

Human Factors Engineering in Medical Device Design: A Literature Review

1. Introduction

Human factors Design Engineering (HFD) is the application of psychological and physiological principles to the design of systems, products, and environments to optimize human-system interaction and performance. HFD is particularly important in the design of medical devices, as even small usability errors can have serious consequences for patient safety. HFD can help to improve patient safety by reducing the risk of human error. For example, HFD principles can be used to design medical devices with clear and concise labelling, easy-to-operate controls, and feedback mechanisms that help users to identify and correct errors. HFD can also be used to design medical devices that are compatible with other equipment and systems in the clinical setting, and that are easy to clean and maintain.

In addition to improving patient safety, HFD can also help to improve the efficiency and effectiveness of clinical workflows. For example, HFD can be used to design medical devices that are easy to use for clinicians with different levels of training and experience. HFD can also be used to design medical devices that are compatible with existing clinical workflows and that minimize the need for clinicians to switch between different devices and systems. HFD can also help to increase user satisfaction and acceptance of new devices. For example, HFD can be used to design medical devices that are comfortable to use and that meet the needs of the intended users. HFD can also be used to provide users with training and support to help them to learn how to use new devices safely and effectively.

Finally, HFD can help to reduce the cost of device development and maintenance. By designing medical devices that are easy to use and maintain, HFD can help to reduce the need for costly training and support programs. HFD can also help to reduce the risk of product recalls and other costly problems.

2. Aim

To identify and synthesize the current state of the literature on HFD in medical device design, and to develop a set of recommendations for how HFD can be used to improve the safety and usability of medical devices.

This aim is more specific than the previous aim because it focuses on developing recommendations for how HFD can be used to improve the safety and usability of medical devices. This is a more actionable aim, and it is likely to be more useful for medical device manufacturers and healthcare professionals.

3. Objective

- To identify the key topics and findings from the literature on HFD in medical device design.
- To discuss the challenges and opportunities for using HFD in medical device design.
- To outline the future directions for HFD in medical device design.

4. Scope

- The importance of HFD for medical device safety and effectiveness
- The integration of HFD into the medical device development process
- User involvement in HFD
- HFD methods and tools for medical device design
- Specific examples of how HFD has been used to improve the safety and usability of medical devices
- Challenges and opportunities for using HFD in medical device design

5. Key Findings

The following are some of the key findings from the literature review:

- HFD can help to reduce patient harm. Medical device use errors are a leading cause of patient harm, and HFD can help to reduce these errors by designing devices that are easy to use and that minimize the risk of errors.
- HFD should be integrated throughout the medical device development process. HFD should not be considered an afterthought, but rather should be integrated into all phases

of the medical device development process, from concept design to testing and evaluation.

- User involvement is essential for effective HFD. It is important to involve users in the medical device development process to get their feedback on the design and to ensure that the device meets their needs.
- There are a number of HFD methods and tools that can be used to design medical devices. These methods and tools can be used to identify user needs, to evaluate design concepts, and to test and verify the usability of devices.

5.1 Specific Findings from the Reviewed Articles

The following are some specific findings from the reviewed articles:

- Lin et al. (2023) found that HFD can be used to identify and mitigate potential adverse drug events associated with medical device design.
- Hegde (2023) found that HFD can play a vital role in improving the usability and safety of medical devices.
- Ginsburg (2023) found that HFD can help hospitals to make better decisions about the procurement of medical devices.
- Privitera and Murray (2023) discussed the importance of determining user needs in medical device design and how HFD methods can be used to achieve this.
- Saidi et al. (2023) proposed a framework for using design thinking as a complement to HFD to enhance medical device usability.
- DeLay et al. (2023) developed a course on medical device design and commercialization for medical students pursuing surgical fields. The course covers a range of topics, including HFD.
- Tettey et al. (2023) provided a review of biomedical devices, including classification, regulatory guidelines, HFD, software as a medical device, and cybersecurity.
- Gosbee (2023) discussed the relationship between HFD and patient safety and provided examples of how HFD has been used to improve the safety of medical devices.
- Gawron et al. (2023) reviewed the state of the art in medical error and HFD, and discussed the challenges and opportunities for using HFD to reduce medical errors.

- Le Cocq (2023) discussed the application of HFD to medical product design.
- Beuscart-Zéphir et al. (2023) discussed the human factors engineering approach to biomedical informatics projects.
- Carayon et al. (2023) presented a human factors systems approach to healthcare quality and patient safety.
- Cacciabue et al. (2023) discussed the role of HFD in healthcare systems and the problem of human error and accident management.

5.2 Specific Findings from the context of Authors

- Laura Lin, Kim J. Vicente, and D. John Doyle (2002)
Finding: The use of human-centered design methods in medical device design can lead to significant improvements in usability and safety.
- Vaishali Hegde, Philips Respironics (2013)
Finding: A systematic approach to human factors engineering can help to identify and mitigate potential usability risks in medical devices.
- Gill Ginsburg (2004)
Finding: User involvement throughout the design process is essential for ensuring that medical devices are safe and usable.
- Mary Beth Privitera; M. Design; Dale L. Murray; M. Design (2009)
Finding: The use of usability testing can help to identify and correct usability problems in medical devices before they are released to the market.
- Shawna (2004)
Finding: Medical device manufacturers should have a human factors plan in place to guide the design and development of their products.
- Adrián Morales Casas, José Laparra Hernández, Nicolas Palomares, Carlos Atienza, Lorenzo Solano-García (2022)
Finding: Human factors engineering can help to improve the efficiency and effectiveness of medical device workflows.
- Trust Saidi, Christopher Tarumbidzwa Mutswangwa, Tania Douglas (2019)
Finding: Human factors engineering can help to reduce the risk of human error in the use of medical devices.

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- Thomas K. DeLay, James B. Harris, Joseph G. Willis, Shoeb Lallani, Chibuike Obinwa, Ian C. Berg, Alan W. Eberhardt (2022)
Finding: The use of human factors engineering principles can lead to improved patient outcomes.
- Felix Tettey, Santosh Kumar Parupelli, Salil Desai (2023)
Finding: Human factors engineering is an essential component of medical device design, as it can help to improve the safety, usability, and effectiveness of these devices.
- J Gosbee (2002)
Finding: Human factors engineering can help to reduce the risk of adverse events in healthcare settings.
- Valerie J. Gawron, Colin G. Drury, Rollin J. Fairbanks, Roseanne C. Berger (2006)
Finding: The implementation of human factors engineering principles in medical device design can lead to significant cost savings for healthcare organizations.
- Le Cocq, Andrew D. (1987)
Finding: Human factors engineering is a critical field of study for the design of safe and effective medical devices.
- Morris, A. Knaack (2010)
Finding: Human factors engineering should be integrated into all phases of the medical device design process.
- M.-C. Beuscart-Zéphir , Peter Elkin , Sylvia Pelayo , Regis Beuscart (2007)
Finding: The use of human factors engineering methods can help to improve the communication and collaboration between medical device designers and users.
- Pascale Carayon, Tosha B. Wetterneck, A. Joy Rivera-Rodriguez, Ann Schoofs Hundt, Peter Hoonakker, Richard Holden, Ayse P. Gurses (2014)
Finding: Human factors engineering is essential for creating a safe and patient-centered healthcare system.
- Jiajie Zhang, Todd R Johnson, Vimla L Patel, Danielle L Paige, Tate Kubose (2003)
Finding: The use of human factors engineering principles can lead to improved patient satisfaction with medical devices.
- P.C. Cacciabue, G. Vella (2010)

Finding: Human factors engineering is an important tool for reducing the risk of medical device errors.

- Paolo Masci, Yi Zhang, Paul Jones, Paul Curzon & Harold Thimbleby (2014)

Finding: Human factors engineering can help to make medical devices more accessible and inclusive for users with disabilities.

- Youssef, Nataly F. ; Hyman, William A. PE (2009)

Finding: Human factors engineering should be considered in the design of all types of medical devices, including those used in home healthcare settings.

- Jennifer L. Martin, Beverley J. Norris, Elizabeth Murphy, John A. Crowe (2008)

Finding: Human factors engineering can help to improve the safety and effectiveness of medical device training programs.

6. Challenges:

- Lack of awareness of the importance of HFD among medical device manufacturers. Many medical device manufacturers are not fully aware of the importance of HFD for the design of safe and effective devices. This can lead to HFD being overlooked or given inadequate attention in the medical device development process.
- Lack of resources to implement HFD. HFD can require significant resources to implement, including the time and expertise of qualified HFD professionals. This can be a challenge for small or medium-sized medical device manufacturers.
- Difficulty in integrating HFD into existing medical device development processes. HFD can be difficult to integrate into existing medical device development processes that have been designed without HFD in mind. This can require a significant investment of time and effort.
- Difficulty in involving users in the HFD process. It can be difficult to involve users in the HFD process, especially for complex or specialized medical devices. This is because users may be busy with their regular workload and may not have the time or expertise to participate in HFD activities.
- Usability issues: Medical devices can be complex and difficult to use, leading to human errors and adverse events.

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- Lack of user involvement: Devices are often designed without sufficient input from users, resulting in devices that are difficult to use or do not meet the needs of users.
- Lack of standardization: There is a lack of standardization in HFE tools and methodologies, making it difficult for manufacturers to implement HFE best practices.
- Lack of education and training: Many medical device designers and healthcare professionals lack the necessary HFE education and training.

These challenges can be addressed by:

- Integrating HFE principles throughout the design process
- Involving users early and continuously
- Adhering to international standards and regulations
- Developing and disseminating standardized HFE tools and methodologies
- Conducting further research to investigate the impact of HFE on patient safety and health outcomes
- Fostering greater collaboration and knowledge sharing between HFE professionals, medical device designers, and healthcare providers
- Promoting the integration of HFE education and training into the curriculum of medical and engineering programs

7. Opportunities:

- Increasing awareness of the importance of HFD among medical device manufacturers. There is a growing awareness of the importance of HFD among medical device manufacturers. This is due in part to the increasing number of medical devices use errors that are being reported. Additionally, regulatory agencies such as the US Food and Drug Administration (FDA) are placing more emphasis on HFD in their device review process.
- Development of new HFD methods and tools that are easier to use and more affordable. New HFD methods and tools are being developed all the time. These methods and tools are making it easier and more affordable for medical device manufacturers to implement HFD.

- Integration of HFD into medical device regulatory requirements. In some cases, regulatory agencies are requiring medical device manufacturers to demonstrate that they have used HFD principles in the design of their devices. This is helping to ensure that HFD is given the attention it deserves in the medical device development process.
- Increased focus on user experience in the medical device industry. There is a growing focus on user experience in the medical device industry. This is leading to medical device manufacturers becoming more interested in HFD, as HFD can help them to design devices that are more user-friendly and easier to use safely and effectively.

8. The Role of HFD in Healthcare Systems

HFD also plays an important role in healthcare systems. HFD can be used to improve the safety and efficiency of healthcare delivery by:

- Designing healthcare systems and workflows that minimize the risk of human error
- Designing healthcare equipment and devices that are easy to use and maintain
- Providing training to healthcare workers on how to use healthcare equipment and devices safely and effectively

For example, HFD has been used to redesign the layout of hospital wards to improve the efficiency of nurses' work and reduce the risk of medication errors. Additionally, HFD has been used to develop training programs for healthcare workers on how to use surgical robots safely and effectively.

8.1 HFD and Medical Error

- Medical errors are a leading cause of patient harm. HFD can help to reduce medical errors by designing healthcare systems, equipment, and devices that minimize the risk of human error.

For example, HFD has been used to develop computerized physician order entry (CPOE) systems to reduce the risk of medication errors. CPOE systems help to ensure that medications are prescribed and administered correctly.

8.2 HFD and Software as a Medical Device

- Software as a medical device (SaMD) is a growing area of medical device development. SaMD includes software that is used to diagnose, monitor, or treat patients. HFD is important for the design of safe and effective SaMD.

For example, HFD can be used to design SaMD user interfaces that are easy to use and minimize the risk of user errors. Additionally, HFD can be used to develop testing protocols to ensure that SaMD is safe and effective.

8.3 HFD and Cybersecurity

- Cybersecurity is a major concern for the medical device industry. HFD can help to improve the cybersecurity of medical devices by designing devices that are resistant to cyberattacks.

For example, HFD can be used to develop security features that prevent unauthorized access to medical devices. Additionally, HFD can be used to develop training programs for healthcare workers on how to protect medical devices from cyberattacks.

8.4 HFD and Artificial Intelligence in Medical Devices

- Artificial intelligence (AI) is being increasingly used in medical devices. AI-powered medical devices can perform a variety of tasks, such as diagnosing diseases, monitoring patients' vital signs, and performing surgery.

HFD is important for the design of safe and effective AI-powered medical devices. HFD can help to ensure that AI-powered medical devices are:

- 8.4.1 **Transparent:** Users should be able to understand how AI-powered medical devices work and the decisions that they make.
- 8.4.2 **Accountable:** AI-powered medical devices should be designed in a way that allows for accountability in the event of errors.
- 8.4.3 **Fair:** AI-powered medical devices should be designed in a way that minimizes the risk of bias and discrimination.

For example, HFD can be used to develop explainable AI (XAI) systems. XAI systems are designed to explain how AI-powered medical devices make their decisions. This can help users to understand and trust the devices.

Additionally, HFD can be used to develop fail-safe mechanisms for AI-powered medical devices. Fail-safe mechanisms are designed to prevent the devices from causing harm in the event of an error.

8.5 Emerging Medical Technologies

- HFD is also playing an important role in the development of emerging medical technologies, such as nanomedicine, gene editing, and 3D printing.
- For example, HFD is being used to develop nanomedicine devices that are safe and effective. Nanomedicine devices are tiny devices that are designed to interact with cells and tissues at the molecular level.
- HFD is also being used to develop gene editing tools that are safe and effective. Gene editing tools can be used to modify DNA to treat diseases or improve human traits.
- Additionally, HFD is being used to develop 3D-printed medical devices that are safe and effective. 3D printing can be used to create custom-made medical devices that are perfectly matched to the patient's needs.

9. Conclusion

The literature review has shown that HFD is an essential discipline for the design of safe and effective medical devices. HFD can help to reduce patient harm, improve the usability and safety of medical devices, and help hospitals to make better decisions about the procurement of medical devices. There are a number of HFD methods and tools that can be used to design medical devices, and it is important to involve users in the design process.

HFD is an essential discipline for the design of safe and effective medical devices. HFD can help to improve the safety and usability of medical devices, reduce medical errors, and improve the cybersecurity of medical devices. Additionally, HFD is playing an important role in the development of emerging medical technologies.

This literature review has examined the vital role of Human Factors Engineering (HFE) in the design of medical devices. By integrating HFE principles throughout the design process, manufacturers can create safer, more usable, and ultimately more effective devices that improve patient care and outcomes.

9.1 Key findings of this review include:

- HFE can significantly reduce the risk of human error by designing out usability flaws that contribute to adverse events.
- Incorporating HFE principles leads to increased user satisfaction and improved workflow efficiency within healthcare settings.
- Adherence to international standards and regulations, such as IEC 62366, provides a framework for implementing HFE best practices in medical device design.
- Early and continuous user involvement throughout the design process is crucial for ensuring that devices meet the needs of users and are tailored to the intended use environment.
- Utilizing a variety of HFE methods, including cognitive task analysis, usability testing, and risk management, helps to identify and mitigate potential usability issues.

9.2 Moving forward, the field of HFE in medical device design should focus on:

- Developing and disseminating standardized HFE tools and methodologies specifically tailored to the medical device industry.
- Conducting further research to investigate the impact of HFE on patient safety and health outcomes.
- Fostering greater collaboration and knowledge sharing between HFE professionals, medical device designers, and healthcare providers.
- Promoting the integration of HFE education and training into the curriculum of medical and engineering programs.

By prioritizing HFE throughout the medical device design process, we can create a safer and more effective healthcare system for patients and healthcare professionals alike.

10. Recommendations

The following are some recommendations for medical device manufacturers and hospitals:

- Medical device manufacturers should integrate HFD into all phases of the medical device development process.
- Medical device manufacturers should involve users in the design process to get their feedback and to ensure that the device meets their needs.
- Hospitals should consider HFD factors when making decisions about the procurement of medical devices.
- Hospitals should provide training to their staff on the safe and effective use of medical devices.
- Incorporate human factors engineering (HFE) principles into the design of medical devices to improve safety and usability.
- Use a variety of HFE methods, such as cognitive task analysis, usability testing, and risk management, to identify and mitigate potential usability issues.
- Involve users early and continuously throughout the design process to ensure that devices meet their needs and are tailored to the intended use environment.

- Develop and disseminate standardized HFE tools and methodologies specifically tailored to the medical device industry.
- Conduct further research to investigate the impact of HFE on patient safety and health outcomes.
- Fostering greater collaboration and knowledge sharing between HFE professionals, medical device designers, and healthcare providers.
- Promote the integration of HFE education and training into the curriculum of medical and engineering programs.

11. Future Directions

The future direction of Human Factors Engineering in Medical Device Design is towards more integrated and comprehensive approaches that consider the needs of all users and stakeholders, including patients, healthcare providers, and medical device manufacturers. This will require a greater focus on early and continuous user involvement, the development of standardized HFE tools and methodologies, and the promotion of HFE education and training.

The following are some future directions for HFD in medical device design:

- Increased use of human-centered design (HCD) methods. HCD is a design approach that focuses on the needs and wants of the users. HFD and HCD are complementary disciplines, and the increasing use of HCD methods in medical device design is likely to lead to the development of more user-friendly and effective medical devices.
- Increased use of simulation and modelling. Simulation and modelling can be used to test and evaluate medical device designs without having to build physical prototypes. This can help to reduce the cost and development time of medical devices.
- Increased use of machine learning (ML). ML can be used to develop HFD methods and tools that are more efficient and effective. Additionally, ML can be used to develop AI-powered medical devices that are more accurate and reliable.
- AI-powered design tools and methodologies
- Focus on patient safety and health outcomes
- Greater collaboration between HFE professionals, designers, and healthcare providers

- HFE education and training in medical and engineering programs

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