Extending STPA to Improve the Analysis of User Interface Software in Medical Devices

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CONTRIBUTIONS

- Extending the STPA analysis to:
  - Identify design issues in medical device user interface (software) that likely enable or promote use errors
  - Define formal requirements for mitigating the identified design issues
- A case study on a medical device to evaluate the effectiveness of the extension

OUTLINE

- Medical device use errors and user interface software
- Extending STPA to improve analysis of user interface software
- Case study

Medical Device and Software

- U.S. Food and Drug Administration is charged with ensuring the safety and effectiveness of medical devices before they enter into the market.
  - Medical devices are classified as Class I, II, and III based on intended use and indications for use.
  - Class II devices need premarket clearance and Class III devices need premarket approval, but exceptions exist.

- Software in medical devices receives regulatory oversight (pre-market review, quality system regulations, and post-market reporting).
  - Level of Concern (LoC): the severity of harm potentially caused by software risks before mitigation.
  - Different LoCs means device makers need to submit different levels of software information.
  - Software in a medical device (SiMD) vs. Software as a medical device (SaMD).

Medical Device Use Errors

- **Use Error:**

  User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user. (IEC 62366)

- **Use Error or User Error?**

  [Use Error] was chosen over … "human error" because not all errors associated with the use of medical device are the result of oversight or carelessness of the part of the user of the medical device. Much more commonly, use errors are the direct result of poor user interface design." (*IEC 62366)*

An Example Medical Device Use Error



Robotic Surgical System Recalled in 2015
(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=135134)

USE Error

Surgeon deviates from the standard procedure and presses the button to retract the catheter when it and the guide wire is being installed.

Result

Unexpected retraction of the catheter, even after the retract button is released.

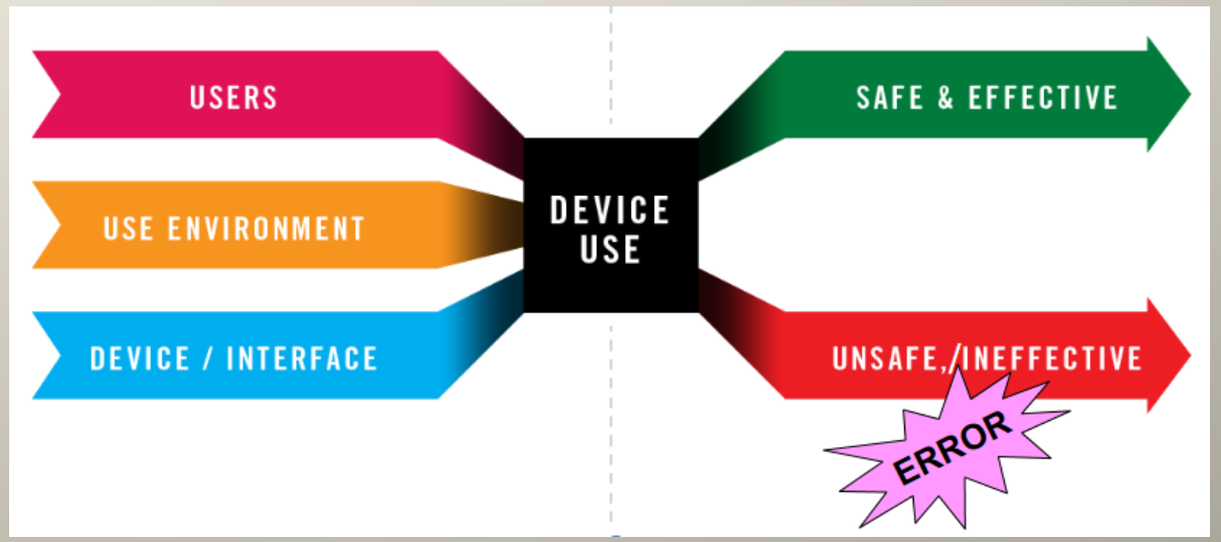
Health Risks

Partial dissection, perforation, hematoma, …

Causal Factors of Use Errors

Use errors can occur due to:

- Limitations and variability of the user's ability to operate the device.
- Unsuitable environmental conditions (lighting, noise, vibration, etc.).
- Poor user interface (UI) design.
  - Size and shape
  - Input widgets (buttons, switches, knobs)
  - Output widgets (display, light, LED, etc.)
  - Connections and accessories
  - Packaging and labeling (including manuals)
  - Software



Human Factors (HF) Considerations of Medical Device Use Safety

Adapted from FDA Guidance on Applying HF and Usability Engineering to Medical Devices, available at https://www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf

An Example Medical Device Use Error (cont'd)



Robotic Surgical System Recalled in 2015
(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=135134)

USE Error

Surgeon deviates from the manual and presses the button to retract the catheter when it and the guide wire is being installed.

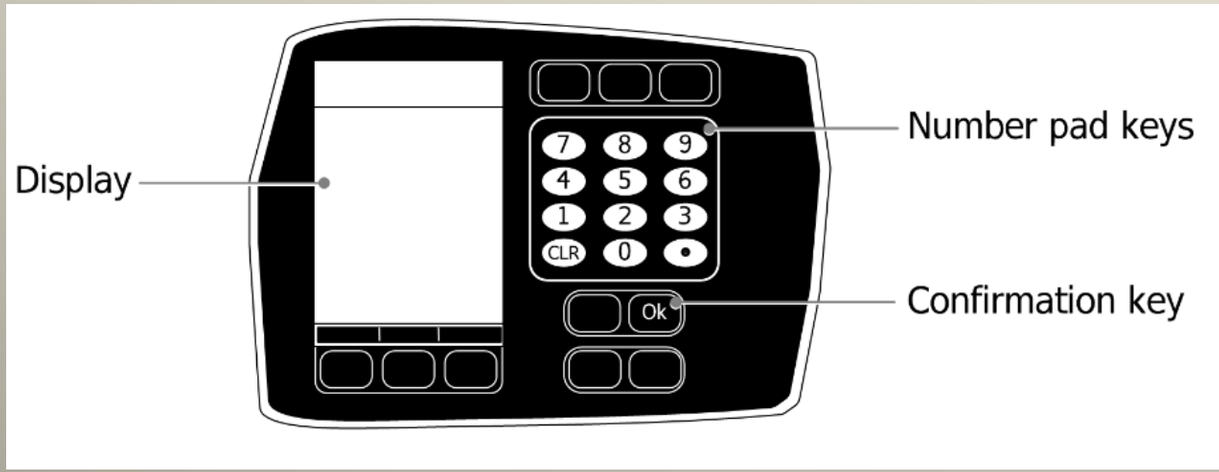
Results

Unexpected retraction of the catheter, even after the retract button is released, causing risks like hematoma or partial dissection.

Root Cause

The UI software failed to prevent inappropriate press of the retract button and then to recognize its release.

Another Example



(Obfuscated) UI Layout of Infusion Pump Recalled from US Market

Use Error

Nurse incorrectly entered the infusion rate as 1105 ml/hr, 10 times more than the prescribed rate 110.5 ml/hr.

Root Cause

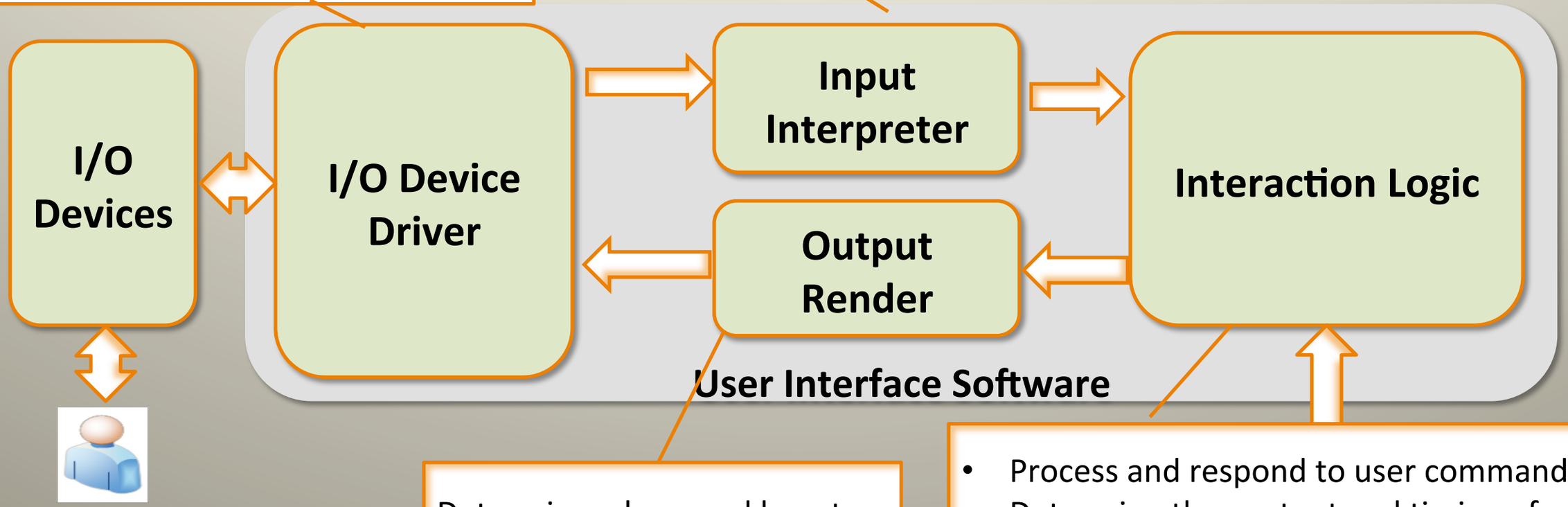
The UI software mistakenly discards the decimal point of the entered infusion rate between 100.1 to 1200 ml/hr without notifying the user [1].

[1] Masci, Zhang, Jones, et al., Formal Verification of Medical Device User Interfaces Using PVS, in proceedings of the 17th International Conference on Fundamental Approaches to Software Engineering (FASE), 2014.

What is UI Software?

Translate use actions to input signals; Instruct output devices to present user feedbacks

Translate user input signals to commands



Determine where and how to present user feedbacks

- Process and respond to user commands;
- Determine the content and timing of user feedback;
- Interact with the rest of device software

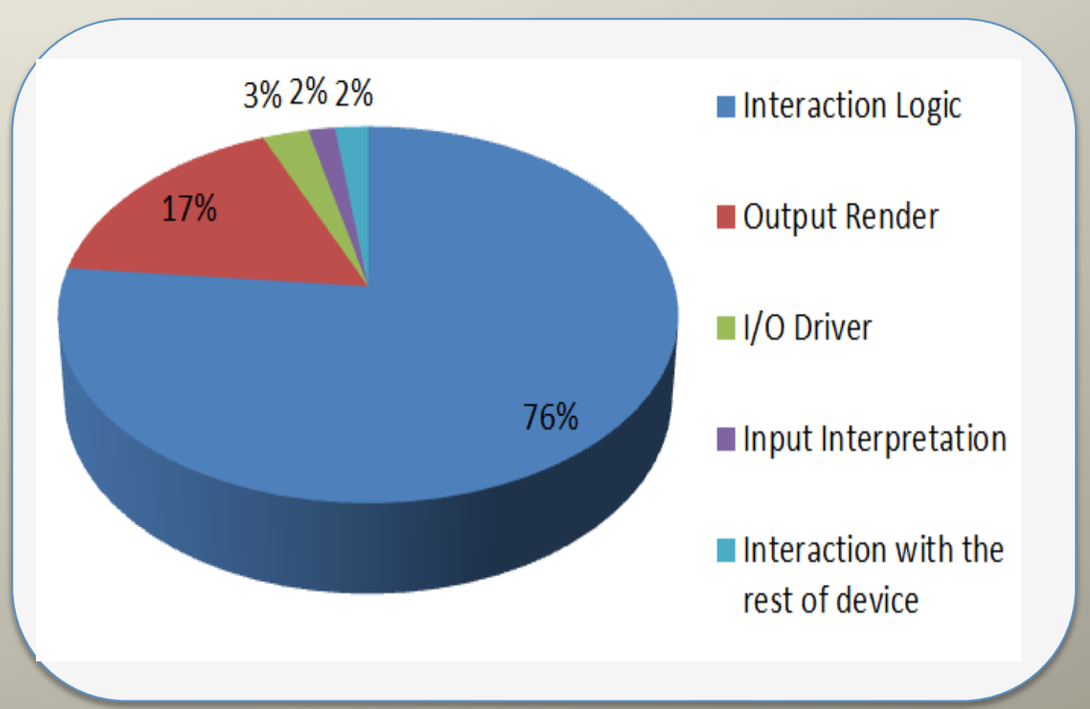
Adapted from *A Generic User Interface Architecture for Analyzing Use Hazards in Infusion Pump Software*, Masci et al., 5th Workshop on Medical Cyber Physical Systems, pp. 1-14, 2014

How Common are UI Software Defects?

According to our study on FDA medical device recall data from 09.2012 to 08.2015

	Year I	Year II	Year III	Total
Device Recalls	2294	2753	2724	7771
Recalls caused by software defects	306	323	284	913
Recalls caused by UI software defects	148	145	128	421

Recalls due to UI software defects account for 46.11% of recalls caused by software defects



The majority of UI software defects are (subtle) interaction logic flaws

Gaps and Challenges

- UI software defects constitute an important cause of medical device user errors.
- Device manufacturers and other stakeholders often address the safety of UI from HF (e.g., ergonomics) perspective.
- Software engineers typically are not involved early on in the UI design.
  - Incomplete analysis of software-related causes to use errors.
  - Inadequate design and verification of software measures for mitigating use-related hazards.

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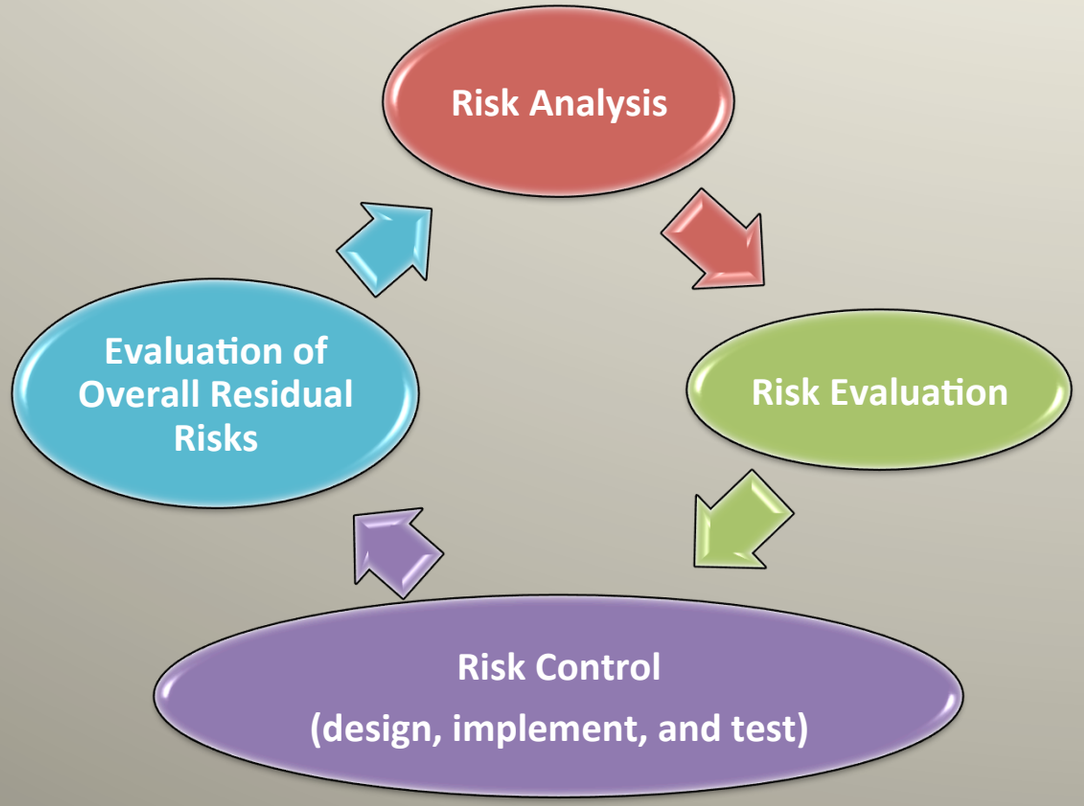
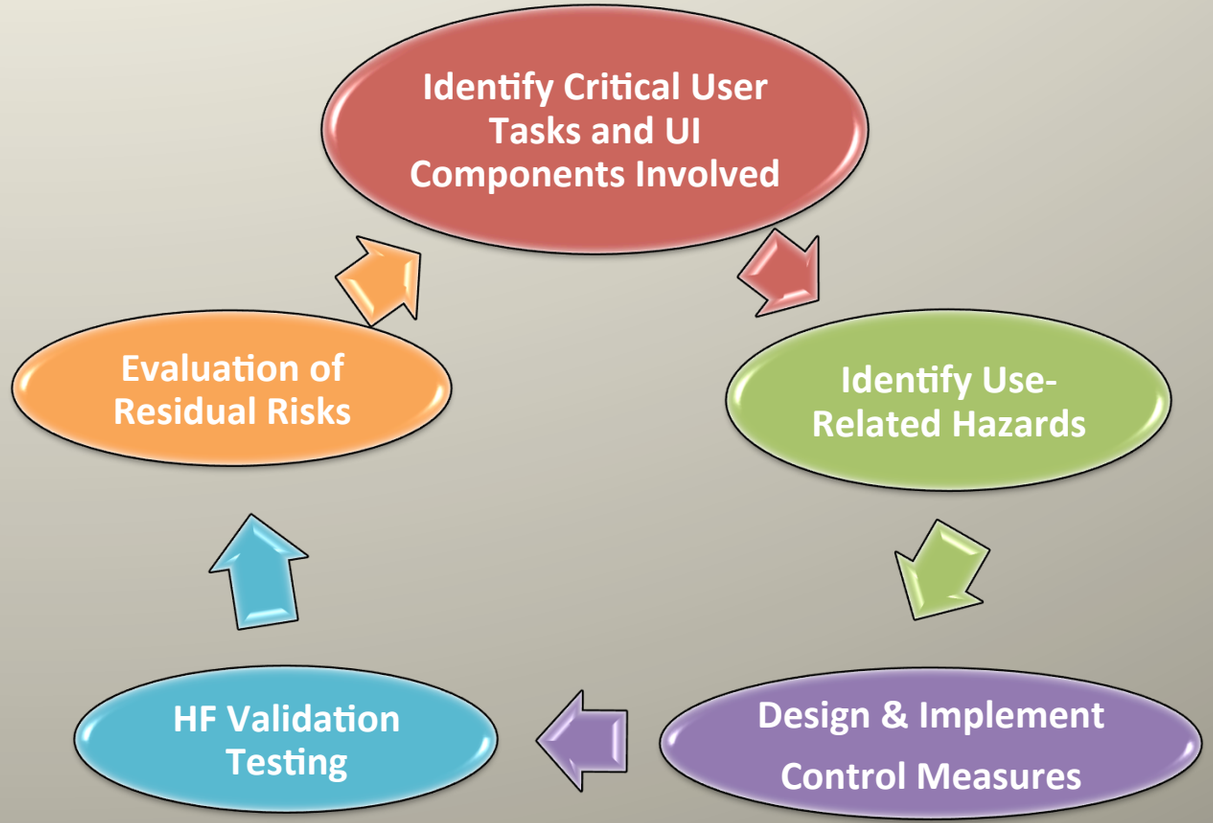
Risk Management Process for Medical Devices



Risk Management Process Defined in ISO 14971



Risk Management Process for Use-Related Hazards Recommended by FDA's HF Guidance

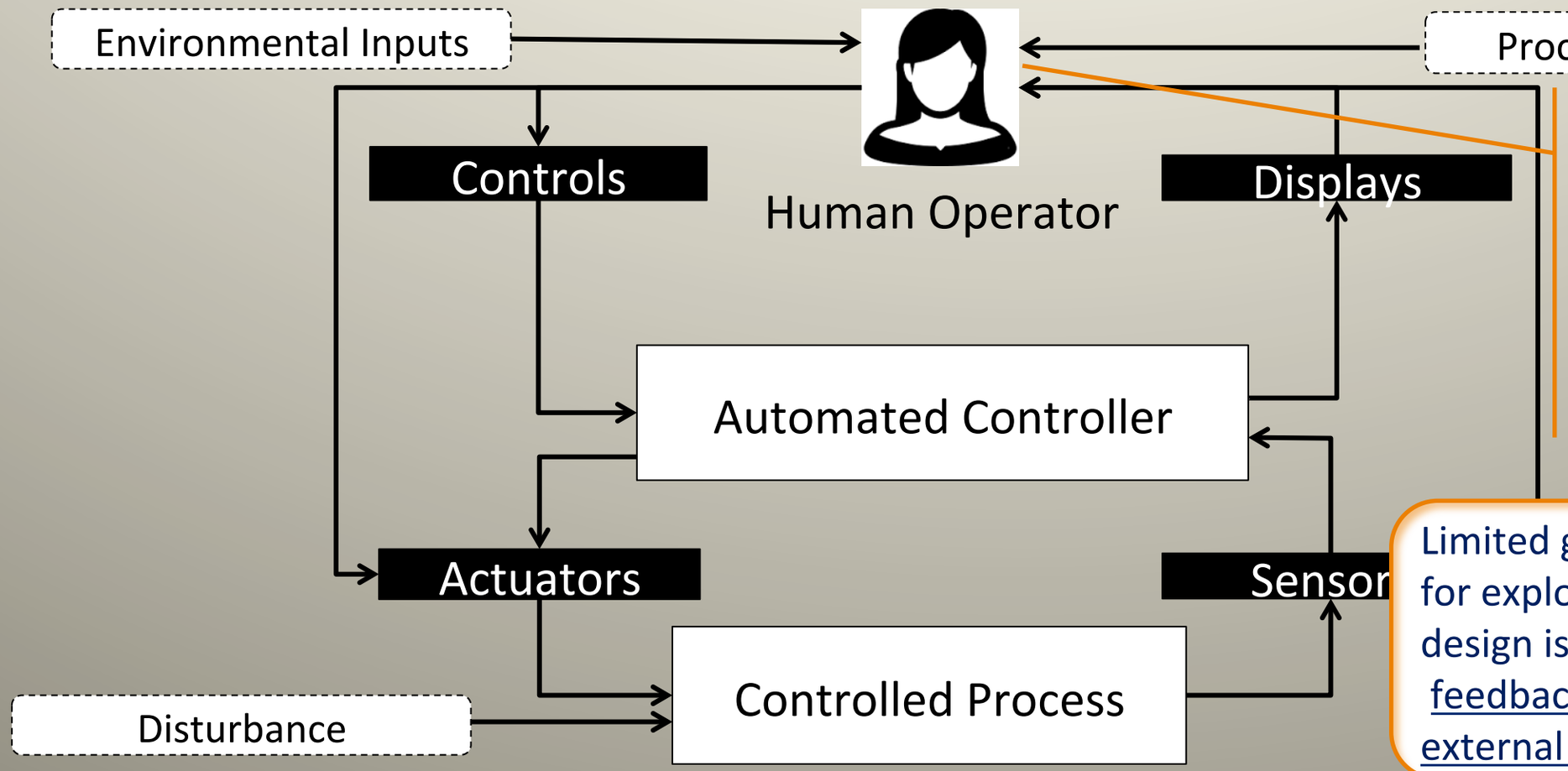
Identification of Use-Related Hazards

- Establishes the foundation for subsequent risk management activities
  completeness vs. reasonableness

- Approaches recommended in FDA HF guidance:
  - Bottom-Up Analysis: Failure Mode Effect Analysis (FMEA)
  - Top-Down Analysis: Fault Tree Analysis (FTA)
  - Known use-related issues

- Limitations:
  - Device-centric: need to bridge device design issues and their impact to users
  - Limited guidance is provided to developers in identifying UI (software) design issues

STPA FOR IDENTIFYING USE-RELATED HAZARDS



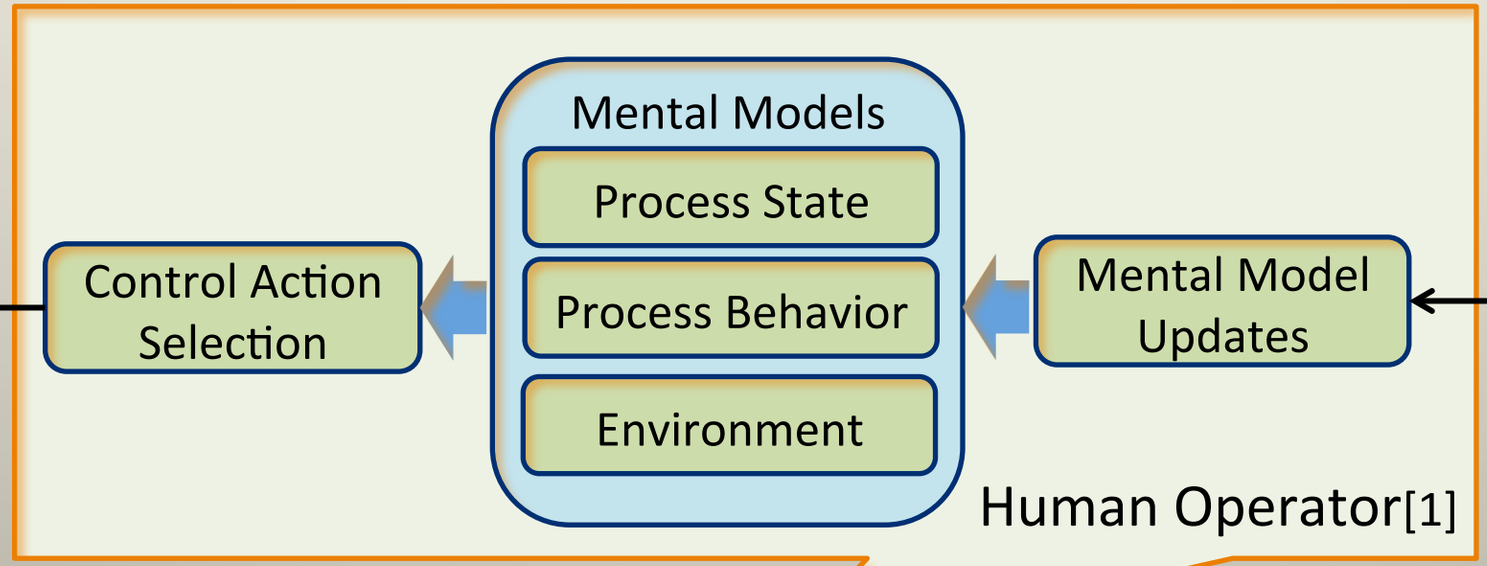
Unsafe Control Actions (UCAs):

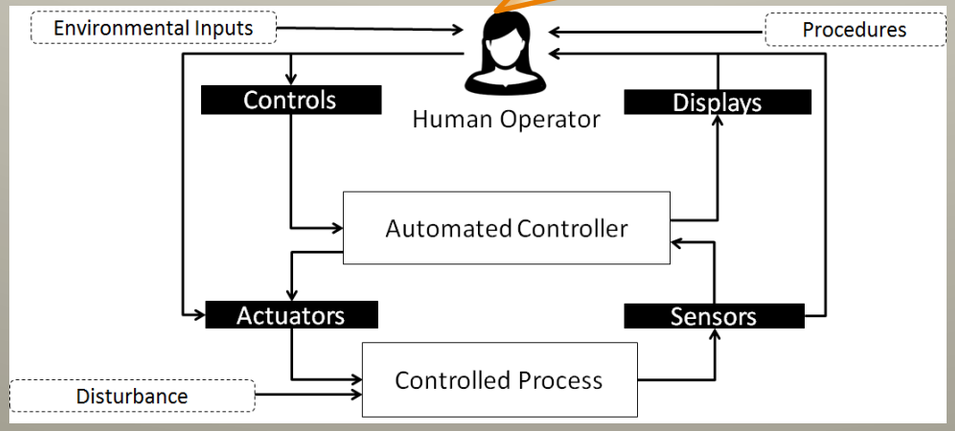
- **Control action not performed or followed;**
- **Unexpected control action performed**
- **Control action performed at the wrong time or in a wrong order**
- **Control action stops too soon or lasts too long**

Limited guide words are provided for exploring three aspects of UI design issues enabling UCAs: feedback, mental model, and external information.

STPA System Model

Extension to STPA Human Operator Mental Model





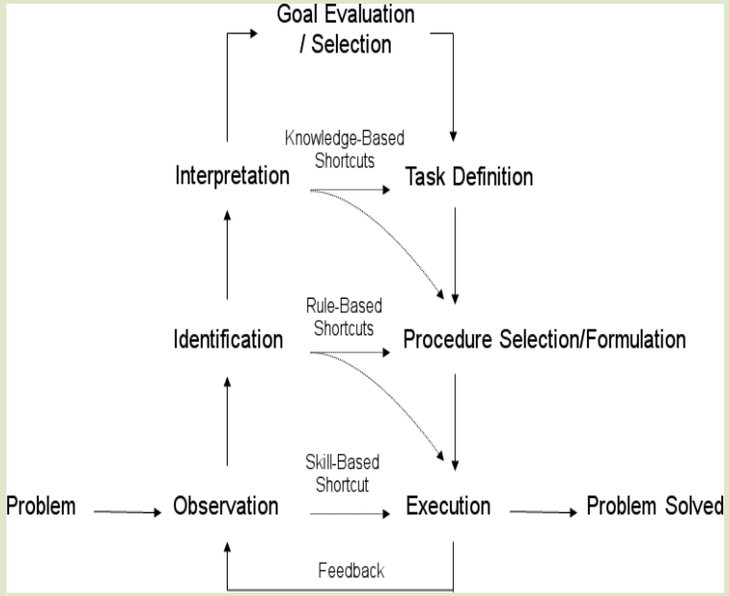
STPA System Model

Detailed guidelines are needed to support systematic identification of UI design issues as causal factors to human UCAs.

[1] Megan E. France, *Engineering for humans: a new extension to STPA*, Master Thesis, MIT, 2017.

OUR SOLUTION: HUMAN-STPA

Rasmussen's Step-Ladder Model to support the analysis of human cognitive causes of UCAs.



Rasmussen's Decision Ladder Model

Human Cognitive Model

+

STPA → Human-STPA

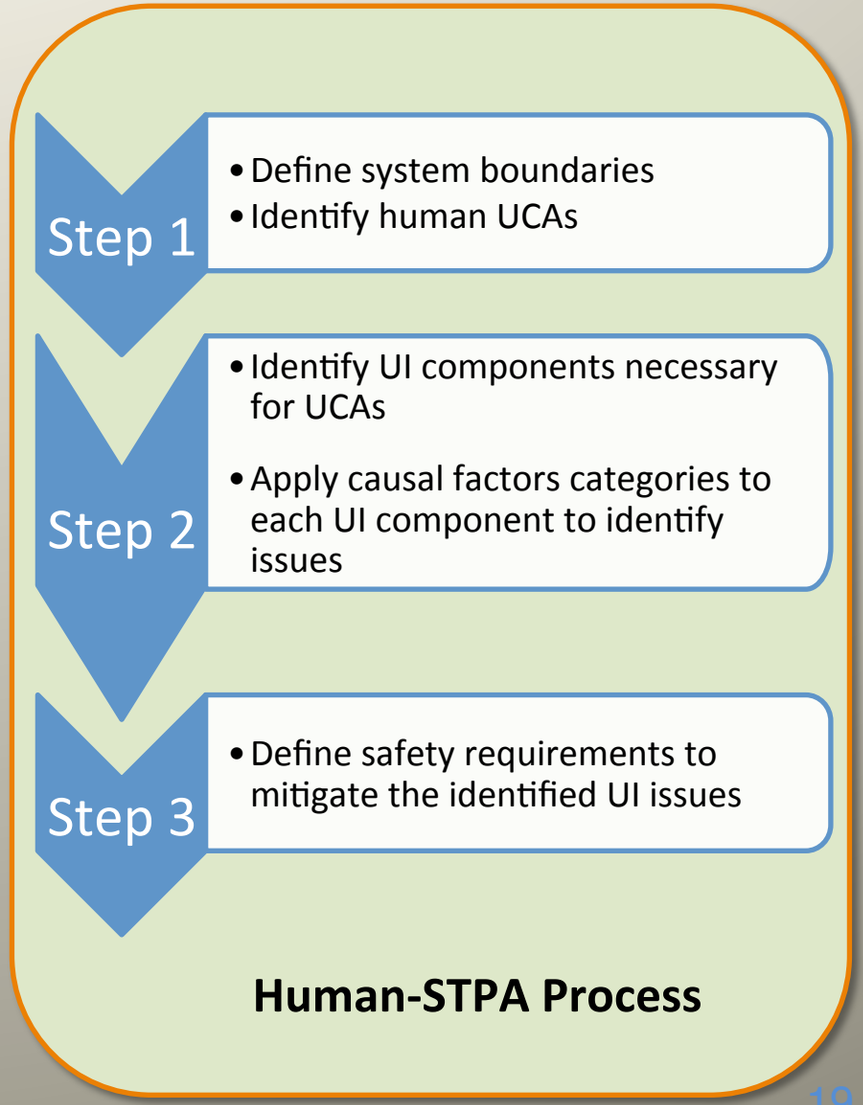
+

HF & Usability Standards

Causal factors categories are derived from UI design principles defined in HF & usability standards

How Human-STPA Improves STPA?

- Introduced 16 new causal factors categories
  - Based on design principles from IEC 62366 and AMMI HE75 standards
  - Provide developers detailed guidelines in identifying use-related safety issues in medical device UI design
- Improved methods for defining safety requirements:
  - Formalizes safety requirements as theorems that can proved against UI design
  - Executable UI safety reference model demonstrates the intended meaning of safety requirements



Human-STPA Process

CAUSAL FACTOR CATEGORIES

Original STPA Categories	New Causal Factors Categories
Feedback	Consistency of feedback, Complexity of feedback Availability of feedback, Salience of feedback
Mental model	Reversibility of control actions Responsiveness to control actions Predictability of controls Forgiveness for erroneous control actions Availability of controls Affordance of controls Consistency of controls Consistency with clinical workflows Complexity of controls
External information	Availability of user manuals Consistency with user manuals Complexity of user manuals

Full details of the causal factors categories are available in *A Hazard Analysis Method for Systematic Identification of Safety Requirements for User Interface Software in Medical Devices*, Masci et al., SEFM'17, pp. 284-299, 2017.

Example Causal Factors Category



Robotic Surgical System Recalled in 2015
(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=135134)

UCA: Retract the catheter too soon
UI component involved: catheter retract button

Category: **Forgiveness of erroneous control actions**
Safety interlocks are not available to prevent accidental activation of critical control actions performed by the user, or block/ mitigate foreseeable user operation errors.

UI Design Issue:
The UI software does not provide means to prevent the press of the catheter retract button when it is not safe to do so.
Note: other UI design issues might also exist.

EXAMPLE CAUSAL FACTORS CATEGORY (CONT'D)



Diabetes Management App silently resets bolus dose recommendation when the user changes phone orientation

UCA: Change phone orientation while configuring bolus dosage
UI component involved: phone

Category: **Predictability of controls**
The UI does not provide means to help the user anticipate the effects or the consequences of control actions.

UI Design Issue: **Lack of feedback**
The UI software does not provide appropriate feedback when the user performs the UCA and the bolus dosage is reset.
Note: other UI design issues might also exist.

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CASE STUDY: GANTRY-2 SYSTEM

- Experimental radiation therapy machine
- Two control consoles: central and remote
- Human operator tasks:
  Set up system/load treatment plan/start treatment /monitor patient and system
- User manual and UI design documentation are available
- Classic STPA has been applied to the UI design of Gantry-2 System [1]



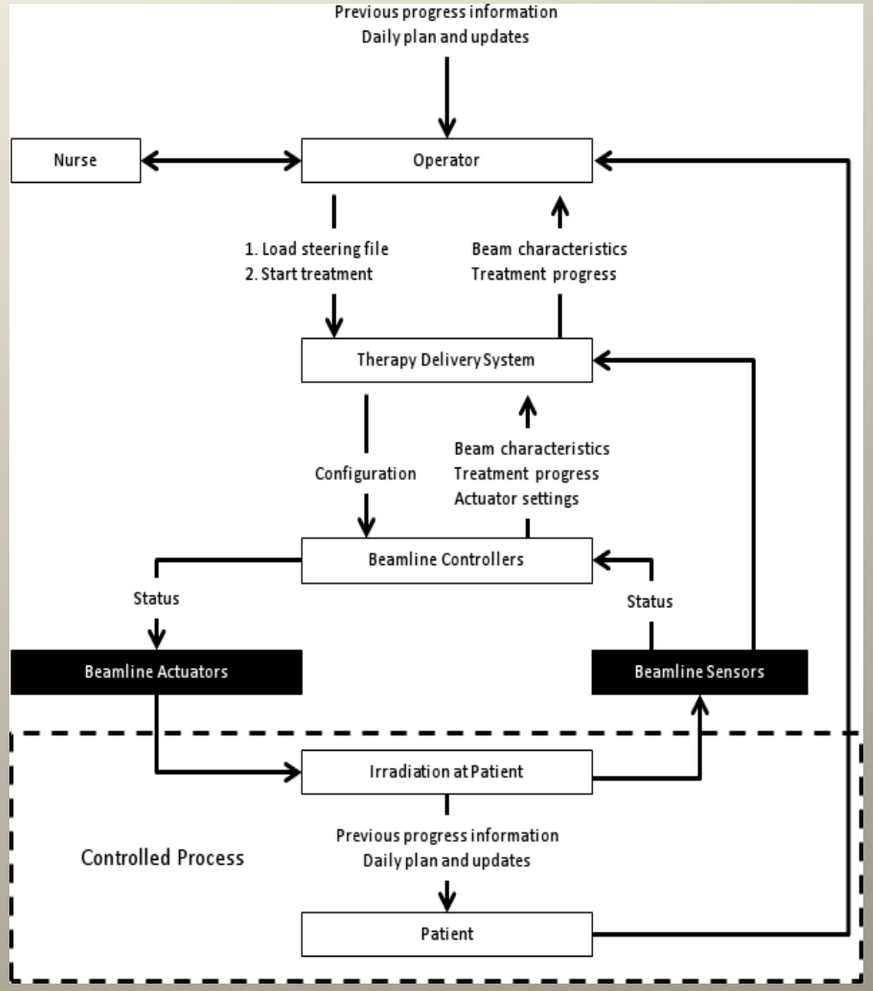
GANTRY-2 System

[1] A. Blandine. System Theoretic Hazard Analysis applied to the risk review of complex systems: an example from the medical device industry. PhD thesis, MIT, 2012.

Case Study Results

- We analyzed the Gantry-2 System using the same control structure and documentation as used in the original analysis [1].
  - Identified all problems reported in the original analysis, and
  - several new issues overlooked in the original analysis

For UCA "*Treatment start command is activated when there is no patient to be treated*", Human-STPA reported 7 new UI software issues not reported in [1].



Gantry-2 Control Structure

[1] A. Blandine. System Theoretic Hazard Analysis applied to the risk review of complex systems: an example from the medical device industry. PhD thesis, MIT, 2012.

Example New UI Issue Identified

UI Design Issue	UI software does not provide feedback when patient is not ready
UI Component(s)	Display
Causal Factors Category	Availability of feedback: Feedback reporting important information or events is erroneous, not visible, partially visible, or is visible at the wron
Safety Requirement	"Patient not ready" ale
Formalized Safety Requirement	FORALL (pre, post: State, c: Console): (init(pre)→ pt_status_visible (on(c)(pre))) ^ (pt_status_visible(pre) ^trans(pre , post)) → pt_status_visible(post))

For every system state *pre*, patient status is visible (*pt_status_visible*) on any control console *c,* and this is also true for any subsequent system state of *pre*.

EXAMPLE NEW UI ISSUE IDENTIFIED (CONT'D)

UI Design Issue	UI software fails to block the operator's accidental press on the start command (e.g., during system maintenance).
UI Component(s)	Start command
Causal Factors Category	Forgiveness for erroneous control actions
Safety Requirement	The UI software shall nc the patient is not ready.
Formalized Safety Requirement	FORALL (st: State): controller(st) ^patient = NOT_READY →NOT per_start(st)

For every system state *st*, if patient status is not ready, then the Start Command (*per_start(st)*) is not allowed.

EXAMPLE NEW UI ISSUE IDENTIFIED (CONT'D)

UI Design Issue	If the treatment activation sequence is interrupted, the UI software always resumes the sequence from where it was interrupted, and does not provide the operator means to stop/abort/restart the activation sequence.
UI Component(s)	UI commands involved in the activation sequence.
Causal Factors Category	Reversibility of control ac… of control actions are no…
Safety Requirement	A control to cancel the tre… available at all UI screens …
Formalized Safety Requirement	cancel_activation_th: FORALL (st: State , c: Console) controller(st).mode /= off → controller(stop(c)(st)).mode = ready

The cancel activation sequence command (*cancel_activation_th*) is available when the device is turned on, and this command should return the system back to the Ready mode.

Benefit of Formalizing Safety Requirements

Formal safety requirements enables the development of UI safety reference models.

- The models' compliance to intended use safety can be established through formal verification (e.g., theorem proving).
- Safety reference models can be used to challenge the actual UI software design (e.g., using model-based test generation).

```
1  gantry2: THEORY BEGIN IMPORTING gantry2_types
2    Console: TYPE = { main, remote }
3    Modes: TYPE = { off, on, ready, radiation, post }
4    UI: TYPE = [# viz: [Attr -> bool],
5                  feedback: [Act -> bool],
6                  alerts: [Alert -> bool] #]
7    Controller: TYPE = [# patient: PatientStatus,
8                          interlock: bool, mode: Modes #]
9    State: TYPE = [# console: [ Console -> UI],
10                    controller: Controller #]
11   %-- actions
12   per_stop(st:State): bool = (controller(st)`mode /= off)
13   stop(c:Console)(st:(per_stop)): State =
14     LET st = action_registered(stop,c)(st)
15      IN st WITH [ controller := controller(st)
16           WITH [ mode := ready ]]
17   %-- ...additional definitions of actions omitted
18 END gantry2
```

Listing 1.1. Fragment of the PVS model of the Gantry-2 system.

PVS Model for Gantry-2 System

The full PVS model and analysis results are available at https://goo.gl/7ftTlv.

DISCUSSIONS

- Formal verification vs. other evaluation methods (e.g., expert review)

  e.g., Consistency with user manuals and Complexity of feedback

- Identification of human UCAs vs. Identification of critical tasks.

  Analytical approaches for identifying critical user tasks, e.g. contextual inquiry or formative evaluations, can help the identification of UCAs.

- Need enhancement on identifying UI issues with supporting similar control actions.

Future Work

- More comprehensive evaluation on realistic systems.
- Automation of applying causal factor categories to UI design.
- Establishing UI safety reference models for classes of devices

Questions?