CHI+MED: Preventing Human Error Caused by Medical Device Design

Paul Curzon
Long-term aim

- to transform the design and use of medical devices
- to help clinicians avoid and recover from human error
Infusion pumps recalls

In the US, 2005-2009
- 87 models recalled
- > 56,000 adverse events
- 710 deaths
- all manufacturers

Most common issues
- Software defects
- User interface issues
The Generic Infusion Pump (GIP): A safety reference architecture for infusion pumps

- Captures common characteristics of marketed infusion pumps
- A basis for reasoning about hazards and infusion pump design issues
- Our focus is on software-related causes of use hazards
- With FDA (US regulator) + University of Pennsylvania
Overview of the GIP-UI architecture

how the device responds to user input

what information is presented to the user

how information is presented to the user
Use GIP-UI to enumerate common design errors that lead to hazards like **over infusion as user fails to enter correct digits**

Structured around modules and interactions between modules:

- **Interaction Logic**: Interaction issues
  - ie how the device responds to user input
  - eg: *Key presses ignored without user awareness*

- **Output Status Manager**: Feedback issues
  - ie *what* information is presented to the user
  - eg: Incorrect / ambiguous values displayed without user awareness

- **Renderer**: Rendering issues
  - ie *how* information is presented to the user
  - eg Inappropriate fonts are used that can be easily misread

Establish cause and effect relationships (design error - hazard)
### Causes of over and under infusion hazards

<table>
<thead>
<tr>
<th>Primary Cause (User Error)</th>
<th>Probable Root Cause (Underlying Design Issue)</th>
<th>Example from marketed pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>The user fails to enter the correct digits</td>
<td>Key press by user erroneously discarded without user’s awareness (interaction logic)</td>
<td>100.1 registered as 1001 with no warning</td>
</tr>
</tbody>
</table>

...
The key sequence 1001

Numbers above 100 cannot include a decimal point …

so it is silently ignored
Devices from different manufacturers have similar problems

The key sequence

```
1 0 0 . 1
```

is registered as 1001

The value is fortunately rejected in this device

As pump configuration limits the rate value to 999 mL per hr
PVSio-web: A model based tool for prototyping interactive systems

- Prototyping of interfaces and interaction design based on mathematical models
- Used to validate and demonstrate links between design errors and hazards
- Working with the FDA has helped identify problems in a series of commercial medical devices
- Hospitals have used in training programmes highlighting safety-related design issues
The hazard analysis is the first step required for defining a safety reference model for user interfaces.
Summary

Developed

• a generic architecture for reasoning about design issues in infusion pumps

• a preliminary hazard analysis for number entry
  • Enumerate design issues linked to hazards
  • Link software-related causes with use hazards

• a model-based rapid prototyping tool for interactive systems

• Found a series of issues in commercial pumps

www.chi-med.ac.uk
Thank You