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CHALLENGES OF CURRENT REGULATION OF AI-BASED HEALTHCARE TECHNOLOGY (AIHT) AND POTENTIAL CONSEQUENCES OF THE EUROPEAN AI ACT PROPOSAL

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Research paper

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Abstract

The utilization of artificial intelligence (AI) in healthcare has been steadily increasing, but the regulation of AI is challenging. Inspired by the recently proposed European AI regulation, we conducted a case study among Finnish healthcare stakeholders to identify challenges that current regulation of AI-based healthcare technology (AIHT) poses to development of AIHT, and what the potential consequences of the recently proposed European AI regulation would be for AIHT development. One of the main challenges we identified is the already existing ambiguity arising from several regulations that AIHT are subject to. More importantly, we found that this ambiguity would even increase through a European AI regulation. Another important finding is that the European AI Act might hamper innovation in AIHT and decelerate the development of AIHT. Our main contribution is to the recent information systems research opening on regulation of technology.

Keywords: Artificial intelligence, AI regulation, Healthcare technology, Ambiguity, AI Act, Digital transformation

1 Introduction

During the past ten years, one of the most disruptive technologies has been artificial intelligence (AI). The utilization of AI is also increasing in the field of healthcare, and today there are many different applications and innovations that try to respond and solve emerging problems of our healthcare system (Kelly et al., 2019). Patient safety, security, privacy, and ethics are fundamentals that guide healthcare practices (Polit and Beck, 2017), and therefore all technologies that are targeted at healthcare need to be validated to prove patient safety and efficacy (Bohr and Memardazeh, 2020).

There are few limitations that decelerate the use of AI in healthcare (Reddy et al., 2020), and one significant, fundamental limitation is that the healthcare sector is justifiable highly regulated (May et al., 2020). Medical devices (MD), including medical software (Hermon et al., 2021), are regulated through numerous laws and regulations that focus on different aspects such as demonstrating the safety and medical-technical performance of the MD, software life cycle processes for the MD software, quality management systems for the MD manufacturers, and application of risk management to the MD (Karrenbauer et al. 2019). While AI is being increasingly integrated in MDs (Kelly et al., 2019), current regulations that concern the MD development do not specifically address AI. This absence of "AI" in regulation has also been observed in the context of explainable AI in auditing (Rebstadt et al., 2022). A lack of a clear regulation of AI use may slow AI implementation in organizations (Bérubé et al., 2021).

To address this "regulatory vacuum" of AI, the European Commission (2021a) has presented a new proposal for the first legal European Union-wide framework on AI: the Artificial Intelligence Act (AI Act). The AI Act classifies AI systems into four risk classes: unacceptable risk, high risk, limited risk, and minimal risk. The AI Act requires providers and users of high-risk AI systems to comply with rules on data and data governance, documentation, and record-keeping, transparency, and provision of information to users, human oversight, robustness, accuracy, and security. For the most part, an AI system is classified as high-risk based on the context in which the system would be used (e.g., access to and enjoyment of essential public services and benefits). However, while the use of AI in healthcare per-se is not proposed to be high-risk, *all* certified MDs that utilize AI would be classified as high-risk AI systems. While the AI Act is expected to become effective in 2024, the proposal has already caused public discussion related to the development and use of AI-based healthcare technology (AIHT) in Europe, including in Finland.

Several IS articles identified research opportunities for IS research related to AI in organizations (see Benbya et al., 2021; Nguyen et al., 2022; Collins et al., 2021 for detailed research agendas and future research questions). Amongst these, the regulation of AI has been identified only by Collins et al. (2021) as a potential area for future AI-related IS research. This is somewhat surprising, given that there has been a recent call for IS research on the regulation of IT (see Gozman et al., 2020), and given that legal conditions have been identified as an environmental determinant that triggers and shapes the digital transformation (Hanelt et al., 2021; Vial, 2019), which is one major interest in IS research. Answering to the call for IS research to get involved into regulation discussions "to inform and advance AI regulation" (Reinecke et al. 2021, p. 1), and against the practical background of the proposed AI Act that would classify all MDs as high risk, we consider the development of AIHT from the perspective of legal regulation (Blind et al., 2017; Martin and Matt, 2018) and ask the question:

RQ: What challenges do healthcare stakeholders see in the current regulation of AIHT, and what would be potential consequences of future AI regulation for the development of AIHT?

We conducted an empirical case study in the Finnish healthcare technology industry and interviewed different stakeholders to identify the challenges that organizations developing AIHT currently face, and what challenges they see to arise from the AI Act proposal and its implementation. We contribute with this research to the recent IS opening on the legal regulation of technology.

2 Related research – Challenges of AI regulation in healthcare

The IS community has addressed diverse topics related to AI. However, the regulation of technology, including that of AI, has received scant attention. With regulation, we here mean "legal" regulation as "any form of 'coercive rule setting' by governments to influence market activity and economic actors' behavior" (Blind et al., 2017; Martin and Matt, 2018, p. 2). Therefore, we turn to other disciplines – mostly the medical and legal research fields – to get an understanding of the challenges of AI regulation in the healthcare.

Healthcare specific regulation of AI is diverse, and different national or regional regulations or laws aim to indirectly regulate AI in healthcare (Jaremko et al., 2019; Recht et al., 2020). The regulation of AI in healthcare is necessary to protect patients' freedom, fundamental rights, as well as their safety and privacy (Mattei, 2020). AI technologies require a lot of data (Forcier et al., 2019), and this increases challenges for healthcare organizations, because they need to solve and manage issues related to data privacy issues (e.g., anonymization, data access related questions), data sharing, and appropriate use of data (Ahmad et al., 2020). In Europe, the General Data Protection Regulation (GDPR) regulates the processing of personal data. The interpretation of how to interpret the GDPR and comply with it has been challenging (Grundstrom et al., 2019). AIHT often utilize sensitive personal data, and certain requirements set in the GDPR, such as the consumer's right to erase personal details in the name of the privacy (Shintre et al., 2019) cause challenges for the development and use of AIHT. As personal and non-personal data can be scattered and non-reliable (Sunrise Winter and Davidson, 2019), it may cause bias (Ahmad et al., 2020) and medical errors (Smith and Heath Jeffery, 2020). Further, getting patient consent – which is required in order to be allowed to process the data - may be impossible or impractical in some cases, e.g., if the patient is unconscious or cognitively impaired (Bester et al., 2016).

One challenge in healthcare is the 'regulatory vacuum' (i.e., existing laws or regulations do not cover a certain aspect) regarding liability in the context of AIHT, because there is a lack of clear standards addressing legal responsibility if AI technologies cause harm (Carter et al., 2020). Another challenge is the black box phenomenon (Forcier et al., 2019; Currie and Hawk, 2020), which is related to transparency: because functioning of AI may be not traceable, it is challenging to guarantee the data safety and to understand how, for example, a specific decision was made (Currie and Hawk, 2020; Grant et al., 2020; Laï et al., 2020). The black box phenomenon and questions of liability are closely related, because liability issues are always present when AI makes wrong decision or decision that causes harm (Laï et al., 2020; Sullivan and Schweikart, 2019). More generally, the lack of legal frameworks that consider responsibility and medical malpractices by machines (Mattei, 2020; Sullivan and Schweikart, 2019) causes challenges.

Another challenge in the healthcare that AI faces is the lack of validation of AI technologies (Recht et al., 2020). Eventually, if AI has got an appropriate regulatory framework and evidence suggests that the use of AI is safe and recommended, the next challenge is how to integrate AI technology into clinical workflow (Grant et al., 2020). In addition, healthcare is quite often a sensitive field with many ethical dilemmas, and the development of AI technologies have created new ethical dilemmas that developers of AI systems as well as healthcare professionals and patients face (Jaremko et al., 2019). Therefore, from the regulatory perspective, ethical issues that arise in healthcare as a result of AI technology need a clear regulatory framework (Allen, 2019). The European Commission has created ethical guidelines for trustworthy AI (European Commission, 2019) and these guidelines should be considered also with AI technologies in the field of healthcare.

3 Research methodology

To answer the research question, we conducted a qualitative case study among Finnish healthcare stakeholders to gain an understanding of the current regulation of AIHT and the potential effects of future AI regulation, specifically the European AI Act.

Data collection. We conducted purposeful sampling (Higginbottom, 2004) and identified 18 informants who represented central stakeholder-clusters of healthcare research, development, and innovation (RDI) in Finland (Ministry of Economic Affairs and Employment, 2019) and who all had intimate knowledge of the healthcare sector, AI, and/or regulation of AIHT. Twelve informants from five different RDI-clusters answered to the interviewee request. In October and November 2021, we conducted qualitative, semi-structured interviews (Myers and Newman, 2007) that consisted of nine question categories: interviewee's background, definition for AI, utilization and development of AI, role of AI in healthcare, regulation of AI in healthcare, AI and AI Act proposal, AI and ethics, AI and data, and future of AI. The average interview length was 60 minutes. Figure 1 summarizes interviewee-related information. Interviews have been transcribed non-verbatim. Presented quotes are our own translations from Finnish to English. The interviewees are referred to as I-1 to I-12 in the remainder of this paper. We also reviewed the regulations that currently regulate in some way AIHT to get a better understanding of the regulatory context and for the data triangulation.

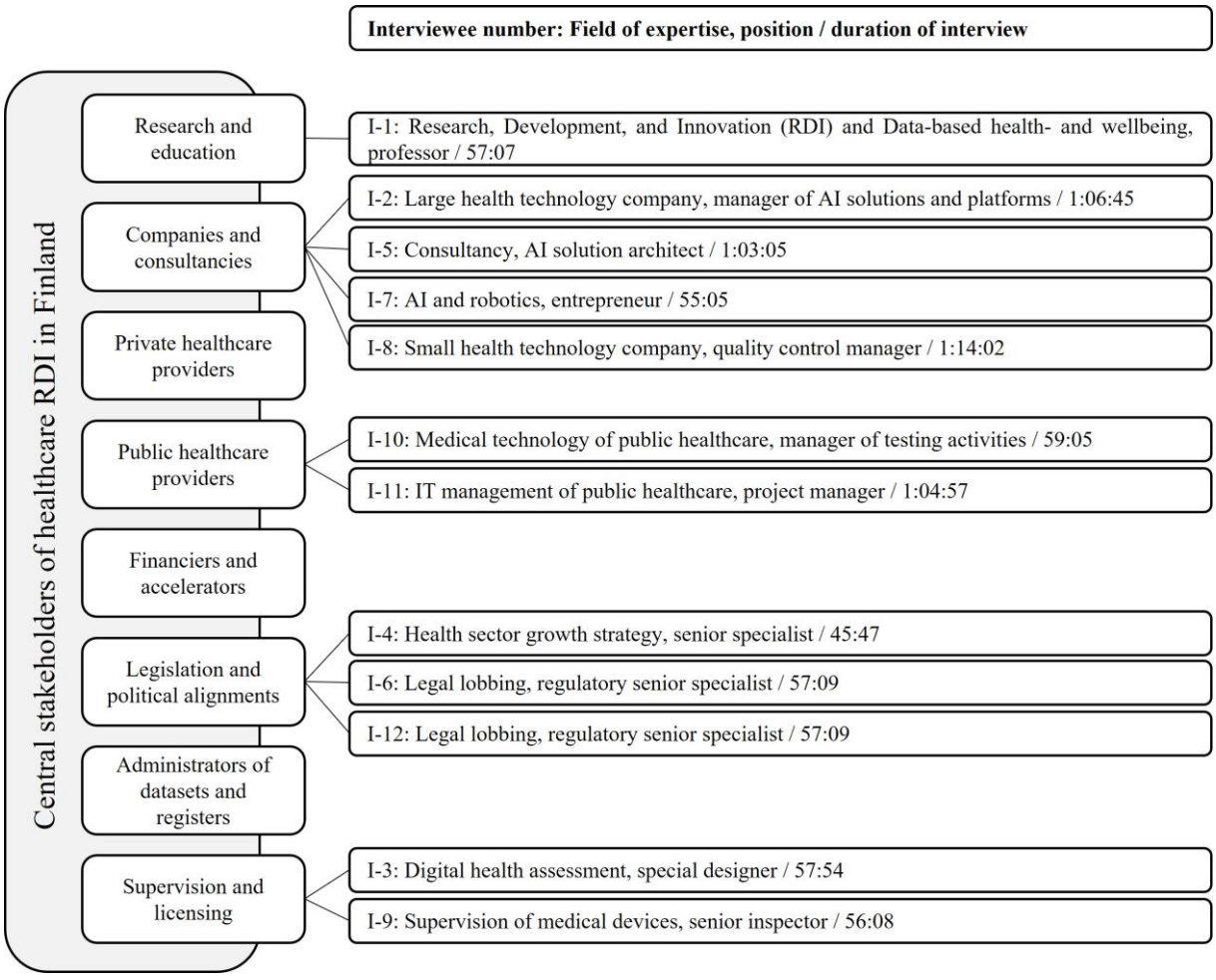

Figure 1. Summary of Interviewees.

Data analysis. We applied inductive content analysis, which is widely used in the field of nursing science (Kyngäs, 2020), but also in other fields of science to analyse qualitative data (Neuendorf, 2017). Inductive content analysis is a discussion between the researcher and collected data, and it includes three phases: data reduction, data grouping and the formation of concepts that can be used to answer the research questions (Kyngäs, 2020). First, interview transcripts were read through several times. After this, the raw data was coded into open codes, which could be either words or a sentence. Open codes

were thematically grouped into subcategories, and these were thematically categorized into categories. Figure 2 exemplifies the analysis and formulation of subcategory "Deceleration of AIHT development".

We first analyzed the data on a more general level to answer questions of how different stakeholders perceived the current regulation of AIHT (resulting in four categories and 15 subcategories), and how they see the future of AI regulation (resulting in 3 categories and 20 subcategories). Then, we extracted from these sub-categories those that indicated either a challenge or a (potential) consequence of current and future AI regulation to answer the research question.

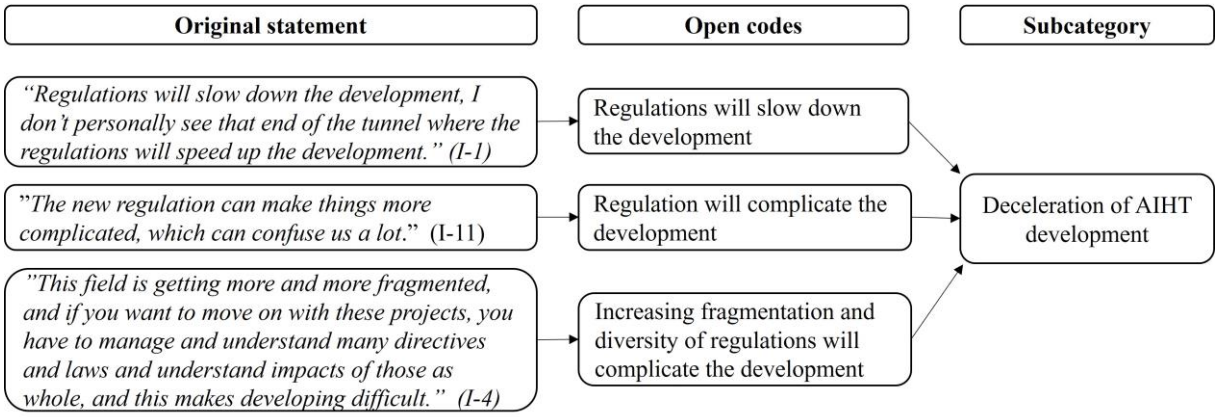

Figure 2. Formulation of subcategory.

4 Findings

We first summarize our findings on how AIHT is currently regulated in the EU and Finland, followed by the challenges current regulation represents for AIHT developers. Then, we summarize our findings regarding challenges related to a future European-wide AI regulation. Figure 3 summarizes our findings in form of the categories and sub-categories we identified in answer to the research question.

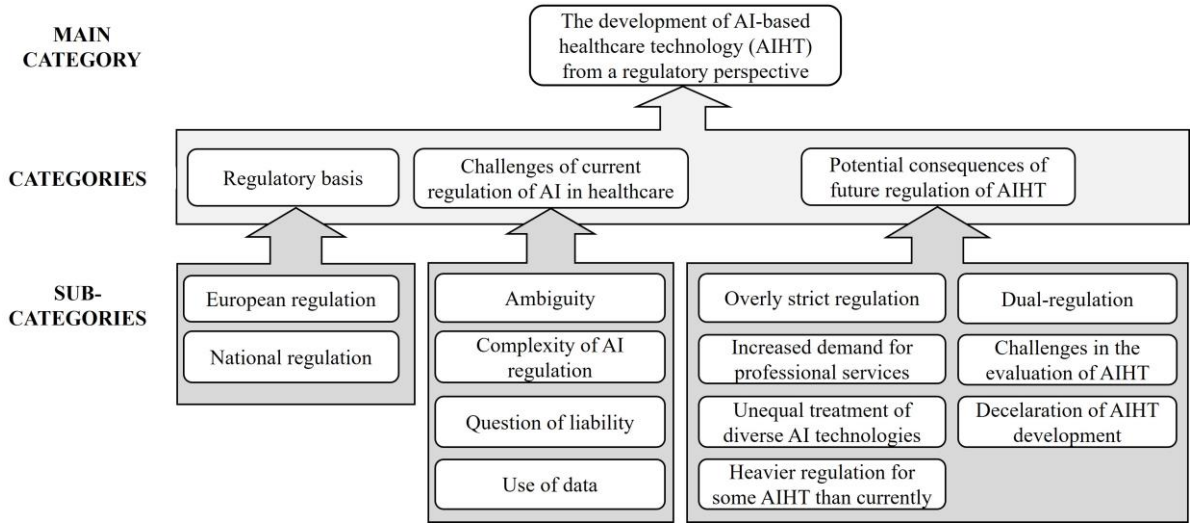

Figure 3. Categorized findings.

4.1 How is AI-based healthcare technology currently regulated in the EU and Finland

In Europe, the European Commission steers the regulation of AI in healthcare technology. Before the year 2017, there were three different directives that regulated MDs. However, due the development of technology, these are replaced with the Medical Device Regulation (MDR) 2017/745, which became effective on May 26th 2021, and the In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746, which became effective on May 26th 2022 (European Commission, 2021b).

The purpose of these regulations is to protect public health and the health of single patients. Compared with the previous MDD, the updated MDR requires every manufacturer to have a quality management system regardless of their risk classification, a person who is responsible for regulatory compliance, and a registration in the European Database on Medical Devices (EUDAMED). Moreover, reporting is required from MD manufacturers, and work distribution and liabilities between manufacturers, authorized representatives, importers, and distributors must be defined individually. Per se, software products – and thus also AIHT – belong to the highest risk class of MDs, and cybersecurity is added into safety requirements. Every device must have a unique device identifier to enhance the tracking of devices. A notified body must be named to guarantee the competence of evaluating instances. (European Commission, 2020a.) IVDR sets requirements for tighter clinical evidence and conformity assessment and clarifies responsibilities of manufacturers, authorized representatives, importers, and distributors (European Commission, 2020b). Data privacy and protection of health information are regulated through the GDPR, and ethical issues related to AI are considered in the EU guidelines on the Ethics of AI (European Commission, 2019).

In addition, data usage is regulated also on a national level **in Finland** through the ***Biobank Act***, the ***Act on the Secondary Use of Health and Social Data***, and the ***Genome Act*** that is currently under preparation: *"In addition, the development of AI requires data and biological samples. So, from this point of view, also the Biobank Act, the Act on the Secondary Use of Health and Social Data, and in future the Genome Act, relate to the development of AI"*. (I-5) Also, the Finnish Ministry of Social Affairs and Health and the Finnish Institute for Health and Welfare indirectly regulate AI use in healthcare through, for example, ***strict information security requirements*** that complicate the use of cloud services.

Adherence to the regulation(s) is supervised by the AIHT manufacturer, a notified body, and a supervisory authority. I-8 pointed out that the current regulation allows the development of AIHT: *"In my opinion, all AI solutions are possible within in current regulation, excluding totally autonomous AI systems"*. There are also ***benefits for companies that are able to show that their products comply with the regulation***, like the representative of large health technology company discussed: *"In my job, the regulation has a positive aspect, it is diacritical thing, because if we obtain the CE-mark, it separates us from many start-up companies"*. (I-2) Regulatory compliance can be used also in marketing of the AIHT. Interviewees felt that the development of AI solutions is already heavily regulated, and that this should be taken into account also when developing the regulation of AI in future.

To summarize, many **existing regulations** currently regulate AIHT on both the European and national level, although only few of these regulations directly mention AI.

4.2 Challenges of current regulation of AI in healthcare

Interviewees recognized four challenges with the current regulation of AI in healthcare. All quote references in this section refer to Figure 4, which summarizes these challenges with representative quotes.

A major challenge in the development of AI-based healthcare technology is **ambiguity that arises within and between different regulations**. Ambiguity was perceived as built-in the development of MDs, because all those ***regulations are interpreted*** by supervisory authorities and notified bodies [Q1]. I-8, the small health technology company representative, also perceived that those interpretations depend on debates and choices made during the development of the technology, e.g., actions related to

data or process management [Q2]. From the perspective of public healthcare, the justification of data usage (e.g., for research, or for information management) influences what kind of regulation should be complied with [Q3]. In addition, ambiguity arises from mismatches between different regulations, such as the MDR and the GDPR. Interviewees also highlighted a need for clear guidance to decrease ambiguity [Q4]. This need for clarity of regulation was also emphasized in the context of sensitive personal data by the regulatory senior specialist [Q5]. Unclear regulatory guidance may cause the need to ***seek frameworks for interpretation from other public authorities*** [Q6].

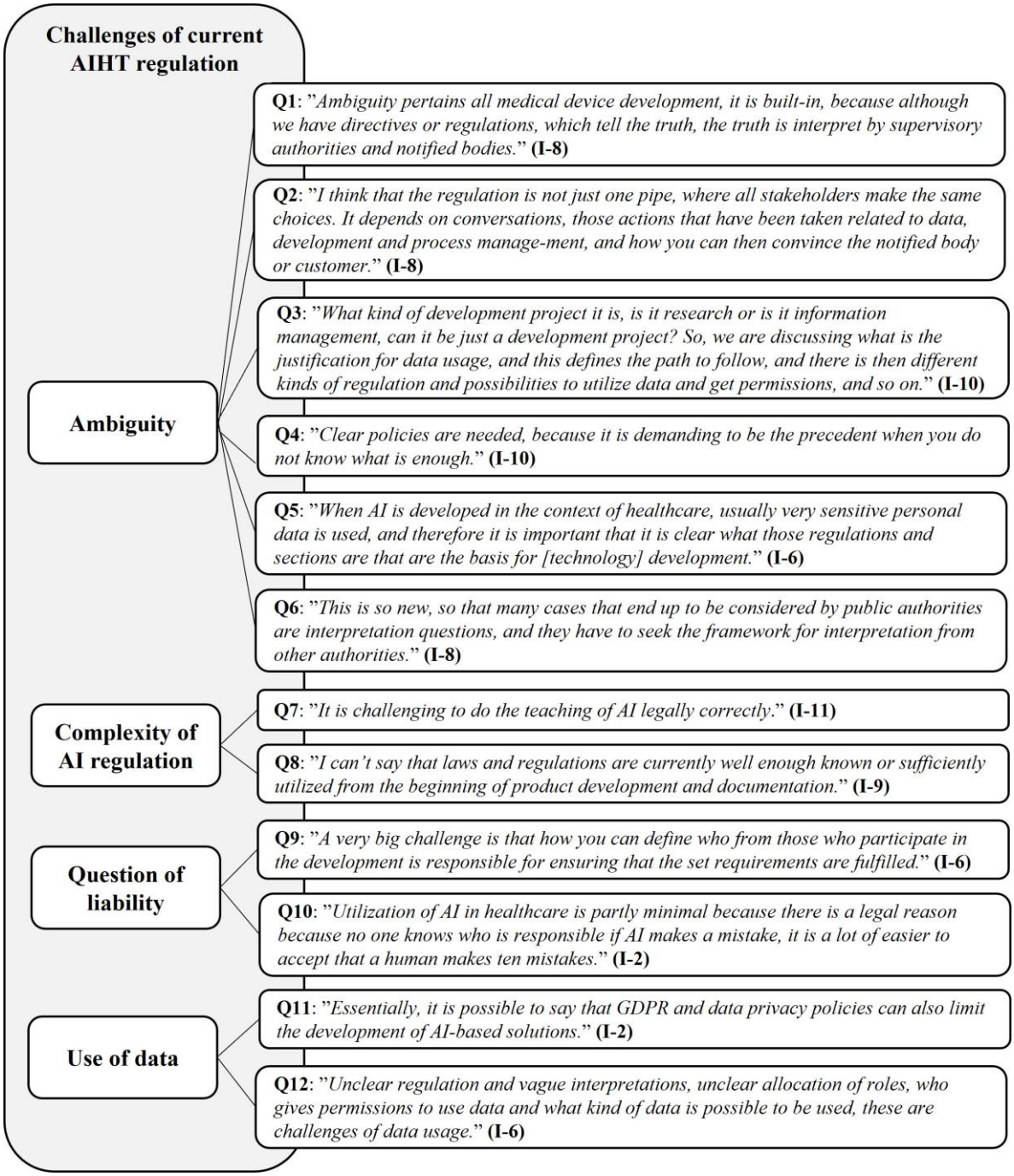

Figure 4. Challenges of current regulation of AI in healthcare.

The current **complexity of AI regulation** in healthcare ***decelerates the development of AIHT.*** Training an AI system in a "legally correct" way was perceived as challenging [Q7]. In addition, awareness of

regulations that currently regulate AI system development is not always sufficient, as the representative of MD supervision indicated [Q8]. The fulfilment of the MDR was perceived as a challenge in itself. As the regulation is unclear and bureaucratic, it is very time-consuming to develop AIHT.

Another aspect and challenge related to the development and the use of AI-based solutions in healthcare was the **question of liability**. From the perspective of one legal lobbying representative, it is challenging to define how responsibilities are divided among those who participate in system development, and how to define who of the participating parties is responsible for ensuring that requirements set by the regulation are actually fulfilled [Q9]. On the other hand, as the representative of a large health technology company indicated, also the use of AI includes risks, ***limiting its use in healthcare*** [Q10].

A main challenge for AIHT development is the **use of data**. Currently, the GDPR and data privacy policies are seen to ***limit the development of AI solutions*** [Q11]. Localisation requirements were seen as challenges in cases where a lot of data and data management tools are required. Also, data access rights and its management are a challenge for the data use [Q12]. Also, the national Act on the Secondary Use of Health and Social Data, and data sensitivity was seen as a challenge. One concern was that too strict data regulation may disable the whole AI sector.

4.3 Potential consequences of future regulation of AIHT

Interviewees pointed out several potential consequences arising from a future European AI Act for the development and use of AIHT. All quote references in this section refer to Figure 5, which summarizes these potential consequences and includes representative quotes.

The representative of consultancy perceived that the regulatory reform may cause **overly strict regulation** that will lead to a situation where ***development and productization of AIHT will move to less regulated environments*** [Q13]. The representative of healthcare growth strategy sees it as questionable that all AI solutions in healthcare are automatically high-risk products, which may cause unnecessary risk-based classification [Q14]. From a national perspective, the representative of a large health technology company as well as a legal lobbying representative argued that ***too strict national regulation will decrease organizations' competitiveness in international markets***, and ***hamper investment and innovation*** [Q15 and Q16]. Moreover, it was seen that on a global perspective, strict and less-strict AI regulation have started to tear countries and continents apart as the representative of small health technology company considered [Q17]. The representative research and education (I-2) was worried about how Europe will fend versus China. A small health technology company representative (I-8) emphasized that the development of innovative AI solutions requires an enabling innovation environment and regulation, otherwise there is a danger that good ideas will not be implemented and not be brought to the market. A representative of legal lobbying (I-6) emphasized that regulation should enable innovation and allow co-creation with patients.

An **increased demand for professional services, such as legal services**, is expected for AIHT development organizations, like in public healthcare [Q18]. The representative of healthcare growth strategy indicated that as a consequence of this, also the lawyers that support AIHT providers will need increased understanding [Q19]. Also, the representative of research and education (I-2) indicated that their organization will increase their expertise as part of their ecosystem and services to then have real experts who are able to answer questions and create RDI co-operation. This, in turn, will ***increase the costs*** related to AIHT development, as pointed out by a representative of legal lobbing [Q20]. The AI Act would cause **unequal treatment of diverse AI technologies**, as one representative of legal lobbing saw it [Q21].

In addition, as another representative of legal lobbing considered, some **currently less regulated AIHT** - as they are no certified MDs - might fall under the AI Act and then **would face heavy regulation**. Such technologies are, e.g., ***assistant technologies, welfare technologies and wearables*** [Q22]. In addition, the representative of a small health technology company argued that ***black-box technologies*** may encounter challenges under the European AI Act.

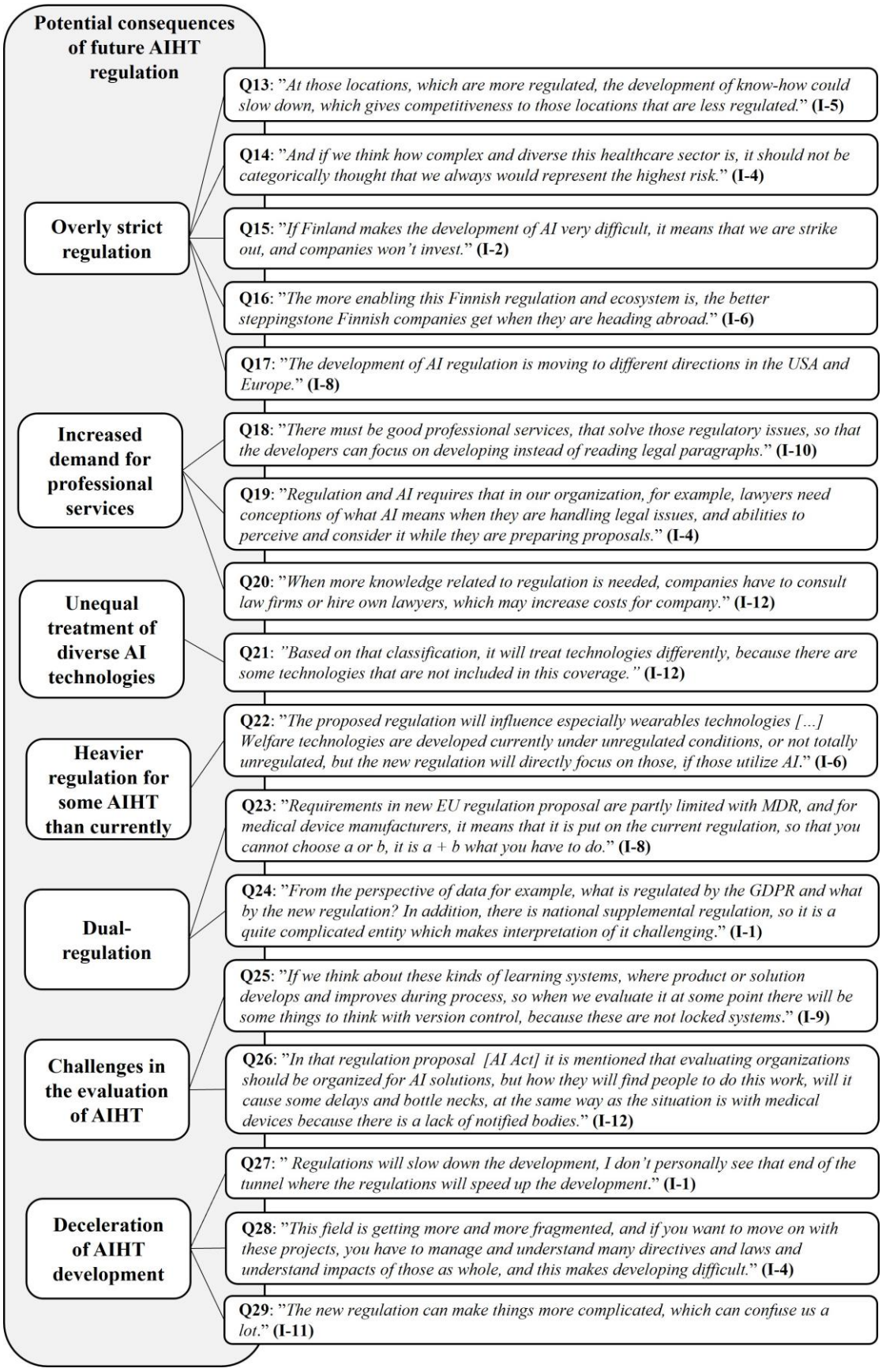

Figure 5. Potential consequences of future AIHT regulation.

Interviewees expected that a **dual-regulation is a likely consequence** of the regulatory reform – if there will be separate regulations for AI (= the AI Act) and for medical devices (= MDR), requirements from both regulations must be fulfilled, as the small health technology company representative concluded [Q23]. The AI Act is partly overlapping with existing regulation**,** such as the MDR and IVDR, as pointed out by I-8. This may lead to conflicts between the AI Act and the MDR, as pointed out by I-11. More generally, the AI Act was seen to ***cause increased difficulties with interpretation*** in relation to other regulations such as the GDPR and national supplemental regulation, opening questions regarding what is being regulated in which regulation [Q24].

From the perspective of supervision, the requirements set in the AI Act proposal also may lead to **challenges in the evaluation of AIHT,** e.g., regarding version control, because AI systems are not "locked" and learn over time [Q25]. According to a legal lobbing representative, also a too small number of those organizations that do evaluation will cause challenges ***and potential bottlenecks in the evaluation of AIHT*** [Q26], which might delay bringing AIHT to market.

Finally, a **deceleration of AIHT development** can be expected as the representatives of different stakeholder groups, such as the comments of the research and education representative [Q27], the legislation and political alignments representative [Q28], and the public healthcare representative [Q29] pointed out.

5 Discussion

With this study, we contribute to the very recent IS research opening on the regulation of technology by increasing understanding on the role of regulation as an environmental determinant that triggers and shapes digital transformation (Hanelt et al., 2021). Collins et al. (2021: 13) proposed that future IS research should address the question "What can researchers and regulators do to keep up with the speed of AI advances?" With the present study, we take a first step towards addressing this question by investigating how current regulation of AIHT and a potential future European AI Act – which can be seen as a regulator's answer to the advances in AI technology and the challenges these advances pose – affect not only (1) the innovation and development of AIHT, but also (2) bringing new AIHT to market and (3) the adoption and use of AIHT.

Figure 6 summarizes our main findings. We make visible potential consequences of the recent European AI Act proposal, ranging from organization-level impacts such as an increase of AIHT development costs, to industry-level impacts such as a deceleration of AIHT development and decreased competitiveness of Finnish/European AIHT providers and a danger that AIHT innovation start-ups might move to less regulated countries.

One important finding is the existence of and challenges stemming from ambiguity in the current regulation of AIHT. This ambiguity mostly stems from differing and conflicting requirements set in different regulations (e.g., MDR and GDPR). Already now, clear guidelines would be needed to decrease this ambiguity. However, according to the interviewees, the AI Act would even add an additional layer of ambiguity. Some earlier IS research has already pointed out that ambiguity in regulation can be problematic (see Väyrynen and Lanamäki, 2020), and our study confirms this. While one stated goal of the AI Act is to "*ensure legal certainty to facilitate investment and innovation in AI*" (European Commission, 2021a, p. 3), our findings suggest that at least for AIHT, it would result in increased ambiguity and a potential decrease in investment in and development of AIHT.

A recent study suggested that government regulation of AI systems may help users trust that an AI system will deliver the service the user expects, and that this in turn may positively affect their willingness to share personal health information (Yan and Xu, 2021). As AI technologies require a lot of data (Forcier et al., 2019), e.g., for training of AIHT, one could expect the AI Act to positively affect user's willingness to share data and thus positively affect development of future AIHT. However, if regulation is ambiguous, the regulative legitimacy of a technology may be contested, because ambiguous regulation leaves room for interpretation (Väyrynen and Lanamäki, 2020). As a result, the increased level of ambiguity regarding AIHT development may actually decrease the trust of users in AIHT.

Another interesting finding concerns the evaluation of AIHT under the AI Act. Currently, the lack of appropriate validation of AI technologies represents a challenge for integration of AIHT in clinical practice (Recht et al., 2020). The AI Act would require AIHT to undergo additional evaluation procedures before they could be brought to market, which would tackle this recognized validation challenge. However, we found that this evaluation requirement may also lead to delays in bringing new AIHT innovations to the market, if not enough evaluation organizations exist, as currently already seems to be the case with notified bodies.

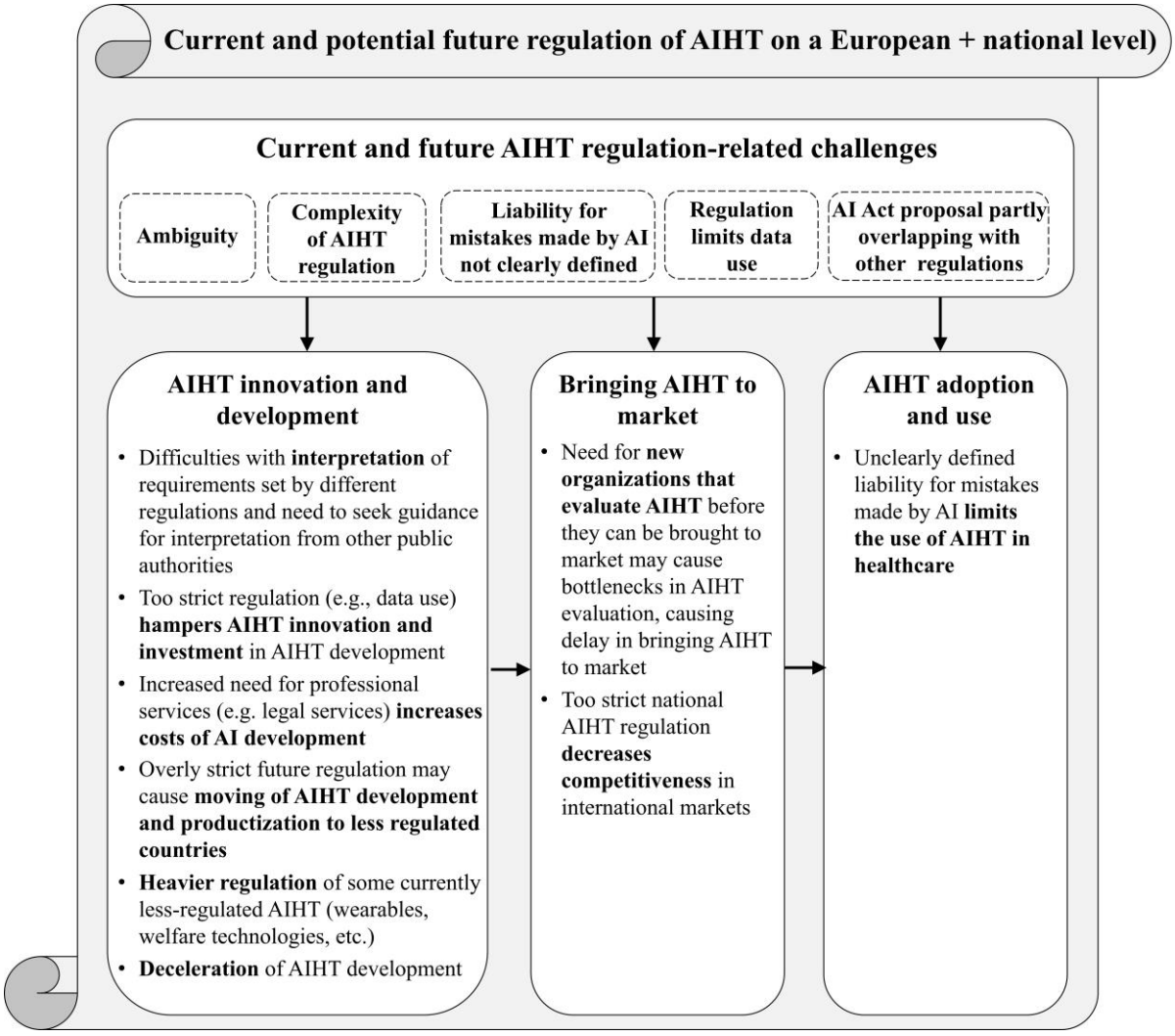

Figure 6. Challenges for AIHT development and potential consequences of the European AI Act.

Nguyen et al. (2022) identified five research opportunities for future AI-focused IS research, including the topic of "AI and markets". Their (ibid: 196) product-centric view sees AI technology as a "product with certain utility and costs for individual and organizations", and "focuses on the economic activity, people, and processes that surround efforts to produce, distribute, and use AI products". They pointed out that new players might emerge around AI products. Our study confirms this assumption: we identified new organizations for AIHT evaluation as such a potential new player emerging – not due to advances in AI development, but rather due to advances in AI regulation. More generally, our findings may provide useful for future IS researchers interested in contributing to "AI and markets" research themes, and we invite future IS research to be attentive to the role of legal regulation when investigating AI-related market dynamics.

Much of the current IS research on the digital transformation focuses on how an organization's use of digital technologies fuels disruptions which trigger strategic responses that in turn rely on the use of digital technologies, to eventually enable changes in value creation paths (Vial, 2019). With this study, we demonstrated that the regulation of technology affects where, when, and at what cost new AIHT innovations are available for organizations to use. Regulation plays a key role in the digital transformation, and we invite future IS research to investigate in more detail different mechanisms through which regulation affects digital transformation on the organization and industry level.

6 Conclusion

With this study, we sought to identify challenges that AIHT providers currently face regarding the regulation of AIHT and gain an understanding of the potential consequences of future AI regulation. We contribute to the recent IS research opening on the legal regulation of technology.

A practical implication of our study for regulators is the identification of a need for a sufficient number of evaluation bodies/companies for AIHT once the AI Act becomes effective. Our findings also have practical implications in form of useful insights to managers of AIHT innovation start-ups who might not yet have given that much thought how the AI Act potentially affects AIHT providers.

One limitation of the study is that we did not interview representatives of all central stakeholder groups of the healthcare RDI cluster in Finland at this stage. We plan to do this in the next phase of this research project. Another limitation is that this study has been conducted in one country only, and even though we involved a wide array of stakeholders with intimate and diverse understanding of the phenomenon we investigated, additional insights may be gained from involving more stakeholders, and conducting a similar study in a different setting (e.g., different European countries). Nevertheless, this limitation opens possibilities for future research to validate and extend our findings.

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