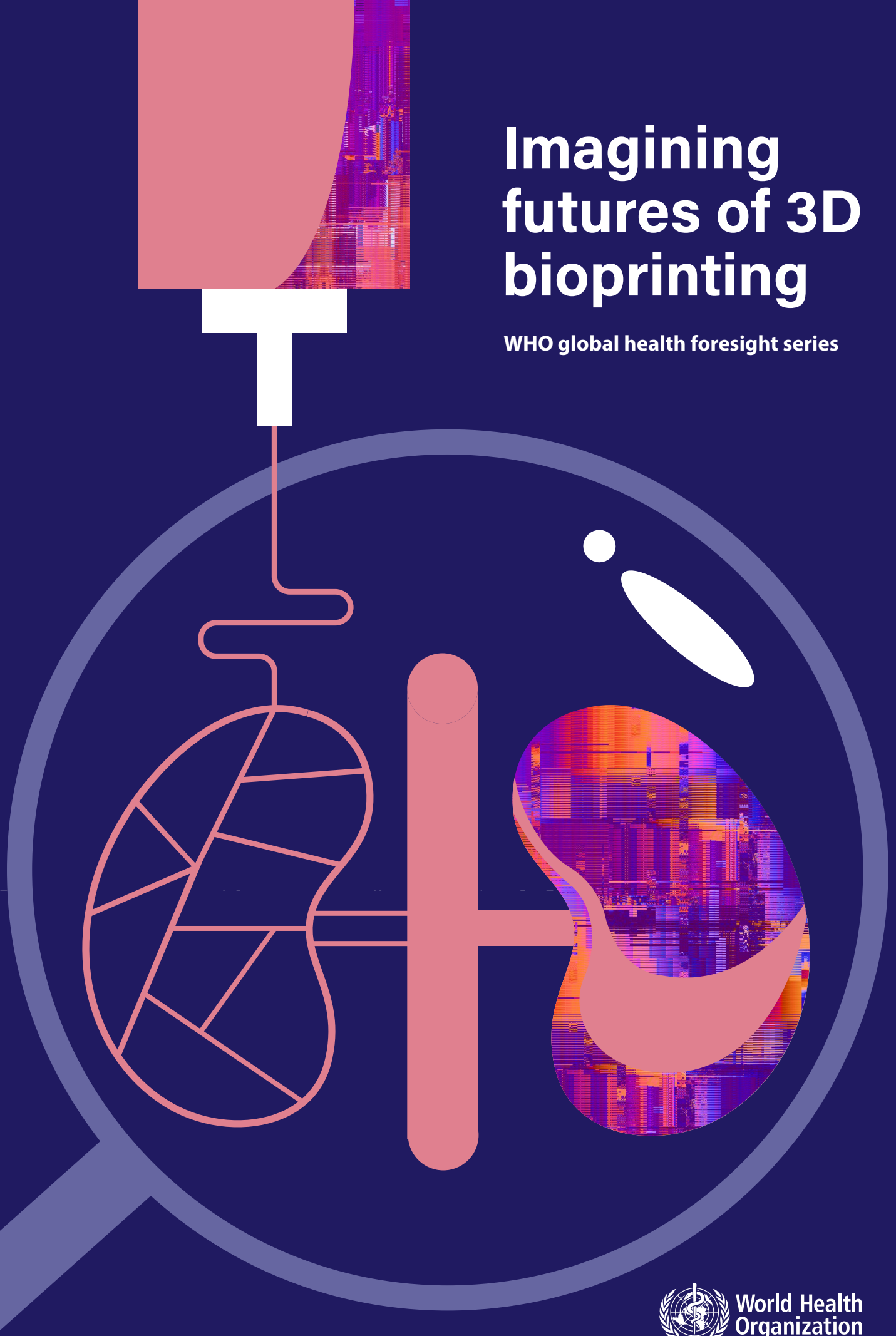


# Imagining futures of 3D bioprinting

WHO global health foresight series



World Health  
Organization



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World Health  
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Imagining futures of 3D bioprinting  
(WHO global health foresight series)

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The project was conducted in a series of virtual workshops involving a core group of experts. The last workshop, for application of the scenarios, involved a larger group of experts. The experts were (in alphabetical order):

*Core group:* Ekaterine Berishvili (University of Geneva, Switzerland); Sang Jin Lee (Wake Forest University School of Medicine, United States of America); Khoon Lim (University of Sydney, Australia); Lorenzo Montrasio (Human Rights and Biomedicine Division, Council of Europe, France); and Buzz Palmer (University of Melbourne, Australia).

*Experts who joined the workshop on application of the scenarios:* Ali Alobaidli (Abu Dhabi Healthcare Company, United Arab Emirates); Linda Ezekiel (Uongozi Institute, United Republic of Tanzania); Marisa Roma Herson (Deakin University, Australia); Vivekanand Jha (George Institute for Global Health, University of New South Wales, India; School of Public Health, Imperial College, London; and Prasanna School of Public Health, Manipal, India); Sang Jin Lee (Wake Forest University School of Medicine, United States of America); Khoon Lim (University of Sydney, Australia); Dominique Martin (Deakin University, Australia); Yoshiaki Maruyama (Pharmaceuticals and Medical Devices Agency, Japan); Francielli Melo (Brazilian Health Regulatory Agency, Brazil); Winfred Nazziwa (National Council for Science and Technology, Uganda); Priscilla Nyambayo (Medicines Control Authority of Zimbabwe, Zimbabwe); Ilona Reischl (Austrian Medicines and Medical Devices Agency, Austria); Laura Ricles (Food and Drug Administration, United States of America); Marisela Rodriguez Salvador (Tecnológico de Monterrey, Mexico); and Esteve Trias (Leitat Technological Center, Hospital Clinic of Barcelona, Spain).

The experts participated as individuals and not as representatives of their organizations.

Yetmgeta E. Abdella, WHO Regional Office for the Eastern Mediterranean, Cairo, Egypt, joined the workshop on application of the scenarios.

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## Declarations of interests

All experts who participated in the core group and those who joined the workshop on application of the scenarios completed declarations of interests, which were assessed by the WHO secretariat with the support of the Office of Compliance, Risk Management and Ethics. The interests declared were considered not to represent a conflict of interest that would preclude participation in the project.

# Executive summary

This report presents the outcomes of a foresight project led by the Emerging Technologies, Research Prioritisation and Support unit and the Blood and Other Products of Human Origin team at the World Health Organization (WHO) on 3D bioprinting and global health. The project was conducted between August and November 2023.

3D bioprinting could be used to meet crucial public health challenges, such as the demand for repair or replacement of human organs and tissues. The foreseen applications of the technology include research, training and various medical uses. Outstanding issues include quality, safety, efficacy, equity of access and ethics, and appropriate regulations and governance should be considered to address those issues efficiently.

The project was conducted with a participatory approach, including horizon scanning and developing scenarios in a series of virtual workshops with a small group of experts. The scenarios were then used to identify actions, which were discussed in a final workshop with a larger group of experts. The approach was an adaptation of work on classical scenarios in the global business network.

Scenario logics were developed from identified drivers of change in 3D bioprinting and global health, with a time horizon of 2033. The logics are based on two variables with drastically contrasting end-points: mode of prioritization (with the end-points “evidence-based focused on public health” and “fragmented interest-driven foci”) and “extent of cooperation” (with “collaborative” and “antagonistic” end-points). These logics resulted in the following scenarios:

- “survival in silos”: antagonistic and evidence-based focus on public health;
- “a new era for humankind”: collaborative and evidence-based focus on public health;
- “sailing in troubled waters”: antagonistic and fragmented interest-driven foci; and
- “follow the rainbow”: collaborative and fragmented interest-driven foci.

These scenarios are not proposed as normative or probable but rather as a group of strongly contrasting general future situations for exploring the topic. They were used to structure discussions on this advanced technology and how it could be used to improve global health.

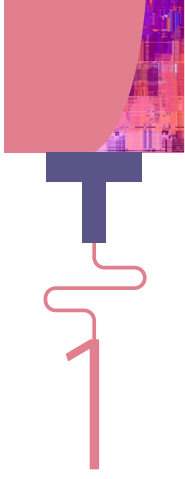
Various aspects of 3D bioprinting and global health were explored, with the opportunities and risks in each scenario and the adaptations, optimization or inventions they would require. The similarities and differences of scenarios were used to develop ideas for action. Discussions on six main topics for near-term actions are summarized according to how people of today could help the people of 2033 to better apply 3D bioprinting for global health:

1. Support harmonized, appropriate regulation of 3D bioprinting.
2. Establish data standards and practices on use of 3D bioprinting in medical applications.
3. Train future clinicians and medical technologists in all regions.
4. Establish a technology and IP platform for innovators and manufacturers.
5. Communicate effectively with the public about 3D bioprinting.
6. Raise global awareness of the availability of 3D bioprinting, and pool resources.

The ideas developed in the project were designed to stimulate conversations and to serve as seeds for new initiatives to guide development of this advanced health and medicine technology.







# Why 3D bioprinting is significant for global health

3D bioprinting refers to the use of 3D printing-like techniques in fabrication of tissues, organs and biomedical parts that imitate natural tissue architecture. Cells and growth factors are used as printing materials, bioinks, to create ex-vivo and in-vitro tissue models. The applications in health care include both clinical treatment to research and training. Possible applications are in regenerative medicine, drug screening, disease modelling and personalized medicine, regeneration of complex tissues and organs, and bio-fabrication of vascularized constructs, functional tissues and organoids. Like any other advanced technology, it raises potential issues, some of which are already known and others that are novel.

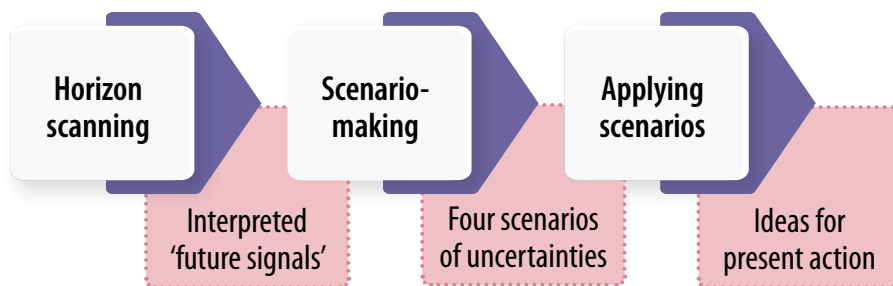
Regulation of this technology is, however, challenging because of the novel combinations and forms of medical interventions that it allows. More work is necessary to ensure the safety and quality of scientific developments (1) and for translating bioprinting technologies into clinical applications and possible commercial products.

Currently, the availability of donated human organs and tissues for transplantation and treatment is limited (2), and this technology could address such unmet medical needs. Emerging applications also include optimization of research methods for drug-screening models and replacing human and animal testing, with implications for the pharmaceutical and cosmetic industries. WHO has published the findings of a global horizon scan of innovations in science and technology that could help solve global health challenges (3), which include tissue engineering, regenerative medicine and biomaterials that could increase the supply of organs and tissues.

The aim of this exploration of plausible 10-year scenarios of 3D bioprinting was to identify present actions to ensure the future availability of safe, effective applications of this advancing technology and equitable distribution of its benefits. The project was also conducted to identify any risks or dual-use issues.

## 2 Approach of this Foresight project

Scenarios are used to imagine and explore futures, to identify any change they would engender and as a basis for present decisions and actions. Scenario approaches are classic foresight methods, of which there are now many variations. This project consisted of three phases: horizon scanning, making scenarios and applying scenarios according to the outcome of each (Fig. 1).



**Fig. 1. Phases of scenario-based foresight**

The aim of this project was to design contrasting, plausible (not probable or desirable) scenarios relevant to 3D bioprinting and global health and to identify potential uses in the present. To ensure a wide range of perspectives, a diverse group of regulators, scientists, medical professionals, public health specialists and innovation researchers was involved, with a balance geographical distribution.

Adaptation of a classic foresight method known as the “global business network” approach to scenarios was selected (4). This adaptation ensures temporal efficiency, as it can be applied in four workshops in only a few weeks. The project started with a core group of five experts who contributed to horizon scanning and developed scenarios in the first three workshops. The group was joined by a larger group of experts for the final workshop, for application of the scenarios.

The scenarios developed should not be considered attempts to predict the future. They were developed and applied to facilitate communication among stakeholders on the potential of 3D bioprinting and to identify ideas for actions in the near future that could be beneficial for global health. In the final workshop, the scenarios were studied for potential benefits, risks and any dual use and for the types of decisions, optimization and inventions that would be required to improve global health in each situation. The results were used to formulate reflections and ideas for present action.

## 3 Drivers of future developments in 3D bioprinting and global health

In our complex world, many systems are interconnected, and many drivers can influence the development of any specific aspect. After a brief horizon scan, the small group discussed the factors that influence how 3D bioprinting and global health might develop up to 2033, which included some signals and new developments, such as in-situ bioprinting with a robotic endoscopic arm (5–7), combining 3D bioprinting and machine learning to build digital twins of human tissues (8), research conducted in space (zero gravity environment) (9–12) and personalized treatment applications (13). The group also discussed the possible environmental impacts of bioinks and other materials (14–16) and the sustainability of some techniques.

Drivers that could influence development of 3D bioprinting and global health from the horizon scanning exercise and the experts' contextual perspectives were categorized as primary, secondary, weak and "wild card" drivers (see Fig. 2). The last group comprises drivers that might have a surprising or unexpected influence. Many sources of social, technological, economic, environmental, political, values and cultural change are reflected in these drivers. The category with the most drivers was technological, while those with the fewest drivers were environment and culture.

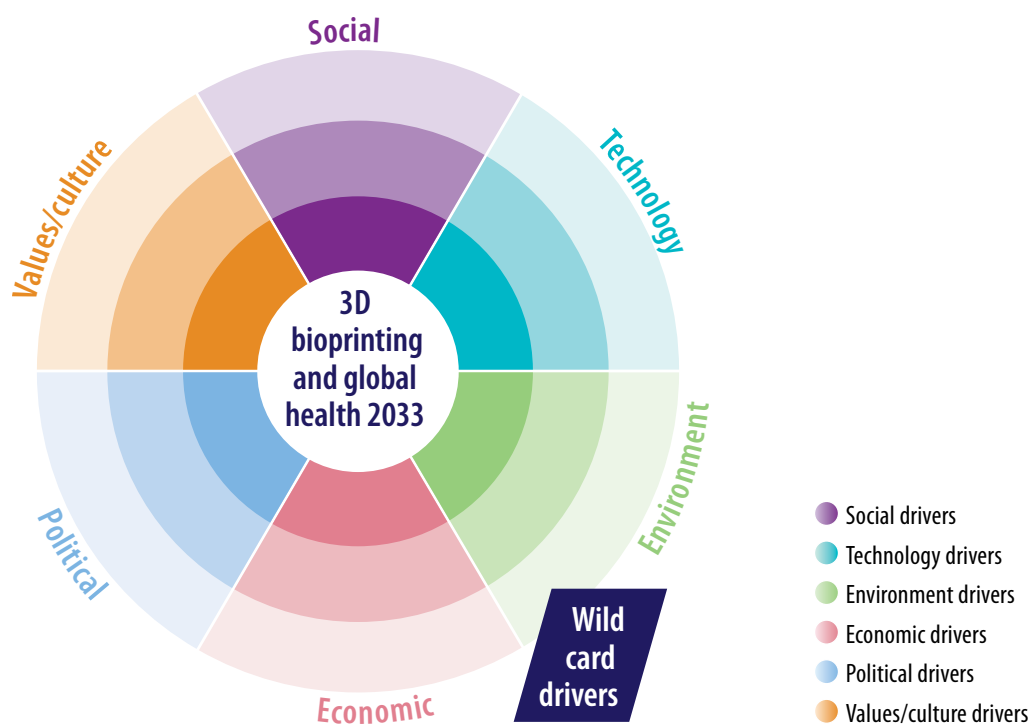
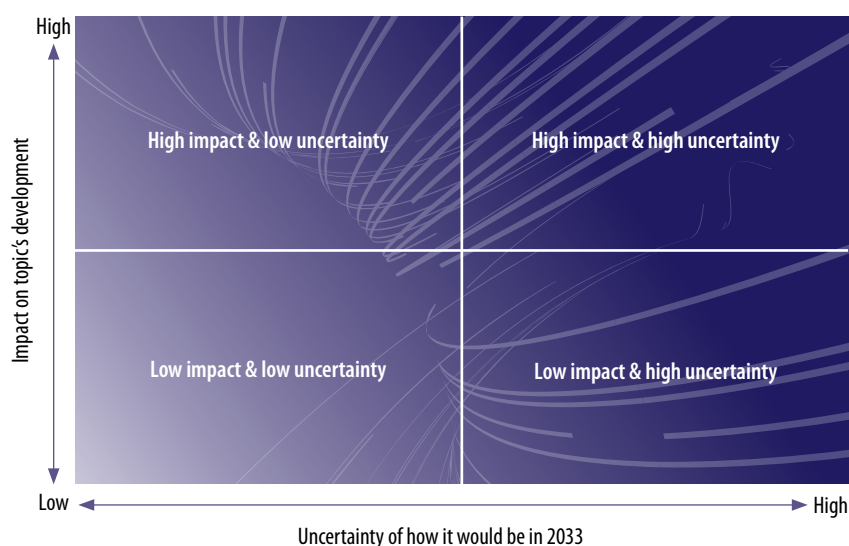


Fig. 2. Primary, secondary, weak and wild-card drivers of 3D bioprinting and global health up to 2033

Cross-cutting issues for about 70 drivers were regulatory effectiveness, quality of evidence, robustness of data, application to public health needs, funding availability and patterns, clinical challenges, innovation pathways, the role of evidence in decision-making and culture, the role of business logics in prioritizing applications, pricing and access, and differences in capacity to apply these therapies in different settings.

The drivers were sorted by the experts on an impact–uncertainty matrix (Fig. 3) according to the answers to two questions: How great an impact would the variable have on developments in 3D bioprinting and global health, and how uncertain would the impact be after 10 years?

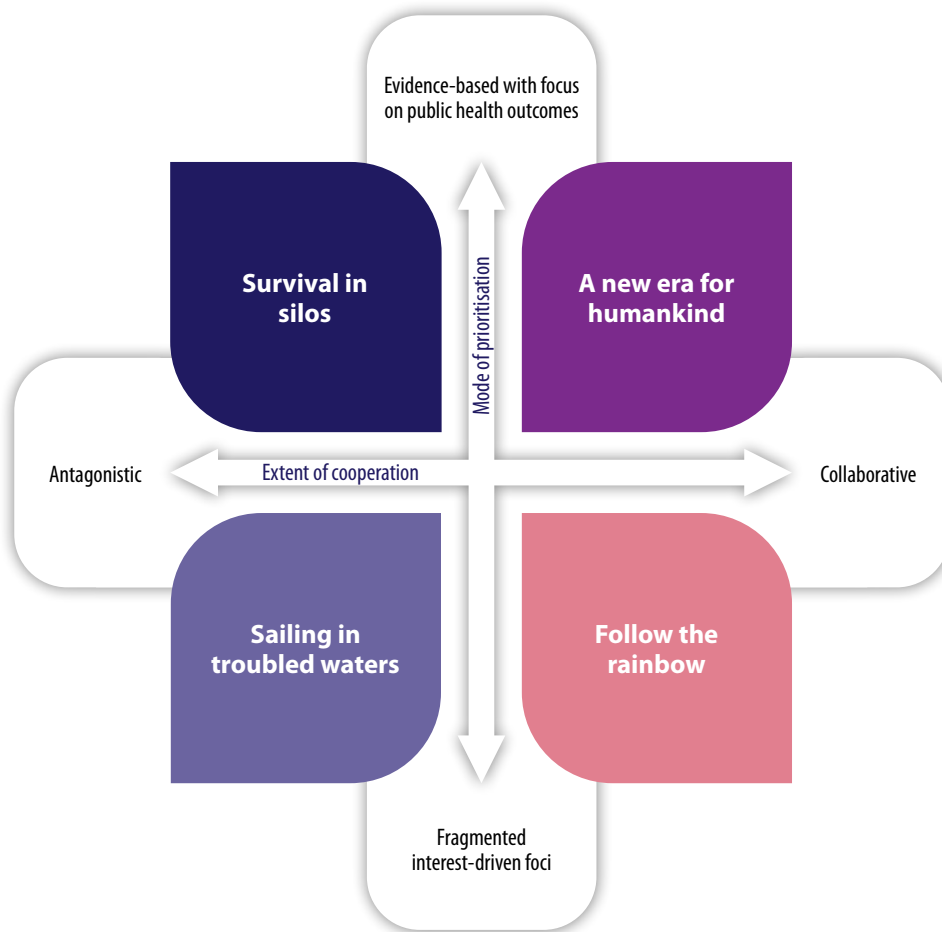


**Fig. 3.** Drivers sorted on an impact uncertainty matrix

To generate four scenarios that cover a wide range of plausible developments of 3D bioprinting, drivers estimated to have both a high impact and high uncertainty (Fig. 3) were chosen. The 24 high-impact, high-uncertainty drivers were formulated as variables that can change status over time (see Annex 1).

Scenario logics were formulated to reflect interactions among these 24 variables and also to conceive plausible divergent conditions 10 years from now that would influence the development and application of 3D bioprinting to improve global health. These resulted in four scenarios (Fig. 4):

- “survival in silos”: research and development are based on scientific evidence within a fragmented system for setting public health priorities;
- “a new era for humankind”: cooperation among stakeholders is strong, and research and development are guided by evidence and prioritization of important public health needs;
- “sailing in troubled waters”: the system is fragmented, with no common approach, and prioritization is based on individual rather than public health needs; and
- “follow the rainbow”: cooperation among stakeholders is strong, but the method for prioritization does not address common public health challenges, and decisions are not based on evidence.



**Fig. 4. Bioprinting and global health scenarios and their logics**

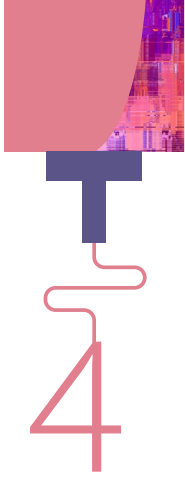
Each scenario was imagined 10 years into the future. Exercises inspired by causal layered analysis (17) were used to identify their distinctive characteristics, which were considered to be the elements of each scenario in terms of world views, systems and actors, imagined future news headlines and use of metaphors as titles (Table 1). The availability of and access to 3D bioprinting and its innovation were also discussed.

**Table 1. Characteristics of the four scenarios for 3D bioprinting and global health**

<b>“Survival in silos”</b>	<b>“A new era for humankind”</b>	<b>“Sailing in troubled waters”</b>	<b>“Follow the rainbow”</b>
Antagonistic cooperation and evidence-based focus on public health	Collaborative cooperation and evidence-based focus on public health	Antagonistic cooperation and fragmented interest-driven foci	Collaborative and fragmented interest-driven foci
<p>Prominent world views:</p> <p>“Trust in science, danger is everywhere.”</p> <p>“The world is unfair, so deal with it.”</p>	<p>Prominent world views:</p> <p>“Humanity is one.”</p> <p>“The world is safer when we set priorities based on evidence.”</p>	<p>Prominent world views:</p> <p>“It’s just how it is.”</p> <p>“I matter most.”</p> <p>“You only live once.”</p>	<p>Prominent world views:</p> <p>“Collaboration is above everything else.”</p> <p>“No need for evidence to know what to do.”</p>
<p>Systems and actors:</p> <p>Research and Innovation are driven by varied interests. Funding systems are fragmented. Areas for application of 3D bioprinting are varied and not only medical.</p> <p>Overall, systems are failing to ensure any form of social justice or equity.</p>	<p>Systems and actors:</p> <p>Well-functioning platforms for dialogue and transparency. Private and public interventions result in lower price and better access to advanced medical technology. Collaboration sometimes reduces the diversity of areas for use of bioprinting. Evidence-based views are globally accepted.</p>	<p>Systems and actors:</p> <p>Wealthy individuals drive investment, and charismatic opinion leaders determine health priorities. More interest in non-care uses of bioprinting. Large companies arbitrarily prioritize medical uses. Few clinics that serve wealthy patients have the skills to use 3D bioprinting to address health challenges. Political leadership on public health issues is ineffective. Lack of harmonization of regulations.</p>	<p>Systems and actors:</p> <p>Governance structures collaborate, but with fragmented outcomes. Political systems have no evidence for setting priorities for advancing bioprinting. Extensive but ineffective collaboration. Patient associations and civil society organizations demand transplants and tissues. The intentions of coalitions of nongovernmental organizations are good, but they have insufficient funding.</p>
<p>Example of news headline:</p> <p>“Another scandal at a functional organ auction”</p>	<p>Example of news headline:</p> <p>“126-nation effort leads to first 3D bioprinted brain with a functioning mind”</p>	<p>Example of news headline:</p> <p>“Health Insurance costs 10 times more than in 2023”</p>	<p>Example of news headline:</p> <p>“World’s richest create a super bioprinter for billionaires to use for extending their lives”</p>
<p>Availability and access:</p> <p>3D bioprinting is available to the wealthy but not the poor, among individuals and between low–middle- and high-income countries.</p>	<p>Availability and access:</p> <p>Safe, reliable 3D bioprinting applications are widely available. The data on effectiveness are robust, shared and comparable.</p> <p>Some trade-offs, such as mandatory inclusion in a global database and penalties for refusing a prescribed treatment.</p>	<p>Availability and access:</p> <p>Price fluctuation, little data-sharing, diverted use of IP rights to restrict access, little public awareness based on facts, frequent disagreements among stakeholders, no harmonization of regulations, little experience, lack of skill in clinics limits the availability of safe, reliable 3D bioprinting.</p> <p>Only a few very rich people can afford and can access 3D bioprinting treatment.</p>	<p>Availability and access:</p> <p>Ensuring safe, reliable bioprinted treatments is difficult and slow. Many clinics have bioprinting skills, but they are spread thinly among many innovation projects. Unproven treatments receive high public visibility.</p> <p>Much effort has been made to ensure equity; however, lack of impact is frequent because of a disregard for evidence.</p>

Each scenario was designed to have both desirable and undesirable characteristics. Although the scenario “A new era for humankind” might appear to be the best for developing 3D bioprinting to address global health needs, all the scenarios have both advantages and disadvantages. They provide equally plausible and contrasting conditions for robust discussion.

Application of the scenarios was discussed by experts in the fourth workshop to determine what might be done today for future development, distribution and use of 3D bioprinting to improve global health. The following sections summarize the discussions on potential risks and benefits, possible dual use, reflections on the initial decisions, optimization and inventions, and ideas for action in the near term.



# Potential risks and benefits and possible dual use

## 4.1 Potential risks

### **“Surviving in silos”**

- Funding allocation due to personal interest makes it difficult to produce robust evidence, and attempting to do so requires more resources and more time.
- Less cooperation means more work for ethics committees.
- Suboptimal regulatory systems and lack of cooperation and of innovation pathways jeopardize the safety of applications.
- The potential for “monopoly” is increased, with a risk of high prices.

### **“A new era for humankind”**

- While trials have shown the effectiveness of 3D bioprinting, transplants might wear out or stop over time, leaving recipients with the objects for the rest of their lives, even if they received well-regulated, better, future versions of the technology.
- The social risks could include social stigmatization of recipients of 3D bioprinting, such as of a child born by use of such a process or a patient who received some forms of 3D bioprinting.
- Ethical issues arise in conscription of enough donors of human biological materials to meet global demand.
- Excessive collaboration may lead to “group thinking” bias or poor decisions about use of 3D bioprinting.
- Collaborations could blur the scope of assessments, even after prioritization based on evidence.

### **“Sailing in troubled waters”**

- Lack of oversight and accountability could result in repetitive, insufficiently justified clinical trials and lack of appropriate information for consent and care for populations.
- Knowledge about 3D bioprinting is not shared among countries.
- Lack of technical knowledge in some areas leaves people open to unknown risks.
- Efforts are diverted to developing products that are not required broadly.
- Research integrity, such as the right to withdraw from research at any time, is ignored.

### **“Follow the rainbow”**

- Lack of evidence-driven prioritization leads to lost time and effort, even if the willingness to collaborate is high.
- Regulations and processes are harmonized, but they are less science-driven, and there is more political pressure.
- The risk of unsafe or less-effective treatments is increased.
- Profit-driven activities do not necessarily meet public health needs.
- The cost of innovation cycles that do not lead to clinical solutions is potentially high.
- As for the “New era for humankind” scenario, collaboration could blur assessments, in this case when priorities are based on multiple interests.

## **4.2 Potential benefits**

### **“Surviving in silos”**

- Reliance on evidence for setting public health priorities inspires confidence in the public about the safety and effectiveness of therapies.
- Although there is antagonism, scientists still add scientific knowledge, with more data and more results.

### **“A new era for humankind”**

- Rare diseases and conditions, neglected diseases of poverty and neglected tropical diseases could benefit from an evidence-driven collaborative approach in all countries, with equity of access between low- and middle-income and high-income countries.
- Extensive collaboration and evidence-based priorities could result in formation of a global oversight entity, which could ensure effective regulation of these technologies.

### **“Sailing in troubled waters”**

- Spill-over innovations are possible benefits, such as unintended development of a new technique that could have a strong impact on public health.
- Reduction in animal testing in several sectors by cross-industry applications of 3D bioprinting.

### **“Follow the rainbow”**

- 3D bioprinting could become more accessible and more equitable, and prices might be reduced by various cooperative initiatives.
- Innovation cycles would be shortened through collaboration.
- Knowledge-sharing among stakeholders and countries is extensive.



### 4.3 General considerations on possible dual use

In this project, dual use is understood as: “Knowledge, information, methods, products or technologies generated by peaceful and legitimate research that may be appropriated for non-peaceful or harmful purposes” (18).

In the discussion on dual use, the example was cited of possible military applications of the technology, such as bio-enhanced soldiers, and of possible applications in bioweapons. Risks of accidental or deliberate misuse of dual use technologies might be less likely in the scenario of “A new era for humankind” than in the other scenarios because of more extensive cooperation among countries and prioritization based on evidence for public health benefits. Potential misapplications of dual use might be more likely in the scenario “Sailing in troubled waters”, which does not include cooperation among countries.



## 5 Fast forward: priorities, optimization and inventions

The scenarios were imagined for 10 years into the future, with a time horizon of 2033. In a “fast-forward” exercise, a future scenario suddenly becomes a reality. Its objective is to compare today’s priorities, systems and resources with the conditions depicted in the scenario. The experts discussed future priorities, optimization and inventions from a global health perspective and compared them with the strengths and limitations of today’s world (see Annex 2). As the scenarios were designed to be equally plausible and to include various uncertainties, the outcomes of the fast-forward exercise indicate differences and similarities in the approaches that may be required in widely different situations.

All four scenarios require responses from stakeholders working to improve global health. Even in the scenario presumed to be most favourable – if it were to be realized sooner than 10 years – stakeholders dedicated to ensuring the availability of and access to the benefits of 3D bioprinting would still have to monitor public health needs to guide development of technologies and ensure knowledge-sharing, applications to regulators for technology for rapid innovations and communication platforms, train clinicians in use of the technology for new applications, and ensure funding for low- and middle-income countries to use new approaches.

In all scenarios, optimizing regulatory processes, producing and using reliable data, maintaining funding, using high-quality technology in clinical settings and finding ways to build effective collaborations could help to achieve global health goals. The fast-forward exercise shows that changes in overall conditions, even if they first appear to be beneficial, will not be permanent, as there will always be more to do in transformation of conditions to guide new medical technologies towards improvement of global health.



## 6 Action to enable use of 3D bioprinting to improve global health

The near-term actions described below are intended to ensure an optimal pathway towards public health benefits with plausible developments in the four scenarios. The list of actions is not exhaustive, and the report reflects the main points discussed. They are intended to serve as starting points for discussion about how 3D bioprinting and its many applications can be developed to improve global health.

These ideas for action are not policy recommendations or official stances of WHO, its Member States or the participants in the foresight project.

The topics, with their general functions in parentheses, are:

- Support harmonized, appropriate regulation of 3D bioprinting (regulation for advanced innovation).
- Establish data standards and practices on use of 3D bioprinting in medical applications (evidence).
- Train future clinicians and medical technologists in all regions (clinical translation).
- Establish a technology and IP platform for innovators and manufacturers (equitable innovation).
- Communicate effectively with the general public about 3D bioprinting (public awareness and trust).
- Raise global awareness of the availability of 3D bioprinting, and pool resources (systems awareness).

The activities for different people on these topics are summarized in Table 2.

### 6.1 Support harmonized, appropriate regulation of 3D bioprinting.

Harmonized, up-to-date standards and requirements are necessary for regulatory assessments to ensure safe, effective health interventions in the field. The standards would ensure the availability of high-quality 3D bioprinted therapies and prevent unproven products from causing harm. Attention would also be paid to equity and environmental sustainability. This will require convergent or harmonized requirements and support for multi-stakeholder consultations throughout innovation.

#### *Activities and structures*

- Support mechanisms to bring stakeholders together to establish and harmonize standards.
- Establish or mobilize communications systems to enable stakeholders to inform each other about technological advancements in 3D bioprinting for health and best practices in regulation.

- Use tools for engagement (such as scientific advice for early consultations) to support innovators and regulators in innovation and regulation.
- Learn from experiences in regulation of tissue engineering and regenerative medicine to optimize regulation.

### *Intended outcomes*

This action supports optimization of regulatory systems for 3D bioprinting to advance the field ethically toward social needs and public health. Harmonized requirements would support regulators and developers around the world in holding early consultations, which would help all the parties involved in developing 3D bioprinting applications to anticipate and agree on the evidence and approaches to ensure quality, safety and efficacy. Such dialogue would clarify regulatory pathways, even for the most complex use cases. Widely shared standards and requirements would result in continuous engagement between stakeholders in 3D bioprinting, use communities and the general public. Up-to-date, harmonized standards and requirements would include issues of equity and environmental impact.

### *Future benefit to people*

Future populations would benefit from this action by timely access to reliable 3D bioprinted therapies when needed. Future providers of such treatments would benefit from the earned public trust of the technologies. Companies and future funders would better understand the promise of this potential new health intervention and the data to be generated for other health interventions with this technology.

## 6.2 Establish data standards and practices for use of 3D bioprinting in medical applications.

Harmonized standards and practices for use of 3D bioprinting in medical applications would be developed, collected, stored and shared to support the development of 3D bioprinting, based on evidence.

### *Activities and structures*

- Convene workshops for all stakeholders in 3D bioprinting to collaborate in formulating standards and practices, to be updated in response to new needs.
- Use a collaborative approach to define shared expectations on how data on 3D bioprinting and its regulation should be produced, stored, used and shared.
- Construct online platforms to share data on 3D bioprinting, and provide easy access to all stakeholders.
- Learn from current activities in Open Science and Open Data.

### *Intended outcomes*

High-quality scientific evidence about 3D bioprinted materials and therapeutics would support communication and implementation of relevant regulations and risk assessments of a wide diversity of products and applications. It could inform policy-makers in guiding developments in 3D bioprinting toward public health outcomes. The standards would also indicate to participants in clinical trials how and where their data can be used, fostering trust. They would contribute to establishing common guidance for health-care providers with respect to patient registries.

### *Future benefit to people*

People would benefit from establishment of data standards and practices, as they would promote information-sharing. They would help future innovators and regulators to work together to increase access to safe, effective 3D bioprinting treatments and support global availability of the technology. Archives of such data would allow future innovators and regulators to follow changes and identify gaps.

## 6.3 Train future clinicians and medical technologists.

Establishment of training programmes and curricula at nursing and medical schools and universities around the world for application of existing and emerging 3D bioprinting would include teaching general skills for translating advanced medical technologies into clinical practice. The programme would culminate in professional licensing agreed by educators, clinicians and regulators. Programmes at universities would include ethical issues associated with advanced medical technologies and also operational technical capacity in academic research. Such programmes could encourage engineers and developers to direct 3D bioprinting towards societal needs and global health. They would also raise awareness about possible dual use and mitigation of such risks. Such training should include contemporary issues in procedures for regulating the technology. So that the rising generation of licensed clinicians and technologists for 3D bioprinting can apply their knowledge, health-care systems (hospitals and large health-care groups) should be involved in delivery of these new technologies.

### *Activities and structures*

- Raise the topic in multilateral educational policy-making in all regions to ensure further development.
- Convene educators to discuss such training programmes and licensing arrangements.
- Develop curricula and modules compatible with health-care training programmes for professionals, from nurses to surgeons.
- Define the competence necessary for professional licensing for 3D bioprinting, and build worldwide consensus among medical educators, professionals and technologists.
- Conduct pilot studies of initial versions of the curricula for professional licensing in several regions in order to adapt them to different contexts.

### *Intended outcomes*

This action would ensure that many hospitals in all regions have medical professionals who can safely and effectively translate advances in 3D bioprinting to meet clinical challenges. It would also improve understanding of the risks associated with this technology category as a whole and support development of safe, effective 3D bioprinting products, services and procedures. This would enable further integration of regulation and development.

### *Future benefit to people*

This action would ensure equity in the availability of and access to 3D bioprinting throughout the world by increasing the number of hospitals in which 3D bioprinting therapies and procedures can be provided safely and ethically to meet clinical challenges. People would benefit from trustworthy licensing schemes based on an evidence-based curriculum and technological skills in these advancing technologies. Future 3D bioprinting innovators would benefit from more hospitals that can offer their products, services and procedures.

## 6.4 Establish a technology and IP platform for innovators and manufacturers.

This action involves creation of a common platform to make advances in 3D bioprinting technology available globally, with efficient adherence to regulatory requirements. This shared resource would enable developers to protect their IP for 3D bioprinting for social benefit by making it available to a wider public. It could also promote standardized starting material or intermediate products, such as bioinks, for various therapies. It could be used for continuous analysis of gaps in applications of bioprinting for clinical purposes, identification of areas not covered by other approaches, cost modelling for priority setting, and the design of cost-effective business models.

## *Structures and actions*

- Convene reliable long-term sponsors of the platform who would manage it impartially and fairly.
- Consider a system for IP protection for other social benefits under suitable licensing schemes.

## *Intended outcomes*

Such a platform would provide a common basis for the technology, which could support equitable access to safe, effective 3D bioprinting for health-care applications. It could also accelerate innovation. Continual identification of gaps would reduce the effort required to identify truly innovative activities in the field of advanced therapy. It would help funders and innovators to target their work to public health needs.

## *Future benefit to people*

The platform could help to ensure that 3D bioprinting improves public health by saving time and resources that could be used by scientists, developers and manufacturers to develop new therapies. Its main advantage would be to make 3D bioprinting available to a wider population.

# 6.5 Communicate effectively with the general public about 3D bioprinting.

Use various ways to make the general public aware of the current situation and the potential benefits of 3D bioprinting for public health to guide public expectations of use of this kind of technology in health care. Communication would ensure that the public is up to date on the latest developments in this class of technology, with realistic estimates of its availability and its approved uses from reputable sources, to protect communities from misinformation. The communications would be available globally, with ensured equity of access and reliability. The action should avoid disruption of existing public awareness campaigns on organ and blood donations. The aim would be to disseminate factual information about 3D bioprinting and set realistic expectations about the kinds of public health issues that could be addressed.

## *Activities and structures*

- Avoid overstating the possibilities of 3D bioprinting, and inform people about how it could actually be used to address public health challenges.
- Clearly distinguish between technology that already exists and is approved and available for use from technology that is under development or technology with only future potential.
- Use the media to provide information about the technology, and ensure that stakeholders work together and broadcast only accurate, factual information that supports public health.
- Hold people accountable if they spread misinformation, because doing so can harm others, for example, by convincing someone not to accept a life-saving treatment or by steering political will away from investing in distribution of 3D bioprinting infrastructure.
- Learn from previous work to address misinformation.

## *Intended outcomes*

This action would result in a better informed public, support people in making critical health decisions involving this technology, and promote popular resistance to misinformation.

## Future benefit to people

This action would foster evidence-based public confidence in 3D bioprinting. People would be better informed for making choices about its uses. Furthermore, when more people understand the technology, they will be able to participate in expressing patient needs. A well-informed public would include funders and investors, who would be better prepared to translate technology into public health priorities.

## 6.6 Raise global awareness about the availability of 3D bioprinting, and pool resources.

Map, monitor and report on emerging applications and access to the benefits of 3D bioprinting. The purpose would be to ensure global awareness of the geographical availability of 3D bioprinting, its costs to health-care systems and patients, issues of access, and the distribution of facilities that provide 3D bioprinting. It would also support pooling of resources for certain activities at regional level. This action could be part of a larger reporting system to monitor the availability of all advanced therapy and medicinal products.

### Activities and structures

- Define the stakeholders to be engaged in producing regular reports.
- Conduct research for the first edition, ensuring longitudinal comparability.
- Publish the report, and disseminate the findings to increase awareness of issues of equity.

### Intended outcomes

This action would foster awareness of issues of equity in access to 3D bioprinting for use in setting priorities.

## Future benefit to people

People would have a better understanding of the development of access to and the availability of 3D bioprinting over time and use it to inform their choices. Between the present and 2033, such reports could guide investments.

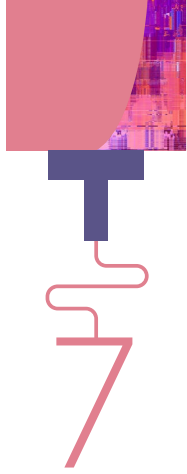
**Table 2. Who would do what?**

Who	What
Policy-makers	Act as a bridge between multilateral and international policy consultations and national consultations. Harmonize expectations of 3D bioprinting. Formulate IP licensing options for a common platform to make advances in 3D bioprinting technology available globally, ensuring variety suitable for all parties. Perform and monitor cost modelling, inform priority-setting and contribute to cost-effective business models for public health benefits in support of universal health coverage.
Regulatory authorities	Provide guidance on regulation of novel health interventions, and potentially update current standards to ensure the same rate as that of the evolution of technology. Review information, and offer guidance on medical communications.
Ethics committees	Monitor research integrity in measuring efficacy, establish processes for anticipating any harm due to new technologies, and ensure equitable access to benefits. Provide examples of ethical challenges, and provide up-to-date guidance on possible ethical issues.

**Table 2. Who would do what? *continued***

Who	What
Scientists	<p>Design and implement valid trials, and share data and results.</p> <p>Teach and communicate effectively about open data practices in science. Share data and results, and include such work in research proposals.</p> <p>Communicate failures to contribute to scientific knowledge.</p> <p>Accurately upload data to online platforms or databases.</p> <p>Review information and upload it onto a public platform or forum to inform and educate stakeholders.</p>
People and communities	<p>Communicate the needs and concerns of people who require specific treatments, raising the visibility of rare conditions.</p> <p>Include the perspectives of people in formulating harmonized recommendations and standards for 3D bioprinting, including environmental harm, the rights of donors of biomaterial, safety and equity of access.</p> <p>Contribute people's perspectives on data standards, such as privacy and protection of rights.</p> <p>Seek clarification from health providers or other reliable sources about the technology.</p>
Companies, manufacturers	<p>Fund the costs of innovation and development.</p> <p>Ensure transparency, and ensure data dissemination. Share data responsibly.</p> <p>Explore IP protection and licensing options for mutual public health benefits.</p> <p>Provide access to 3D bioprinting technologies and tools for their application to medical schools, ensuring global equity.</p> <p>Ensure access to data about 3D bioprinting ventures, investments and sales.</p> <p>Contribute to cost-effective business models.</p> <p>Review information, and post it on a public platform or forum for other stakeholders.</p>
Clinicians, health professionals	<p>Provide feedback on the relative advantages of 3D bioprinting technology as compared with other medical technologies, such as use of stem cells and regenerative medicine. Advise on standards for patient registries.</p> <p>Be informed, and stay up to date. Share factual information with the general public. Be prepared to guide people influenced by misinformation towards fact-based health decisions.</p>
Clinical care settings	<p>Provide a practical perspective on the skills required in clinics for use by curriculum developers. Offer internships for students.</p>
International organizations	<p>Prioritize establishment of training programmes and their potential benefits for public health to their member states.</p> <p>Raise or allocate funds for reporting the evolution of emerging applications and access to 3D bioprinting. Conduct research and publish analyses.</p>
Universities, health-care educators	<p>Ensure that advancements and developments in 3D bioprinting technologies include research. Work with ethical committees to foster competence in ethics. Associate with other universities internationally to develop standards and approaches.</p> <p>Establish collaboration for establishing and maintaining commonly agreed curricula. Pilot-test training programmes. Support graduates in finding jobs in clinics.</p>
Media	<p>Ensure dissemination of accurate information on 3D bioprinting. Avoid overstating the possibilities of unproven applications.</p>
Funders	<p>Release data on their investments in 3D bioprinting capacity, training or research.</p> <p>Perform and monitor cost modelling, inform priority-setting, and contribute to costing of effective business models.</p>
Member States	<p>Provide data on the availability of 3D bioprinting.</p> <p>Include analyses of the benefits of emerging applications of and access to 3D bioprinting in strategic health planning and priorities.</p>





## Discussion

The purpose of this scenarios project was to explore plausible future developments in 3D bioprinting in relation to its potential contribution to global health. The issues considered were equitable access to the potential benefits and widespread availability of high-quality, safe, effective 3D bioprinting services, products and procedures.

This project emphasizes the importance of collaboration to address global health challenges. Optimal development of this technology requires cooperation and collective work by various professionals – scientists, technicians, regulators, policy-makers and physicians – and also communities. 3D bioprinting technology has a number of possible applications in various fields. A number of challenges should be addressed proactively to ensure health-related interventions that benefit the largest number of people. Bioprinting includes various techniques and biomaterials, and consideration of aspects that could impede effective translation from research and development into effective, widely used clinical practices were highlighted. Those discussed were:

- regulations, with use of experience in regulation and innovation for tissue engineering and regenerative medicine to optimize regulatory pathways, and support for interactions between developers and regulators early in development;
- data standards and practices, with use of high-quality scientific evidence for informed risk assessments;
- training programmes for health-care professionals by integration into university curricula;
- a collaborative technology platform to encourage transparency and collaboration in research and development;
- effective communication about the technology by building trust in the scientific evidence and combatting misinformation; and
- raising global awareness about the benefits of the technology and opportunities for pooling resources.

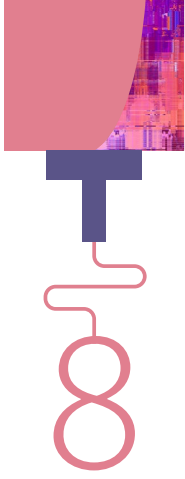
While many good practices are already available for these aspects, they should be adapted to the unique needs of stakeholders in 3D bioprinting.

### *Reflections on the exercise*

This foresight exercise was adapted to the timeframe of the project and conducted virtually. A limitation of such rapid deployment is lack of time to address some of the topics raised during scenario-making in depth. Scenario-making by a small group of experts made it difficult for the larger group to join in the discussion later, as they had less orientation and context; however, the perspectives of participants in many different sectors and regions resulted in productive exchanges of ideas and co-creation. Longer engagement of the larger group would have resulted in even more insights and ideas for action. The process of scenario-making is itself a means for exchange and co-creation, and ways in which this could be done by a larger group should be investigated.

This project chose a participatory approach to scenario-making to ensure different perspectives and to imagine scenarios with logics. Imposition of topical coherence among the scenarios had both a benefit and a limitation. The coherence helped to structure discussion of its two differences: “mode of collaboration” and “basis of prioritization”; however, this approach can exclude similar or alternative scenario logics or topics (19).

This report is best read as a synthesis and refinement of discussions of the future by a diverse group of experts . The scenarios presented are not intended to address comprehensively all dimensions and aspects of the development of 3D bioprinting and global health. They were used to structure discussions on how this advanced technology could be used to improve global health.



## Conclusions

The project addressed some of the changes and challenges that influence the development of 3D bioprinting and its contribution to improving global health. Four scenarios were formulated with scenario logic on the “extent of cooperation among actors” and “mode of prioritization”. Elements of each scenario may already be present in some communities; the scenarios serve the purpose of exploring the question: “What if this is the future at a general global level?” This type of reflection can include consideration of the strategies and actions that would be most appropriate for specific situations and those that are robust and might be useful in many futures and in many places.

The project was enriched by the participatory approach to creating these scenarios and applying them to find ideas for action and to engaging productively in discussion of emerging health technologies such as 3D bioprinting.

This project illustrates the importance of collaboration and collective work for optimal development of 3D bioprinting. Actions to promote effective translation from research and development to efficient, widely used clinical practices include harmonized, appropriate regulations; data standards and practices; training programmes for clinicians and technologists in all regions; effective scientific communication about the technology; and raising global awareness about the benefits and gaps and opportunities for pooling resources.

Foresight exercises create a space for constructive, collective consideration of emerging technologies and the potential risks and opportunities, with the objective of reducing inequity in access to scientific advances.

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# Annex 1. High-impact, high-uncertainty variables

Scenario variable	Description (in the context of this project)
Public expectations of 3D bioprinting	Overstatement and misinformation about unproven 3D bioprinting therapies as “miracle treatments” raise public expectations of this class of therapy.
Effects of climate change	Frequency, distribution, and extent of natural disasters and global pandemics; risk of transmission of zoonotic diseases
Commercial innovation and corporate venturing	Variation or similarity in patterns for commercial innovation and venturing of 3D bioprinting products and services (e.g. external start-ups vs entrepreneurship), including capital flows and regional distribution
Overall funding for 3D bioprinting	The amount and distribution of all types of funding (e.g. public, private, philanthropic, venture) for developing 3D bioprinting
Official development assistance and related research funding	Official funding allocated for research conducted with and for less wealthy nations and providing aid to these nations to achieve their health goals
Public investment	Both overall public investment in innovation, research and development and that specifically for 3D bioprinting
Availability and quality of infrastructure in low- and middle-income countries	Availability of infrastructure that enables access to the benefits of the technology in low- and middle-income countries by providing high-quality, reliable products and services related to 3D bioprinting
Adaptability and efficiency of regulations	Capacity of regulators for timely adaptation to developments in 3D bioprinting, such as introduction of new categories of tissue or procedures
Trust in institutions	Degree of public trust in institutions, including for governance, regulation and scientific knowledge, linked to the variables “corruption” and “extent of war” and stream of mis- or dis-information (see below)
Extent of war	Number and intensity of armed conflicts between countries and other groups; resources dedicated to war-making; multilateral diplomacy dedicated to war-related issues rather than, e.g. global health and collaborative research and development
Means for low- and middle-income countries to benefit from medical advances	Clarity and availability of pathways for innovation transfer, adaptation of safe, effective 3D bioprinting technologies in various settings
Spread of disinformation and misinformation	Spread and societal uptake of dis- and misinformation affects several aspects of global health. For example, extensive spread and uptake reduce societal respect for the science behind regulation.
Number of stories about successful use by celebrities	Major regional and international celebrities who undergo successful medical therapy based on 3D bioprinting could increase societal and political interest in this technology.
Availability of 3D bioprinted tissue and of natural tissues and organs	Availability of 3D bioprinted tissues or organs as compared with natural sources (e.g. human donor or other animal) for organ and tissue transplantation
Quantity and quality of data on quality, safety and effectiveness (limits)	Evidence of quality, safety and efficiency is necessary to regulate and establish safe 3D bioprinting therapies and treatments. Amount of dependable data from trials made available to the research community for timely use in regulatory reviews
Information on quality and safety of 3D printed tissues	Availability and use of reliable means (new or existing) for assessing the quality and safety of 3D bioprinted tissue that facilitate making such assessments
Data collection and sharing practices	Practices of collection and sharing of data on 3D bioprinting and associated issues, including timeliness of data availability, veracity of data, openness of data and protection of the privacy of data subjects. Role of private (trade secrets and copyright) vs public interests (open access, regulatory review)
Translation of 3D bioprinting technology to clinical use	Gaps between laboratory and industry 3D bioprinting technical innovations and practical application in clinical contexts. Distribution of ability to translate among practitioners
Regulation outcomes: safety and efficacy of 3D bioprinted therapies	How well regulations ensure desirable safety and efficacy
Military interest in 3D bioprinting	Extent to which the military is interested in 3D bioprinting, the purpose and the limits
Frequency and handling of significant mistakes involving 3D bioprinting	Frequency of severe mistakes, their handling by the medical community and 3D bioprinting providers and the public reaction. Values drive and are driven by such mistakes, as are societal perception and trust in 3D bioprinting therapies.

<b>Scenario variable</b>	<b>Description (in the context of this project)</b>
<b>Values of rising business leaders</b>	The rising generation of business leaders and start-up founders and entrepreneurs may be motivated more by social impact than making profits. This would change the priorities of innovators for 3D bioprinting therapy and their openness to ensuring access and equality.
<b>Prioritization of unmet clinical challenges</b>	Priority attributed by health service providers, public health innovators and funders of research and development to addressing unmet clinical challenges such as rare tissue-related conditions or orphan diseases
<b>Extent of corruption</b>	Extent of corruption in the public and private sectors, such as bribery, nepotism, organized extortion and organized crime networks

# Annex 2. Reflections from the fast-forward activity

Scenarios were imagined for 10 years into the future, with a time horizon of 2033. In a “fast-forward” exercise, a future scenario suddenly becomes a reality. Its objective is to compare today’s priorities, systems and resources with the conditions depicted in the scenario.

## Survival in silos

**Situation:** Research and development are based on scientific evidence within a fragmented system for setting public health priorities.

### Priorities

- Establish or empower an organization for 3D bioprinting through a global health policy for a relevant strategic approach.
- Identify and map key actors.
- Establish guidelines for identifying actual policy needs.
- Attempt to simplify the technology for each actor, as there is no cooperation.
- Identify public health needs, and compare with the intended value of various 3D bioprinting products.
- Organize a system based on criteria for technology assessment and the associated foreseen public health value.

### Optimization.

- Enable sharing of evidence.
- Extend access to subsets of the population.
- Establish registries of the outcomes of use of 3D technology.
- Promote harmonization to enable access.
- Identify means to share and promote access to health technologies and innovation, e.g. governance of IP rights.
- Identify opportunities and relevant stakeholders for global cooperation.

### To find or invent

- Find reliable partners and a sustained source of funding.
- Invent health-care planning and strategies, including funding, to ensure equitable access.



## A new era for humankind

**Situation:** Cooperation among stakeholders is strong, and research and development are guided by evidence and prioritization of important public health needs.

### Priorities

- Continuously assess the health needs of the population to ensure that the many new, high-quality 3D-bioprinted approaches match and can be developed to meet those needs, staying one step ahead.
- Consider public health needs in investment in 3D bioprinting systems.
- Involve regulators in monitoring products that may become unnecessary or less effective with new innovations.
- Ensure long-term evaluation of the effects of 3D bioprinting approaches.

### Optimization.

- Improve training, so that more clinicians can take advantage of 3D bioprinting procedures.
- Apply evidence-driven guidelines by e.g. increasing the number of trials, to increase the availability of high-quality, safe, effective 3D bioprinting products, services and approaches.
- Support all countries in improving local ability to assess evidence and decide on 3D bioprinting for public health.
- Increase and replicate funding mechanisms for regional cooperation, such as the European Neighbourhood Policy.
- Optimize regulatory approaches for timely adoption of the technology.

### To find or invent

- Establish regional and global networks for cooperation.
- Increase the capacity of resource-limited settings to use rapidly advancing health innovations such as 3D bioprinting. This includes uniform knowledge-sharing and exposure of health authorities to application of new technologies to ensure that populations everywhere can rapidly benefit from health innovations.

## Sailing in troubled waters

**Situation:** The system is fragmented, with no common approach, and prioritization is based on individual rather than public health needs.

### Priorities

- Map actors and technology: Who does what? What exists?
- Identify the needs of the population: Where are the gaps in health care?
- Develop knowledge and information about 3D biotechnology and its potential.
- Build capacity in media and public communication, particularly to answer questions about the global inequality of the benefits of 3D bioprinting.
- Consider national and regional differences, and direct work towards equitable access to the outcomes of research and development on 3D bioprinting in low- and middle-income countries.

### Optimization.

- Build on any agreed principles and shared values among stakeholders.
- Further develop and better use existing communication networks and information exchange platforms.
- Invest in training, and ensure that knowledge is captured in a “technology watch” by legislative authorities to better integrate new areas into functional frameworks.

### To find or invent

- Obtain resources to establish platforms for knowledge-sharing.
- Develop a system for channelling funds to unmet needs.
- Develop national guidelines, policies and regulations to regulate 3D bioprinting, especially in resource-limited settings.

## Follow the rainbow

**Situation:** Cooperation among stakeholders is strong, but the method for prioritization does not address common public health challenges, and decisions are not based on evidence.

### Priorities

- Collect information to understand risks and outcomes.
- Ensure clear public governance with regulators and ethical committees.
- Create a common platform for technologies and regulations to ensure efficient cooperation on starting points and on investments.

### Optimization.

- Develop mechanisms for establishing common priorities. Use structured processes to analyse research and development on use of 3D bioprinting in health, identify gaps for decision-making to meet public health needs.
- Leverage interest in cooperation for producing truly robust scientific evidence.
- Build on processes for identifying safe, effective health technology, and provide evidence to improve its quality.

### To find or invent

- Find reliable financial resources and stakeholders for 3D bioprinting for the benefit of public health with evidence-driven priorities.
- Develop tools to demonstrate efficacy (such as registries) to provide data for decisions.
- Ensure healthy competition and healthy disagreement.



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