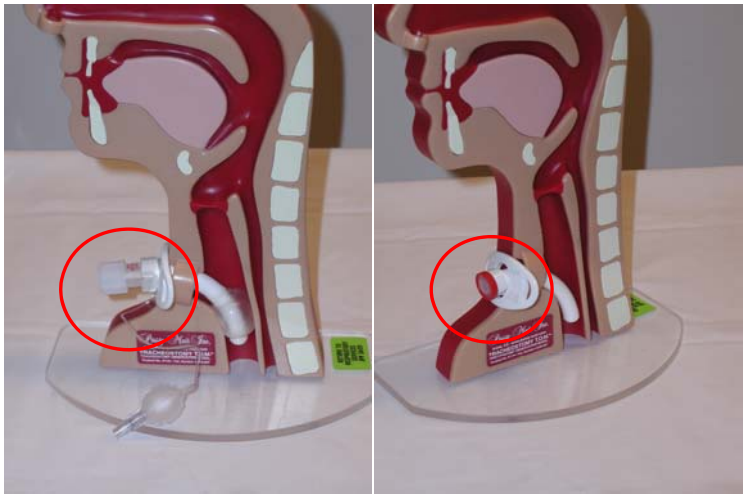
Shiley - Regular



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Shiley – XLT (extended)

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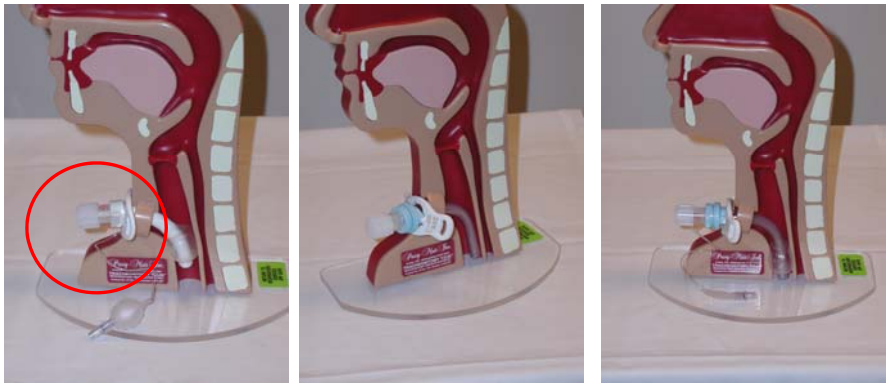
The caps

regular | extended | extended



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Can Human Factors improve the procurement process?

Can Human Factors improve the procurement process?

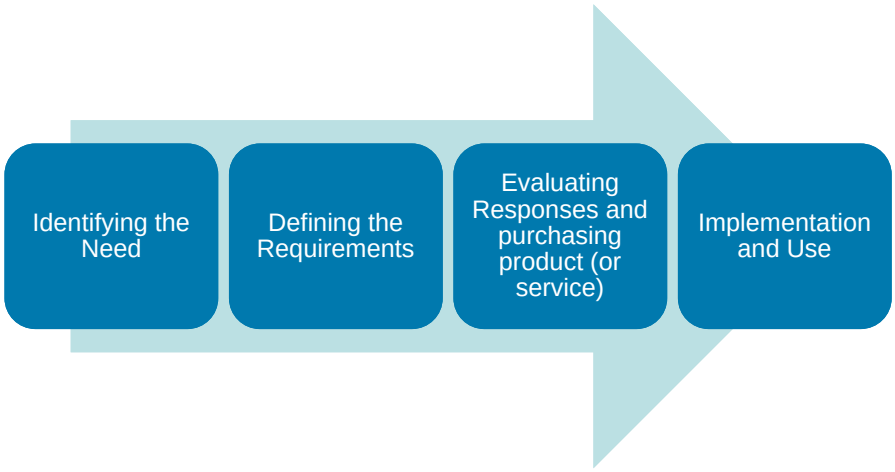
Yes

All Stakeholders

Clinical Representation
Reprocessing
Infection Control
Occupational Health & Safety
Facilities & Maintenance
Supply & Purchasing

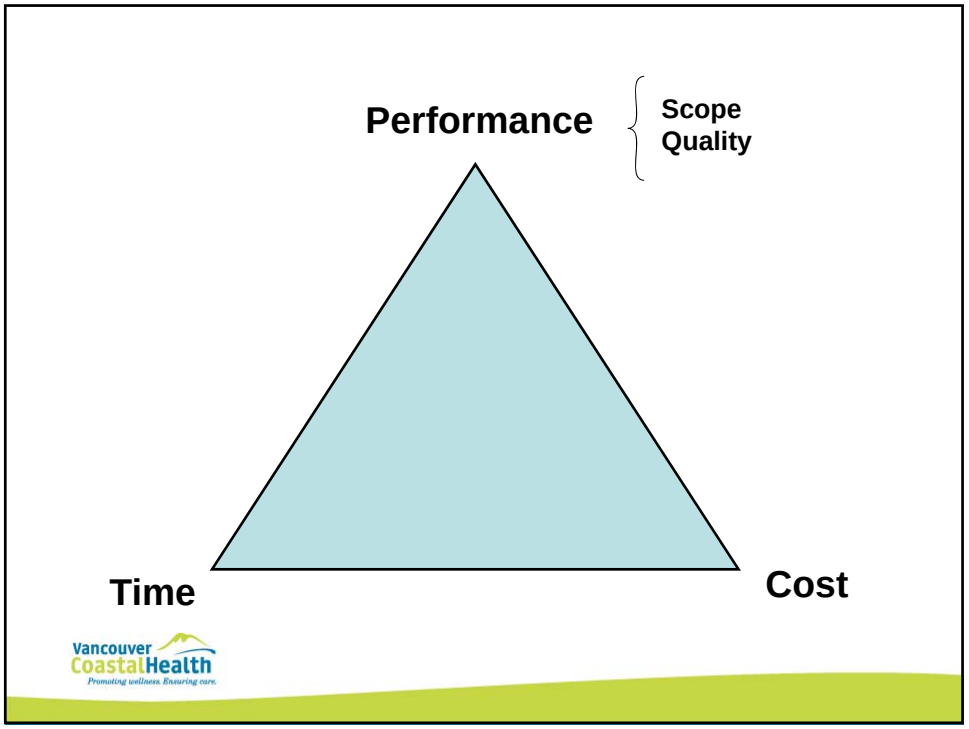
The Procurement Process

Phases

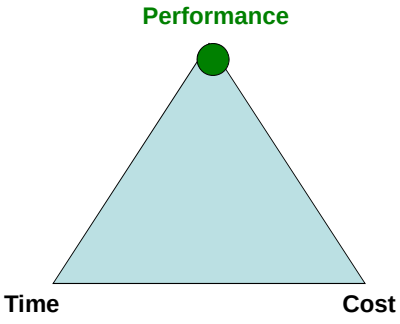


Triple Constraints

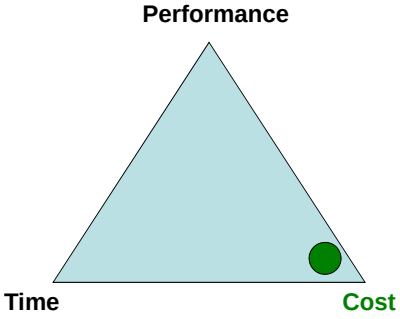
Performance, Cost, Time



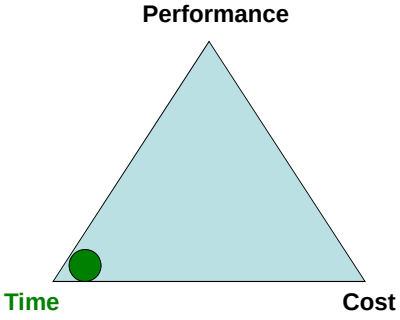
Must	
Should	
Nice	



Must	
Should	(-?)
Nice	



Must	
Should	+?
Nice	



Formal Large-scale Procurements

- Tenders
- Requests for proposals

Similar content; different approach

Key Differences:

- Definition of solution before going to market
- Flexibility during evaluation / negotiation

Tender	Characteristics	RFP
✓	Services / work, methods and outcomes are clearly defined and specified	
✓	The contract award is based on evaluation criteria that places a higher weight on price than value	
✓	There is a definite intention to enter into a contract.	
✓	Industry / market have specific quantifiable / qualifiable expectations	✓
	Problem-solving techniques for strategies have a greater emphasis	✓
	New or alternative methods, technologies, innovations or creativity are sought	✓
	Some of the services or work can be specified, while some of these required services or work cannot	✓
✓	The final results / outcomes, deliverables and process, including methodology, are clearly defined and can be specified	Not Usually

Where does Human Factors fit in Procurement?

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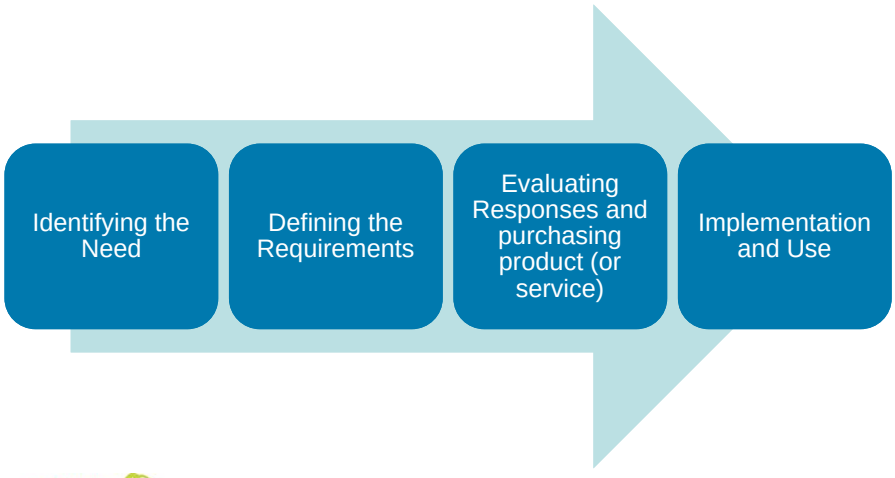
Phases



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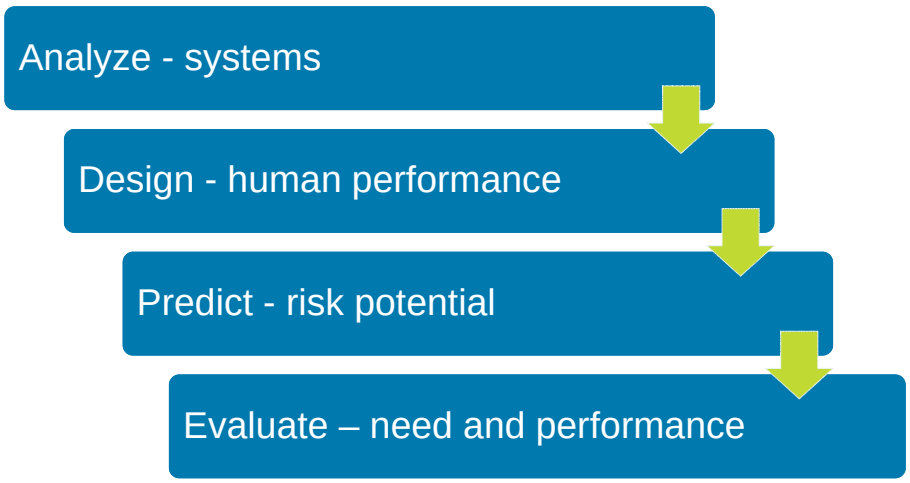
Human Factors



Evaluating Devices Before Purchase

- Regulatory bodies (FDA, Health Canada, Accreditation Canada) recognize that a poorly designed device can induce errors and operating inefficiencies even when operated by a well-trained and competent user
- What tips can provide support to decision-makers during the procurement process?

Hierarchy of Effectiveness

1. Forcing functions (MOST EFFECTIVE)
2. Automation / computerization
3. Simplification / standardization
4. Reminders, checklists, double checks
5. Rules and policies
6. Education
7. Information (LEAST EFFECTIVE)

*From Canadian Root Cause Analysis Framework

Epidural Pump Acquisition

Background

- Request for Proposal prepared and published December 2008
- Four vendors replied at closing during March 2009
- Evaluations commenced April 2009
- Implementation occurred in November 2009

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Typically Procurement Decisions influenced by:

- Cost
- Estimated life cycle of product
- Vendor support
- Convenience of maintenance
- Having the latest & greatest
- Clinical opinion

Human Factors in Procurement Evaluation

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Multidisciplinary Evaluation Team

- Healthcare Technology Management (VA)
- Biomedical Engineering (SPH)
- Quality & Patient Safety (VCH)
- Nurse Clinicians (SPH)
- Clinical Nurse Specialists (VA)
- Anesthesiologists (VA; SPH)
- Pharmacists (VCH, VA, SPH)

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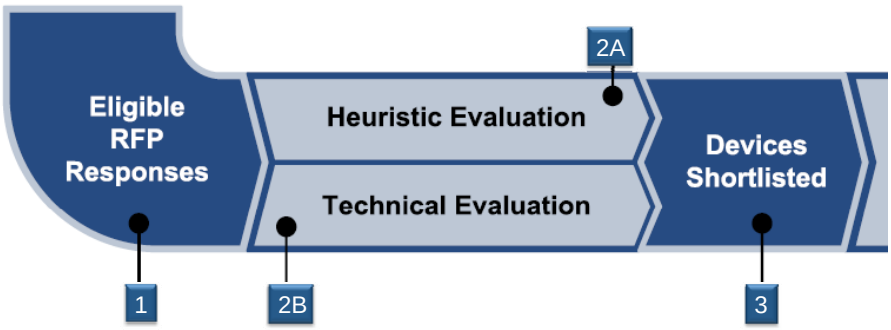
Phase 1 – Shortlist Devices



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Heuristic Evaluation

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- Discount usability evaluation technique (Jakob Nielsen, 1994)
- Used as a first step to evaluate usability
- General guidelines or informal “rules of thumb”
- Evaluate independently
  - 3-5 evaluators
  - identify violations
  - assess severity of each violation
- Identify positive & negative features

Heuristic Evaluation Benefits

- Low cost
- Low time commitment
- Ease of application
- Improves design and redesign processes

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Examples of Heuristics and Evaluation Methodology

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Heuristic Evaluation

Step 1: Identify Usability Issues

Step 2: Determine Heuristics Violated

Step 3: Assign Severity Rating to Violated Heuristics

Step 4: Recommend Improvements

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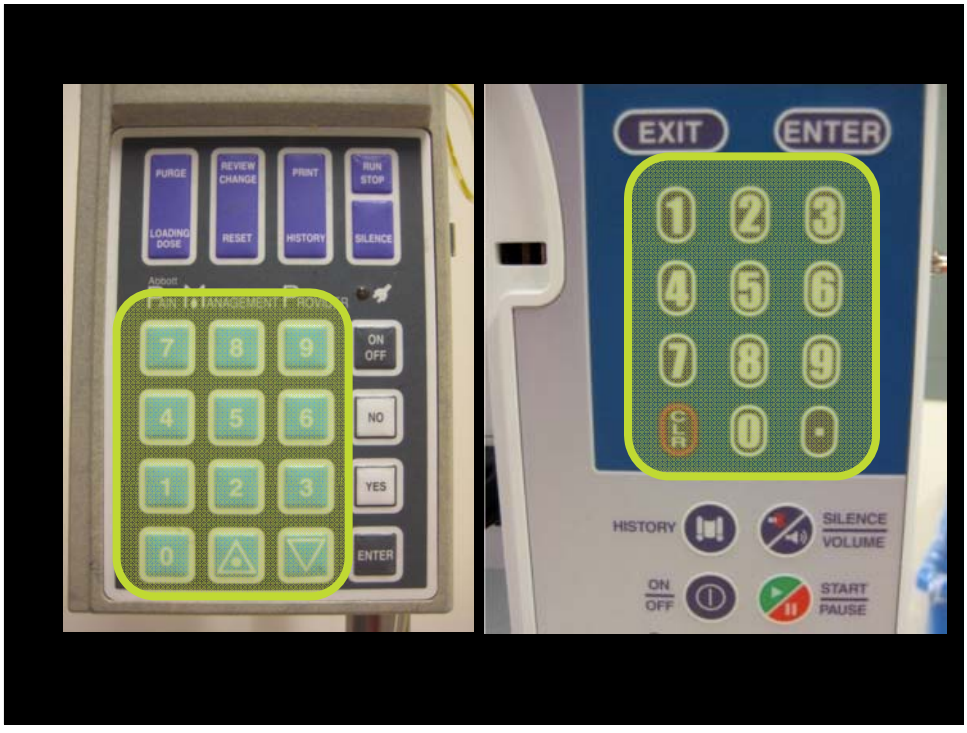
Step 1:

Identify Usability Issues


PURGE
LOADING DOSE
REVIEW CHANGE
RESET
PRINT
HISTORY
RUN STOP
SILENCE
Abbott
PAIN MANAGEMENT PROVIDER
ON OFF
NO
YES
ENTER
EXIT
ENTER
CLR
HISTORY
SILENCE
VOLUME
ON OFF
START
PAUSE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PURGE
LOADING DOSE
REVIEW CHANGE
RESET
PRINT
HISTORY
RUN STOP
SILENCE
Abbott
PAIN MANAGEMENT PROVIDER
7
8
9
ON OFF
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5
6
NO
1
2
3
YES
0
ENTER
EXIT
ENTER
1
2
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0
HISTORY
SILENCE
VOLUME
ON
OFF
START
PAUSE

Step 2:

Determine Heuristics Violated

Code	Heuristics
A.	Visibility of System Status
B.	Match Between System and Real World (user focus)
C.	User Control and Freedom
D.	Consistency and Standardization
E.	Error Prevention (focus on users and tasks)
F.	Recognition Rather Than Recall
G.	Flexibility and Efficiency of Use
H.	Aesthetics and Minimalist Design
I.	Help Users Recognize, Diagnose, and Recover From Errors
J.	Visual Representation
K.	Auditory Representation

Nielsen, 1994

Step 3:

Assign Severity Rating to Violated Heuristics

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Severity	Rating	Description
0	**Not a Problem**	Comments, notes, feature/element you liked
1	**Aesthetic Issue**	Not satisfying to use
2	**Minor Usability Issue**	**Low Priority:** Problem is a nuisance, but does not prevent accurate work. Many users will never realize or experience the problem
3	**Major Usability Issue**	**Medium Priority:** Users are prevented from completing tasks related to high or medium priority user goals. May involve delays and frustration due to inadequate feedback, inefficient workarounds, or sub-optimal task flow
4	**Severe Usability Issue**	**High Priority: Must be corrected before purchasing.** Users are unsuccessful in completing tasks related to high priority user goals. Incorrect results and the potential for critical adverse events

Step 4:

Recommend Improvements

Issue	Pump can start with the cover closed but not locked
Heuristic Violated	E = Error Prevention
Severity Rating	4 (Severe; Correct before purchasing)
Recommendation	Pump should have a sensor (auditory and visual) on the lock not just the cover to ensure safety and to not rely on user memory

Issue	No clear way to exit the Bolus Dose screen without giving a patient a bolus. The user must press Cancel twice to exit
Heuristic Violated	C = User Control & Freedom D = Consistency (user in control) F = Recognition rather than Recall (minimize memory load)
Severity Rating	4 (Severe; Correct before purchasing)
Recommendation	Provide a clear exit (add Exit key to bottom of screen with a screen asking user to confirm that they do not want to proceed with a bolus). User can enter 0.0 as a dose and again confirm that they are not giving a dose

Issue	The drug rate and concentration can be changed manually after the use has selected the protocol. The user must remember to press enter after making such change; if the user selects the arrow key, the change is not saved and value reverts back to previous setting
Heuristic Violated	E = Error Prevention,
Severity Rating	4 (Severe; Correct before purchasing)
Recommendation	A confirmation screen must be present and ask the user if they accept the value and change. Only one button (yes or no) will confirm the value.

Heuristic Evaluation Findings

Device	Heuristic Violations	Maximum Severity Rating
Pump A	28	4
Pump B	17	4
Pump C	3	4
Pump D	2	4

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Pump A

Heuristic Violations	Example
28	• Tube loading problems • No review capability before starting the epidural pump • Event logs and pump history are erased when a "new patient" is selected

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Pump B

Heuristic Violations	Example
17	• When reviewing program and making adjustments, scrolling to the next field does not save the changes unless ENTER is pressed • Non-traditional numeric layout • Potential flow inaccuracy if pump is dropped while loading cradle is open

Pump C

Heuristic Violations	Example
3	• Abbreviations of medications on display lead to confusion (example: Fe, Bup, Hm) • Mixing up route of infusion (Epidural vs. PICRA) • Protocol number (Protocol 01 - Bup 0.2% (2 mg/mL)

Pump D

Heuristic Violations	Example
2	• Front button on pump says PCA dose • While running on battery, display screen goes into sleep mode minimizing the feedback that the pump is on.

Shortlist

Device	Heuristic Violations	Maximum Severity Rating
~~Pump A~~	~~28~~	~~4~~
~~Pump B~~	~~17~~	~~4~~
Pump C	3	4
Pump D	2	4

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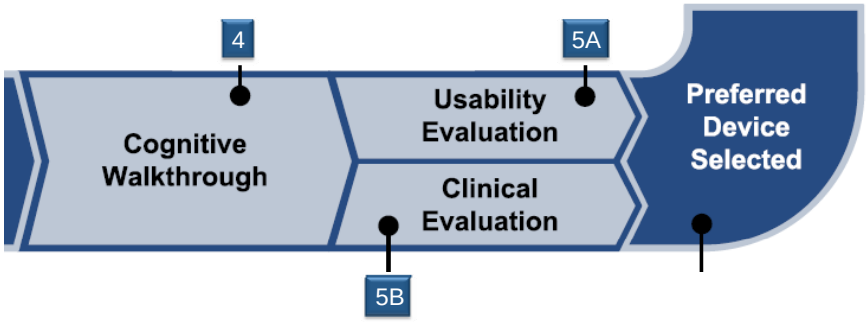
Phase 2 – Selection of Device



Cognitive Walkthrough

Cognitive Walkthrough

1. Identify how each product meets functional needs
2. Determine how pump parameters/protocols to be programmed for clinical environments
3. Perform pre-determined tasks to assess the usability and ease of use

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Assessment Criteria
1. When asking users about their work is not effective
2. When we want users to become experts
3. When we want the system to be able to cope with the unexpected
4. In complex systems, to understand how the system works, before beginning a design

Criteria to assess the application of a formative analysis to the domain of hemodialysis (Adapted from Burns & Hajdukiewicz, 2004, and Lamsdale, 2007).

Walkthrough completed with representative pump users

2 Anesthesiologists

3 Clinical Nurse Specialists

1 Nurse Clinician

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Usability Evaluation

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Usability Evaluation

- Effectiveness
  - Percentage of task completion
  - Ratio of success to failures
- Efficiency
  - Time to complete a task
  - Time to learn
  - Percent or number of errors
- User Satisfaction
  - Functions and features
  - Number of times expressed of frustration or dissatisfaction

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1. Identify design problems that may affect performance, cost, and/or time
2. Provide additional information for decision making
    1. e.g. details re: implementation concerns, trouble-shooting, error recovery, training design
3. Quantify level of consistency between new product and current workflow – degree of standardization and error potential

Nurses perform realistic epidural tasks in a simulated environment

1

Collect Qualitative & Quantitative Data

2

Identify user errors; inability of users to complete tasks; and increases to task time

3

Emphasis is *not* on evaluating nurses, but how the pump fits into their workflow

Usability Evaluation

Participants: 18 nurses (T8/T9-VGH)
3 nurse educators (SPH)

Training: 15-minute session for each pump each covered the same principles, examples, and user interaction

Videotaped sessions upon consent

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Usability Evaluation

Three Use Cases:

1. Epidural infusion with morphine
2. Changing the epidural infusion to another bag of medication with HYDROmorphone
3. Starting a new regional (PICRA/Peri-Neural) bupivacaine infusion

Questionnaire: Usability Evaluation and Clinical Trail

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Pump C: User Comments

"In an effort to make the pump safe and secure, I think user-friendliness got left behind :-)"

"Cassette difficult to mount"

"Too many buttons. Difficult to remember what function is under what button"

"I hate air alarms. Too many alarms for this pump. The pump alarms when you put a code in!!"

"Pump is not very intuitive"

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Pump C: Usability Concerns

- Abbreviations of medications:
  - HYDROmophone 20 mcg/mL + bupivacaine 0.1% (1 mg/mL) = “Hm20/Bup0.1”
- Mixing up route of infusion (Epidural vs. PICRA)
- Protocol numbers
  - Protocol 01 - Bup 0.2% (2 mg/mL)
- Lack of informative double-checks
- Confusion between ENTER and START buttons
- Acronym use throughout pump settings

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Pump C: Usability Concerns

- Progress beep on pump sounds like error-beep on APMP
- Locking sequence and passcode speed
- Difficulties removing batteries
- Issues with cassette loading
- Issues with Lockbox – durability, hinged at centre

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Pump C: Positive Observations

- Forced double-check / confirmation of settings
- Layout matches user's workflow
- Displayed information can be seen in minimum lighting conditions
- The tubing can be loaded into the pump quickly

Pump D: User Comments

"Clearly laid out + intuitive"

"Love it!!"

"This is a fantastic pump -> Worried about cost for batteries and use of battery life"

Pump D: Usability Concerns

- PCA dose on front faceplate – confusing
- Sleep mode on screen after 15 seconds
- Tubing caught in lockbox – upstream occlusion
- Lockbox too big

Pump D: Positive Observations

- Easy to learn (training < 10 min)
- Users quickly and accurately complete task sequence
- Forced double-check / confirmation of settings
- Layout matches user's workflow

User Preference

Clinical Evaluation

- Vancouver General Hospital and St. Paul's sites
- 31 question survey with 7-point Likert Scale
  - (0-6 strongly disagree to strongly agree)
- Over 100 responses over 2 weeks

Final Results	Pump C	Pump D
Average Score	4.36 out of 6.00	5.59 out of 6.0
Percentage	72.7%	93.2%

Based on all quantitative and qualitative evaluations, an epidural pump was selected that was supported by Technical, Human Factors & Clinical perspectives.

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Recommendations

- System difficulties can be corrected if identified
- “Training is the last bastion of poor design”
- Heuristic Evaluation & Usability Evaluation
- System Analysis (multidisciplinary approach)

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Conclusions

- Proactive about safety rather than reacting to harm
- Identify cognitive process improvement opportunities that positively influence the safety, efficiency, and overall wellness of workers and their environments
- Analyze potential adoption of new technologies for user interaction and performance

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