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# THE FEASIBILITY AND BARRIERS OF 3D PRINTING IN MEDICAL APPLICATIONS IN ESTONIA

Master`s thesis

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TALLINNA TEHNIKAÜLIKOOL
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# 3D-PRINTIMISE RAKENDAMINE JA TAKISTUSED EESTI MEDITSIINIS

Magistritöö

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Tallinn 2020

# 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

The last two decades has brought rapid evolving in 3D printing, which has enabled breakthroughs to use it for the benefits of health. Therefore, medical industry has gained much interest in 3D printing, especially surgical specialties. On the same time there is a gap surrounding the topic of 3D printing in the context of Estonia. The aim of the thesis is to investigate feasibility and potential barriers of three-dimensional (3D) printing implementation for routine use in Estonian healthcare.

The main part of the thesis contains extensive literature overview, which is supported by semi-structured questionnaire about the attitudes of Estonian physicians regarding 3D printing. In addition, semi-structured interview was conducted with biomedical engineer to catch the importance of 3D printing through a technical look. Interview with Estonian Health Insurance Fund (EHIF) helped to understand the legal considerations with the aspects of reimbursement of the technology. Combination of these three views provided an overview of the value of 3D printing in Estonian healthcare.

Analysis of the responses demonstrated that 3D printing is still far from standard clinical practice in Estonian healthcare. The main surgical domains where 3D printing is used are orthopedics and maxillofacial surgery. The results indicated that 3D printed models use in pre-surgical phase was supported by most of physicians. In general, physicians pointed out the following advantages of 3D printed models: provide additional information compared to 3D virtual models, better surgical complexity understanding and well-suited for reproducing anatomical details of an organ. The production of implants is seen as important, but not well used application by Estonian hospitals. The biggest barriers for the implementation of this technology is cost and lack of regulations. The vast majority (90%) of questionnaire respondents highlighted the need for legal regulations. On this basis, it can be said that safety is a key factor to drive widespread adoption of 3D printing. Further research is needed to evaluate sustainable and cost-effective applications for Estonia.

This thesis is written in English on 70 pages, including 6 chapters, 15 figures and 4 tables.

# Annotatsioon

## 3D-printimise rakendamine ja takistused Eesti meditsiinis

Viimased kakskümmend aastat on kaasa toonud kiire arengu 3D-printimises võimaldades seda tehnoloogilist lahendust kasutada ka tervishoius. Kolmedimensiooniline printimine on pälvinud suurt huvi meditsiinis, eriti kirurgilistel erialadel. Samas on teaduslikke artikleid 3D-printimise kasulikkusest Eesti tervishoius vähe. Käesoleva magistritöö eesmärgiks on uurida 3D-printimise sisse viimist Eesti tervishoiu tavapraktikasse ja selle rakendamise võimalikke takistusi.

Lõputöö põhiosa sisaldab ulatuslikku kirjanduse ülevaadet, mida toetab poolstruktureeritud küsimustik Eesti arstide suhtumise kohta 3D-printimisse. Lisaks tehti 3D-printimise tehnilise poole olulisuse uurimiseks poolstruktureeritud intervjuu biomeditsiiniinseneriga. Intervjuu Eesti Haigekassaga aitas aga mõista juriidilisi kaalutlusi tehnoloogia hüvitamise aspektidest. Need kolm sihtrühma võimaldasid anda hea ülevaate 3D-printimise olukorrast Eesti tervishoius.

Uuringute tulemused näitasid, et 3D-printimine ei ole Eesti tervishoius laialdaselt kasutusel. Ortopeedia ning näo- ja lõualuukirurgia on peamised kirurgilised valdkonnad, kus 3D-printimist kasutatakse. Enamik arste toetas 3D-prinditud mudelite kasutamist operatsioonieelses faasis. Arstid tõid välja 3D-prinditud mudelite järgmised eelised: lisateabe pakkumine võrreldes 3D-virtuaalsete mudelitega, kirurgiliselt keerukate operatisoonide parem mõistmine ning elundi anatoomiliste detailide oskuslik taasesitamine. Implantaatide tootmist on peetud oluliseks, kuid Eesti haiglad kasutavad seda rakendust vähe. Suured kulutused ja regulatsioonide puudumine ning ohutusega seonduv on peamisteks takistavateks teguriteks. 90% küsimustikule vastanutest tõstis esile 3D-printimise õigusliku reguleerimise vajalikkust. Täiendavad uuringud on vajalikud hindamaks jätkusuutlikke ja kulutõhusaid rakendusi Eestis.

Lõputöö on kirjutatud inglise keeles 70 leheküljel ning sisaldab 6 peatükki, 15 joonist ja 4 tabelit.

# List of abbreviations and terms

| | |
|---|---|
| 3D | Three-dimensional |
| SFF | Free-form technology |
| RP | Rapid prototyping |
| AM | Additive manufacturing |
| CNC | Computer Numerical Control |
| EUR | Euro |
| OR | Operation room |
| SLA | Stereolithography |
| CT | Computed Tomography |
| MRI | Magnetic resonance imaging |
| DICOM | Digital Imaging and Communications in Medicine |
| STL | Standard tessellation language file |
| CAD | Computer-aided design |
| 2D | Two-dimensional |
| FDM | Fused deposition modelling |
| SLS | Selective laser sintering |
| ABS | Acrylonitrile butadiene styrene |
| PLA | Polylactic acid |
| DLP | Digital light processing |
| FDA | Food and Drug Administration |
| TE | Tissue engineering |
| AD | Alzheimer’s disease |
| ECM | Extracellular matrix |
| QA | Quality assurance |
| EHIF | Estonian Health Insurance Fund |

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# 1 Introduction

Medical imaging and bioengineering have made a huge impact to the modern surgical practice, fathering a new child in the form of three-dimensional (3D) printing [1]. This technology has been adopted by surgeons in an increasing extent and in a large variety of applications, hence 3D models can be made from a wide range of human anatomy [2].

Three-dimensional printing is a manufacturing method in which objects are made by fusing or depositing materials in layers to produce 3D physical objects on the basis of a specific digital design used as a blueprint. This process has several nicknames such as solid free-form technology (SFF), rapid prototyping (RP) or additive manufacturing (AM) [1], [3]–[16].

The use of 3D printing methods offers several advantages over Computer Numerical Control (CNC)-based production methods, which was the main method fabricating unique parts before discovering RP possibilities. Firstly, with 3D printing, it is easy to make complex structures. Thus, no traditional design constraints. Moreover, high precision allows to make internal cavities, textured surfaces, and intricate shapes. Secondly, less used material, which leads to reduced waste and cost. Thirdly, setup costs and times are comparatively low, while production costs and times are basically the same as in CNC milling. Thereby, both prototypes and final versions of implants can be made quickly, taking only hours. Apart from difficult cases that can take weeks. So, 3D printing has grown from an era of mass production to an era of mass personalization, where artists from all walks of life are using greater imagination or original ideas to produce unique products [1], [5]–[6], [10].

Three-dimensional printing is an additive manufacturing technique with increasing use in medical sector [7], [12]. Ballard et al. [17] demonstrated the growth of 3D printing in publications. Pubmed.gov was screened using the phrase “3D printing”, which resulted six papers in 2000, 61 papers in 2010, and more than 1100 papers in 2016.

3D printing has made a substantial breakthrough and integrated itself into various markets. In 2012, the AM was assessed to be worth 2.0 billion, three years later 4.8 billion and by the year 2017 close to 8.2 billion euros (EUR). The healthcare sector accounted for 16.4% of the industry's total revenue, consumer products 21.8% and motor vehicles 18.6% in 2013 [11]. Moreover, 3D printing in the medical area has been predicted to be worth 3.25B EUR by 2025. In addition, between 2017 and 2025 the industry’s compound annual growth rate is presumed to reach 17.7% [13].

Three-dimensional printers are used in the medical field to decrease healthcare costs and improve patient care and outcomes [11]. Over the past few years’ 3D printing has become less expensive and thus used more in routine clinical care. As an illustration, 3D printed skull could cost up to 2,150 € in the 1990s, whilst the same model today would be around two hundred euros. 3D printing process is fast and cost-effective due to the new generation consumer grade 3D printers. Clinicians experience hardship in convincing managers of the potential cost/benefit ratio using 3D models in patient care. The first reports 20 years ago of the benefits of RP apply today showing reduced intra-operative time and improved outcomes. Therefore, it is essential to show precisely these cost-savings within the patient pathway to ensure funding for the models [9].

Anatomical models and stimulators were used in medicine centuries ago. To represent disease states stone and clay models were utilized. During the past years, there have been urge to find new techniques for surgical planning and training to decrease patient mortality, surgical complications, and operation room (OR) time. Regardless of these efforts, a recent study has shown that more than 250,000 patients die each year as a result of “medical errors”. This would be the third leading cause of death in the United States after heart disease and cancer. In fact, it is predicted that more than 4000 cases of surgical “never events” will occur in the United States alone. Thereby, effective preoperative planning and clinical training would be crucial to overcome these concerns [18]. A preliminary review of the relevant literature indicated that 3D printing could be adapted for medical purposes in Estonia as well. Therefore, the initial aim of the current thesis is to investigate feasibility and potential barriers of 3D printing implementation for routine use in Estonian healthcare.

# 2 Background information

This section highlights the importance of 3D printing in healthcare based on a literature overview. In addition, advantages and disadvantages of 3D printing will be discussed as well.

## 2.1 Three-dimensional printing principle

The first 3D printing technology was proposed by Charles W. Hull in 1986, he used stereolithography (SLA) to make polymer objects [7], [12], [19]. RP technologies have been divided into several process categories such as material extrusion, material jetting, binder jetting, powder bed fusion, direct energy deposition, vat photo-polymerization, and sheet lamination according to the standard of ISO/ ASTM 52921:2013 [3].

Currently, there is no standard 3D printing process in healthcare and medical research, because 3D printing has not yet reached to its maximum capacity [11]. The first step in the process of 3D printing patient-specific organ model starts with obtaining anatomical information of the patient's organ of interest via different imaging modalities, which must be volumetric (Figure 1). Therefore, well-suited are computed tomography (CT) scan, high-definition ultrasound, magnetic resonance imaging (MRI) or angiography [1], [5], [8], [17]–[18]. Volumetric 3D echocardiography is comparatively cheap, does not have ionizing radiation and is well accessible. For now, primary imaging modality for 3D printing has been CT, because of excellent spatial resolution as it provides submillimeter tissue resolution to identify bone and pathologic calcium deposition. In comparison with MRI, computer tomography could image patient with metal implants, pacemakers and pacemaker wires. As a downside CT uses ionizing radiation and iodinated contrast media to distinguish tissue composition [8].

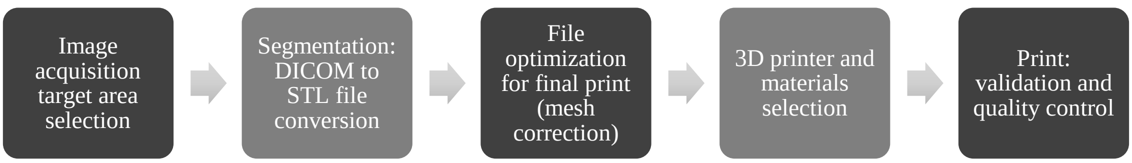

Figure 1. 3D printing workflow [20].

Medical imaging modalities are primarily in Digital Imaging and Communications in Medicine (DICOM) format, but unfortunately, there is no 3D printer that is able to print the model in DICOM format. For that reason, DICOM image is converted to STL (STereoLithography, sometimes referred to as Standard Triangle Language or Standard Tessellation Language) format. Therefore, first step is to identify the region of interest of an organ using appropriate segmentation process. Software's good for that purpose are Vitrea and Mimics. Next step is to generate a STL file for the 3D printing process. Frequently, this STL file needs to be further modified using Computer-Aided Design (CAD) software to adjust the deformities in the STL model (like gaps between segments of the model) and making it perfect for 3D printing. Finally, STL model is ready to be sliced into horizontal layers to generate the G-code, which is then suitable for 3D printing [1], [5], [8], [12], [18]. Recent growth of 3D printing technologies has profited from the open-source movement, expired patents and free file-sharing on the internet [9].

Another fascinating utilization for 3D printing is 3D surface scanning technology which plays a viable role in healthcare producing orthotics/prosthetics or casts. 3D scanning is a process, where digital 3D images are constructed using collected data of shape and possibly its appearance from analyzed object via laser light. Most importantly, the scanning technology cannot use computer algorithms nor interpretations from two-dimensional (2D) pressure readings. There are three acceptable types of 3D digital scanners: 1) laser triangulation (red light), 2) structured light (white or infrared light) and 3) contact digitization. Although, there are several casting methods one can employ to make an impression of the foot such as plaster casting, slipper casting and impression foam that can be successful in case performed properly. 3D scanners compared to plaster casting are cheaper, time-saving, allow to scan quickly large number of people, measurement is robust and efficient, additional orthotics can be ordered remotely and at any time. But still, there are many occasions when traditional methods are preferred, e.g. athletes with certain foot types and rearfoot/forefoot imbalances, prescription orthotics [21]–[22]. Basically, it is up to a doctor to decide which solution is better for his/her patient.

## 2.2 Three-dimensional printing technologies

3D printing technologies have provided several auspicious applications in medicine in recent times [3], [7]–[8]. As there are over 20 different 3D printing processes [5], the most frequently used additive manufacturing methods (Figure 2) are listed below:

I. **Fused deposition modelling (FDM)** is when computer-controlled extrusion nozzle is used to make heat-softened polymers to deposit to layers [8]–[9], [12], [23]. This technique is used by most economical consumer printers [1], [24]. FDM was developed and patented by Crump in 1989 and was commercialized in 1990 by Stratasys. These printers can be bought in cheaply and have low maintaining costs. For instance, filament material cost only 21.5 EUR/kg [9].

II. **Stereolithography** uses a photopolymer resin, on which an optical light such as ultraviolet laser light or visible light energy source works. Selected surface areas of the liquid are hardened. The depth of material increases as the floor of the fluid container gradually descents. The final shape is formed, when successive layers of resin are cured on top of each other [1], [8]–[9], [12], [23]–[24]. This technology was developed and patented in 1986 by Chuck Hull, who founded the company 3D Systems [25].

III. **Selective laser sintering (SLS)** is where focused energy source (such as an electron beam or a laser) is used to sinter powdered materials, e.g., titanium, stainless steel and nylon. As the laser scans the surface, material is heated and fused together [1], [9], [12], [24]. This method is used for building functional prototypes or medical implants, like sternal or facial bone replacements [8]. SLS technology is precise but with high start-up costs [9]. Originated by Carl Deckard and Joseph Beaman in the Mechanical Engineering Department at the University of Texas-Austin in the mid-1980s [25].

IV. **Ink-jet based 3D printing** – the model is built up gradually layer by layer as binder solutions are printed onto a thin layer of powder. Moreover, the developing model has the powder operating as a support structure. Multiple materials can be deposited simultaneously when multiple printheads are used in the same inkjet system. Such printers can provide 0.1mm resolution. The technology was developed at the Massachusetts Institute of Technology in 1993 [9].

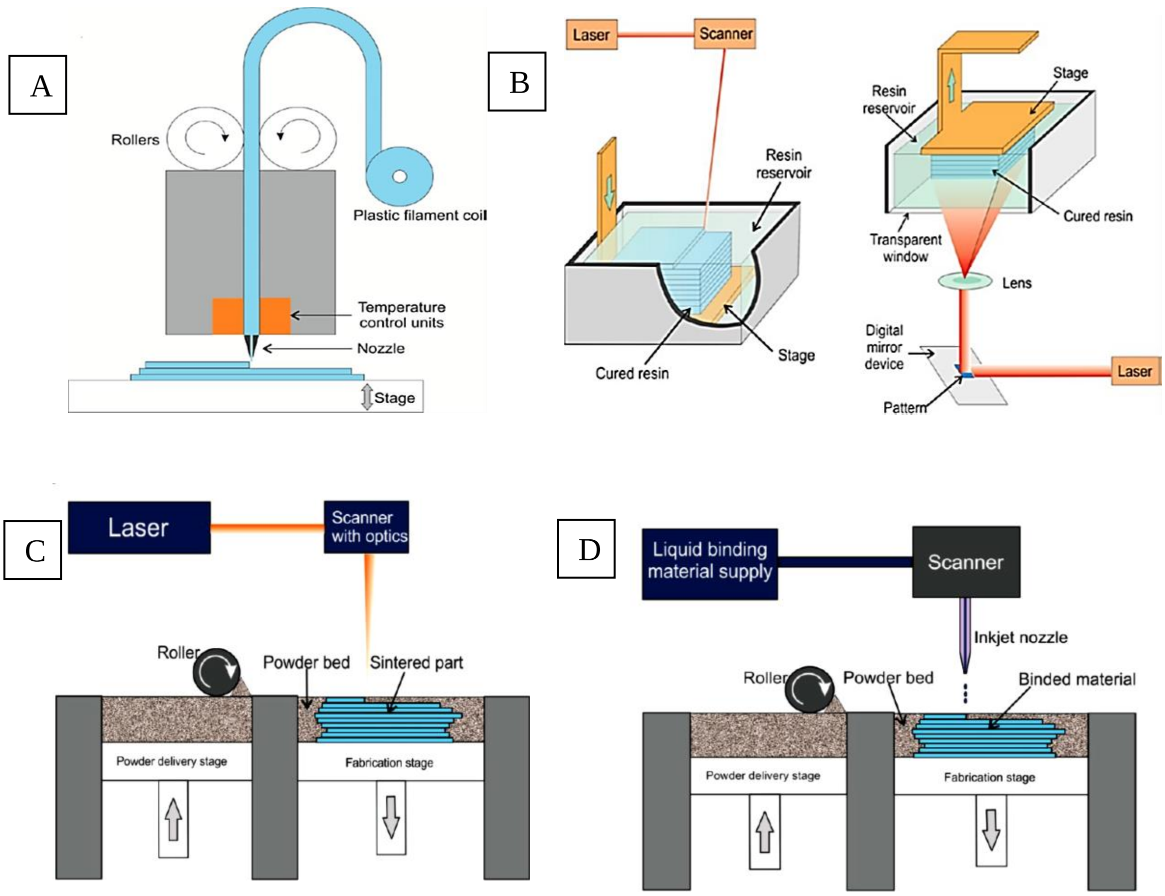


Figure 2. A – Schematic of an FDM 3D printer, B – Schematic of an SLA 3D printer (left – direct writing, right – mask-based writing), C – Schematic of an SLS 3D printer, D – Schematic of an inkjet printing apparatus [25].

3D printing is rapidly evolving field with numerous manufactures. As each printing method has its own strengths and weaknesses, like choice of materials, longevity, construction duration and precision [11]. SLS and SLA printers are used more in medical applications rather than FDM printers. Although, they are much faster and cost-effective. Additionally, FDM printers use materials with a low melting point as SLS and SLA printers can withstand common sterilization procedures prior to surgery. However, as a negative side, these printers involve thorough training and technical knowledge before use [1]. Depending on the desired outcome one should choose the right technology [20]. Several 3D printers are available for commercial use with different technologies and materials (Table 1).

Table 1. 3D printing technologies and materials [12].

| Technology | Description | Material |
|---|---|---|
| **Binder jetting** | Liquid binding agent is dispersed on powder material selectively binding it together | Ceramic, metal, sand, plastic |
| **Bio-ink or ink jet printing** | Droplets of stem cells or living cells are dispersed layer by layer (i.e. organ creation) | Stem cells |
| **Digital laser sintering** | Direct metal laser melting ore | Metal |
| **Digital light processing (DLP)** | Traditional light source or laser used to harden photopolymer | Photopolymer |
| **Direct metal deposition** | Laser used to melt metallic powder | Metal, titanium |
| **Electron beam melting** | Election beam melts and fuses material in a vacuum with no air and free from gaps | Metal, steel, titanium |
| **FDM or fused filament fabrication** | Thermal energy used to fuse materials | Plastic, acrylonitrile butadiene styrene (ABS), polylactic acid (PLA) |
| **Laminated object manufacturing** | Material is layered and cut to shape using a laser or blade | Glass, metal, foil paper, plastic |
| **Material jetting** | Printer head releases drops of material on platform | Wax, gels |
| **Power bed fusion** | Laser sinters bed of metal powder | Metal |
| **Selective laser melting** | Laser used as a heat source to melt materials into desired shapes | Metal, metal alloy, cobalt, aluminum |
| **SLS** | Laser sinters material, which is bound into solid objects (similar to welding) | Nylon, ceramic, glass, metal |
| **SLA** | Ultraviolet light source used to harden photopolymer | Photopolymer resin |

## 2.3 Three-dimensional printing materials

Nowadays, different printing techniques and materials provide better opportunity to reproduce the patient anatomy as it closes the gap between the real anatomy and the manufactured one. However, nearly all available printing materials are inflexible [20].

3D printers have different indicators such as technique used to create each layer, use of material, build volume and layer resolution [7]. Increasing array of materials are available for manufactures to choose from such as plastics, metals, rubber, wax, ceramics, powders, liquids, wood, or even living cells/biomaterial [1], [3], [6], [9], [15], with various degrees of strength hardness, elasticity and durability [5], [10]–[11]. The choice of material depends on the printer. Commonly, FDM uses hard plastics such as ABS and PLA. In case flexibility is not important factor for planning, then these models are good for visualization of intracardiac anatomy. Each material has its own Shore value (hardness) and therefore differ due to rigidity [7]. Newer 3D printers are also capable of printing in multicolor and -material giving opportunity to make complex models [7], [9].

Several suitable 3D printing materials are obtainable to make an object desired (Table 2). Metals, resins, and wax are frequently used 3D printing materials in healthcare [12]. For instance, human body can be characterized with rigid and soft materials. Human bones are rigid and ligaments or articular cartilage are soft. Most of the materials are rigid. The simplest and easiest biological tissue produced by 3D printing are bones. Usually, in bone structure modelling ABS, powder of plasters or hydroquinone are used [20].

Table 2. 3D printing materials and their characteristics [12].

| **Material** | **Strength** | **Color** | **Min Wall Thickness (mm)** | **Layer Thickness (mm)** | **Biocompatibility** | **Flexibility** |
|---|---|---|---|---|---|---|
| ABS | Strong | Many | 1 | 3 | Yes | No |
| Ceramic | Delicate | White | 3 | 6 | Yes | Yes |
| Cobalt chromium | Strong | Blue | N/A | N/A | Yes | No |
| Gold or silver | Strong | Gold or silver | 0.5 | 10 | Yes | Yes |
| Nylon | Strong | Optional | 1 | 10 | Yes | Yes |
| Polyether ether ketone | Strong | Brown or grey | 1 | 10 | Yes | Yes |
| Polyjet resin | Strong | Transparent | 1 | 10 | Yes | Yes |
| Resin | Delicate | Transparent | 1 | 10 | Yes | Yes |
| SLA resin | Strong | Transparent | 1 | 10 | Yes | Yes |
| Stainless steel | Very strong | Gold or bronze | 3 | 6 | Yes | No |
| Titanium | Strongest | Silver | 0.2 | 30 | Yes | No |

Extrusion-based printing, inkjet-based printing, light-assisted 3D printing and particle fused-based 3D printing are mostly used in medical and pharmaceutical applications. All medical and pharmaceutical biopolymers intended for 3D printing must meet strict requirements. Due to physiological conditions and their association with the local body environment. Figure 3 shows the key material property requirements for medical 3D printing [3].

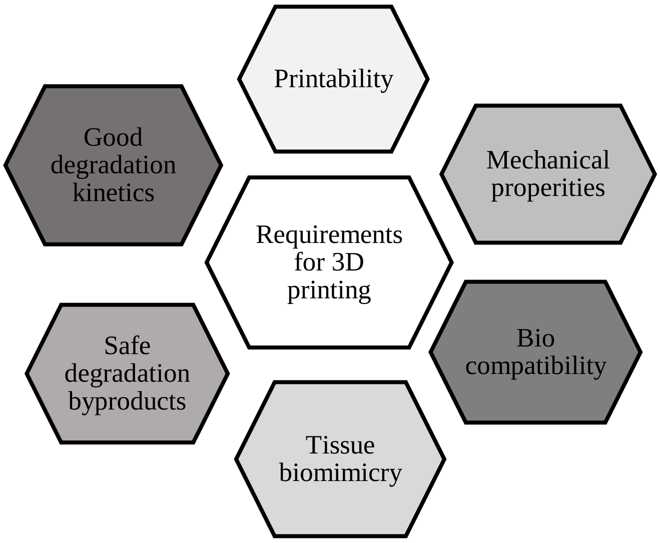


Figure 3. Requirements for 3D printing in medicine [3].

Not only printability, biocompatibility, degradability, exhibiting tissue biomimicry and appropriate mechanical properties determine what kind of material should be used for 3D printing applications in medicine and pharmacy but also should take into consideration sound processing and printer friendliness. This allows accurate and easy 3D construction with great resolution, structural stability and high shape precision [3].

Presently, there are still a lot of obstacles to overcome before 3D printing technology would be used as a common fabrication technology. One of the barriers to the wide-scale adoption of 3D printing technologies is limited variety of available, environmentally- and printer-friendly materials. Recently the focus has been in sustainable economy for various products fabrication like natural and renewable biopolymers rather than using fossil oil-based plastics. Alternatives to fossil resources could be woody and agricultural residuals and biomass from marine [3].

## 2.4 Three-dimensional printing applications in medicine

3D printing is ever-growing technology, which helps to save and improve people's lives unimaginable up to now, by offering more and more applications in healthcare. Ballard et al. and Aimar et al. pointed out wide range of healthcare settings where 3D printing has been used for instance cardiology, cardiothoracic surgery, gastroenterology, general surgery, critical care, orthopedic surgery, otolaryngology, interventional radiology, neurosurgery, ophthalmology, oral and maxillofacial surgery, plastic surgery, transplant surgery, podiatry, pulmonology, urology, vascular surgery and radiation oncology [7], [17], [20]. Currently, almost every surgical specialty has highlighted the applications for 3D printing.

The application areas of 3D printing technology are expanding, especially in surgery. For instance, 3D printed models have been used for different purposes such as anatomical and operative planning and for creating different surgical guides in dental, oncologic, plastic and reconstructive surgeries along with patient education and improved patient consent [26]. The current medical applications of 3D printing can be categorized into a number of categories: surgical preparation and education, prosthetics and/or orthotics, dental, bioprinting/tissue fabrication, pharmaceuticals and manufacturing of medical tools and devices. Details of these medical uses are given below.

### 2.4.1 Surgical preparation and education

The potential applications of 3D printing in clinical medicine are abundant. Ballard et al. argued that treatment planning is a multistage process. Thus, operative time is saved when clinical and imaging information is integrated to make the best medical decision [17]. Many studies have reported that individualized preoperative planning helps to decrease time spent in the operating room (OR) and leads to fewer complications as well. Additionally, healthcare costs will be diminished because reintervention rates and postoperative stays are dropping [7], [20], [24], [27]. Researches, which were carried out decades ago, suggested that approximately 20% reduction in OR time was possible when 3D models were used in surgical planning. Furthermore, data from recent meta-analysis of 158 articles, showed that OR time was declined in 52 (33%) of the articles [28].

Moreover, 3D printed models are becoming increasingly useful tools in today´s practice of personalized medicine, as healthcare professionals are able to create realistic organ replicas with such accurate anatomic detail that it eases surgical planning before treatments and gives intraoperative visualization. Models are believed to be more instructive compared to CT or MRI scans, because of 3D view. Obviously, patient-specific models of diseased or cancerous organs have positive aspects in surgical procedures such as increasing efficiency, reducing blood loss, providing appropriate pathology, which ultimately improves treatment results. In this regard, anatomical models have been used in complicated operations (full-face transplant, spinal procedures) effectively [1], [11]–[13], [24], [27], [29]–[30]. Yan et al. stated that 3D printed models help doctors to study patient's condition to make better plans for the operation as 3D printed models show the real condition of various tissues and organs in vivo [14].

It should be stressed that even a small error in navigating complex anatomy can have potentially hazardous consequences. According to neurosurgeons a realistic 3D model can be beneficial in finding the safest surgical corridor and to study from problematic cases. In addition, cases of complex spinal deformities aid from the use of 3D models. Plus, gastroenterologists train with 3D anatomical models to gain better results in surgery, as colorectal cancer is the most commonly diagnosed cancer in both men and women in the United States each year [29].

Multiple subspecialists use 3D models as a cornerstone, where to discuss the surgical plan, pathological condition, predicted outcomes, and perioperative care. In short, they make conscious efforts to reduce medical errors. What is more, 3D models facilitate communication between medical personnel and patients/caregivers. In this way, disease process, advantages, disadvantages and alternatives are understood better [7], [10]. A study conducted by Anwar et al. [7] showed that cardiac models were useful as 11 caregivers who completed the questionnaire for cardiac models claimed that the models were "very helpful" (score 5 of 5) in improving anatomical understanding. Biglino et al. [31] shared the same opinion as they pointed out that 3D models are good for counselling to improve the family's experience with medical staff.

In healthcare settings, 3D printing has a meaningful purpose to be an important teaching and training tool for medical students and residents as well for counselling patients and their families about treatment possibilities [1], [11]–[13], [24], [27]. Importantly, the models give the ability to learn from hands on experience in a non-stress environment. Moreover, the doctors could use printed parts to prepare for the surgery so there would be less surprises on the table [17]. The Centre for Research in Education and Simulation Technologies is supporting the use of 3D printing to educate residents with the use of surgical simulations and anatomic models [12]. The combination of 3D printing with simulation techniques results in fewer errors and cause less complications, thereby patient comfort and safety increases [32]. The reason for choosing 3D models instead of cadavers could be availability, fewer health and safety issues as well as ethical problems [1], [8].

Nowadays patient education has become a top priority for most health care providers, because patients tend to search for the information about their illnesses and symptoms. The problem arises when showing patients their CT or MR scans as they do not understand the two-dimensional representation of three-dimensional anatomy. Radiologist could be the middleman to improve patient understanding by showing the anatomic model directly or by suggesting clinicians to use the model with patients. Studies have shown that 3D models help to improve patients understanding of their medical conditions, thereby 25% higher patient consents scores were obtained. Ultimately, 3D models increase patient satisfaction by helping clinicians to be more effective communicators [1], [8], [17], [20]. For example, in a study by Wake et al. [33] 5-point Likert scale survey was utilized to investigate the impact of 3D printed and augmented reality models for patient education in the context of renal and prostate cancer. They found out that all types of patient-specific 3D models were useful for patient education, but the biggest influence had 3D printed models in patient understanding of anatomy, disease and the surgical procedure.

### 2.4.2 Prosthetics and/or orthotics

3D printing has been vital to the health care sector to create both standard and complex custom-made prosthetic limbs and surgical implants. Dental, spinal and hip implants were fabricated using the same method as well. Previously, clinical implants had to be valid before taking into use, which was a long-lasting process [15], [17]. Furthermore, this technology gives possibility to choose prior to the implantation the size of the prosthesis's components, making it very accurate [2]. Medical personnel tend to use specific software like Mimics Innovation Suite (Materialise, Leuven, Belgium) to design prosthetic implants. Usually, subscription costs are quite high (thousands of euros per year) [10].

One of the early adopters of 3D printing technology were orthopedic, maxillofacial, and cardiothoracic surgeons. Within orthopedic surgery, tibial fractures were fixated using custom external fixation hardware, which was created using 3D printing. In maxillofacial surgery, a titanium mesh was printed to reconstruct the maxillary defect. Cardiothoracic surgeons have used 3D printing possibilities greatly as anatomic models were used in planning congenital heart disease corrections, primary cardiac tumor resections, septal myectomies and cardiac schwannoma resections. 3D models use in preoperative planning has contributed advancements toward custom prostheses production [2], [24].

Food and Drug Administration (FDA) has already approved many 3D-printed prostheses such as dental crowns, skull plates, hearing aids, spinal cages, screws, bone tether plates, facial implants, knee trays, surgical instruments, hip cups, and Invisalign braces [17]. Furthermore, a study conducted in 2015 revealed that more than 100,000 acetabular (hip cup) implants were fabricated using AM and nearly 50,000 of them were implanted into patients [34].

Prosthetic replacement takes weeks to months and thanks to the possibilities of 3D printing this could be faster and cheaper to the amputees, concurrently providing the same functionalities as traditional one. The low price makes them especially suitable for children, because they outgrow their prosthetic limbs so fast [13]. Prosthesis can cost up to 93,000 €, but with 3D printing the cost shrinks to 930 € or less [35]. Approximately 200,000 amputations are performed in United States each year, with prosthetics price from 4600-46000 € replacement or alterations, which is time-consuming and expensive. 3D printing allows patient to design a prosthetic that fits directly to their needs. Poorly fitted prosthesis could lead to serious consequences such as patient discomfort, embarrassment and even depression. Moreover, AM technology can be applied when prosthetics are in contact with patients, since it is easy to produce complicated geometries from a variety of materials [17], [34]. In particular, Body Labs has created a system, which gives patients opportunity to model prosthetics using scanning of their own limbs in order to make a more personalized fit [13].

Custom implants are used in dental and maxillofacial reconstruction. They are particularly useful after tumor resection, trauma surgery and for the reconstruction of temporal (including middle ear ossicles), calvarial, mandible and zygomatic bone. 3D printed implants have a place in soft tissue reconstructions of head and neck as well. These operations can cause cosmetic deformities that can be reduced with 3D printed implants [16]–[17].

Diverse set of raw materials are available, including biocompatible materials like biodegradable polyesters and titanium to make prostheses [2], [24]. In healthcare, a prostheses or prosthetic implant is considered as a medical device when produced or prescribed by healthcare provider. Another option for manufacturing customized prosthesis is using patient's own cell lines that grow into a 3D scaffold with the name of "bioprinting" [16]–[17].

Also, 3D printing could be used to produce permanent implants that are left in the patient's body at the end of the surgery. These implants are used in very complicated surgeries and anatomically unique and distinct regions, which are made to fit perfectly, because of osseointegration. Mostly used in spine tumor surgeries as a filler for the resected portion of the spine, with positive results. There is another alternative use for 3D printing, such as designing interbody cages. The incorporation of surface roughness and porosity, which is similar to natural bone, has been related to bone growth activity. As an example, spinal braces have been found to be comfortable, more efficient and patient-friendly, because they are customized using the patient own body and shape [1].

### 2.4.3 Dental

3D printing has been integrated in dentistry in different fields from orthodontics to general dentistry. Nowadays, 3D printing is being used to fabricate authentic and personalized braces, dental bridges and restorations, portable crowns, prosthesis with frameworks and bases [27].

Printing process could take place in dentist's office or in labs which makes procedure much easier and faster. In dental area, most commonly used technologies are DLP and SLA. Dental printers are very accurate, and they use different types of resins to create dental models [27], [36].

The most well-known 3D printed applications in dentistry are transparent aligners and night guards. Aligners have become particularly popular by the reason of invisibility and being alternative to braces. In the beginning, dentist or orthodontist scans the patient's teeth and then uses special software to create a 3D model of their teeth. Model is made using of two options. In the first case, vacuum is used to form a plastic sheet over the model, which later becomes the aligner. In the second case, doctor uses the model of the patient's teeth to model the aligner itself, which will be afterward printed out. Previous example needs a very high-definition dental 3D printer with a unique resin. 3D printer is a good option, for aligners and night guards, because of speed. A full batch will be ready in few hours [36].

Dental crowns can be made using 3D printing by scanning the broken tooth and making the model of the crown using special software. 3D printing is not only cheaper for the patient and the dentist but also shortens the time of the process from several weeks to less than 30 minutes. The main reason for using 3D printed dental models are easiness to make and powerful tool for a dentist to check their work before starting the surgical process. The procedure is done by scanning the patient mouth and designing a model similar to an aligner just with one exception, openings exactly where surgery needs to be done to verify that implant, aligner or crown will be a fit. Since no mold is needed, it minimizes the waiting time and the feature can be fabricated directly [27], [36].

### 2.4.4 Bioprinting/Tissue Fabrication

Many people are affected by tissue/organ failure, attributable to diseases, accidents, birth defects, and aging, which is a vital medical issue [15], [20]. Far from that, Yan et al. stated the shortage of organs is a huge clinical obstacle to overcome worldwide [14]. Unfortunately, so far, organ failures are mainly treated with organs donated for transplantation form living or deceased donors [15], [20]. Traditional methods may have downsides like secondary injuries, complications and limited donors available. Bioprinting provides a way to overcome these problems by manufacturing patient-specific tissue engineering (TE) scaffolds, repairing tissue defects in situ with cells, and directly print tissues and organs. In that way, printed organs and implants match perfectly with the patients damaged tissue and may also have cell arrangements and material microstructures to facilitate differentiation and cell growth. This invention could eventually solve the donor-shortage problem [14].

Currently researchers are finding ways how to develop functional liver, kidney and other solid organs for transplantations. Medical imaging is playing an important role in the progress of regenerative medicine. It provides a non-invasive means for damaged tissue determination, contributes valuable information in the creation and implantation of organs [24].

The first 3D human kidney tissue was printed in 2015 by Organovo. Using similar technologies human skin and cardiac tissue were printed. However, printing vascularized organ such as kidney is challenging. Some of the biggest obstacles' researchers face today are how to accurately replicate the architecture of blood vessels, connective tissues and other supporting tissues in and about visceral organs [17]. Generally, printed organs are non-lymphatic, non-vascular, without nervous tissue, thin and inside empty. The host vascular system provides nourishment to the organ by diffusion. Problem arises when oxygen diffusion between host and transplanted cell ascends and tissue thickness exceeds 200 micrometers. Therefore, improvements need to be done to print organs with complex and multicellular structure with vasculature. That has not achieved yet [15]. First additive manufacturing experiments have been done on mice and rats, but, in fact, no 3D printed organ has been used in humans [17]. For example, researchers from Princeton University implemented a bionic ear using 3D printing that had much better hearing ability than humans [16].

Bioprinters use a bio-ink to layer living cells guided by computer pipette to make artificial living tissue in a laboratory setting [13], [37]. In the future, animal models may be replaced by bioprinted organs to test for the new drug. Implantable tissues can be designed with 3D printing as well. As an example, transplanting synthetic skin to patients with burns, and testing cosmetic, pharmaceutical and chemical products [20].

As mentioned above 3D printing has several benefits. According to The Guardian, the technology is anticipated to be worth around 1.2 billion euros by 2021 and affecting the cost of various medical procedures. The National Foundation for Transplants has pointed out that typical kidney transplant costs an average of 307,000 € whereas conventional 3D bioprinter was sold for 9,300 €. It seems not too distant future for prices of medical procedures and biomedicines to drop drastically when competition increases due to 3D printers [38].

Today hundreds of millions of people worldwide suffer from neurological disorders. These disorders include Parkinson's disease, Alzheimer's disease (AD), and spinal cord injuries. It is estimated that there are 46 million people with AD worldwide whose treatment cost approximately 760 billion EUR in 2015. Without having a permanent cure, this situation is becoming worse, mostly in countries with poor healthcare systems. The brain research is impeded by ethical restrictions on humans and animals. For that reason, it is urgently needed cheap artificial in vitro models that could allow mimicking and studying of the brain tissue [39].

Scientists have been working on neural tissue engineering methods to construct a utilizable brain model. TE method works, in such way, that patients' tissues grow on scaffolds, which provides a support for guided cells to develop into a functional tissue. Scaffold materials need to have certain essential properties of a pristine extracellular matrix (ECM). These are chemical composition, nanotopography, mechanical stability, porosity and biocompatibility. Until now, not many neural cell studies have been conducted on 3D printed scaffolds. Mostly used synthetic polymeric inks were polyethylene glycol diacrylate, poly(2-hydroxyethyl methacrylate) or polyurethane. Surely, synthetic polymers are suitable for certain applications, but natural polymers tend to achieve better genuine mimicking of ECM conditions [39].

### 2.4.5 Pharmaceuticals

Personalized medicine could transform the way people treat themselves. Person's unique genomic portfolio makes them susceptible to specific diseases. Specifically, in case, they cannot take a certain medicine because of an allergy to one of the ingredients. With this in mind, in fabricating process this component will be excluded. Patients' genetic makeup dictates the treatment option [15], [40].

The 3D printing process of pills consists of layers of layers put together of powdered drug, which would dissolve faster than average pills. This process provides the possibility to personalize the quantity needed by the patient [20]. The first 3D printed drug was approved in August 2015 (the Spritam Levetiracetam) by the FDA in United States. Introduced by pharmaceutical company named Aprecia. This is a medicine for epileptics to reduce seizure. The process is built up layer-by-layer, and consists of active and inactive ingredients. Bioprinting can be used to limit or completely eliminate systemic toxicity by localizing drug delivery [17], [35].

The drug-printing opens new era where drugs can be made safer and more effective. For some it's hard to consume big tablets, but with drug printing, it can be made more appealing. Especially children, who would prefer to eat modified drugs with desired color, size and shape rather than regular one. It is important to express that changing the shape of a capsule does not have to affect dose and drug properties, like dissolution rate or drug release [20].

Moreover, when medication is produced in-house, it can be time-saving and especially useful in urgent situations when patient all needs, especially, clinical, genetic and metabolic characteristics must be taken into account. As a result, costs and prices will be cut down. In particular, pharmacists do not have to store large quantities and varieties of dosage forms as base components do not take so much space [4].

### 2.4.6 Manufacturing of medical tools and devices

With the help of 3D printing it is possible to create surgical instruments to operate on small areas without causing unnecessary extra damage to the patient. For instance, produced sterile surgical instruments are hemostats, forceps, scalpel clamps and handles. One of the main reasons why 3D printing is preferred over traditional manufacturing methods is the production cost, which is substantially lower than alternative [13], [20].

One of the most active users of RP guides and tools are craniofacial surgeons and orthopedic surgeons. In the year of 2014 RP techniques were used in Egypt to help total or partial knee replacement surgeries by fabricating 23 custom surgical guides and templates. Additionally, more than 112 surgical guides were made to help several craniofacial surgeries and nine different titanium alloy Ti-6Al-4V craniofacial implants were surgically implanted into patients [34].

Here is an example how 3D printing gives path to innovation and rapid prototyping. In hand surgery bone reduction clamp was needed. Benefits of using the clamp: 1) less operative exposure and 2) more kinetically feasible fraction reduction. So, commercial 3D printing company was used to create a stainless-steel customized clamp. The clamp was successfully used intraoperatively as it was able to go through sterilization, thereby was reusable. Total cost of the six prototypes and the final stainless-steel clamp was around 1850 € [17].

Having a 3D model beforehand gives surgeons possibility to choose right tools for the surgery. Furthermore, surgical instruments can be designed and printed for each patient dependently. Currently, most popular material used for printing is metal and trend is toward printers capable of mass production. As an illustration, Dr. Dana Piasecki from

OrthoCarolina cooperated with Stratasys. The surgeon made a 3D printed metal surgical tool for a surgery of anterior cruciate ligament. The tool was designed with CAD files and the surgical prototype was printed using FDM. Lastly, Inconel 718 with Direct Metal Laser Sintering fabricated the product. A quality management system is a base for creating tools locally in hospitals. This is vital, because of safety issues, to ensure that tools are biocompatible and without cytotoxicity, before using them in the OR. With this in mind, surgeons are able to design their own tools with the material of interest [11].

## 2.5 Promising application areas for 3D printing

3D printed applications are constantly improving, especially the quality aspect. Therefore, makes it suitable to use on patients. Anatomical models can be used for different purposes, mainly divided as follows: surgical planning, surgical guides and implants. In the table below is brought out potential advantages and disadvantages of the domains where the use of 3D printing is relatively common or has been used multiple times [41].

Table 3. 3D printing applications used on patients, with clinical and economic outcomes [41].

<table>
<tr><td colspan="2">CUSTOM IMPLANTS<br>Use for cranial surgery, dentistry, and maxillofacial surgery (discussed in 28 studies).</td></tr>
<tr><th>Positive sides</th><th>Negative sides</th></tr>
<tr><td>• Reduce OR/treatment time (17 out of 28 studies)<br>• Good accuracy and improved medical outcomes (25 studies)<br>• Increased cost-effectiveness (one study)</td><td>• Increased costs (14 studies)</td></tr>
<tr><td colspan="2">ANATOMICAL MODELS<br>Use for implant shaping in maxillofacial surgery (discussed in nine studies).</td></tr>
<tr><th>Positive sides</th><th>Negative sides</th></tr>
<tr><td>• Reduced time (five studies)<br>• Good anatomical representation (eight studies)<br>• Improved surgical outcomes (nine studies)</td><td>• Exposure to ionizing radiation (two studies)<br>• Increased costs (two studies)</td></tr>
<tr><td colspan="2">Selecting patients for cardiovascular surgery (discussed in two studies).</td></tr>
<tr><th>Positive sides</th><th>Negative sides</th></tr>
<tr><td>• Good at representing the actual pathology (one study)</td><td>• Increased costs (one study)</td></tr>
</table>

**ANATOMICAL MODELS**

Use for surgical planning in cardiovascular surgery, vascular neurosurgery, dental surgery, general surgery, maxillofacial surgery, neurosurgery, cranial/orbital surgery, orthopedics, and spinal surgery (discussed in 89 studies).

| Positive sides | Negative sides |
|---|---|
| • Reduced OR time (48 studies/13 studies supported this claim with actual statistics)<br>• Good accuracy of printed parts (80 studies/4 studies supported this claim with statistics)<br>• Improved medical outcomes (73 studies) Decreased exposures (eight studies)<br>• Decreased costs (four studies)<br>• Cost-effective (eight studies/ four studies in maxillofacial surgery) | • Increased OR time (two studies)<br>• Increased exposure to ionizing radiation (three studies)<br>• Increased costs (32 studies/ 21 studies supported this claim with numbers or statistics) |

**MOLDS FOR PROSTHETICS**

Used to produce molds for making prosthetics in cranial surgery, maxillofacial surgery, and ear surgery (discussed in three studies).

| Positive sides | Negative sides |
|---|---|
| • Printed parts were accurate and improved the medical outcome (three studies)<br>• Reduced OR time (one cranial study)<br>• Reduced costs and cost-effective (one study of ear surgery) | |

**SURGICAL GUIDES**

3D printed surgical guides were used in orthopedics, neurosurgery, dental surgery, spinal surgery, and maxillofacial surgery (discussed in 137 studies).

| Positive sides | Negative sides |
|---|---|
| • Reduced OR time (53 studies/28 studies supported this claim with numbers or statistics)<br>• Good accuracy (88 studies)<br>• Reduced radiation (nine studies/ including six of the 11 spinal surgery studies)<br>• Improved clinical outcomes (86 studies)<br>• Cost-effective (10 studies) | • Increased OR (seven studies/ five studies supported this with statistics)<br>• Insufficient accuracy (10 studies/ six studies supported this with numbers or statistics)<br>• Negative impact on clinical outcome (seven studies, all knee orthopedics)<br>• Expensive (39 out of 42 studies/19 supported this with statistics)<br>• Not cost-effective (six studies) |

From all applications, this technology appears to be most useful for maxillofacial surgery for using surgical guides and models for shaping implants as well as spinal and maxillofacial surgery for using models in surgical planning [41]. Seen in table 4.

Table 4. Advantages of 3D printing by surgical fields [41].

| SURGICAL FIELD | APPLICATION | BENEFICIAL (HOW?) |
|---|---|---|
| **Orthopedics** | Complex hip replacements | • Improve medical results |
| **Cranial surgery** | Cranial (mostly orbital) fractures | • Anatomical models used as guides prior to and during surgery, better pathology understanding and pitfalls avoidance.<br>• Models are used to shape the implants prior to surgery, resulting improved fit of the implant, medical outcome, and reduced surgical time. |
| | Surgical guides | • Reduce OR time and improve medical outcomes, due to the accurate translation of the preliminary surgery. |
| **Spinal surgery** | Spinal models | • Improve operation planning and clinical outcome, while reduce operation time.<br>• Reduce exposure to ionizing radiation. |
| | Surgical guides | • Reduce OR time and improve medical outcomes, due to the accurate translation of the preliminary surgery |
| **Maxillofacial surgery** | Maxillofacial models | • Improve operation planning and clinical outcome, while reduce OR time.<br>• Used to shape implants (3D printed trays and fixation plates) prior to surgery, enhancing surgical speed, while improving clinical and esthetical outcomes. |
| | Surgical guides (mandibular reconstructions, orthognathic surgery) | • Translate the surgical planning accurately and make the outcomes less dependent on the surgeon's experience. |
| **Cardiovascular surgery** | Percutaneous valve implantation, repair of aorta and cranial aneurisms, and surgical planning of complex congenital heart malformations | • Anatomical models are useful for planning vascular procedures<br>• Models improve patient selection for endovascular procedures, as compared with standard medical imaging. |
| **Dental surgery** | Tooth transplant surgery | • 3D models of teeth are used to prepare the donor site, improving the procedure's success rates.<br>• Anatomical models are used to make drilling guides for dental implants and to make custom obturators for. |

Tack et al. [41] brought out from the analyze of 227 surgical papers the main advantages that were pointed out by other authors, such as decrease of surgical time, advances in medical outcomes and reduce of radiation exposure but added that the subjective character and lack of evidence supported majority of these advantages. Moreover, this does not allow to make conclusive statements. In this regard, several authors have indicated that the use of 3D printing for medical purposes is advisable and more beneficial in complicated situations as well as with less skilled surgeons.

## 2.6 Challenges with medical 3D printing

There are numerous factors influencing quality of 3D printing such as technological and manufacturing process, material selection and technical limitations of the technology (Figure 4) [42].

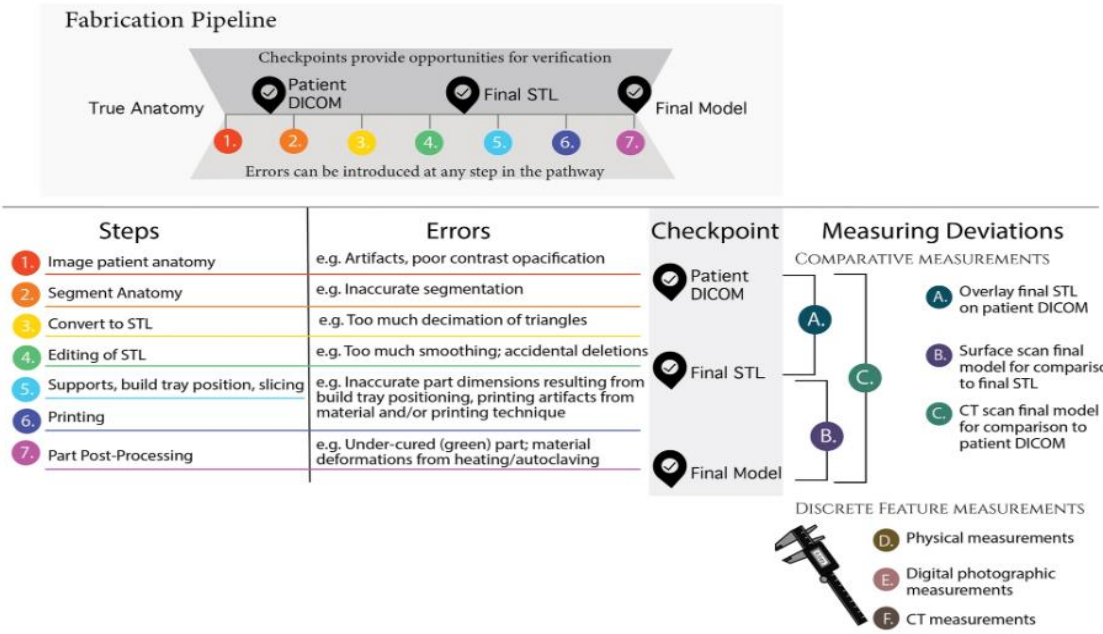


Figure 4. 3D printing model verification [43].

As a matter of fact, 3D printing requires a minimum level of image and resolution quality. In specialized fields, like vascular surgery, it can be very challenging because successful printing is bound up with imaging quality and printer's availability. Additionally, one has to be very careful when converting data from one file type to another for errors not to occur. It was also noted that problems arose with accuracy (poor image resolution) and artefacts' (CT cannot scan metal) [42]. Inaccurate models, as a result, could mislead the physicians to misdiagnose, delay in treatment or mismanage patient [44].

Concerns have raised with materials availableness and mechanical properties to be suitable for 3D printing. Another issue that gain prominence, an urge for a better understanding of what material microarchitectures or internal structures give best results. Several weaknesses have been addressed with 3D printing, namely, not all surgically important information (joint instability) can be replicated and, with some types of imaging real-time information cannot be provided [42].

According to a study in maxillofacial surgery, 3D printing was more often outsourced to a commercial medical devices manufacturer rather than printed in-house. Not very complicated printing (e.g. anatomical models) fits more for in-house 3D printing. Self-printing can bring several concerns with safety and utility issues of such a device [42].

One of the biggest barriers in 3D printed medical products is the lack of a comprehensive regulatory framework [45]. For instance, Canada has developed guidance for manufacturers, who wish to obtain licenses for 3D printing medical devices. The document stated [42]:

- The starting materials, additives and the 3D printing technique used for production should be specified.
- Manufacturers should point out if all or part of the device is 3D printed.
- In submission should be stressed why 3D printing was suitable option for manufacturing.
- In case of using, removing or recycling of layering materials it should be validated.
- Final device needs biocompatibility testing.
- Verification and validation of the software for design and printing purposes is needed.
- Should be consider how the final product may be affected by the sterilization.
- It is good to keep track of the maintenance and cleaning records of printer.

Notwithstanding, 3D printing health technologies regulation in Europe is complicated and from 2017 controlled by three frameworks: 1) The Active Implantable Medical Devices Directive, 2) the Invitro Diagnostic Medical Devices Directive, and 3) the European Medical Device Regulation. Legal regulation depends on the type of device, whether it is mass-produced or patient-specific [42]. Guidance document is good for analyzing and controlling risks specific to 3D printing.

Additionally, quality assurance (QA) programs should be established for the 3D printing. As these QA programs exist in many areas of medicine, e.g. medical imaging. In radiology, these programs are used for dose reduction, appropriate use calculation, radiologist interpretations and results reporting. Not many hospitals have adapted and used QA programs for 3D printing and phantoms creation that test the performance and precision of 3D printers and materials yet [43]. What is very important, there are experts who have started discussing the matter of legal interest which comes with 3D printing. Notable examples include public safety, liability and intellectual property rights [30].

Some experts argue that 3D printing causes the dual use dilemma. To be more specific, bioprinting can be used for virtuous and destructive purposes. This particular field has received a lot of attention in the past couple of years. More or less, because of QA issues of these printed medical products. Correspondingly, how to ensure pure and non-contaminated cells preparation. Therefore, the research ethics committees at universities and research institutes have great significance in monitoring and approving such research projects [30].

Another concern that is evolving with the development of technology for printing multi-material products is the possible damage from unknown chemicals. The pharmaceutical industry is of interest in this regard, especially since the branded medicines are quite expensive. This could instigate some consumers to create their own generic drugs. Possible side-effects could be overdose or accidental poisoning of miscalculation of the chemical compounds. For example, this could lead to another problem as emergency specialists use a pharmacological classification system that classifies medicines and household substances. When a person swallows a new chemical mixture that is not in their database, it is more difficult for medics and physicians to administer the appropriate antidote and overall save lives [30].

Some experts believe that RP opens an edgeless legal arena for liability cases where a 3D printed product causes injury, whether it be physical, emotional, economic, etc. For instance, imagine a situation, when the defective part of the specific refrigerator model lights up and destroys many customers' properties. Therefore, the appliance manufacturing company must reimburse the expenses. Another scenario where the same part was created as a blueprint by 3D printing designer, thereafter gave free online access. Then, a person downloads the part, prints it, and installs it in their refrigerator. Who would be responsible if the part malfunctions and engulfs the house? Would it be the refrigerator owner, the author of the 3D printing blueprint, or the appliance manufacture? This is just one example, illustrating the legal complexity that comes with AM [30].

## 2.7 Healthcare management system in Estonia

Estonia is a country on the east coast of the Baltic Sea with a population of 1.3 million [46]. In Estonia healthcare is mainly financed through the state budget. Precisely from the health insurance budget through the Estonian Health Insurance Fund (EHIF) and through direct allocations. In addition, health care is funded from the municipal and city budgets, through patient co-payments (e.g. visit fees for specialist visits) and other sources [47].

Responsibility for the management and supervision of healthcare system and development of health policy belongs to the Ministry of Social Affairs and its agencies. The Ministry of Social Affairs and other institutions under its administration such as the State Agency of Medicines and the Health Board and the EHIF have responsibilities, including planning, managing, regulating and funding the health system functions [48].

The EHIF is an active purchaser of services, whose responsibilities include the contracting of health service providers, financing of healthcare through health services, reimbursement of medical costs in case of temporary disability and payment of maternity benefits [48]. Health Insurance Act regulates financing of health care [47]. The Act states that some considerations have to be considered upon entry of a service in the list of health services: "the proven medical efficacy of the health service; the cost-effectiveness of the health service; the necessity of the health service in society and the compatibility of the service with national health policy and correspondence to the financial resources of health insurance" [49].

Estonia has come a long way in terms of e-health solutions and services, including electronic health records, digital images, e-prescriptions and e-consultations. However, there is room for improvement, so that data can be better used to integrate services, make clinical decisions and measure outcomes [46]. Therefore, also 3D printing possibilities should be considered.

# 3 Research methodology

This chapter describes research objectives, methods and materials. Ethical side of the study is considered as well.

## 3.1 Research objectives

The initial aim of the current thesis is to investigate feasibility and potential barriers of 3D printing implementation for routine use in Estonian healthcare. Sub-goals of the research are listed:

- Conduct semi-structured interviews with physicians cognizant of 3D printing and some of hospital biomedical engineers to get their perception of 3D printing and future prospects.
- Evaluate the merit of 3D printing in Estonian healthcare based on the results of the interviews.
- Carry out an interview with an Estonian Health Insurance Fund employee to assess the legal side of adding 3D printing to the benefit package of EHIF.

## 3.2 Methods and materials

The study focus is to find and bring out 3D printing merits in Estonian healthcare. Semi-structured interviews were conducted with physicians in the fields were 3D printing was most frequently used based upon the results showed in scientific papers. At first, literature overview was made to find out what were the main purposes of 3D printing used in medicine. Literature search was conducted using the following bibliographic databases: PubMed, ScienceDirect and Google Scholar. The search was completed on December 2019 and limited to English-language documents published after January 1, 2009. Author screened the literature search results and reviewed the full text of all potentially relevant studies. Out of several applications author decided to find out how patient-specific models and implants benefit from 3D printing. In addition, what are Estonian physicians' beliefs about 3D printing in their specialty as well as Health Insurance Fund employee and some of hospital biomedical engineers' opinions on the matter and future prospects.

### 3.2.1 Semi-structured interview and web-based questionnaire

In order to find out the attitudes of Estonian physicians and hospital biomedical engineers regarding 3D printing semi-structured interview guide in Estonian and English was developed. Questions for the interview were gathered using different studies [16], [31], [50]–[53] and thereupon modified.

At the beginning of the questionnaire, brief literature overview of 3D printed anatomical models use in surgery was provided. In the introduction part the author of the thesis explained the purpose and use of the study and sought the consent as well as availability of the respondents for the study.

The interview started with asking demographic information including gender, profession, length of working experience. The guide made for hospital biomedical engineers had additional questions regarding experience in 3D printing, technical skills and time spent on 3D printing. For the most part, the questions created for Estonian physicians (Appendix 1-2) were compatible with hospital biomedical engineers (Appendix 3-4). The questionnaire consisted of 7 different topics:

1. Essence of 3D printing
2. Adoption of 3D printing
3. Value of 3D printing
4. Application fields and impact
5. Patient-specific 3D printed anatomical models for preoperative planning
6. The use of 3D printing technology in creating custom implants
7. Regulatory challenges.

Each topic had small background information given. The semi-structured interview employed a blend of closed- and open-ended questions.

Google Forms application was used to gather information about Estonian physicians' perceptions in 3D printing, for that purpose web-based questionnaire was developed. The web-based questionnaire was identical with premade semi-structured guide made for Estonian physicians. The reason in favor of web-based questionnaire was that it is rapidly deployed and completed by the respondents as well as limitations of physical meetings caused by Covid-19 pandemics. Data from the questionnaire was opened with MS Excel and used for data analyses. Open-ended questions were translated from Estonian to English and grouped into themes. The frequency of responses was calculated.

The next step was to find most active 3D printing users across disciplines from scientific papers. These were cardiac surgeons, oral and maxillofacial surgeons, orthopedics, vascular surgeons, neurosurgeons, gastroenterologists, urologists and plastic surgeons. Using Google search engine and supervisor's personal contacts, the information about Estonian specialty doctors from the two biggest hospitals in Tallinn (East Tallinn Central Hospital and North Estonia Medical Centre) were gathered. The list of potential respondents was created from the collected information. Altogether 62 emails were sent to the doctors of the target groups. From 62 physicians, 11 (17.7%) were women and 51 (82.3%) men. Majority of these physicians' (49) practice in North Estonia Medical Centre and 21.0% (13) in East Tallinn Central Hospital. To be more specific, the survey was sent out to eight (12.9%) cardiac surgeons, eight (12.9%) oral and maxillofacial surgeons, 23 (37.1%) orthopedics, two (3.2.%) vascular surgeons, eight (12.9%) neurosurgeons, four (6.5%) gastroenterologists, eight (12.9%) urologists and one (1.6%) plastic surgeon. The reason to interview the doctors from the selected hospitals only was previously collected knowledge that 3D printing in Estonia is practiced mainly there.

The study was carried out from the 25$^{th}$ of March to 25$^{th}$ of April 2020. On the first day of the study, an email was sent to all the participants. The email consisted of the introduction of the topic of the thesis and author as well as short description of the questionnaire and direct link to the questionnaire. A reminder email was sent two weeks after the initial one, since extra reminders are effective for increasing response rate [44]. The email also contained contact information of the thesis author, in case clarifications or further information was needed.

Interviews by telephone were held with a physician in 25$^{th}$ of March 2020 and hospital biomedical engineer in 31$^{th}$ of March 2020. The semi-structured interview guides were used during interviews. Each individual interview lasted approximately one hour. Before telephone contact, an email was sent out asking permission to conduct telephone interview. Thereafter, an agreement was reached, where date and time of the interview as well as content was outlined. The semi-structured interview guide was provided in advance, for participants to be better prepared and to think about their willingness to participate. Two emails were sent out to two different hospital North Estonia Medical Centre and East Tallinn Central Hospital biomedical engineers.

Secondary data (previous researches) as well as theoretical perspectives and discourses relating to the subject were also used to gain in-depth analysis and therefore understanding of the findings.

### 3.2.2 Unstructured interview

Initial plan was to use similar semi-structured interview guide created for physicians and hospital biomedical engineers, but as the conversation progressed, the incompatibility of the questionnaire with the interviewee became clear. Another approach was chosen, the unstructured interview. This basically means that the questions are not predetermined and interviewer can ask questions that arise during the conversation. The interview was held with an Estonian Health Insurance Fund employee, who is responsible for potential reimbursement of 3D printing. The interview guide was formed in Estonian and English (Appendix 5-6). The introduction part of the interview coincided with Appendix 1-4. In the introduction phase the thesis topic was introduced as well as author and the aim of the study. Five questions and two sub-questions were created. Interview questions were open- and closed-ended. The interview ought to find answers how 3D printing can be added to the EHIF benefit package and how far is the process right now, e.g. what steps have been taken towards the main goal. The telephone interview took place in 1$^{th}$ of April 2020 and lasted about 45 minutes.

## 3.3 Ethical Considerations

The research was purely for academic purposes and confidentiality of participants was assured.

# 4 Results

The results of the web-based questionnaire and the interviews are complementary to each other. The web-survey helped to bring out the users of 3D printing, including positive and negative sides of the service. The interview with the hospital biomedical engineer gave overview of the technical side of the 3D printing as well as overall opinion about 3D printing necessity and future prospects. The interview with EHIF chief specialist opened up the legal side of 3D printing and what roll EHIF plays in 3D printing. Combining these three views give better overview of how 3D printing has been adopted in Estonian healthcare as well as factors of influence.

## 4.1 Results from semi-structured questionnaires with doctors cognizant of 3D printing

Within one week 13 out of 62 (21%) answers were received, as well as five replied to the email (did not submit answers to the questionnaire, thereby excluded from the study) that it was not part of their area of interest. Additionally, one reminder email was sent to the list of physicians. The final response rate turned out to be 29%, with 18 respondents (Figure 5).

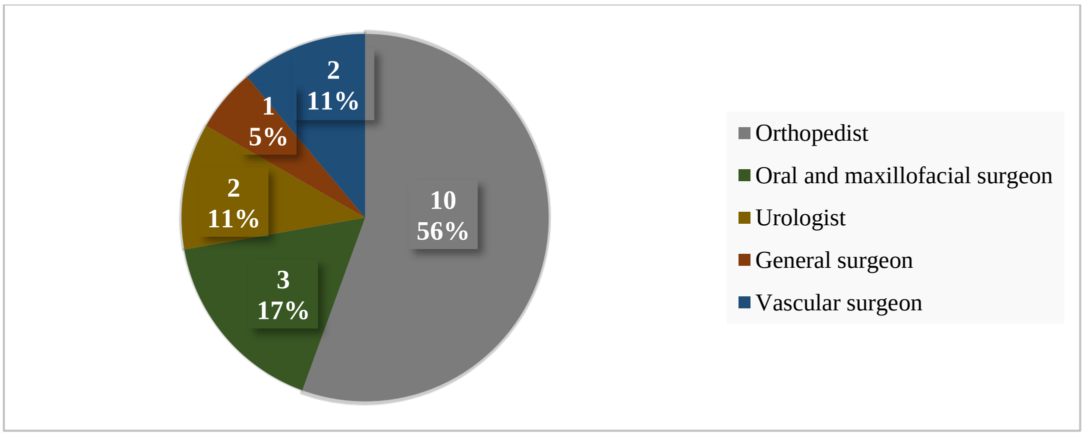


Figure 5. Response rate per specialty

Occupation and length of working experience (years).

- Orthopedist (43, 38, 32, 20, 2×10, 7, 2×6, 5 years)
- Oral and maxillofacial surgeon (35, 33, 9 years)
- Urologist (20, 39 years)
- General surgeon (27 years)
- Vascular surgeon (20, 10 years)

**Topic 1:** Essence of 3D printing

The most active 3D printed applications users in Estonia are orthopedists and oral and maxillofacial surgeons based on the results (Figure 6). Relatively small share, 6% of the respondents, are using monthly 3D printed applications and 39% few times a year. Answer "Not at all" accounts for a largest share (56%), which means that 3D printed applications have not find the way into these physicians' practices yet.

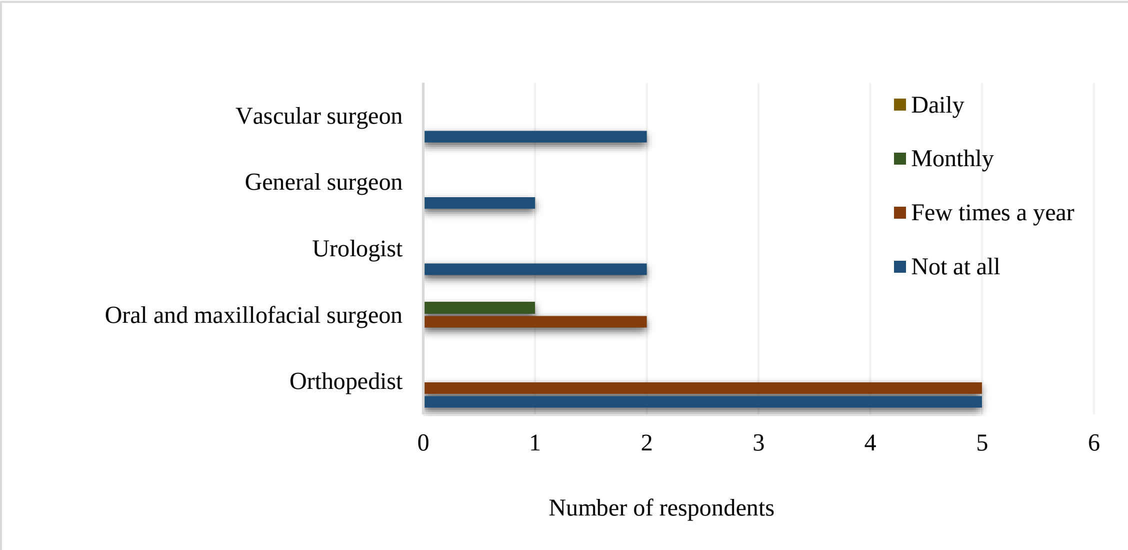


Figure 6. 3D printed applications use per specialty

The answers regarding the question "Which 3D printed applications have you used?" were scattered, caused by specialty differences and awareness of the possibilities of 3D printing technology. Thereby, some physicians said that they haven't used any 3D printed applications. Although, other physicians indicated that they have used applications for reconstruction of facial-skull defects/traumas, treatment planning of occlusion (bite) correction, ankle and foot replacement (3D printed implants) and various computer programs (ProPlan CMF, KLS Martin IPS, Blender) for virtual operations on brain and skull as well as printing the operation guide. In addition, physicians have used models of pelvis, vertebral column, skull, ankle, foot, forearm, wrist, elbow joint, jaws, face.

**Topic 2:** Adoption of 3D printing

All 18 physicians agreed with the background statement, which stated that surgeons have adopted three-dimensional printing in an increasing extent and in a large variety of applications. One of the reasons, why 3D printing is used in medicine is that it makes possible to print patient-specific models of interested organs. One surgeon stressed that in case of static structures (hard tissue) the technical capability exists right now, but with soft tissue the use is problematic, due to a change in time. It was also said by the respondent that this is definitely the area with rising interest. Adding that 99% of the work can be done with ready-made anatomical implants but 3D printing would be excellent with difficult cases such as tumors, bone loss, where other solutions cannot be applied. One respondent noted that in Estonia few people suffer aneurysm, thereafter makes it less relevant to vascular surgeons.

Respondents had several explanations why the interest had increased with 3D printing: 1) time-savings in operations, 2) more precise compared to alternatives, 3) possible to find optimal solutions over standard, 4) objective planning, documentation and implementing of treatment, 5) 3D images and models provide better and more accurate spatial view of the structures and problems, which ultimately allows to accurately plan the next steps for surgery, 6) simplifies the job, 7) good for major pelvic deformities and bone loss replacement as well as execution of aortic endovascular interventions – fenestrations, 8) existing research methods do not always provide full information about the place of the pathology and adjacent structures. Therefore, 3D printing is best choice.

Responding physicians listed different healthcare settings where three-dimensional printing can be used: 1) in all surgical disciplines (e.g. esophageal surgery, liver surgery, rectal surgery, intra-abdominal soft tissue tumor surgery) as a learning material and for educational purposes – gives better overview, thereby enables physicians to better plan the volume of surgery and perform organ-saving operations, 2) in all disciplines dealing with bone structures (in the near future, this will be a routine in many cases) including bone and joint defects modeling, 3) in the field of orthopedics, there are usually two options. Firstly, pre-operative 3D models for more accurate planning of operations (skeletal system tumors, malunion of bones and complex fractures). Secondly, in exceptional cases printing of implants. 4) beneficial in preoperative planning when performing aortic endovascular interventions.

**Topic 3:** Value of 3D printing

When the respondents were asked to evaluate the 3D printing value in their specialty then stood out that oral and maxillofacial surgeons think that it is rather important or even very important. In comparison, also some orthopedists see that it is very important or important while other specialties believe that it has less value or no value at all. Moreover, some did not know how to answer to this question or had no opinion. In addition, one vascular surgeon thinks that it is important, but colleague did not know how to respond. Same with urologists, one feels that 3D printing is very important and other said to be unimportant.

Multiple choice question was asked to highlight the overall value that physicians see in 3D printing (Figure 7). The respondents who did not find suitable answer elected “other” and provided their own answer. Most of the respondents feel that the technology increases quality and efficiency. Few respondents added their own opinion. One of them stated that it is more like an additional option or a back-up plan. Other stressed that it improves the safety, gives better vision and knowledge of the risks of kidney surgery. In addition, one respondent feels that it reduces surgery time and complication rate.

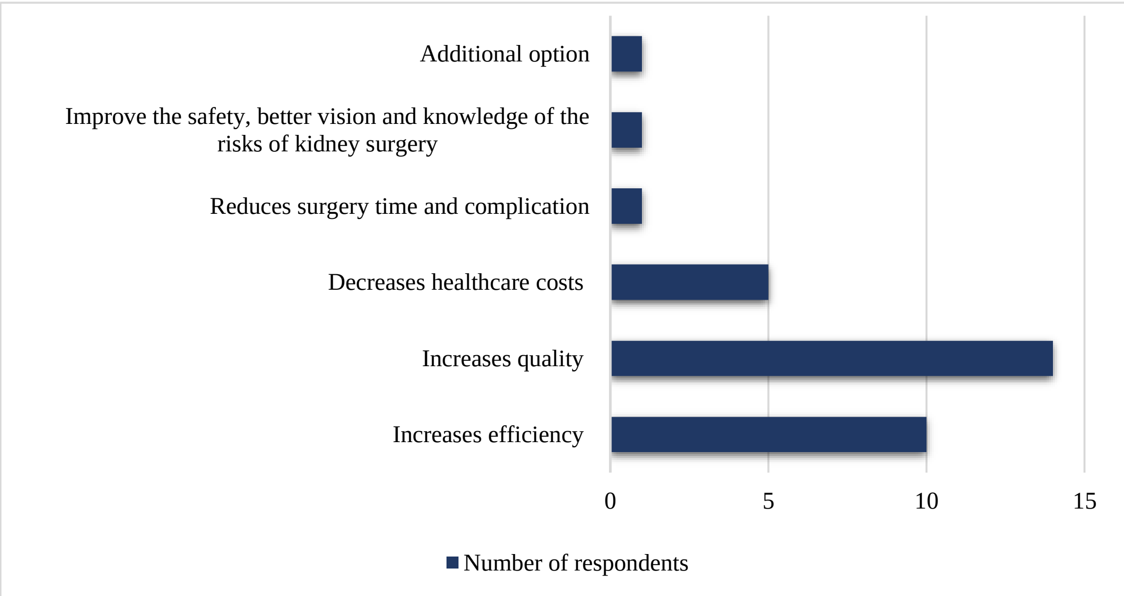


Figure 7. 3D printing value in healthcare

Most of the respondents feel that 3D printing is rather badly implemented or they don’t know/have no opinion about how 3D printing is implemented in Estonian healthcare (Figure 8), viewed from their professional perspective. Only one orthopedist believes that it is well implemented in orthopedics. 5 out of 18 had different opinions, such as not used in urology, current health financing system does not support the use of 3D printed models (too expensive), development is in the early stages, few enthusiasts are using the technology now but believed to be rising trend.

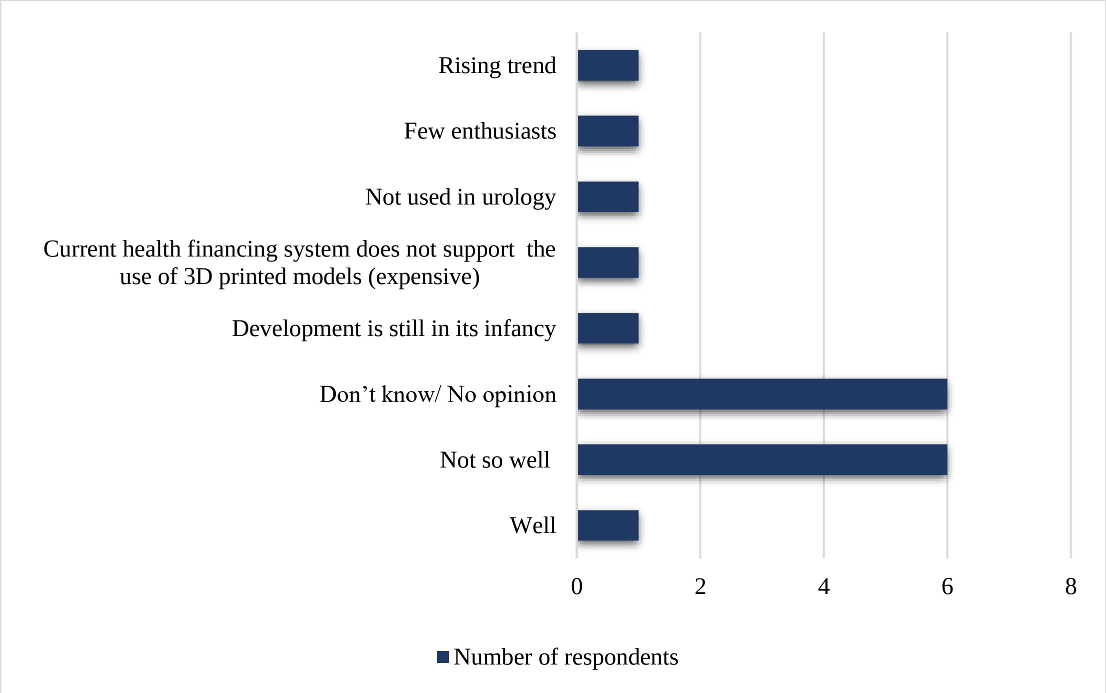

Figure 8. 3D printing implementation in Estonian healthcare

Possible ways how 3D printing may affect the medicinal sector in Estonia in 5-10 years are listed below:

1. Significantly, probably will be used more and actively.
2. Hopefully, will influence in positive direction.
3. Scope depends on the area.
4. Improves quality, shortens the duration of the treatment and is definitely written in the treatment guidelines after few years.
5. Allows for more accurate planning of the operation volume.
6. It could bring major changes in the treatment of endoprostheses complications.
7. If opportunities arise for metal printing for individual implants in Estonia, this will change the method of bone tissue treatment.
8. Given the relatively small market in Estonia and the high cost of specific solutions, the impact of overall healthcare is not significant. However, there are more chances to success in dealing with specific situations.
9. In complicated cases it would be considerable, but in routine care not. Unless the price goes down.
10. The majority of surgical treatment planning for skeletal deformities and complex fractures are probably done with 3D models.

**Topic 4:** Application fields and impact

Todd Pietila, Materialise's Business Development Manager for Hospital 3D Printing, has said that "Forward-looking hospitals are implementing on-demand 3D printing service lines and, in turn, are reaping benefits of an improved patient experience, better training of physicians and growth in innovation which can drive non-traditional revenue streams in addition to the inherent cost saving that can be realized [50]." Most of the respondents somewhat agreed with Pietila's saying. Statements are correct but unfortunately not all of the claims work in Estonian society. At first, it needs more investments in technology, education, science and training to pay off. One physician added that this isn't applicable to Estonian healthcare financing model and so-called principle of solidarity. One thought that the claim was very provocative, hard to evaluate cost-effectiveness, needs lot of research, not unambiguous, usefulness needs to be checked and proven. Two of the respondents were not that sure about overall cost savings. An additional two respondents strongly disagreed with the statement, because it sounded rather like an advertisement. Moreover, prices will increase with 3D technology and prosthetic systems are still expensive. What is more, global corporations do not lower prices because in-house 3D printing is used.

Majority (72%) of respondents thought that using 3D printed models during the clinical case discussion have positive influences such as make it easier, faster, give better and more specific visualization of the problem, good for planning surgical manipulations and educational purposes as well with complicated cases. In addition, choosing the right technique for the operation depends on the simulation results. Two respondents said that only small portion of cases where this technique should be considered, generally marginal percentage of regular work. One respondent felt that a top specialist does not need a 3D model to visualize anatomical or pathological structures. Moreover, CT or MRI reconstructions can be viewed instead.

Less than half of the respondents (8) reported that 3D printed models are useful for implant production, one of them added in case of indication. One physician said that these are individual solutions for specific cases. One of them did not know about 3D printed models' usefulness for implant production, as one claimed this to be low. One respondent stressed that price difference is important factor, stock versus custom made implants, and it definitely does not favor 3D printed implants. One comment left in the free text option expressed the need for FDA and CE approval prior to implantation, but was rather positive as 3D models improve accuracy and save time in operations. In addition, one respondent added that vascular prostheses as implants cannot be produced with 3D printing.

Most of the respondents thought that 3D printed model will simplify the clinical case discussion with the patient. Two respondents noted that it is relatively expensive solution, cheaper alternatives are available. Another indicated that it is not cost-effective solution right now. Also, one physician pointed out that it will not significantly change anything.

Three-dimensional models offer additional information to the related 3D virtual model believed by 61.1% of the respondents and seen in Figure 9. One respondent added that they are not 100% necessary and in simple cases 3D virtual model is enough. This figure shows that 16.7% shared the response "Don't know/No opinion" and "Gives same information as 3D virtual model". However, one respondent had totally different opinion and said that 3D printed models do not offer addition information compared to 3D virtual model.

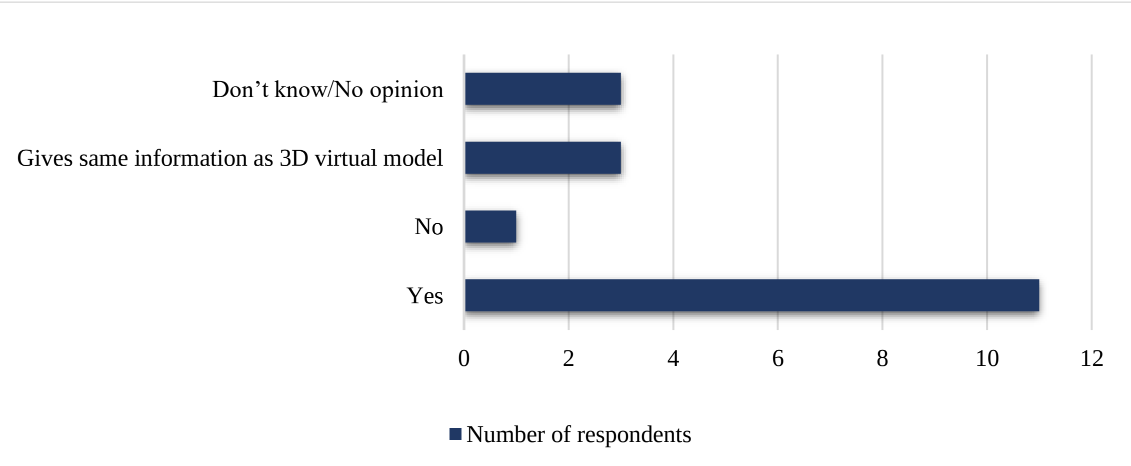


Figure 9. Answers to the question:" Do you think the 3D printed models can offer additional information to the related 3D virtual model?"

Respondents were asked to evaluate the accuracy of 3D printed models in reproducing the anatomical details of an organ. Nearly a half believes that it is very good or good. Six respondents did not know or had no opinion. None of the respondents claimed that 3D printed models reproduce poorly anatomical details.

All of the respondents answered "yes" to the question whether 3D printed model offer addition information in understanding the surgical complexity or not. Except one, who did not answer the question and skipped it.

A 5-point Likert scale was used to rate how much respondents agreed or disagreed with the following statements: 1. The 3D printing would improve my work, working skills, work methods, 2. The 3D printing would not enhance my effectiveness at workplace, 3. The 3D printing would be helpful getting informed consent, 4. The 3D printing would not improve work quality, 5. 3D printed models are highly useful in anatomy education, 6. 3D printed models solve the ethical problems brought by cadaver-based anatomy education, 7. 3D printed models have important role in surgical training, 8. Useful explaining anatomy to students/residents, 9. Not useful explain anatomy to patients, 10. Would use 3D models with students/residents, 11. Would not use 3D models with patients and 12. I manage to cope with difficult situations without using 3D printed models.

Firstly, majority of the respondents (over 50%) felt that 3D printing would improve their work (working skills, work methods), especially work quality. Thereby, effectiveness at workplace will be increased. In addition, 3D printed models are believed to be highly useful in anatomy education and explaining anatomy to students/residents and patients. Therefore, 3D models are great tools to use to illustrate communication.

Secondly, only a small minority thought that 3D printed models would solve the ethical problems brought by cadaver-based anatomy education. Mainly respondents disagreed (27.8%), strongly disagreed (27.8%) or did not have opinion (27.8%) about the statement.

Thirdly, in terms of whether physician manage to cope with difficult situations without using 3D printed models, responses were all across the board. Seven respondents (38.9%) believed that they do not need 3D models in complicated situations. Five respondents (27.8%) were neutral in the question, having no opinion. As with six respondents (33.3%) felt that 3D models would be helpful in complex circumstances.

**Topic 5:** Patient-specific 3D printed anatomical models for preoperative planning

88.2% of the respondents felt that 3D printed models are useful in preoperative planning (Figure 10), in which 35.3% believed these to be very useful. Apart from two respondents who answered “Don’t know/No opinion”. Also, one respondent skipped the question.

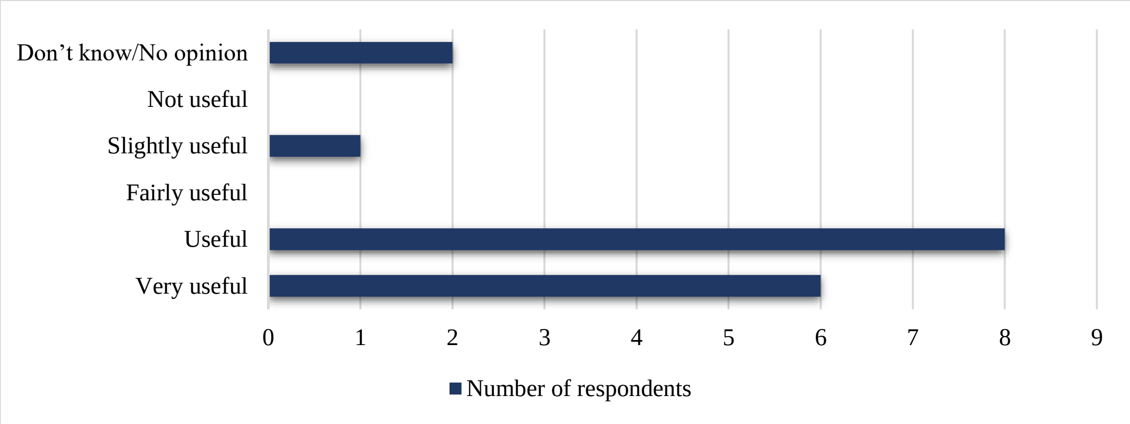


Figure 10. Usefulness of 3D printed models in preoperative planning

Most of the respondents answered to the question “How many of your current patients will go to another facility to have pre-surgical 3D printing?” that they do not know or cannot estimate the number. One oral and maxillofacial surgeon suggested that approximately 30% of the patients will go to another facility. However, some orthopedists thought that the number might be five to six or 10 to 15 per year. This question chose not to answer 4 out of 18 respondents. Three respondents said that patients won´t change the facility.

There was no explicit opinion whether the service will attract new patients or not. Most of respondents answered hard to say, few, does not bring new patients, Estonia is a small country. Two of the respondents had more positive predictions. One oral and maxillofacial surgeon believed that the number will increase about 30% and one orthopedists said approximately 20 new patients will come annually.

Currently, few Estonian surgeons have planned surgeries with the help of 3D printed applications with some exceptions. They are few oral and maxillofacial surgeons and orthopedist who use 3D printed applications in surgeries. For example, one oral and maxillofacial surgeon stressed that the opportunity for that arose beginning of 2020 and from the same specialty surgeon pointed out that they are doing in Neck and Head Center altogether approximately 20-25 surgeries per year and another colleague does circa 33 surgeries per year. Three orthopedists ought to do one to two operations in a year compared to another orthopedist who does five to seven operations per year.

Majority of the respondents stressed that it is difficult to predict the growth percentage for the number of procedures performed each year.

**Topic 6:** The use of 3D printing technology in creating custom implants

About three-quarters of respondents (77.8%) said that no patients have come with the wish having 3D implants. Answer “Rarely” pointed out four physicians (22.2%).

Most of the respondents had never ordered implants from biomedical engineers or associates, and small portion had mainly ordered pelvis, scull, anklebone or foot implants. The most beneficial implant for the surgeon depends on the specialty.

When the respondents were asked to evaluate how much time usually takes to get the custom implant (from the need till getting the product) several answers were provided such as couple of days, depends on the case five hours to seven days, one to three weeks. One respondent knew to say that companies have promised three weeks to one month. Some respondents have skipped the question as some did not know how long it could take.

The question: “How good is the prosthesis/implant quality made with 3D printer?” had only two sorts of answers, which were “Do not know/No opinion” (66.7%) and “Better than hand-made implants” (22.2%) seen in Figure 11. In addition, two people skipped the question. From this we can conclude that those, who have been dealing with 3D implants, strongly express that 3D implants are better than hand-made implants. They supported the statement by saying that 3D implants are better because of accuracy, fit perfectly and take into account individuality. Also, better integrated with program analysis.

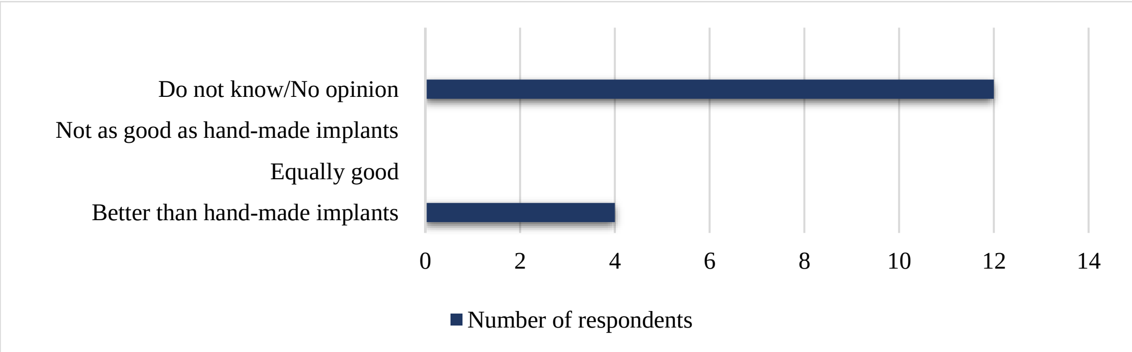


Figure 11. Protheses/implant quality made with 3D printer

Figure 12 shows how important would be such a service, which provides 3D printed implants to the people, outlined on the basis of specialties. Orthopedists and oral and maxillofacial surgeons felt that 3D printed implants attach importance. In comparison, vascular surgeons and urologists did not see the importance. General surgeon decided not to answer to this question.

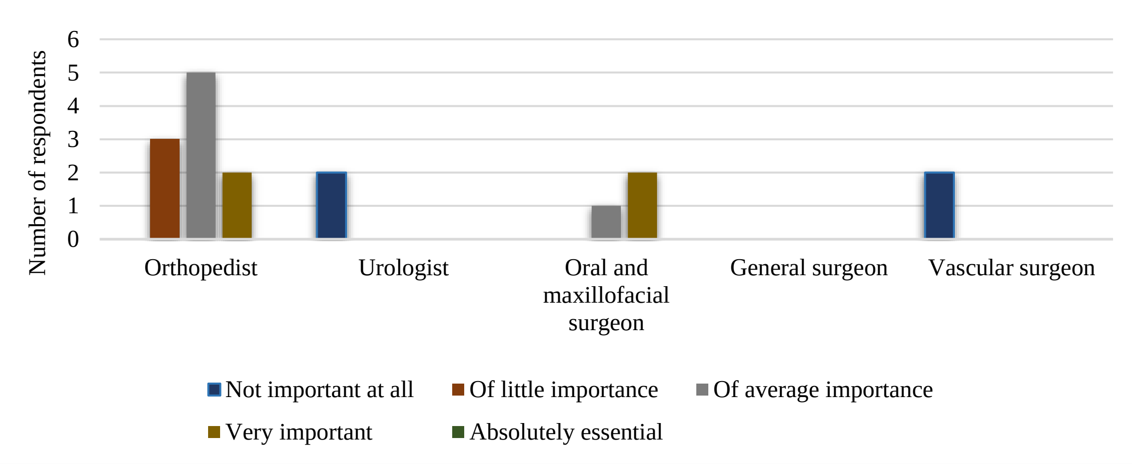


Figure 12. Answers to the question: "How important would be such a service in your field of work, which provides 3D printed implants to the people?"

**Topic 7:** Regulatory challenges

None of the respondents know for sure how 3D printing is regulated by law in Estonia and what problems might rise with implanting 3D printing in healthcare. Few examples suggested by respondents were financial problems or data protection issues, slow printing process, problems with introducing foreign-bodies into the body and overall safety concerns.

Importance of legal regulation of medical 3D printing was shown in Figure 13. Half of the respondents (9) believed that it is very important aspect to consider and in addition, 22.2% felt that it is rather important issue. Three respondents tended towards the slight importance. One respondent did not know or had no opinion. In addition, one respondent chose not to answer to the question.

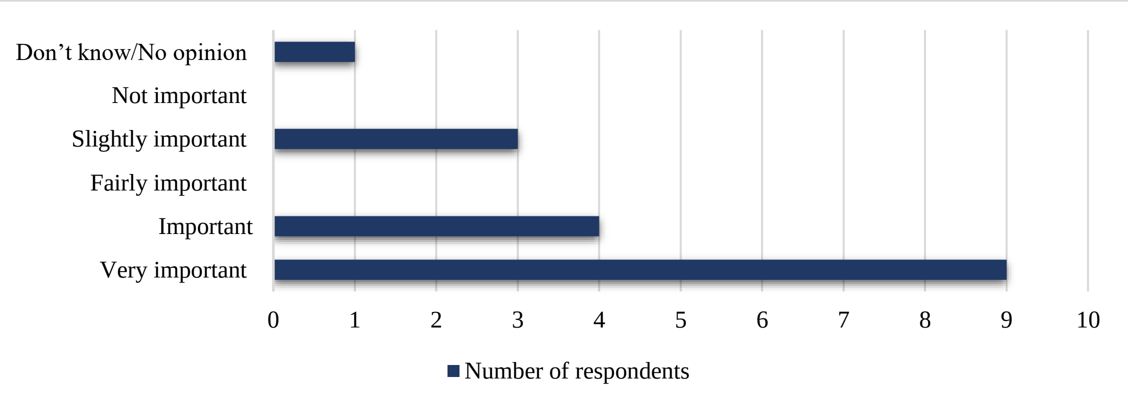


Figure 13. Importance of legal regulation of medical 3D printing

## 4.2 Results from semi-structured interviews with hospital biomedical engineers

Initial plan was to make two interviews with biomedical engineers one from the East Tallinn Central Hospital and other North Estonia Medical Centre to see how well 3D is implemented in real hospital settings. Taking, as an example, two biggest hospitals in Estonia. Unfortunately, it did not accomplish entirely, because only one contact was managed to create.

Currently, a fraction of the quality engineer`s work in the East Tallinn Central Hospital belongs the design of 3D models from CT images. Clearly, 3D printing is still its infancy and can be explained, by the fact that this opportunity has been available for two years only. The first year has brought about four to five cases and in 2020 the number has been twice as many. The biomedical engineer thought that the use of 3D printed models is on the rise.

Mainly, the complexity of the case dictates how much time is needed for the design. To be more specific, simpler cases such as 3D models of the lumbar spine can take about half an hour, when discs are well distinguishable. On the other hand, complicated cases of spine can take even 16 hours, when CT pictures are in bad quality, occurs many artefacts (cavities or peaks in the original geometry of the structure), which needs to be removed.

East Tallinn Central Hospital uses open-source software 3D Slicer to design 3D models. The 3D Slicer shows CT images on three different axes, referred to as longitudinal, lateral and vertical. Forth image is a 3D model, which is being created. The design process starts with selecting appropriate images from the image bank. Soft tissues are well expressed with MRI and hard tissues with CT. Most of 3D models are from spine and foot. Then segmentation is used to create a structure which will be read and printed by a 3D printer. Prior to printing mesh manipulation is done to make an object as real as possible, depending on the quality of CT images. Spine surgeons have been the most active users of 3D printed models, followed by orthopedists, who use 3D printing before surgery to better understand what anatomical structures or traumatic changes are expected during surgery. For instance, in case of fragmented fracture, the orthopedist is able to examine the pieces before the operation and plan the strategy how to assemble them.

The quality engineer believed that 3D printing is very essential in complicated cases and brought as an example of a child with severe scoliosis. The surgeon wanted a 3D model of a child's spine and when printed out the size of the model was only 15 cm, which surprised the surgeon who had not anticipated that. The quality engineer added that using possibilities of 3D printing will increase efficiency and quality, decrease healthcare costs and surgery time, which can lead to a reduction in blood loss. Also pointed out "bioprinting" that could in the future influence Estonian healthcare.

The engineer believed that 3D printed models offer additional information to the related 3D virtual model and are good to reproduce the anatomical details of an organ. Added that, certainly, 3D models are suitable for better understanding of surgically complex situations. Agreed with the statement that "3D printed models are highly useful in anatomy education", because they provide better understanding of the subject and disagreed with "3D printed models solve the ethical problems brought by cadaver-based anatomy education". The engineer indicated that it is not a real tissue, hence no authentic palpation. In addition, claimed that implant production needs more precision compared to anatomical models.

Moreover, 3D printing should be valued more in Estonia. As an example, in East Tallinn Central Hospital minority of physicians/surgeons know that they have in hospital such a department which is designing 3D models. Therefore, not well implemented and better information sharing is necessary.

The expectation how the medicinal sector in Estonia will be affected by 3D printing in five to ten years, by the way, is that each major hospital has in-house printer or nationwide printing center is built, providing services to all hospitals. Additionally, it should be research and development center, which facilitates co-operations with researchers and investors. Unfortunately, 3D printing is not financed by EHIF. Thus, quite expensive service and cost-savings may not be immediately apparent. Currently, low growth rate is predicted in the number of procedures performed with the help of 3D printing per year.

Final section was about regulatory challenges. The quality engineer was not aware of how 3D printing is regulated by law in Estonia. Specified that there should be a list of materials that are approved by law to use on people and added that legal regulations of medical 3D printing are important. Possible problems that may arise with the implementation of 3D printing in healthcare are too high expectations and speaking of technical side 3D model's quality is directly affected by CT images quality. Therefore, it is vital to have good quality medical images to start the designing process.

## 4.3 Results from interview with EHIF specialist

The EHIF reimburses the medical institutions for many different medical services, procedures, medicines, etc. as a part of the health insurance package. The list of health services includes the services, the prices and the condition of payments. The list is updated once a year according to the need and the Health Insurance Act [54].

The basic principles of the benefit package are set out in the Health Insurance Act and §31 states how amendments can be made to the list [54]. The actual benefit package consists of "the List of Health Services (governmental decision), the List of Reimbursed Pharmaceuticals (ministerial decision) and the List of Reimbursed Medicinal Products (ministerial decision)" [46].

Most often, defining the benefit package fall under the responsibility of the EHIF. This is done with collaboration with other interested parties like the Estonian Hospital Association and the Medical Professional Associations. In addition, from 2018, the Ministry of Social Affairs can make proposals on the benefit package, thereby asks EHIF to present an application [46].

The process starts (Figure 14) when the EHIF initiates an application to make changes in the benefit package (inclusion of a new service or change in the price of existing service), after which the final decision is made by government, who endorses the list of services and gives each item a reimbursement price. The Health Insurance Act sets out four criteria for changing the benefits package, which experts take into account when evaluating the new service. Listed below [46], [54]:

1. **The effect on the patient's health or the medical evidence base,** meaning that, new service must have a greater positive effect on the patient's health compared to the existing service proven by research. The assessment is done by an expert recommended by the Faculty of Medicine of the University of Tartu or the State Agency of Medicines.

2. **The cost-effectiveness** is mostly assessed by EHIF health economists. The aim is to evaluate the health benefits of using the new service and the cost of achieving it compared to the existing alternative. Therefore, it is possible to assess the balance between the additional benefit and the necessary additional cost.
3. **Appropriateness and compliance with national health policy.** The impact on the health insurance budget is mostly assessed by EHIF health economists.
4. **The impact on society and healthcare policy** is evaluated by the Ministry of Social Affairs. The necessity of the service to the society is examined (e.g., the compliance with the development plans, the availability of the infrastructure necessary for provision of the service and personnel training opportunities are assessed) and health policy priorities are identified.

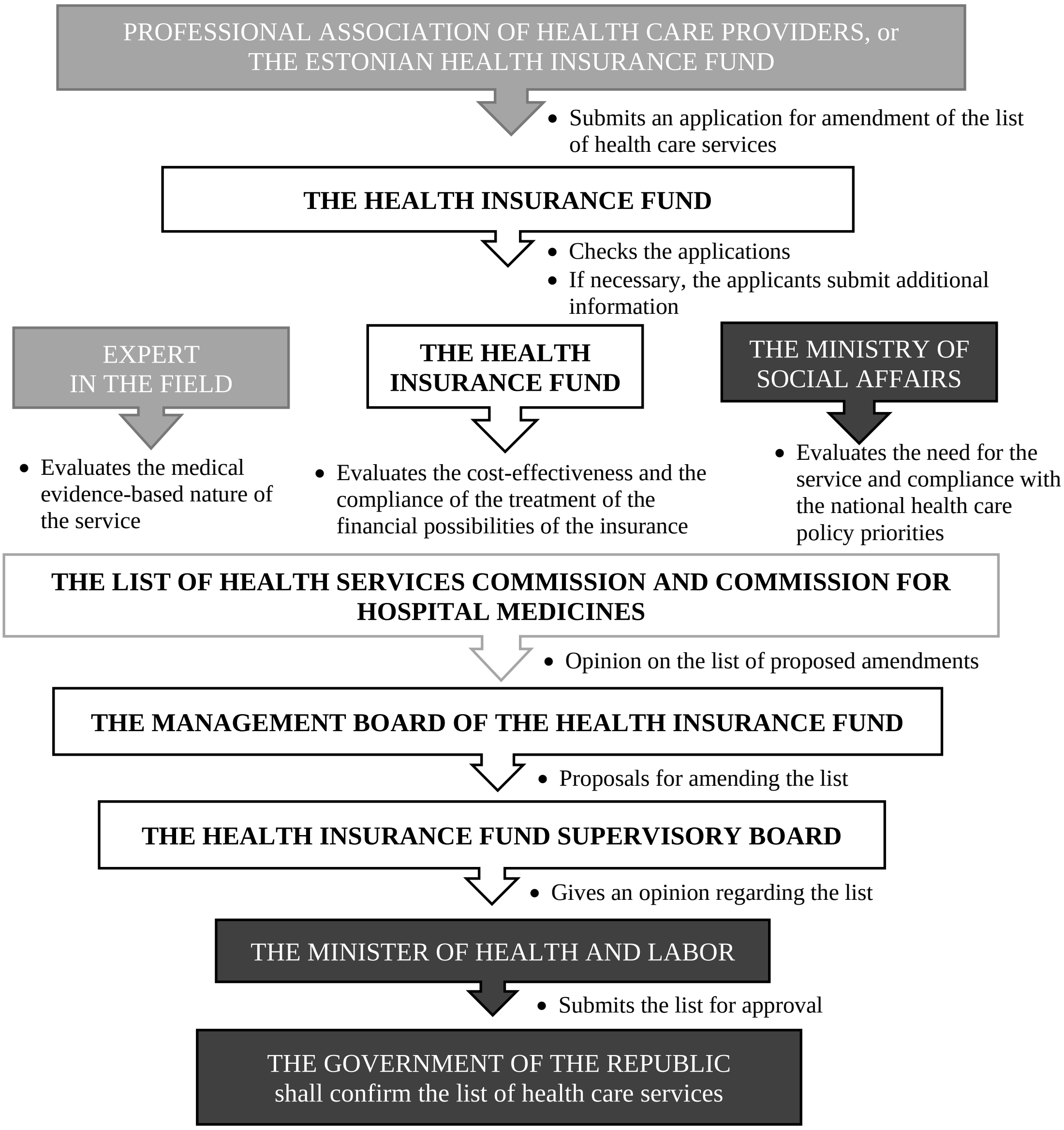


Figure 14. The process of amending the list [54].

The new technologies go through Health Technology Assessment prior to adding to the benefit package, which facilitates the decision-making based on recommendations and conclusions came from the assessment. Correspondingly, the information is used to adjust medical practices and clinical guidelines having new knowledge on efficacy, safety and sustainability [46].

On the 3rd of September 2018, Estonian Association of Maxillofacial Surgery submitted an application to add to the EHIF benefit package a new service, which would use CT for 3D virtual surgical planning and prototyping of a skull. This approach would especially be used in more complex cranioplasties, cranial or facial reconstructions and orthognathic surgeries. As of 16th of January 2019, the commission of the list of the health services decided that the application still lacks evidence-based research. Moreover, emphasized that 3D printing use for preoperative planning would not be an independent service more likely a tool for planning the operation. Therefore, this method should be financed through the prices of the respective services and not as a stand-alone service. In addition, it was pointed out that 3D printing can be used for production of implants, which was not currently requested, but the need for that may arise in the presence of a printer. Printing of implants must be seen as a stand-alone service and its effectiveness, safety and cost-effectiveness measured. This is a multidisciplinary issue, as the field is evolving rapidly and 3D printing is being used across a variety of specialties [55].

This technology is not yet financed by Estonian Health Insurance Fund, because it is a long process to get 3D printing accepted as a service (usually takes a year, but in complicated cases could take more). To get acceptance, it has to be considered on what purpose it would be used, whether a helping tool or as a separate service. Health technology assessment report is needed to measure the efficiency, safety and cost-effectiveness of 3D printing across disciplines. Thereafter, specific areas are selected in which cost-effectiveness will be assessed, by the help of Tallinn University of Technology.

The Health Insurance Fund pays benefits for dental care and dentures. EHIF covers healthcare services offered only by contract partners. The benefit applies to essential dental care services. Dental care belongs to primary care unit not specialized medical care unit classified by EHIF. Therefore, it is important to understand that changes proposals for reimbursements have to go through the right department.

# 5 Discussion

The modern surgical practice is influenced by 3D printing worldwide. In this thesis, Estonian physicians' perceptions about 3D printing were gathered using a web-based questionnaire. In addition, practical side as how 3D designing process works and what were the most popular applications ordered from physicians was obtained using semi-structured interview. To illustrate better of legal situation with 3D printing, interview with the specialist of EHIF was conducted. To conclude all the knowledge, the feasibility and potential barriers of 3D printing in Estonian healthcare can be brought out and evaluated.

The growing appeal of this research area, mainly caused by the need for improved visualization and surgical outcomes, can be observed from the increased number of scientific papers published in the journals since 2010 [17]. This has inspired physicians to use 3D printed anatomical models, patient-specific guides, and 3D printed prosthetics [41]. Increasing number of 3D printed surgical applications have made it interesting to analyze the current implementation of this new technology. Unfortunately, it has not found so many enthusiasts among physicians in Estonia. Therefore, minority of Estonian physicians are using the possibilities provided by 3D printing. From the results can be concluded that 3D printing is still in the early stage of development in Estonia, which is supported by fact that Estonian physicians are not that familiar with 3D printing (56% of physicians said that they haven´t use any 3D printed applications) as only orthopedists and oral and maxillofacial surgeons have used 3D printed applications. Pointing out that disparity between same specialty members existed. Also, the relatively small number of users can be explained by the fact that the clinical impact of this technology is still unrecognized [56]. In this regard, this point of view was also supported by the respondents of the questionnaire.

It has been pointed out by researchers that orthopedic surgery and oral and maxillofacial surgery were basically the first ones to use 3D printing technology. Initially 3D printers could only print hard materials and were, therefore, suitable to fields that cope with hard tissue [2], [24], [42]. Oral and maxillofacial surgeon stressed that in case of hard tissue the technical capability exists right now, but with soft tissue the use is still problematic. The simplest and easiest biological tissue produced by 3D printing are bones [20]. For that reason, East Tallinn Central Hospital is mainly producing models of bones from spine and foot. In addition, some physicians have used models of pelvis, skull, forearm, wrist, elbow joint, jaws and face. Bones are rigid material and therefore, contrast on medical images produced with CT is better compared to soft tissues. Mostly 3D printed models were made of plastic due to the aspect that it is cheaper compared to substitutes and meets the target set.

All respondents agreed that 3D printing has been adopted in an increasing extent and in a large variety of applications. The opinions about the increase of interest in 3D printing varied among physicians. Thus, 3D printing was believed to be more accurate compared to alternatives, reduce OR time, provide objective planning, documentation and implementing of treatment, thereby making physician job easier. While existing research methods do not always provide full information about the place of the pathology nor adjacent structures. For these reasons, respondents thought that it would be good idea to consider the possibilities of 3D printing. It should be stressed that some physicians reported that 3D printing can be applied in all surgical disciplines, namely esophageal surgery, liver surgery. Moreover, in all disciplines dealing with bone structures. However, 3D printed applications are seen mostly as teaching and learning material, useful tools to aid preoperative planning and implant production.

Not all physicians see value in 3D printing, especially specialties were 3D printing is not common. For instance, vascular surgery and urology. On the contrary, oral and maxillofacial surgeons and orthopedics see a lot of potential in 3D printing. As they are the most active users of 3D printed applications in Estonian hospitals. A study [56] conducted in Finland reported that heavy users of AM were maxillofacial surgery, plastic surgery, pediatric surgery, orthopedics and neurosurgeons, while non-users were general/gastrointestinal surgery, urology, vascular surgery and gynecology. For the most part, the study coincides with the findings of this particular study. Apart from the fact that the study carried out by the thesis author did not have so wide range of specialties represented and included.

The majority of 3D printed anatomical models are for preoperative planning and guides for aiding surgery [2], [51]. One of the most valuable resource in medicine is time, due to the fact that it is limited. The main benefits of using 3D printed models in orthopedics and oral and maxillofacial surgery were found to be decreased OR time and increased surgical accuracy [57]. Supported by the results of the web-based study, which revealed that physicians believe 3D printing will increase efficiency (55.6%) and moreover quality (77.8%).

At the moment, the range of possibilities of 3D printing is limited to the price of the service and lack of scientific proof of safety and cost-effectiveness. The industry will benefit from the innovations when the userbase of additive manufacturing is expanding. Moreover, Aquino et al. [4] believed that there are economic, social, ethical, organizational and cultural factors that impede the creation of smarter and more sustainable healthcare. With this in mind, several challenges still require addressing to fully implement 3D printing into Estonian healthcare. In particular, clinical guidelines are needed to outline the appropriateness of 3D printing for specific clinical scenarios adjusted for Estonia. Therefore, the importance of 3D printing in each specialty should be investigated and brought out. Ultimately, applied for routine work. For instance, vascular surgeon stated that with 3D printing it is impossible to make vascular prothesis as implants.

Another important factor, current health financing system does not support the use of 3D printed models – no reimbursement is available. Therefore, these applications are too expensive to use in everyday practice. In addition, some physicians believed that costs will increase with 3D technology, especially prosthetics. Accordingly, changes should be made to the reimbursement system, to ensure widespread use, especially in specialties were 3D printing is not being used yet (e.g. urology). It is believed that the comparatively small number of users will increase and more physicians start to use 3D printing in case EHIF decides to include 3D printing as a service into the benefit package. For that it is needed to have a confirmation from the government, who makes the final decision by approving the list of services and by setting each item a compensation price. This is necessary to bring the prices down and thereby making it available for a larger number of people, who can wider the area of possible applications. Although, Jones et al. is [16] convinced that production costs will decrease as the technology matures.

By extension, some experts argue that teamwork is necessary between industry, academics and government (EHIF having leading position) to ensure safety for those people whose life will be improved by 3D printing. Likewise, some authors have expressed concerns with lack of randomized controlled trials to evaluate quality and quantity of existing evidence on 3D printing in health and other relevant medical outcomes. Hence, being barrier to the adoption of 3D printing [42]. Full implementation of 3D printing can only be achieved when all sectors seen in Figure 15 approach the center and concentric circles are stages of implementation, which needs to be established. The first step is to understand the value of 3D printing [58].

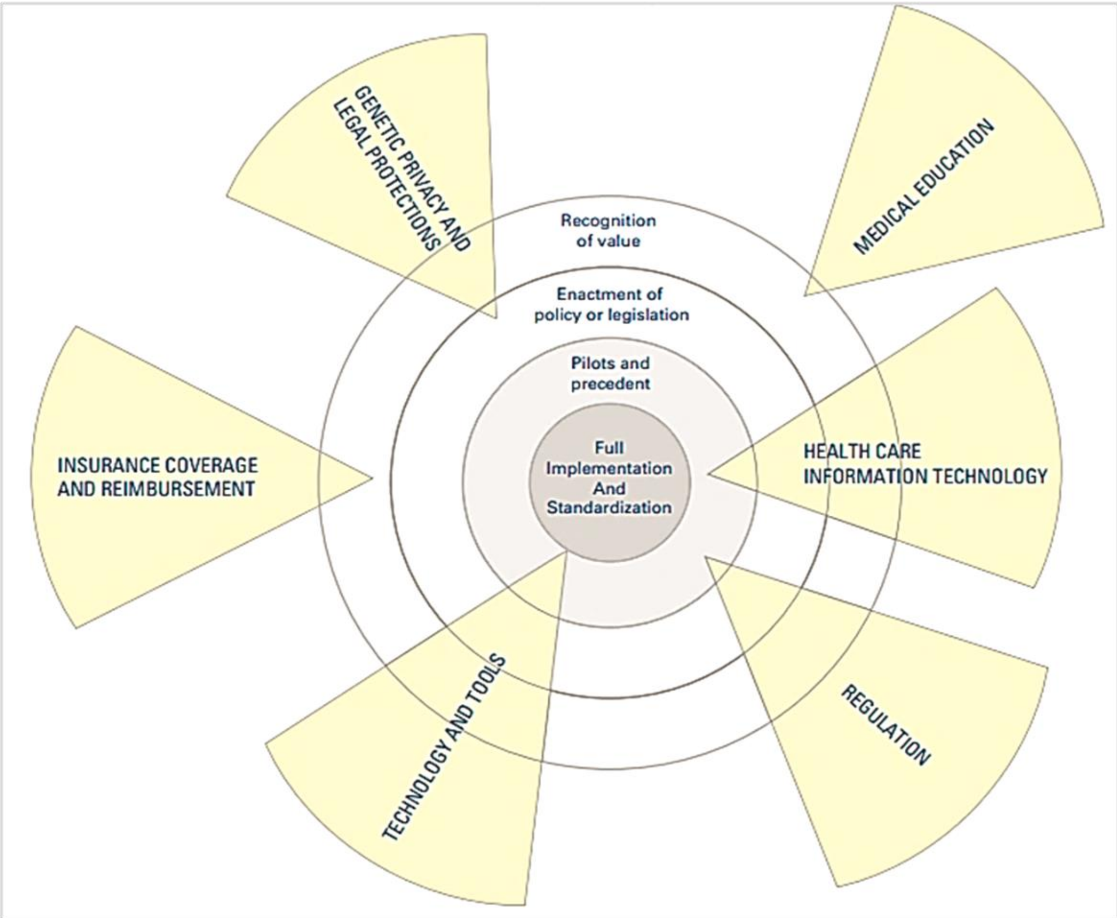


Figure 15. Full implementation pathway to personalized medicine [58].

Physicians usually investigate pathologies using 2D X-rays or 2D images obtained with MRI or CT. To do this, the surgeon needs to have obtained distinguished visual skills. Moreover, recent improvements with 3D renderings of CT, MRI, conventional radiography and ultrasound imaging provide improved visualization of complex pathologies, but still lack tactile features [41]. Two respondents pointed out that experienced physicians, who have practiced in their field for a long time, usually have the ability, termed as cognitive fusion, to imagine the 3D models simply by looking at the X-ray images. For that reason, it may be more beneficial for younger generation e.g. residents who do not have yet the right skills nor knowledge prior to comprehend 3D complexity. Several authors [1], [24], [41] have shared the same idea to use 3D printing for medical purposes, especially in complicated situations and with less skilled surgeons.

According to Anwar et al. [7] and Biglino et al. [31] anatomical models are good for improving anatomical understanding and for counselling purposes. Overwhelming majority of the respondents (77.8%) agreed with the statement that 3D models will simplify the clinical case discussion with a patient. 3D printed models can positively impact numerous metrics such as improve physicians work (proficiency, practices) and work quality by increasing effectiveness. In addition, vast majority believed that 3D printed models are highly useful in anatomy education and for explaining anatomy to students/residents, 88.9% and 88.3% respectively.

The power of 3D printing in producing anatomical models for preoperative planning has been recognized by many researchers [1], [11]–[13], [24], [27], [29]–[30]. For example, 88.2% of the web-based questionnaire respondents felt that 3D printed models are useful in pre-surgical phase, mostly because they offer additional information in understanding surgical complexity and were believed to reproduce accurately the anatomical details of an organ, supported by nearly half of respondents. A little over 61% reported that 3D models offer additional information to the related 3D virtual model. Using 3D printed models before and during surgeries enable physicians to better plan, practice and determine the optimal surgical approach [29]. As pointed out by a urologist the price of 3D printing is too high to use it in everyday practice. Therefore, it has to become less expensive. Due to high cost of 3D printed models it is still far from standard clinical practice. Right now, there are substitutes doing basically the same job as 3D printed models. Well advanced augmented reality glasses are one example.

Some studies [1] and [8] have brought out that 3D models would be better to use instead of cadavers because of availability, less health and safety issues and ethical problems. The results from the questionnaire (83.3% including 27.8%, who were neutral) were surprisingly rather not supportive about the statement that 3D printed models would solve ethical problems brought by cadaver-based anatomy education. Biomedical engineer explained it by saying 3D models are not made of real tissue, hence no authentic palpation, which would make it more genuine. Contrarily, Jones et al. [16] believed that human cadavers and cadaveric prosections will be replaced by 3D models when models achieve sufficient complexity and costs are reduced.

Meanwhile, some critics do not believe in 3D printing and have called it overhyped, gimmick and passing fad [29]–[30]. One of the barriers mentioned by the quality engineer was unrealistic expectations towards 3D printing, that may affect technology adoption, because results are expected too soon. One physician addressed concern about 3D printing, because she cannot see any benefit using 3D printing in her field of work, which is neck and sinus surgery. In addition, vascular surgeons and urologists cannot see the importance in a service that provides 3D printed implants to the people. Moreover, most therapeutic devices (implants, prosthetic limbs and orthotics) are not advanced enough, because lack of research is done in a clinical setting measuring efficacy and effectiveness [57]. In addition, the quality engineer added that designing of implantable devices is more complex and time-consuming compared to making anatomic models. The study conducted by Martelli et al. [51] supported the statement. On the contrary, orthopedists and oral and maxillofacial surgeons see the value in 3D printed implants. Therefore, should be addressed how to maximize the benefits offered by 3D printed application, because additive manufacturing provides endless possibilities.

Whereby applications must be well-developed and used for the benefit of humanity, taking as an example “bioprinting” and other applications that are used to improve public health. There is a growing interest towards bioprinting that is still in baby steps. This application of 3D printing is considered promising by physicians and biomedical engineer.

Aquino et al. [4] claimed that the constant developments in technologies, namely biotechnology and 3D printing, are expected to improve medical or health outcomes, on the other hand, they might pose different and new challenges in the field of health. In this regard, Mason et al. [42] stated that 3D printing and bioprinting do not fit into the existing regulatory framework, thereby presenting challenges. Results from the study indicated that legal regulations of medical 3D printing are important, supported by the data, which showed 88.9% of respondents felt that way. It should be noted that none of the respondents neither biomedical engineer knew how 3D printing is regulated by law in Estonia. Subsequently, physicians mentioned issues that may arise with 3D printing are financial, problems with data protection, printing process is taking too much time, general safety that should be dealt with. In the future, when 3D printing is well-implemented and adopted, it may start to produce problems, due to lack of regulations. Therefore, this matter should be addressed beforehand. Moreover, regulatory decision-making should be established on sound science and technology [29].

Applications produced using 3D printing for medical purposes should be categorized by their intended use, respect to risk they pose. The Estonian Health Board or Terviseamet in Estonian has the responsibility of regulating medical devices. These regulations are set of rules that manufactures have to follow and tend to vary significantly depending on the country [59]. Usually regulations are quite complex as how to bring a new device into market, thereby not to endanger patients and be effective.

In the European Union medical devices are categorized into four classes: Class I, Class IIa, Class IIb, and Class III. Devices belonging to Class I possesses the lowest risk and Class III the highest risk. Estonia belongs to the European Union, thus uses the same risk-based medical device classification model [59]. So, basically, classification provided by FDA can be applied in case of Estonia as well.

Medical models grouped [60]:

- **Group I Anatomical Models** – used as a tool for education, surgical planning, patient consent, and reference during surgery. Pathology may be highlighted but imaging data is not altered. These models are not considered medical devices, rather a hard copy output, similar to printing medical images on film.
- **Group II Modified Anatomical Models** – used to mirror or modify anatomy and designing grafts. These models are considered medical devices.
- **Group III Virtual Surgical Planning with Templates/models/guides** – used to augment the surgical procedure with specific steps planned in advance, that are carried out in surgery using 3D printed guides or templates. These models are considered medical devices.

Christensen and Rybicki [60] stated that hospital-based 3D printing and out-sourced models should have the same standards, in which safety and efficacy is considered. Most importantly, “patient-first” interest being the top priority. Author of the thesis agrees with the novel aspects mentioned above. And added that doing so creates transparency. According to Pettersson et al. [56], when outside providers are used, it may prevent further integrating 3D printing into routine use. Moreover, turnaround time is reduced when the design and production is done in-house. For example, Oulu University in Finland, has its own 3D printer but cannot provide the service for other hospitals due to different standards applied to production of medical models in-house and for outside customers. Therefore, it essential to have same regulations for in-house and outside customers, to ease the integration process of AM to clinical work.

## 5.1 Limitations

Although, the web-based questionnaire provides fast and easy data gathering, unfortunately, the comparatively small number of respondents makes the findings of the study rather suggestive than conclusive. In this regard, the response rate of the study among predefined specialties of Estonian physicians was 29%. In addition, only those predefined specialists, whose contact information was available on the hospital's website or could be obtained from the supervisor of the thesis, were included in the list of contacts. Thus, there is no general knowledge of how many specialists are working in East Tallinn Central Hospital and North Estonia Medical Centre. It is also necessary to take into account the fact that some doctors may work in both hospitals, which creates duplicated data.

Namely, a larger survey sample size may be needed to draw conclusions which most accurately represent the use and value of 3D printing. The structured questions and thoroughness of the survey were also intentional to make the most appropriate decisions regarding the information available. Only one interview was decided to carry out with the employee of EHIF, because additional ones would not have provided new knowledge associated with 3D printing. A semi-structured interview was decided to use with biomedical engineers, since comparatively small number of respondents existed.

Pettersson et al. [56] pointed out that the numerical data provided by the respondents were rather opinions and recalls and not based on trustworthy registers or statistics. Therefore, over- or underestimation is possible. The same limitation is of concern to this study as well.

## 5.2 Recommendations for future research

Tack et al. [41] said that the majority of investigated studies, brought out that medical outcomes were improved using 3D printing. Apart from the enthusiasm, only 14% of the studies supported this claim with numbers or statistics. Hence, this achievement is rather subjective than objective. More detailed approaches utilizing case studies and observation methods may be appropriate to gain a more in-depth picture of the ways in which 3D printing benefits patients and physicians. After reviewing the results of this survey, it is clear that more research will be necessary to continue monitoring the evolving trend of 3D printing. While it is far from widespread, there is evidence in both the survey results from web-based questionnaire and interviews with biomedical engineer and EHIF specialist that cost-benefit ratio should be identified to make decisions about sustainable applications in Estonian healthcare.

For the future research, author of the thesis, would recommend to find out what kind of applications are sustainable in Estonian healthcare. Right now, this question could not be answered because of lack of evidence, scientific research supporting the data. More specific research in the field is needed and it has to be in-depth. The thesis author used application-based distribution, but better would have been specialty-based distribution, which gives much better overview of how exactly 3D benefits specialties. To elaborate the idea, different professional association leaders should be contacted to find out, where and how would they use 3D printing. Specialty specific data from scientific papers should be gathered and shared. Ultimately, the results should be compared. Alternative would be to use the same approach like researchers did in Finland [56], scan the field to find the users of 3D printing.

Medical industry would benefit more out of accurate research on effectiveness and safety of 3D printing. Therefore, data should be gathered systematically using large studies, which allows to make greater consideration of the value of this technology. The Belgian Health Care Knowledge Centre suggested that framework called IDEAL (idea, development, exploration, assessment and long-term study) should be adopted to address the issues that may arise in data collection and implementation phase of 3D printing. Also, the framework would be helpful to clarify the principles of reimbursement of 3D printing in healthcare [42], [61].

# 6 Summary

Three-dimensional printing is far from common in Estonia. Only orthopedists and oral and maxillofacial surgeons have used 3D printed applications. Therefore, more research is needed to monitor the ever-changing industry of 3D printing. It is believed that the relatively small number of users will expand, when EHIF includes 3D printing into the benefit package. The reimbursement will fuel the enthusiasm and thereby widespread the acceptances and adoption of the service.

Even though the small number of respondents prevents drawing general conclusions about the value of 3D printing, it can be concluded that 3D models are well-received by physicians. Especially, in preoperative phase, since 3D models offer additional information compared to 3D virtual models and provide better understanding of surgical complexity. Moreover, they are well-suited for reproducing organ anatomical details.

Estonian physicians see benefits of 3D printing as well as challenges. An excellent tool for preoperative planning, especially in complex cases, as 3D printing increases efficiency and quality, believed by most of physicians. The production of implants is important, but not well used application in Estonia. Majority of physicians (90%) highlighted the need for legal regulation of 3D printing as none of respondents knew how 3D printing is regulated by law in Estonia.

Moreover, reimbursement of 3D printing will possibly contribute to the use of additive manufacturing across disciplines. However, 3D printing is not without its limitations and critics. 3D printing in medicine can be illustrated with the saying “A sword that cuts both ways”, meaning that it is an extraordinary piece of tool for complicated cases (which need different approach), on the other hand, it has several technical and regulatory challenges that should be considered prior to use.

Legal regulation is necessary in 3D printing to ensure safety. To achieve these ends, collaborations must be established between academics, industry, and government institutions towards additive manufacturing technology. Importantly, academics need to conduct more research to evaluate the outcomes of 3D printing. Furthermore, 3D printing should be used in medicine, in such, clinical scenarios that are scientifically approved.

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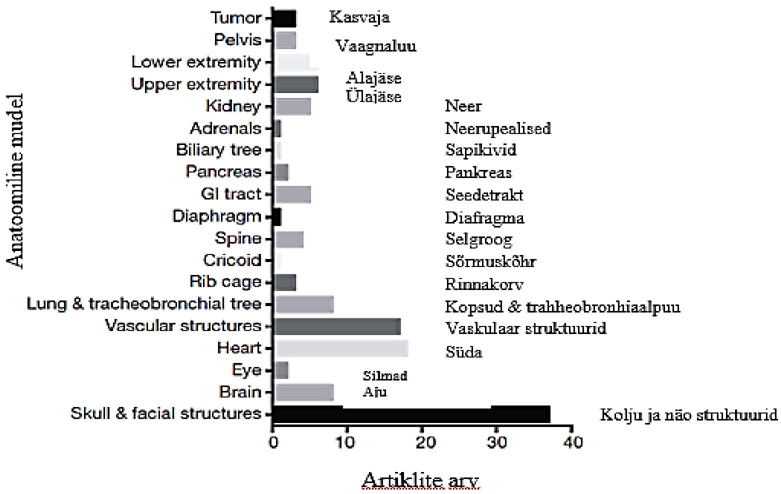
# Appendix 1 – Questionnaire for doctors, who use 3D printed applications in their work in Estonian

### Küsitlus arstidele, kes kasutavad oma töös 3D-prinditud rakendusi

SISSEJUHATUS

3D-prinditud mudeleid on võimalik teha põhimõtteliselt kõikidest inimese anatoomilistest organitest, mida saab opereerida. Hoang et al. [2] on väitnud, et 3D-printimise üheks levinumaks kasutusalaks kirurgias on anatoomiliste mudelite valmistamine. Uurimistöös leiti, et 126 ariklit uuris 3D-prinditud mudelite kasutust, samas kui 36 artiklit keskendus peamiselt kirurgiliste instrumentide kasutusele ning 18 artiklit implantaatidele, proteesidele, lahastele ja välistele fiksaatoritele. Martelli et al. [51] viis läbi sarnase uuringu, kus 158 artiklist 71,5% kasutas anatoomilisi mudeleid preoperatiivses faasis. Anatoomilisi mudeleid kasutatakse peamiselt kahel eesmärgil: 1) operatsioonieelsel ettevalmistusel ja õpetusel. Operatsioonieelne planeerimine on levinum, kuna operatsiooniaeg väheneb 5,7 kuni 63 minutit, mis võib viia verekaotuse ja suremuse vähenemiseni [9]. Hoang et al. [2] leidis, et 83 artiklis kasutati anatoomilisi mudeleid preoperatiivses planeerimises, 36 artiklis aga õpetuslikul eesmärgil ning 7 artiklis kasutati mudeleid mõlemal otstarbel. Enamikes uuringutes on kinnitust leidnud 3D-printimise kasulikkus nii operatsioonieelses kavandamisetapis kui ka meditsioonitöötajate koolitamisel. Allolev tulpdiagramm näitab illustreerivalt, kuidas 3D-prinditud mudeleid kasutatakse kirurgias [2].




Joonis A. Avaldatud artiklite arv erinevate anatoomiliste mudelite kohta [2].

Erihuvigrupp on algatanud kvaliteedi ja ohutuse stipendiumiprogrammi, mille raames üritati välja selgitada, millistes kliinilistes stsenaariumites oleks otstarbeks kasutada 3D-printimist, põhinedes teadusartiklitele. Siinkohal olen välja toonud mitmeid näiteid 3D-printimise asjakohase kasutamise kohta ning samuti ekspertide arvamused [62].

**Kardiokirurgia ehk südamekirurgia** – kaasasündinud südamehaiguste korrigeerimise planeerimiseks kasutatakse anatoomilisi mudeleid, mis oli loodud patsiendi enda anatoomiat kasutades, näitena suurte arterite transpositsioon, vatsakestevaheseina defekt, kopsutüve stenoos ja kahepoolse parema vatsakese korrektsioon. Prinditud mudeleid kasutatakse operatsioonieelses ettevalmistuses ka primaarse südamekasvaja resektsioonis, vaheseina müektoomias, südame schwannoma resektsioonis, lapspatsiendile südame siirdamises, kellel on üheventrikulaarne süda, südamesiseste defektide korrigeerimises, ektoopilise tümoomi resektsioonis, täielikus aordikaare asendamises, kopsu subsegmentektoomias, kopsuvähi resektsioonis ning keerulise söögitoru patoloogia korral [2]. Erihuvigrupp on toonud välja omalt poolt soblikud kasutusalad 3D-printimises nagu ühise arteriaalse tüve korrektsioon, osaline anomaalne kopsuvenoosne ühendus, täielik anomaalne kopsuvenoosne ühendus, Fallot' tetraad koos peamiste aortopulmonaalsete kollateraalarteritega, paaris sissevooluavaga parem või vasak vatsake, tasakaalustamata AV kanal, kongenitaalselt korrigeeritud TGA (suurte arterite transpositsioon), suurte arterite transpositsioon ja paaris äravooluga parem või vasak vatsake [62].

**Näo- ja lõualuukirurgia** – 3D-mudeleid on kasutatud operatsioonieelse klapi kujundamisel Parry-Rombergi sündroomi ravis ning koljuõõne luu siirdamise planeerimisel. Anatoomilisi mudeleid on prinditud mitmesugustest kolju ja näoluudest, et kujundada titaanimplantaate. Kolju ning orbitaalmudelite printimine vormimaks sünteetilist võrestikku posttraumaatilise orbitaaldeformatsiooni korrigeerimiseks, mandibulaardefekti printimine kirurgilise juhendi kavandamiseks ning vaagna mudeli kasutamine vaagnast siiriku lõikamise kirurgilise juhendi väljatöötamiseks [2]. Erihuvigrupi poolt pakutud näited: keerulised koljuluumurrud, näomurrud, kolju- ja näoluude kaasasündinud väärarengud, huule-ja suulaelõhed, kõrvaväärarengud, lõualuude muud keerulised haigused, healoomulised kasvajad (luu) ja pahaloomulised kasvajad (pehme kude) ning nii lihtsad kui ka keerulised dentofatsiaalsed anomaaliad, sh. väärarengud ja pahaloomulised kasvajad (luu) [62].

**Ortopeedia –** Lihasluukonna ja sidekoe haiguste korral on mudeleid kasutatud alaealiste skolioosiga patsientide korrigeeriva operatsooni kavandamisel. 3D-mudeleid kasutatakse nimmepiirkonna diskektoomia revideerimises, suurte abaluusidemete osteokondroomi korrigeerimises. Lisaks on kasutust leidnud ka vaagnaoperatsioonidel ning õlaliigese rekonstruktiivsetel operatsioonidel, õlaliigese ebastabiilsusest tingituna [2]. Erihuvirühma poolt esile toodud järgnevad juhud: keeruline puusanapi murd, valesti kokkukasvanud luumurd, puusa düsplaasia, luu/pehmete kudede kasvajad, koos liigese- ja neurovaskulaarse koosmõjuga, kaasasündinud sekundaarne lülisamba anomaalia, skolioos [62].

**Vaskulaarkirurgia ehk veresoontekirurgia** – aordi aneurüsmide mudeleid on kasutatud sobilike preparaatide valikuks aneurüsmi ravis [2]. Näited toodud erihuvirühma poolt oleksid patsiendile kohandatud aordi stentprotees, veresoonte kaasasündinud väärarengud [62].

**Neurokirugia** – Anatoomilisi mudeleid on kasutatud keeruliste koljuosade ja kraniovertebraalsete ristmike deformatsioonide planeerimisel [2].

**Gastroenteroloogia ehk seedetrakti haigused** – Maksakasvajate intraoperatiivseks tuvastamiseks kasutatakse 3D-prinditud mudeleid, mis muidu oleksid ultraheli ajal nähtamatud [2].

**Uroloogia** – 3D-prinditud anatoomilisi mudeleid on kasutatud neerukasvajate osalise adrenalektoomia ja osalise nefrektoomia operatsioonieelses planeerimises ning patsiendi harimiseks enne resektsiooni tundma õppimaks enda anatoomiat nii neeru kui ka kasvaja osas [2].

**Plastikakirurgia** – 3D-printimist on kasutatud pöidla luulise anatoomia kujutamiseks erinevates suundades operatsioonieelses planeerimises, et aidata kaasa klappide väljatöötamisele ning lõikamisele [2].

- Uurija ja uurimistöö tutuvustamine
- Konfidentsiaalsuse tagamine ja magistritöö tulemuste avaldamine ning rakendamine

Lugupeetud küsimustikule vastaja!

Minu nimi on Reelika Riis ja ma õpin Tallinna Tehnikaülikoolis Infotehnoloogia teaduskonnas Tervishoiutehnoloogiat. Magistriõppe raames teostan uuringut, mille eesmärgiks on selgitada välja 3D-printimise rolli Eesti tervishoius. Viimastel aastakümnetel on 3D-printimine leidnud rohkelt kasutust meditsiinis, sellepärast on Eesti Haigekassa otsustanud tellida tervishoiutehnoloogiate hindamise aruande, milles hinnatake 3D-printimist erialade üleselt ja erinevatel eesmärkidel (preoperatiivne kasutamine, implantaatide printimine). Sellest vajadusest on tekkinud ka minu lõputöö teema, mis aitaks antud valdkonna võimalusi rakendada ka Eesti kontekstis, põhinedes teaduslikele artiklitele. Minu uurimistöö seisukohalt väga oluline teada saada Teie seisukohti uuritavas valdkonnas, kuna olete otseselt 3D-printimise huvirühmas (nii võimaliku kasutajana kui ka teenuse pakkujana).

Küsimustikule vastamine on anonüümne ja Teie iskuandmed on kaitstud. Projektis osalemine on vabatahtlik ja seetõttu on teil õigus keelduda mistahes küsimustele vastamast. Lisaks sooviksin saada nõusolekutmärkmete tegemiseks, tagamaks kvaliteetset informatsiooni käsitlemist.

INTERVJUU

Demograafilise informatsiooni küsimine (sugu, amet, tööstaaž)

**Teema 1:** 3D-printimise olemus

*Taustainfo: Kolmemõõtmeline printimine on kolmemõõtmeliste esemete valmistamine. Seda tehnoloogiat on hakatud kasutama üha enam ka tervishoius [7], [12].*

1. Kui tihti olete oma töös kasutanud 3D-prinditud rakendusi? a) mitte üldse b) mõnikord aastas c) igakuiselt d) igapäevaselt
   1.1. Palun märkige keskmiselt mitu korda olete kasutanud 3D-prinditud vahendeid näiteks kuus/aastas.
2. Milliseid rakendusi olete kasutanud?
3. Milliste piirkondade mudeleid olete kasutanud?

**Teema 2:** Kolmemõõtmelise printimise kasutuselevõtt

*Tasutainfo: Kolmemõõtmeline printimine on saanud kirurgide poolehoiu ning leidnud kasutust paljudes erinevates rakendustes. Üheks põhjuseks võib tuua selle, et 3D-mudeleid on võimalik valmistada erinevatest anatoomilistest struktuuridest [2].*

1. Kuidas suhtute taustainfos toodud väitesse?
   1.1. Mis võib olla suurenenud huvi põhjuseks?
2. Kus näeksite 3D-printimise võimalikkust Teie valdkonnas ja millised oleksid eelised?
   2.1. Milliste operatsioonide puhul oleks 3D-printimise kasutuselevõtt põhjendatud/kasulik?
3. Millistest 3D-anatoomilistest struktuurides oleksite ise huvitatud? Tooge näiteid
   3.1. Juhul, kui Haigekassa otsustaks Teie osakonda finantseerida, siis mis otstarbel Te seda kasutaksite? (Vaata eessõna)

**Teema 3:** Kolmemõõtmelise printimise väärtus

*Taustainfo: 3D-printimine on teinud läbi olulise läbimurde ja integreerunud erinevatesse valdkondadesse. Prognooside kohaselt on 3D-printimine meditsiinivaldkonnas 2025. aastaks väärt 3,25 miljardit eurot. Tööstuse aastaseks liitkasvumääraks ennustatakse vahemikus 2017–2025 ligi 17,7% [13].*

*1.* Kuidas hindaksite 3D-printimise tähtsust/väärtust Teie valdkonnas? a) Vähese tähtsusega b) Tähtis c) Väga tähtis d) Tähtsusetu e) Ei tea/ Ei oska öelda
   *1.1.* Millist väärtust 3D-printimine pakub? a) Tõstab efektiivsust b) Suurendab kvaliteeti c) Vähendab tervihoiu kulutusi d) Muu
*2.* Kui hästi on 3D-printimine kasutusele võetud Teie valdkonnas? a) Hästi b) Halvasti c) Ei tea/ Ei oska öelda d) Muu
*3.* Milliseid 3D-printimise tehnoloogiaid on kasutusel Teie valdkonnas kui üldse? a) Sulatatud sadestumise vormimine (FDM) b) Stereolitograafia (SLA) c) Selektiivne lasertehnoloogia (SLS) d) Tindipõhine 3D-printimine e) Muu f) Ei tea/ Ei oska öelda
*4.* Kuidas 3D-printimine võiks mõjutada Teie valdkonda 5 aasta pärast/ 10 aasta pärast?

**Teema 4:** Rakendusvaldkonnad ja mõju

*Taustainfo: Kolmemõõtmelisi printereid kasutatakse meditsiinivaldkonnas eelkõige tervishoiukulutuste vähendamiseks ja patsiendi rahulolu suurendamiseks ning* *ravitulemuste parandamiseks. Materialise'i 3D-printimise äriarendusjuht Todd Pietila on öelnud, et tulevikku suunatud haiglad rakendavad nõudluspõhiselt 3D-printimise teenuseliine ja lõikavad seeläbi kasu patsientide suurenenud rahulolust, arstide paremast koolitatusest ning innovatsiooni kasvust, mis võib lõpputulemusena anda kulude kokkuhoiu [50].*

1. Kas olete samal arvamusel Todd Pietilaga? Palun täpsustage
2. Millisena hindate 3D-mudelite kasulikkust kliinilise haigusloo arutamisel?

   … implantaatide tootmisel?

   2.1. Kas Teie arvates 3D-prinditud mudelid kergendavad haigusjuhtumi analüüsi patsiendiga?
3. Kas 3D-prinditud mudelid pakuvad oluliselt paremat informatiivset väärtust kui 3D-kujutised? a) Jah b) Ei c) Sama informatiivsed kui 3D-kujutised d) Ei oska öelda e) Muu
4. Kuidas hindate 3D-prinditud mudelite täpsust elundi anatoomiliste detailide taasesitamisel? a) Väga hea b) Hea c) Keskmine d) Kehv e) Väga kehv f) Ei tea/ Ei oska öelda
5. Kas Teie arvates 3D-prinditud mudelid sobivad kirurgiliselt keerukate olukordade paremaks mõistmiseks?

Hinnake iga järgneva väite puhul skaalal 1-5, kui palju Te järgmiste väidetega nõustute või ei nõustu:

| **1-ei nõustu üldse, 2-ei nõustu, 3-neutraalne, 4-nõustun, 5-nõustun täielikult** | | | | | |
|---|---|---|---|---|---|
| 3D-printimine parandaks minu tööd, tööoskusi ja töömeetodeid | 1 | 2 | 3 | 4 | 5 |
| 3D-printimine ei suurendaks minu tõhusust töökohal | 1 | 2 | 3 | 4 | 5 |
| 3D-printimine oleks abiks patsiendi teavitatud nõusoleku saamiseks | 1 | 2 | 3 | 4 | 5 |
| 3D-printimine ei parandaks minu töökvaliteeti | 1 | 2 | 3 | 4 | 5 |
| 3D-prinditud mudelid on väga kasulikud anatoomiaõppes | 1 | 2 | 3 | 4 | 5 |
| 3D-prinditud mudelid lahendavad eetilised probleemid, mis kaasnevad katseloomade kasutamisega | 1 | 2 | 3 | 4 | 5 |

| 1-ei nõustu üldse, 2-ei nõustu, 3-neutraalne, 4-nõustun, 5-nõustun täielikult | | | | | |
|---|---|---|---|---|---|
| 3D-prinditud mudelitel on tähtis roll kirurgilises väljaõppes | 1 | 2 | 3 | 4 | 5 |
| Kasulik anatoomia selgitamiseks õpilastele/residentidele | 1 | 2 | 3 | 4 | 5 |
| Ei ole kasulik anatoomia selgitamiseks patsientidele | 1 | 2 | 3 | 4 | 5 |
| Kasutaksin 3D-mudeleid õpilaste/residentidega | 1 | 2 | 3 | 4 | 5 |
| Ei kasutaks 3D-mudeleid patsientidega | 1 | 2 | 3 | 4 | 5 |
| Ma tulen igal-juhul toime keeruliste operatsioonidega ka ilma 3D-mudelita | 1 | 2 | 3 | 4 | 5 |

**Teema 5:** Patsiendispetsiifilised 3D-prinditud anatoomilised mudelid operatsioonieelseks planeerimiseks

*Taustainfo: Anatoomilisi 3D-mudeleid on prinditud eelkõige kahel otstarbel: 1) operatsioonieelseks kavandamiseks ja 2) õpetuseks. Operatsioonieelse planeerimisega on suudetud vähendada operatsiooniaega 5,7 kuni 63 minutit ja sellega on kaasnenud verekaotuse ja suremuse vähenemine [9].*

1. Kuidas hindaksite 3D-prinditud mudelite kasulikkust operatsioonieelses planeerimises? a) Väga kasulik b) Kasulik c) Üsna kasulik d) Vähe kasulik e) Ei ole kasulik f) Ei tea/ Ei oska öelda g) Muu
2. Kui paljud Teie praegustest patsientidest läheksid mõnda teisse asutusse, juhul kui neile pakutaks operatsioonieelset 3D-printimise teenust?
3. Kui palju uusi kliente saaksite sellise teenuse pakkumisega?
4. Kui mitu 3D-prinditud mudelite abil teostatud plaanilist operatsiooni teete aastas keskmiselt?
5. Millist kasvuprotsenti prognoosite teostatud protseduuride arvule igal aastal?

**Teema 6:** Patsiendile kohandatud implantaatide loomine kasutades 3D-printimise tehnoloogiaid.

*Taustainfo: 3D-printimist kasutatakse kõige enam kliinilises keskkonnas kirugiaeelsel planeerimisel, operatsiooniaegsel juhendamisel ja patsientidele kohandatud* *implantaatide valmistamisel. Lisaks sellele on implantaadid ja protseduurilised tööriistad kohandatud just sobivaks patsiendi enda anatoomiat arvesse võttes [41].*

1. Kui tihti patsiendid tulevad Teie juurde sooviga saada endale 3D-prinditud implantaate? a) Väga tihti b) Mõnikord c) Harva d) Mitte kunagi e) Muu
2. Milliseid implantaate olete lasknud haigla biomeditsiinitehnika inseneridel või koostööpartneril teha?
3. Millised implantaadid on Teie arvates kõige suurema tähtsusega?
4. Milliseid inimese anatoomilisi piirkondi lasete printida kõige enam?
5. Kui palju aega keskmiselt kulub patsientidele kohandatud implantaatide saamiseks (alates vajaduse tekkimisest kuni implantaadi kätte saamiseni)?
6. Millise kvaliteediga on 3D-prinditud proteesid/implantaadid? a) paremad kui käsitsi tehtud implantaadid b) Võrdselt head c) Mitte nii head kui käsitsi tehtud implantaadid d) Ei tea/Ei oska öelda
7. Millist eelist näete 3D-prinditud implantaatidel võrreldes käsitsi tehtud implantaatidega?
8. Kui hästi suhtuvad inimesed 3D-prinditud implantaatidesse? a) Väga hästi b) Hästi c) Arvamus puudub d) Halvasti e) Pole teadlikud 3D-prinditud implantaadidest
9. Millist materjali kasutatakse kõige enam implantaatide loomisel?
10. Kui tähtis oleks Teie erialal selline teenus, mis pakuks 3D-prinditud implantaate inimestele? a) Poleks üldse tähtis b) Väikse tähtsusega c) Keskmise tähtsusega d) Väga tähtis e) Elutähtis

**Teema 7**: Korralduslikud väljakutsed/süsteemi kitsaskohad

*Taustainfo: Selge ja struktureeritud eeskirja puudumine 3D-prinditud seadmete tootmises piirab võimalikku tehnoloogilist aregut [45].*

1. Kas olete kursis sellega, kuidas 3D-printimine on Eesti seadustega reguleeritud? Kui jah, siis kuidas?
2. Kui tähtis oleks meditsiinilise 3D-printimise õiguslik regulatsioon? 1) Väga tähtis 2) Tähtis 3) Üsna tähtis 4) Vähe tähtis 5) Ei oma tähtsust 6) Ei tea/ Ei oska öelda
3. Millised probleemid võivad tekkida 3D-printimise kasutuselevõtuga tervishoius? Kas Teil on isiklikke kogemusi sellega?
   3.1. Millised võimalikud lahendused leiaksite probleemidele?

LÕPETUS

- Kas Teil on antud teemaga tekkinud lisamõtteid/ettepanekuid ja sooviksite neid minuga jagada?
- Juhul, kui intervjuude analüüsimisel peaks tekkima lisaküsimusi, kas tohiks Teiega veel ühendust võtta?
- Tänan Teid panustatud aja ja abi eest selle teema edasiviimisel.

# Appendix 2 – Questionnaire for doctors, who use 3D printed applications in their work in English

INTRODUCTION

Basically, 3D model can be printed of every part of human anatomy that can be operated on. According to Hoang et al. [2] anatomic model fabrication is prevailingly the most common use of 3D printing in surgery. In his review, there were 126 publications reporting the use of 3D printed anatomic models compared to 36 publications on surgical instruments and guides and 18 publications on implants, prosthesis, splints, and external fixators. Martelli et al. [51] conducted similar study where out of 158 study 71.5% reported producing anatomical models. Anatomic models are used mainly for two purposes such as preoperative planning and education. Preoperative planning is prevailing, because intraoperative time is saved from 5.7 to 63 minutes, which leads to reduction in blood loss and morbidity [9]. Hoang et al. [2] found that anatomic models for preoperative planning were used in 83 studies as 36 of then used models for education and 7 studies used the models for both purposes. In the majority of these studies, 3D printing has been useful tool in both the preoperative planning stage as well as in educating medical personnel. Diagram showed below outlines how 3D printed anatomical models were used in surgery [2].

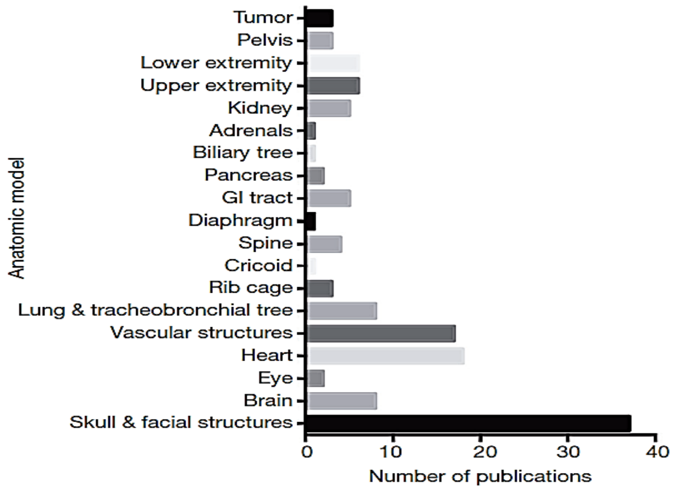



Figure A. The range and commonality of anatomic models printed [2].

The Special Interest Group has initiated the quality and safety scholarship to find out in which clinical scenarios is advisable to use 3D printing, based on peer-review data. Here

I have brought out several examples of appropriate use of 3D printing and also experts' opinions [62].

**Heart diseases –** anatomic models of patient anatomy were used for planning congenital heart disease correction such as transposition of the great arteries, ventricular septal defect, pulmonary stenosis, and double outlet right ventricle correction. Also, printing models to prepare for primary cardiac tumor resection, septal myectomy, cardiac schwannoma resection, pediatric cardiac transplantation in a patient with a univentricular heart, correction of intracardiac defects, ectopic thymoma resection, complete aortic arch replacement, pulmonary subsegmentectomy, lung cancer resection, and complex esophageal pathology [2]. Examples suggested by The Special Interest Group Truncus Arteriosus, Partial and Total Anomalous Pulmonary Venous Connection (PAPVR/TAPVR), Tetralogy of Fallot, with major aortopulmonary collateral arteries, Double Inlet/Outlet Left/Right Ventricle, Unbalanced AV canal, Congenitally Corrected TGA and Transposition of the Great Arteries [62].

**Craniomaxillofacial –** 3D printed models have been used to assist preoperative flap design in the treatment of Parry-Romberg syndrome as well as to plan for split Calvarial bone grafting. This concept has been extensively applied in Oral Maxillofacial Surgery for example, published applications include printing anatomical models of a variety of cranial and facial bones to shape titanium implants, printing a skull and orbital model for the molding of synthetic scaffolds in the correction of post-traumatic orbital deformity, printing a mandibular defect to design a surgical guide, and using a model of the pelvis to design a surgical guide for pelvic graft harvest [2]. Examples suggested by The Expert Group: Complex Skull Fractures, Complex Facial Fractures, Complex Congenital Malformations of Skull and Facial Bones, Complex Cleft Lip and Palate, Complex Ear Malformations, Complex Osteochondroplasias, simple and complex Dentofacial Anomalies Including Malocclusion, Complex Other Diseases of Jaw, Complex Benign Neoplasms (Bone), simple and complex Malignant Neoplasms (Bone), and Complex Malignant Neoplasms (Soft Tissue) [62].

**Musculoskeletal** – models have been used to plan for corrective surgery in adolescent scoliosis patients. 3D models were used in planning for revision lumbar discectomy, the correction of a large scapular osteochondroma, pelvic surgery, and surgical correction of recurrent anterior shoulder instability [2]. Examples suggested by The Special Interest

Group: complex acetabular fracture, hip dysplasia, fracture malunion, bone/soft tissue neoplasm with joint and neurovascular involvement and secondary to congenital vertebral anomaly scoliosis [62].

**Vascular –** aortic aneurysm models were used to assist in choosing an appropriate devise for aneurysm repair [2]. Examples suggested by The Special Interest Group: patient-specific aortic stent design and vascular malformations [62].

**Neurosurgery –** have used anatomic models of complex skull base and craniovertebral junction deformities in their planning [2].

**Hepatobiliary** – uses 3D printed models to identify hepatic tumors intraoperatively that would otherwise be invisible on ultrasound [2].

**Urology** – 3D printing of anatomic models has been used for the pre-surgical planning of partial adrenalectomy, partial nephrectomy in the resection of renal tumors, and for educating patients about the anatomy of their kidney and tumor before resection [2].

**Plastic Surgery –** have used 3D printing in preoperative planning to depict the boney anatomy of the thumb in various orientations, to assist flaps design and harvest [2].

- Providing the interviewee with the leaflet on the study design.
- Introducing the aim of the thesis and the interviewer.
- Explaining about confidentiality and use of the study outcomes.

Dear Respondent,

My name is Reelika Riis and I am a student at Tallinn University of Technology, Department of Information Technologies. I am conducting a research to measure 3D printing value in Estonian healthcare, as a part of my Master’s thesis in Healthcare Technology curriculum. In recent decades, 3D printing has been used extensively in medicine, which is why the Estonian Health Insurance Fund has decided to commission a health technology assessment report evaluating 3D printing across disciplines and for different purposes (preoperative use, implant printing). This need has also given rise to the topic of my graduation thesis, which would help to apply the possibilities of this field in Estonian context, based on scientific articles. It is very important for my research to find out your views on the matter because you are directly in the 3D printing target group (both as a potential user and as a service provider).

The information I would like to collect from you is purely for academic purposes and will therefore not be used for any other purposes. You are therefore kindly requested to participate in this research by answering all the questions as fully as possible.

Data will be collected anonymously during this experiment and no personal data will be obtained. Participation in the project is voluntary and therefore you have the right to decline answering any questions. Also, I would like to ask for your permission to make notes of our conversation in order to have a good quality interview.

INTERVIEW

Asking demographic information (gender, profession, length of working experience)

**Topic 1:** Essence of 3D printing

*Background: Three-dimensional printing is an additive manufacturing technique with increasing use in medical sector [7], [12].*

1. How often have you used in your workplace 3D printed applications? a) Not at all b) Few times a year c) Monthly d) Daily
   1.1. On average, how many times have you used 3D printed applications per month/year?
2. What kind of applications have you used?
3. Models of which regions have you used?

**Topic 2:** Adoption of 3D printing

*Background: Three-dimensional printing has been adopted by surgeons in an increasing extent and in a large variety of applications. One reason may be that 3D models can be made from a wide range of human anatomy [2].*

1. How do you feel about the background statement?
   1.1. What do you think is the reason behind the increasing interest?
2. Where could 3D printing be used in your specialty and what benefits would you see?

2.1. What kind of operations would benefit from 3D printing?

3. What kind of 3D anatomical structures are you interested in? Give examples

3.1. In case Health Insurance Fund decides to finance your department what would be the first thing you use it on? (Look preface)

**Topic 3:** Value of 3D printing

*Background: 3D printing has made a substantial breakthrough and integrated itself into various markets. It has been forecast that 3D printing in the medical field will be worth 3.25 billion EUR by 2025. The industry's compound annual growth rate is presumed to reach 17.7% between 2017 and 2025 [13].*

1. How would you evaluate 3D printing value in your specialty? a) Low value b) Moderate value c) High value d) None e) Don't know/ No opinion

1.1. What value 3D printing provides? a) Increases efficiency b) Increases quality c) Decreases healthcare costs d) Other

2. How well is 3D printing implemented in your specialty? a) Well b) Not so well c) Don't know/ No opinion d) Other
3. Which types of 3D printing technologies are used in your specialty if any? a) Fused deposition modelling (FDM) b) Stereolithography (SLA) c) Selective laser sintering (SLS) d) Ink-jet based 3D printing e) Don't know/ No opinion f) Other
4. How will 3D printing affect your specialty in 5 years; in 10 years?

**Topic 4:** Application fields and impact

*Background: Three-dimensional printers are being used in the medical field to decrease healthcare costs and improve patient care and outcomes. Todd Pietila, Materialise's Business Development Manager for Hospital 3D Printing, has said that "Forward-looking hospitals are implementing on-demand 3D printing service lines and, in turn, are reaping benefits of an improved patient experience, better training of physicians and growth in innovation which can drive non-traditional revenue streams in addition to the inherent cost saving that can be realized [50]."*

1. Do you share the same opinion as Todd Pietila? Please specify
2. How do you evaluate the usefulness of the 3D printed model during the clinical case discussion? …for implant production.

2.1. Do you think the 3D printed model can simplify the clinical case discussion with the patient?

3. Do you think the 3D printed models can offer additional information to the related 3D virtual model? a) Yes b) No c) Gives same information as 3D virtual model d) Don't know/ No opinion e) Other
4. How do you evaluate the accuracy of 3D printed models in reproducing the anatomical details of an organ? a) Very good b) Good c) Fair d) Poor e) Very poor f) Don't know/ No opinion
5. Do you think 3D printed models are suitable for better understanding of surgically complex situations?

For each of the following statements, on a scale of 1-5 please rate how much you agree or disagree with the following statements:

| **1-strongly disagree, 2-disagree, 3-neutral, 4-agree, 5-strongly agree** | | | | | |
|---|---|---|---|---|---|
| The 3D printing would improve my work, working skills, work methods | 1 | 2 | 3 | 4 | 5 |
| The 3D printing would not enhance my effectiveness at workplace | 1 | 2 | 3 | 4 | 5 |
| The 3D printing would be helpful getting informed consent | 1 | 2 | 3 | 4 | 5 |
| The 3D printing would not improve work quality | 1 | 2 | 3 | 4 | 5 |
| 3D printed models are highly useful in anatomy education | 1 | 2 | 3 | 4 | 5 |
| 3D printed models solve the ethical problems brought by cadaver-based anatomy education | 1 | 2 | 3 | 4 | 5 |
| 3D printed models have important role in surgical training | 1 | 2 | 3 | 4 | 5 |
| Useful explaining anatomy to students/residents | 1 | 2 | 3 | 4 | 5 |
| Not useful explain anatomy to patients | 1 | 2 | 3 | 4 | 5 |
| Would use 3D models with students/residents | 1 | 2 | 3 | 4 | 5 |
| Would not use 3D models with patients | 1 | 2 | 3 | 4 | 5 |
| I manage to cope with difficult situations without using 3D printed models | 1 | 2 | 3 | 4 | 5 |

**Topic 5:** Patient-specific 3D printed anatomical models for preoperative planning

*Background: The 3D printing of anatomic models is largely done for two purposes, preoperative planning and education. Preoperative planning is the most common one, because of intraoperative time saved ranging between 5.7 to 63 minutes, and associated reduction in blood loss and morbidity [9].*

1. How do you evaluate the usefulness of the 3D printed models? a) Very useful b) Useful c) Fairly useful d) Slightly useful e) Not useful f) Don't know/ No opinion
2. How many of your current patients will go to another facility to have pre-surgical 3D printing?
3. How many new patients will you attract by offering the service?
4. On average, how many 3D printed planned surgeries will you do per year?
5. What growth percentage do you expect each year in the number of procedures performed?

**Topic 6:** The use of 3D printing technology in creating custom implants

*Background: 3D printing is mostly used in clinical settings for pre-surgical planning, intra-operative guidance and the production of custom implants. Moreover, implants and procedural tools are tailored to fit the anatomy of individual patients [41].*

1. How often your patients want to have 3D implants? a) Very Often b) Sometimes c) Rarely d) Never e) Other
2. What implants have you ordered from biomedical engineers or associates?
3. What implants do you see are the most beneficial ones?
4. What region of human anatomy do you print the most?
5. How much time usually takes to get the custom implant (from the need till getting the product)?
6. How good is the prosthesis/implant quality made with 3D printer? a) Better than hand-made implants b) Equally good c) Not as good as hand-made implants d) Do not know/No opinion f) Other
7. What benefits do you see using 3D printing implants rather than regular hand-made implants?
8. How susceptible are people using of 3D printing implants? a) Extremely b) Very c) Do not have opinion d) Badly e) Not at all

9. What materials are used the most in making implants?
10. How important would be such a service in your field of work, which provides 3D printing implants to the people? a) Not important at all b) Of little importance c) Of average importance d) Very important e) Absolutely essential

**Topic 7:** Regulatory challenges

*Background: The absence of a clear and structured regulation of the production of 3D printed devices will continue to limit the mainstream applications of this technology [45].*

1. Are you aware of how 3D printing is regulated by law in Estonia? If yes, then how?
2. How important would these regulations be? a) Very important b) Important c) Fairly important d) Slightly important e) Not important f) Don't know/ No opinion g) Other
3. What problems might rise in implementing 3D printing at healthcare settings? How has been your experience with this?
   *3.1.* What kind of solutions would you find?

CLOSING

- Asking the interviewee if he/she wants to add anything.
- Asking permission to get back to interviewee for any clarifications/further information.
- Thanking interviewee for time and inputs.

# Appendix 3 – Questionnaire for hospital biomedical engineers in Estonian

**Küsimustik haigla biomeditsiinitehnika inseneridele, kes tegelevad DICOM piltide töötlusega 3D-printimiseks ettevalmistamisega.**

Sissejuhatuse osa kattub Appendix 1 tooduga.

INTERVJUU

Demograafilise informatsiooni küsimine (sugu, amet, tööstaaž)

Kogemus 3D-printimise alal, aastates

Tehnilised oskused 1$^{st}$ 4ni 1-algaja 4-ekspert

Ajakulu 3D-printimisel, mitu tundi nädalas

**Teema 1:** 3D-printimise olemus

*Taustainfo: Kolmemõõtmeline printimine on kolmemõõtmeliste esemete valmistamine. Seda tehnoloogiat on hakatud kasutama üha enam ka tervishoius [7], [12].*

1. Kui tihti olete printinud 3D-rakendusi? a) mitte üldse b) paar korda aastas c) igakuiselt d) igapäevaselt
   1.1. Mitu korda keskimiselt olete printinud 3D-rakendusi kuus/aastas?
2. Milliseid rakendusi olete printinud?
3. Milliste piirkondade mudeleid olete printinud?
   ... kõige enam?

**Teema 2:** Kolmemõõtmelise printimise kasutuselevõtt

*Tasutainfo: Kolmemõõtmeline printimine on saanud kirurgide poolehoiu ning leidnud kasutust paljudes erinevates rakendustes. Üheks põhjuseks võib tuua selle, et 3D-mudeleid on võimalik valmistada erinevatest anatoomilistest struktuuridest [2].*

1. Kuidas suhtute taustainfos toodud väitesse?
   1.1. Mis võib olla suurenenud huvi põhjuseks?
2. Kus näeksite 3D-printimise võimalikkust tervishoius ja millised oleksid eelised?

**Teema 3:** Kolmemõõtmelise printimise väärtus

*Taustainfo: 3D-printimine on teinud läbi olulise läbimurde ja integreerunud erinevatesse valdkondadesse. Prognooside kohaselt on 3D-printimine meditsiinivaldkonnas 2025. aastaks väärt 3,25 miljardit eurot. Tööstuse aastaseks liitkasvumääraks ennustatakse vahemikus 2017–2025 ligi 17.7% [13].*

1. Kuidas hindaksite 3D-printimise tähtsust/väärtust Eesti tervishoius? a) Vähese tähtsusega b) Tähtis c) Väga tähtis d) Tähtsusetu e) Ei tea/ Ei oska öelda f) Muu
   1.1. Millist väärtust 3D-printimine pakub? a) Tõstab efektiivsust b) Suurendab kvaliteeti c) Vähendab tervihoiu kulutusi d) Muu
2. Kui hästi on 3D-printimine kasutusele võetud Eesti tervishoius? a) Hästi b) Halvasti c) Ei tea/ Ei oska öelda d) Muu
3. Kui heal tasemel on 3D-printimine Eesti tervishoius? a) Vähe arenenud b) Arenenud c) Kõrgelt arenenud d) Ei tea/ Ei oska öelda
4. Milliseid 3D-printimise tehnoloogiaid on kasutusel Eesti tervishoius kui üldse? a) Sulatatud sadestumise vormimine (FDM) b) Stereolitograafia (SLA) c) Selektiivne lasertehnoloogia (SLS) d) Tindipõhine 3D printimine e) Muu f) Ei tea/ Ei oska öelda
5. Kuidas 3D-printimine võiks mõjutada Eesti tervishoidu 5 aasta pärast/ 10 aasta pärast?

**Teema 4:** Rakendusvaldkonnad ja mõju

*Taustainfo: Kolmemõõtmelisi printereid kasutatakse meditsiinivaldkonnas eelkõige tervishoiukulutuste vähendamiseks ning patsiendi rahulolu suurendamiseks ja ravitulemuste parandamiseks. Materialise'i 3D-printimise äriarendusjuht Todd Pietila on öelnud, et tulevikku suunatud haiglad rakendavad nõudluspõhiselt 3D-printimise teenuseliine ja lõikavad seeläbi kasu patsientide suurenenud rahulolust, arstide paremast koolitatusest ning innovatsiooni kasvust, mis võib lõpputulemusena anda kulude kokkuhoiu [50].*

1. Kas olete samal arvamusel Todd Pietilaga? Palun täpsustage

2. Kas 3D-prinditud mudelid pakuvad oluliselt paremat informatiivset väärtust kui 3D-kujutised? a) Jah b) Ei c) Sama informatiivsed kui 3D-kujutised d) Ei oska öelda e) Muu
3. Kuidas hindate 3D-prinditud mudelite täpsust elundi anatoomiliste detailide taasesitamisel? a) Väga hea b) Hea c) Keskmine d) Kehv e) Väga kehv f) Ei tea/ Ei oska öelda
4. Kas Teie arvates 3D-prinditud mudelid sobivad kirurgiliselt keerukate olukordade paremaks mõistmiseks?

**Teema 5:** Patsiendispetsiifilised 3D-prinditud anatoomilised mudelid operatsioonieelseks planeerimiseks

*Taustainfo: Anatoomilisi 3D-mudeleid on prinditud eelkõige kahel otstarbel: 1) operatsioonieelseks kavandamiseks ja 2) õpetuseks. Operatsioonieelse planeerimisega on suudetud vähendada operatsiooniaega 5.7 kuni 63 minutit ning sellega on kaasnenud verekaotuse ja suremuse vähenemine [9].*

1. Millised materjalid on head tervishoius kasutatavate 3D-prinditud mudelite loomiseks?
2. Kuidas hindaksite 3D-prinditud mudelite kasulikkust? a) Väga kasulik b) Kasulik c) Üsna kasulik d) Vähe kasulik e) Ei ole kasulik f) Ei tea/ Ei oska öelda
3. Millised anatoomilised mudelid on Teie arvates Eesti tervishoiu seisukohalt tähtsad?
4. Hinnake keskelt läbi aastas 3D-mudelite abil teostatavate protseduuride arvu.
5. Kui mitut 3D-prinditud mudelite abil teostatud plaanilist operatsiooni aitate aastas keskmiselt läbi viia?
6. Millist kasvuprotsenti prognoosite teostatud protseduuride arvule igal aastal?

**Teema 6:** Patsiendile kohandatud implantaatide loomine kasutades 3D-printimise tehnoloogiaid.

*Taustainfo: 3D-printimist kasutatakse kõige enam kliinilises keskkonnas kirugiaeelsel planeerimisel, operatsiooniaegsel juhendamisel ja patsientidele kohandatud implantaatide valmistamisel. Lisaks sellele on implantaadid ja protseduurilised tööriistad kohandatud just sobivaks patsiendi enda anatoomiat arvesse võttes [41].*

1. Kui tihti patsiendid võiksid vajada 3D-prinditud implantaate? a) Väga tihti b) Mõnikord c) Harva d) Mitte kunagi e) Ei oska öelda f) Muu
2. Kui tihti prindite 3D-implantaate?
3. Milliseid implantaate teete?
4. Millised implantaadid on Teie arvates kõige suurema tähtsusega?
5. Milliseid inimese anatoomilisi piirkondi prindite?
   5.1. Millist inimese anatoomilist piirkonda prindite kõige enam?
6. Kumb on kergem, kas implantaatide või anatoomiliste mudelite printimine?
7. Kui palju aega keskmiselt kulub patsiendile kohandatud implantaatide tegemiseks?
8. Millise kvaliteediga on 3D-prinditud proteesid/implantaadid? a) paremad kui käsitsi tehtud implantaadid b) Võrdselt head c) Mitte nii head kui käsitsi tehtud implantaadid d) Ei tea/Ei oska öelda e) Muu
9. Millist eelist näete 3D-prinditud implantaatidel võrreldes käsitsi tehtud implantaatidega?
10. Kui hästi suhtuvad inimesed 3D-prinditud implantaatidesse? a) Väga hästi b) Hästi c) Arvamus puudub d) Halvasti e) Pole teadlikud 3D-prinditud implantaadidest f) Muu
11. Milliseid materjale kasutatakse kõige enam implantaatide tegemisel?
12. Kui tähtis oleks selline teenus, mis pakuks 3D-prinditud implantaate inimestele? a) Poleks üldse tähtis b) Väikse tähtsusega c) Keskmise tähtsusega d) Väga tähtis e) Elutähtis

**Teema 7:** Korralduslikud väljakutsed/süsteemi kitsaskohad

*Taustainfo: Selge ja struktureeritud eeskirja puudumine 3D-prinditud seadmete tootmises piirab võimalikku tehnoloogilist aregut [45].*

1. Kas olete kursis sellega, kuidas 3D-printimine on Eesti seadustega reguleeritud? Kui jah, siis kuidas?
2. Kui tähtis oleks meditsiinilise 3D-printimise õiguslik regulatsioon? a) Väga tähtis b) Tähtis c) Üsna tähtis d) Vähe tähtis e) Ei oma tähtsust f) Ei tea/ Ei oska öelda
3. Millised probleemid võivad tekkida 3D-printimise kasutuselevõtuga tervishoius? Kas Teil on isiklikke kogemusi sellega?
   3.1. Millised võimalikud lahendused leiaksite probleemidele?

LÕPETUS

- Kas Teil on antud teemaga tekkinud lisamõtteid/ettepanekuid ja sooviksite neid minuga jagada?
- Juhul, kui intervjuude analüüsimisel peaks tekkima lisaküsimusi, kas tohiks Teiega veel ühendust võtta?
- Tänan Teid panustatud aja ja abi eest selle teema edasiviimisel.

# Appendix 4 – Questionnaire for hospital biomedical engineers in English

**Questionnaire for hospital biomedical engineers, who are involved in ensuring accurate segmentation and transformation of DICOM data to 3D printing compatible files.**

Introduction part is identical with Appendix 4.

INTERVIEW

Asking demographic information (gender, profession, length of working experience)
Experience in 3D printing, in years

Technical skills 1 to 4 1- rookie 4 -expert
Time spent on 3D printing, in hours per week

**Topic 1:** Essence of 3D printing

*Background: Three-dimensional printing is an additive manufacturing technique with increasing use in medical sector [7], [12].*

1. How often do you print 3D applications? a) Not at all b) Few times a year c) Monthly d) Daily
   1.1. On average, how many times have you printed 3D applications per month/year?
2. What kind of applications have you printed?
3. Models of which regions have you printed?
   … the most?

**Topic 2:** Adoption of 3D printing

*Background: Three-dimensional printing has been adopted by surgeons in an increasing extent and in a large variety of applications. One reason may be that 3D models can be made from a wide range of human anatomy [2].*

1. How do you feel about the background statement?

1.1. What do you think is the reason behind the increasing interest?

2. Where could 3D printing be used in healthcare settings and what benefits would you see?

**Topic 3:** Value of 3D printing

*Background: 3D printing has made a substantial breakthrough and integrated itself into various markets. It has been forecast that 3D printing in the medical field will be worth 3.25 billion EUR by 2025. The industry's compound annual growth rate is presumed to reach 17.7% between 2017 and 2025 [13].*

1. How would you evaluate 3D printing value in Estonian healthcare? a) Low value b) Moderate value c) High value d) None e) Don't know/ No opinion f) Other
   1.1. What value 3D printing provides? a) Increases efficiency b) Increases quality c) Decreases healthcare costs d) Other
2. How well is 3D printing implemented in Estonian healthcare? a) Well b) Not so well c) Don't know/ No opinion d) Other
3. How advanced is 3D printing in Estonian healthcare? a) Less advanced b) Advanced c) Highly advanced d) Don't know/ No opinion
4. Which types of 3D printing technologies are used in Estonian healthcare if any? a) Fused deposition modelling (FDM) b) Stereolithography (SLA) c) Selective laser sintering (SLS) d) Ink-jet based 3D printing e) Other 6) Don't know/ No opinion
5. How will 3D printing affect the medicinal sector in Estonia in 5 years; in 10 years?

**Topic 4:** Application fields and impact

*Background: Three-dimensional printers are being used in the medical field to decrease healthcare costs and improve patient care and outcomes. Todd Pietila, Materialise's Business Development Manager for Hospital 3D Printing, has said that "Forward-looking hospitals are implementing on-demand 3D printing service lines and, in turn, are reaping benefits of an improved patient experience, better training of physicians and growth in innovation which can drive non-traditional revenue streams in addition to the inherent cost saving that can be realized [50]."*

1. Do you share the same opinions as Todd Pietila? Please specify

2. Do you think the 3D printed models can offer additional information to the related 3D virtual model? a) Yes b) No c) Gives same information as 3D virtual model d) Don’t know/ No opinion e) Other
3. How do you evaluate the accuracy of 3D printed models in reproducing the anatomical details of the organ? a) Very good b) Good c) Fair d) Poor e) Very poor f) Don’t know/ No opinion
4. Do you think 3D printed models are suitable for better understanding of surgically complex situations?

**Topic 5:** Patient-specific 3D printed anatomical models for preoperative planning

*Background: The 3D printing of anatomic models is largely done for two purposes, preoperative planning and education. Preoperative planning is the most common one, because of intraoperative time saved ranging between 5.7 to 63 minutes, and associated reduction in blood loss and morbidity [9].*

1. What kind of materials are good to produce 3D printed models in healthcare?
2. How do you evaluate the usefulness of the 3D printed models? a) Very useful b) Useful c) Fairly useful d) Slightly useful e) Not useful f) Don’t know/ No opinion
3. What kind of anatomical models are beneficial to Estonian healthcare?
4. Estimate the number of procedures that are performed with the help of 3D models.
5. On average, how many 3D printing planned surgeries will you help to do per year?
6. What growth percentage do you expect each year in the number of procedures performed?

**Topic 6:** The use of 3D printing technology in creating custom prostheses

*Background: 3D printing is mostly used in clinical settings for pre-surgical planning, intra-operative guidance and the production of custom implants. Moreover, implants and procedural tools are tailored to fit the anatomy of individual patients [41].*

1. How often patients might need 3D printed implants? a) Very Often b) Sometimes c) Rarely d) Never e) I don`t know f) Other
2. How often do you print 3D implants?
3. What implants do you make?
4. What implants do you see are the most beneficial ones?

5. What region of human anatomy do you print the most?
6. Is it easier to print implants rather than anatomical models?
7. How much time could take to make and print the custom implant?
8. How good is the prosthesis/implant quality made with 3D printer? a) Better than hand-made implants b) Equally good c) Not as good as hand-made implants d) Do not know/No opinion
9. What benefits do you see using 3D printing implants rather than regular hand-made implants?
10. How susceptible are people using of 3D printed implants? a) Extremely b) Very c) Moderately d) Slightly e) Not at all f) Other
11. What materials are used the most in making implants?
12. How important would be such a service, which provides 3D printing implants to the people? a) Not important at all b) Of little importance c) Of average importance d) Very important e) Absolutely essential

**Topic 7:** Regulatory challenges

*Background: The absence of a clear and structured regulation of the production of 3D printed devices will continue to limit the mainstream applications of this technology [45].*

1. Are you aware of how 3D printing is regulated by law in Estonia? If yes, then how?
2. How important would these regulations be? a) Very important b) Important c) Fairly important d) Slightly important e) Not important f) Don’t know/ No opinion
3. What problems might rise in implementing 3D printing at healthcare settings? How has been your experience with this?
   3.1. What kind of solutions would you find?

CLOSING

- Asking the interviewee if he/she wants to add anything.
- Asking permission to get back to interviewee for any clarifications/further information.
- Thanking interviewee for time and inputs.

# Appendix 5 – Interview guide in Estonian

**Küsimustik Haigekassa töötajatele, hindamaks seaduslikku poolt 3D-printimisteenuse Eesti Haigekassa loetellu lisamiseks**

SISSEJUHATUS

• Uurija ja uurimustöö tutvustamine

Lugupeetud küsimustikule vastaja!

Minu nimi on Reelika Riis ja ma õpin Tallinna Tehnikaülikoolis Infotehnoloogia teaduskonnas Tervishoiutehnoloogiat. Magistriõppe raames teostan uuringut, mille eesmärgiks on selgitada välja 3D-printimise rolli Eesti tervishoius. Viimastel aastakümnetel on 3D-printimine leidnud rohkelt kasutust meditsiinis, sellepärast on Eesti Haigekassa otsustanud tellida tervishoiutehnoloogiate hindamise aruande, milles hinnatake 3D-printimist erialade üleselt ja erinevatel eesmärkidel (preoperatiivne kasutamine, implantaatide printimine). Sellest vajadusest on tekkinud ka minu lõputöö teema, mis aitaks antud valdkonna võimalusi rakendada ka Eesti kontekstis, põhinedes teaduslikele artiklitele.

Uurimuses osalemine on vabatahtlik ja seetõttu on teil õigus keelduda mistahes küsimustele vastamast. Lisaks sooviksin saada nõusolekut märkmete tegemiseks, tagamaks kvaliteetset informatsiooni käsitlemist.

• Demograafilise informatsiooni küsimine (amet, tööstaaž)

INTERVJUU

1. Kuidas toimub uue teenuse lisamine Eesti Haigekassa nimekirja?
    1.1. Kui pikk on protsess uue teenuse lisamiseks Eesti Haigekassa nimekirja?
2. Millised kriteeriumid peavad olema täidetud, et saada Eesti Haigekassalt rahastust soovitavale teenusele?
3. Millest on tekkinud Eesti Haigekassa huvi 3D-printimise kasutusvõimaluste suhtes Eesti tervishoius?

3.1. Millises järgus on Eesti Haigekassa poolt tellitud 3D-printimise tervisetehnoloogiate hindamise aruanne?

4. Kas Eesti Haigekassa rahastab praegusel hetkel mingit 3D-prinditud rakendust?
5. Kas hambaravis kasutatavad 3D-prinditud implantaatide rahastamine kuulub ka eriarstiabiosakonna töö hulka? Kui ei, siis kuidas see on reguleeritud.

LÕPETUS

- Kas Teil on antud teemaga tekkinud lisamõtteid/ettepanekuid ja sooviksite neid minuga jagada?
- Juhul, kui intervjuude analüüsimisel peaks tekkima lisaküsimusi, kas tohiks Teiega veel ühendust võtta?
- Tänan Teid panustatud aja ja abi eest selle teema edasiviimisel.

# Appendix 6 – Interview guide in English

**Questionnaire for EHIF employees to assess the legal side of adding a 3D printing service to the EHIF benefit package**

INTRODUCTION

• Introducing the interviewer and the aim of the thesis

Dear Respondent,

My name is Reelika Riis and I am a student at Tallinn University of Technology, Department of Information Technologies. I am conducting a research to measure 3D printing value in Estonian healthcare, as a part of my Master's thesis in Healthcare Technology curriculum. In recent decades, 3D printing has been used extensively in medicine, which is why the Estonian Health Insurance Fund has decided to commission a health technology assessment report evaluating 3D printing across disciplines and for different purposes (preoperative use, implant printing). This need has also given rise to the topic of my graduation thesis, which would help to apply the possibilities of this field in Estonian context, based on scientific articles.

The information I would like to collect from you is purely for academic purposes and will therefore not be used for any other purposes. You are therefore kindly requested to participate in this research by answering all the questions as fully as possible.

Participation in the project is voluntary and therefore you have the right to decline answering any questions. Also, I would like to ask for your permission to make notes of our conversation in order to have a good quality interview.

• Asking demographic information (profession, length of working experience)

INTERVIEW

1. How is a new service added to the list of the Estonian Health Insurance Fund?
   1.1. How long is the process for adding a new service to the list of the Estonian Health Insurance Fund?

2. Are there any criteria that must be met in order to qualify for funding from the Estonian Health Insurance Fund?
3. What has aroused the interest of the Estonian Health Insurance Fund in the possibilities of using 3D printing in Estonian health care?
   3.1. At what stage is the 3D printing health technology assessment report commissioned by the Estonian Health Insurance Fund?
4. Is the EHIF currently funding any 3D printed application?
5. Is the financing of 3D printed implants for dental use also part of the specialized healthcare unit job? If not, how is it regulated.

CLOSING

- Asking the interviewee if she wants to add anything.
- Asking permission to get back to interviewee for any clarifications/further information.
- Thanking interviewee for time and inputs.