# A Use Error Taxonomy for Improving Human-Machine Interface Design in Medical Devices

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## ABSTRACT

Use error is one of the leading causes of medical device incidents. It is crucial for all stakeholders to have a unified means to better understand, classify, communicate, and prevent/avoid medical device use errors. In this paper, we present our ongoing work on developing a new use error taxonomy for medical devices that has the potential to enable fine-grained analysis of use errors and their root causes in system design. Our ultimate goal is to create a generic framework that can be used by medical device designers to better identify effective design solutions to mitigating use errors.

## KEYWORDS

Human-Machine Interface (HMI); Use error; Medical devices.

## 1 INTRODUCTION

Medical Cyber-Physical Systems (CPS) typically incorporate a Human-Machine Interface (HMI) that serves as a centralized or distributed portal for users to monitor and control the system. Consider for example the Integrated Clinical Environment [8] (ICE), an interoperable infrastructure that coordinates multiple medical devices, medical apps, and other equipment to accomplish a shared clinical mission. ICE systems often provide a centralized HMI to allow the users to monitor and control the devices connected to the system. The HMI might also include safety interlocks and other intelligences (e.g., a centralized smart alarm system) to facilitate effective and safe user-system interaction.

It is thus critical to the safety of medical CPS to design safe HMIs that ensure expected user-system interactions and prevent potential *use errors*. Use error is an act of omission or commission performed by the user that causes a device to respond unexpectedly [7]. Preventing use errors has been long acknowledged as a top priority in medical device design [1, 13]. From a system engineering standpoint, use errors are often induced by flaws in the HMI design. In fact, investigations of incidents with medical devices usually reveal that HMI design flaws, rather than the lack of user training or inadvertent user behavior, constitute the main source of use errors [2, 10].

To design safer HMIs that prevent use errors and facilitate the recovery from use errors when they occur, developers need to have a clear understanding of the relation between HMI design aspects and use errors. A standard way to build this understanding is by using a *use error taxonomy* that classifies use errors in accordance with systematic criteria. Developers can use the taxonomy as a reference, to check what types of use errors typically occur during user-system interaction, as well as when the errors are likely to occur. In addition, a use error taxonomy can also help developers distinguish intricate differences between use errors stemming from different causes, and in turn devise effective measures to prevent and mitigate future use errors.

Numerous use error taxonomies have been proposed for medical systems with different degrees of specificity, scope, and coverage (see [17] for a survey). These taxonomies can be categorized in two main types: *model-based taxonomies*, which build on human cognitive models (an example taxonomy of this type is that proposed by Zhang et al. [21]); and *data-driven taxonomies*, which build on statistical data on use errors (an example taxonomy of this type is that presented in [20] for number entry errors). In general, model-based taxonomies promote more systematic classification of use errors, and their applicability typically extends across multiple device types [17].

However, existing taxonomies have a variety of limitations that might result in incorrect, incomplete, or inaccurate classification of use errors. On the one hand, data-driven taxonomies often include ad-hoc error categories derived from statistics on medical incidents. They are usually limited to the current understanding and knowledge about use errors with a specific system. On the other hand, model-based taxonomies usually build on Norman's action theory model [3], which explains human decision-making as a sequential process with seven conceptual cognitive stages. Whilst Norman's action theory provides mental scaffolding for reasoning about the causal relation between HMI design aspects and use errors, the model over-simplifies an aspect of human cognition that is important in the medical domain: *skilled behavior* due to well practiced activities (e.g., learnt through training) or related to actions (predominantly motor actions) that can be performed with little conscious attention. This causes the taxonomies built on Noman's model to fall short when dealing with use errors committed by trained personnel, which is often the case with clinical operators of medical devices.

In the paper, we present a use error taxonomy for medical devices that aims to address the limitations of existing taxonomies, and


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explore the benefits of using a cognitive process model that is more sophisticated than Norman's action theory model. In particular, we consider Rasmussen's *decision-ladder framework* [15], which is also extensively used in the avionics sector to analyze use errors committed by pilots.

**Contributions.** The main contributions are: (i) the development of a use error taxonomy for medical devices to help developers reason about use error types and their relation with HMI design; (ii) an initial evaluation of the benefits of the developed taxonomy with respect to existing taxonomies.

## 2 RELATED WORK

Various approaches have been developed in recent years to classify use errors with medical devices and better understand their causes in system design.

In [12], Leveson's System Theoretic Accidents Models and Process (STAMP) framework is used as a basis to classify medical errors. STAMP is designed to support the analysis of causal factors not only at the level of unsafe actions committed by individual users, but also at management levels. While this broader view is certainly useful for healthcare providers to investigate system- and organizational-level causes of use errors, the error model used in the framework only coarsely classifies use errors into three categories: feedback, control action, and knowledge errors.

In [14], a Human Factors Classification Framework (HFCF) [19] from the avionics domain is adapted to the analysis of medical device-related incidents. The framework is built on Reason's error model [16] Similarly to the approach based on STAMP, HFCF considers use errors from a system-level perspective, and includes only five use error categories: decision errors, skill-based errors, perceptual errors, routine violations, and exceptional violations.

In [5] and [4], participatory design methods were used to create use error taxonomies for Computerized Physician Order Entry (CPOE) and tele-medicine systems. Participatory design builds on focus group discussions involving relevant stakeholders, including human factors specialists, cognitive specialists, social scientists and clinicians. The taxonomies produced in these works have shortcomings similar to those faced by data-driven taxonomies, i.e., the classification is not systematic and focuses on a specific type of medical systems.

## 3 BACKGROUND

Similarly to Norman's actions theory model, the Decision-Ladder framework describes human problem-solving as a seven-stage cognitive process. As illustrated in Figure 1, these stages include: (i) goal formation, where one decides what needs to be done; (ii) intention formation, where one decides a strategy to achieve the selected goal; (iii) actions specification, where one identifies a concrete sequence of actions to implement the selected strategy; (iv) actions execution, where one performs the identified sequence of actions; (v) perception, where one monitors the effects of the actions; (vi) interpretation, where one develops an understanding of the perceived system state; and (vii) evaluation, where one decides whether the goal has been achieved. Failure to complete any cognitive stage is interpreted as a precursor to use error.

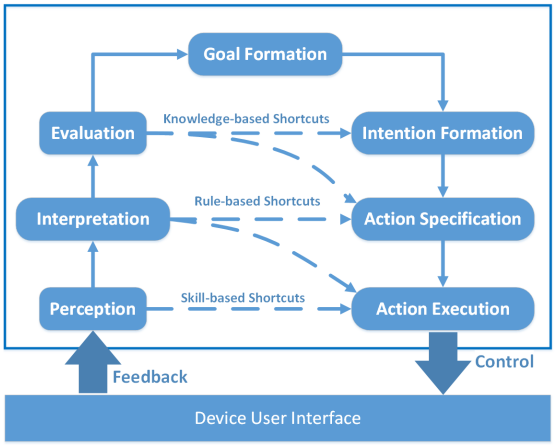


**Figure 1: The Decision-Ladder Framework.**

The advantage of the Decision-Ladder framework lies in that one can traverse the cognitive stages in a non-sequential order, by taking certain *cognitive shortcuts* to skip cognitive stages. The cognitive shortcuts are useful for representing "rule of thumb" solutions adopted by experienced users when solving common problems [6, 9]. It should be noted that, when used appropriately, cognitive shortcuts can greatly improve interaction performance and also reduce use errors. The Decision-Ladder model includes three types of shortcuts:

- *Skill-based shortcuts:* heuristics adopted by skilled users when performing highly practiced actions during tasks (mainly motor tasks) – skilled users can complete these tasks with little or no feedback from the device.
- *Rule-based shortcuts:* heuristics adopted by trained users when performing procedural tasks they have learned through training or from previous experience – trained users typically rely on waypoints to monitor progress and status of procedural tasks.
- *Knowledge-based shortcuts:* heuristics adopted by experienced users when facing unfamiliar situations – experienced user tends to formulate an action plan by finding an analogy between the unfamiliar situation and some known patterns of events, and then execute the action plan (likely using skill- or rule-based shortcuts).

The use of cognitive shortcuts may vary across different users, depending on the heuristics they have learned and their past experience with a particular device.

## 4 THE USE ERROR TAXONOMY

We follow the guidelines in [21] to develop our taxonomy:

- Step 1: Identify generic use error types by applying systematically a human error model to the cognitive stages of the selected cognitive model.
- Step 2: Elaborate an interpretation of the generic use error types with examples of the error types in the medical domain and typical HMI design flaws contributing to them. The elaboration is expected to better explain how the taxonomy is applied medical devices and medical CPS.

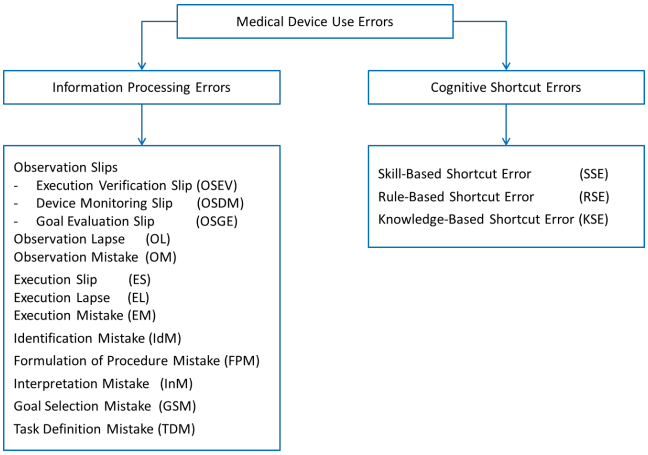


**Figure 2: Use error types in our taxonomy**

## 4.1 Generic Use Errors Types

To identify generic use error types, we build on Reason's Generic Error Modeling System (GEMS) [16], which is a de-facto standard approach. GEMS defines three generic error types:

- *Slips* - actions not carried out as intended;
- *Lapses* - missed actions due to temporary failure of concentration, memory, or judgement;
- *Mistakes* - errors due to erroneous action plans.

Slips and Lapses are skill-based errors, while Mistakes are rule- or knowledge-based errors.

Applying GEMS to the Decision-Ladder framework is conducted by exploring the possibility of instantiating each error type at each stage and shortcut of the framework. This results in 16 use errors types (see Figure 2): 13 types of *information processing errors* due to failure to complete one or more cognitive stages; and 3 types of *cognitive shortcut errors* due to misuse of cognitive shortcuts during inappropriate situations. Note that not all GEMS error types can be applied to all stages. For example, slips or lapses are not applicable to the interpretation stage, as this stage relates to knowledge-based behaviors of the user.

We argue that the 16 identified types of use errors constitute a fairly complete classification of use errors because: (1) the Decision-Ladder framework covers both human decision-making activities and the user's expertise levels, and (2) the systematic application of GEMS to each stage and shortcut in the Decision-Ladder framework, wherever possible, enables us to cover human errors at any point of user-system interaction.

## 4.2 Medical Device Use Errors Types

We tailored the generic description of the identified use error types to the medical domain by using information from medical incidents reported in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database [18]. To this end, we have analyzed 50 incident reports involving use errors in 2014 and 2015.

The rest of this section presents the identified use error types, example medical incidents involving the error, and typical HMI design issues contributing to these error types. It is worth noting that the HMI design issues (and examples) presented for the use error types are not meant to be exhaustive. Instead, they provide useful information for developers to better explore HMI design issues that likely contribute to medical device use errors. For the ease of reference, each error type is assigned with an error code.

#### 4.2.1 *Mistakes.*

**Observation Mistake (code: OM)**: Failure to locate relevant feedback provided by the device, potentially resulting in observation or posterior use of information that is not relevant or suitable for the upcoming task. Typical HMI design flaws contributing to this type of error include:

- Information overload on the HMI;
- Lack of guidance, either on the HMI or in the training material, on how to access relevant information on the HMI.

**Identification Mistake (code: IdM)**: Failure to identify which perceived device stimuli or information resource is important for the task being carried out. That is, the user is able to correctly perceive feedback from the device, but fails to focus on relevant information. Typical HMI flaws contributing to this type of error include:

- Ambiguous presentation of information on the HMI (e.g., the device uses 'mg' as a shorthand for micrograms, whereas the user is trained to read 'mg' as milligrams);
- Lack of guidance, either on the HMI or in the training material, on how to identify relevant information on the HMI (e.g., a light is blinking to indicate some problem, but the user was unaware of the importance of that warning);
- Erroneous feedback on the HMI inducing confirmation bias (e.g., feedback on the HMI suggests data entry is completed when the device is still waiting for a confirmation action from the user).

**Interpretation Mistake (code: InM)**: Failure to assign a correct meaning to correctly identified information, or to understand the implications of actions. Typical HMI design flaws contributing to this type of error include:

- Widgets on the HMI are labelled inconsistently across different device modes (e.g., the user is confused about how to cancel an action, as the soft key for the Cancel action is labelled as "Cancel" or "Back" in different device modes);
- The HMI provides incomplete information that causes the user to fail to understand the implications of their actions (e.g., the HMI display reports the infusion rate value without reporting the units during data entry).

**Goal Selection Mistake (code: GSM)**: Failure to identify what needs to be achieved next. Typical HMI design flaws contributing to this type of error include:

- Information overload on the HMI (e.g., the HMI displays guidance instruction for the current action and the next required action at the same time);
- Incomplete feedback on the HMI (e.g., feedback on the HMI does not indicate that the device is in error condition);
- Incorrect documentation of what can be done with the device.

**Task Definition Mistake (code: TDM)**: Failure to define a correct strategy to achieve the selected goal. Typical HMI design flaws contributing to this type of error include:

- The HMI does not provide appropriate functionalities necessary to accomplish required tasks;

- Lack of guidance on the HMI or lack of documentation on which device functionalities should be used to achieve a goal (e.g., a nurse fails to stop an infusion because it is unclear what sequence of actions should be used to stop the pump).

**Formulation of Procedures Mistake (code: FPM)**: Failure to select the actions necessary for implementing the selected strategy. The difference between TDM and FPM errors is that the former are errors in deciding a strategy (e.g., adjust the dosage of the therapy to be delivered) whereas the latter are errors in deciding the actual sequence of actions (e.g., using the UP arrow key to adjust the dosage of the therapy). Typical HMI design flaws contributing to this type of error include:

- The HMI fails to respond to well-established user actions in a predictable way (e.g., the data entry system silently changes mode of operation in some boundary cases because, e.g., the keys for increasing/decreasing the infusion parameters become MR (memory recall) and MC (memory clear) functions in certain circumstances);
- Lack of feedback on the HMI or lack of documentation about how to address abnormal situation (e.g., error conditions). This flaw is particularly subtle, because it may result in misapplication of rules that are good in normal situations that are apparently similar to the present error situation but in reality are radically different.

**Execution Mistake (code: EM)**: Failure to perform an action. Typical HMI design flaws contributing to this type of error include:

- Faulty HMI interlock that assigns the wrong priority to user actions that could be performed simultaneously (e.g., simultaneous presses of the 'stop' and 'retract' buttons is erroneously treated as 'retract');
- Lack of HMI interlocks that protect against dangerous actions during exploratory behavior (e.g., when the nurse is investigating ways to address an error condition);
- Lack of documentation or inappropriate HMI functions available to the user to perform required actions.

*4.2.2 Slips.* **Observation Slips**: Involuntary error occurring due to failure to perceive device stimuli in different modalities (visual, auditory, haptic, etc.). Typical HMI flaws contributing to this error include:

- HMI design flaws in the way information is presented (e.g., the size, font, and spacing of letters do not allow clear reading of labels, such as in the case "VTBI 19" and "VBTI9").
- Missing feedback on the HMI (e.g., a patient records screen does not provide sufficient information to allow unique identification of a patient, resulting in that clinicians accidentally derive information from the wrong patient or perform actions on the wrong patient record).

Observations slips are closely related to issues in device feedback, and can be further divided into three sub-types based on when an observation slip occurs in the interaction process.

*Execution Verification Slips* **(code: OSEV)**. Observation slips occurring after the user executes an action. This type of slip might occur because the HMI fails to provide feedback in a timely manner when the user performs an action, or after the user has performed an action. This design issue can lead to cascading use errors because the user will tend to lose situational awareness about whether the device has actually registered the performed actions.

*Device Monitoring Slips* **(code: OSDM)**. Observation slips occurring when the user checks the device state (e.g., failure to recognize that the device is running out of battery because the volume of audible alerts is too low to be noticeable).

*Goal Evaluation Slips* **(code: OSGE)**. Observation slips occurring when the user checks whether a goal has been achieved (e.g., failure to understand if a therapy has been successfully started due to the lack of salient audio-visual feedback indicating such event).

**Execution Slip (code: ES)**. Involuntary error occurring during the execution of an action. Typical HMI design flaws contributing to this type of error include faulty HMI design does not take into account one or more of the following situations: natural variability of motor actions performed by users; foreseeable accidental motor actions performed by users (e.g., the HMI erroneously wraps-around the rate value, and the user accidentally sets the rate to *max rate* rather than 0 because of an unintended additional click on the DOWN button when the rate value is already 0); foreseeable data entry errors (e.g., typos, number inversions, pressing of multiple buttons at the same time).

*4.2.3 Lapses.* **Observation Lapse (code: OL)**. These use errors are due to flaws in the user's encoding and memorization of device stimuli. They occur mainly due to inattention, memory loss, or interference. Typical HMI design flaws contributing to this type of errors include faulty HMI design erroneously delays feedback without the user's awareness.

**Execution Lapse (code: EL)**. These use errors are related to inattention, interruption, and/or intrusion into familiar patterns of activity. Typical HMI flaws contributing to this type of error include erroneous design of automated HMI functions that were meant to optimize interaction with the HMI, or handle exceptional use cases (e.g., the HMI silently discards data entry when the user pauses data entry for a period of time).

*4.2.4 Shortcut Errors.* **Skill-based Shortcut Errors (code: SSE)**: Use errors during the execution of highly practiced tasks/actions (typically motor tasks). Typical HMI design flaws contributing to this type of error include:

- Faulty HMI interlocks that penalize expert behavior (e.g., the nurse quickly presses [2] [2] [.] [3] and the device erroneously registers "0.3" instead of 22.3 because the first two key presses were performed too quickly and the HMI erroneously discards them as if they were a key debounce);
- Incorrect HMI layout for highly practiced motor actions (e.g., the HMI uses a numeric keypad with a phone layout in certain modes, and with a calculator layout in other modes).

**Rule-based Shortcut Errors (code: RSE)**: Errors committed by the user during the execution of tasks/actions based on learned rules (heuristics). This type of error occurs when problem-solving strategies normally working in standard situations fail in the present context. Typical HMI flaws contributing to this type of error include:

- The HMI does not provide sufficient information to help the user reason about the implication of applying a learned rule in the present context (e.g., the HMI associates "slide left" to Confirm and "slide right" to Decline, which is opposite to

typical designs, and does not provide visual cues indicating such non-standard association);
- Feedback on the HMI fails to call the user's attention to the inappropriateness of certain user actions in the current context (e.g., the data entry system always allows the user to enter an infusion rate with a fractional part, but only accepts it when the infusion rate is less than 100 mL/h. No feedback is provided indicating such constraint, or informing the user whether the entered rate can be accepted by the device).

**Knowledge-based Shortcut Errors (code: KSE)**: Errors committed by the user during the execution of familiar tasks in unfamiliar situations. This type of use error involves the adoption of an erroneous problem-solving strategy based on stereotyped response to familiar systems states/modes. Typical HMI design flaws contributing to this type of error include:

- The HMI provides inconsistent functionalities in conceptually similar situations;
- Feedback on the HMI is not sufficient to discriminate whether the device is in normal operating conditions or in abnormal/error states.

## 5 PRELIMINARY EVALUATION

We applied our taxonomy to classify a set of medical device use errors (reported in our previous work [11]), which allowed us to evaluate the quality of the taxonomy from two perspectives:

- **Applicability**: the completeness and ease of use of the taxonomy when applied to classify real-world use errors;
- **Accuracy**: the ability of the taxonomy in distinguish use errors that are similar but their differences are worth highlighting (e.g., because they require different mitigation strategies).

### 5.1 Use Errors for Classification

Details of the data set of real-world use errors considered in our exercise can be found in [11], which includes 53 use errors collected from the analysis of 16 medical devices from 10 different manufacturers, and from use-related adverse events reported in the FDA's MAUDE database for infusion pumps, ventilators, patient monitors, and infant warmers in the decade 2000–2010. These use errors and their root causes have been reviewed and confirmed by a team of device experts and healthcare practitioners.

### 5.2 Applicability

Figure 3 illustrates the distribution of the considered use errors in our taxonomy (full details are available at https://goo.gl/eZAsRD).

For each use error in the dataset, except for one, we were able to classify it to a single use error type. The only exception use error has the following description: *The user entered an incorrect key sequence "0 9" that was erroneously accepted and registered as "9" without any warning*. We classified this error as both Execution Slip (ES) and Skill-based Shortcut Error (SSE), because it can be interpreted as either an error committed while performing a motor action, or an error committed during a routine task.

This exercise demonstrates that most use error type descriptions in our taxonomy offer sufficient guidelines in classifying real-world use errors, while it is possible to refine some of these descriptions to better distinguish use error types that potentially overlap with each other.

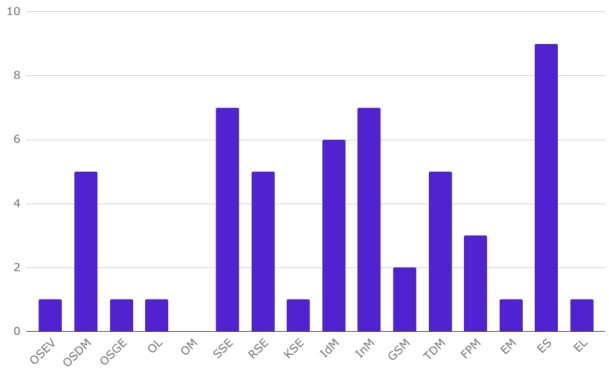


**Figure 3: Classifying use errors with our Taxonomy.**

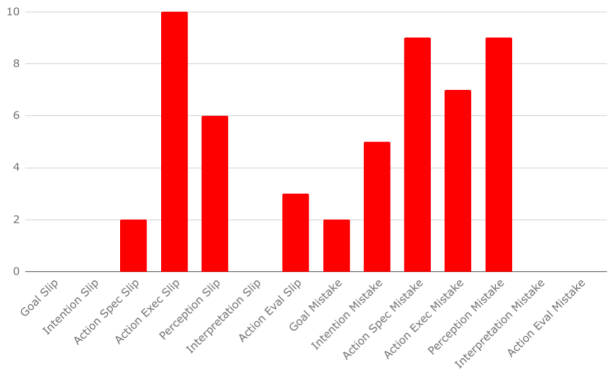


**Figure 4: Use error classification with Zhang et al.'s taxonomy.**

### 5.3 Classification Accuracy

We applied the taxonomy proposed by Zhang et al. [21], one of the most comprehensive taxonomies for medical use errors to date, to classify the same set of use errors, and compared its classification results with ours. This allows us to compare the classification accuracy of these two taxonomies. To ensure a correct and fair comparison, we strictly followed the definitions of error categorizes in [21] during the classification.

Figure 4 shows the classification results using Zhang et al.'s taxonomy. Comparison between Figures 3 and 4 indicates that use errors distribute more evenly in our taxonomy. It is also interesting to note that 5 out of 14 error categories in the taxonomy of Zhang et al. did not capture any use error, as compared to just 1 out of 16 with our taxonomy. This might indicate either that our taxonomy has a finer level of granularity that enables more accurate classification of use errors, or that we held incorrect understanding of Zhang et al.'s taxonomy during classification. In either case, a study on a more comprehensive set of real-world use errors is needed to confirm the trend and and the reasons behind the trend. We plan it as future work.

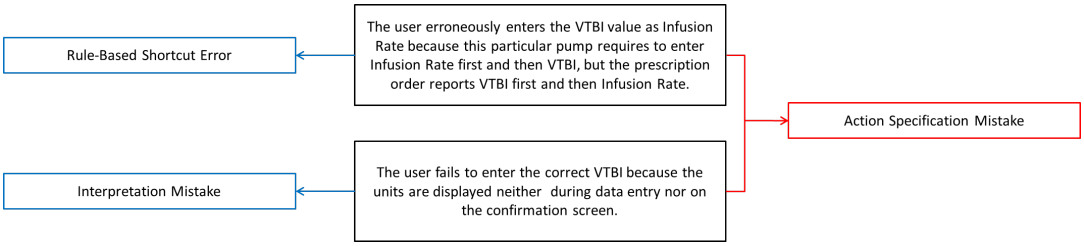


**Figure 5: Two Example Use Errors and Their Classification**

| **Zhang et al.'s Taxonomy** | **Our Taxonomy** |
|---|---|
| Goal Slip/Mistake | Goal Selection Mistake |
| | Task Definition Mistake |
| | Knowledge-based Shortcut Error |
| Intention Slip/Mistake | Identification Mistake |
| | Interpretation Mistake |
| | Rule-based Shortcut Error |
| Action Specification Slip/Mistake | Interpretation Mistake |
| | Formulation of Procedures Mistake |
| | Rule-based Shortcut Error |
| Action Execution Slip | Execution Slip |
| | Skill-based Shortcut Error |
| Action Execution Mistake | Execution Mistake |
| | Skill-based Shortcut Error |
| Perception Slip | Observation Slip - Device Monitoring |
| | Observation Lapse |
| Perception Mistake | Observation Mistake |
| | Identification Mistake |
| Interpretation Slip/Mistake | Interpretation Mistake |
| | Knowledge-based Shortcut Error |
| Evaluation Slip/Mistake | Observation Slip - Goal Evaluation |
| | Observation Slip - Execution Verification |

**Table 1: Taxonomy alignment.**

During the comparison of these two taxonomies, we encountered two use errors that demonstrate the potential advantages of our taxonomy. As illustrated in Figure 5, two use errors were both classified as Action Specification Mistakes using the taxonomy of Zhang et al., while our taxonomy classified these errors as different use error types. In particular, our taxonomy classified one of these two errors as a Rule-based Shortcut Error (see the top of Figure 5), because the error was due to the fact that the heuristic adopted by the clinician was appropriate for similar clinical contexts but not for the current context. The other use error (shown at the bottom of Figure 5) was classified as an Interpretation Mistake by our taxonomy, because the HMI design flaw leads to a situation where the user is not provided with complete situational knowledge nor an understanding of the possible implications of the action.

Classifying these two use errors to different categories can help developers better understand their root causes in HMI design and devise more appropriate mitigation measures. For example, the first use error can be mitigated by designing an HMI that accepts infusion parameters in the same order as that used in the prescription. The second can be mitigated by displaying the volume units next to its value during data entry.

**Alignment with Zhang et al.'s taxonomy.** Table 1 presents the alignment of our taxonomy with Zhang et al.'s. This alignment is particularly helpful to understand the difference between these two taxonomies, and makes it easier to compare use errors classified using one taxonomy with use error reports classified using the other.

## 6 CONCLUSION

We have presented a use error taxonomy for medical devices with the aim to improve the understanding and awareness of all stakeholders on medical device use errors. The preliminary evaluation results of the taxonomy are promising, in that it allowed us to better distinguish use errors reported in medical device incidents as compared to existing taxonomies. This is critical for developers to understand the root causes of use errors and devise appropriate mitigation measures. Future work will concentrate on validating the taxonomy by applying it to larger datasets, and we will explore how to further refine the taxonomy to better distinguish similar use errors that warrant different mitigation strategies.

## 7 ACKNOWLEDGMENTS

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