Are Results from Human Factors Studies Communicated Consistently and Transparently?

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Objective

- To use a targeted literature review to investigate whether the results of human factors studies are reported consistently and transparently.

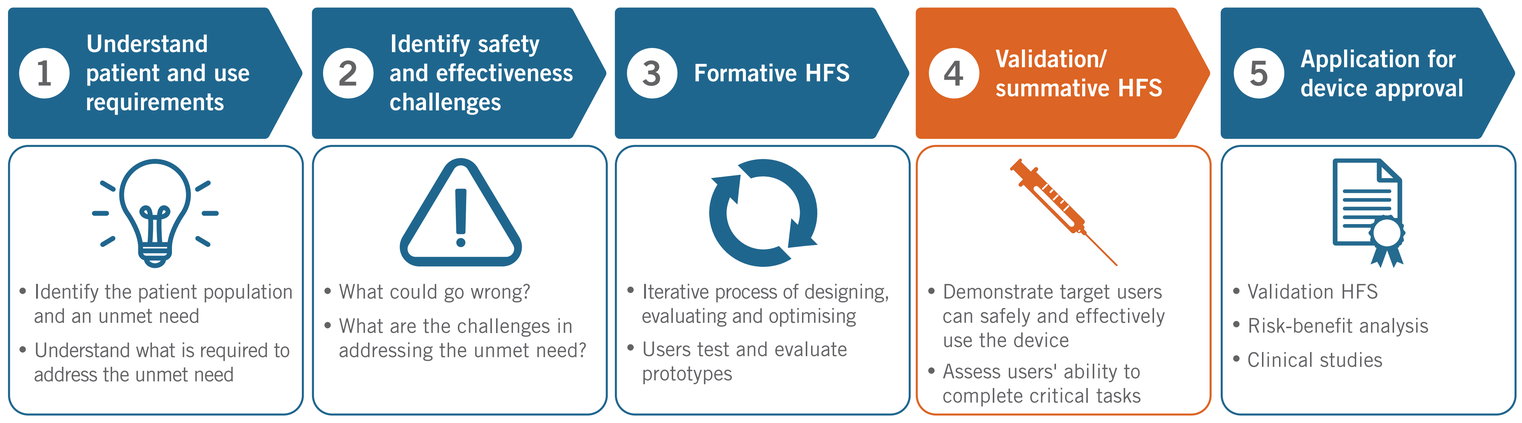
Background

- Validation human factors studies (HFS) are performed to demonstrate medical device usability and safety, and are required for approval of drug-device combinatorial products by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) **(Figure 1)**.
- End users perform a series of critical tasks, pre-defined as important for safe and effective use of the medical device.
- The results from validation HFS can help end users make informed decisions when choosing a medical device.
- The FDA and the EMA make general recommendations for reporting HFS,[1,2] with the aim of increasing consistency and transparency in reports. However, these criteria are ambiguous and not required for device approval.
- Currently, no guidelines exist for reporting HFS results.

Research Design and Methods

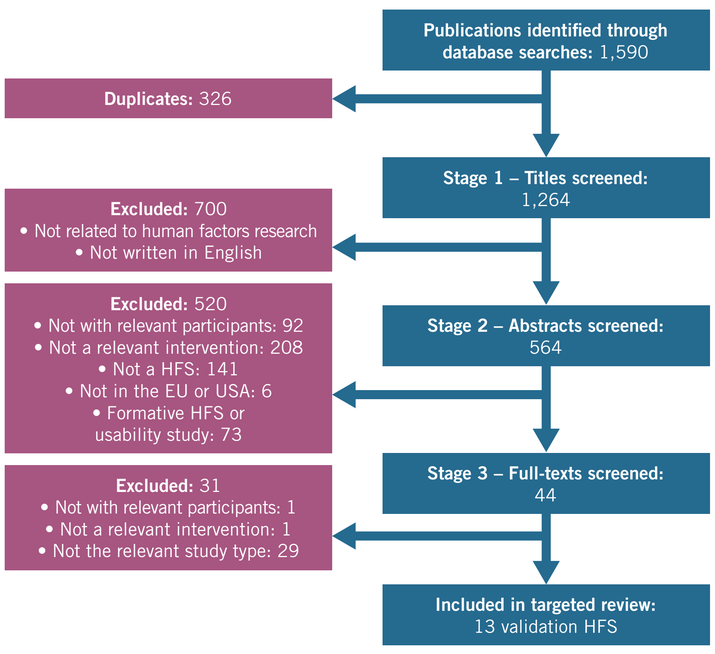
- A targeted search of MEDLINE®, Embase and Cochrane databases was conducted on 27/07/2018 to identify HFS published since January 2017 in the EU or USA. The search strategy included terms for human factors testing, devices and technologies, the patient population and publication type.

Figure 1 | Validation HFS in the device development process



HFS: human factors studies.

Figure 2 | PRISMA diagram



HFS: human factors studies.

- Each publication was assessed by a single reviewer at each review stage to identify validation HFS for inclusion.
- Initially, publication titles were reviewed to exclude publications unrelated to human factors testing, or not written in English.
- The abstracts of remaining publications were reviewed against pre-specified eligibility criteria **(Figure 2)**.
- The full-texts of remaining publications were reviewed against the same pre-specified criteria.
- Pre-defined extraction tables, based on FDA and EMA recommendations,[1,2] were used to record whether validation HFS publications included specific study information.

Results

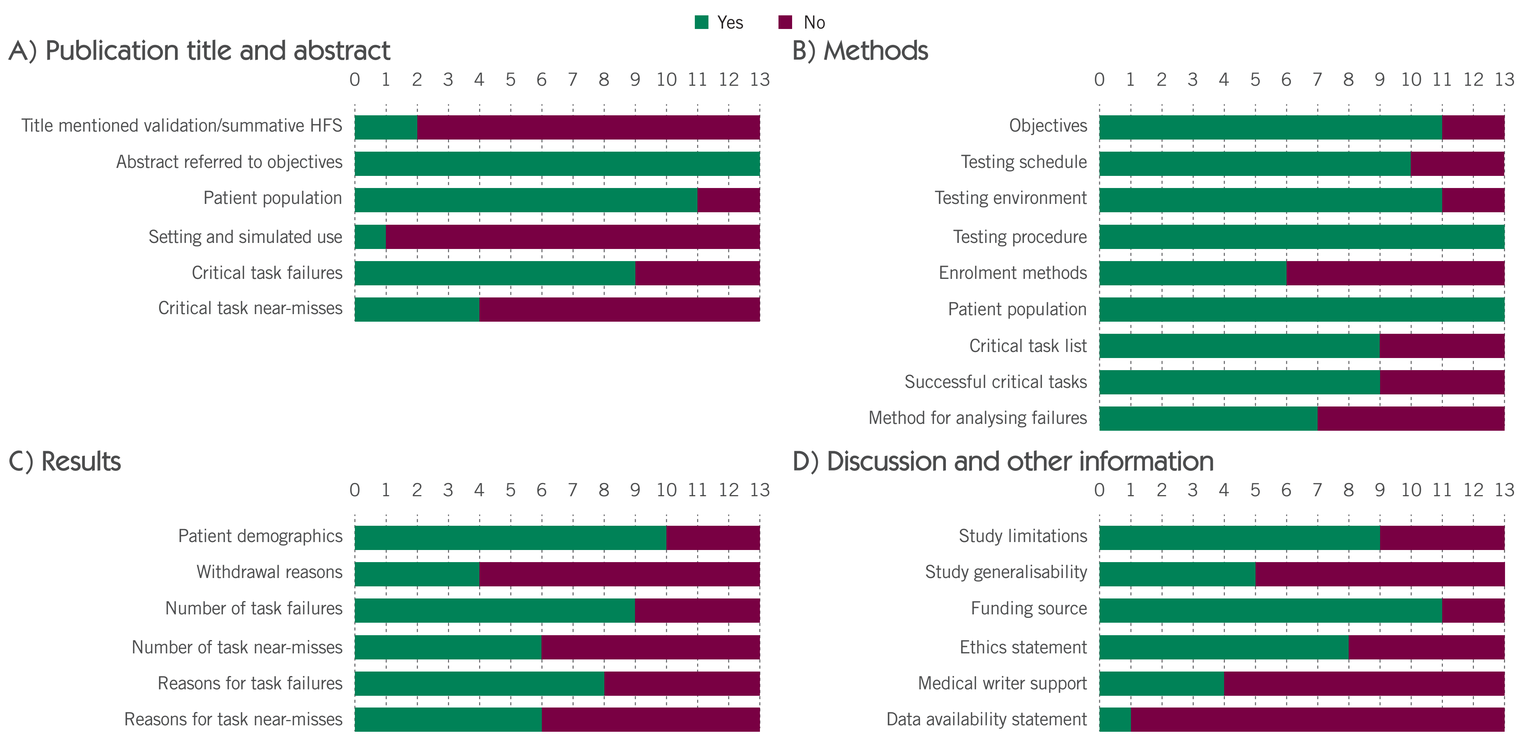
Literature Search Results

- 1,590 publications were identified through database searches. Of these, 13 were identified as validation HFS and included in the targeted literature review **(Figure 2)**. Formative HFS, usability studies, and HFS of unknown type were excluded.

Data Extracted from Validation HFS

- The number of included validation HFS publications meeting each reporting criterion are presented in **Figure 3**.
- Publications consistently reported study objectives, patient population, testing protocol (including the schedule, environment and procedure) and the funding source of the study (reported by ≥10/13 [75%] publications) **(Figure 3)**.
- The title and abstract of publications did not consistently report all information **(Figure 3A)**:
  - 11/13 titles did not mention the study type (i.e. validation HFS)
  - The simulated use setting and the number of near-misses were not reported by 12/13 and 9/13 studies, respectively
- Inconsistent reporting was also found in the main text of the publications with ≤6/13 (<50%) publications reporting the following information:
  - Enrolment methods or withdrawal reasons **(Figure 3B/C)**
  - Number or reason for critical task near-misses **(Figure 3C)**
  - Study generalisability **(Figure 3D)**
  - Medical writer support or data availability **(Figure 3D)**

Figure 3 | Number of publications meeting each criterion used to assess the reporting of HFS



HFS: human factors studies.

Conclusions

- Validation HFS-specific study information, such as critical task near-misses, is reported inconsistently.
- Inconsistent reporting makes it difficult for readers to interpret the results of validation HFS.
- Guidelines could aid the consistent and transparent reporting of HFS results.

Importance of Consistent Reporting

- Inconsistent reporting can make it more difficult for users to compare medical device safety and usability.
- End users cannot make fully informed decisions about the medical devices they use if data interpretation is difficult.
- Treatment experience may be negatively affected if end users are not using medical devices most suited to their needs.

Abstract

Objective

The design and usability of medical devices directly impact users' experience. Human factors studies (HFS) support and evaluate the design and usability of devices by assessing the performance of end users on a set of 'critical tasks' essential for safe and effective use; these studies can help users to make informed choices when selecting devices or technologies. Additionally, the FDA and EMA require a validation/summative HFS to be performed on the finalised device for regulatory approval of drug-device combination products.[1,2] Currently, there are no HFS reporting guidelines. The objective of this study was to review publications reporting HFS results to identify inconsistencies in study reporting.

Research Design and Methods

MEDLINE®, Embase and Cochrane databases were searched on 27/07/18 to identify validation HFS published since January 2017 in the EU or USA. A single researcher reviewed studies against pre-defined inclusion and exclusion criteria. Congress or review publications and interventional studies were excluded. Publications were compared to investigate differences in reported study details.

Results

1,264 studies were identified, 13 were validation HFS. Only 2/13 HFS titles stated the study was validation/summative; 11/13 described the patient population; 9/13 provided a list of critical tasks assessed to demonstrate safe and effective use; 9/13 studies reported the number of critical task failures, 8/9 of these studies reported reasons for failures. 6/13 reported the number of critical task near-misses.

Conclusions

Validation HFS are inconsistently reported, potentially making interpretation of results difficult for users. Medical writers can assist by transparently reporting HFS. Clear reporting guidelines could improve the consistency and transparency of future HFS reporting.

References

1. FDA. 2016. https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm484345.pdf [Last accessed: 18/09/2018]; **2.** MHRA. 2017. https://assets.publishing.service.gov.uk/government/uploads/system/ uploads/attachment_data/file/645862/HumanFactors_Medical-Devices_v1.0.pdf [Last accessed: 18/09/2018].

Author Contributions

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: EP, SW, VO, SF; Drafting of the publication, or revising it critically for important intellectual content: EP, SW, VO, SF; Final approval of the publication: EP, SW, VO, SF.

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