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ASSESSMENT OF DIGITAL HEALTH TECHNOLOGIES: STRONG STRUCTURATION THEORY APPROACH

Master's thesis

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DIGITAALSETE TERVISETEHNOLOOGIATE HINDAMINE: STRUKTURATSIOONITEOREETILINE LÄHENEMINE

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Background: Digital health technologies (DHT) range from mobile applications to artificial intelligence and robotics. Usage of DHT varies from disease treatment to health promotion and improvement of well-being. Since the amount of DHT is rising in the world, and in order to provide the best possible solution for the end-users, DHT must be assessed. Some European countries have their assessment frameworks already working but Estonia does not. **This thesis aims** to study through the lens of strong structuration theory (SST) what are the opportunities and areas of improvement when implementing DHT assessment in Estonia. **Methods:** This study used two qualitative methods for data collection – non-participant observation and focus group discussions formed by 19 public and private sector representatives health (technologies) field. Data was collected from three workshops, which were held in MS Teams. For this current thesis, secondary data analysis was applied on the recorded and transcribed data. **The results** of this study have been divided into four categories according to SST – external structures, internal structures, action and outcomes. Results pointed out several aspects which support the assessment process, such as already existing regulations, examples from abroad and local initiatives of mapping the assessment aspects. The dispersed information and lacking linkages between institutions, in addition to documentation not available for those needing it, were found to be problematic aspects related to DHT assessment process. Clear decision of the assessor was not agreed on. **Conclusions:** Producers know their responsibilities but their need of help encounters the scarce and scattered competence of external structures. Uniform rules and defined criteria, in addition to continuous collaboration between external structures and agents, are the aspects which must improve to provide safe and reliable DHT for the end-users. Dynamic interaction between the producers of DHT and external structures, which form the environment for action, is essential as the input of both parties affect the outcomes.

This thesis is written in English and is 66 pages long, including 6 chapters, 2 figures and 2 tables.

Annotatsioon

Digitaalsete tervisetehnoloogiate hindamine: strukturatsiooniteoreetiline lähenemine

Taust: digitaalseid tervisetehnoloogiaid, alates mobiilirakendustest kuni tehisintellekti ja robootikani, kasutatakse muuhulgas haiguste ravimiseks, tervise edendamiseks kui ka heaolu parandamiseks. Digitaalsete tervisetehnoloogiate arv maailmas on tõusmas ning pakkumaks parimat võimalikku lahendust lõpp-tarbijale, digitaalsed tervisetehnoloogiad vajavad hindamist. Mõningatel Euroopa riikidel on juba olemas hindamisraamistikud, aga Eestil veel ei ole. **Eesmärk:** uurida läbi strukturatsiooniteoreetilise lähenemise, millised tegurid toetavad ning millised tegurid vajavad täiendamist digitaalsete tervisetehnoloogiate hindamise juurutamisel Eestis. **Metoodika:** uuringus kasutati kahte kvalitatiivset meetodit – mittesekkuvat vaatlust ning arutelusid fookusgruppides, mille moodustasid 19 avaliku- ja erasektori esindajat tervise(tehnoloogiate) valdkonnast. Kolme MS Teamsis peetud töötoa lindistused transkribeeriti ning nende põhjal teostati käesoleva magistritöö raames teisene andmeanalüüs. **Tulemused** jagati nelja kategooriasse vastavalt strukturatsiooniteooriale – välised struktuurid, sisemised struktuurid, tegevus ja lõpptulemus. Mitmed tegurid, nagu olemasolevad regulatsioonid, näited välismaalt ning kohalikud algatused hindamisaspektide kaardistamiseks toetavad hindamisprotsessi. Hajus informatsioon, puuduvad ühendused asutuste vahel ning mitte-avalik dokumentatsioon leiti olevat problemaatilised tegurid. Selge kokkuleppeni, kes on hindaja, ei jõutud. **Järeldused:** tootjad tunnevad oma vastutusalasi, kuid vajades abi, põrkuvad vastu väliste struktuuride laiali olevat ning puudulikku kompetentsi. Vaja oleks ühtseid reegleid ja kriteeriume, ning pidevat koostööd struktuuri ja agentide vahel, et pakkuda lõpp-tarbijale turvalist ning usaldusväärset toodet. Dünaamiline koostöö tootjate ning tegutsemiskeskkonda pakkuvate väliste struktuuride vahel on vajalik, sest mõlemate osapoolte tegevus mõjutab lõpptulemust.

Lõputöö on kirjutatud inglise keeles ning sisaldab teksti 66 leheküljel, 6 peatükki, 2 joonist, 2 tabelit.

List of abbreviations and terms

CE	*conformité européenne*
DHT	Digital Health Technologies
DTAC	Digital Technologies Assessment Criteria
EU	European Union
EHIF	Estonian Health Insurance Fund
FDA	U.S. Food and Drug Administration
GP	General Practitioner
HAE	Health Application Evaluator
HTA	Health Technologies Assessment
HWISC	Health and Welfare Information Systems Centre
ICT	Information and Communication Technologies
IT	Information Technologies
IVD	*In vitro* Diagnostic Device
IVDR	*In vitro* Diagnostic Device Regulation
MD	Medical Device
MDR	Medical Device Regulation
MoSA	Ministry of Social Affairs
MVP	Minimum Viable Product
NHS	National Health Services
NIHD	National Institute for Health Development
NICE	National Institute for Health and Care Excellence
ST	Structuration theory
SST	Strong structuration theory
TalTech	Tallinn University of Technology
UK	United Kingdom
WHO	World Health Organisation

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1 Introduction

In the world of ageing societies it is expected that in the year 2050 there is double the count of 60 year old people and older, moreover the number of over 80 year old people will triple [1]. In European Union (EU) Member States the number of people under 55 years will decrease about 13.5% by that time [2]. Policymakers need to make decisions on how to foster innovation and digital transitions to increase productivity [3]. Shrinking working-age population and lack of or unevenly distributed medical workforce [4] have revealed the need to promote information and communication technology (ICT) tools, which would help to enhance home-based health care [5], to keep-up independent life at older age [4] and to mitigate physicians' work [6]. The potential of the use of innovative ICT tools in health care to predict, prevent and promote health in future has been pointed out [5]. Moreover, the shift to digital health is besides technological change also a change in roles (of health care professionals, patients and policy makers) [6].

COVID-19 pandemic has shown the rapid growth of the digital technologies market [7], [8], [9], had its impact on boosting telehealth and e-consultations [10] and indicated the need for remote patient monitoring. Self-monitoring with different digital tools outside the boundaries of traditional health care settings, where one option to intervene is possible through mobile applications, has increased after COVID-19 pandemic [8]. For example, the number of mobile applications related to health in two of the biggest market share holders (altogether over 95% of the market [11]) Google Play and Apple store have around 90 000 [12] and 123 000 [11] respectively mobile applications to download. Among average applications, which are for a wider population, the number of condition-specialised applications is also rising [8]. Digital therapeutics and digital care tools which focus on more specific and narrow clinical indications in order to treat, manage or prevent the condition with software are now noticed by policy makers [8] and as the COVID-19 pandemic has reflected, rapid integration into practice is needed [9].

However, it is not clear yet how the technology should be incorporated for example in public health care [13]. If the technologies are meant to strengthen primary care it is essential to have top-level policy and reimbursement schemes meeting different

stakeholders needs [14]. As some EU member states already have their models for digital health technologies (DHT) assessment [15] and reimbursement [16], [17] up and running, Estonia is still considering the possibilities of who should assess, what type of DHT and which aspects of DHT to assess [18].

Similarly to other countries, Estonia also needs to find solutions for medical workforce shortages, development of e-services and changes in financing as the health care system so far is not sustainable [19]. Estonia is known as a digitally advanced country gaining the top scores of different comparative lists (EU countries in Digital Economy and Society Index [20] and eGovernment maturity [21]). About 92% of households in Estonia have internet connection [22] and almost all public services are digitally available for citizens [23]. But with the growing health care needs of an ageing population the shift to more sustainable (digital) systems in health care is needed [24]. Development of digital services must be faster and the outcomes more user-friendly [23], moreover, patients must take charge in health topics and focus on prevention [24]. COVID-19 outbreak demonstrated that rapid adoption of telemedicine services in Estonia is possible, but also outlined the problems related to reimbursement and regulations of new digital solutions [25].

To study implementation and adaptation of new structures, some studies have used strong structuration theory (SST) to describe the continuous and dynamic processes between agents and structures [26], [27], [28], [29]. In the centre of SST there are four elements: external structures, internal structures, active agency and outcomes [29], which help researchers to understand the context of how the individual (agent) is situated in the webs of relationships between the structures [28]. Agent is guided by its internal structures (world-views, habits and knowledge) and external structures (institutions, laws, guidelines) and acts according to these structures, leading to outcomes which can change or maintain the external structures [28], [29]. To understand the reasoning of agents and structures in Estonian DHT assessment context the author of this thesis used SST to provide a novel view on the topic.

Problem statement: The number of digital health technologies has rapidly grown in recent years [8] and in order to provide reliable and safe DHT product or service to end-users there is a need for assessment [30]. Many countries already have an assessment framework for DHT [16], [17],[31]. Estonia has started the assessment framework build-up [18].

Aim: The aim is to study through the lens of strong structuration theory what are the opportunities and areas of improvement concerning DHT assessment implementation in Estonia.

Research question 1: What aspects of DHT assessment are supportive?
Research question 2: What aspects of DHT assessment are problematic?
Research question 3: Who and to what extent should contribute to different DHT assessment aspects?

2 Background

In this section an overview of the relevant topics related to DHT and their implementation is given. First chapter will introduce the concept of DHT, also the topic of COVID-19 pandemic and its impacts on health care is reviewed. Then the already existing frameworks from Europe are described, which is followed by an overview of the Estonian current health care system with its collaborators. Finally, the structuration theory and strong structuration theory are introduced.

2.1 Digital Health Technologies

The World Health Organization (WHO) describes health: *"...a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity* [32]". Digital health is a term for information and communication technologies to manage diseases and health risks and to promote wellness [33]. The term digital health is extension of the term e-health, comprising also the use of smart wearable devices, telehealth and telemedicine, health information technology, mobile health (mHealth) and personalised health, expanding to digital technologies such as artificial intelligence and robotics [33], [34], [35].

Digital health technologies (DHT) range from mobile applications, software used by clinicians to artificial intelligence and machine learning. They are tools to improve diagnosis or treatment of a disease or to improve individuals health and well-being [34]. The United Kingdom National Institute for Health and Care Excellence (NICE) describes DHT as: "*Apps, programs and software in the health and social care system. They may be standalone or combined with other products such as medical devices or diagnostic tests*" [36]. WHO has outlined that digital health should be integrated in every Member State's health care system [35] and the digitalisation (in health, business, climate etc politics [37]) is also one of the European Commission's six targets for the years 2019-2024 [38]. One of the Commission's digital strategy priorities is to create "European health data space" where studies, treatment and diagnosis are person-centred and the

information is reliable [37]. Intention is that people are in charge of their own health – promotion, prevention and chronic disease monitoring through innovative digital solutions should be in the hands of the individual [38].

New ICT tools should be easily adaptable to existing health care systems and to increase patient acceptance, moreover new systems should be created in cooperation with the end-users [5]. Although the patient's self-care improves due to more available hardware and software [6], there is also a risk that patients are unable to orientate in the endless amount of potentially unsafe or unreliable DHT, so policymakers and doctors have the duty to involve patients in their own care and decision making [6]. The further the 21st century goes, the more digitally wise persons or "digital natives" [39] there will be, so patients must no longer be passive, but motivated to use the digital tools and information in their hands [6]. Those grown with digital technologies will use them also in seeking medical aid, which indicates the need to integrate digital health to health care with correct and safe manner [6]. Health information technology facilitates patient to manager or patient to care coordinators communication on higher levels [5]. However, before validating digital tools, different decision makers have to see the proof of the digital product or service and also clinical trials may be needed [33]. The problems of incorporating innovative practices in public health decision making are: new practices are often pilot experiments, fragmented, not part of broader context and not easily scalable [5].

Medical equipment, medical devices and medicinal products can be assessed by health technologies assessment (HTA) bodies [40]. In December 2021 new regulation came into force attempting to unify the HTA requirements in the EU [40]. HTA is a multidisciplinary process which concludes medical, economical, ethical, and social aspects of technology in an unbiased way and is performed in order to provide input for policymakers in their decisions [41], [42]. However, the HTA has deficiencies in assessing digital health technologies as the latter needs assessment also in aspects such as accessibility, data security and data protection [30] in addition to cybersecurity, patient safety or technical reliability, and HTA does not provide decision makers enough information about DHT [43]. EU regulation concerning HTA is fairly new, but it has the potential of filling some gaps also in DHT assessment. Regulation suggests building national HTA systems, moreover stresses the importance and possibilities of the digital market, which complements the HTA evidence base [40]. So far, an example of adding components to traditional HTA in order to assess digital health technologies is provided

in Haverinen et al study [30]. In which, based on systematic review and interviews, they built an assessment tool similar to HTA, but the tool is advanced and can be used in mobile applications, artificial intelligence and robotics related health care assessment [30].

During the COVID-19 pandemic [44] and lockdowns [45] people had to adopt new ways of coping with their everyday life. In order to avoid contact with other people, digital health solutions had their role to play and first signs showed the switch from face-to-face visits to virtual visits in primary care [46]. ICT tools diminished the bureaucracy related to health [46] and increased the number of direct-to-consumer digital services, but the lack of reimbursement framework set back the telehealth services adoption by public institutions [10]. Similarly to the rapid adoption of vaccines and drugs against novel coronavirus, also the new digital strategies should be adopted [47]. Suggestions for faster DHT adoption include calls for governmental action - public institutions need to be open to innovation and coordination between institutions has to improve [10]. COVID-19 pandemic has proven the acuteness of incorporating digital solutions into health care and demonstrated DHT ability of making life easier for people, but more definitive decisions from policymakers is expected [9].

2.2 Existing frameworks in Europe

Estonia is geographically situated in Europe, belongs to the EU [48] and follows its legislation and regulations, also the assessment frameworks described in this thesis are concentrated on EU level. As a former EU member, framework from the United Kingdom (UK) is additionally inspected in this chapter. Although the U.S. Food and Drug Administration (FDA) is also dealing with similar topics on how to evaluate and reimburse DHT [34], this study is focusing on European level frameworks highlighting the already working assessment pathways in Germany, Belgium, Finland, and UK . Table 1 gives an overview of four existing European assessment models.

Table 1. Overview of European assessment frameworks (adapted by the Author according to [16], [17], [49], [31]).

	Germany [16]	**Belgium** [17]	**Finland** [49]	**UK** [31]
What is assessed?	Applications (native/desktop/ browser applications)	Mobile applications	Mobile applications, robotics, artificial intelligence	All new digital technologies
Intention	Safely integrate applications in healthcare with proof.	Integrate mobile applications into healthcare system	Reliable and objective recommendation for health care workers	Meeting standards, confidence for users
Criteria	3 main categories with subcategories	3-level pyramid	5 categories	5 categories
MD (with *CE*-marking	Yes	Yes	Yes	Yes
Financing	Yes	Yes/No	No	Yes/No
Valid	Up to 1 year (if not meeting all criteria), otherwise until significant changes	N/A	3 years	N/A

As seen from the Table 1, European assessment models have similarities such as all of them assess only those technologies already having *CE* (*conformité européenne)* marking (they have to be Medical Device Regulation (MDR) compliant in EU [50]) and listed as medical devices (MD) or *in vitro* diagnostic devices (IVD). "*Medical devices are products or equipment intended for a medical purpose* [51]" and they provide "*innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease* [52]". MD manufacturer has to take into consideration it has all the needed documentation: about clinical evidence and risk management, technical aspects, post-market surveillance arrangements and clinical follow-up plans, in addition to the quality management system and implementation plan [53]. Table 1 also outlines the difference between countries' assessment models, where Germany and Belgium assess only mobile applications [16], [17] while Finland has extended its assessment also to robotics and artificial intelligence solutions [49]. One emerging

difference compared to others is that the UK suggests all new digital health technologies should pass assessment [31].

The most rapidly evolved example of a digital health framework is the DiGA process, which leads the digital transformation in Germany [54]. Germany was the first country allowing doctors to prescribe mobile applications, financed by local health insurance [55]. DiGA means "digital health applications" (*Digitale Gesundheitsanwndungen*) for diagnosis, treatment, alleviating symptoms, monitoring illness, or supporting a healthy lifestyle. DiGA is *CE*-marked medical device which is based on digital technologies and used by patient only or by patient together with health care provider [16]. Assessment is based on 3 categories with subcategories and after passing, DiGA gets reimbursed for one year during which it must prove its effectiveness in order to prolong the financing period. DiGA directory aims to be a transparent and trustworthy place for patients and physicians to make decisions and a place where positive effects of the DiGA are displayed [16].

Second already working framework is from Belgium and also focusing on financing mobile applications in the end [17]. Belgium has a platform called mHealthBelgium which collects the information of health-related mobile applications, their features and financing in one place, intending to integrate applications into health care. Three national authorities cooperating with different stakeholders have formed a validation pyramid for mobile applications [17]. After meeting the first level requirements the application can proceed to the second level. Finally, when the application meets also second level requirements it can proceed to the third and final level where the application has to prove its socio-economic value and can apply for funding [17].

Finland does not have a national procurement system for DHT but it has a tool for manufacturers self-assessment and product development called Digi-HTA which is available on request [15]. Based on assessment it can be decided how suitable the assessed product is for health care use. The tool has five assessment domains: effectiveness, safety, cost, data security and protection; and usability and accessibility. Based on the assessment product gets a recommendation (up to 10 points) which is valid for 3 years [49].

The UK has the Digital Technology Assessment Criteria (DTAC) as a national baseline criterion. DTAC is meant for healthcare organisations but also for developers of digital technologies to check the minimum baseline standards for entering the health and social

care sphere in the UK. DTAC focuses on five main areas of assessment criteria. These criteria are necessary to meet in order to enter National Health Service (NHS) health and social care and get the national level procurement for DHT [31]. NHS is working with NICE evidence standards framework to provide DHT developers with certain norms to achieve clinically effective and valuable products [36].

While developing a new assessment framework it is essential to understand the wider concept and the notion that technologies do not exist on their own – change in technologies go hand in hand with changes in social, organisational and economic sphere [56]. It is also suggested to first assess performance and usability and then the value of information of new technologies before their large-scale deployment [57]. If technologies are meant to be used in new settings, a faster assessment approach could be used [57].

2.3 Estonian health care system

Estonia has solidarity based compulsory health insurance and the health and social care is led by the Ministry of Social Affairs (MoSA) [58]. MoSA area of government covers several agencies and bodies such as Estonian Health Board (EHB), National institute for Health Development (NIHD), Health and Welfare Information Systems Centre (HWISC), Estonian Health Insurance Fund (EHIF) etc. [19]. These public authorities have different responsibilities and tasks in the Estonian health care system. Figure 1 illustrates how DHT aspects or functions are related to public authorities.

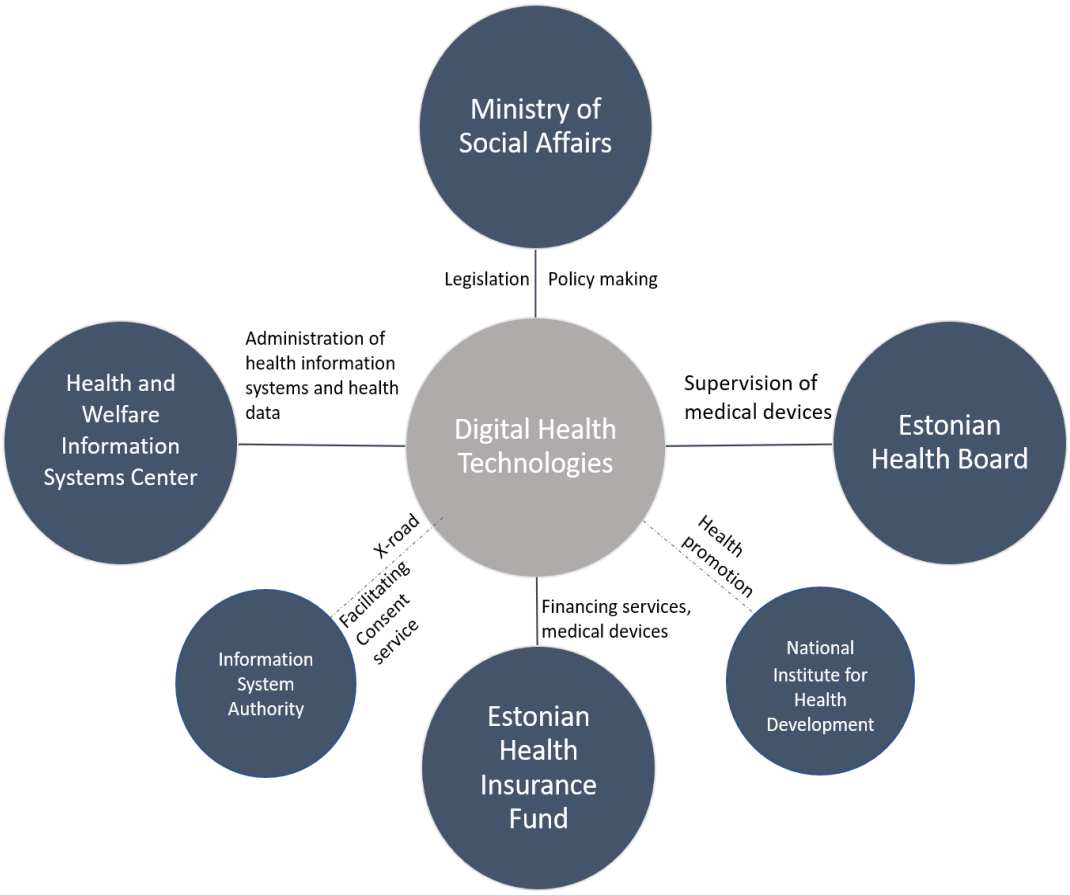

Figure 1. Public institutions' linkage to DHT.

As mentioned above MoSA is the highest authority responsible for legislation and policymaking related to health services and institutions under MoSA [58]. EHB, among other duties, is responsible for medical device surveillance. So, in case DHT is registered as MD or IVD, it has to be registered in EHB database and meet the requirements [59]. These requirements are set by European commission regulations concerning MD [60] and IVD [61]. EHB is responsible for the Medical Device Database in Estonia [62]. However, as EHB has stated, registration in the database does not mean MD meets the quality requirements and approval of EHB [62].

NIHD is a research and development body who carries public health related research, promotes health and runs disease prevention programmes, they administer Estonian health statistics and influence health policy [63]. NIHD is leading the project about personalized medicine [64] which follows the frames of Estonian e-health strategy [65].

The study of personalized medicine is among other aspects also about the possible digital solutions related to the topic [64].

HWISC is developing information technology projects related to the health and social sector, advising public institutions about development and administration of ICT systems and responsible for the health data transfer between information systems [66]. Estonian Information System Authority administers the X-road through which (health) data is exchanged between institutions [67], also the consent service for those who wish to share personal data with service providers is developed by Estonian Information System Authority [68]. In case there is a need that DHT would collect and process personal data, consent service would be the mediator between personal data and companies using it. At the time of writing current thesis, consent service is still in the piloting phase [69].

EHIF solidarity based health insurance means that the employed population pays taxes to cover also the children, students, pensioners and unemployed persons (also called noncontributors [19]) insurance. Everybody receives the same level of insurance regardless of the size of contribution [70]. EHIF budget has been in deficit since the year 2013 and the amount of noncontributors is forming over 50% of the insured [19]. EHIF admits the challenges of ageing society and limited resources of funding and states its mission to be better prevention, early intervention in addition to better coordinated care [71]. EHIF strategy for the years 2020-2023 states also that one of their priority will be supporting digital solutions development and usage in health care [71]. Along with the ageing populations in the world [1], Estonian population is ageing too. It is assumed that in the year 2035 every fourth person in Estonia is older than 65 years and the number of people in working age is decreasing by 35 000 people [71]. As the population is ageing, so are the doctors ageing, which is in addition to uneven distribution and lack of new generation of physicians causing the deficiency of health care professionals in the future [71]. So far Estonia has 3,5 doctors per 1000 inhabitants (EU average is 4,9) [73], but the number is predicted to fall [72] and even worse is the situation with nurses, where the number of nurses in Estonia is significantly below EU average respectively 6,6 and 9,1 per 1000 inhabitants [74], [19].

To tackle the problems of ageing and lack of workforce in future, long-term strategies are suggested in health care [19]. Also the shift to health promotion and safety of data sharing with digital health applications enabling health promotion is proposed [24]. National

Health Plan for the years 2020-2030 suggests cooperation between public institutions, private sector and third parties, recommends individual's responsibility over his/her health promotion and proposes incorporation of innovative solutions into healthcare [75]. COVID-19 pandemic elevated the need to implement new solutions into health care, so EHIF has initiated a remote health care services innovation contest where 4 out of 33 projects got funding for preparation and implementation [76]. In order to evaluate such innovative projects, EHIF has adopted and translated NICE framework to assess the effectiveness and economic value of DHT [77]. As the adoption of NICE framework was the first step towards Estonian own assessment framework, EHIF elaborated the idea and initiated the second step in the form of workshops [18]. Representatives from public and private institutions, hospitals and enterprises met to build a framework for Estonian context about how to assess DHT, how to possibly reimburse them and safely integrate them in Estonian health care system [18].

2.4 Structuration theory

The theory of structuration is developed by British sociologist Anthony Giddens and it is based on the dichotomy of structure and agency [78]. Structure is considered as sets of rules and resources and agents perform their daily actions in this structure [79]. Agents (as individual actors) are at the same time and in different ways positioned in everyday life, in their life-span and in social institutions [79]. The duality of structure is formed by structure and agency, which are not independent but dependant on each other, producing and reproducing themselves [79]. Structures are enabling and constraining the agent and its action [79]. It is argued that the power of agent to intervene makes social change possible [80]. Theory did not want to emphasize either agent nor the social structure but to picture those two as equally contributing in the development of society [80]. As at the time of the development the theory had an unconventional approach in social sciences, it got a lot of attention and critique [78]. Giddens drew an overview of 20th century's sociologists' worldviews and stated that his intention was not to invent anything new or replace the older ones, but to bring out the shortcomings in earlier theories. With the criticism and further development of concepts from earlier theories, Giddens presented his structuration theory (ST) [79]. One aspect in previous social theories that Giddens argued against was the individual seen as a passive creature in society who is the receiver of messages and acts only according to institutions' orders [81].

ST has been interpreted in many ways. Pozzebon et al [78] suggested to use three basic elements of structuration theory in empirical (IT) research: duality of structure, time/space distanciation and actors' knowledgeability. Interactions between people, technologies and social action has been studied through the lens of structuration [82] where Orlikowski adapted Giddens schema of dualistic agent and structure, replaced the structure with different technological aspects and presented how the change in technology's "*ongoing (re)constitution*" [82] and interaction between people and technology happened [82]. Orlikowski pointed out that organizational change does not depend only on the investment or deployment of technology but on the way they act with technologies-in-practice [82].

Shaw et al conducted an overview of different social practice theories in their study and ended up finding a common line across all these theories: technology use in healthcare is dependent on the actions of end-users and local and distant contextual factors influencing the action [83]. As the time-frame of this current thesis is narrow, giving the author no options to dig in depth of all the theories of social practices, the list of Shaw et al [83] gave a comprehensive overview of the different social theories to choose from. Most suitable was strong structuration theory [29], [28].

2.4.1 Strong structuration theory

Stones claimed that Giddens' structuration theory was too abstract, philosophical and difficult to use in empirical research and proposed revision to the framework of ST [29] by building bridging concepts between abstract and real levels of structuration theory. In strong structuration theory (SST) some central elements of ST were kept but also new concepts were added giving a more systematic overview of the elements and their relations [29]. Quadripartite nature of structuration [29][p.84] was introduced by Stones which is an extension from Giddens duality of structure and has four separate but connected aspects: external structures, internal structures, active agency (or action) and outcomes [29]. External structures are separate from the agent and form the environment of action. Internal structures are part of the agent and can be divided into conjunctural (knowing one's role or positions) or general-dispositional structures (unnoticed states which are drawn on without thinking or noticing). Active agency is the way agent uses their internal structures whether routinely or strategically. Outcomes are actions or interactions of external and internal structures, which can be changed or reproduced and

they can be intended or unintended [29], [28]. Above mentioned four main aspects form the core of this thesis. These four categories are the base for the coding scheme which is described in chapter 3.4.1.

Strong structuration theory was praised by Jack et al [84] as a well-articulated theory offering wider value for organizational research. They brought out the aspects of how structuration theory of Giddens [79] explained by Stones [29] could be used empirically [84]. Jack et al emphasized the differences between Giddens and Stones theories: when Giddens described three modalities of structure (signification, legitimation, domination), Stones replaced them with four components framework and this allowed a broader approach for interpretation. Also, the aspect of data collection while using SST – it does not deny or favour any specific data collection method [84]. Comparison of ST and SST is brought in Table 2.

Table 2. Comparison of ST and SST (adapted by the author according to [79], [29]).

<table>
<tr><th></th><th></th><th>**ST** [79]</th><th>**SST** [29]</th><th></th></tr>
<tr><td>Structure</td><td rowspan="3">Duality of structure</td><td>Rules and resources</td><td>External structures</td><td rowspan="4">Quadripartite of structuration</td></tr>
<tr><td>Agency</td><td>Agent</td><td>Internal structures</td></tr>
<tr><td></td><td></td><td>Active agency (action)</td></tr>
<tr><td></td><td></td><td></td><td>Outcomes</td></tr>
</table>

In Table 2 the comparison of ST and SST outlines the main differences of these theories. While ST has two components, structure and agency, which form the duality of structure [79], SST divides agency in two (internal structures and active agency) and adds the outcomes component. The action results in outcomes, when the agent draws on the internal and external structures. Duality from ST is expanded to four elements in SST or so called quadripartite of structuration [29]. SST has been used to study implementation of IT system for medication optimization in primary care [26], clinical decision support system implementation [27], email consultation implementation among general practitioners (GP) [85] and resistance to newly implemented expert system [86].

Studies on GPs showed that when internal structures (GPs and pharmacists) behaviour changed, it resulted in changes of external structures (social and organisational context) [26]. Another study used SST to understand processes of change among internal

structures (paramedics and technology) and how the use or non-use of implemented new system changes the external structures (NHS policy and local services) [27]. SST has been used to understand changes in macro- (policy documents), meso- (GPs) and micro-levels (patients) when implementing a new system. Successful implementation was considered to be internal structures (patients and their relationships to doctors') modifying external structures (rules and policies) [85]. Also, adoption failure of new IT-system has been studied with SST, where internal structures' (GPs) low adoption rate did not lead to change in external structures (policies, norms, new technology) and instead grew resistance towards the new system [86].

Based on the previous studies mentioned above, the SST with its four elements appeared to be a suitable analytical frame for this thesis to study the aspects influencing DHT assessment.

3 Materials and methods

This section provides information about the materials and methods used in studying problems and possible solutions related to DHT assessment in Estonian context. This research was conducted by applying secondary data analysis on the original research of "Digital Health Technologies assessment framework workshops. Report." [18].

The data collected for qualitative analysis used two methods – focus group discussions and non-participant observation of the workshops. Study site was Estonia and data was collected in November and December 2021. This study is aligned with the recommendations of Standards for reporting Qualitative research [87].

3.1 Study design

The study, from which data for this thesis originates, took place in Estonia where EHIF initiated a project to build a framework for DHT assessment. Project was performed by Tallinn University of Technology (TalTech) employees, also the author of this study was part of the research team. Initial assignment given by EHIF consisted of questionnaire, workshops and feedback which were used to submit the final report [18]. Only the data collected from workshops was used in this thesis, leaving the questionnaire and feedback aside. Since the COVID-19 pandemic situation in Estonia did not favour face-to-face meetings, three workshops in November and December 2021 were held online, using MS Teams [88]. MS Teams is software enabling conference calls with video, where participants can see and hear each other, are able to share screens and can be divided in smaller groups for groupworks [88].

Each of the three workshops lasted about four hours including small breaks and the content of the workshops was built up based on questionnaire answers received before the first workshop. All workshops had two tasks which were tackled in smaller groups of people. One non-participating observer was studying each group performing their assignment. Smaller groupworks were followed by the entire group discussion where the ideas were presented and explained. Participants used Miro dashboard to write down their

opinions, thoughts and suggestions and to complete the tasks given before. Miro platform is virtual whiteboard, which is used online and people with different locations can fill the whiteboard in real time, simultaneously seeing other collaborators work and writing [89]. Every group had the same tasks and same Miro-board to fill-in. Miro board had virtual sticky-notes for writing down the ideas of participants and to organize them within the group as wished. Figures in Miro-board were meant to assist participants to complete their tasks and to concentrate on the topic.

First two workshops had the same topics for focus group discussions. In the beginning of the workshops the groups were given an assignment to discuss over the topic what kind of DHT should be evaluated. Second discussion topic was about what aspects of DHT and by whom should be assessed. In the third workshop participants discussed the possible models for the framework and next steps.

3.2 Data collection

Data collection methods of this study were non-participant observation and focus group discussions. Non-participant observation is a research method where the observer is not contributing in the study settings he/she is viewing and remains as an "outsider" being known or unknown to participants [90]. The observer does not talk to participants, does not ask questions or advise them in their assignments. Non-participant observation is a method which provides profound insight and significant data of actual situation [91] and helps to avoid external opinions intruding on the situation under observation [92]. These were the reasons why non-participant observation study was chosen as one of the research methods. In the workshops, where the data was collected, four non-participant observers were contributing. They were introduced in the beginning of the workshops and accepted by the participants. Besides listening and observing workshops, observers made notes, recorded the discussions, and later transcribed them verbatim for analysis.

In addition to non-participant observation, focus group interviews were used for data collection. Focus group interview is a widely used and popular method in qualitative research [91], [93] and the methodology has been defined also as group or focus group interview or focus group discussion. In focus group discussions the researcher is ensuring participants, who have common interest in the topic, actively discuss with each other [94], [93]. Focus group discussion is used in research areas where professional practice is

problematic, also to explore insights to people with similar conditions or background, to plan interventions, to develop guidelines among experts [94] and to get initial information about novel or unexplored behaviour patterns [95]. Focus group method is suitable to use in research where participants may have not thought deeply about the topic, are uncooperative or are from such a group whose voice otherwise would not be heard [96]. Moreover, focus group discussions offer a good base to catch difficult topics or different actions which modify the group and its thinking [95]. The reason why the focus group method was chosen was the urge to explore participants' viewpoints of already existing evidence and to detect aspects which would not arise from individual interviews. In this study there was one moderator, who guided the focus group discussions and pointed out the necessary questions or tasks.

3.3 Study population

Focus group sampling of participants can be systematic random selecting, where sample pools or software is used for selection or the selection can use purposive sampling [95]. Purposive sampling allows one to take into account the characteristics related to the topic discussed [95] and to demonstrate the variety of viewpoints and knowledge within the group [94]. Group composition is suggested to compile in a way participants would share at least one thing in common, are like-minded in terms of research topic and share similar social and cultural background [94], [93]. Size of the sample differs in literature depending on the method chosen but is usually around 6-10 participants [93], [95]. Too small a group has the risk of some people not showing up and too big a group may be difficult to moderate, also some participants may feel left out of discussion [95]. It is common to ask for more people to attend as some would not turn up and it is also suggested that the number of focus groups should be minimal in order to perform better analysis with optimal workload [95]. Considering the above-mentioned suggestions from literature, this study used purposive sampling and the common shared factor among participants chosen for group discussions was relation or interest to (digital) health (technology) through occupation or workplace. Aligned with recommendations, the size of the focus groups was chosen near optimal and for ensuring participants turn up several notifications were sent by email before workshops. Invitation emails also required reply from the participants. Invitations were sent to 12 people to attend the first workshop, to 10 people to attend the second workshop and to 19 people for the third workshop. First

focus group consisted of 10 participants from public institutions (MoSA, Information System Authority, EHB, HWISC, EHIF, NIHD, TalTech). Second focus group had 9 participants from private companies (start-ups, technology company, pharmacy company and hospitals). Third workshop gathered people from both previous workshops and had altogether 13 participants from the public and private sector.

3.4 Data analysis

Conversations during workshops were recorded with MS Teams and transcribed verbatim. Recordings were sent to transcription through a platform which enables Estonian recordings transcription and is developed in the department of Cybernetics in TalTech [97]. Transcriptions were received by email in .txt file format [97]. Written files of texts were read and corrected by four observers.

3.4.1 Analytical framework

For data analysis qualitative content analysis was applied. Transcripts were systematically analysed with deductive content analysis. Deductive content analysis is a theory-based approach, where the coding scheme, categories and definitions for analysis are designed using formal theory with its concepts [98]. In this thesis SST was used and data was analysed according to the four elements described in chapter 2.4.1. forming the initial categories for coding. Thematic codes are shown in Figure 2.

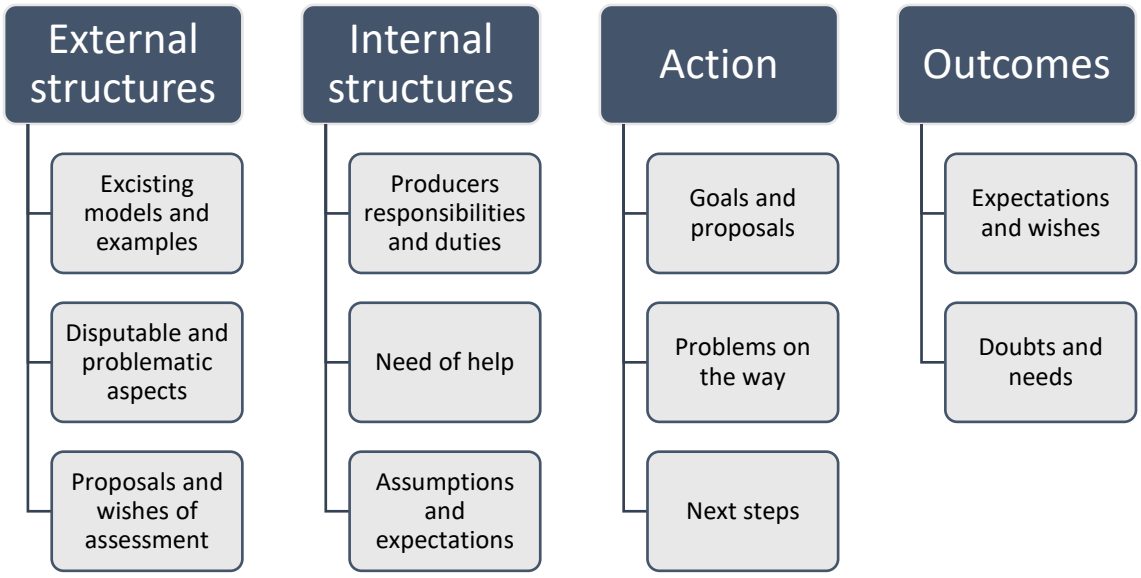

Figure 2. Thematic coding scheme.

After the initial grouping between four categories and repetitive reading of the transcripts the text was coded using inductive coding and colouring the lines according to codes in MS Excel. Then the codes were grouped into bigger groups under the labels shown in Figure 2. First it was considered to include multilevel analysis with interactions in micro, meso and macro level, as in some studies [85], [28]. However, as the interactions between DHT producer (internal structure) and regulators or policymakers (external structure) in this current study were considered two-dimensional macro-micro level interactions, the author of this study concentrated only on these two levels of interaction leaving the meso-level (GPs or doctors using DHT) for future studies.

As the data analysis of this study was based on secondary data usage, not all transcripts used for analysis were edited by the author of this study. Due to uneven quality of transcripts some quotations have more specific pseudonyms than others. This study used the pseudonymisation process where each participant got an individual pseudonym when possible or group code when not individually identifiable. Quotations were marked with letter and number combinations representing the focus group discussion in workshops (W1, W2, W3). The participants were given pseudonyms PU1-PU10 representing public sector participants or PR1-PR9 representing private sector participants. In case lines were identifiable only on group level, the workshop number was after group identifier (GR1-GR4). Quotations were translated from Estonian to English by the author of this thesis. Repetitive thoughts of participants were collected under certain codes and only the most relevant or interesting quotations were brought out in results.

3.5 Ethical considerations

Sometimes the non-participant observation method has been regarded problematic in terms of getting consent from participants [99]. In this study the concern was not relevant as the participants of the workshops were informed in the beginning of workshops about the non-participant observers, about the recordings of the workshops and also about the purpose of the study. Participants were informed about the original data usage purpose, which was the report [18] and the secondary data usage as this thesis. All participants were voluntarily taking part of the focus group interviews and no sensitive or confidential information was touched upon during the discussions. Moreover, all participants had the opportunity to familiarize themselves and comment on the report before publishing.

Ethical committee approval for this study was not needed as this study was about policy design, participants gave their consent and the data was pseudonymised [100]. MS Teams discussion recordings were deleted after transcription.

4 Results

This chapter gives an overview of public and private sector representatives' ideas, opinions and perceptions about DHT assessment analysed through the SST perspective. Topics are divided into four main categories according to SST followed by subcategories of different codes.

4.1 External structures

External structures category included codes such as already existing guidelines about foreign frameworks, EU and local regulations, examples from abroad, problematic aspects and missing structures but also proposals or hopes for future development regarding assessment.

4.1.1 Existing models and examples

During discussions the topic of already existing guidelines emerged several times. When the producer of DHT wants interface with health information system, it has its own rules:

„.Criteria should be publicly available and then respectively interface with whom – it will be checked, if the needed documentation and all things are existing."(GR4-W3)

As the excerpt reveals the rules on how to interface with health information system already exist but they have to be brought out more clearly and understandably for the producer. Besides interfacing health information system, big part of discussions was concerning medical devices, their registration and related legislation:

„Finally, the medical device is registered by an organisation responsible for the MD list, but they take international notified body validation as basics." (PR2-W2)

This statement points out the complexity and settings of the medical device process – rules are set on the international level; Estonian authorities just confirm the compliance and add devices in the national registry. First, it must have *CE*-marking, which is set on European level and is a prerequisite for market entry. All medical devices must follow the European Commission's Medical Device Regulation:

„We might not be able to be FDA compliant but we could at least be MDR compliant.“ (PR1-W2)

As the quotation announces there are international regulations in place and if it is not possible to comply with all of them (such as FDA requirements in the USA) then at least European Union regulations should be aligned with. It was suggested that Estonia cannot have national categories that have looser criteria than international categories.

One of the European level existing models that participants were discussing and bringing out as a good example, was evidence standards framework form UK:

“I think this framework itself, what NICE framework already is, should be, like, a guide to developers of new solutions." (PU4-W3)

This quote demonstrates the knowledgeability of other frameworks existing and producers being familiar with them. Participants stated that NICE has functionality levels for applications, and it already works as a guideline for newcomers to understand which path to follow. In addition to UK framework, DiGA from Germany was also mentioned several times and appraised:

„The target of DiGA is similar, to assess technical, distinct data protection, and safety aspects.“ (PR1-W2)

The excerpt brings out DiGA fast-track process and the aspects it already assesses. It was suggested that Estonia should take into consideration other countries’ assessments:

„Solutions assessed according to certain standards in other countries conform to our baseline criteria.“ (GR4-W3)

This line represents the willingness to accept foreign assessment standards and to apply those standards also in Estonia so that DHT will not be re-assessed in Estonia. Statement also outlines the need for uniform baseline criteria in Estonia. Belgian assessment framework and Finnish Digi-HTA were also mentioned as examples from abroad to consider adopting in Estonian context:

„In Belgium there are also responsibilities shared - who does what part of the pyramid. There is not just one organisation assessing /.../ It is made clear for the solution provider where to get help.“ (PR7-W2)

This quotation marks the participants’ awareness of foreign assessment systems and suggests an example from Belgium’s assessment pyramid, where every level is the responsibility of a different organisation, as a good and understandable example to learn from. Additionally, this result indicates that unlike Belgium, Estonian producers do not know where to get help from. As seen from Figure 1 (chapter 2.3), institutions somehow

related to DHT do not have clear linkage between each other or the producer. In addition to Belgium's pyramid model, assessment scale from Finland was discussed:

„For example, in Finland, when you want to check which applications have passed the assessment /.../ you go there and check the list of who have passed. In addition, passing is not zero or one, passing is that in some aspects you have received three in the scale of five, some aspects you received five. It is not like pass or fail." (PR7-W3)

As this excerpt indicates, participants appreciated the Finnish Digi-HTA criteria where meeting the criteria of assessment is not just conforming or not conforming but gaining points on a certain scale. Lower scores point out the areas of improvement for the producers to understand where they are and how to evolve. From foreign examples the discussion returned in Estonian context and participants agreed that laws were already in place:

„Parts of the processes are set in laws for different systems. Figuratively speaking, the Ministry of Social Affairs is a regulatory entity. MD list law is written there. MoSA is the boss of HWISC and so on…" (PU3-W3)

This quote indicates that laws under the Ministry of Social Affairs area of government concerning for example work of EHIF, HWISC, NIHD, EHB etc. are in force and no major changes are needed to start the assessment processes of DHT. This result could indicate that from the state's point of view everything seems to be set. But as previous quotes have shown, producers do not know where to get help. The most mentioned existing example was Health Application Evaluator (HAE) from TalTech:

„I think that what TalTech has, the Health Application Evaluator, it is very good as MVP (minimum viable product)*. I understood that it has already done the first round of assessment. When we take results from testing, take workshops' results as addition and make so-called vol two. Maybe we are overthinking. Solution does not have to begin from zero." (PR7-W2)*

This excerpt represents one of many HAE favouring thoughts. Participants were thinking about how not to complicate things but to combine already existing models such as HAE to some new ideas to get an MVP and start experimenting. It was suggested that HAE could cooperate with different governmental parties and at those times when the product is not a MD (yet). Overall opinion was that HAE would be a good tool for assessing digital solutions. Discussion about HAE suggests that parts of HAE could cover basic assessment. It was discussed whether MDs needed basic assessment and those not MD would need to pass HAE:

„I don't know, I would take that HAE as a base and say, like, dwelling from that today." (GR1-W3)

This quote suggests that HAE is already a working frame and if the assessment process is to be divided in several steps, HAE was suggested to cover the baseline. In addition to laws and regulations under MoSA governance, also the Estonian Information System Authority consent service and its linkage to assessment was discussed:

„...when [using] *consent service, then it needs an extra process with Estonian Information System Authority. However, HAE should already take into consideration those things* [how to interface with consent service] */.../ then producers are willing to pay because it will take less time to get consent service interface." (PU3-W3)*

This suggestion highlights the aspects HAE should include in their service in order to smoothen the process for producers. Excerpt implies that consent service has additional requirements for service providers and these requirements should be taken into account already in the basic assessment process. Participants expected this to make the consent service interface faster and easier for the producer.

To sum up, existing regulation of medical devices, already working assessment models from Europe and services on the local level are known to participants to some extent. Many already processes, such as HAE and consent service, moreover laws needed for assessment were mentioned during discussions and integrating them into the assessment process was suggested.

4.1.2 Disputable and problematic aspects

In addition to many good examples from abroad, participants also found problems with applying frameworks developed elsewhere:

„MDR classification has to be taken as a baseline. NICE after Brexit makes no sense." (PR2-W2)

This quotation indicates the doubts whether NICE framework was a good idea to take as a baseline in Estonia. Since the UK is not anymore part of the EU, changes in the UK may not align with EU norms. Although MDR and NICE framework's essence is not the same, participants thought that similarly to other countries, MDR should be taken as a base. Missing competence was also brought out:

„Today in Estonia there is no consulting competence. There is MDR and IVDR (*In vitro* Diagnostic Device Regulation) *competence shortage in Estonia." (PR1-W2)*

This excerpt denotes the problem which was mentioned several times during discussions: the lack of consultation competence in Estonia, especially related to medical device consultation. In addition to competence shortage, assessment related maintenance and financing questions arose:

„Other requirements and things are emerging, how is somebody going to maintain it, complement it, mend it? Then there is a question: who will do it and with what money?" (GR4-W3)

This statement demonstrates one of the problems participants elevated during discussions. As the assessment was considered to be an on-going and evolving process, there has to be somebody who is up to date with all changes related to assessment aspects. This in turn needs financing but who should cover the costs remained open during the discussions. Another problem with potential assessor arose during discussions:

„Question is that who or what that umbrella organisation [organisation who gathers assessors of different aspects together] *would be and how long the assembly of that would take? When we are compiling some umbrella organisation, the compilation takes about a hundred years, and then we are shooting ourselves in the leg." (PR1-W3)*

This excerpt shows scepticism towards the compilation of a new organisation for assessment. According to participants the compilation would take too much time and producers in need of help would not benefit from it for a long time. Making a new organisation just for assessing was not greeted idea. Results from the previous chapter (4.1.1) outlined the need for a place where to get help. Participants asserted that if organisations such as EHIF or TalTech and the ministry were working on their own, they would need somebody who holds the whole picture together to avoid fragmentation. But this could rise other type of problems:

„...when we see that governmental institution should be responsible for assessment, then this governmental institution already has a fixed working plan for the next year. First, we need to find the resources, those people who will do it." (GR4-W3)

This quotation refers to the rigid planning systems of governmental institutions, which leave little room for changes and new plans. Result also outlines the lack of human resources. Problem of lacking consensus was stressed:

„What we are missing today in the country, is the mutual understanding and agreement who is providing this assessment service and that he really is trustworthy service provider."(GR4-W3)

This quotation represents one main problem that emerged during discussions. The role of assessor cannot be given to somebody without wider consensus. Moreover, as the aspects of assessment vary depending on the DHT the assessor must cover all of them. Lacking agreement leads to the problem where again the producer does not know where to get help when needed. In addition to missing consensus the problem of missing parties arose:

„We have had regulators and financers and producers in workshops but the ones for whom we are creating the system are missing, so the representatives of users would be involved more loudly." (PR7-W3)

Nevertheless, many representatives from different fields were present, the participants still felt that users and patients' or doctors' representatives were missing. Doctors' opinions were not included in discussions although they would possibly be the mediators between patients and DHT producers. In addition to missing spokespersons, participants were missing guidelines:

„For example, I don't have an overview of those today already existing documents, which would possibly help us to compile this assessment framework." (GR4-W3)

This excerpt outlines the problem that even the parties in the middle of assessment related topics today do not have overview of the needed documentation. Participants referred to hints of some organisations having their own guidelines, but these guidelines are not publicly available. This in turn leads to the situation where the new-comers (producers) or end-users (patients) are unaware how to make right decisions about DHT. Participants suggested these guidelines, which are not available today, should be made accessible for everybody.

To conclude, several problematic aspects concerning foreign models, lacking competence for consultation and scattered or missing guidelines were elevated. Moreover, the lack of mutual agreement of assessor, maintenance and financing aspects and missing parties emerged during discussions.

4.1.3 Proposals and wishes of assessment

Topics about and around medical devices remained during discussions and opinions varied. However, suggestions for assessment of medical devices emerged:

„Medical device theme must be assessed. EHIF won't be assessing CE-marking compatibility. It should come elsewhere." (PR7-W2)

As the quotation indicates MD topic was confronted several times. Some participants considered it sufficient when the MD is registered, as it has to fulfil many requirements already by then and should not pass additional assessment. Some participants disagreed and claimed the compliance to the framework has to be checked also with MDs. Suggestions were that at first MD and non-MD should be looked together:

„…the assessor should be providing an opportunity to assess whether it is MD or not. And if it is, then what to do?" (PR2-W2)

This quotation suggests that the producer of DHT would get an idea how to proceed. Getting *CE* marking for MD is a long process as it was also stressed during discussions. That is why also non-MD assessment was suggested to be included in the framework:

"This assessment cannot be done by anybody else than the Estonian Health Board when it concerns compatibility to MD requirements." (PR2-W2)

As the excerpt states, participants thought EHB to be the best assessor for medical devices. From the specific MD topic, the discussions elaborated to the topic and proposals who should be the assessor:

„If there is an HTA-body, it will be ordered from them. If not, then from universities." (PR7-W2)

This quotation represents the suggestion to check also the HTA aspects. Statement refers to the fact that if the country has an HTA organisation, the assessment should be ordered from them. But if the country does not have an HTA-body then academic organisations should proceed with assessment. In addition to one assessor, dividing areas of responsibility were suggested:

„Different roles for different parties. Interoperability – HWISC. Cost-effectiveness – EHIF..." (PR2-W2)

As this excerpt indicates some roles were suggested by the participants. *„Cost-effectiveness assessment, it is possible only by EHIF" (PU1-W3),* was stated, as DHT needs to be compared with other similar products. EHIF was considered having competence in that field and they are responsible for financial compensation of services and devices provided to insured people.

In addition to specific roles, participants wished for unambiguous rules which would apply to all parties involved in assessment:

„When the provider of a technological solution is approaching for example a hospital, then they should have all the data protection spheres similar, so they do not have to approach every hospital and pass a new data protection assessment." (PR1-W2)

As the excerpt indicates, the need for uniform requirements emerged. According to participants, the situation today is that every hospital has its own requirements. Suggestion was to unify these requirements and make a common list:

„White or green book – or how you call them, best practice agreement. This kind of agreement could be established and this is the checklist.“ (GR4-W3)

This quotation encourages gathering all criteria together to form the guidelines for producers to follow the certain steps to reach their goal.

To conclude, several suggestions of roles and tasks emerged during discussions. EHB, EHIF and HWISC were suggested to take certain responsibilities. Also, a uniform list of requirements which would apply to everyone was suggested.

4.2 Internal structures

Internal structures category included codes representing the responsibilities and duties of producers. Also, their need of help in different aspects and assumptions or expectations about the assessment process.

4.2.1 Producers' responsibilities and duties

During the discussions unclear aspects and responsibilities of assessment emerged which caused uncertainty among DHT producers:

„I am confused about the assessment part. So, these institutions set the criteria and producer assesses?“ (PU4-W3)

The product or service provider was confused about the assessment. Some suggested that different institutions only set the criteria but do not assess. Assessment would be based on the checklist compatibility controlled by the producer. It was agreed that criteria must be transparent so the producers would be able to check them when needed. The first level assessment was understandable:

„On the lowest level the producer can show how in this certain context the medical device is effective.“ (PU4-W3)

This means that it is producers' responsibility to prove their product is meeting the lowest criteria. It was also stated that everything cannot be controlled from outside:

„Assessment can be executed only by the producer. And must be executed by the producer only. Because only this way it is constantly adequate.“ (PU4-W3)

As this excerpt states, assessment of DHT must be fully the producers' responsibility. Moreover, the producer knows if any changes are made with their product and knows also when to retake the assessment. Other parties are not as up to date with renewals. Some agreed on this statement, but some added that in the end and after the self-assessment, there should be also a third party to check if the assessment matches the requirements:

„Number one is clearly self-assessment; number two is involving other parties in this system." (GR4-W3)

This quotation indicates that first producers must pass assessment on their own and then involve other institutions or third parties to validate their self-assessment. Still the main responsibility lies on producer:

„Nobody takes away the producer's responsibility. Data protection and so on is solely producer's responsibility."(PU6-W1)

Aspects such as data protection compliance were claimed to be purely the responsibilities of producers. It was stressed many times during discussions that responsibility cannot be given to anybody else.

To conclude, according to participants' opinions the producer of DHT carries the main responsibility to comply with rules and regulations. If the assessment is divided in several levels, then the participants suggested including third parties in higher levels to validate the self-assessment.

4.2.2 Need of help

Although the producers' full responsibility and self-assessment was accepted and agreed on, also problems emerged concerning the further path:

„Okay, now I can meet the requirements of the lowest level, but if I would like to be steadier, then the highest level to strive for would be...?" (PU4-W3)

This excerpt demonstrates the lack of knowledge concerning criteria after basic level assessment. If the producer would like to move on to achieve higher goals, the levels are not marked and also guidelines are missing:

„Quite many producers need assistance to orientate in this system." (PR5-W2)

As this quotation states, help and guidance for producers is needed. The main problem participants elevated during discussions:

„Yes, today we have read ourselves wiser, how this process is possible to compile. But this process is still not clearly explained, which steps to take one after another.“ (PR1-W2)

Participants agreed that even if everything remains producer's responsibility the steps of the processes are not understandably explained and in which order to pass them. This outlines the missing or incomplete structures for producers to move on.

To sum up, producers of DHT were considered to need help in orienting in the system. It was stated that clear guidelines about the steps and their sequence were missing.

4.2.3 Assumptions and expectations of producers'

Participants expressed their wishes about market entry placing themselves in foreign shoes and explained it to others:

„When we have software developed in the EU and they can sell it straight to Estonia, that local distributor will check from the list that I have this kind of solution and I have assessed it.“ (PU4-W3)

This proposal describes the potential way for new foreign solutions to enter the Estonian market without complications. Participants stated that the clearer the assessment checklist for producers the easier market access would be. Moreover, compatibility was expected also the other way around:

„When you make it, it should be competent also elsewhere in the world.“ (PR1-W2)

This is an assumption of service providers that the DHT should not be country-specific and the quotation refers to the fact that assessment should be internationally valid. Example from abroad was appraised:

„Belgian schema is from the service provider point of view very clear.“ (PR1-W2)

This quotation expresses the knowledgeability of other frameworks. Belgian assessment model was brought out as a good example to learn from. However, concerning Estonian checklist:

„We should not overdo it. That we are compiling the world's coolest and most thorough assessment model. We should think what would be optimal, what does not scare producers away.“ (PR7-W3)

It was suggested to carefully think which kind of assessment aspects to include in criteria. As too complicated requirements may repel the producers. The focus must remain on the fact that the producer follows the checklist:

„It should help enterprises to classify their product“ (GR1-W3)

Participants assumed that a checklist would be a helpful tool for producers to identify in which level they belong, and every level would have their own requirements. Some things were clear:

„It is very clear to us that the framework could and should cover clinical safety and data protection aspects. And data protection assessment should be set on the national level.“ (PR1-W2)

As this quotation states, participants expected aspects like clinical safety and data protection to be part of the assessment and be the same nationwide. When assessment process with its guidelines is not in place and DHT have not properly gained the quality labels (of assessment as suggested during discussions) some participants assumed:

„Patients don't dare to take the solution in use. They are not able to assess whether the solutions on the market are safe or not“ (GR4-W3)

This quotation presumes that if the digital solution is not assessed or validated properly, potential users do not dare to use it. So, the producers *“... want to improve their safety and show they are better than just any solution downloaded from the Apple Store” (GR1-W3)* to gain patients’ trust. Also, the health care workers perspective was considered:

„It is important that a health care worker dares to prescribe the application with this medication to the patient. That he/she is convinced the application is safe and does what promised.“ (PR7-W3)

During discussions participants assumed that the health care workers wish DHT to be proven safe and trustworthy before they dare to recommend it. This in turn refers to the aspect that a proper and easily available assessment process is needed. DHT assessed, accepted and taken into use build confidence among health care workers, end-users and also new producers willing to enter the market. Expectation concerning market entry was:

„When technology is already brought to market by somebody, well then I don't have to prove again, that it works“ (GR1-W3)

This statement represents the experience of others and marks that it is harder to be first one in the market while next ones are following the path already proven.

To conclude, participants had several expectations concerning the assessment from the user, assessor, and producer perspective. The assessment was expected to be universal, not too complicated and it should build confidence among its users.

4.3 Action

Action category comprised codes such as goals and proposals, problems and difficulties, in addition to suggestions for the next steps to be taken in the assessment process.

4.3.1 Goals and proposals

Depending on the target of DHT producer, participants of workshops had proposal to divide the assessment process in parts:

„Need to separate in two: one that solution would fit in the health system and other to be financed.“ (PU2-W1)

As this excerpt suggests, the assessment process should be different depending on the goal of the product. If the goal is getting reimbursement, the assessment should be different from the goal of fitting into the health system. When separated, also the responsibilities should be clearly defined:

“Yes, I want to start using consent service. Yes, I want to get reimbursed! You have different channels, which have to be in place and someone explicitly in charge of them.” (GR1-W3)

This quotation demonstrates varying goals of DHT producers and stresses the need of having certain instances responsible for them. Nevertheless, the different objectives of different solutions, the main goal was:

„We should have one central place where assessment is done and if needed, advice can be asked.“ (PR1-W3)

This quotation expresses the producers wish to have one central place for getting advice before and during the assessment. The same central place should also be the place for assessment.

To sum up, the first action goal is to assess digital solutions which are meant for the patient. Second goal is to have the assessment and consultation in one central place. Moreover, to have a flexible assessment process.

4.3.2 Problems on the way

Discussion about how universal or detailed assessment framework should be was raised as an issue during discussions:

„On the one hand universal would be doing everything with one process but on the other hand the local specificities will appear too“ (PR2-W2)

This quotation reveals the complexity of executing assessment. Participants were debating whether to take over some existing foreign framework, but some said that local or national differences would appear during assessment. That is why an entirely international framework would be difficult to adopt, participants stated.

Another problem participants highlighted during discussions was to bear in mind when assessing varieties between DHT must be taken into consideration:

„It has to be clarified that all solutions will never be assessed. Moreover, it is not the goal for everybody. But for someone it is.“ (GR1-W3)

It was stressed that not all digital solutions need assessment and many of them do not even want it. However, depending on the goal, whether it is a best practice label or reimbursement there will be producers who wish assessment.

To sum up, the scope of the assessment process and how universal it must be were the problems highlighted during discussions. It was also acknowledged that all DHT would not get assessed.

4.3.3 Next steps

Suggestions for how medical devices should pass the assessment were varying but one idea emerged and was also greeted by others:

“When the application has met medical device requirements and has CE-marking, the main assessment is done. Then only nuances can be checked, safety or data protection aspects. But then passing assessment framework in this way is not needed.” (PR3-W2)

As this excerpt suggests, those DHT already having medical device status would not need to pass the assessment. Some things should be checked to get the confirmation of compatibility to the requirements but not the whole assessment. In addition to taking the MD requirements into consideration, also the foreign experience should be investigated:

„Maybe somebody asked from EHIF whether they looked at and compared foreign models? Actually, it should have started from that.“ (PR7-W3)

This quotation represents the participants’ complaints about the lacking overview of other countries’ assessment models. It was suggested to do the overview to compare the Estonian model to other countries frameworks. It was stated that the comparison would

ease producers' work. On the local level mapping the already existing guidelines and responsible authorities was suggested:

„One action would be that we map the process, the simple process created. I would call it process MVP." (PR1-W3)

Participants agreed on the fact having the fragments of guidelines and instructions, but these pieces are scattered and need to be mapped and organised into a project. Some participants proposed to compile a national working group for mapping, but others said workshops already were the working group. In order to proceed with assessment process build-up, participants stressed the importance of all parties' perspectives to be accounted:

„We have to build these processes in parallel. From the aspect what information this producer needs from our system and vice versa, what information we need of this producer /.../ it is very important to have both perspectives" (GR1-W3)

As this quote indicates, to proceed, all perspectives need to be taken into account. Assessment framework cannot be just from one perspective but it has to consider both parties' expectations. The following steps were suggested:

„One is defining the requirements and second is to reconcile with them. And actually, the third is assessing." (PU4-W3)

As the excerpt announces, actions can be separated into three steps. First step would be clearly defining the requirements for assessment. Second step would be the producer fulfilling the requirements and the final step would be the DHT getting assessed. As a next step, the responsibilities must be taken:

„I think all parties of the system must start building this competence and start thinking about the in-house processes to understand what it means when tens and tens of solutions start coming." (GR1-W3)

This quotation outlines the need of everybody to start thinking about what they can do now in their institutions, the in-house processes – how to change them to be prepared for assessment of products or solutions coming.

To conclude the next steps suggested by participants, all perspectives must be included, foreign models must be compared, mapping of the journey as MVP is to be started and in-house processes must be thoroughly planned.

4.4 Outcomes

Outcomes category included the codes representing the expectations and wishes of the participants and their vision of ideal assessment. This section also included the codes of hesitation, doubts and needs in order to perform assessment.

4.4.1 Expectations and wishes

Although it was expected to have outcomes concerning assessment aspects, the main expectations were about the framework itself. Participants expressed their vision:

„Framework should be applicable reasonably and optimally for very different solutions." (PU8-W1)

This quote expresses the ideal outcome of the assessment framework and how participants would like to see it. Not complicating things for producers was considered important during discussions. It was also added that *„Framework should apply also to the state" (PU1-W1),* meaning solutions provided by governmental institutions should also pass the assessment. Moreover *„Framework should say who assesses what" (PU3-W1)* making the clear role distribution. Moreover, without clear guidance and mapped process, the producer cannot be the only one responsible for meeting the (un-written) criteria. Implementing the assessment process should not be requiring too many resources, administration burden and placing extra systems. Also, the scope of assessment was agreed to be patient targeted DHT:

„Framework should concentrate on solutions which are for patients. Those on the market and those coming. Narrow clinician-targeted solutions, there is anyway much work." (PR2-W2)

Participants agreed on the focus of assessing just patient targeted DHT, *„…those applications where the patient is involved. Patient is in a vulnerable position." (PU3-W3)* as it was thought the patient may not be able to assess themselves whether the solution is reliable. The main idea of assessment was described as follows:

„Purpose on the background is that we would have solutions available for people and the most precious ones would get in use." (PU3-W3)

This quotation represents the participants' understanding of the assessment process and the intention of assessed DHT getting into wider use among people. Moreover, to be trusted on the market so the users can distinguish trustworthy solutions.

Participants expressed their wish to have one institution responsible for all e-health related topics in Estonia as today the responsibilities are scattered:

„It would be nice if we had clear e-health authority in Estonia, which we are trying to form with one project.“ (GR4-W3)

This quotation indicates the wish of Estonia having somebody particularly responsible for e-health and all related to it. The Ministry of Social Affairs was mentioned to be in theory the one who is responsible for topics related to health. However, as participants stated, in real life the e-health authority is missing and as expressed, the three workshops are not enough to compile the nationwide authority.

To sum up, the outcomes that participants wished to see were concerning the optimal and reasonable assessment framework for the solutions that are in the use of patients to provide safe and reliable products.

4.4.2 Doubts and needs

Parallel to picturing the ideal outcomes of assessment framework also doubts arose:

„We don't want to agree on a checklist and then everybody will be pressuring the producer with this checklist /.../ We want this competence to concentrate somewhere and start growing there.“ (PR7-W3)

This excerpt reveals the worries participants had. They worried about the results when the agreement on assessment checklist aspects would be completed but every institution would use it on their own. The fear of pressuring may come from the lack of trust, when there is an institution who would like the producer to prove again the aspects they already have. This may lead to frustration on the side of producers. Gathering all competences in one central place was considered essential among participants. As mentioned before (in chapter 4.1.3) one central place for advice and assessment is needed and when the central place exists, and demand of assessment and advice is growing, the better this central place would get. Concerning competences and roles participants doubted:

„We can't distribute roles when the other party is not willing to take the responsibility.“ (PR5-W3)

Participants were worried about role distribution. During discussions, different roles for different institutions were shared but in real life things can be different and initial ideas of the responsible institutions may not be realized as suggested. The suggested roles can be taken as guide for negotiations to receive the desired outcome. Whether it is one

organisation responsible for holding the picture together or several institutions with their marked linkage with each other, everyone knows their part of the assessment process.

To conclude, assessment has points where the expected outcome may not be as desired and participants were doubting whether the outcomes in real life correspond to the ideas sketched during discussions.

5 Discussion

This chapter discusses the results through the lens of SST combining them with findings from previous studies. The author tries to answer the research questions, brings out the main limitations of the study and provides suggestions for the future studies on this topic.

5.1 External structures

When inspecting the results from the SST point of view, then the external structures of this current study are formed by laws, regulations and guidelines of different institutions or organisations. External structures form the surroundings enabling or constraining agents' everyday actions and can also be referred to as macro-level [29]. Results pointed out already existing structures such as guidance on how to interface with health information system, MDR from the EU with its explicit rules and also other countries' frameworks where agents could orientate. Existing foreign frameworks such as NICE from the UK [36], DiGA fast-track from Germany [16], assessment pyramid from Belgium [17] and Digi-HTA tool from Finland [49] are introduced in chapter 2.2. These examples were brought up in discussions as already working frameworks to learn from. Laws concerning institutions under MoSA were confirmed to be sufficient, without the need of major changes in order to assess DHT. Also, HAE as MVP for basic assessment and consent service supplementing the gaps in data sharing, were considered adequate. Seemingly the external structures are in place and the representatives of these institutions confirm the readiness for DHT assessment.

However, despite all alignments and existing documentation, the findings of this study revealed problematic aspects concerning the external structures. One of the problems was NICE framework, which had been previously partially adjusted for Estonian context but since Brexit the doubts among participants arose. Although NICE framework and MDR are covering different aspects, changes from UK may not be lined up with EU regulations. As other countries are aligning with MDR which seems to be the tendency in EU according to participants, Estonia should not choose the different path. Findings emphasized the problem that there is no MDR consultation competence in Estonia. So, if

the MDR as an already existing set of requirements is to be taken as a base for assessment, external structures in the form of consultation providers for producers are missing. But without the competent consultation, producers face difficulties in their performance. One controversial aspect concerning the assessment process was whether there should be several assessors or just one. If the responsibilities are shared between institutions in a way everyone being responsible for their own area, the question of who or what would be holding the whole picture together remains.

As outlined in SST, structures and agents with their action and outcomes are connected in continuous and dynamic interaction with each other [29]. Also, the structure should be uniform and not scattered as resulted from this study. There was no consensus of who would be a trustworthy assessor and who would keep the assessment running. Moreover, how to maintain and finance assessment outlined the problems of external structures which hinder the assessment process. This systematic problem of external structures lacking agreements and having no common understanding of the assessment process increases the confusion among producers of where to get help. Another problematic aspect, which resulted from this study, was concerning missing spokespersons. Patients' and doctors' representatives should also contribute when aspects of assessment are discussed. They are considered to form the meso-level between macro- and micro-level agents. Previous studies have also researched the interactions between these three levels to improve the understanding about problematic aspects when implementing new systems [85]. Including the meso-level agents (doctors or other health care workers) and their perspective would add another dimension and possible inputs for improving the assessment process. It would be beneficial for both the structure (policy makers, macro-level) and the agent (producers, micro-level) when these meso-level agents would be mediating both parties' wishes in order to reach reliable and safe DHT for the end-users. Findings from previous studies highlight the importance of involving all stakeholders and patients in development of new structures of health care for the best possible solution [5].

Besides the existing and disputable aspects, which form the external structures for DHT assessment, findings of this study also provided suggestions for assessment processes and roles related. One suggestion was to have clarity in MD assessment process and to find out HTA processes in Estonia. Results revealed hypothetical role distribution in several areas of responsibilities. EHIF was considered to be responsible for cost-effectiveness studies, HWISC of interoperability and EHB for MD compatibility checking. However,

these were just suggestions to think about and not formal agreements. Results brought out also suggestions for having unambiguous guidelines for different levels of assessment, how to reach them and who is assessing. This result is supporting both the external structures and producers as when the uniform guidelines about how and where to get help on certain topics are clearly outlined, producers can orient themselves in the system and the possibility to get more and better DHT on the market increases.

As the findings from previous studies confirm, the implementation of innovation is not an immediate event but an ongoing process across the organisation [27]. Also, the implementation of DHT assessment is a process with many stages and participants. The assessment process should be structured simply and complemented all the time taking the feedback into account. Findings from previous studies also imply that if the understanding of the complexity of technology is not well-explained to the decision-makers, they may easily abandon the adoption [83]. The biggest fear, which resulted from this study, was the assessment process to be a rigid governmental project, which takes too much time to even start with. As found from the previous studies, top-down approach in implementing new systems may fail if dialogue between implementers (external structures) and users (agents) of the system is missing [86]. In order for the assessment process to be adopted and succeeded in Estonia, a top-down approach should be avoided. Moreover, the users such as doctors' and patients' representatives must be involved to create an assessment system which takes all perspectives into account.

To conclude, external structures in international and local context exist but the linkage and communication between different authorities is missing. No matter which foreign model to adopt, also the consultation for producers must be available. It is essential to have common agreement between the external structures to form the surroundings for producers to navigate and to know who assesses certain aspects.

5.2 Internal structures

Employing SST the producer (agent or micro-level as in SST [29]) of DHT is seen as an object surrounded by external structures, policy makers' rules and demands. First impression of this study is that external structures leave little room for the producer's opinion (internal structure). According to SST, agents' internal structures are formed when they draw on their dispositions and knowledge about external structures and their

intentional or unintentional action can change these structures [29]. DHT producers' responsibilities and knowledge of the existing structures about for example MDR, laws and checklists of hospitals was demonstrated in the findings. However, producers were confused about whether they should self-assess themselves or get assessed by a third party. This, as mentioned before, refers to the missing connections and lacking mutual understanding between the parties of external structures from which agents are trying to draw on. As the findings of this study outlined, producers understood and agreed on the proposed multi-level assessment. In such an assessment model the lowest level would be wholly producers' self-declaration and when reaching higher levels, additional assessor would be included. Full responsibility of DHT producers was denoted as assessors from outside would not know the nuances of the product nor the right time to re-assess. However, in certain levels self-assessment is not enough and parties from outside must be included in the assessment process.

Although knowing their product and responsibilities, results outlined, that producers need help in some aspects. One aspect where help is needed is when the producer meets the criteria but wants to achieve more and reach for the higher levels. This result refers again to the insufficient external structures, which are not providing unambiguous rules or concrete authority for agents to approach. Scattered information, missing connections between institutions responsible for certain assessment related aspects and lacking agreement of common rules result in hindering producers in their processes. Which in turn slows down the market access of new DHT. Results confirmed that it is possible to find the needed information but the process of looking for every aspect from different places and with different rules is exhausting for producers. Therefore, one place or mapped path to follow was the wish of producers in this study.

Suggestions on how to improve the assessment process from the producer's perspective concerning external structures were brought out. It was suggested to have similar criteria for foreign and local producers, in a way there is no duplicating assessment whether going abroad or coming to the Estonian market. Findings of this study demonstrate the producer's knowledgeability of other assessment frameworks, such as Belgium's' pyramid, DiGA and Digi-HTA and the desire to integrate (parts of) foreign models into the Estonian assessment process. This would also facilitate the effort of external structures as there is no need to start from the beginning. Producers expected the assessment framework to be optimal and helpful, guiding them to get assessed. One fear, producers

had was concerning the users like patients and doctors who are afraid to take the DHT in use if it is not proven safe. This again refers to the need of including agents from meso-level (health care workers) in discussions. Findings from previous studies state that patients need to take charge of their health prevention and promotion in order for the future of health care to be sustainable [24]. Although patients' perspective was not included in this study it can be deduced that their role adopting or refusing the use of DHT influences the whole process of assessment. If the end-users demand better quality, producers want to provide it. So, when this quality is evinced through thorough assessment also the external structures understand the importance of common agreement.

To sum up, findings about internal structures presented agents' thoughts concerning the assessment aspects. Producers agreed that they have the responsibility of passing the assessment and demonstrated knowledgeability of being familiar with other countries' assessment frameworks. However, they were missing the guidance and clear instructions from external structures how to orientate in the system and to increase trust among users.

5.3 Action

Conforming to SST, the action or active agency is when drawing on their internal structures and existing external structures agent creates new structures [29]. In this current study results proposed actions such as dividing assessment in separate paths based on the goal, whether it is reimbursement or fitting in the health system. This separation would help the producer to orientate in the system and choose the right way for assessment depending on their DHT type. But again, this must be agreed on between the institutions forming the external structures. Results highlighted the problems of whether the assessment should be as universal as possible to fit also with foreign assessment criteria. However, this result indicates again the need of common agreements in the external structures and if choosing some already existing frame from abroad, it must be tailored to meet the local nuances. Also, the fact that not all DHT want assessment and not all will be assessed. This finding refers to the fact that the assessment process is not meant for every digital solution coming to market. However, it must be made clear who would and should pass the assessment as this aspect may confuse producers.

Comparing foreign assessment models, mapping the local processes and taking all perspectives into account were suggested as next steps. Action in terms of investigating

and understanding institutions in-house processes was also proposed. All these suggestions mentioned require action where macro-level agents, the representatives of different institutions, perform the actions for the improvement of external structures. When done so, micro-level agents (producers) can perform their actions by passing the assessment. As found from previous studies, the reasons for poor adoption of health technology should be regarded as agents' action on many levels (micro and meso) not just actions between agent and structure [85].

To sum up, as this current study investigated discussions and ideas from brainstorming, also the results concerning action are hypothetical, not real actions taken with actual results. Findings of this study bring out the potential and suggested actions for decision makers and regulators of external structures to provide the sufficient surroundings for producers.

5.4 Outcomes

In SST the outcomes are described as agents' action according to their knowledge and dispositions where the action changes or maintains the external structures [29]. In this study such outcomes cannot be measured as there was no actual action to study. Therefore, outcomes similarly to action are hypothetical wishes and ideal pictures of what should change.

Based on findings of this study one expected outcome was the assessment framework to be optimal and having the focus on patients. Moreover, the outcome of assessment was hoped to get the best solutions for the end-users and them to be reliable. Another expectation was to have clear e-health authority in Estonia. To achieve these outcomes also in real life there must be changes in both external and internal structures. Scattered and confusing external structures in addition to disoriented producers should lead to an outcome which indicates the need for change among external structures. Lack of guidance for producers and no common understanding of the assessment scope among macro-level agents should lead to an outcome where the guidance and unity is created. In case of a positive scenario and change - linkages between institutions start forming, agreements on assessment aspects are set and e-health authority is formed. In case of maintaining the current situation, nothing in structures changes. At the time writing this current thesis there is no clear e-health authority in Estonia. MoSA is responsible for regulating health

related areas, under their governance are NIHD, HWISC, EHB and EHIF but the connecting institution is missing. Estonian e-health strategy [65] is from the year 2015 and at the time writing this thesis there is no newer one to follow. When the actions proposed in this study would lead to working/leading group formulation, who in turn would map the processes and appoint the areas of responsibilities, the path for easier and better assessment would be formed. In this way solution providers get the right picture in the first place, follow the right instructions and through assessment gain credibility, trustworthiness, and confidence. Through these process' improvements the market access of novel and safe DHT would be faster and the health care sector would benefit. However, the doubts about how to achieve trust between the producer and assessor were outlined. Worry about once complying with the checklist, would it be accepted also elsewhere remained. Without trust the outcome is that nothing changes in external structures leaving more work for the producer and causing frustration. Moreover, without the role distribution among macro-level agents of external structures, again the producer is in the position as today. Previous studies have shown that if problems occurred during adoption of a new system there is a strong need for the support from external structures [27]. Another study indicated that if the agents' perspective has not been included in the development of a new system, the outcome might be refusal or abandonment of the system [86].

To conclude, an ideal picture of assessment framework exists with its focus on the patient as a vulnerable end-user. However, the lead of the assessment process is missing and without one institution holding the assessment process together or explicit role distribution with every instance knowing their place and being able to guide the producer, there is no desired outcome.

5.5 Limitations and future studies

As this study applied secondary data analysis, the author of this study did not have the ability to form the questions and tasks of workshops, nor to choose the participants. Also, as the original study was missing perspectives of end-users and doctors' representatives, this can be limiting the results of both the original and this secondary research. One limitation of this study was the wide scope of discussions starting from the arguments of which digital technologies to discuss up to the topics where to get financing for the

assessments. As the participants represented different institutions and companies, also the opinions varied causing a myriad of ideas and opinions but fever clear decisions. As a brainstorm method, focus-group discussions are a good way to get a wide range of opinions. However, to reach clear decisions as hoped initially, this method is not the best. Clear pre-set interview questions would be beneficial for further studies to get precise answers unlike focus group discussions' continuous and vague text flow. Another limitation was the uneven quality of transcripts since there were four observers using their own techniques to document discussions. Also, the sudden topic changes during discussions and participants' uncertainty and confusion of tasks, made it difficult to differentiate whether the participants were talking about the assessment itself or the assessment framework compilation. During the discussions these two above mentioned aspects were mixed, and, in some places, it may remain unclear of which the participants were discussing.

For the future studies some points would need more investigation. If continuing with SST approach the study subject should include meso-level (health care workers) agents between macro-level (policy and decision makers) and micro-level (producers of DHT) agents. These meso-level interactions could facilitate understanding their attitudes towards DHT or aspects related to adoption of new DHT.

5.6 Conclusion

Based on the results analysed through the SST perspective the author of this study found several aspects which support the assessment process in Estonia – external structures formed by MDR, foreign frameworks, HAE and consent service are existing and adoptable.

Results of this study outlined that there is room for improvement in many aspects. External structures with their various institutions are scattered without proper communication and linkage between each other. Although the producers are knowledgeable of their self-responsibility of passing the assessment, they are missing guidelines and mapped paths set from the external structures. Moreover, the lacking consultation competence was highlighted.

Action taken in situations with indistinct circumstances can lead to outcomes where nothing changes in the external structures and assessment process fails. However, there is a possibility that the outcomes point out the difficulties of agents navigating in the system without help. This in turn improves the communication between the external structure institutions and the forthcoming DHT producers are able to provide reliable and safe products for the end-users. The interaction between agents and structures is an ongoing process which improves through time – new producers draw on their knowledge about external structures leading to action and outcome which in turn changes the external structures to better assist the producers.

This also answers the third research question: contribution to DHT assessment aspects should be both structure and agent's responsibility, where both parties listen to each other, adjust it according to the feedback and continuously complement the assessment process. Nevertheless, the external structures' communication and interdependencies must be clearly defined.

The four main conclusions from this study with suggestions from the author are:

1. Poor communication and missing linkages between institutions or organisations that form the external structures, must improve. In order to do so, representatives of these institutions have to familiarize themselves with the topic of DHT and its aspects and make available the documentation needed for producers. Cooperation and constant complementation of processes based on feedback is essential.

2. Producers understand their responsibilities in the DHT assessment process and know the need for their contribution in meeting the criteria. These criteria must be clearly defined as a mapped path to follow step by step. If such a path is missing, producers need certain advisory body guiding them in problematic aspects.

3. Producers' action in the current situation, where the outcome points out the incompleteness of external structures, should be leading to improvement of these structures. In this way, the potential of new DHT with proven quality for meeting the needs of end-users, is covered.

4. External structures, which form the environment for agents to act, must be in dynamic interaction with these agents. When the external structures enable and

constrain the agents' action, the outcomes point out the missing aspects of these structures. In this way opportunity for external structures to improve is given, which in turn enhances the agents' action.

6 Summary

The aim of this study was to analyse aspects related to DHT assessment implementation in Estonia. By using the strong structuration theory as an analytical frame, the author of this study intended to find out which aspects support the assessment of DHT, which aspects need improvement and who should be responsible for the assessment process. This study applied secondary data analysis on data collected from workshops with two methods – non-participant observation and focus group discussions.

Firstly, the results pointed out several aspects which support the assessment such as existing local and international regulations. Also, the MVP, which has already started mapping the assessment process and the willingness to avoid complicated or duplicating work for parties involved. Additional supportive aspects were producers' knowledgeability and self-responsibility.

Secondly, some aspects of the assessment process need to improve. Most problematic aspects were the lacking consensus among the external structures' decision makers, the abeyance of existing documentation of others and the communication void between institutions. Moreover, the confusion among producers, their frustration about ambiguous rules of different institutions and their strive for help.

Finally, the role and extent of responsibilities of the assessment process in Estonia were not agreed on. However, as according to SST the structure and the agent are in a continuous interaction complementing each other, it can be deduced that both are responsible. Neither structure can improve, nor can agents act better without complementing each other. That is why the Estonian institutions/organisations must cooperate to find unity in assessment aspects.

To conclude, with the intention to provide safe and reliable DHT for the end-users to facilitate the health care system's sustainability, there is a need for all parties to be involved. Regulatory entities and DHT producers complementing each other's work related to assessment aspects will eventually lead to an ecosystem where the parties know their roles and act accordingly.

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