Forum: World Health Organization (WHO)

Issue: Ensuring the ethical use of 3D printing in the medical field

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Position: Deputy President

Personal Introduction

Dear delegates,

I would like to welcome you all to this year's ACGMUN conference, specifically to the World Health Organization (WHO). My name is Danae Moutzouridou, I am a grade 10 student at Pierce – The American College of Greece. It is my utmost honor to serve as one of your Deputy Presidents of the World Health Organization in this year's ACGMUN. My experience in MUN has proven to be very rewarding over the past few years, as I have had the pleasure of earning new experiences and expanding my knowledge.

Moving forward, the WHO is a remarkable way to involve yourself in medical related global issues. I would like to congratulate you on your quickly approaching participation in ACGMUN, themed "Balancing Infinite Opportunities". I hope you enjoy the conference as a whole and I encourage you to prepare thoroughly and use it as a chance to improve, socialize, develop your skills and have fun.

The following study guide will introduce you to the topic of "Ensuring the ethical use of 3D printing in the medical field" as well as supply you with details on the topic, along with an overview. Apart from this study guide, I strongly advise you to expand your knowledge on the topic by conducting your own research and collecting information relevant to your country's stance on it. If you have any further questions, please contact me via email at: danaemoutzouridou@gmail.com

I wish you the best of luck with your preparation!

Kindly yours,

Danae Moutzouridou

Topic Introduction

Medicine is one of the most promising fields in terms of 3D printing, often referred to as “additive manufacturing”, and its use is constantly increasing, in clinical and research medical fields. More specifically, medical 3D printing is an emerging technology that includes the formation of replicas of anatomical structures, organs, prosthetics, implants and devices. Furthermore, medical 3D printing helps healthcare professionals in diagnosing, planning complicated treatments, and the treatment itself, while it also plays a crucial role in emergency situations.

The fact that medical 3D printing usually requires the creation of personalized or customized to the patient’s needs devices, there is room for unethical practices, such as the production of unsafe medical devices, private patient data misuse, patient consent not being considered and inequity to the use of medical 3D printing. Additionally, the way that medical 3D printing is regulated is not nearly enough to prevent and terminate unlawful behaviour, and exploitation of vulnerable patients and users. So, this leads to many questions towards medical 3D printing, and most importantly the ethicality behind it.

Though, since 3D printing in the medical field is a relatively new technology, it raises many concerns regarding many aspects of it. Medical 3D printing leads on a series of challenges and has brought many ethical considerations that must be addressed, across a wide range of issues such as cost, shortage of regulation, safety, and privacy. While the technology is extremely promising regarding speed, customization, accessibility and more, these ethical questions will only become more pressing as the technology progresses and advances, and they need to be resolved in order for medical 3D printing to be responsibly used and to develop correctly and ethically in the near future.

Definition of Key Terms

3D printing

“3D printing, also known as additive manufacturing, involves creating three-dimensional objects layer by layer from digital models. This technology enables the production of complex shapes and structures with precision, using materials like plastics, metals, and ceramics.”[1]

[1] Remmy, Musa. "Kenya Red Cross Society: Innovations in 3D Printing." *Prezi.com*, 30 Oct. 2024, prezi.com/p/i8e2emn8nim3/kenya-red-cross-society-innovations-in-3d-printing/.

Medical device

"A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose."[2]

Custom 3D medical device

The use of 3D printing in medical device design allows the creation of customized products and device components, as well as easy creation of adjustments throughout the design and development process, to fit the unique shape and measurements of individuals.[3]

Prosthesis

"A device, such as an artificial leg, that replaces a part of the body."[4]

Bioprinting

"A technology where bioinks and biomaterials, mixed with cells, are 3D printed, often to construct living tissue models. The process of 3D bioprinting follows that of additive manufacturing, where a digital file acts as a blueprint to print an object layer-by-layer."[5]

Medical ethics

"Medical ethics is the disciplined study of morality in medicine and concerns the obligations of physicians and health care organizations to patients as well as the obligations of patients."[6]

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[2] "Medical Devices." *World Health Organization (WHO)*, 2 July 2020, www.who.int/health-topics/medical-devices#tab=tab_1.d

[3]Chininis, Jeff. "3D Printing in Medical Device Design." *Vantage Medtech*, 15 Dec. 2023, vantagemedtech.com/3d-printing-in-medical-device-design/.

[4]"NCI Dictionary of Cancer Terms." *Comprehensive Cancer Information - NCI*, www.cancer.gov/publications/dictionaries/cancer-terms/def/prosthesis.

[5]"Bioprinting Explained (simply!)." *CELLINK*, 31 Oct. 2023, www.cellink.com/blog/bioprinting-explained-simply/.

[6] Chervenak MD, Frank A., and Laurence B. McCullough PhD. "Seminars in Perinatology." *ScienceDirect*, Dec. 2009, www.sciencedirect.com/science/article/abs/pii/S0146000509000640.

Background Information

During the 1980s, medical 3D printing first developed. It is important to note, that it has made significant progress regarding its cost, its accessibility and its method. Today 3D printing in medicine usually follows a certain process. Prior to the process of 3D printing, a digital mode l is developed to describe the structures that will be printed, where specific models for 3D printing are copied from 3D imaging processes (MRI and X-Ray, CT). There are several possible uses of additive manufacturing for medical purposes like, the creation of personalized medical devices, implants, and prosthetics, and even fabrication of human tissue to be used for transplantation. Such technologies have the ability to improve treatments for conditions spanning from bone cancer to hearing loss, making them important candidates for treating various health issues.

Furthermore, along with other modern technologies such as Artificial Intelligence, the generation of durable medical products, precisely customized to the patient's needs, offers a modern approach to traditional healthcare as teaching or diagnostic tools and allows the improvement of patient care. The printed structures often serve hospital's and organization's surgery planning, and are used as help for teaching of complicated medical procedures, which improves the experience for individuals. Hospitals that wish to add 3D printing to their treatment plan or teaching methods do so, starting with a low amount of resources building their way up slowly.

Historical Background of 3D Printing in the medical field

The new technology, 3D printing, began in 1984 when Chuck Hull filed a patent for an object producing three-dimensional structures by "stereolithography" (3D printer). A few years later bioprinting had its first steps, signaling the beginning of 3D printing in the medical field. Soon after, Hull founded the company "3D Systems", which developed the first 3D printer. Later on, the Surgical and Prosthetic Design team at the National Centre for Product Design and Development Research (PDR) started working on surgical and prosthetic design with many National Health Service (NHS) Hospitals throughout the UK from 1998.

However, the healthcare industry officially began independently using 3D printing on their own accord in 2000. Medical 3D printing is now used more in healthcare, especially in surgical cases. Then, it printing was trialed with a series of groundbreaking tests, focusing on bioprinting which had not been studied sufficiently until then, run by a research body at Boston Children's Hospital, collaborating with

Harvard Medical School, the research was on 3D printing of tissues and organs but they are not ready for clinical use yet. However, they managed to build the first synthetic scaffolds for the human bladder, making it one of the earliest uses of 3D printing in the medical field. Moving on, the Centre for Applied Reconstructive Technologies in Surgery (CARTIS) was officially set up in 2006 at Cardiff Metropolitan University, progress has been made, and now a range of highly developed surgical 3D printing services are offered. Later on the first-ever 3D-printed prosthetic leg was created, marking an important event for the development of medical 3D printing, but also raising many ethical concerns on accessibility, patient data privacy and much more. Even though most companies are focusing on using 3D printers for orthopedic procedures and others are pushing the boundaries in the field of bioprinting. After some time of companies pushing towards bioprinting, a year later, Organovo, a company that specializes in 3D printing in the medical field, bioprints the first blood vessels and then develops the first fully cellular and commercially available 3D printed liver tissue but it is only for research and drug development purposes only, though, it is important proof of the concept.

Regarding drugs and medications, for the first time, the FDA approved the first 3D printed medication tablet, but never approved any more again. The reasons behind the FDA not approving more 3D printed drugs are that medical 3D printing is still new, but also, the strict regulatory framework of the pharmaceutical field needs a long time to adjust, meaning that pharmaceutical regulatory bodies must establish a new regulatory framework for medications that are not made in pharmaceutical factories and clarify their ethical side. There are also technical challenges to address, therefore, there is a need to further advance the development of fillers that meet both printing requirements and healthcare ethical standards. Furthermore, a need for strict monitoring to ensure that tablets are printed with precision and without defects, still exists.[7]

As medical 3D printing developed, more and more opportunities for groundbreaking innovations arised. For example, between 2011 and 2012, the first 3D printed prosthetic started being designed, by an American artist, Ivan Owen. His work began when he created a mechanical hand, collaborated with a carpenter and posted online about it. A mother, who needed a hand for her five-year-old boy who was missing four fingers and prosthetics were expensive and would need to be replaced once in a while to assist him as he grew, saw it. Then Owen seeked the donation of 3D printers from a manufacturer and made the first printed mechanical hand that could scale to fit as the child grew. Though he did not patent it, instead, the small team posted the plans online so anyone with a 3D printer

[7] "FDA Approves First Prescription Drug Made Through 3D Printing." *The Guardian*, 4 Aug. 2015, www.theguardian.com/science/2015/aug/04/fda-first-prescription-drug-3d-printing. Accessed 4 Aug. 2015.

could improve the design and print. This led to the beggining of E-Nable, a non-profit organization with a big network of volunteers worldwide, able to develop prosthetic devices for out-of-reach communities.[8]

Finally, a few years later, bioprinting made a huge step regarding innovation, with a 3D printed heart with a network of blood vessels capable of contraction being first printed by Israeli scientists, at Tel Aviv University, led by professor Tal Dvir. His team and he described it as a "major medical breakthrough" and planned to transplant the 3D bioprinted hearts to animals, hoping they will advance possibilities for human transplants.[9]

Industrial 3D printers in medicine

SLA (Stereolithograpy)

To begin with, SLA 3D printers are a type of 3D printers that use a laser setting in order to transform liquid resin to hardened plastic.It is one of the most often used methods as it is very precise. In addition resins used with SLA printers are elastic, long-lasting, and biocompatible. These types of printers are usually used for dental implants, surgical guides, prosthetics, implants and some times bioprinting.[10]

SLS (Selective Laser Sintering)

Moving on, such printers use a laser to fuse small particles of polymer powder, specifically making SLS an effective and efficient option for complicated mechanical parts. It is able to create parts with excellent mechanical capabilities making SLS the most used polymer additive manufacturing technology. SLS powders, such as nylon, can be biocompatible, safe and have the ability to be sterile, and printed structures may be highly detailed. These traits make them ideal for medical use, such as the creation of prosthetics, orthopedic implants and medical devices.

[8] SPS. "Part 1: A Brief History of 3D Printing in the Orthotic & Prosthetic Industry." *SPS Blog*, 4 Nov. 2019, blog.spsco.com/brief-history-of-3d-printing-oandp.
[9] "Israeli Scientists 'print 3D Heart Using Human Tissue'." *BBC Breaking News, World News, US News, Sports, Business, Innovation, Climate, Culture, Travel, Video & Audio*, 15 Apr. 2019, www.bbc.com/news/av/world-middle-east-47940619.
[10] Ibid

FDM (Fused Deposition Modeling)

With FDM 3D printers medical device parts are created as the printer melts thermoplastic filament, which a nozzle places layer by layer in the print area. Plus, FDM 3D printers are the most used form of 3D printing at the consumer level, also usually used by medical professionals. Medical professionals use them for a variety of reasons, like personalized orthotics and prosthetics and anatomical models for surgery planning and educational purposes.

Direct metal laser sintering (DMLS) and selective laser melting (SLM)

Lastly, these printers function similarly to SLS printers, except they fuse metal powder particles together layer by layer again by using a laser. With these printers and this method, we are able to produce strong, precise, and complicated metal devices, making these 3D printers ideal for various applications in the medical field, such as prosthetics, surgical instruments and in the dentistry sector.

3D printing process in the medical field

The 3D printing process varies depending on which type of 3D printer is used, however, FDM printers are the ones often used by medical professionals. They are utilized by them because they are easy to use, small, require inexpensive filament, and their commercial availability, determines them ideal for medical professionals to use. As they are additive machines, these printers successively deposit layers of filament through a heated nozzle, until the desired shape is achieved. However, some printers let the user adjust the temperature of the nozzle, allowing the use of a variety of materials with different melting points. Throughout the process of 3D printing, FDM printers move the nozzle “drawing” a layer of molten material onto the printer bed. Once a layer is placed, the nozzle automatically is raised and another layer is placed onto the prior. Sometimes, a raft is used, which is a thin layer of material which is laid down, acting as a base to stabilize the structure as the machine prints. In fact, important factors to take into consideration while printing a structure are print speed, amount of filament, and layer thickness.[11]

[11] Mardis, Neil J. "Emerging Technology and Applications of 3D Printing in the Medical Field." *PMC Home*, July 2018, pmc.ncbi.nlm.nih.gov/articles/PMC6140256/#sec2.

Benefits of 3D printing in the medical field

Customization and Personalization

Customization and personalization are crucial for efficient results if the devices are printed in a correct manner. First of all, it allows the user to produce custom-made medical products, for example, 3D printing customizable prosthetics and implants. Additionally, through additive manufacturing we can produce tools and fixtures that are more suitable for utilization in operating rooms, over traditionally produced ones. Also, medications and drugs can easily be personalized as many patients' treatment requires specific dosages which usually take some time to be made. On that account, 3D printing provides great advantages for patients and medical professionals, as custom-made devices, implants, drugs, and tools can positively impact the duration of surgery, recovery duration, and the success of the procedure.[12]

Increased Cost Efficiency

One more advantage of the use of 3D printing, is the fact that it reduces manufacturing costs by limiting the use of unnecessary resources. Especially in products, such as prosthetics, that require high modification, in order to tailor to the needs of each patient. As a result, once manufacturing costs are lowered, the cost of the products produced also decreases, making it more accessible.

Enhanced Productivity

Moving on, 3D printing technology is much faster than traditional methods of producing devices that need shaping, a long production and delivery time. Therefore, hospitals and medical organizations can have a more rapid reaction towards a variety of cases, like emergency situations. For example, during a crisis, if a patient is in need of an implant, device or prosthetic, a 3D printer could create it in hours or even minutes making action time faster. In addition, when a device is traditionally manufactured, customization could potentially take a lot of time to happen, while when it is 3D printed, customization and personalization happens much quicker and uncomplicated.

[12] Ventola, Lee C. "Medical Applications for 3D Printing: Current and Projected Uses." *PMC Home*, Oct. 2014, pmc.ncbi.nlm.nih.gov/articles/PMC4189697/#sec3.

Variety of materials

While using this technology, users are exposed to a big range of 3D printing machines which function with different materials. With many materials being available, additive manufacturing becomes a possible method of treatment for more cases, than when there is a limited variety of materials, as some are not able to be used for certain structures. For example, a prosthetic leg cannot be made using steel because it is very heavy for that purpose.

Challenges of 3D printing in the medical field

Even if medicine is one of the leading sectors in terms of using 3D printing for treatment and device production, several challenges, needing to be overcomed, still occur to this day, on many different parts of 3D printing, including privacy, regulation, questioning of ethicality, safety and more.[13-14] Most importantly, the ethics of the use of 3D printing are often questioned, especially since it is a relatively new technology and there are many gaps to be filled with unlawful behavior.

Shortage of regulation

To begin with, a challenge being faced in the 3D printing field in medicine, is the shortage of regulation. Medical additive manufacturing is a modern technology, meaning no clear guidelines exist on ensuring the compliance with global ethical standards, safety and effectiveness of 3D printed products. As well as unethical behaviour is hard to prevent from happening due to regulations not being further emphasized in the legal system.

High cost of 3D printers and materials

The price of 3D printers and materials needed is often an obstacle in the medical field, causing many individuals to not be able to be treated using such technology. The cost of 3D printers has been decreasing as the years pass, though, they still are high-cost for some medical centers. Also, the price of 3D printing materials is sometimes higher compared to the cost of standard manufacturing materials, causing several ethical questions,, but that is not always the case. Sometimes, due to the high pricing of certain materials and services, 3D printing is often questioned on its ethicality.

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[13] "3D Printing." *Healthie | HIPAA Compliant EHR and Engagement Software*, www.gethealthie.com/glossary/3d-printing.
[14] "Advantages & Disadvantages of 3D Printing in Pharmaceutical Industry." *One Moment, Please..*, 2Bdigital, 2bdigital.ae/disadvantages-of-3d-printing-in-pharmaceutical-industry/.

Shortage of trained personnel

Due to the fact that medical 3D printing is newly developed, there is a shortage of trained personnel. Trained personnel need to have very specific characteristics in order to produce 3D printed devices efficiently, effectively and of course in an ethical manner. Trained individuals can lower the risks relating to ethicality, as usually they fairly use information, treat patients for medical purposes only and of course have a lower chance to produce unsafe devices. So, there is demand for trained professionals and experts which can lawfully use the machines, plus, design the structures to be printed.

Efficiency and safety of 3D printers

Many concerns raised are about the safety and efficiency of 3D printers, because as mentioned above additive manufacturing is a recently developed technology and is not a form of treatment that has been around for very long. However, oversight from a recognized organization is possible, for instance the FDA, making sure products are made carefully. Yet, authorized organizations cannot oversee all procedures, making the quality doubtable, as a chance for faulty 3D and errors still remain. Due to such national and global organizations not being able to supervise and monitor all procedures, there is room for unethical utilization of medical 3D printing, like misuse of private patient data, faulty productions, human enhancement and more.

Lower quality

Another ethics-related challenge being faced by the healthcare industry, is the fact that 3D printed medical devices may not meet the highest quality standards. Sometimes the results have no flaws, yet other times small errors occur. An important part of 3D printing that needs to be taken into consideration, is the fact that it is unlikely to produce 3D products without some degree of flaw. Prior to usage of the devices, the flaws need independent correction, meaning production companies must dedicate supplementary time and resources to bring satisfactory quality or needs. As a result, companies may be questioned on whether they follow the safety

and quality standards or if they do not because of the extra time needed to correct the devices. So, the ethicality is often a concern on these matters.

Uses of 3D printing in the medical field [15] [16]

Bioprinting tissues and organs

An important use of additive manufacturing in the medical field is bioprinting tissues and organs. The machines used for this purpose, bioprinters, use a computer-led nozzle to place living cells, one top of another to create artificial living tissue in a lab. These artificial tissues or organoids may be used for medical research as they are similar to organs, and are sometimes considered as decreased cost alternatives to human organ transplants. For instance, bioprinting has also been working on 3D printing skin parts that may be used directly on burn victims.

Surgery preparation assisted by the use of 3D printed models

Another popular use of this technology is surgery preparation by creating patient's organ replicas (also known as models) that surgeons can use to practice on, before performing complex operations. This process makes procedures faster, reduces post-procedure trauma for patients and increases the success rate of operations as they are performed beforehand. As an example, in UAE, where medical institutions have a mandate to use 3D printed practice models often, doctors successfully operated on a patient that endured an aneurysm in four veins, because beforehand a 3D printed model of their arteries was used to rehearse the surgery. Today, this type of procedure has been performed successfully a lot and is becoming a routine practice.

3D printing of surgical instruments

With the use of 3D printing sterile surgical instruments, scalpels and clamps can be 3D created, which is a substantial advantage for the medical industry. That is because 3D printed

[15] Nawrat, Allie. "3D Printing in the Medical Field: Four Major Applications Revolutionising the Industry." *Medical Device Network*, 7 Aug. 2018, www.medicaldevice-network.com/features/3d-printing-in-the-medical-field-applications/?cf-view.
[16] Paul, Gordon M., et al. "Medical Applications for 3D Printing: Recent Developments." *PMC Home*, Jan. 2018, pmc.ncbi.nlm.nih.gov/articles/PMC6139809/#sec7.

tools can be precise and small, making the operation on tiny areas less damaging, and the tools can also be tailored depending on the characteristics needed for each operation. Though, the main benefit offered from producing surgical instruments is the production costs are much lower.

Custom-made prosthetics using 3D printing

Additive manufacturing can be used to produce prosthetic devices that are customized to suit the wearer. In most cases, individuals that need prosthetics wait a long time before they receive prosthetics the usual way. However, 3D printing makes the process less time consuming, and creates lower cost products that have the same functionality as traditionally created prosthetics. Plus, 3D printing allows the patient to design a prosthetic that meets their needs, with the help of a medical professional.

Medication and drug delivery

Finally, drug delivery will definitely change as 3D printing becomes necessary in the pharmacy sector. It is important to note that drugs and medication can be customized to each patient's needs, as doses for each individual can be modified. As a result, 3D printing allows personalized treatment methods, and helps patients taking heavy medication. Also under development are 3D printed drug delivery devices which fit exactly to the anatomy of a patient, meaning that personal data are used for their design and precise production, which can possibly raise ethical questions.

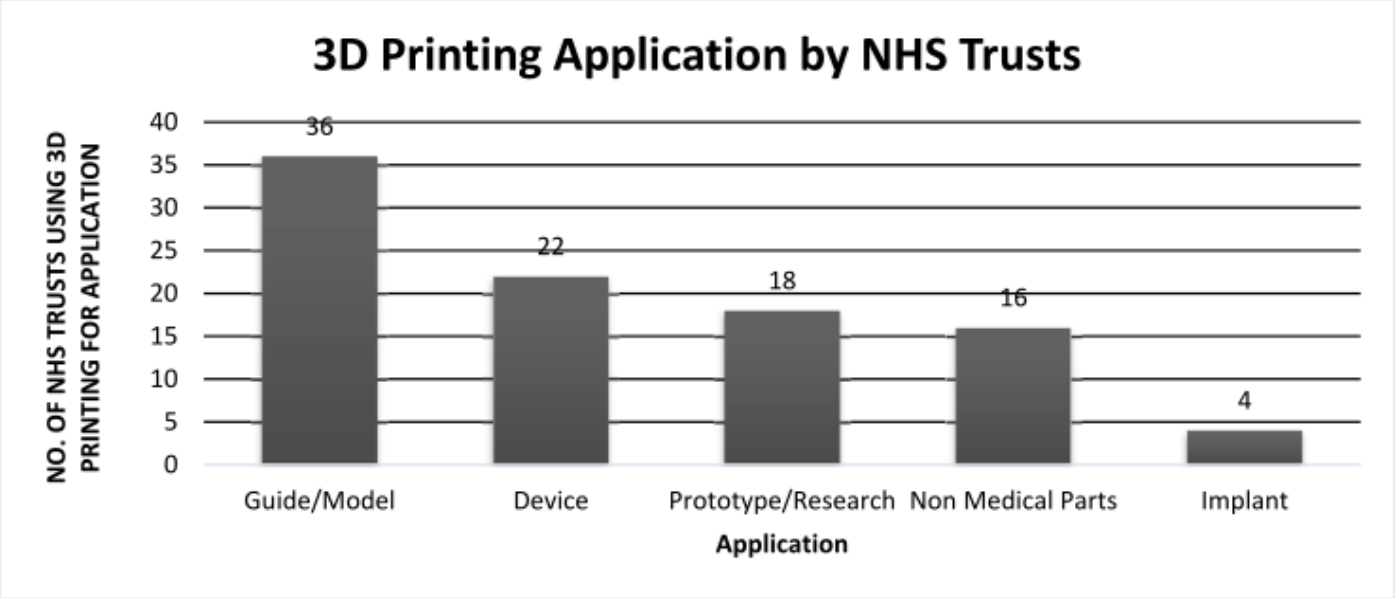

Figure 1: Graph showing the number of NHS Trusts utilising 3D printing for different applications.[17]

Ethical Considerations of Medical 3D printing

Even though 3D printing offers advanced solutions and personalized treatments to a big number of patients, the use of it in the medical field raises many ethical concerns, especially for personalization, that need to be acknowledged as these emerging technologies develop, in order for responsible and ethical use of such technologies to be ensured. Some major ethical concerns on the use of 3D printing include, medical 3D printing being available for use for everyone, the safety of treatments that involve 3D printing and human enhancement for multiple purposes.[18]

[17] Azeem, R. U., Moghaddam, S. K., Kaye, R., Malcolm, M., Di Ilio, V., Umar, Y., & Cheong, Y. K. (2024, September). *3D printing adoption in NHS trusts within the United Kingdom*. ScienceDirect. https://www.sciencedirect.com/science/article/pii/S2405886624000186

[18] Doods, Susan. "3D Printing Raises Ethical Issues in Medicine." *ABC (Australian Broadcasting Corporation)*, 11 Feb. 2015, www.abc.net.au/science/articles/2015/02/11/4161675.htm.

Justice to access to 3D printing

One major ethical concern is fair and equal access to 3D printing technologies, regardless of an individual's social and economical status, gender or where they live. Treatments and prostheses due to a lot of factors can be unreachable for some, as a well-known opinion that disparities in health between rich and poor are empowered in the healthcare sector. For example, a part of 3D printing that makes it prohibitive for some individuals, is the price of treatments and devices, especially personalized ones. More specifically, the cost and time needed to provide customized prostheses has been a barrier for many patients that are not able to access or afford it. The medical community hopes that 3D printing will be able to mitigate such disparities.

Safety of 3D printing

Many ethical concerns have been raised regarding the safety of 3D printing, as it is a relatively new technology and people are not fully convinced about its effectiveness and safety. With that being said, materials being used today have been tested for safety over a long period of time, so it is very unlikely that there are any new risks, though, any flaws during the process, can lead to significant damage to the person. 3D bioprinting treatment includes using a patient's stem cells to customize the treatment to that patient, and not to develop a treatment that can be tested on anybody, meaning that each individual could have a completely different reaction to 3D bioprinting associated treatment. Also, for example, the creation protheses, involve customization and personalization to the patient, making each application for similar purposes completely different. The safety of a treatment that involves 3D printing, depends on many different ethical factors, like the responsibility that the devices should meet the quality standards, proper testing and approval of the treatments, patient consent and patients being provided enough information and insight.

3D printing for human enhancement

One of the first reasons additive manufacturing for medicine was questioned, is human enhancement. Human enhancement means using the technology to develop and improve human capacities beyond what is normal for human beings, and currently is still an ethical question. The debate about human enhancement is mostly known to the field of sports where athletes have used

medical technology to become beyond “natural", which is considered unethical. This results in the skepticism that 3D printing may cause disparities between "enhanced" and normal individuals.

Privacy concerns

Medical 3D printing could notably impact individuals’ privacy, especially as it becomes more common, everything is exposed to tracking and observation, which becomes an important challenge to the privacy of individuals. Contrasting to the Internet, 3D printing enlarges the invasion’s level by allowing products to be tracked live. Similar futuristic technologies like AI, and AR, could make this further powerful, allowing health monitoring, likely without patient consent. With 3D printing being involved with AI and data, companies are able to trace user behavior with very invasive methods. So, this raises questions about patients not being in charge ofl their personal information, as these processes may function without the patient’s knowledge. “It also provides a challenge to the nature of legal regulation, as the underlying technologies are precise in application compared to the generalised principles of law.”[19]

Major Countries and Organizations Involved

United States of America (USA)

The United States is a country importantly involved with 3D printing in the medical field. The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) regulates the companies that manufacture, label, and import medical devices sold throughout the United States. All devices made using additive manufacturing are subject to regulatory requirements and evaluated depending on their safety, ethicality and effectiveness which is information submitted by the manufacturer. The requirements apply to medical devices before they are put into market, and some other requirements apply to products after they are put into market. Moving on, the FDA points out transparency in its regulations, as it comes together with manufacturers to make sure that data and general information about 3D printing and medical devices is easy to access. This is necessary in order

[19] Jones, A., & Griffin, J. G. (n.d.). *View of 3D printing and the right to privacy: Proposals for a regulatory framework | European Journal of law and technology*. European Journal of Law and Technology. https://ejlt.org/index.php/ejlt/article/view/743/1001

for trust to be built in the 3D printing medical industry and ensuring that individuals are fully informed about their treatment, solving the questions of informed decision-making and patient consent.[20-21]

The People's Republic of China (PRC)

China is also very involved in medical 3D printing as the nation is utilizing 3D printing technology more and more in the production of medical devices and is creating replicas of limbs and other body parts, dental implants, surgical tools and bone plates. In the Chinese healthcare sector, 3D printing technology is often used due to its ability to generate specialized and precise medical devices. Therefore, an important market for additive manufacturing exists in China due to the country's increasing demand. China has regulations set for 3D printing medical devices that are supervised by the China Food and Drug Administration (CFDA). These regulations can be a barrier for some manufacturers and can slow down the making of new devices. For example, the regulations specifically point out data privacy and consent when individuals' medical data are used for the making of personalized and custom 3D printed health related devices. Manufacturers are obligated to make sure that their patients' information is safe, guarded, private, and utilized only once informed consent is given by the patient.[22] Today, the materials obtainable for 3D printing in China are restricted, which limits the types of devices that can be produced. It is well known that additive manufacturing equipment is high cost, and that price can be a barrier for some manufacturers, even in China, however, the nation deeply questions the ethics of medical 3D printing and is cautious on basing it on ethical standards through regulations. Many popular 3D printing companies are Chinese, such as: UnionTech, Beijing LongYuan Automated Fabrication System Co. Ltd.

South Korea

South Korea is a nation that is very much connected with the 3D printing industry in the medical field. Every year, a large number of patients globally choose South Korea for 3D printing treatments, making South Korea a famous medical tourism location because of its good quality and reasonable cost. In addition, trials and research on the utilization of 3D printing in the medical sector

[20] "FDA's Role in 3D Printing." *U.S. Food and Drug Administration*, 4 Dec. 2017, www.fda.gov/medical-devices/3d-printing-medical-devices/fdas-role-3d-printing.
[21] "Medical Applications of 3D Printing." *U.S. Food and Drug Administration*, 4 Dec. 2017, www.fda.gov/medical-devices/3d-printing-medical-devices/medical-applications-3d-printing#:~:text=3D%20printers%20are%20used%20to,copies%20of%20the%20same%20device.
[22] Insights10. "China 3D Printing Medical Devices Market Analysis." *Healthcare Market Research Firm and Syndicated Reports*, www.insights10.com/report/china-3d-printing-medical-devices-market-analysis/?srsltid=AfmBOoq_bcbJoPO20lT4oNWzw1Zk0V2VkKLewZfTZn03j_4CGo26bJ5K

are led by South Korean facilities and companies, meaning this field is likely to evolve positively in the near future because of this research conducted. Most importantly, South Korea has shown impressive support for the growth of the 3D printing sector for medical purposes, for example, through the National 3D Printing Strategic Plan. In South Korea, the Medical Device Act regulates the licensing, production and importation of 3D printed medical products. More specifically, manufacturers should be granted permission from the Ministry of Food and Drug Safety (MFDS) that takes into consideration a variety of factors, prior to marketing their products. Finally, to make sure that already existing medical products are safe and efficient, the MFDS monitors them and is always informed if any incidents occur nationwide.[23] [24]

Kenya Red Cross Society (ICHA)

The Kenya Red Cross Society is a non-governmental organization that was established in 1965 and plays a vital role in humanitarian aid, using its extensive network to respond successfully to crises and catastrophes in Kenya. First of all, it is part of the global Red Cross Movement and also is a leading humanitarian organization with a mission to mitigate human suffering, especially in vulnerable populations and far regions. Moreover, ICHA has implemented 3D printing technology to create essential supplies rapidly and at low cost during emergencies, reducing reliance on traditional methods and empowering rapid action in crises. However, the organization endures many challenges in implementing 3D printing technology for example, technical challenges such as clarifying the quality and safety of 3D printed medical supplies. Also, ICHA collaborates with companies and universities to perfect and expand 3D printing methods and creates quicker response to emergencies or incidents, thus, has better outcomes in humanitarian crises by utilizing modern solutions like 3D printing. In conclusion, their use of 3D printing advocates for solutions amended to local necessities, increasing the chances for swift action to many emergencies.[25]

The United Nations International Children's Emergency Fund (UNICEF)

The United Nations International Children's Emergency Fund is a non-governmental organization founded in 1946 that works in the world's most isolated places to reach the disadvantaged

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[23] Insights10. "South Korea 3D Printing Medical Devices Market Analysis." *Healthcare Market Research Firm and Syndicated Reports*, www.insights10.com/report/south-korea-3d-printing-medical-devices-market-analysis/?srsltid=AfmBOopDaFs7l0Sg5odupQj3KfPXiYlHFvM_p9EVyMHafNEtXZo6yAGS.
[24] *3D heals*, 3dheals.com/exploring-3d-printing-policy-changes-impacting-healthcare-and-biotechnology-guide/#google_vignette.
[25] Remmy, Musa. "Kenya Red Cross Society: Innovations in 3D Printing." *Prezi.com*, 30 Oct. 2024, prezi.com/p/i8e2emn8nim3/kenya-red-cross-society-innovations-in-3d-printing/.

children and prioritizes the rights of all minors worldwide. In particular, the organization supports child health, sanitation, education, HIV prevention, medical treatment for mothers, and the protection of children from abuse and exploitation. As well as it provides support and security to communities and children during humanitarian crises. Their mission involves utilizing medical 3D printing in providing better lives for children and communities, especially while trying to give them normal lives as providing such developments to the most disadvantaged is necessary for that goal to be accomplished. Lastly, UNICEF believes and tries to act on their belief that it is important to bring healthcare, including 3D biofabrication and additive manufacturing to the most isolated, under developed and inaccessible communities. As the organization puts in a lot of effort to bring the technology of medical 3D printing to the most disadvantaged and far regions, they are also trying to solve the question of ethicality relating to medical 3D printing being difficult to access for some people. UNICEF, tries to involve everyone that needs this technology regardless of their personal traits.[26-27]

Blocs Expected

Alliance 1: Countries with major use of medical 3D printing that value the ethical use of it

In this alliance, the countries that should be grouped together are the nations that utilize 3D printing technology in the medical field a lot and value the ethical use of it. Also, these countries could have established guidelines and laws and can be dedicated to ensuring the ethical use of medical 3D printing, data safety, equal access and protecting patients, as they recognize it as a major concern that must be solved in the near future. However, it should be open to any nation that may not be very experienced but is already taking steps to develop medical 3D printing in their medical system and to ensure it is used ethically. Some examples of countries that should be included in the first bloc, are the Germany, Canada, the UK and France.

Alliance 2 : Countries that question the ethics of 3D printing in the medical field

This alliance includes countries that are not as familiar with the use of 3D printing for medical purposes or have not integrated it in their healthcare system at all. Furthermore, they may question whether 3D printing for medicine is based on ethical standards more extendedly than others, or they may not have much compliance with the ethical standards. In this bloc, the nations might be cautious with it because of several ethical questions, involving quality, legal approval, the purpose of its use,

[26] "Frequently Asked Questions." *UNICEF*, www.unicef.org/about-unicef/frequently-asked-questions#1.
[27] Powell, Sean. "Health Technologies for the Most Disadvantaged." *UNICEF*, 12 Jan. 2016, www.unicef.org/innovation/stories/health-technologies-most-disadvantaged.

informed decision making and more. For example in this alliance, countries like Russia, Brazil, and nations in Africa are included.

Timeline of Events

Date	Description of Event
8 August 1984	Chuck Hull files patent for 3D printer.
1988	Bioprinting first demonstrated by 2D micropositioning of cells. First commercially available 3D printer is developed.
1998	PDR and NHS across the UK start working on surgical and prosthetic design.
2000	Medical field officially starts using 3D printing.
2006	Range of highly developed surgical 3D printing services are offered. The first ever commercial bioprinter is launched.
2004	Dr. Forgacs engineered 3D tissue with only cells and no scaffolds
2008	A groundbreaking 3D-printed prosthetic leg has been introduced.
2009	Blood vessels start being 3D bioprinted.
April 2014	First 3D printed fully cellular human liver tissue is made.
3 August 2015	FDA approval of the first and only 3D printed tablet.
January 2016	FDA's draft guidance entitled *Postmarket Management of Cybersecurity in Medical Devices*[28]

[28] Tabibkhoei, F. (2016, August 26). *3D printing poses unique security risks for medical devices*. 3DHeals. https://3dheals.com/3d-printing-poses-unique-security-risks-medical-devices/

4 December 2017	FDA guidance to manufacturers of 3D printed medical devices
2018	National Medical Products Administration (NMPA) guideline on the regulation and registration of 3D printed devices[29]
15 April 2019	A 3D heart with network of blood vessels capable of contraction is bioprinted at Tel Aviv
26 May 2021	EU Medical Device Regulation (MDR)[30]

Previous Attempts to Solve the Issue

U.S. Food and Drug Administration's (FDA's) Guidance for Technical Considerations for Additive Manufactured Medical Devices[31]

The U.S. Food and Drug Administration is in charge of protecting public health by making sure drugs, biological products, and medical devices are efficient, secure and are used ethically and by confirming the safety of the food supply, cosmetics, and manufactures that release radiation. In order to tackle many issues related to medical 3D printing and unethical behaviour, they released "Guidance for Industry and Food and Drug Administration Staff for Technical Considerations for Additive Manufactured Medical Devices" which is a guidance document that outlines technical considerations associated with 3D printing and sets standards and guidelines. It was an effective attempt, but it was limited by several factors like the following: the FDA may not have sufficient resources to effectively oversee devices that may be manufactured, increasing numbers of healthcare providers adopt 3D printing without clear federal guidance or oversight, this guidance isn't a legal binding document, meaning no one is obliged to follow it.

[29] Sik, W. M. (2022, January 21). *3D printing in medical: What is it? And why is it important?* Novus Life Sciences. https://www.novusls.com/post/3d-printing-in-medical-field
[30] Pettersson, B. V., Ballardini, R. M., Mimler, M., Li, P., Salmi, M., Minssen, T., Gibson, I., & Mäkitie, A. (2024, May 29). *Core legal challenges for medical 3D printing in the EU*. PMC Home. https://pmc.ncbi.nlm.nih.gov/articles/PMC11171897/
[31] Brief, Issue. "FDA's Regulatory Framework for 3D Printing of Medical Devices at the Point of Care Needs More Clarity." *The Pew Charitable Trusts | The Pew Charitable Trusts*, 27 July 2022, www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/07/fdas-regulatory-framework-for-3d-printing-of-medical-devices-needs-more-clarity.

European Union Medical Device Regulation (MDR)[32][33]

The European Union Medical Device Regulation, is a set of regulations set in May 2021, overruling the Medical Device Directive (MDD), by the European Union. It sets clear guidelines for the ethical use of all medical devices, including 3D printed ones and ensures safety, transparency and consistency throughout the European Market. The shift from the old MDD to the new set of regulations (MDR), was driven by several factors. The EU faced several medical device safety scandals, prompting the need for stricter regulations and guidelines. Plus, different EU member states interpreted existing laws differently, leading to inconsistencies and monitoring challenges also occurred meaning that there were limited methods to effectively monitor compliance with medical device regulations. The MDR has faced many challenges such as slow progress, the manufacturer's reluctance to understand and invest in MDR compliance and the slow introduction of guidance, meaning that it was not as effective as needed to ensure complete ethical compliance.

The American Society of Mechanical Engineers' Medical 3D Printing Education Program[34][35]

The American Society of Mechanical Engineers (ASME), introduced a program related to medical 3D printing in 2015. This particular initiative took place at ASME annual conferences throughout the year. Moving forward, this program was designed to assemble engineering and medical professionals aiming to talk over emerging technologies such as 3D printing and its use in the medical field. The ASME and the experts invited, provided education and training generally on the utilization of additive manufacturing, with its use in the medical field and on using it for surgical training. However, the program's goal was to help experts in the engineering and medical sector, comprehend the uses of additive manufacturing technologies and the advantages they offer, specifically medical devices, such as prosthetics, surgical planning, and potential medical uses. Despite the fact that this program was very well organized and thorough, Unfortunately, it did not offer many observable changes on ensuring the ethical use of 3D printing in the medical field.

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[32] "EU MDR: What is It and Why is It Necessary?" *Quality Custom Medical Components and Assemblies | Saint-Gobain*, www.medical.saint-gobain.com/resources/blog/eu-mdr-what-it-and-why-it-necessary.
[33] Risborough, Paul. "Five Reasons Not to Delay Your MDR Certification." *NAMSA*, 1 Dec. 2023, namsa.com/resources/blog/five-reasons-not-to-delay-your-mdr-certification/.
[34] Butterman, Eric. "Medical Training with 3D Printing." *The American Society of Mechanical Engineers*, 23 July 2015, www.asme.org/topics-resources/content/medical-training-with-3d-printing.
[35] "Medical Additive Manufacturing 3D Printing Year in Review 2019-20." *The American Society of Mechanical Engineers*, resources.asme.org/hubfs/AM%20Summit/Medical%20AM3DP%20Year%20In%20Review%2019-20.pdf.

Possible Solutions

Ensuring transparency and accountability

A major problem that occurs when proposing the use of 3D printing for medical purposes is that the patients may lack trust in the treatment's safety and on whether it is based on ethical standards. Even though this is not an issue that happens constantly, it is crucial that the patients completely trust their treatment plan. Thus, by ensuring transparency and accountability the patients can be certain their treatment is following ethical guidelines. In order to ensure that, patients must be thoroughly informed about the process and they must be aware of risks, or any possible inconveniences. Moving on, transparency in the design and approval of 3D-printed medical devices is also vital, as it guarantees that the devices being used for treatments meet the safety requirements that are determined by whether guidelines and laws were followed. That means that the medical professionals that will be using them are sure of their effectiveness and that they are based on ethical guidelines and standards, and that the patients do not have to worry about danger regarding the way they are designed and manufactured. Finally, constant improvement is very important, and that can be achieved through transparency and accountability between medical professionals and manufacturers. Sharing of knowledge, designs, failed attempts and improvements in the 3D printing process betters the technology, which ensures that medical 3D printing progresses in an ethical and more efficient manner.

Health patient data privacy and security

With the protection of users' data, the ethical use of 3D printing is promoted, as patients' sensitive personal data being mishandled is a major current ethical question relating to medical 3D printing. For starters, this outcome could be achieved by the implementation of vigorous data security measures that could be implemented on the patients' data being used for the creation of personalized or customized 3D printed devices, like prosthetics, implants, or tissue printing. These measures could be a variety of different ones, like access control; which ensures authorization is necessary for use and viewing of patients' personal health data. Access could only be given to medical professionals, and manufacturers that are in need of it to produce the device. At the platforms or secure environments these information is stored, monitoring should be applied, where moderators can view who and when viewed the documents. Also, the way patient information is stored and transmitted is an important factor, thus, it must be stored in secure environments that are in compliance with health data regulations, making the information less vulnerable to cyberattacks. Additionally, clear and strict guidelines and regulations should be set up, ensuring that any transmission of patient data is necessary, protected from cyberattacks and is based on informed patient consent. Moving forward,

informed patient consent should be further emphasized, meaning that patient data should not be stored or transmitted in any way if the patient is fully informed and does not agree with them being used this way. Furthermore, patients should be able to withdraw consent and when that is done, all of their data should be properly handled in accordance with the patient's decision. To sum up, strict data security and privacy measures should be applied in order to address the important ethical question of patient private health data being misused in the medical 3D printing field.

Monitoring and reporting mechanisms

Finally, integral concerns are usually raised on the safety and ethics of the use of 3D printing in the medical field by medical doctors, manufacturers and patients. By creating monitoring and reporting mechanisms such concerns can be addressed and the technology and methods will be revised and substantially less riskier to be utilized. These mechanisms can verify that 3D printed medical devices and products always align with safety standards. By using these mechanisms, rapid identification of problems can happen and any harm created by additive manufactured devices can be resolved. Apart from this, a secure environment can be created where individuals are able to anonymously report unethical or illegal practices being used for treatment. This platform will be secure, by setting independent regulatory bodies, that will be in charge of maintaining confidentiality and privacy during the process, and look into any concerns and the reports. This means that 3D printing companies and medical professionals are going to comply with the standards set, if they fail to, they are at a crucial risk of being reported and investigated. To conclude, by creating monitoring and reporting mechanisms, trust can be formed within the medical 3D printing industry, among corporations, medical professionals and patients. Such trust is integral for the ethical progress of the healthcare industry's use of 3D printing.

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