Comparative Human Factors Studies

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Disclaimer

This presentation was prepared by Molly Story in her personal capacity. The opinions expressed herein are the author's own and do not reflect the views of her employer, Sanofi.

Human factors engineering for medical devices

- **Goal:** ensure that the medical device is safe and effective enough to allow onto the market
  - **In the US**: Show that you followed a sound human factors process and followed FDA guidance and recognized international standards, e.g.:
    - IEC 62366-1:2015, *Medical devices Part 1: Application of usability engineering to medical devices*
    - FDA/CDRH Guidance (2016): *Applying Human Factors and Usability Engineering to Medical Devices*
    - FDA/CDER/CBER draft guidance (2016): *Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development*
    - FDA/CDER draft guidance (2017): *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*

Human factors engineering for medical devices

- Methods: qualitative, not quantitative
  - **Observe** intended users performing essential and critical tasks of use.
    - Essential tasks = tasks required for use of the device for its intended purpose;
    - Critical tasks = tasks on which use error could result in serious harm;
  - **Interview** users afterward about any use errors & difficulties that occurred.
    - Get users' perspectives on why use errors / difficulties occurred.
  - **Analyze** the data to determine root causes and priority for change.
    - Decide what caused the use errors and difficulties (root causes);
    - Determine what might have happened as a result (consequences & severity);
    - Determine what changes are necessary to reduce the use-related risks to acceptable levels.

FDA/CDER Draft Guidance Document / Generics

- **Background:** FDA/CDER/CBER (2019), *ANDA Submissions — Content and Format,* Section II
  - "Under section 505(j) [of the FD&C Act], an ANDA applicant can rely on FDA's previous finding that the RLD is safe and effective so long as the ANDA applicant demonstrates that the **proposed drug product** and the **RLD** are **the same** with respect to active ingredient(s), dosage form, route of administration, strength, and, with certain exceptions, labeling."
    - Note that the regulation pertains specifically to the **drug product**, not the drug delivery device.

- ANDA = Abbreviated New Drug Application
- RLD = reference listed drug

FDA/CDER Draft Guidance Document / Generics

- **Background:** FDA/CDER (2019), *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA,* Appendix A.i
  - The goal is to "…confirm that the use error rate, for the critical tasks(s)… is not worse than the corresponding use error rate for the RLD when used by patients and caregivers in representative use scenarios and use environments…."
  - "FDA would generally accept a proposed generic combination product that had the same rates of error as the RLD, as demonstrated by an adequately designed comparative use human factors study or studies."
    - The terms "**severity**" and "**harm**" do not appear in the guidance document.

International Standard on HF for Medical Devices

- **Guidance from IEC 62366-1:2015**
  - Section 5.5, Select the hazard-related use scenarios
    - "The manufacturer shall select the hazard-related use scenarios to be included in the summative evaluation.
    - " The manufacturer shall select either:
      - "all hazard-related use scenarios; or
      - "the subset of the hazard-related use scenarios based on the severity of the potential harm that could be caused by use error (e.g. for which medical intervention would be needed)."
  - Annex A, section 3.21: rationale for definition of use error
    - "During the usage of a medical device, not every occurrence of a use error causes a hazardous situation and not every occurrence of a use error leads to harm. The same type of use error could lead to harm in one situation, while it is harmless in another."

Personal Analysis of Guidance Document / Generics

- **Aspects with which I agree:**
  - Compare the user interactions with both products, as identified in the task analyses and described in the instructions for use.
  - Identify the possible use errors that users could make due to user confusion between the reference product and the proposed new product.
  - Perform an analysis to determine the potential for hazardous situations and harm resulting from use errors associated with the differences in design.
  - If the differences are more than "minor," perform a human factors evaluation of the proposed new product with the intended users.
    - People who are naïve to the device type, and
    - People who are familiar with the existing / predicate / RLD device(s).

Personal Analysis of Guidance Document / Generics

- **Aspects that concern me:**
  - Belief that use errors are equal, and number of use errors is meaningful.
    - Study participants might make use errors on different tasks with the 2 devices, leading to different hazardous situations with different levels of potential harm.
  - "**Minimize differences**" between the proposed new device and the RLD
    - Appears in the guidance 5 times;
    - No mention is made of intellectual property or possible patent infringement.
  - No guidance is provided regarding changes made to the RLD device in the future.
    - Attempts to make all devices that deliver the same RLD constantly "the same" over time will be futile – and not in the best interest of patients.
  - Sponsors are encouraged to make their **instructions** the same, too.
    - A lot of old instructions are bad, especially if they were written before human factors assessments became expected and common practice.

Human factors engineering for medical devices

- Human factors testing assesses device's user interface, *not the user.*
  - When use errors occur, they indicate that something went wrong in the interactions between user and device; and human factors engineers *blame the user interface, not the user.*
- Methods: qualitative, not quantitative
  - ***Numbers don't tell the story because use errors are not equal.***
  - Common use errors might not matter.
    - Example: inserting a blood glucose test strip into a BG meter upside-down
      - Up to 50% probability

Uncommon use errors might matter a lot.

- Example: filling abdominal cavity, rather than pain pump, with pain medication
  - At time of FDA action: 8 deaths and 270 serious injuries; occurrence rate : 0.01%

THANK YOU