# Evaluating Usability Barriers in Health Technology: Government Perspectives and ISO Standard Alignment

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*Abstract*— This study investigates how government authorities in Norway perceive usability barriers in health technology and assesses their alignment with international usability and software quality standards. A content analysis of 15 government reports reveals that the most frequently cited barriers—system complexity, accessibility issues, and integration challenges—closely align with key usability requirements in these standards. The findings suggest that adopting these usability principles as guidelines in health technology development could enhance effectiveness and accessibility. This study underscores the importance of structured usability frameworks in addressing real-world challenges.

## Keywords-Usability in Health Technology; Standards; ISO 9241-11; ISO/IEC 25010; Government Policy in Digital Health.

## I. INTRODUCTION

Existing research has provided valuable insights into how healthcare teams interact with digital tools, emphasizing the need for seamless integration and userfriendly design to support clinical workflows and patient care [1]. However, the usability of health technology systems remains a major challenge [2]. There are continued usability challenges in health technologies, affecting both patients and healthcare professionals. Research shows that usability flaws can lead to medical errors, patient harm, and frustration among clinicians, contributing to burnout [2][3].

Government plays a crucial role in the success of health technology [4]. Government agencies are often responsible for funding early-stage innovations, setting regulatory standards, and coordinating between public and private sectors to ensure the smooth deployment of digital health solutions. Unlike research papers, which aim to contribute new knowledge to an academic field, government reports prioritize practical information and real-world applications. By analyzing the government's perceived usability barriers, we aim to look at the problem from a top-down perspective and get a better understanding of whether the industry standards meet the government's perceived need.

The two standards from the International Standardization Organization (ISO) and International Electrotechnical Commission (IEC), evaluated in this paper, are widely used in the fields of user experience design, software development, and systems engineering to ensure high-quality, user-friendly, and effective systems:

1) ISO 9241-11:2018: Ergonomics of human-system interaction – Part 11: Usability: Definitions and concepts [5]. This standard focuses on usability, providing definitions, principles, and concepts for understanding how to assess the usability of systems, including software and hardware. It emphasizes the importance of usability in terms of user effectiveness, efficiency, and satisfaction when interacting with a product or system.

2) ISO/IEC 25010:2023: Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Product quality model [6]. This standard provides a framework for evaluating the quality of software and systems. The models include various characteristics like functionality, reliability, usability, and maintainability, which are used to assess and ensure software quality. Usability is framed within the concept of interaction capability (a shift from earlier versions that treated usability as an independent characteristic). The standard defines usability in terms of how effectively, efficiently, and satisfactorily a system or product can help users achieve their goals in a specified context. It includes six sub-characteristics that detail usability requirements:

- Appropriateness
- Recognizability: Users can quickly identify if the system meets their needs.
- Learnability: The system should be easy for users to learn, reducing the time and effort required to start using it effectively.
- Operability: Attributes that make the system easy to control and operate.
- User Error Protection: Mechanisms that help prevent user mistakes or mitigate their impact.
- User Assistance: Systems should offer guidance and support features to aid users in understanding and using them effectively.
- Accessibility: Ensuring usability across a diverse range of users, including those with disabilities.

Previous research has explored how the ISO 9241-11 standard is applied in real-world settings in healthcare. In [7], the authors highlight both the benefits and challenges of using ISO 9241-11 for setting usability targets. The findings in the article show that while the standard provides a solid foundation for usability, determining the right levels of effectiveness, efficiency, and satisfaction can be complex, and requires further methodological support. Another relevant research paper explores how the ISO/IEC 25010:2011 standard is applied to medical device software, and highlights the importance of qualities such as usability, reliability, security, and maintainability [8].

The remainder of this paper is structured as follows: In Section 2, the methodology is described, in Section 3, the results are presented together with recommendations for future research, and in Section 4 we draw the conclusions.

# II. METHODOLOGY

This research employs a hybrid content analysis approach to systematically examine the usability and quality requirements discussed in reports published by Norwegian government authorities. 15 reports were selected for analysis, all sourced from public authorities in Norway, and published between 2021 and 2024. The documents include government reports, healthcare surveys, technology assessments, and strategy papers on digital health and Artificial Intelligence (AI) in clinical settings. The reports have a total of 366,611 words, equivalent to between 1200 and 1500 pages.

The process of content analysis was based on extracting meaningful information from the reports using predefined themes and keywords, which were based on the concepts laid out in the two ISO standards. Themes and keywords were selected through iterative reading of the reports and validated against the terminology used in the standards to ensure alignment. Both manual and automated techniques were used to ensure comprehensive coverage of the reports.

In addition, a manual in-depth analysis of the content in the reports and the requirements in the two ISO standards were conducted.

# A. Quantitative and Qualitative Content Analysis

To systematically analyze the documents, a set of keywords and themes were defined in advance. These keywords were derived from the critical components of ISO 9241-11:2018 and ISO/IEC 25010:2023 and were supplemented by terms identified as relevant to health technology usability in the reports. The keywords were grouped under the following themes: Security, Efficiency, Satisfaction, Learnability, Usability, Accessibility, User Experience, User Engagement, Interoperability, Technical Barriers.

The analysis involved both manual review and the use of automated analysis to extract text, count keyword occurrences, and identify recurring themes across the documents. A Chi Square Test was used to evaluate distribution of the themes. This provided a frequency-based view of the data, allowing for insights into which topics were most emphasized in relation to usability and system quality. These frequencies were also compared across the reports to identify patterns, such as which aspects of usability or quality were prioritized in different contexts.

After identifying the key themes and barriers, a manual in-depth analysis of the content in the reports and the requirements in the two ISO standards where conducted, the findings from the reports were systematically mapped to the relevant principles from both ISO standards. The dataset is available online [9].

## III. RESULTS

A main finding from the analysis is that all the reports described usability or related topics such as ease of use or user-centered design in the context of health technologies, though the frequency and depth of these discussions vary. Data Saturation was achieved even though the sample was limited. This shows that the government consistently recognizes usability as an important factor when discussing health technology.

The Chi Square Test in Table I with a p-value of 0 demonstrates that the themes are not equally distributed. Certain themes (like security) are disproportionately emphasized, while others (like technical barriers) are underrepresented. This supports the idea that specific aspects of usability (e.g., security, efficiency) receive far more attention than others, which could influence the focus of health technology development. Security is not analyzed further as the focus is usability, and security is a substantial area that would require separate analysis and evaluation against other standards, such as the ISO/IEC 27000 family of standards on information security management.

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Theme Code	Observed	%	Expected*	Chi- Square	p- Value
Security	581	36			
Efficiency	383	24			
Satisfaction	204	13			
Learnability	203	12			
Usability	112	7	162.4	1090 67	0
Accessibility	60	4	102.4	1900.07	0
User Experience	37	2			
User Engagement	23	1			
Interoperability	16	1			
Technical Barriers	5	0			

Degrees of freedom: 9, \*value for equal distribution

# A. Reccuring Themes

The main recurring themes were identified as follows: *1) User-Centered Design:* 

Nearly all reports stress the importance of designing health technologies with the end-users in mind, whether they are

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healthcare professionals or patients. Usability in this context means creating interfaces and workflows that are intuitive, reducing cognitive load, and ensuring that users can achieve their objectives effectively. This is strongly tied to the ISO 9241-11 emphasis on the effectiveness, efficiency, and satisfaction of users.

## 2) Seamless Integration and Interoperability:

Usability challenges are frequently linked to issues of system interoperability, where healthcare professionals struggle to interact efficiently with multiple systems that do not communicate well. This issue is critical for effective digital health solutions, and usability suffers when systems require users to navigate disjointed interfaces.

## 3) Ease of Use for Healthcare Providers:

Usability for healthcare providers, specifically in terms of reducing complexity in accessing, documenting, and sharing patient information, is a recurring theme. Many reports call for technologies that are simple, easy to learn, and support fast decision-making, directly corresponding to ISO/IEC 25010:2023's emphasis on usability attributes such as learnability, operability, and user error control.

## 4) Patient Empowerment and Accessibility:

Many reports emphasize the need for health technologies to be usable not just by healthcare professionals but by patients as well. This includes creating interfaces that are accessible, ensuring inclusivity for users with different abilities and technical proficiencies. Making systems accessible to a broad user base also aligns with ISO standards, which emphasize user satisfaction and accessibility.

# 5) Error Reduction and Safety:

Usability is closely linked to patient safety, as emphasized in the reports. Poor usability can lead to errors, particularly in clinical settings where systems that are difficult to navigate or understand can cause mistakes in treatment or data entry. ISO standards also emphasize the error control aspect of usability, ensuring that systems minimize the potential for user errors.

#### 6) Training and Support for Users:

Several reports highlight the need for comprehensive training and ongoing support for users to maximize the usability of health technology systems. This is particularly important for systems with steep learning curves, where even well-designed interfaces can be difficult to use without proper instruction.

# 7) Adaptability and Customization:

Health technologies are increasingly required to offer customizable options for different user groups (e.g., different levels of healthcare professionals, patients). Usability is enhanced when users can adapt systems to their specific workflows or preferences, making them more efficient and effective in their tasks.

In summary, user-centered design, system integration, ease of use for healthcare professionals, patient accessibility, error reduction, training and support, and adaptability are recurring usability themes across the reports, and are thus perceived as the most important components in a government perspective. These themes highlight the essential qualities that health technologies need to embody to align with ISO standards for usability.

#### B. Government Perceived Barriers

Challenges and barriers related to usability in health technologies were identified as follows:

# 1) Digital Divide and Accessibility Issues:

Access to technology and digital literacy are highlighted as significant barriers, particularly for vulnerable populations such as the elderly, low-income groups, or those with limited technical skills. These populations struggle with accessing and effectively using digital health services. In reports discussing patient portals, many individuals from disadvantaged backgrounds report difficulties using these systems due to insufficient training or lack of access to necessary devices.

# 2) User Interface Complexity:

Many users, both patients and healthcare providers, report that complex or unintuitive interfaces in health technologies like patient portals, EPJ systems, and telemedicine platforms hinder effective use. Systems with overly complex designs reduce the ease of use, especially in highpressure healthcare environments. Healthcare providers have highlighted challenges in using systems that require extensive training to navigate, reducing efficiency and increasing errors.

## 3) Usability for Vulnerable Populations:

Vulnerable groups, including those with disabilities or chronic illnesses, report that many health technologies are not designed with their specific needs in mind, leading to usability issues. For example, individuals with chronic diseases or disabilities find it difficult to use mobile health apps that do not accommodate specific needs. Lack of accessibility features (e.g., for visually impaired users) and poor adaptability to different patient needs are recurrent themes.

#### 4) Interoperability and Integration Challenges:

A lack of interoperability between different systems (e.g., between hospitals, clinics, and patient devices) makes it harder for healthcare providers to access relevant information, which in turn affects user experience and the overall usability of health technology. Reports frequently mention difficulties in integrating telemedicine platforms with other health systems, causing fragmented workflows and data management issues.

#### 5) Technical Barriers and System Downtime:

System downtime and technical issues are frequently mentioned as barriers to the usability of health technology. These interruptions not only reduce user trust but also compromise patient care and data access. Users express frustration when health systems experience downtime or fail to deliver expected results efficiently during clinical operations.

## 6) User Trust and Satisfaction:

Lack of user trust in digital solutions is another barrier to widespread adoption. Users, both healthcare providers and patients, often feel unsure about the reliability of new technologies, which limits engagement and satisfaction. Patients often feel disconnected or uncertain when using telehealth services due to inadequate technical support or system reliability. These insights show that while digital health technologies offer significant potential, there are numerous usability barriers that need to be addressed for better adoption and effectiveness. Solutions, such as improving system interfaces, enhancing interoperability, and ensuring systems are designed with vulnerable populations in mind will help address these challenges. Table II summarizes how the two ISO standards can aid in solving the recurring barriers.

TABLE	II. RECURRING BARRIERS	

Barrier	ISO 9241-11:2018	ISO/IEC 25010:2023	Can ISO Standards Solve This?
Digital Divide and Accessibility Issues	Emphasizes context of use, ensuring that systems are designed for a diverse range of users, including those with limited digital skills or access to technology.	ISO/IEC 25010:2023 includes accessibility as a sub- characteristic of usability, pushing for systems that cater to the needs of vulnerable populations, such as the elderly and disabled.	Partially. The standards provide principles for accessible design, but the digital divide often stems from external factors, such as lack of access to devices or internet connectivity, which standards alone cannot address. Government policies or broader infrastructure improvements are needed alongside these usability guidelines.
Complexity	and efficiency, ensuring that systems are designed to be intuitive and easy to navigate	learnability as critical components of usability, ensuring that systems should be easy to learn and operate, minimizing the cognitive load for users.	design and evaluation stages, these standards can significantly reduce interface complexity by enforcing user-centered design and ensuring that systems are intuitive and straightforward to use.
Usability for Vulnerable Populations	Specifically considers the context of use for different user groups, which can ensure that systems are designed to be inclusive of vulnerable populations.	Emphasizes accessibility and user satisfaction, pushing for systems that are not only functional but also usable for people with disabilities or chronic conditions.	Yes, to a significant extent. If developers follow these guidelines, they can create inclusive designs that accommodate the needs of vulnerable groups. However, this requires a commitment from developers to prioritize accessibility and ensure that systems are tested by diverse user groups during the design phase.
Interoperability and Integration Challenges		Includes compatibility and interoperability as critical quality characteristics, ensuring that systems can work together without causing usability issues.	Partially. While the standards promote interoperability, they cannot fully solve integration challenges caused by legacy systems, incompatible infrastructure, or organizational issues. To achieve seamless integration, there must be broader cooperation between vendors, developers, and healthcare institutions to implement systems that follow standardized data formats and communication protocols.
Technical Barriers and System Downtime		Addresses reliability by requiring systems to minimize downtime and ensure that recovery from failures is efficient.	Partially. The standards can push for more reliable systems, but issues like system downtime are often due to infrastructure, network failures, or inadequate resources. While following standards can help reduce technical problems, solving them completely often requires investments in IT infrastructure and system maintenance.
User Trust and Satisfaction	Includes user satisfaction as a core component of usability, ensuring that systems are designed to meet user expectations and needs.	Emphasizes user satisfaction and trust through consistent reliability, security, and usability characteristics.	Yes, to a large extent. By focusing on usability, security, and reliability, ISO standards can improve user trust in health technologies. However, achieving trust also requires good communication, training, and support, which go beyond what the standards themselves prescribe.

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Barrier	ISO 9241-11:2018	ISO/IEC 25010:2023	Can ISO Standards Solve This?
Training and Support Needs	Stresses the importance of learnability, meaning that systems should be easy to learn and use. This aligns with the need for less training if systems are inherently user-friendly.		While standards can help design learnable systems, the need for ongoing training and support depends on how well healthcare institutions implement the technologies and provide resources for users. Standards cannot replace the need for user education, but they can reduce the complexity that necessitates heavy training.

# C. Seven key usability improvements

Based on the results from the content analysis, we suggest highlighting seven reoccurring key usability

improvements shown in Table III. The table summarizes how these highlighted key improvements map to the requirement in the two ISO Standards:

Usability Improvement Suggestions	ISO 9241-11 (Usability)	ISO/IEC 25010 (Quality Model)	
1. Improve User-Centered Design	Aligns with Effectiveness, Satisfaction, and Context of Use. User-centered design ensures that the system meets user needs and is effective in various contexts.	Maps to Usability (Subcharacteristics: Learnability, Operability, User error protection, User interface aesthetics). Focus on making systems easy to use and visually intuitive.	
2. Enhanced Training and Support Relates to Satisfaction and Efficiency. Users who are well-trained can achieve tasks more efficiently, leading to higher satisfaction.		Falls under Usability (Learnability) and Maintainability (Subcharacteristic: Modifiability). Well-supported systems improve long-term usability and adaptability.	
3. Simplify Interfaces and Reduce Complexity	Focuses on Effectiveness and Efficiency. Simplified interfaces help users complete tasks more quickly and accurately, leading to improved usability.	Related to Usability (Operability) and Functional Suitability (Subcharacteristic: Functional appropriateness). The system should provide necessary functions in a way that users can easily access and understand.	
4. Increase System Interoperability	Related to Context of Use, ensuring that systems work smoothly in various environments and contexts without creating barriers for the user.	Primarily aligns with Compatibility (Subcharacteristics: Interoperability, Co-existence). Systems need to work together seamlessly to prevent usability issues caused by fragmented workflows.	
5. Accessibility for Vulnerable Populations	Related to Satisfaction and Context of Use. Ensuring usability for a diverse range of users, including those with disabilities or limited digital literacy.	Falls under Usability (Accessibility). The system must be accessible to users with a range of abilities and needs, ensuring inclusivity and equal access.	
6. Strengthen Feedback Loops Involves Measurement and Evaluation Usability, ensuring that user feedback is continuously collected and used to impro- usability.		Related to Maintainability (Subcharacteristic: Modifiability). Continuous feedback allows the system to be adjusted and improved over time. It also ties into Usability (User error protection and User satisfaction).	
7. Provide Clearer Guidelines for Digital Health	Falls under Effectiveness, ensuring that new systems are assessed for their usability in meeting user goals.	Maps to Functional Suitability and Usability. Guidelines ensure that systems meet functional needs and provide the right level of usability, ensuring Reliability and Quality from the outset.	

## TABLE III. KEY IMPROVEMENTS TO USABILITY

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#### D. Limitions and Future Research

This study is based on 15 Norwegian government reports, which may limit the generalizability of findings to other health systems or user contexts. The focus on policylevel documents also excludes perspectives from patients, clinicians, or developers. Additionally, the use of ISO 9241-11 and ISO/IEC 25010, while widely accepted, may overlook alternative frameworks relevant to specific healthcare settings.

Future research could include broader stakeholder input, cross-country comparisons, or real-world testing of ISO standards in health technology design and evaluation. Future research should also explore how these standards can be operationalized in national strategies, and how policymakers can support more consistent usability evaluation across public health projects.

### IV. CONCLUSION

The findings in this content analysis show that the government perception on barriers and improvements in relation to usability in health technologies, align closely with the usability requirements set in ISO 9241-11:2018 "Ergonomics of human-system interaction – Part 11: Usability" and ISO/IEC 25010:2023 " Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Product quality model".

From this, we draw two conclusions:

- The requirements in ISO 9241-11:2018 and ISO/IEC 25010:2023 are highly relevant to the practical challenges faced in Norway.
- It would make a great deal of sense to use ISO 9241-11 and ISO/IEC 25010:2023 as requirements or guidelines for developing and accessing health technologies in Norway.

The findings suggest that the standards can serve as practical tools for shaping digital health policies by providing structured usability requirements that align with real-world challenges identified in national reports. Integrating these standards into policy frameworks and procurement processes could improve the quality, accessibility, and adoption of health technologies

However, the standards cannot fully solve external challenges like the digital divide, infrastructure issues, or organizational hurdles related to system integration. These standards, when properly implemented alongside broader efforts, can significantly improve the usability and quality of health technologies.

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