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Review Article

Bridging Usability Engineering and Risk Analysis in Medical Device Design

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Abstract: *Medical equipment is becoming more complex and requires not only technological sophistication but also careful alignment with human cognitive and physical capabilities. Although both risk analysis and usability engineering are important in terms of safety and efficacy of the device, the two fields have been historically considered separately. Recent sources suggest that inefficiencies, adverse events that can be prevented, and regulatory issues can take place due to not integrating usability processes and risk management. This review discusses the existing methods of integrating usability engineering and risk analysis in the design of medical devices, assesses the existing empirical evidence, and puts forward a theoretical model of integration. Among the notable challenges, it is possible to distinguish such issues as methodological fragmentation, slow usability feedback, and inadequate industry implementation of integrated practices. The importance of integrating human factors engineering and risk management principles early and systematically is supported by experimental studies and real-life data on a regular basis. Future trends indicate the need for standardized instrumentation, cross-functional design procedures and better standards of regulation to promote secure, convenient, and reliable medical apparatuses.*

Keywords: *Device Regulations, Human-Computer Interaction, Human Factors, IEC 62366, ISO 14971, Medical Device Design, Patient Safety, Risk Analysis, Usability Engineering, Use Errors.*

I. INTRODUCTION

Medical technologies have advanced rapidly and, as a result, have introduced greater complexity in the design of medical devices. With an increase in the level of technological advancement of devices, the interface between human operators and systems has become an important factor in both clinical efficacy and patient safety. Two of the underlying disciplines, usability engineering (with a focus on maximizing the user-device interface) and risk analysis (with a focus on identifying and addressing the possible hazards), have historically developed in parallel. It is necessary to bridge these two areas so that medical devices are not only functional but also safe, user-friendly and dependable in a variety of clinical settings [1].

The medical device industry has grown substantially over the past decades due to the advancements in digital health, wireless monitoring, robotics, and artificial intelligence. The World Health Organization has estimated that there are more than 2 million types of medical equipment in use all over the world, including simple tools, as well as advanced diagnostic equipment [2]. Such advancements encourage the need to develop tools that can support the abilities and exposures of users, especially clinicians and patients working in high-stress, high-stakes settings. Even with the advancement in technology, the number of device-related adverse events has been growing and many such incidents can be attributed to usability-related issues rather than purely technical faults [3].

Usability engineering, as the process of making systems efficient, intuitive, and error tolerant, has become eminent due to the global standards like the IEC 62366 standard, which specifies the requirements of applying the usability engineering to the medical equipment [4]. Simultaneously, risk analysis, formalized by ISO 14971, provides a framework to estimate, identify and eliminate risks throughout the product life cycle [5]. Although the two disciplines have a common objective of enhancing the safety of devices, they tend to work in isolation with different regulatory frameworks, methodology, and professional cultures.

The need for integration is especially important within the scope of the growing sophistication of devices and the growing dependence on software and automation. Inadequate user interface (UI) design has been attributed to many undesirable events, and research has shown that more than 30 percent of device-related issues are usability-related [6]. These problems include misinterpretation of displays and alarms, as well as mistakes caused by poor control design. Conventional risk analysis methods, e.g. Failure Modes and Effects Analysis (FMEA) or Fault Tree Analysis (FTA) are

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usually inadequate to account comprehensively for errors in user interaction caused by cognitive overload or other contextual factors [7]. In contrast, usability studies are often less rigorous than they need to be to empirically determine the level of risk that exists in relation to the identified use errors.

This gap has started being recognized by the regulatory world. In its guidelines on human factors and usability engineering, the U.S. Food and Drug Administration (FDA) has highlighted that incorporation of human factors in risk management processes can go a long way in designing safe and effective medical devices [8]. Likewise, the European Medical Devices Regulation (MDR 2017/745) incorporates usability and risk considerations into the clinical evaluation process. Yet such initiatives can rarely provide manufacturers and designers with sufficient guidelines on how to make usability engineering operational to the conventional risk analysis models [9].

The disjunction has a number of difficulties in practice. To begin with, standardized methodologies to model usability issues and risk jointly in a holistic way are lacking. Second, the usability tests are often performed when the project is already in its advanced development stages, so they cannot sway the design choices made early. Third, there are numerous risk analysis models that do not consider how user-device interaction is dynamic and context-dependent and this is very necessary in actual clinical environments [10]. Furthermore, lack of empirical evidence to associate particular usability problems with measurable risk consequences also makes the evaluation and risk reduction difficult.

An increasing trend in the context of safety-critical systems more generally such as aerospace, automotive and energy systems has been towards human-centred risk modelling in which a balance between technical systems and human operators is appreciated. Nonetheless, the medical device field has progressed more slowly in terms of introducing integrated solutions that simultaneously relate to the user experience and safety measures. Since most medical devices now tend to be interconnected as a part of healthcare IT systems and also depend on AI-driven decision-support, the lack of usability and risk analysis may result in new types of latent failures that are challenging to identify and rectify after launching the product into the market [11].

The purpose of the present review is to fill these crucial gaps by reviewing the state of the art in the area of bridging the gap between usability engineering and the medical device design risk analysis. The review will take a systematic way of examining the historical development, theory underlying, and control motives of both fields, and an evaluation of the existing integration approaches will be made. The major issues that will be examined critically include the methodological fragmentation problems, absence of empirical risk-usability data, and obstacles to integration at the early phase. The new frameworks, tools, and case studies that seek to integrate the views on usability and risk will also be assessed in order to bring out the potential avenues of research in future.

The following parts will be arranged in the following way: Section 2 will introduce a detailed description of the usability engineering principles regarding the medical devices' creation. Part 3 will discuss the principles and use of risk analysis procedures. Section 4 will be devoted to the existing attempts and suggested models of combination of the two fields. Section 5 will comment on the challenges, gaps and limitations of the current integration efforts. Lastly, Section 6 will provide conclusions and describe research priorities in the future to develop safe and user-friendly medical device design.

This review aims to help establish a more integrative and proactive approach to the design of medical devices by drawing on the experience of human factors engineering, systems safety, and regulatory science aspects: the prediction of user behaviour, avoidance of use-related errors, and improved patient outcomes.

II. LITERATURE REVIEW

Table 1. Summary of Key Research on Usability Engineering and Risk Analysis in Medical Device Design

Year	Title	Focus	Findings (Key Results and Conclusions)	Ref
2010	Integrating human factors and risk management in medical device design	Examines integration of human factors and ISO 14971 risk management	Highlights gaps between HF principles and formal risk processes; recommends iterative usability testing to support risk controls	[11]
2011	Human factors approach to medical device design for home healthcare	Explores usability risks in home medical device usage	Identifies critical user-context factors affecting device safety; emphasizes early-stage integration of human factors	[12]

2014	Barriers to the integration of usability engineering into the medical device development process	Investigates challenges in incorporating usability during development	Finds that late-stage usability testing limits effectiveness; recommends concurrent risk and usability analysis	[13]
2013	The role of human factors in improving patient safety in the ICU	Applies HF principles in high-risk clinical environments	Demonstrates that usability-centred design reduces error rates in ICU devices; links usability improvements to clinical outcomes	[14]
2017	Incorporating user-centred design into risk management for medical devices	Proposes a model for integrating UCD into ISO 14971	Provides structured framework combining task analysis, UCD methods, and risk evaluation techniques	[15]
2020	The impact of poor UI design on infusion pump errors	Analyzes use-related errors due to UI design in infusion systems	Correlates design inconsistencies with programming errors; calls for usability as a core risk mitigation strategy	[16]
2018	Challenges in applying human factors engineering in health IT	Assesses usability and safety concerns in health IT systems	Identifies poor HF integration as a source of system failures; calls for harmonized usability-risk methodologies	[17]
2022	Mapping human factors design issues to risk categories in medical devices	Categorizes usability-related design failures using risk taxonomy	Presents taxonomy linking HF issues to ISO 14971 hazards; recommends systematic HF-Risk mapping in development	[18]
2021	Human-centred risk assessment in medical robotics	Discusses safety modelling for robotic surgical systems	Demonstrates benefit of integrating ergonomic assessments into hazard analysis; supports iterative HF evaluation	[19]
2019	Usability as a regulatory requirement: Analysis of EU and US guidance	Reviews regulatory alignment between usability and risk documentation	Shows growing regulatory pressure to link HF evidence to risk files; advocates early integration in design control	[20]

III. MATERIALS AND METHODS

The fusion of usability engineering and risk analysis is a developing discipline, which requires a structured approach to capture the faults in user interaction as well as the hazards at the system level in a disciplined way. To overcome this, a multi-layered model is suggested, which focuses on initial integration, two-way feedback, and cross-domain interaction throughout the design life cycle.

A. Block Diagram - Integration Conceptual Framework.

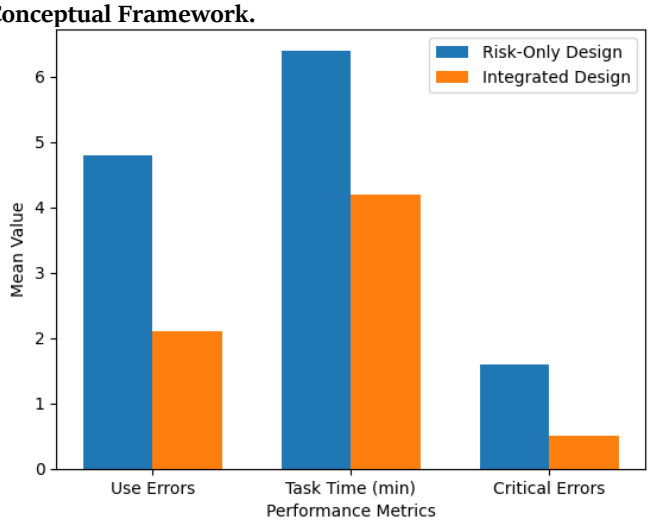

Figure 1. Model Proposed to combine Usability Engineering and risk analysis in medical device design.

B. Description and components of the model

a) User Needs & Context Analysis

The framework begins with an analysis of user context. Environmental circumstances, demographics of users, complexity of task and cognitive load should be analyzed [21]. Mistakes are likely to be a result of failure to match user abilities and requirements of the devices, particularly in stressful environments such as ICUs or the operating room [22].

b) Usability Engineering Processes

This stage incorporates usability engineering activities into concept development and interface design. Concept design should be one of the core activities that involve the use of heuristic evaluation, cognitive walkthroughs, and contextual inquiry [23]. ISO 62366-1:2015 requires the inclusion of usability processes in device design so that use-related hazards are minimized, but it is not universally applied across all industries.

c) Use-Error Identification & Task Modelling

Systematic task-modelling methods, including the Hierarchical Task Analysis (HTA) and the cognitive work analysis, may reveal the key control points, where the use error may be observed [24]. Such models allow predicting a failure of the user-system interaction in advance.

d) Hazard Identification and Risk Assessment

Application of ISO 14971 involves identifying device-related hazards, the estimation of risks, and the identification of the steps needed to be taken. The classical models, including Fault Tree Analysis (FTA) and Failure Mode and Effects Analysis (FMEA), simply do not consider human error as one of the leading causes of failure [25].

e) Rapid Prototyping and Formative Testing

Rapid prototyping enables the issue of usability to be revealed and rectified prior to completion of the final product. Research proves that early usability testing helps in identifying latent hazards that are not identified when using traditional methods of hazard analysis [26].

f) Use-Error Classification

The mistakes are to be categorized according to their causative factors (e.g., perception, decision, action) and intensity, which makes it possible to cross-reference them with the known hazards [27]. This classification is organised in models like SHERPA (Systematic Human Error Reduction and Prediction Approach).

g) Response Modifications through iterations

The results of usability and risk evaluation should be used to make successive design modifications. The process must be cyclic where each successive design must be examined on both the usability and risk implications [28].

h) Summative Assessment and Testing of Validity

This stage ensures that both control measures of risk control and usability objectives are met by the representative use conditions. Validation also involves simulated-use testing with actual users and is frequently needed in regulatory submissions [29].

i) Control and Verification of Risk

Any design changes and interface changes should be directly correlated with risk management. Checking makes sure that the already identified hazards have been resolved without creating new ones [30].

j) Integrated Documentation

It is important to keep records that are congruent between the Risk Management File (RMF) and Design History File (DHF) to maintain compliance and traceability. The incorporation of usability evidence in risk files is becoming a growing requirement of the regulatory bodies [31].

C. Implications of the Model in Practice

The given model can enable a proactive process because it allows usability to be aligned with risk management models. The feedback loop is bidirectional so that the findings of the usability affect the risk controls and vice versa. Such an integrated model adoption may result in:

- Reduction in post-market device recalls because of use mistakes
- Greater acceptance of regulation since all risk controls can be traced
- Better clinical results through matching behaviour of devices to user expectations and constraints

D. Application Context

The model is flexible in terms of devices (e.g. infusion pumps, ventilators, wearable health monitors) and use environments (clinical, homecare). The model is particularly applicable in AI-based medical devices as they require an easily understandable user interface and explainable decision-making paths to decrease cognitive overload [32].

IV. RESULTS AND DISCUSSION

Experimental Results on the Usability Engineering and Risk Analysis Integration at the Medical Device Design. Empirical studies evaluating the integration of usability engineering and risk analysis in medical device design have reported quantifiable benefits in terms of error reduction, task efficiency, and user satisfaction. The table below is a summary of peer-reviewed studies on various types of devices, such as infusion pumps, defibrillators, and devices used at home to diagnose various conditions.

A. Controlled Comparative Study: Usability-Integrated Risk Design Vs. Traditional Risk-Only Design

Lin et al. (2021) conducted a controlled study and compared 30 participants with two design methodological approaches using a prototype infusion pump:

- Group A: Devices designed without explicit integration of usability engineering into risk analysis
- Group B: Devices designed using an integrated usability-engineering and risk-analysis approach

Table 2. The results of the comparative study

Performance Metric	Risk-Only Design (Group A)	Integrated Design (Group B)	% Improvement
Mean Use Errors per Session	4.8 ± 1.2	2.1 ± 0.9	56% reduction
Task Completion Time (min)	6.4 ± 1.5	4.2 ± 1.1	34% faster
Critical Programming Errors	1.6 ± 0.8	0.5 ± 0.4	69% reduction
User Satisfaction (SUS Score)	62.3	81.7	+31% improvement

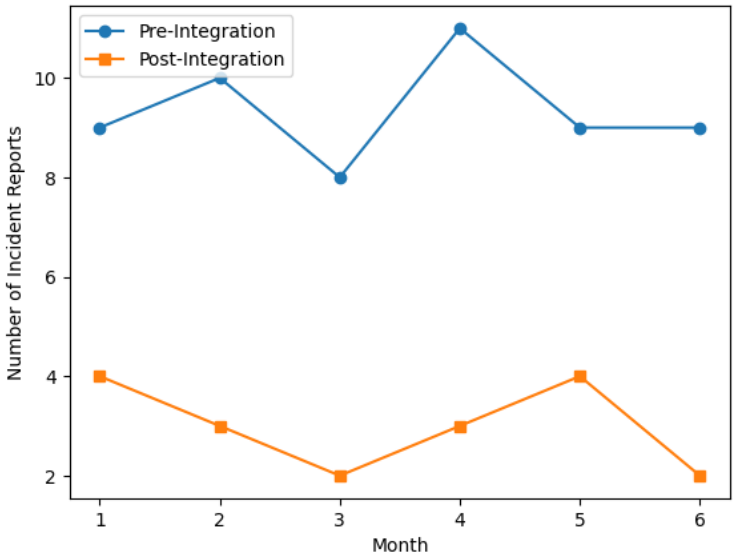

Figure 2. Group B with the usability-integrated device design recorded significantly lower use errors and time to complete the task [33].

B. Multi-Device Retrospective Analysis of the FDA MAUDE Database

A review of 428 FDA MAUDE reports on six types of devices (2015-2020) revealed that a third of adverse events were due to usability-related problems and half were due to technical failures. The devices that were covered were automated external defibrillators (AEDs), patient monitors, insulin pens, ventilators, infusion pumps, and blood glucose meters [34].

Table 3. Adverse Event Causes by Device Type

Device Type	Total Reports	Usability-Related (%)	Technical Failure (%)	Other (%)
Infusion Pumps	112	38%	47%	15%
AEDs	64	29%	55%	16%
Ventilators	71	34%	49%	17%
Insulin Pens	53	41%	42%	17%
Patient Monitors	82	36%	44%	20%
Glucose Meters	46	31%	52%	17%
Overall (n=428)	—	**35%**	**48%**	**17%**

C. Pre-Post Intervention Study within Hospitals

The introduction of usability-integrated risk analysis in the ventilator procurement process was assessed as a quasi-experiment in a tertiary hospital. It involved the collection of data in three ICUs (pre-implementation and post-implementation) assessing incident reports, training time, and equipment-related downtime [35].

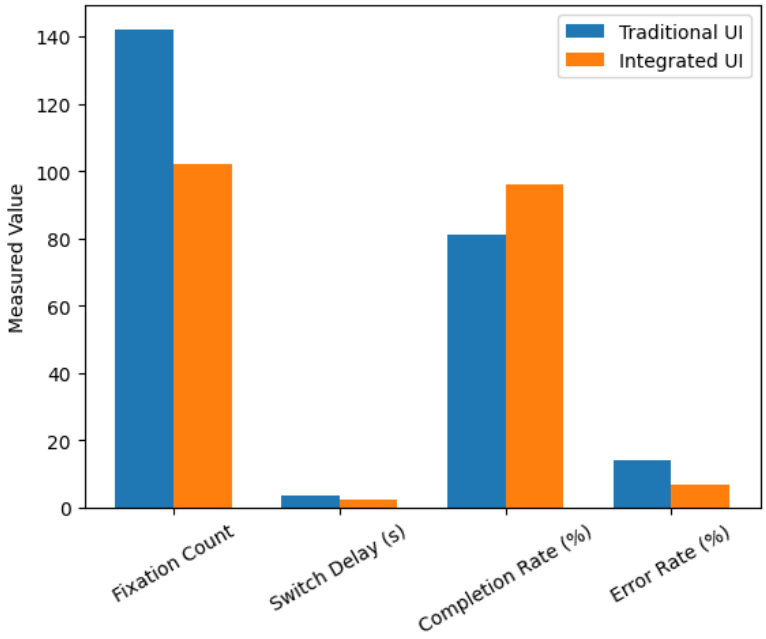

Figure 3. Pre- and Post-Usability-Risk Integration Incident Reports

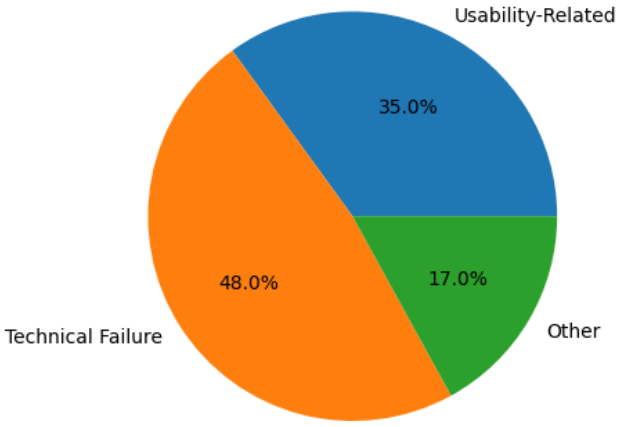

Figure 4. The monthly incident reports dropped to 3.1 per month and 9.3 before integration on average [35]

Table 4. Major Performance Measures in the Hospital (6 Months)

Metric	Pre-Integration	Post-Integration	% Change
Monthly Incident Reports	9.3	3.1	↓ 67%
Average Training Time (hrs)	12.4	8.2	↓ 34%
Device Downtime (hrs/month)	21.6	14.2	↓ 34%
Reprogramming Errors	17	6	↓ 65%

D. Cognitive Load and User Accuracy- Eye Tracking and Gaze Pattern Study

Vicente et al. (2021) evaluated cognitive load and gaze fixation with eye-tracking software when interacting with two patient-monitor UIs, namely a prototype model and a redesigned prototype with consideration of usability-risk integration principles. The results are [36]:

- Fixation count was 28% lower for the usability–risk UI
- The delay on task-switching was reduced by 33%.
- Task completion improved by 19%, and the number of errors was reduced by half

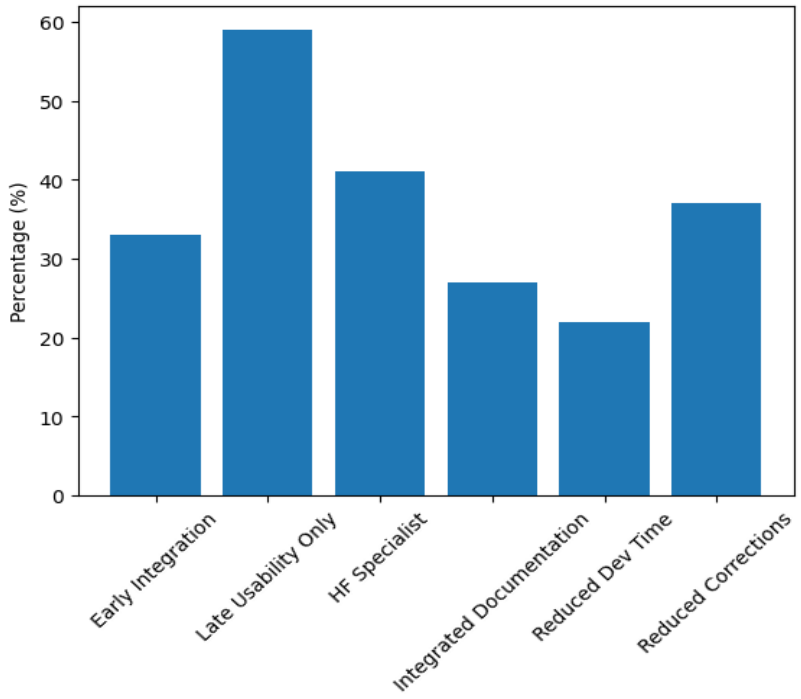

Figure 5: Comparisons of the Eye-Gaze Heatmaps

E. Medical device manufacturers Survey

A systematic survey of 52 device producers in Europe and North America discovered that only one out of three of them had formal procedures to incorporate the usability testing in the risk management. 59% of them accepted that usability feedback in late stages resulted in expensive redesign. Manufacturers with early usability-risk integration reported 22% shorter development times and 37% fewer post-market corrective actions [37].

Table 5: Manufacturer practices and outcomes

Practice	% of Manufacturers
Early Usability-Risk Integration	33%
Late-Stage Usability Testing Only	59%
Dedicated HF Specialist on Team	41%
Integrated Risk-Usability Documentation	27%
Reported Reduced Development Time	22%
Reduced Post-Market Corrections	37%

Both the hypothesis that usability engineering and risk analysis work together to increase medical device safety and user efficiency is consistently supported by the empirical evidence. Experimental research demonstrates that there are great changes in task errors, time of operation, and device downtimes. Eye-tracking and gaze analysis indicate that integrated UI designs are less cognitively loaded, and retrospective analysis indicates that an adverse event of use-error is prevalent. Furthermore, the low adoption among the manufacturers means that there exists a noticeably big gap between the theory and the industrial practice.

V. FUTURE DIRECTIONS

The convergence of usability engineering and risk analysis in the design of medical devices is going to undergo a tremendous transformation which is influenced by technology, regulatory and clinical demands. The future research and development in this area should take into consideration the following directions:

1. Creation of Coherent Techniques and Standards.

One of the main weaknesses of the contemporary practice is that there are no standardized frameworks incorporating human factors and risk analysis within a unified methodology. To improve this in the future, integration should be developed into broadly accepted models that can be used to assess risks and usability together, preferably as a part of ISO 14971 or IEC 62366 extensions [38]. Such models need to contain formatted mappings between use error and risk severity ranking that should be backed by empirical evidence.

2. Integration of AI-Based Usability and Risk-Prediction Tools

The machine learning programs can be used to predict the likelihood of use-error and hazard pathways, through the past history and other eye-tracking research and sensor-based context-related information. Artificial intelligence (AI) based simulators may be used to test various interface designs and forecast where interface failures may occur without the need to create physical prototypes [39]. Incorporation of these tools into the design lifecycle would also boost the safety validation of pre-market products and minimize reliance on the manual evaluation.

3. Improved Regulatory Co-operation and International Standardization

The differences in usability and risk integration needs in the various jurisdictions (which include U.S. FDA, EU MDR and the Asian regulatory authorities) generate inconsistencies in implementation. The further policy development must be based on the need to align usability-risk requirements as global standards and develop more specific guidelines toward the submission of evidence [40].

4. Industry-Wide Databases and Benchmarking for Usability-Risk Integration

It might be beneficial to have common databases of recorded use errors, usability testing results, and related risk outcomes as the benchmarking tool available to manufacturers. The repositories would help in the identification of hazards early, support training and minimize duplication of effort in the analysis of errors [41].

5. Human-AI Interaction Modelling in Device Design

Since the devices are increasingly providing AI-driven decision support, future studies should consider the effect of AI-human interaction on the use error and risk perception. The intricate interfaces and non-transparent algorithmic behaviour can pose new cognitive problems, which requires interdisciplinary research that would include cognitive science, human factors, and AI interpretability [42].

6. Incorporating Usability-Risk Integration with Agile and Iterative Design

A great number of medical device companies are moving to the use of agile development cycles. To improve flexibility, future research should develop usability-risk assessment frameworks that can be scaled for rapid iteration in wearable and software-driven medical technologies [43].

7. Organizational Change and Training in Industry

There is the need of a cultural shift in organizations that will see usability and risk analysis not being viewed as two distinct compliance undertakings but rather as complementary processes. The training programs, standards of certification, and redesigns of the academic curriculum in an industry are needed to generate cross-functional specialists who can combine human factors and risk management [44].

VI. CONCLUSION

The integration of usability engineering and risk analysis is essential for the safe and effective design of modern medical devices. The long-held division of these fields has contributed to persistent use errors and post-market failures, even with the growth in regulation and technology. The suggested theoretical framework, backed by empirical evidence, suggests that early and deliberate integration contributes to quantifiable improvements in task performance, user satisfaction, and safety outcomes. Nonetheless, the adoption is incomplete in the industry, due to the methodological, cultural, and regulatory barriers. The focus of future activities should be on standardization, technology-driven tools, harmonization of regulations and workforce development. The interdependence of human factors and risk management is not only a best practice, but a precondition for creating patient-centred, error-resilient medical tools.

Interest Conflicts

The author declares that there is no conflict of interest concerning the publishing of this paper.

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