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Safety assurance cases, proof and the prevention of user error

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Overview

- To what extent should usability-related hazards be part of certification?
- When users make mistakes is more training the best solution?
- Can formal methods help provide evidence?
- Our current work on CHI+MED looks at human error verification with respect to medical devices?

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Systematic User Error

- UK: 10,000 adverse events are reported per year due to use error of healthcare ICT systems.
- User/operator error is often systematic.
- It arises due to poor human-computer system design,
  - either of devices or
  - of the system in which they are embedded.

- A demonstration of systematic human error…

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Should we fix the person or the system?

- When a nurse enters the wrong rate into an IV infusion pump, it might be
  - the nurse's incompetence,
  - poor training
- but it could also be
  - poor pump interface/interaction design,
  - poorly designed processes,
  - wrong information from the pharmacy,
  - wrong identification of the patient.

- Currently in the medical device domain the device design is rarely even in the frame as a cause
  - Operated according to spec (that's ok then)

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Design and verify to avoid error

- We can design resilient systems that prevent systematic human error.
- Verification tools are required to support related claims about risk reduction
  - that should be part of an assurance case.
- A variety of approaches have already been trialed on real systems.

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Checking designs against specific properties

- Create a ‘battery’ of template usability properties
- Instantiate to the device.
- When a property fails it provides material for discussion with experts about the failure’s implications.
- So far applied to:
  - Infusion pumps, in-car systems and aircraft cockpits

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Checking against mental models

- A mental model represents the user's assumptions about how a device works
  - as suggested by human factors experts or derived from training material.
- The model may match the device's behaviour or highlight a mismatch.
- So far applied to (eg by Rushby et al):
  - aircraft cockpit system

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Checking against a user model

- Cognitive science knowledge is built into a generic model about plausible user actions
- It is instantiated to both:
  - a device model and
  - intended user activities.
- The combined model is analysed by checking whether user goals are achieved on all paths.
- Applied so far to
  - an IV infusion pump.

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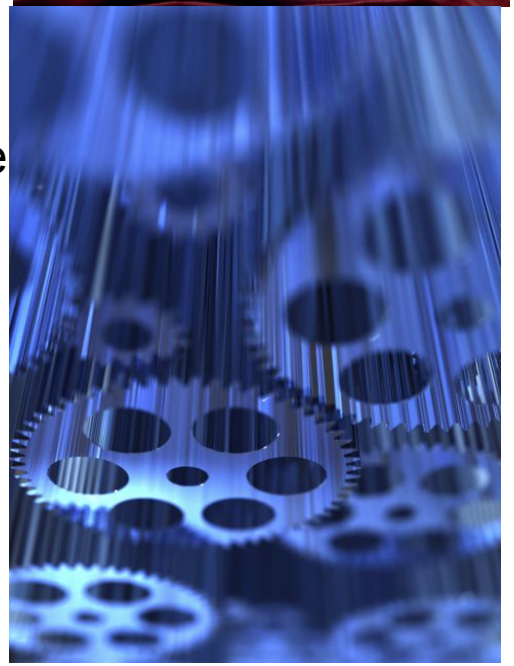
Checking information flow

- The larger socio-technical systems can be studied from a distributed cognition perspective,
  - eg the operation of a day-care unit
- Information resources constrain the activities carried out by users.
  - These constraints drive the analysis of plausible user trajectories.
  - Training manuals versus actual practice?
- So far applied to:
  - an ambulance dispatch system and
  - a hospital day care unit.



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Summary

- User error can be systematic
- System design can make it more or less likely
- Verification tools can highlight poor design in this regard
- They can be used as part of a safety case

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Questions for Discussion

- What role should proof play in certification of user error based hazards?
- What properties does a method need?
  - Need to fit with existing engineering processes?
  - Simple easy to understand results?
- Which kind of technique is most appropriate for safety cases?
  - Which is best for giving a checkable evidence trail?
- Is there a place for certification of use in context (eg of a day-care unit operation)

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Thank You

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