*Examples of Importance and Impact*A classic: Therac-25 disasters It still happens: Lifecare infusion pump Palm Beach ballot Business examples Cost Justification

Medical Human Factors

Therac-25

- Machine has low-power focused bean and high-power x-ray modes
- User error correction never anticipated or tested
- Poor error messages and feedback worsen accident: "Malfunction 54" did not communicate nature of error or success/failure of treatment
- Context of use made things worse: no intercom or closecircuit TV

Lecture 1-2

Slide 2

Medical Human Factors (2)

- Lifecare 4100 infusion pump
 - (Tallahassee Democrat newspaper, 2000)
 - Pump automatically administers drug infusions, can be set at different dosage levels
 - Fatalities and near fatalities caught FDA attention
 - "Human error" blamed
 - U of Toronto studies revealed difficult UI
 - Default setting could cause fatal concentrations
 - Manufacturer says users should read manual, users often blame machine for changing concentrations on its own
 - Liability problems complicate case, no FDA action

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Lecture 1-2

Slide 3

Subsequent Developments

(Vicente, 2002)

- Reporters, lawyers, manufacturer interested in Toronto (Vicente) studies
 - Improved UI reduced errors in laboratory
 - Done prior to events
- Manufacturer does not act, additions deaths
- · Letter to clinicians warning lack of training
- Vicente, manufacturer, consultant trade published rebuttals
 - Vicente claims ethics violations
- Call to FDA to regulate human factors / safety in medical devices just as in nuclear power plants

Lecture 1-2

Slide 4

Subsequent Developments (Andre, 2000)

- · Explicitly states connection with Abbott Labs
- Disputes explanation of error as acceptance of default
 Gives example of transposing numbers
 - Claims errors can happen even if setting is required (no default)
- Vicente took a specific scenario and fixed that
 - Fixing one problem can have unintended consequences in other area
- In most cases device is not mis-programmed
- Changing device might cause negative transfer
 Vicente suggested high concentration presented as default rather
 - than low practiced responses might cause huge errors

Lecture 1-2

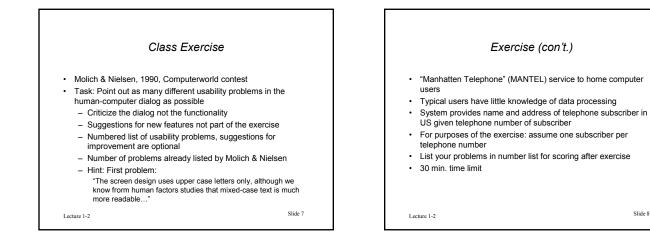
Slide 5

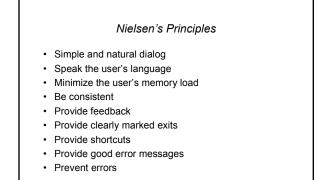
Subsequent Developments

Thought Questions

- How do you assess what is a human error and a design induced human-system error?
- · How do you assess impact of a fix?
- · How could it be done in this case?

Slide 6





Lecture 1-2

Slide 9

Lecture 1-2

Example: From Mauro (1994) · Printer manufacturer - serious usability problem - printer driver installation & operation 50% of first 100,000 customers called customer care - \$.5 million per month Poor reputation - Overloaded customer care phone system • Delivered fix on new diskettes to 200,000 customers - \$ 900,000 · Problem could have been fixed in usability testing - Tested internally by engineering group - found no problems Slide 10

Slide 8