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Effects of Medical Device Regulations on the Development of Stand-Alone Medical Software: A Pilot Study

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Abstract. *Background:* Medical device regulations which aim to ensure safety standards do not only apply to hardware devices but also to standalone medical software, e.g. mobile apps. *Objectives:* To explore the effects of these regulations on the development and distribution of medical standalone software. *Methods:* We invited a convenience sample of 130 domain experts to participate in an online survey about the impact of current regulations on the development and distribution of medical standalone software. *Results:* 21 respondents completed the questionnaire. Participants reported slight positive effects on usability, reliability, and data security of their products, whereas the ability to modify already deployed software and customization by end users were negatively impacted. The additional time and costs needed to go through the regulatory process were perceived as the greatest obstacles in developing and distributing medical software. *Conclusion:* Further research is needed to compare positive effects on software quality with negative impacts on market access and innovation. Strategies for avoiding over-regulation while still ensuring safety standards need to be devised.

Keywords. Medical Device Regulations, Clinical Decision Support Systems, Patient Safety

1. Introduction

Software that guides medical decision making has the potential to significantly transform and improve medical care. The increasing role of software in medical decision making also warrants caution about potential negative impacts experienced by end users. Such negative impacts can be caused by a wide variety of problems including errors or omissions in recommendations given to users, or by distracting and misleading users through usability issues. [1]

To address these issues, medical software products meeting certain criteria are covered by medical device regulations (MDR) under most jurisdictions. For example, in the USA, the distribution of medical devices is regulated by the U.S. Food & Drug Administration (FDA). [2] In the European Union, medical devices are regulated by Directive 93/42/EEC issued by the Council of the European Union. [3]

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Importantly, these regulations also apply to 'standalone' medical software, i.e. software that is not connected to medical hardware, including mobile apps or web applications. [4] Thus, slight variations of the following heuristics are commonly used to determine whether such software is subject to MDR: (1) The software performs an action on data different from storage, archival, communication or simple search, (2) the performed action is for medical purposes, (3) the performed action is for the benefit of the individual patient. If all three points apply to the software in question it most likely qualifies as a medical device and is subject to MDR.

Previous research indicates that current regulations and standards might not be flexible enough to be applied to the growing sector of medical standalone software, such as mobile medical devices. [5] It is currently not clear how effective medical device regulations applied to software products are in improving software quality and safety. Furthermore, it is not known to what extent such regulations might also have negative effects, e.g., by obstructing the development of innovative medical software and decreasing its availability to medical professionals and patients.

In this pilot study, we explored software developers' perceptions of the ease of application of international medical device regulations and their views about the impact of these regulations on the development and distribution of standalone medical software.

2. Methods

We conducted an online survey among a convenience sample of domain experts with a past or ongoing involvement in a stand-alone software project where medical device regulations applied. Eligibility criteria required participants to have been involved in at least one software project where they have either (1) successfully achieved certification according to medical device regulations, (2) where they were actively working towards certification, (3) where MDR applied but where they had not yet actively worked towards certification, or (4) where they were planning to add functionality to their software so that MDR would apply.

Since medical software products are commonly distributed internationally, implicating that the respective products have to conform to multiple national and international regulations and legislations, we did not limit our target group to a specific country or region.

The survey consisted of three parts. In the first part, participants were asked about their roles in developing medical software. The second part encompassed 25 items using a 5-point Likert scale ranging from strongly agree to strongly disagree, asking respondents to indicate their level of agreement with several statements. These statements encompassed the impact of current medical device regulations on market access, software development processes, and the safety and quality of life of patients. The final part of the questionnaire consisted of four demographic questions.

Potential participants were identified through public registers of medical device associations, health start-up portals, app stores, references listed on websites of MDR consulting companies, academic research papers, and professional networks. In total, we identified 130 potential participants stemming from academia or industry, with the majority being located in European countries. Personal invitations were sent to all identified individuals in several waves between March 8 and April 5 2017.

3. Results

3.1. Characteristics of survey participants

In total, 23 participants completed the questionnaire, resulting in a response rate of 17.7%. Out of those, two participants had to be excluded because they did not meet inclusion criteria. Thus, the responses of 21 participants were considered for further analyses.

Demographic characteristics and experience with medical software development of survey participants are summarized in Tables 1 and 2, respectively. Ages ranged between

Table 1. Demographic characteristics of the survey participants.

	n	%
Gender		
Male	18	85.7%
Female	1	4.8%
Not stated	2	9.5%
Age		
20-39 years	9	42.9%
40-59 years	10	47.6%
60 years or older	1	4.8%
Not stated	1	4.8%
Residence		
Europe	19	90.5%
Asia	1	4.8%
Not stated	1	4.8%
Sector		
Academia	3	14.3%
Industry	18	85.7%
Main role in software project(s)		
Software engineering / software design / programming	4	19.0%
Middle or upper management	11	52.4%
Quality assurance	3	14.3%
Scientific research	1	4.8%
Regulatory / legal advice	2	9.5%
Years of experience working on software falling under MDR		
Less than a year	2	9.5%
At least one year but less than three years	6	28.6%
Three years or more	13	61.9%
Company / organization size		
Less than 10 employees	8	38.1%
10 - 49 employees	9	42.9%
50 - 249 employees	2	9.5%
Not applicable	2	9.5%
MDR relevant to participants' software projects		
Medical Device Regulations of the European Union or one of its members states	20	95.2%
Medical Device Regulations of the United States of America	4	19.0%
African Medical Device Regulations	1	4.8%
Asian Medical Device Regulations	1	4.8%
Types of software		
Mobile apps	10	47.6%
Desktop software	4	19.0%
Software embedded or linked with Electronic Health Record systems or Electronic Order Entry systems	8	38.1%
Web-based applications or services	12	57.1%
Other	4	19.0%
Which end-users did these software projects target?		
Medical professionals (e.g., medical doctors, nurses, pharmacists)	19	90.5%
Patients	7	33.3%

Table 2. Reported difficulties encountered in developing and distributing software falling under MDR, as well as various other questions. Underlined results indicate median responses.

	Strongly disagree	Disagree	Neutral / Don't know	Agree	Strongly agree
A) We found it difficult to develop and distribute software when medical device regulations applied because of...					
The uncertainty about whether medical device regulations applied (n=21)	3	6	2	8	2
The uncertainty about which medical device risk class applied to the software (n=21)	1	3	5	7	5
The additional time needed for development (n=21)	1	1	2	9	8
The additional costs (n=21)	0	1	3	8	9
The constraints imposed on the features of the software (n=21)	0	4	5	9	3
The constraints imposed on the software development process (n=21)	0	4	4	8	5
Our lack of expertise in regulatory matters (n=21)	1	2	7	7	4
Associated legal risks (n=21)	0	6	5	8	2
The heterogeneity of medical device regulations in different legislations (e.g., between the European Union and the United States) (n=21)	0	3	5	8	5
Frequent changes to medical device regulations (n=21)	1	9	5	5	1
B) Other questions					
At least initially, we found it difficult to judge if medical device regulations applied to our software (n=20)	0	8	1	6	5
When the customers are patients, they sufficiently recognize and reward certification so that it pays off to go through the regulatory process. (n=21)	2	7	10	1	1
When the customers are medical professionals (e.g., medical doctors, nurses, pharmacists), they sufficiently recognize and reward certification so that it pays off to go through the regulatory process. (n=21)	1	3	9	7	1
When the customers are institutional buyers (e.g., large health care organisations, hospitals), they sufficiently recognize and reward certification so that it pays off to go through the regulatory process. (n=21)	1	1	2	11	6

28 and 64 years with a median age of 40 years. Most respondents (n=19) were located in one of the European Union's member states. Consequently, for the majority of respondents, MDR of the European Union or one of its member states were relevant to their software projects.

Most respondents (n=14) had been involved in one or more software projects that successfully achieved certification according to medical device regulations. Five participants were involved in software projects where they were actively working towards certification. The remaining two respondents were either involved in software

Table 3. Reported effects of MDR on developed software products. Underlined results indicate median responses (where two responses are underlined, the median is between responses).

	Much worse	Worse	Slightly worse	No effect	Slightly better	Better	Much better	Don't know / Not applicable
Which effects did medical device regulations have on the following aspects of your software?								
Usability (n=21)	0	1	3	6	5	4	1	1
Reliability (n=21)	0	1	0	6	3	8	1	2
Protection of patients from harm (n=21)	0	1	0	6	6	4	3	1
Data security (n=21)	0	0	0	9	4	5	2	1
Performance (e.g., speed of execution, memory use) (n=21)	0	1	3	16	0	0	0	1
Feature richness (n=21)	0	2	5	11	1	1	0	1
Software maintainability (n=21)	2	1	4	6	5	1	0	2
Ability to change or add features when software has already been deployed (n=21)	4	5	3	6	0	0	1	2
Possibility of software customization/configuration by end users (n=21)	2	5	4	7	0	0	0	3

projects where MDR applied but where they had not yet actively worked towards certification, or they were planning to add functionality to their software so that MDR would apply. More than two thirds (n=16) of the participants had hired an external consulting organization to assist in the regulatory process in at least one project.

3.2. Difficulties with developing and distributing medical software

Reported difficulties with developing and distributing medical software caused by MDR are summarized in Table 2, section A. More than half of the respondents (n=11) agreed that they found it difficult to judge whether MDR applied to their software. The additional time and costs for regulatory processes were perceived as the greatest obstacles in developing medical software. The uncertainty about whether MDR apply, which risk class applies, lack of expertise in regulatory matters, heterogeneity of medical device regulations, constraints imposed on the software development process and on the features of the software were also perceived as barriers. However, associated legal risks and frequent changes to MDR played a lesser role.

We asked participants if they perceived that patients, medical professionals or institutional buyers (e.g. large health care organizations, hospitals) sufficiently recognize and reward certification so that it pays off for software developers to go through the regulatory process. On average, this was confirmed only for institutional buyers (Table 2, section B).

3.3. Effects of MDR on software products

Reported effects of MDR on developed software products are summarized in Table 3. On average, participants reported that going through the required certification process had slightly positive effects on the usability, reliability and data security of their software,

and only slightly improved protection of patients from harm. They reported no effect on software performance.

Slightly negative effects on feature richness and software maintainability were perceived by a small subset of participants. Most negative effects were reported for the ability to change or add features in already deployed software and the possibility of software customization and configuration by end users.

4. Discussion

4.1. Principal results

MDR aim to improve healthcare by ensuring that devices conform to safety standards and reflect the latest progress in science. Thus, they do not only apply to 'classical' medical devices such as pacemakers, insulin pumps, or in-vitro diagnostics, but also to medical standalone software. However, the requirements in the development and distribution of user-friendly and reliable medical standalone software may differ strongly from the development of more traditional medical devices, e.g. in terms of the need for customizability or ongoing updating and adding of new features. This raises the question whether current regulations and associated required certification processes are appropriate to duly serve their purpose in improving the quality of those products without unnecessarily impeding market access of potentially valuable software.

Our results indicate that the first challenge in developing and distributing medical standalone software lies in clarifying whether the software in question is at all subject to MDR. Within the past seven years, national and international regulatory agencies aimed to address this issue by publishing guidance documents and software classification schemes. These include the MEDDEV 2.1/6 published by the European Commission or the guidelines of the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) and the International Medical Device Regulator Forums (IMDRF). [6,7] These documents can certainly help developers of medical standalone software by providing a rough guidance. Nevertheless, the various manifestations and wide range of applications of medical standalone software may not be fully covered by these documents. Thus, it is difficult to achieve legal certainty whether a specific software product needs certification, and to identify which risk class applies to the product in question.

Despite past and ongoing efforts of dedicated working groups such as the Global Harmonization Task Force (GHTF) [8] and its successor, the International Medical Device Regulators Forum (IMDRF) [8], to create international standards and thereby harmonize existing national and international MDR, the heterogeneity of regulations under different legislations still manifests as an obstacle in developing and bringing to market internationally competitive products.

Our results suggest that, overall, medical device regulations can help to slightly increase patient safety by improving certain aspects of software products. Further research is needed to compare these positive effects with the potentially negative impact current regulations and associated certification procedures may have on innovation in the health IT sector.

The process of developing and distributing medical software is very resource-intensive, both in terms of financial expenditure and time. It also imposes restrictions on the functionality of software products. These additional burdens may especially

discourage smaller-sized companies and startups from entering this market segment and consequently slow down innovation.

One solution to potential over-regulation proposed by Yang and Thompson is to implement a 'substantial dependence' standard to discern software that should be regulated from software that does not need regulation. [9] According to this standard, a software product that guides medical decision making would not need regulation if (1) the software is transparent in its data and recommendations, (2) the user is competent to interpret the recommendations, and (3) the user has adequate time to reflect on the recommendation.

4.2. Limitations

The convenience sampling approach in this small-scale pilot study somewhat limits the generalizability of our findings to the larger population of medical software developers. However, the results provided herein can serve as a foundation for follow-up qualitative or quantitative research exploring certain aspects, e.g., potential options to improve the current situation, in more detail.

The majority of respondents were employed at companies with less than 50 employees. Larger companies and organizations may have fewer difficulties complying with MDR, and are not well-reflected in the sample. Furthermore, the majority of our studies' respondents had already achieved certification in at least one project. Views and assessments of this sample may differ from views of those who abstained from entering this market segment because of the regulatory burden.

We did not seek information regarding the regulatory class of the software being developed, the main business of the organization responding, whether the organization developed within a quality management system (ISO 13485 or ISO 9001) or whether it worked to key medical software standards. As a result of a new risk classification system for medical software introduced by the new European MDR (2017/745) that came into force on 25 May 2017, more software will be assigned higher risk classes (II or III), thus being subject to even stricter requirements and scrutiny processes. Data collection of our study took place between March and April 2017, therefore the results presented herein only partially reflect the new regulatory situation. Future research should explore the implications of the new European MDR that will apply after a transitional period of three years (i.e. spring 2020) for the development and distribution of medical standalone software.

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