

Screening for Drug Similarities with Human Factors Engineering & Failure Mode and Effects Analysis

FDA – ISMP – PhRMA Meeting

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www.patientsafety.gov



Overview

- Confusion goes well beyond “naming” of drugs
- Brief overview of
 - Failure Mode and Effects Analysis (FMEA)
 - Human factors engineering (HFE)
- HFE is needed for FMEAs
- Research on relative value of tools is scary

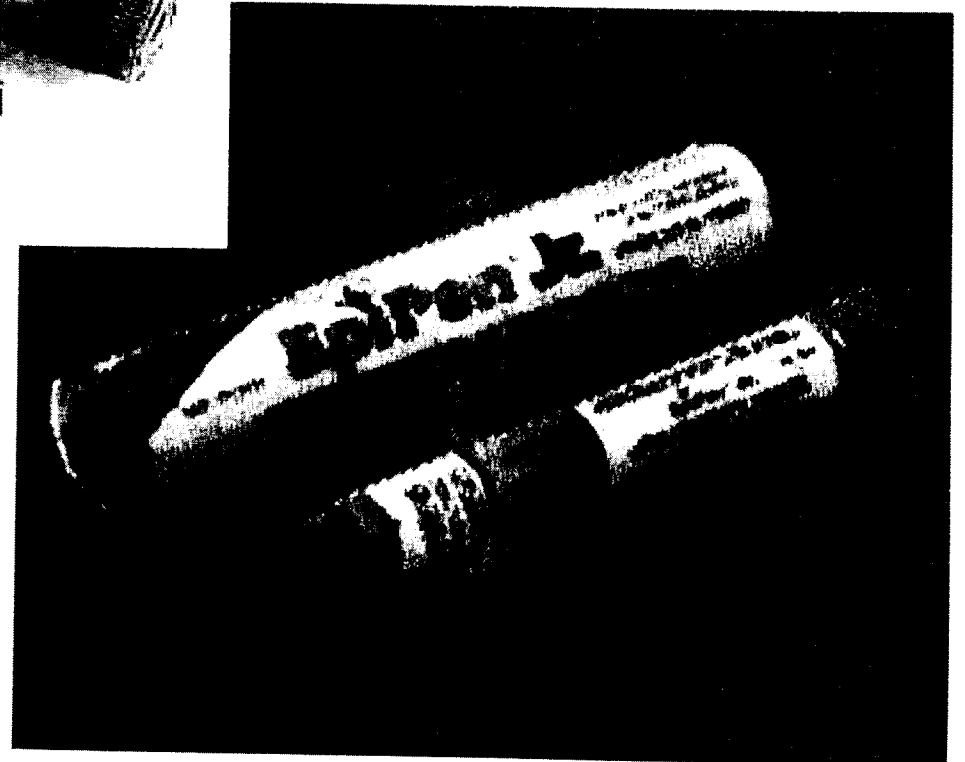
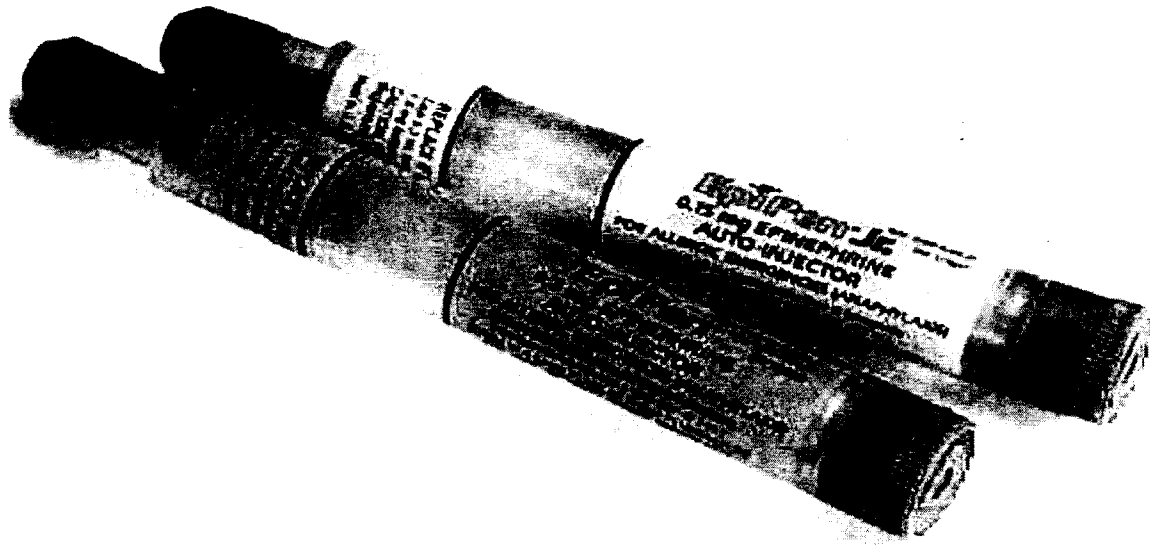


Medication Delivery Confusion

→ from the Simple to Complex

- Name of the medication
- Color, shape, consistency of the medication and packaging
- Indication for usage
- Packaging and location
- “Usual” or “Expected” delivery mechanism
- Metaphor conjured up
- “Appearance” in cyberspace (CPOE, BCMA, automated dispensing device)

What kind of confusions do you see/hear/sense?





Questions related to confusion...

- What does it look like?
 - In its protective tube?
 - Out of its package?
- What is it called?
- What could it be called?



FMEA – tool

- Choose a topic, device, software, or work area
- Form an interdisciplinary team (expert committee)
- Flowchart process and sub-processes
- “Determine” the following:
 - Failure mode and failure mode cause
 - Severity, probability, and visibility
- Develop actions or develop redesigns to resolve causes



HFE – tools and a discipline

- **Designing systems** to fit human capabilities and limitations
- Using methods to gather unique information on:
 - Hidden **needs** and **problems** of the end-user
 - **Human-system interaction** data which CANNOT be found with typical techniques
- **Using knowledge bases** about human-system interaction
 - Senses, biomechanics, anthropometrics
 - Cognitive and organizational psychology



HFE Quiz

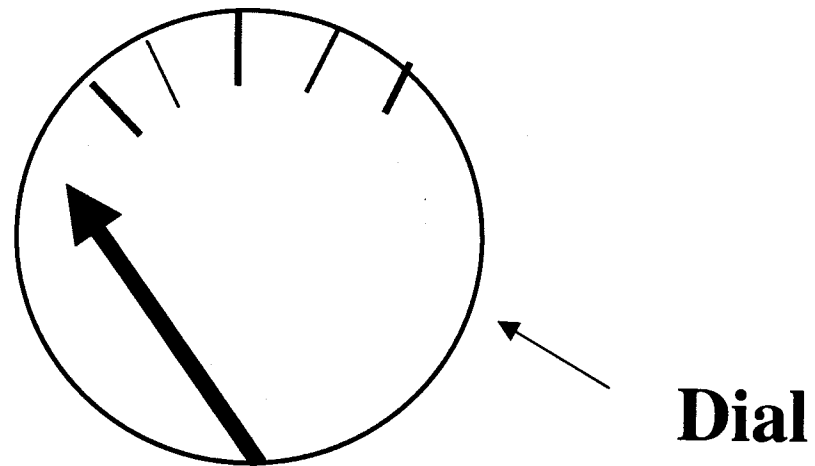
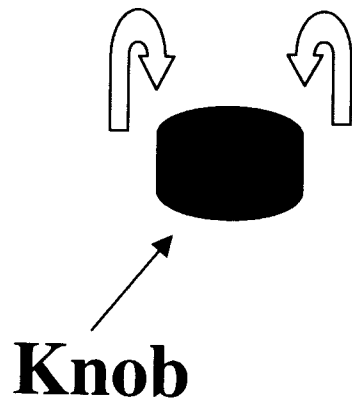
Warning labels are effective in changing behavior...?

- All of the time, if people are motivated
- For some people, if the labels are readable and understandable
- Some of the time, if people are paying attention
- Not enough information to tell

**Wogalter MS, Young SL, Laughery KR. Human Factors Perspectives on Warnings, Volume 2. Santa Monica, CA: HFES Press, 2001.

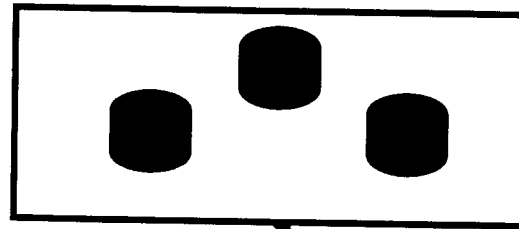
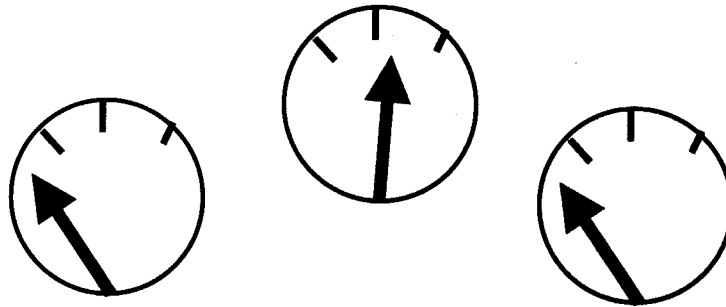
HFE Quiz (cont.)

- Do you rotate the knob **clockwise** or **counter-clockwise** to move the arrow on this dial to the center position?



HFE Quiz (cont.)

- Which blue knob controls the dial on the right? Why?



Control
Panel



HFE Demonstration

- Look at the next slide
- Count the number of words in the paragraph that are repeated



Exercise

- The last time we got together to camp in Nova Nova Scotia we decided that it would be too cold to sleep in a tent. So, I called the motel motel that was located near Peggy's Cove on on top of the hill. We should call each other and talk about these plans once and for all. If you cannot call me, the the best way to get in touch is by fax fax machine.



How many words are repeated?

- The last time we got together to camp in **Nova Nova** Scotia we decided that it would be too cold to sleep in a tent. So, I called the **motel motel** that was located near Peggy's Cove on on top of the hill. We should call each other and talk about these plans once and for all. If you cannot call me, the the best way to get in touch is by **fax fax** machine.

Answer is "3"?



How many words are repeated?

- **The** last time **we** got together **to** camp **in** **Nova Nova** Scotia **we** **we** decided **that** it would be too cold **to** sleep **in** a tent. So, I called **the motel motel that** was located near Peggy's Cove **on on** top of **the** hill. **We** should **call** each other **and** talk about these plans once **and** for all. If you cannot **call** me, **the the** best way **to** get **in** touch is by **fax fax** machine.

Or is the answer 6?...or is it 14?

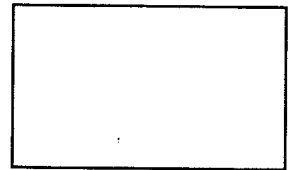


HFE and Medication Confusion Lesson

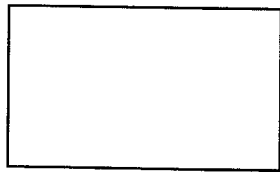
- What did you think the instructions meant?
 - i.e., the meaning of the word “repeated”
- We gather some of what we think is most important, and then we interpret that
- **Examples:**
 - “Give the Potassium IV Push” (not “IV Trickle”)
 - ISMP has one or more examples each month

Demonstration: Stroop Test

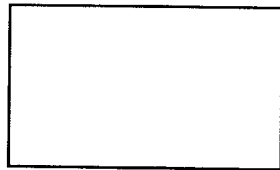
Row 1




Row 2



Row 3





**State the Color of the Text as Fast as
You Can...**

Row 1 Red Blue Green Yellow

Row 2 Yellow Green Blue Red

Row 3 Green Red Yellow Blue



**State the Color of the
Text as Fast as You Can...**

Row 1 **Red Blue Green Yellow**

Row 2 **Yellow Green Blue Red**

Row 3 **Green Red Yellow Blue**



HFE and Medication Confusion Lesson

- Discordant cues cannot be “ignored”
- Have you ever heard (or said to someone):
 - “Ignore the color or shape, just read the label”
 - ECRI and CGA have advised this for medical gases

See <http://faculty.washington.edu/chudler/words.html#seffect> for freely available demo



Case Study: HFE analysis of “confusion”

- Hospital in Salt Lake City had many issues with code teams
- One issue they observed many times was confusion and delay with medication drawer retrieval
- They performed usability (HFE) testing with
 - 9-11 end-users
 - Retrieving 10 medications
 - Five versions of the drawer

*McLaughlin RC. Redesigning the crash cart: usability testing improves one facility's medication drawers. *Am J Nurs.* 2003;103(4):64A,64D,64G-64H.

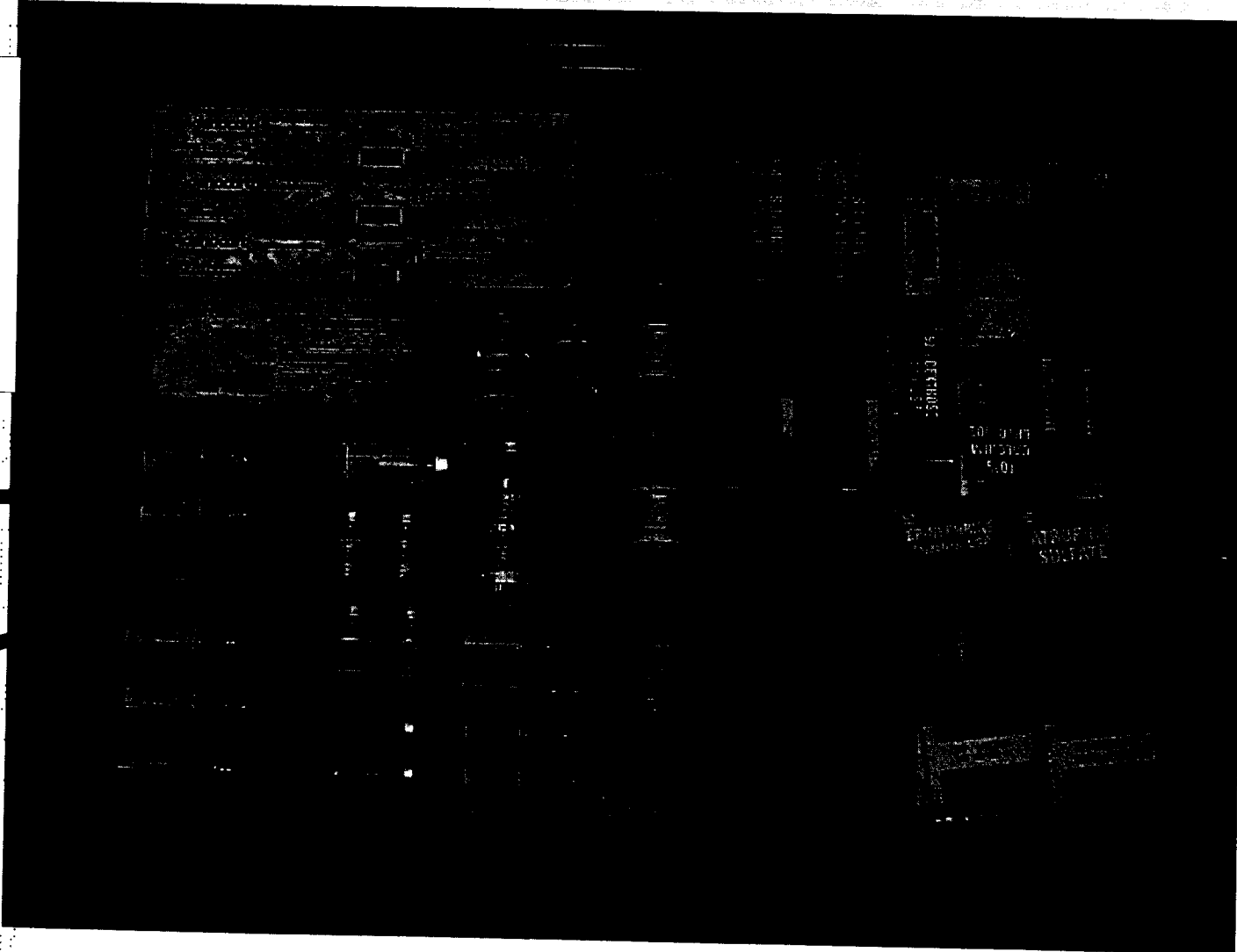
Baseline Drawer ("Laundry hamper")
Range = 2:43-3:58 min, Avg=3:07 min



Code Cart Drawer Fifth Version

Range = :55-1:25 min, Avg=1:08

**Note the
lack of
labels for
each spot**





FMEA – augmented with HFE


- **More savvy in choosing** a topic, device, software, or work area
- **Adding a HFE expert** to your interdisciplinary team
- Flowchart process and sub-processes
- **More accurately develop and test** the following:
 - Failure mode and failure mode cause
 - Severity, probability, and visibility
- Develop actions or develop redesigns to resolve causes



Relative Value of Techniques to Find “confusion” and other design issues

- Most of comparative studies done with software evaluations, but some with consumer devices
- Expert Evaluators (Highly mixed results)
 - ✓ 5 experts = 75% 10 experts = 85%
 - ✓ 2 experts = 90% 5 experts = 55%
 - ✓ Experts (20%); HFE alone (40%); Combo (60%)
- User and Usability testing (slightly more stable)
 - ✓ 4-6 participants = 90%
 - ✓ Watch out! Preference and confidence not correlated with performance

* Jacko JA, Sears A. The Human-Computer Interaction Handbook. Mahwah, NJ: Lawrence Erlbaum Associates, 2003.



Relative Value of Techniques to Find “confusion” (cont.)

- User and Usability testing (slightly more stable)
 - ✓ 4-6 participants = 90%
 - ✓ Watch out!
 - For each type of end-user
 - Preference and confidence not correlated with performance
 - Severity of problems “missed” uneven

* Jacko JA, Sears A. The Human-Computer Interaction Handbook. Mahwah, NJ: Lawrence Erlbaum Associates, 2003.



Human Factors Engineering and Patient Safety Growing in many Sectors

- Medication Safety and HFE research and courses
 - University of Wisconsin and Madison VA; College of Pharmacy (Skibinski & Karsh)
 - Ohio State Univ College of Pharmacy (Schneider)
- Growing presence in industry
 - Mostly device companies, and some pharmaceuticals
- Related Government Efforts
 - FDA-CDRH (www.fda.gov/cdrh/humanfactors.html)



Conclusions

- Confusion goes well beyond “naming”
- HFE is needed for FMEAs
- Research on relative value of tools is limited
- Human Factors Engineering (HFE)



Bibliography

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