Using the FDA MAUDE and Medical Device Recall Databases to Design Better Devices

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Abstract

This article provides recommendations to manufacturers on using the Food and Drug Administration's MAUDE (Manufacturer and User Facility Device Experience) and Medical Device Recall databases to identify unknown use issues, discover design opportunities, and improve one's risk management file. These recommendations are based on the experiences of researchers who have spent time analyzing and working with both database systems and have developed a methodology for each. Manufacturers can leverage the suggested practices described in this article to address regulatory requirements.

As medical devices and human–system interactions become more complex, usability issues are a persistent challenge and are gaining more recognition for their impact. A 2016 Johns Hopkins study reported that medical errors are the third leading cause of death in the United States.[1] Prioritizing human factors is imperative to decrease the occurrence of design flaws, eliminate or reduce use-related hazards, improve patient adherence, and ultimately ensure safe outcomes for end users of medical devices.

Objectives

This article seeks to guide manufacturers on using the Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) and Medical Device Recall (hereafter referred to as Recall) databases to gain knowledge about medical device usability issues and develop safer devices. To achieve this objective, the researchers describe the two databases, demonstrate how to extract data from each, suggest ways to classify the data by root cause and identified trends, and explain how the findings can be used to develop better devices.

Postmarket Surveillance

Regulatory bodies are increasingly emphasizing that medical device manufacturers use postmarket surveillance data for usability-related improvements during the product development process.

The new European Union (EU) Medical Device Regulation (MDR) stresses a priority on continuous review of postmarket issues and analysis of those issues, specifically that manufacturers should have "a postmarket surveillance system in place which should be proportionate to the risk class and the type of device in question."[2] The MDR also explicitly states that data from postmarket surveillance activities should feed into multiple areas, including the risk–benefit analysis, manufacturing instructions, corrective and preventive actions, and—most importantly for this article—"for the identification of options to improve the usability, performance and safety of the device."[3]

In addition, the FDA guidance for human factors[4] recommends implementing design modifications "in response to postmarket use error problems." During the previous few years, the FDA has communicated that pre- and postmarket surveillance and data analysis, as part of a product's life cycle, are fundamental to device design. This emphasis by the agency is highlighted by its initiation of the Medical Device Innovation Consortium (MDIC) and the National Evaluation System for health Technology (NEST). MDIC and NEST were formed to assist the medical device ecosystem in using real-world data and evidence throughout the product life cycle, with the following stated as their goal: "Our mission is to catalyze the timely, reliable, and cost-effective development of Real-World Evidence to enhance regulatory and clinical decision making."[5]

Similarly, the technical information report AAMI TIR50:2014, *Post-market surveillance of*

use error management, encourages manufacturers to "proactively mitigate potential use errors and optimize the user experience while operating the device in question."[6] The TIR details how to discover potential use errors early in the development process and how to better analyze complaint data based on root cause and level of completeness. The TIR also goes into depth on the issues of reporting culture in hospitals, as well as the inputting (and respective employee training on how to uncover information), triaging, and analysis of this data.

These regulations and guidance stress the importance of postmarket surveillance being a priority for medical device manufacturers. Although a wealth of data exists within the FDA MAUDE and Recall databases, guidance on how to mine and analyze the existing data for postmarket surveillance applications, particularly with usability in mind, is minimal.

Other Relevant Databases

Although this article will focus on the FDA MAUDE and Recall databases, other databases can be useful to device manufacturers, including Medical Product Safety Network (MedSun) and Eudamed. The primary goal of MedSun, which is an adverse event reporting program launched in 2002 by the FDA, is to work collaboratively with the clinical community to identify, understand, and solve problems related to the use of medical devices. Clinical communities such as hospitals, nursing homes, and outpatient treatment and diagnostic centers are required to report medical device problems that result in serious illness, injury, or death. They also are highly encouraged to voluntarily report problems with devices, such as "close calls," potential for harm, and other safety concerns.[7]

Compared with the FDA MAUDE and Recall databases, MedSun has a similar user interface but contains less identifying information for specific devices other than manufacturer name and device brand. This is consistent with its intended purpose of encouraging clinical personnel to share and report problems regarding medical devices, as less information needs to be included in a MedSun report.

Another database that could be useful is a new Eudamed database, which is scheduled to be launched in May 2022, per the new EU MDR. The Eudamed database will be a multipurpose European database platform intended "to function as a registration system, a collaborative system, a notification system, a dissemination system (open to the public), and will be interoperable."[8] After it is fully developed and launched, the public will be able to access market surveillance data on medical devices, including data obtained in accordance with the vigilance procedure on incidents or near incidents that occur during the use of devices. At this point, however, comparing this new Eudamed database with other databases described in this article is not possible until the updated Eudamed database is released. Of note, the current Eudamed database, which launched in May 2011, is not publicly accessible and serves as a central repository for information exchanged among national competent authorities and the European Commission.

MAUDE and Medical Device Recall Databases

Introduction to the Databases

Both the FDA MAUDE and Recall databases contain information about issues with medical devices that are on the market in the United States. The MAUDE database contains adverse event reports that involve end user interactions with medical devices (also known as medical device reports). These adverse events describe suspected device-associated deaths, serious injuries, and malfunctions, with a wide range of causes (e.g., from manufacturing to usability issues). The FDA Recall database provides information about medical devices that are defective or otherwise pose a health risk and describes how manufacturers are responding to these issues.

The purpose of these databases differs. MAUDE is a form of postmarket surveillance, meaning that the database provides continuous feedback about medical devices that are on the market. This database allows the FDA and device manufacturers to monitor device performance over time. Meanwhile, the FDA Recall database notifies users of devices (e.g., patients, clinicians)

that a "recall" has been issued. A recall means that the manufacturer must address the problem or remove the device from its environment of use. A recall can include notifying patients and clinicians of a problem and/or requiring the destruction of all affected devices, or another course of corrective action.

The FDA collects information for each database from both voluntary sources and mandatory reports. For the MAUDE database, although anyone can submit a medical device report to the FDA, manufacturers and user facilities such as hospitals and nursing homes are required to do so. Depending on the nature of the adverse event, different regulations for the report apply. For example, federal regulations require manufacturers to report to the FDA within 30 calendar days of acquiring information that reasonably suggests one of their devices may have malfunctioned or contributed to a death or serious injury. Manufacturers required to report to the FDA within five working days if an event requires action other than routine maintenance or service to prevent a public health issue.[9] In contrast, recalls are generally initiated by a company voluntarily, but they also can be required by the FDA if a company refuses to recall a device associated with significant health problems or death, or based on findings during an inspection. After a recall is initiated, the FDA classifies the risk and therefore the recall class (1, 2, or 3), monitors the recall until the product no longer violates the law and no longer presents a health hazard, and then terminates the recall.[10]

Both databases provide valuable information on medical device usability issues. For this reason, the researchers will describe how to extract, classify, and analyze data from each database.

Search Techniques

Data can be extracted from the databases via two methods: (1) using the provided search functions (Simple/Quick Search and Advanced Search) or (2) downloading the data and conducting a manual search. Depending on the researcher's interests, different techniques are recommended.

For the MAUDE database, a Simple Search allows the researcher to identify device issues by searching terms (e.g., specific device, issue of interest). This search will produce all MAUDE events relevant to the search query, which may result in a substantial number of results, depending on the device and topic. Researchers can use the Simple Search to collect an exhaustive database of all potentially relevant issues and then export these data to Excel through an option provided on the MAUDE website.

After the search data are exported, the researcher has a choice to either review all data line by line or, if the amount of data is significant and there is a desire to further filter the data for relevance, keywords can be used. Searching for terms such as "inadvertent" or "intended use" within the exported data file can help identify a subset of event data that are likely to be relevant to human factors (see "Appendix 1: Human Factors Keywords" in the supplemental material, available online at https://aami-bit.org). It can also be helpful to use terminology that may not be common to the human factors community, such as "user error," or search for phrases that may blame the user. (Although the human factors community does not attribute blame to the user, reports to MAUDE often contain language that ascribes blame.) Then, the researcher can review each of the potentially relevant events by reading Event Descriptions and analyzing them for use-related issues, which are further described in the issue classification section below.

For the Recall database, Quick Search consists of a single search field and is ideal for searching very specific, very recent (i.e., within the last one to two years), or less common devices (i.e., devices that currently do not have many recalls). If Quick Search returns too many results, the researcher can try narrowing the search using keywords (online Appendix 1) or try an Advanced Search.

MAUDE's Advanced Search consists of nine search fields:

1. Product Problem
2. Product Class
3. Event Type
4. Manufacturer
5. Model Number
6. Report Number

7. Brand Name
8. Product Code
9. Date (or range of dates) the report was received by the FDA

Each field can be used to narrow the data of interest to the researcher, such as Product Class, Manufacturer, Brand Name, or date range. For this search, the researchers recommend using a Product Problem such as "Use of Device Problem" or "Human-Device Interface Problem" to identify human factors or use-related issues. Either of these categories can be selected through a drop-down menu at the Advanced Search page. These categories can be applied as filters for events that have been flagged with that category.

Of note, these categories are not associated with all relevant events. This means that when a researcher is using the Advanced Search function and selects a Product Problem field, all results for that search should be analyzed for potential use-related issues, but this should not be considered a complete data set. Due to an incomplete categorization of adverse events, many potential use-related issues have not been associated with an appropriate Product Problem. Therefore, to identify a comprehensive set of human factors–related events, a Simple Search is required (as described previously). The Advanced Search allows the researcher to review events that have already been categorized and can be useful if the Simple Search function produces an unmanageable number of events or if a more cursory search is desired.

The Recall database's Advanced Search consists of 11 input entry fields:

1. Product Name
2. Product Code
3. In Vitro Devices
4. Recall Class
5. PMA/510(K) Number
6. Recall Date
7. Recall Number
8. Reason for Recall
9. Recalling Firm
10. Root Cause (see "Appendix 2: Root Cause Classifications from the FDA Recall Database Advanced Search," available online at https://aami-bit.org)
11. Sort by

One strategy for using Advanced Search for recall data is to fill in as many search fields as possible or desired and click through the results individually. However, if a search returns a large number of results, downloading all of the reports of interest and conducting a manual search is recommended.

Although there are multiple ways to download and view files from both databases,[11] exporting the files to Excel is recommended for each. Using filters allows users to search by more than one entry per search field category and to remove irrelevant data (e.g., Event Type: Malfunction). In addition, or alternatively, users can search by keyword(s) in Excel. Although this technique is more manually intensive, additional functionalities such as sort, filter, and the generation of pivot tables can streamline data analysis.

Issue Classification

After identifying or extracting the data, the next step is to classify the issues/recalls by their relevance to human factors. In other words, locate the errors that were the result of an end user's actions rather than an issue in manufacturing the device. For example, a faulty battery may cause the device to fail, which would be a manufacturing issue because the issue occurs without user involvement. Alternatively, a very low battery indicator that is dismissed as unimportant by the user could be a use-related issue related to the design of the indicator. This would be a use-related issue because the user's response to the device (or in this case, lack of response) could affect the delivery of treatment negatively.

After issues are identified as human factors challenges, they can be used to investigate opportunities for design or product improvement. For example, imagine that a MAUDE search is conducted to flag potential use-related issues via relevant keywords as described. One of the events identified for analysis describes a patient who accidentally pushed the "extra dose" button on their infusion pump, resulting in the delivery of an additional dose of medication. In this case, the event was flagged because of the use-related keyword "accidentally." Thinking through the event

itself, this patient completed an action that was unintended by the manufacturer (and by the patient) and that resulted in an adverse result. This indicates a use-related issue (i.e., a use error).

A researcher should review each flagged Event Description to determine whether a device malfunction or manufacturing issue is mentioned. In some instances, a device malfunction may be the root cause of the event rather than a use error. If no device malfunction or manufacturing issue is described, then one could assume the device was functioning properly during this instance (i.e., there was no malfunction and the patient activated a function offered by the device).

To consider a second example of a MAUDE event that has been identified as potentially related to human factors, consider a nurse who reprogrammed an infusion pump with the intent of changing the dose to 25 µg/hour but instead changed the dose to 25 mL/hour (250 µg/hour). This signals a human factors use error. Again, the device performs as intended (i.e., increases the dose as programmed), but the unintended action performed by the user (i.e., setting the wrong dose) results in harm to the patient. In this case, the event describes an instance where the implemented risk mitigations may have been insufficient because a use error that led to a harm occurred. A manufacturer that has discovered this issue or pattern of issues might consider improvements such as visibly emphasizing the units in the user interface design, including a confirmation step prior to changing the dose or allowing dose value safety limits to be set to prevent a potentially lethal dose from being administered.

In the Recall database, certain use-related issues can be easily identified by searching for recalls using specific FDA root cause categories (also referred to as FDA Determined Cause). A list of these FDA root cause classifications can be found in online Appendix 2. Entries that are more likely to contain human factors-related recalls are those in which the end user's actions caused an issue. An example of an FDA Determined Cause from the Recall database that is typically a use-related issue is "Device Design." An example of a recall within this root cause category provided from the database is as follows: If a flow clip is incorrectly inserted into an infusion pump and the pump door is forced closed, then the pump door may break. This is a use-related issue because if the user performs unintended actions on the device (incorrect clip insertion, forcing the pump closed), the device fails to act as intended and potentially causes harm to the user or patient.

In some cases, the researcher must look beyond the FDA root cause to consider the scenario presented in the data. An example of one of these ambiguous FDA root cause categories that may still contain recalls that are use related is the category of "Other." An "Other" example from the FDA Recall database for an infusion pump alarm is as follows: An infusion pump malfunctioned and emitted an alarm, but the pump user dismissed or cleared the alarm and continued using the pump. This continued use of a malfunctioning device may put the patient at risk. But who is to blame: the device or the user? Although the FDA Determined Cause does not point to any specific root cause, a human factors engineer would consider incorrect response to an alarm and incorrect use of a malfunctioning device as use-related issues. That is not to say that the user is at fault—only that a use error has occurred and mitigations are needed. Considering a theoretical analysis of this case, the root cause may have been inattention (e.g., the participant was focusing on some other aspect of the process and simply dismissed the alarm) or cognitive overload (e.g., more than one alarm was emitted at a time, thereby overwhelming the user and causing them to dismiss the alarm).

Data Analysis: Infusion Pump Example

The following example illustrates how MAUDE and Recall error data related to infusion pumps can be used to (1) identify design opportunities, (2) strengthen use-related risk files, and (3) justify residual risks. Although this methodology can be applied to any product within the databases, only infusion pumps were analyzed for this example (and throughout the article).

First, infusion pump data were downloaded from the MAUDE database and

filtered via the issue of "Use of Device Problem." The search yielded 77 results, which were pared down to 65 results by removing duplicate reports, reports unrelated to human factors, and reports that did not have enough information to identify the use error or cause.

Infusion pump data also were downloaded from the Recall database and filtered by the date range of 2002 to February 25, 2019. The search yielded 491 recalls, which were pared down by removing duplicate reports, recalls that were unrelated to human factors, and recalls that did not have enough information to identify the use error or cause.

Next, two human factors engineers reviewed each of the results to determine whether they were related to human factors. If both reviewers agreed, it was accepted, and if the reviewers disagreed, the research team met to discuss the event and reach a consensus.

To help identify human factors–related issues, the data sets were scanned for use-related keywords such as "accidentally," "mistakenly," "incorrectly," "incorrect," "unintended," "intended," "inadvertently," and "operator error." Some of the common themes that were identified for issues relating to human factors were:

- Accidental button press
- Incorrect dose and/or rate
- Incorrect mode/setting
- Error codes
- Standby requiring user reset
- Malfunctions requiring user confirmation
- Line/pump mix-up
- Improper removal
- Keypad lockout
- Incorrect mode/setting
- Procedure not followed
- Patient interference
- Instructions for use/translation/labeling

Additional details related to the specific examples of use-related issues and recalls for infusion pumps that were identified by the researchers can be found in Tables 1 and 2.

Design Opportunities

After categorizing the MAUDE events, the researchers began identifying trends and potential design opportunities. An obvious trend was that most use errors (39 of 65 [60%]) involved entering the dose or flow rate. Although the reason for these errors was not always apparent, in some cases the reader can infer that the user did not acknowledge a decimal point (e.g., inputting 30 instead of 3.0) or did not notice a difference in units (e.g., mL/hour versus mL/24 hours). These errors potentially could be mitigated through design. For example, the size of the decimal point could be increased for noticeability and/or the numbers following the decimal point could be sized differently for distinction. In addition, the system could require the user to input or select the preferred units of measure rather than providing default units or automatically calculating the units. For manufacturers developing related devices, this is a potential insight to include in their risk documentation. Per the FDA guidance on applying human factors,[4] at this point manufacturers can update their design control and risk management strategy to include any additional mitigations implemented as a result of this potential risk.

Consistent themes also were identified within each category of use-related issue (User interface, Device, Other). For example, on more than one occasion involving the use of two pumps, the medication was incorrectly loaded to the wrong pump. In one event description, a user explained that after programming the pumps, she placed them on standby to load the medication, and during this process, the pump screens went blank. If these screens instead indicated what medication they were programmed to infuse, she may have been less likely to mix up the medications. Alternatively, if a confirmation step were required to encourage the user to double check the medication is set up correctly, she may have realized her mistake and corrected it prior to delivering the medication.

For these and other examples, several potential design mitigations could be put in place to protect against the resulting use errors. Even infrequent errors are opportunities for improvement and should be considered, particularly if they could result in a hazardous situation of high severity.

Next, the researchers identified trends in the recall data. Frequently, the issues

Issue	Event
Accidental button press	• Users accidentally pressed "start" after programming the infusion because they were accustomed to older pumps that required two steps to start the pump ("enter" then "start") and thought they were just entering the program. • When attempting titration on line A, a user inadvertently pressed the backprime button. No solution container was attached to line B, which is needed for successful backpriming; therefore, the device alarmed.
Incorrect dose and/or rate/ concentration	• The intended rate was 3.0 mL/hour, but the actual rate was programmed to 30.0 mL/hour. • The intended concentration was 25,000 unit/500 mL, but the actual concentration was set to 1,000 unit/500 mL. • The user mistakenly titrated the infusion with the rate instead of the dose (decreasing the infusion by 2 mL/hour instead of by 2 units). • The rate (allegedly) was set to 19 mL/hour instead of 1.5 mL/hour. • The intended rate was 0.14 mg/kg/hour, and the actual rate was programmed at 140 mL/hour (wrong entry field). • User programmed 4.5 mg instead of 45 mg. • The user programmed using a dose rate of mL/hour instead of the intended mL/24 hours. • The intended concentration of 40 g/1,000 mL was to be infused at a rate of 300 mL/hour with a volume to be infused of 50 mL. Instead, the user selected 4 g/50 mL (incorrect concentration) at a rate of 125 mL/hour (incorrect rate), then later titrated the rate to 200 mL/hour with a volume to be infused of more than 500 mL (incorrect volume). • The user accidentally set the rate to 30 mL/hour instead of the intended 3 mL/hour.
Issue	**Event**
Incorrect mode/setting	• The device was placed in delay mode, and no after callback was programmed; therefore, the device did not alarm when the infusion completed. • The device was programmed in piggyback mode instead of the intended concurrent mode. • The device was left in standby mode instead of in the intended delivery mode, and the user did not notice. • The user chose a basic infusion, infusing 15 g over 20 minutes instead of the intended dose of 4 g over 15 minutes, to be followed by a continuous infusion. • The user programmed a primary infusion, while unbeknownst to the user a secondary setting, not intended for the current patient, was not cleared from the previous patient and affected the present infusion.
Line/pump mix-up	• Two lines were mistakenly switched. • Two pumps were programmed but the two medications were hung for the incorrect pumps. • Two pumps were programmed, one for oxytocin and one for $MgSO_4$. When attempting to increase the rate of the oxytocin pump, the user inadvertently increased the rate of the $MgSO_4$ pump instead. • Tubing sets were removed from a patient when the patient requested to use the toilet. Tubing sets were later reconnected incorrectly, with the Gemstar tubing set connected to the patient's IV access site and the Plum tubing set connected to the patient's epidural access site.
Improper removal	• The user removed the tubing set from the device but did not disconnect it from the patient or close the Cair clamp, so the infusion continued.
Procedure not followed	• The device alarmed with an "out-of-range alarm," but the nurse overrode it and continued programming and unknowingly delivered the wrong medication. • The tubing set was stuck in the door instead of being inserted into the tubing guide underneath the door as intended, resulting in less medication being delivered. • A user responded to an "infusion complete" alarm message and erroneously shut off the pump and disconnected the patient. As the infusion was for a life-sustaining medication, the bag needed to be replaced upon completion of the first bag.
Keypad lockout	• The keypad did not respond when the user attempted to program the device, leading to a delay in critical therapy, because the keypad was locked unbeknownst to the user.
Patient interference	• Patient accidentally pushed the extra dose button on their pump. • Patient tampered with the pump to deliver boluses of pain medication (not intended by the physician).

Table 1. Summary of infusion pump use-related issues found in the Food and Drug Administration's MAUDE (Manufacturer and User Facility Device Experience) database.

Issue	Event
Device difficulties	• If the intravenous (IV) set anti–free-flow clip is incorrectly inserted into the pump and the pump door is forced closed, the clip catch on the inside of the pump door may break. If the clip catch is broken and the door opened, free-flow protection is ensured. If the IV set is then removed from the pump without closing the roller clamp, the clip may not re-engage the tubing, leaving an open fluid path with free-flow potential. • The company received reports that the device powers down without an alarm. Investigation concluded that if the battery cap is not fully tightened as intended by the manufacturer, the pump may power down and a brief "chirp" will sound. This may occur if the user has not sufficiently tightened the battery cap or if the battery cap is damaged. • It has been determined that with low probability, overinfusion may occur as a result of an open safety clamp fitment on the pumping segment, whether opened intentionally in the course of expected clinical practice or as a result of inadvertent action. The overinfusion occurrence is dependent on the user not closing the roller clamp first, as required by clinical practice.
Incorrect mode/setting	• The company recalled its insulin infusion pumps because it received reports that users have accidentally programmed the pump to deliver the maximum bolus amount. • Exposure to magnetic resonance imaging resulted in damage to the component that monitors and controls movement of the motor in the insulin infusion pump. Although alarms occurred as a result of the damage, some users cleared these alarms and continued using the pump. Under such conditions, the pump will significantly overdeliver, potentially causing severe hypoglycemia.
Software/error codes	• The company received a complaint that an error code displayed on the programmer when the physician attempted to interrogate an implanted pump. The error code prevented the physician from updating the pump; however, the pump was providing therapy. • Pump keyboard entries by the patient could have resulted in the patient having unintended access to programming screens and have led to in improper drug dosage. • The company became aware of an increase of mechanical errors experienced by customers using its insulin infusion pump when the insulin pumps display two error messages. If the user does not act on the error messages appropriately, insulin delivery will be stopped and, if unnoticed, may lead to severe hyperglycemia.
Malfunctions requiring user confirmation	• The insulin pump may lose time and date settings during a power interruption (e.g., battery change) due to a faulty capacitor. If the capacitor fails, the time and date will return to default setting. Although the pump prompts customers to confirm the time and date, if the user does not recognize the time and date have returned to default, then a shift of their basal rate time block could occur.

Table 2. Summary of infusion pump use-related issues found in the Food and Drug Administration's Medical Device Recall database. Note: The search included some but not all results for insulin pump recalls.

identified were related to the user interface, particularly when the system required the user to reset or confirm values. For some issues, a combination of a manufacturing and design malfunction or error is present, and the expectation is that the user not only understands that an error has occurred but also knows what to do next. Researchers should take the time to parse through recall data in order to separate manufacturing recalls from the use-related recalls, as many can have multiple components.

These product recall examples can be useful for other companies to consider because they can help in anticipating common industry errors to potentially mitigate in their own designs. Some devices also had issues with doors and clamps not functioning as designed, which is another opportunity for manufacturers to ensure that they test their products with potential users to confirm that users are able to use devices as intended.

Risk Management

In addition to identifying design opportunities, manufacturers also can use MAUDE and Recall data to inform their risk management process (risk analyses and risk management file). The MAUDE database can be used to help identify potential use errors. For example, patient interference provides not only a design opportunity but a piece of information to consider during a use-related hazard analysis or use failure mode and effects analysis (uFMEA) process. Even if a manufacturer has no complaints related to a certain type of error (e.g., patient tampering with infusion pump keypad), a company may find these types of errors on

similar devices when looking through MAUDE. This could help companies consider the foreseeable misuse of certain errors to be more probable. Newly identified risks that competitive products have experienced in the market can be included within manufacturer risk processes and analyzed for design improvement opportunities, thereby driving continuous improvement for the new product.

Recall data are more useful for general error and problem sourcing. Companies can use recall data to find the issues that caused a recall in similar products. This research can be used preventively during the uFMEA process to consider potential use errors as well. Recall data also can be used as a resource for companies that have to recall their product, as they are required to outline their recall plan in Recall database reports. Then, other companies with similar devices can source ideas for their recall plans from the database, as needed.

Finally, MAUDE data also could be used to justify residual risk. As human factors engineers, it must be mentioned that mitigations, no matter how well intentioned, should be tested with representative users in representative use environments to ensure the risk is indeed mitigated, particularly during design validation, per the FDA guidance. For cases where residual risk is identified, an analysis of the use errors found during testing along with MAUDE findings may help manufacturers justify whether the residual risk is acceptable.

If a residual risk includes a use error that may lead to harm, MAUDE events can be analyzed for similar use errors and their level of harm can be compared with that of the identified residual risk. For example, in a hospital setting with many different infusion pumps, a nurse who was accustomed to a newer pump and its processes started an infusion with an older pump. The newer pump had only one step ("start"), whereas the older pumps required two steps to start the pump ("enter" then "start"). The nurse thought that he had started the infusion but had only completed step 1 of 2 to start the pump due to negative transfer from the previous pump design. The pump then alarmed to notify the nurse that the infusion was in standby mode, allowing him to correct the situation and start the infusion before harm occurred. This event could be included as justification for a residual risk of not delivering a dose to the patient, because the user corrected the error and no harm occurred during actual use.

Of note, one event does not serve as complete justification for residual risk but rather should be incorporated as one contributing event of many. Also, these events determined from database reviews should be brought to the attention of the company's medical team to perform a thorough multidepartment analysis of the true impact and risk to patients.

More generally, residual risk justification can come through comparing the harm included in the risk documentation to the harm experienced in MAUDE event reports. If there is a collection of MAUDE events that describe a given use error and the events show that the harm does not occur, then these data may be considered as additional justification for the residual risk.

Discussion

Strengths and Limitations of the Databases

Although both databases can provide valuable information to manufacturers, each has different strengths and limitations.

MAUDE database strengths. First, MAUDE has a greater frequency of device usability issues because even rare and unlikely errors often are reported, whereas the Recall database includes mostly issues that have been defined as serious enough to remove the device from the market or require a change. Second, MAUDE reports are more comprehensive—they often include the sequence of events leading to the error, though the root cause is not often clear and is left to the reader to analyze and identify. This additional context helps the manufacturer identify possible root causes, allowing them to uncover more potential sources of error than if the root cause were provided. In other words, MAUDE data do not have to be conclusive to inspire design improvements and quality system updates. Third, whereas recalled devices require action steps from the manufacturer to fix or

prevent the error, errors reported to MAUDE can remain unresolved, which leaves opportunity for product improvements or new product development for other manufacturers. By identifying the cause of the error and redesigning the device with the problematic feature removed or the problem mitigated, manufacturers have not only created market potential but also achieved a competitive edge by avoiding competitors' mistakes.

MAUDE Database Limitations. The limitations of the MAUDE database specifically, per the MAUDE website, are that the data submitted could include "incomplete, inaccurate, untimely, unverified, or biased data." In addition, many use errors are underreported.[12] As a result, the FDA stresses, particularly for postmarket surveillance, that a collection of sources in addition to MAUDE data be referenced for a representative understanding of event frequency.

Recall Database Strengths. First, the Recall database allows users to search by root cause, which can help manufacturers find out why use errors occurred without having to read the sequence of events. This can save the manufacturer the time and effort of trying to uncover the issue themselves and brainstorm possible reasons why use errors occurred. Second, when devices are recalled, action is required by the manufacturer until the FDA terminates the recall. By reading what other manufacturers have done to resolve similar issues, other manufacturers can preemptively make those same resolutions and updates to their quality system to avoid a recall of their product. Last, the data input into the Recall database is directly from the FDA or manufacturers, giving it more credibility compared with user-inputted reports.

Recall Database Limitations. The limitations of the Recall database are (1) usability issues can be difficult to identify and categorize due to how the database is currently organized and (2) actions are already being taken by the manufacturers to resolve the issues, which limits market potential for other manufacturers. Human factors/usability issues are not specifically called out in the Recall database as a specific search criterion, and attempting to filter by root cause (FDA Determined Cause) can be unreliable as well.

Conclusion

Summary of Strengths and Limitations of the Databases

The main strengths of both the MAUDE and Recall databases are the search functionalities, which enable researchers to input various pieces of information about a device to find specific results, and the ability to download large quantities of data to analyze for trends. By searching the databases for use errors occurring in products with similar user interfaces (or in predicate devices) but not leading to serious adverse events, manufacturers can substantiate their claim that their use errors pose minimal risk. Information about known use problems and residual risk justifications are important aspects in human factors engineering reports submitted to the FDA.

Both databases also can be used to identify patterns of issues and root causes of existing issues with other devices, allowing manufacturers to make more strategic and economical decisions regarding improvements during product development, improvements to quality systems, and ultimately deliver better products. Both databases are limited in that (1) they require manual parsing of large amounts of data, which can be time consuming and is not intuitive to all users and (2) they can be vague in their reports/product descriptions, making it difficult to identify potential improvements. Although both databases have limitations, the data they provide remain valuable for understanding usability issues.

Recommendations for Manufacturers

This article provides guidance to manufacturers on using the FDA MAUDE and Recall databases to gain knowledge of medical device usability issues, identify trends, brainstorm opportunities for improvement, justify residual risks, and ultimately develop safer devices. Manufacturers can leverage the insights provided here to use these databases as tools for improved product development.

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