It’s Only Human
.... Factors that is

Mary E. Burkhardt, MS, RPh, FASHP, FSMSO
Medication Safety Enthusiast
And Mere Human

In honor of Laura Lin Gosbee, MS
Objectives:

• Discuss the relevance of human factors engineering to pharmacists and pharmacy technicians.

• Describe the impact of human factors on medication safety.

• Identify practical applications of human factors engineering that can be applied to the pharmacy work environment.
James Bagian, MD, PE
Former Director of VA National Center for Patient Safety

• “When I went to work full time in safety, I came to realize that I knew lots about medication systems and almost nothing about safety (as a science)”
  • Mary Burkhardt 2001

• “Patient safety is not about preventing “errors”. Patient safety is about preventing injury”
  • Jim Bagian STS 29 and 40
Human Factors Engineering

• Definition:

  – Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to the design in order to optimize human well-being and overall system performance.
  
  – It is a bit of a cross between psychology and engineering
  
  – It is the “core science” of safety just like microbiology is the core science of infection control
What is Human Factors Engineering?

- Designing systems (stuff) to fit human capabilities and limitations

- Using scientific methods to gather unique information on:
  - Hidden needs of the end-user
  - *Human-Machine interaction* data which CANNOT be found with typical techniques

- Taking advantage of knowledge bases about human-system interaction

- Well designed systems (based on HFE) are safer, less expensive and result in better user satisfaction
Human Factors Model

**Senses**
- Vision
- Hearing

**Psychomotor**
- Hand
- Eye movements

**Input Devices**
- Keyboard
- Voice recognition

**Output**
- CRT
- Sound
Essentially, making the glove to fit the hand, not the hand fit the glove.
Where can I use HFE?

- Use during RCAs
- Use prior to procurement
- Use during HFMEAs
- To test changes
- To re-design systems
- To design training
Human Factors Engineering Domains

- Physical ergonomics (eg. work stations)
- Cognitive ergonomics (eg. decision making)
- Organizational ergonomics (CRM)
- System design and automation
- Instructional design and training
- Web and software design and usability
- Safety, accidents and human error
- Displays and controls
- New trend / terminology = Aging in place for homes designed to meet your needs as you age
HFE professionals are commonly found

- Highly complex and hazardous industries
  - Aviation, nuclear power, chemical refineries where the impact of failure is catastrophic
- Highly automated environments
  - Software design; usability; cognitive task analysis
- Highly competitive environments
  - Website design (think Amazon, Ebay, Staples, etc.)
- Other:
  - Automotive design and safety engineering
  - Packaging design
  - Instructional design
  - Design for special populations (Michael Graves)
  - Traffic safety
Causal and Contributing Factors in Safety Events

- **Task**
  - Pace of work – Frequency of task

- **Operator**
  - Physical Ability, Level of Attention, Personality

- **Machine**
  - Controls & Display, Mechanical Design

- **Environment**
  - Lighting Levels, Humidity, Noise
A publication from NASA about decision making in pilots. One could easily substitute Pilot with Pharmacist and have a good resource document for decision-making and decision support systems.
The moral of the story:

Don’t Just Paint Forklifts!!
The dire consequences of ignoring HFE

- Many serious large-scale technological systems' accidents, having grave consequences, such as those of Three Mile Island (TMI), Bhopal, and Chernobyl, have primarily been attributed to `operator error.' However, further investigation has revealed that a good majority of these incidents are caused by a combination of many factors whose roots can be found in the lack of human factors (micro- and macro-ergonomics) considerations.
Three Mile Island

- The accident began at 4 a.m. on Wednesday, March 28, 1979, with failures in the non-nuclear secondary system, followed by a stuck-open pilot-operated relief valve (PORV) in the primary system, which allowed large amounts of nuclear reactor coolant to escape. The mechanical failures were compounded by the initial failure of plant operators to recognize the situation as a loss-of-coolant accident due to inadequate training and human factors, such as human-computer interaction design oversights relating to ambiguous control room indicators in the power plant's user interface. In particular, a hidden indicator light led to an operator manually overriding the automatic emergency cooling system of the reactor because the operator mistakenly believed that there was too much coolant water present in the reactor and causing the steam pressure release. [3]
My idea for improving the EMR

Improve situation awareness (creatinine up, the kidney flashes; MRI of brain abnormal, the brain flashes)

Reduce alert fatigue

Help target the right provider to the right “system”

This is basically what Three Mile Island did to reduce complexity after their event (high level alerts with intuitive ways to drill down for more detail)
HFE Quiz

What is the most conspicuous color?

1. Black
2. Yellow
3. Red
4. Not enough information to tell
HFE issues are EVERYWHERE!!

Issues arise in simple systems and consumer products as well.:  
✓ Smart phones and other hand held devices that continue to shrink yet grow more complex (a phenomenon referred to as "creeping featurism")  
✓ millions of VCRs blinking "12:00" across the world because very few people can figure out how to program them  
✓ or alarm clocks that allow sleepy users to inadvertently turn off the alarm when they mean to hit 'snooze'.  
✓ E-prescriptions that are legible but not more clear  
✓ E-prescriptions that never get picked up (wrong pt?)
Additional Common HFE issues

- Way finding in airports, malls etc.
- GPS use (makes you less able to navigate)
- Entrance doors to buildings (people get trapped and injured)
- The location of controls in rental cars
- Switching systems (tab versus return)
- Roads and transportation safety
- Opening plastic containers
- Limited grip strength/arthritis
HFE in the Kitchen
Designing around human need
Good design in health care
True or false?

- Color coding IMPROVES medication safety.
Demonstration: Stroop Test

Row 1

Row 2

Row 3
Now, State the Color of the Text as Fast as You Can...

<table>
<thead>
<tr>
<th>Row 1</th>
<th>Red</th>
<th>Blue</th>
<th>Green</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Row 2</td>
<td>Yellow</td>
<td>Green</td>
<td>Blue</td>
<td>Red</td>
</tr>
<tr>
<td>Row 3</td>
<td>Green</td>
<td>Red</td>
<td>Yellow</td>
<td>Blue</td>
</tr>
</tbody>
</table>
Again, State the Color of the TEXT as Fast as You Can...

<table>
<thead>
<tr>
<th>Row 1</th>
<th>Red</th>
<th>Blue</th>
<th>Green</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Row 2</td>
<td>Yellow</td>
<td>Green</td>
<td>Blue</td>
<td>Red</td>
</tr>
<tr>
<td>Row 3</td>
<td>Green</td>
<td>Red</td>
<td>Yellow</td>
<td>Blue</td>
</tr>
</tbody>
</table>
Color coding increased medication errors

Because like the Stroop test showed, your brain reads color first.

Figure 5. Two Ophthalmic Products of the Same Pharmacologic Class with Similar Packaging and Color Scheme. Image provided courtesy of ISMP.
A few good examples of “color differentiation”
Multiple dose container information not conspicuous enough

Oral Sodium Phosphate (OSP) Products for Bowel Cleansing (marketed as Visicol and OsmoPrep, and oral sodium phosphate products available without a prescription)
[Posted 12/11/2008] FDA has become aware of reports of acute phosphate kidney injury associated with the use of oral sodium phosphate bowel cleansing products. FDA cautions health care professionals and patients of this risk and recommends the following:
Software System Defect – 155 VA hospitals

• When ordering medications in CPOE (CPRS), the software would auto-fill the drug name when three letters were typed. The first drug on the list with the first three letters was entered unless you kept typing.
  – Example: Qui → Quinidine, when Quinine was desired
• Fixes put in place by IT address above and related vulnerabilities:
  1. OR*3*190 – Medication name - no longer allow auto-selection based on 3 character match
  2. OR*3*231 – Dosage, Schedule & Route will no longer allow auto-selection unless a unique entry is found
• Then, on to LAB, and on to Radiology, but where else?
“Look-up-alikes”

- Carafate & carbamazepine
- carbamazepine & carbidopa/levodopa
- clonazepam & clonidine
- clonidine & clozapine
- digoxin & diphenhydramine
- etidronate & etodolac
- Flagyl & Flexeril
- glipizide & glyburide
- Levodopa & levofloxacin
- methadone & methotrexate
- penicillamine & penicillin
- prednisone & primidone
- quinidine & quinine
- tramadol & trazodone

Tired and inexperienced house staff commonly missed the drug name confusion because there was no expectation or knowledge that this was possible. Also happened with route, and strength (Low molecular weight heparin 15 mg (1/2 a syringe) converted to outpatient order – defaulted to 150 mg dose
HFE Success story – spice rack design: A girl who likes to cook, some free help from university students, a local plastics vendor and a real life problem to solve.....

http://www.youtube.com/watch?feature=player_detailpage&v=HsLKQ_8ztiM

You can also just search YouTube for:
Medication tray – VA Ann Arbor

Publication of full results are pending in the Joint Commission Journal on Quality and Patient Safety
“Before” design – inflexible and unsafe

Lipstick tube design decreased label reading

Auxiliary labels no assurance and misleading

Shortages created havoc

Drug name not conspicuous on the right tray

Trays were same size – 2 of 1 instead of 1 of each
Pharmacy and IE Student project spawns two US Patents

Their improved design

Our prototype

Additional product spawned
4 layouts narrowed down to design 3 – currently in live pilot
What is this regulator used for?
(hook the patient to the green spigot)
HFE uses in healthcare
LASA issues: Things we know

- Regulatory – FDA forbids “stem names” used in trade names, thankfully, but the USAN (United States Adapted Names) commission has been remiss in changing some drug names known to have high injury or fatality rates (e.g. hydromorphone world wide)
- Actual events – many hundreds of thousands of events happen because of phonologic (sound) or orthographic (shape) similarity. Many go undetected or unreported
- Verbal order reduction – reduces the phonologic similarity risk as long as the providers select the correct drug from the prescribing system
- CPOE drug name selection is similar to shooting fish in a barrel – there are many chances to get it wrong. The drug file may be pharmacy-centric but orderable items should be provider and diagnosis centric.
- CPOE has had “look-up-alike” issues as well
- Distractions in the workplace contribute
- Up to 25% of reported medication events involve drug name confusion
Example from Canada:
• APO-amoxicilllin
• APO-ampicillin
• APO-amphotericin

• (APO = Apothetec – a generic drug company)

Explanation:
• The brain reads on the periphery of the words, making the drug names difficult to pick out from a long list. The differences are hidden in the center of the word.
• In the USA the stylized name are forbidden
Other things we know

• The “when” to a drug name mix up is influenced by environmental and workplace (HFE) issues
  – Noise, distractions, production pressure and other stressors
• The “what” to a drug name mix up is related to orthography and phonology (which pair or triplet will be confused)
  – The drug name pairs confusion events are often repeated and can go in either direction
• The numerical measurement of similarity of the drug name is correlated with increased likelihood of confusion
  – Source = Bruce Lambert, linguistics consultant to FDA and ISMP
Human factors in label and web design
Tricky Boxes

Challenge:
• How quickly can you determine whether a product is for use in the eye?
• Both forms of Sodium Hyaluronate are stored under refrigeration.
• Both are 10mg/ml concentrations.
• If only one was present, could you easily identify the ophthalmic use v. orthopedic use?
• How would you know that there was more than one option available?
Tricky boxes...

• The two drugs were manufactured in two different countries by two different companies.
• Coincidentally, both companies selected similarly designed packaging.
• How is this similar to/different from the issues identified with the confusion of heparin concentrations appropriate for infants v. adults?
Human Factors Engineering Principles:

- **Consistent Model**: the similarity in the packaging of the products could cause a mix up to occur.
- Another means of identification should be used to avoid confusion (use images to confirm function).
- It is not obvious at a glance what each product is used for – products should be packaged so that the user can easily and quickly tell what the product is.
- Support situational awareness: don’t stock Sodium Hyaluronate for orthopedic use in ophthalmic procedure rooms.
Solution:

- Add image to label in addition to text – adding drawing or photo of appropriate human anatomy.
Rank Order of Error Reduction Strategies

1. Education & Information
2. Rules & Policies
3. Checklists & Double-check Systems
4. Standardization & Protocols
5. Automation & Computerization
6. Forcing Functions & Constraints
Use of software significantly reduced the need for corrections to chemotherapy orders
Where to get more information:

The HFE “BIBLE”
This project was the genesis of the talking injectable drug Auvi-Q design.
The module presents a model of human interaction with machines, computers, or other systems and potential environmental influences on that interaction. This model conceptually divides a system into a "human-side" and a "machine-side" to illustrate and describe these interactions. Understanding the comparative strengths and weaknesses of the human versus the machine side of a system is crucial to the design of systems that capitalize on human capabilities and compensate for human limitations.

Users Interacting With Complex Systems

FAA Standard Terminal Automated Replacement System (STARS)

Highway Traffic Management Center (Department of Transportation, DOT, photo)

http://www.hf.faa.gov/Webtraining/HFModel/HFModel1.htm
Further information:

• Websites:
  • Human Factors and Ergonomics Society
  • [http://baddesigns.com/](http://baddesigns.com/)
  • FDA tubing misconnections (search from FDA.gov)
    – Not for the faint of heart – work related to AMIA and other groups working to prevent misconnections of tubing (Enfit is phase #1)
  • Patientsafety.gov (NCPS website) but their office is in Ann Arbor – they have a human factors museum – hands on experience of real cases
  • [http://www.humanfactors.com/](http://www.humanfactors.com/) excellent resource for HFE user experience design work
Your assignment:

• Go and identify safety hazards in your own work environment

• Communicate the hazard to management and coworkers

• Learn more about human factors by attending future conferences or doing independent reading

• Watch your environment around you to find more HFE issues. (Send pictures to me if you want to)
"When you put it like that, it makes complete sense."

Questions?

maryburkhardt@comcast.net